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

On March 22, 2023, Nyxoah SA (the "Company") issued a press release announcing its financial and operating results for the year ended December 31, 2022. The press release is attached as Exhibit 99.1 and is incorporated by reference herein.

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 22, 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 22, 2023

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

Exhibit 99.1

REGULATED INFORMATION

Nyxoah Reports Fourth Quarter and Full Year 2022 Financial and Operating Results

Completed all 115 implants in the DREAM U.S. pivotal study

Mont-Saint-Guibert, Belgium – March 22, 2023 09:05pm CET / 4:05pm 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 reported financial and operating results for the fourth quarter and full year 2022.

Recent Financial and Operating Highlights

- Completed all 115 implants in the DREAM U.S. pivotal trial, with 12-month data expected early next year.
- Filed the first module in the modular PMA submission.
- Submitted 12-month data[1] on the first 34 DREAM patients as a late-breaking abstract to SLEEP 2023 demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in-line with expectations. These data are preliminary and not conclusive of final DREAM success.
- Achieved quarterly sales of €1.3 million resulting in a sequential German market share gain.
- Ended the year with 38 active German accounts, up from 12 entering 2022.
- Strengthened supply chain with Belgium manufacturing facility receiving clearance from the EU notified body.
- Implanted the first patients in the ACCCESS U.S. IDE pivotal study to treat complete concentric collapse (CCC). Implant completion expected in 2024.
- Total cash position of €94.8 million at the end of 2022.

2023 Key Objectives

- Focus on patient follow up in the DREAM study resulting in reaching the primary endpoints.
- U.S. regulatory, manufacturing and market access readiness.
- Drive further revenue and market share growth in Germany.

"With all 115 implants completed in the DREAM study and our first PMA module submitted, we achieved key milestones towards U.S. FDA approval. Our attention now focuses on patient follow up. With the clearance of our second manufacturing site, we have strengthened our supply chain to meet increasing demand," commented Olivier Taelman, Nyxoah Chief Executive Officer.

Mr. Taelman continued, "Commercially in Europe, we are excited to see the continued demand growth for Genio in Germany. Our growing experience with CCC patients in Europe, driven by our expanded label, reinforces our confidence in our ongoing U.S. ACCCESS study."

[1] For the trial to be successful, of the 115 patients, at least 63% of patients need to be AHI and ODI responders at the 12-month follow-up.

REGULATED INFORMATION

Fourth Quarter and Full Year 2022 Results

UNAUDITED CONDENSED CONSOLIDATED FINANCIAL INFORMATION – CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS FOR THE THREE MONTHS AND YEARS ENDED DECEMBER 31, 2022 AND DECEMBER 31, 2021 (in thousands)

	For the three months ended December 31,		For the year ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenue	€ 1,307	€ 295	€ 3,084	€ 852
Cost of goods sold	(465)	(105)	(1,150)	(303)
Gross profit	**€ 842**	**€ 190**	**€ 1,934**	**€ 549**
Research and Development Expense	(4,575)	(3,335)	(15,861)	(12,344)
Selling, General and Administrative Expense	(5,363)	(3,937)	(18,855)	(14,712)
Other income/(expense)	46	539	283	265
Operating loss for the period	**€ (9,050)**	**€ (6,543)**	**€ (32,499)**	**€ (26,242)**
Financial income	(4,609)	3,603	6,763	3,675
Financial expense	1,153	(588)	(4,320)	(2,072)
Loss for the period before taxes	**€ (12,506)**	**€ (3,528)**	**€ (30,056)**	**€ (24,639)**
Income taxes	(790)	(2,720)	(1,169)	(2,980)
Loss for the period	**€ (13,296)**	**€ (6,248)**	**€ (31,225)**	**€ (27,619)**
Loss attributable to equity holders	**€ (13,296)**	**€ (6,248)**	**€ (31,225)**	**€ (27,619)**
Other comprehensive income/(loss)				
Items that may not be subsequently reclassified to profit or loss (net of tax)				
Remeasurements of post-employment benefit obligations, net of tax	70	(68)	70	(68)
Items that may be subsequently reclassified to profit or loss (net of tax)				
Currency translation differences	(82)	(17)	(96)	121
Total other comprehensive income/(loss)	**€ (12)**	**€ (85)**	**€ (26)**	**€ 53**
Total comprehensive loss for the year, net of tax	**€ (13,308)**	**€ (6,333)**	**€ (31,251)**	**€ (27,566)**
Loss attributable to equity holders	**€ (13,308)**	**€ (6,333)**	**€ (31,251)**	**€ (27,566)**
Basic loss per share (in EUR)	€ (514)	€ (238)	€ (1,209)	€ (1,161)
Diluted loss per share (in EUR)	€ (514)	€ (238)	€ (1,209)	€ (1,161)

REGULATED INFORMATION

UNAUDITED CONDENSED CONSOLIDATED FINANCIAL INFORMATION – CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS OF DECEMBER 31, 2022 AND DECEMBER 31, 2021 (in thousands)

	As of December 31,	
	2022	**2021**
ASSETS		
Non-current assets		
Property, plant and equipment	€ 2,460	€ 2,020
Intangible assets	39,972	25,322
Right of use assets	3,159	3,218
Deferred tax asset	47	46
Other long-term receivables	173	164
	€ 45,811	**€ 30,770**
Current assets		
Inventory	882	346
Trade receivables	1,463	226
Other receivables	1,775	2,286
Other current assets	1,284	1,693
Financial assets	76,968	-
Cash and cash equivalents	17,888	135,509
	€ 100,260	**€ 140,060**
Total assets	**€ 146,071**	**€ 170,830**
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	4,440	4,427
Share premium	228,275	228,033
Share based payment reserve	5,645	3,127
Other comprehensive income	176	202
Retained loss	(118,212)	(87,167)
Total equity attributable to shareholders	**€ 120,324**	**€ 148,622**
LIABILITIES		
Non-current liabilities		
Financial debt	8,189	7,802
Lease liability	2,586	2,737
Pension liability	-	80
Provisions	59	12
Deferred tax liability	-	5
	€ 10,834	**€ 10,636**
Current liabilities		
Financial debt	388	554
Lease liability	719	582
Trade payables	4,985	3,995
Current tax liability	3,654	2,808
Other payables	5,167	3,633
	€ 14,913	**€ 11,572**
Total liabilities	**€ 25,747**	**€ 22,208**
Total equity and liabilities	**€ 146,071**	**€ 170,830**

Revenue

Revenue was €1.3 million for the fourth quarter ending December 31, 2022, compared to €295,000 for the fourth quarter ending December 31, 2021. Revenue for the full year of 2022 was €3.1 million, compared to €0.9 million for the full year of 2021. The increase in revenue was attributable to the Company's commercialization of the Genio® system, primarily in Germany.

Cost of Goods Sold

Cost of goods sold was €465,000 for the three months ending December 31, 2022, representing a gross profit of €0.8 million, or gross margin of 64.4%. This compares to total cost of goods sold of €105,000 in the fourth quarter of 2021, for a gross profit of €190,000, or gross margin of 64.4%.

For the full year ending December 31, 2022, total cost of goods sold was €1.2 million, representing a gross profit of €1 million, or gross margin of 62.7%. This compares to total cost of goods sold of €303,000 for the full year of 2021, for a gross profit of €0.5 million or gross margin of 64.4%.

Research and Development Expenses

Research and development expenses were €4.6 million for the three months ending December 31, 2022, versus €3.3 million for the prior year period, reflecting the Company's investments in the development of next generation versions of the Genio® system as well as ongoing clinical studies, most notably DREAM in the U.S.

For the full year ending December 31, 2022, research and development expenses were €15.9 million, versus €12.3 million for the full year of 2021.

Selling, General and Administrative Expenses

Selling, general and administrative expenses rose to €5.4 million for the fourth quarter of 2022, up from €3.9 million in the fourth quarter of 2021. This was due primarily to increased commercial efforts in Germany and other European markets, as well as investments in Nyxoah's corporate infrastructure. The Company expects to continue adding headcount across the organization ahead of the U.S. commercial launch.

For the full year ending December 31, 2022, selling, general and administrative expenses were €18.9 million, up from €14.7 million for the full year 2021 due to increased commercial efforts in Germany and investments in Nyxoah's corporate infrastructure.

Operating Loss

Total operating loss for the fourth quarter and full year 2022 was €9.1 million and €32.5 million, respectively, versus €6.5 million and €26.2 million in the fourth quarter and full year 2021, respectively. This was driven by the acceleration in the Company's R&D spending, as well as ongoing commercial and clinical activities.

Cash Position

As of December 31, 2022, cash and financial assets totaled €95 million, compared to €135.5 million on December 31, 2021. Total cash burn was approximately €3.4 million per month during 2022.

Full year report 2022

Nyxoah's financial report for the full year of 2022, including details of the audited consolidated results, are available on the investor page of Nyxoah's website (https://investors.nyxoah.com/financials).

Conference call and webcast presentation

Nyxoah will conduct a conference call open to the public today at 10:30pm CET / 4:30pm ET, which will also be webcast. To participate in the conference call, please access the following link to register for a dial-in number: https://register.vevent.com/register/BIfc3a52c9352e4e42958e9d816245b3b9

A question-and-answer session will follow the presentation of the results. To access the live webcast, go to https://investors.nyxoah.com/events. The archived webcast will be available for replay shortly after the close of the call.

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.

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; 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.

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