
**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 2024

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 5, 2024, Nyxoah SA (the “Company”) issued a press release announcing its financial and operating results for the year ended December 31, 2023. 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 5, 2024](#)

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 5, 2024

By: /s/ Loic Moreau

Name: Loic Moreau

Title: Chief Financial Officer



REGULATED INFORMATION

Nyxoah Reports Fourth Quarter and Financial Year 2023 Financial and Operating Results

Expect to report DREAM U.S. pivotal study efficacy and safety data by early April

Achieved record quarterly sales of €1.8 million

Mont-Saint-Guibert, Belgium – March 5, 2024 10:05pm 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 financial year 2023.

Recent Financial and Operating Highlights

- Filed the third out of four modules in the U.S. modular PMA submission.
- Achieved quarterly sales of €1.8 million, representing sequential quarterly growth of 87% and increasing 42% year-over-year.
- Achieved 2023 full year sales of €4.3 million, representing 41% year-over-year growth.
- Ended the year with 48 active German accounts, up from 38 entering 2023.
- Total cash position of €57.7 million at the end of 2023.

2024 Strategic Priorities

- Complete patient follow up in the DREAM U.S. pivotal study and report efficacy and safety data by early April.
- File the fourth and final module in the modular PMA submission.
- Accelerate investments in the U.S. commercial organization in preparation for a late 2024 launch.
- Complete enrollment in the ACCESS complete concentric collapse (CCC) U.S. pivotal study.
- Increase hypoglossal nerve stimulation (HGNS) market penetration and Genio market share in Europe.

“In 2023, we completed enrollment in our DREAM U.S. pivotal study, presented positive early DREAM efficacy and safety data, initiated enrollment in our ACCESS U.S. pivotal study for complete concentric collapse and raised capital from both existing and new investors. These accomplishments strengthen our confidence for a transformational 2024.” commented Olivier Taelman, Nyxoah Chief Executive Officer. “We are excited to report DREAM data in the coming weeks, finalize the regulatory FDA submission and pave the way for bringing Genio® to patients in the U.S.”

Mr. Taelman continued, “Commercially in Europe, this quarter’s performance was the strongest in Nyxoah’s history driven by a targeted direct-to-consumer (DTC) effort and I applaud our European commercial team for their execution. I look forward to a further increase in therapy penetration from our partnership with ResMed in Germany.”



REGULATED INFORMATION

Fourth Quarter and Full Year 2023 Results

UNAUDITED CONDENSED CONSOLIDATED FINANCIAL INFORMATION – CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS FOR THE THREE MONTHS AND YEARS ENDED DECEMBER 31, 2023 AND DECEMBER 31, 2022 (in thousands)

	For the three months ended December 31,		For the year ended December 31,	
	2023	2022	2023	2022
Revenue	€ 1,824	€ 1,307	€ 4,348	€ 3,084
Cost of goods sold	(726)	(465)	(1,656)	(1,150)
Gross profit	€ 1,098	€ 842	€ 2,692	€ 1,934
Research and Development Expense	(7,321)	(4,575)	(26,651)	(15,861)
Selling, General and Administrative Expense	(4,893)	(5,363)	(21,687)	(18,855)
Other income/(expense)	279	46	544	283
Operating loss for the period	€ (10,837)	€ (9,050)	€ (45,102)	€ (32,499)
Financial income	582	(4,609)	4,174	6,763
Financial expense	(964)	1,153	(3,729)	(4,320)
Loss for the period before taxes	€ (11,219)	€ (12,506)	€ (44,657)	€ (30,056)
Income taxes	326	(790)	1,445	(1,169)
Loss for the period	€ (10,893)	€ (13,296)	€ (43,212)	€ (31,225)
Loss attributable to equity holders	€ (10,893)	€ (13,296)	€ (43,212)	€ (31,225)
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	81	70	81	70
Items that may be subsequently reclassified to profit or loss (net of tax)				
Currency translation differences	(32)	(82)	(120)	(96)
Total other comprehensive income/(loss)	€ (39)	€ (12)	€ (39)	€ (26)
Total comprehensive loss for the year, net of tax	€ (10,844)	€ (13,308)	€ (43,251)	€ (31,251)
Loss attributable to equity holders	€ (10,844)	€ (13,308)	€ (43,251)	€ (31,251)
Basic loss per share (in EUR)	€ (379)	€ (514)	€ (1,545)	€ (1,209)
Diluted loss per share (in EUR)	€ (379)	€ (514)	€ (1,545)	€ (1,209)



REGULATED INFORMATION

UNAUDITED CONDENSED CONSOLIDATED FINANCIAL INFORMATION – CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS OF DECEMBER 31, 2023 AND DECEMBER 31, 2022 (in thousands)

	As at December 31	
	2023	2022
ASSETS		
Non-current assets		
Property, plant and equipment	€ 4,188	€ 2,460
Intangible assets	46,608	39,972
Right of use assets	3,788	3,159
Deferred tax asset	56	47
Other long-term receivables	1,166	173
	€ 55,806	€ 45,811
Current assets		
Inventory	3,315	882
Trade receivables	2,758	1,463
Other receivables	3,212	1,775
Other current assets	1,318	1,284
Financial assets	36,138	76,968
Cash and cash equivalents	21,610	17,888
	€ 68,351	€ 100,260
Total assets	€ 124,157	€ 146,071
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	4,926	4,440
Share premium	246,127	228,275
Share based payment reserve	7,661	5,645
Other comprehensive income	137	176
Retained loss	(160,829)	(118,212)
Total equity attributable to shareholders	€ 98,022	€ 120,324
LIABILITIES		
Non-current liabilities		
Financial debt	8,373	8,189
Lease liability	3,116	2,586
Pension liability	9	-
Provisions	185	59
Deferred tax liability	9	-
	€ 11,692	€ 10,834
Current liabilities		
Financial debt	364	388
Lease liability	851	719
Trade payables	6,155	4,985
Current tax liability	1,988	3,654
Other payables	5,085	5,167
	€ 14,443	€ 14,913
Total liabilities	€ 26,135	€ 25,747
Total equity and liabilities	€ 124,157	€ 146,071



REGULATED INFORMATION

Revenue

Revenue was €1.8 million for the fourth quarter ending December 31, 2023, compared to €1.3 million for the fourth quarter ending December 31, 2022. Revenue for the full year of 2023 was €4.3 million, compared to €3.1 million for the full year of 2022. 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 €726,000 for the three months ending December 31, 2023, representing a gross profit of €1.1 million, or gross margin of 60%. This compares to total cost of goods sold of €465,000 in the fourth quarter of 2022, for a gross profit of €842,000, or gross margin of 64.4%.

For the full year ending December 31, 2023, total cost of goods sold was €1.6 million, representing a gross profit of €2.7 million, or gross margin of 62%. This compares to total cost of goods sold of €1.2 million for the full year of 2022, for a gross profit of €1.9 million, or gross margin of 62.7%.

Research and Development

For the full year ending December 31, 2023, research and development expenses were €26.7 million, versus €15.9 million for the full year of 2022.

Operating Loss

Total operating loss for the fourth quarter and full year 2023 was €10.8 million and €45.1 million, respectively, versus €9.1 million and €32.5 million in the fourth quarter and full year 2022, 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, 2023, cash and financial assets totaled €57.7 million, compared to €94.9 million on December 31, 2022. Total cash burn was approximately €4.6 million per month during 2023.

Full year report 2023

Our independent auditor has not yet completed the audit of the financial statements for the year ended December 31, 2023. When published, the Nyxoaah financial report for the full year of 2023 will be available on the investor page of Nyxoaah's website (<https://investors.nyxoaah.com/financials>).



REGULATED INFORMATION

Conference call and webcast presentation

A webcast of the call will be accessible via the Investor Relations page of the Nyxoah website or through this link: [Nyxoah's Q4 2023 earnings call webcast](#). For those not planning to ask a question of management, the Company recommends listening via the webcast.

If you plan to ask a question, please use the following link: [Nyxoah's Q4 2023 earnings call](#). After registering, an email will be sent, including dial-in details and a unique conference call access code required to join the live call. To ensure you are connected prior to the beginning of the call, the Company suggests registering a minimum of 10 minutes before the start 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.



REGULATED INFORMATION

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, 2022, filed with the Securities and Exchange Commission ("SEC") on March 22, 2023, 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:

Nyxoah

David DeMartino, Chief Strategy Officer

david.demartino@nyxoah.com

+1 310 310 1313