
**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 May 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 May 16, 2023, Nyxoah SA (the “Company”) issued a press release announcing its financial and operating results for the first quarter of 2023. A copy of the Company’s press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Additionally, on May 16, 2023, the Company announced its unaudited first quarter results for 2023, which are further described in a First Quarter 2023 report attached hereto as Exhibit 99.2.

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.

The information in the attached Exhibit 99.2 shall be deemed to be incorporated by reference into the registration statements on Form S-8 (Registration Numbers [333-261233](#) and [333-269410](#)) 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.

Exhibits

[99.1](#) [Press Release, dated May 16, 2023](#)
[99.2](#) [First Quarter Report 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: May 16, 2023

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



REGULATED INFORMATION

Nyxoah Reports First Quarter 2023 Financial and Operating Results

Mont-Saint-Guibert, Belgium – May 16, 2023 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 first quarter 2023.

Recent Financial and Operating Highlights

- Completed all 115 implants in the DREAM U.S. pivotal trial, with 12-month data expected in the first quarter of 2024.
- Initiated the modular PMA submission with the filing of the first module.
- Submitted 12-month data¹ 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. The abstract will be presented in a late-breaking poster session on June 6th. These data are preliminary and not conclusive of final DREAM success.
- Implanted the first patients in the ACCESS U.S. IDE pivotal study to treat complete concentric collapse (CCC). Implant completion expected in 2024.
- Hired Christoph Eigenmann as Chief Commercial Officer.
- Raised €19 million from new and historical shareholders including ResMed, Cochlear and Robert Taub, Nyxoah’s Chairman and Founder.
- Ended the quarter with 40 active German accounts and quarterly sales of €441 thousand.
- Expanded European market access with first implants in Austria.
- Strengthened the supply chain with the Belgium manufacturing facility receiving clearance from the EU notified body.

“In 2023, our focus is in the U.S. on DREAM patient follow up resulting in reaching the primary endpoints. I am excited by the data on the first 34 patients and look forward to sharing the full abstract results at SLEEP 2023 next month. Our increasing conviction in DREAM outcomes is accelerating investment in our commercial organization, starting with the addition of Christoph as Chief Commercial Officer,” commented Olivier Taelman, Nyxoah’s Chief Executive Officer. “Christoph’s hire, along with the €19 million raised from key investors, puts us in a strong position as we embark on our next stage of growth.”

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

First Quarter 2023 Results

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

	For the three months ended March 31	
	2023	2022
Revenue	€ 441	€ 660
Cost of goods sold	(175)	(289)
Gross profit	€ 266	€ 371
Research and Development Expense	(6,157)	(3,595)
Selling, General and Administrative Expense	(5,551)	(4,193)
Other income/(expense)	46	136
Operating loss for the period	€ (11,396)	€ (7,281)
Financial income	625	1,576
Financial expense	(958)	(788)
Loss for the period before taxes	€ (11,729)	€ (6,493)
Income taxes	(182)	(208)
Loss for the period	€ (11,911)	€ (6,701)
Loss attributable to equity holders	€ (11,911)	€ (6,701)
Other comprehensive loss		
Items that may be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	(28)	(102)
Total comprehensive loss for the year, net of tax	€ (11,939)	€ (6,803)
Loss attributable to equity holders	€ (11,939)	€ (6,803)
Basic Loss Per Share (in EUR)	€ (0.460)	€ (0.260)
Diluted Loss Per Share (in EUR)	€ (0.460)	€ (0.260)

**UNAUDITED CONDENSED CONSOLIDATED FINANCIAL INFORMATION – CONSOLIDATED STATEMENT
OF FINANCIAL POSITION AS OF MARCH 31, 2023 (in thousands)**

	As at	
	March 31 2023	December 31 2022
ASSETS		
Non-current assets		
Property, plant and equipment	€ 2,721	€ 2,460
Intangible assets	42,447	39,972
Right of use assets	3,669	3,159
Deferred tax asset	50	47
Other long-term receivables	169	173
	€ 49,056	€ 45,811
Current assets		
Inventory	1,249	882
Trade receivables	1,499	1 463
Other receivables	1,419	1 775
Other current assets	1,663	1 284
Financial assets	62,403	76 968
Cash and cash equivalents	33,664	17 888
	€ 101,897	€ 100,260
Total assets	€ 150,953	€ 146,071
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	4,859	4,440
Share premium	243,488	228,275
Share based payment reserve	6,582	5,645
Other comprehensive income	148	176
Retained loss	(130,051)	(118,212)
Total equity attributable to shareholders	€ 125,026	€ 120,324
LIABILITIES		
Non-current liabilities		
Financial debt	8,381	8,189
Lease liability	3,112	2,586
Pension liability	25	-
Provisions	74	59
Deferred tax liability	-	-
	€ 11,592	€ 10,834
Current liabilities		
Financial debt	390	388
Lease liability	711	719
Trade payables	5,012	4,985
Current tax liability	3,619	3,654
Other payables	4,603	5,167
	€ 14,335	€ 14,913
Total liabilities	€ 25,927	€ 25,747
Total equity and liabilities	€ 150,953	€ 146,071



REGULATED INFORMATION

Revenue

Revenue was €441,000 for the first quarter ending March 31 2023, compared to €660,000 for first quarter ending March, 31 2022.

Cost of Goods Sold

Cost of goods sold was €175,000 for the three months ending March 31, 2023, representing a gross profit of €266,000, or gross margin of 60.3%. This compares to total cost of goods sold of €289,000 in the first quarter ending March 31, 2022, for a gross profit of €371,000, or gross margin of 56.2%.

Research and Development Expenses

Research and development expenses were €6.2 million for the three months ending March 31, 2023, versus €3.6 million for the prior year period, driven by an acceleration in clinical activities, notable the start of the ACCCESS study.

Selling, General and Administrative Expenses

Selling, general and administrative expenses rose to €5.6 million for the first quarter of 2023, up from €4.2 million in the first quarter of 2022. This was due primarily to increased commercial efforts in Germany and other European markets, as well as investments in Nyxoaah's corporate infrastructure. The Company expects to continue adding headcount across the organization ahead of the U.S. commercial launch.

Operating Loss

Total operating loss for the first quarter 2023 was €11.4 million versus €7.3 million in the first quarter of 2022. This was driven by the acceleration in the Company's R&D spending, as well as ongoing commercial and clinical activities.



REGULATED INFORMATION

Cash Position

As of March 31, 2023, cash and financial assets totaled €96.1 million, compared to €94.9 million on December 31, 2022. Total cash burn was approximately €4.9 million per month during the first quarter of 2023.

First Quarter 2023 Report

Nyxoah's financial report for the first quarter of 2023, including details of the 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://edge.media-server.com/mmc/p/imeku8f7>

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.



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, 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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INTERIM FINANCIAL REPORT

FIRST QUARTER 2023

1. BUSINESS UPDATE

A. CLINICAL UPDATE

DREAM US: IDE PIVOTAL STUDY

Nyxoah initiated its pivotal DREAM IDE trial in the United States in December 2020 to support an application seeking FDA marketing authorization and, ultimately, reimbursement in the U.S. for bilateral hypoglossal nerve stimulation for the treatment of moderate-to-severe obstructive sleep apnea ("OSA"). The DREAM trial is a multicenter, prospective, open-label trial in which patients who undergo implantation of the Genio[®] system will be followed for five years post-implantation to assess the safety and efficacy of the Genio[®] system in patients with moderate-to-severe OSA.

The trial was initially expected to enroll 134 patients who will undergo the implantation procedure with 12-month effectiveness and safety primary endpoints across 18 centers in the United States and six international sites. In April 2022, the FDA approved the Company's request to reduce the trial's sample size to 115 patients from 134 after reviewing data from the BETTER SLEEP trial (see below).

The primary safety endpoint is incidence of device-related severe adverse events ("SAEs") at 12-months post implantation. One of the co-primary effectiveness endpoints is the percentage of responders with at least a 50% reduction on the apnea-hypopnea index ("AHI") with hypopneas associated with a 4% oxyhemoglobin desaturation and a remaining AHI with hypopneas associated with a 4% oxyhemoglobin desaturation less than 20, together with a 25% reduction on the oxygen desaturation index ("ODI") between baseline and 12-month visits. Patients with moderate to severe OSA (AHI score between 15 and 65) and aged between 22 and 75 years are eligible for enrolment if they failed, did not tolerate or refused positive airway pressure ("PAP") treatment. Patients with a body mass index above 32 kg/m², a complete concentric collapse ("CCC") observed during a drug induced sleep endoscopy and combined central and mixed AHI above 25% at baseline polysomnography are to be excluded.

Enrollment in the DREAM trial is now complete, and 115 patients had undergone a Genio[®] implantation procedure. The Company anticipates having 12-month clinical data in the first half of 2024 and has submitted the first module in the module PMA. No SAEs have been reported to date.

BETTER SLEEP: ACHIEVED PRIMARY ENDPOINT IN BOTH CCC AND NON-CCC PATIENT COHORTS

In March 2022, the Company attended the World Sleep Congress in Rome, Italy, and presented data generated from its BETTER SLEEP trial, a multicenter, prospective, open-label, two-group clinical trial, designed to assess the long-term safety and performance of the Genio[®] system for the treatment of adult OSA patients with and without CCC of the soft palate over a period of 36 months post-implantation. The BETTER SLEEP trial included a subgroup of CCC patients, which is a patient population that is contraindicated for unilateral hypoglossal nerve stimulation.

In the BETTER SLEEP trial, 42 patients were implanted with the Genio[®] system, 18 of whom presented with CCC (or 42.9% of the total implanted population) at eight research centers in Australia. The primary safety endpoint was the incidence of device-related SAEs six months post-implantation. The primary performance endpoint was achieving at least a 4-point reduction in the apnea-hypopnea index (4% oxygen desaturation, or AHI4) from baseline at six months for the entire patient cohort. Patients with moderate to severe AHI scores (15 < AHI < 65) and aged between 21 and 75 years were eligible for enrollment if they failed, refused or did not tolerate PAP treatment. Patients with a body mass index above 32 kg/m² were excluded.

Three patients in the non-CCC arm and three patients in the CCC arm did not complete their six-month polysomnography, and as a result, the analysis was calculated based on 36 patients (21 non-CCC and 15 CCC). Of these 36 patients, there were 23 responders (64%), including nine of the 15 CCC patients (60%) and 14 of the 21 non-CCC patients (67%), at six months. The overall reduction was statistically significant with an 11-point reduction ($p < 0.001$), with statistically significant reductions of 10 points ($p = 0.001$) in the CCC cohort and 11 points ($p < 0.001$) in the non-CCC cohort. In addition, mean AHI4 reduction exceeded 70% among responders in both CCC and non-CCC cohorts. These results are subject to final review and validation.

With respect to the primary safety endpoint, preliminary unadjudicated safety data showed four SAEs in three patients during the six-month post-implantation period. Of those, two SAEs in one patient were reported as device related, one SAE in one patient was reported as procedure and device related, and one SAE in one patient was reported as unrelated to procedure or device. Final review and adjudication of SAEs and adverse events ("AEs") have not yet been completed by an independent clinical events committee and as a result the characterization of SAEs or AEs could be subject to change.

While additional data, including responder rates, remains subject to ongoing review and continues to be analyzed, the Company observed in the per protocol group a 70% responder rate in the non-CCC patient subgroup based on the Sher criteria. The per protocol group consisted of 35 patients and excluded five patients from the mITT analysis population: two of these patients were lost to follow-up, one patient did not comply with the study protocol, and two patients were removed from the study by the investigator, one for hostility towards staff and one having returned to continuous positive airway pressure, therapy.

The Company expects to announce additional data with respect to the trial as further analyses are conducted and seeks to publish the full data set from the trial in a peer-reviewed publication. There will be no additional enrollment in the BETTER SLEEP trial. However, the Company will continue to monitor patients in the evaluable patient population and plan to continue evaluating over the course of three years following implantation.

The data generated from this study were used to expand the Company's CE mark for the Genio® system to treat patients demonstrating CCC at the soft palate level, and the first commercial Genio® implants occurred in CCC patients in Germany during the first quarter of 2022.

ACCESS U.S. IDE STUDY SEEKING APPROVAL TO TREAT CCC PATIENTS

In the United States, supported by the BETTER SLEEP study data, the FDA in September 2021 granted Breakthrough Device Designation for the Genio® system in order to shorten the approval path to treat CCC patients. Following a series of sprint discussions with the FDA regarding the design of a trial called ACCESS to assess the safety and efficacy of the Genio® system on CCC patients, the FDA approved the Company's IDE application in July 2022.

In this study, Nyxoah will implant up to 106 patients across up to 40 implant sites with co-primary efficacy endpoints of AHI responder rate, per the Sher criteria, and ODI responder rate, both assessed at 12 months post-implant. The initial clinical sites are being activated, and the first patients have been implanted.

B. EUROPEAN COMMERCIALIZATION

During the first three months of 2023, Nyxoah recognized total revenue of €441,000, primarily in Germany.

Nyxoah's commercial strategy is focused on creating a Center of Excellence ecosystem, with a high level of clinical expertise between implanting ENT surgeons and sleep physicians who are able to provide more treatment options to their large patient pools. As of March 31, 2023, the Company has activated 40 active centres across Germany, up from 38 as of December 31, 2022.

The company has also focused on entering new European markets. The Company has secured DRG reimbursement in Switzerland, hospital reimbursement in Spain and generated its first commercial implants in Austria.

2. FINANCIAL HIGHLIGHTS

Revenue was €441,000 for the three months ending March 31, 2023, compared to €0.7 million for the three months ending March 31, 2022. The decrease in revenue was attributable to transitory factors with strong revenue uptake expected in Q2.

Cost of goods sold was €175,000 for the three months ending March 31, 2023, compared to €289,000 cost for the three months ending March 31, 2022. The decrease in cost of goods sold was attributable to the sales of the Genio® system in Europe.

Selling, general and administrative expenses increased by €1.4 million or 33% from €4.2 million for the three months ending March 31, 2022 to €5.6 million for the three months ending March 31, 2023, mainly due to an increase of costs to support the commercialization of Genio® system in Europe, scale up of the Company and also due to a start of new ERP system implementation.

Before capitalization of €2.7 million for the three months ended March 31, 2023 and €3.4 million for the three months ended March 31, 2022, research and development expenses increased by €1.8 million or 26%, from €7.0 million for the three months ended March 31, 2022, to €8.9 million for the three months ended March 31, 2023, due to the combined increase of €1.2 million in clinical expenses, €0.7 million in manufacturing and QA activities and €0.2 million due to a start of new ERP system implementation, which was offset by a decrease of €0.3 million in R&D activities.

Nyxoah realised a net negative financial result of €333,000 for the three months ending March 31, 2023 primarily driven by the exchange rate appreciation of dollar versus euro. This compares to a net positive financial result of €0.8 million for the three months ending March 31, 2022.

Nyxoah realized a net loss of €11.9 million for the three months ending March 31, 2023, compared to a net loss of €6.7 million for the three months ending March 31, 2022.

Cash and cash equivalents

On March 31, 2023, cash and cash equivalents and financial assets totalled €96.1 million, compared to €94.9 million on December 31, 2022. The increase in cash and cash equivalents resulted mainly from net cash used in financial activities of 15.4 million due to capital increase and offset by net cash flows used in operating activities and in investing activities.

3. 2023 OUTLOOK

The Company expects to continue ramping up sales in Germany as well as in other European countries where we are already present.

In the US, the Company will focus on patient follow-up in the DREAM IDE trial resulting in reaching primary endpoints and implant the first patients in the ACCESS IDE study for CCC patients. Nyxoah will begin preparations to enter the US market with regulatory, manufacturing and market access readiness.

4. RISK FACTORS

We refer to the description of risk factors in the Company's 2022 annual report, pp. 58-83. In summary, the principal risks and uncertainties faced by us relate to our financial situation and need for additional capital, clinical development of our product candidates, commercialization and reimbursement of our product candidates, our dependence on third parties and on key personnel, the markets and countries in which we operate, the manufacturing of our product candidates, legal and regulatory compliance matters, our intellectual property, our organization and operations.

5. FORWARD-LOOKING STATEMENTS

This interim management report contains forward-looking statements. All statements other than present and historical facts and conditions contained in this report, including statements regarding our future results of operations and financial position, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this report, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements. By their nature, forward-looking statements involve risks and uncertainties, and readers are cautioned that any such forward-looking statements are not guarantees of future performance. Nyxoah's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including Nyxoah's expectations regarding the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements; Nyxoah's reliance on collaborations with third parties; estimating the commercial potential of Nyxoah's product candidates; Nyxoah's ability to obtain and maintain protection of intellectual property for its technologies; Nyxoah's limited operating history; and Nyxoah's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in Nyxoah's 2022 annual report. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. Nyxoah expressly disclaims any obligation to update any such forward-looking statements in this document, to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by applicable law or regulation.

NYXOAH SA

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION AS AT AND
FOR THE THREE MONTHS ENDED MARCH 31, 2023 –
INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(unaudited)

(in thousands)

		As at	
	Notes	March 31 2023	December 31 2022
ASSETS			
Non-current assets			
Property, plant and equipment	7	€ 2 721	€ 2 460
Intangible assets	8	42 447	39 972
Right of use assets	9	3 669	3 159
Deferred tax asset	19	50	47
Other long-term receivables		169	173
		€ 49 056	€ 45 811
Current assets			
Inventory	10	1 249	882
Trade receivables	11	1 499	1 463
Other receivables	11	1 419	1 775
Other current assets	12	1 663	1 284
Financial assets	14	62 403	76 968
Cash and cash equivalents	13	33 664	17 888
		€ 101 897	€ 100 260
Total assets		€ 150 953	€ 146 071
EQUITY AND LIABILITIES			
Capital and reserves			
Capital	15	4 859	4 440
Share premium	15	243 488	228 275
Share based payment reserve	16	6 582	5 645
Other comprehensive income	15	148	176
Retained loss		(130 051)	(118 212)
Total equity attributable to shareholders		€ 125 026	€ 120 324
LIABILITIES			
Non-current liabilities			
Financial debt	17	8 381	8 189
Lease liability	9	3 112	2 586
Pension liability		25	-
Provisions		74	59
Deferred tax liability		-	-
		€ 11 592	€ 10 834
Current liabilities			
Financial debt	17	390	388
Lease liability	9	711	719
Trade payables	18	5 012	4 985
Current tax liability	19	3 619	3 654
Other payables	20	4 603	5 167
		€ 14 335	€ 14 913
Total liabilities		€ 25 927	€ 25 747
Total equity and liabilities		€ 150 953	€ 146 071

The accompanying notes are an integral part of these condensed consolidated interim financial statements.

NYXOAH SA

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION AS AT AND
FOR THE THREE MONTHS ENDED MARCH 31, 2023 -
INTERIM CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS

(unaudited)

(in thousands)

	Notes	For the three months ended March 31	
		2023	2022
Revenue	22	€ 441	€ 660
Cost of goods sold	22	(175)	(289)
Gross profit		€ 266	€ 371
Research and Development Expense	22	(6 157)	(3 595)
Selling, General and Administrative Expense	22	(5 551)	(4 193)
Other income/(expense)		46	136
Operating loss for the period		€ (11 396)	€ (7 281)
Financial income	24	625	1 576
Financial expense	25	(958)	(788)
Loss for the period before taxes		€ (11 729)	€ (6 493)
Income taxes	19	(182)	(208)
Loss for the period		€ (11 911)	€ (6 701)
Loss attributable to equity holders		€ (11 911)	€ (6 701)
Other comprehensive loss			
Items that may be subsequently reclassified to profit or loss (net of tax)			
Currency translation differences		(28)	(102)
Total comprehensive loss for the year, net of tax		€ (11 939)	€ (6 803)
Loss attributable to equity holders		€ (11 939)	€ (6 803)
Basic Loss Per Share (in EUR)	26	€ (0.460)	€ (0.260)
Diluted Loss Per Share (in EUR)	26	€ (0.460)	€ (0.260)

The accompanying notes are an integral part of these condensed consolidated interim financial statements

NYXOAH SA

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION AS AT AND
FOR THE THREE MONTHS ENDED MARCH 31, 2023 -
INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(unaudited)

(in thousands)

	Attributable to owners of the parent					
	Common shares	Share premium	Share based payment reserve	Other comprehensive income	Retained loss	Total
Balance at January 1, 2023	€ 4 440	€ 228 275	€ 5 645	€ 176	€ (118 212)	€ 120 324
Loss for the period	-	-	-	-	(11 911)	(11 911)
Other comprehensive loss for the period	-	-	-	(28)	-	(28)
Total comprehensive loss for the period	-	-	-	€ (28)	€ (11 911)	€ (11 939)
Equity-settled share-based payments						
Granted during the period	-	-	1 009	-	-	1 009
Forfeited during the period	-	-	(72)	-	72	-
Transaction cost	-	(267)	-	-	-	(267)
Issuance of shares for cash	419	15 480	-	-	-	15 899
Total transactions with owners of the company recognized directly in equity	419	15,213	937	-	72	16,641
Balance at March 31, 2023	€ 4 859	€ 243 488	€ 6 582	€ 148	€ (130 051)	€ 125 026

	Attributable to owners of the parent					
	Common shares	Share premium	Share based payment reserve	Other comprehensive income	Retained loss	Total
Balance at January 1, 2022	€ 4 427	€ 228 033	€ 3 127	€ 202	€ (87 167)	€ 148 622
Loss for the period	-	-	-	-	(6 701)	(6 701)
Other comprehensive income for the period	-	-	-	(102)	-	(102)
Total comprehensive loss for the period	-	-	-	€ (102)	€ (6 701)	€ (6 803)
Equity-settled share-based payments						
Granted during the period	-	-	665	-	-	665
Exercised during the period	5	125	(4)	-	4	130
Total transactions with owners of the company recognized directly in equity	5	125	661	-	4	795
Balance at March 31, 2022	€ 4 432	€ 228 158	€ 3 788	€ 100	€ (93 864)	€ 142 614

The accompanying notes are an integral part of these condensed consolidated interim financial statements.

NYXOAH SA

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION AS AT AND
FOR THE THREE MONTHS ENDED MARCH 31, 2023 –
INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Notes	For the three months ended March 31	
		2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax for the year		€ (11 729)	€ (6 493)
Adjustments for			
Finance income		(625)	(1 576)
Finance expenses		958	788
Depreciation and impairment of property, plant and equipment and right-of-use assets	7, 9	318	255
Amortization of intangible assets	8	237	208
Share-based payment transaction expense	16	1 009	665
Increase/(Decrease) in provisions		41	10
Other non-cash items		(164)	180
Cash generated before changes in working capital		€ (9 955)	€ (5 963)
Changes in working capital			
Decrease/(Increase) in inventory	10	(367)	45
(Increase)/Decrease in trade and other receivables	11	132	884
Increase/(Decrease) in trade and other payables	18, 20	(427)	(392)
Cash generated from changes in operations		€ (10 617)	€ (5 426)
Income tax paid		(51)	(65)
Net cash used in operating activities		€ (10 668)	€ (5 491)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	7	(423)	(128)
Capitalization of intangible assets	8	(2 713)	(3 412)
Purchase of financial assets - current	14	(16 997)	(44 032)
Proceeds from sale of financial assets - current	14	31 383	-
Interest income on financial assets		116	-
Net cash used in investing activities		€ 11 366	€ (47 572)
CASH FLOWS FROM FINANCING ACTIVITIES			
Payment of principal portion of lease liabilities	9	(200)	(146)
Repayment of other loan		(21)	(21)
Interests paid		(7)	(109)
Repayment of recoverable cash advance	15	-	-
Proceeds from issuance of shares, net of transaction costs	15	15 632	130
Other financial costs		(22)	(2)
Net cash used in financing activities		€ 15 382	€ (148)
Movement in cash and cash equivalents		€ 16 080	€ (53 211)
Effect of exchange rates on cash and cash equivalents		(304)	489
Cash and cash equivalents at January 1	13	€ 17 888	€ 135 509
Cash and cash equivalents at March 31	13	€ 33 664	€ 82 787

The accompanying notes are an integral part of these condensed consolidated interim financial statements.

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

1. General information

Nyxoah SA (the “Company”) is a public listed company with limited liability (naamloze vennootschap/société anonyme) incorporated and operating under the laws of Belgium and is domiciled in Belgium. The Company is registered with the legal entities register (Brabant Walloon) under enterprise number 0817.149.675. The Company’s registered office is in Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

The Company is a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea, or OSA. Our lead solution is the Genio[®] system, a CE-Marked, patient-centric, minimally invasive, next generation hypoglossal neurostimulations therapy for OSA. OSA is the world’s most common sleep disordered breathing condition and is associated with increased mortality risk and comorbidities including cardiovascular diseases, depression and stroke.

The Genio[®] system is the first neurostimulation system for the treatment of OSA to include a battery-free and leadless neurostimulator capable of delivering bilateral hypoglossal nerve stimulation to keep the upper airway open. The product is intended to be used as a second-line therapy to treat moderate to severe OSA patients who have either not tolerated, failed or refused conventional therapy, including Continuous Positive Airway Pressure, or CPAP, which, despite its proven efficacy, is associated with many limitations, meaning compliance is a serious challenge. In addition, other second-line treatments are more suitable to treat mild to moderate OSA (such as oral devices) or highly invasive. Compared to other hypoglossal nerve stimulation technologies for the treatment of OSA, the Genio[®] system is a disruptive, differentiating technology that targets a clear unmet medical need thanks to its minimally invasive and quick implantation technique, its external battery and its ability to stimulate the two branches of the hypoglossal nerve.

Obstructive sleep apnea is the world’s most common sleep disordered breathing condition. OSA occurs when the throat and tongue muscles and soft tissues relax and collapse. It makes a person stop breathing during sleep, while the airway repeatedly becomes partially (hypopnea) or completely (apnea) blocked, limiting the amount of air that reaches the lungs. During an episode of apnea or hypopnea, the patient’s oxygen level drops, which leads to sleep interruptions.

Nyxoah SA has established three wholly owned subsidiaries: Nyxoah Ltd, a subsidiary of the Company since October 21, 2009 (located in Israel and incorporated on January 10, 2008 under the name M.L.G. Madaf G. Ltd), Nyxoah Pty Ltd since February 1, 2017 (located in Australia) and Nyxoah Inc. since May 14, 2020 (located in the USA).

The interim condensed consolidated financial statements of Nyxoah SA and its subsidiaries (collectively, the Group) as of March 31, 2023 and for the three months ended March 31, 2023, have been authorized for issue on May 16, 2023 by the Board of Directors of the Company.

2. Significant accounting policies

Basis of Preparation of the interim condensed consolidated financial statements

The Company’s interim condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 – Interim Financial Reporting (“IFRS”), as issued by the International Accounting Standards Board (IASB). They do not include all the information required for complete annual financial statements and should be read in conjunction with the Company’s last annual consolidated financial statements as at and for the year ended December 31, 2022.

Except for the application of standards, interpretations and amendments being mandatory as of January 1, 2023, the accounting policies used for the preparation of the interim condensed consolidated financial statements are consistent with those used for the preparation of the Company’s annual consolidated financial statements as of and for the year ended December 31, 2022.

The consolidated financial statements are presented in thousands of Euros (€) and all values are rounded to the nearest thousands, except when otherwise indicated (e.g. € million).

The preparation of the interim condensed consolidated financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company’s accounting policies. The areas involving a higher degree of judgement or complexity, are areas where assumptions and estimates are significant to the consolidated financial statements. The critical accounting estimates used in the preparation of the interim consolidated financial statements are consistent with those followed in the preparation of the Company’s annual consolidated financial statements as of and for the year ended December 31, 2022.

An entity shall determine the net defined benefit liability (asset) with sufficient regularity that the amounts recognized in the financial statements do not differ materially from the amounts that would be determined at the end of the reporting period. The current pension obligation results from defined benefit liability does not materially differ on a nine months basis therefore the Company has determined to recognize the net defined benefit liability on annual basis being at the end of the reporting period.

Going concern principle

The Unaudited Interim Condensed Consolidated Financial Statements have been prepared on a going concern basis. As at March 31, 2023, the Company had cash and cash equivalents of €33.7 million and financial assets of €62.4 million. Based on cash flow forecasts for the remaining period of 2023 and 2024, which include significant expenses and cash outflows in relation to – among others – the ongoing clinical trials, the continuation of research and development project, and the scaling up of the Company’s manufacturing facilities. The Company believes that this cash position will be sufficient to meet the Company’s capital requirements and fund its operations for at least 12 months as from the date these financials are authorized for issuance.

The Company does not believe that the Ukraine war will have an impact on the Company’s going concern. The Company does not have business relationships with Russia nor Ukraine. There is no direct nor indirect impact of the conflict on the day to day business of the Company. The Company is not specifically impacted by inflation, supply disruption or cyber attacks due to the current geopolitical conflict

New and amended standards and interpretations applicable

Effective for the annual periods beginning on January 1, 2023

The Group has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective.

Several amendments and interpretations apply for the first time in 2023, but do not have an impact on the interim condensed consolidated financial statements of the Company:

- IFRS 17 Insurance Contracts (applicable for annual periods beginning on or after January 1, 2023)
- Amendments to IFRS 17 Insurance contracts: Initial Application of IFRS 17 and IFRS 9 – Comparative Information (applicable for annual periods beginning on or after January 1, 2023)
- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting Policies (applicable for annual periods beginning on or after January 1, 2023)
- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates (applicable for annual periods beginning on or after January 1, 2023)
- Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction (applicable for annual periods beginning on or after January 1, 2023)

3. Critical accounting estimates and assumptions

The preparation of interim financial statements in accordance with IFRS requires management to make judgments, estimates and assumptions that may significantly affect the reported amounts of revenues, expenses, assets and liabilities, and the disclosure of contingent liabilities at the end of the reporting period.

Refer to the disclosure note 5 from the Group’s 2022 year-end consolidated financial statements for further details about the main critical accounting estimates and assumptions.

4. Segment reporting

Based on the organizational structure, as well as the nature of financial information available and reviewed by the Company’s chief operating decision makers to assess performance and make decisions about resource allocations, the Company has concluded that its total operations represent one reportable segment. The chief operating decision maker is the CEO.

5. Fair Value

The carrying amount of cash and cash equivalents, trade receivables, other receivables, other current assets and financial assets approximate their value due to their short-term character.

The carrying value of current liabilities approximates their fair value due to the short-term character of these instruments. The fair value of non-current liabilities (financial debt and other non-current liabilities), excluding the derivative financial liabilities, is evaluated based on their interest rates and maturity date. These instruments have fixed interest rates and their fair value measurements are subject to changes in interest rates. The fair value measurement is classified as level 3.

The derivative financial liabilities and assets which consist of foreign currency options and foreign currency forwards are measured at fair value through profit and loss. Fair value is determined by the financial institution and is based on foreign currency forwards rates and the maturity of the instrument.

(in EUR 000)	Carrying value		Fair value	
	As at March 31, 2023	As at December 31, 2022	As at March 31, 2023	As at December 31, 2022
Financial Assets				
Other long-term receivables (level 3)	169	173	169	173
Trade and other receivables (level 3)	2 915	3 237	2 915	3 237
Foreign currency forwards (level 2)	3	1	3	1
Other current assets (level 3)	1 663	1 284	1 663	1 284
Cash and cash equivalents (level 1)	33 664	17 888	33 664	17 888
Financial assets (level 1)	62 403	76 968	62 403	76 968

(in EUR 000)	Carrying value		Fair value	
	As at March 31, 2023	As at December 31, 2022	As at March 31, 2023	As at December 31, 2022
Financial liabilities				
Financial debt (level 3)	125	146	118	138
Foreign currency option (level 2)	108	10	108	10
Recoverable cash advances (level 3)	8 646	8 431	8 646	8 431
Trade and other payables (level 1 and 3)	9 507	10 142	9 507	10 142

6. Subsidiaries

For all periods that are mentioned in this report, the Company owns 100% of the shares of Nyxoah LTD, an Israeli company located in Tel-Aviv that was incorporated in 2009 and has a share capital of NIS 1.00.

The Company also owns 100% of the shares of Nyxoah PTY LTD, an Australian Company located in Collingwood that was incorporated in 2017 and has a share capital of AUD 100.

In May 2020, the Company incorporated Nyxoah Inc, an US-based company located in Delaware with a share capital of USD 1.00. The Company owns 100% of the shares of Nyxoah Inc.

7. Property, Plant and Equipment

The total acquisitions for the three months ended March 31, 2023 amount to €423,000 (2022: €128,000) and were mainly related to laboratory equipment and furniture and office equipment. Assets under construction were transferred to leasehold improvements for an amount of €0.6 million and to laboratory equipment for an amount of €139,000.

The depreciation charge amounts to €136,000 in 2023 and to €101,000 in 2022 for the three months ended March 31.

8. Intangible assets

(in EUR 000)	Development cost	Patents and licenses	Total
Cost			
Opening value at January 1, 2022	25 610	591	26 201
Additions	3 412	-	3 412
Cost at March 31, 2022	29 022	591	29 613
Opening value at January 1, 2023	41 073	591	41 664
Additions	2 713	-	2 713
Cost at March 31, 2023	43 786	591	44 377
Amortization			
Opening amortization at January 1, 2022	(837)	(42)	(879)
Amortization	(197)	(11)	(208)
Amortization at March 31, 2022	(1 034)	(53)	(1 087)
Opening amortization at January 1, 2023	(1 608)	(85)	(1 693)
Amortization	(227)	(10)	(237)
Amortization at March 31, 2023	(1 835)	(95)	(1 930)
Net book value at March 31, 2022	27 988	538	28 526
Net book value at March 31, 2023	41 951	496	42 447

There is only one development project: The Genio[®] system. The Company started amortizing the first-generation Genio[®] system in 2021. The amortization amounted to €237,000 for the three months ended March 31, 2023 (2022: €208,000) and is included in research and development expense.

The Company continues to incur in 2023 development expenses with regard to the improved second-generation Genio[®] system and clinical trials to obtain additional regulatory approvals in certain countries or to be able to sell the Genio[®] System in certain countries. The total capitalized development expenses amounted to €2.7 million and €3.4 million for the three months ended March 31, 2023, and 2022, respectively.

9. Right of use assets and lease liabilities

For the three months ended March 31, 2023, the Company did enter into new lease agreements for €68,000 (2022: €96,000). On top of that an existing lease contract has been extended for 15 years, resulting in an increase of the RoU asset and lease liability with €0.7 million. The repayments of lease liabilities amounted to €171,000 (2022: €146,000). The depreciations on the right of use assets amounted to €182,000 and €154,000 for the three months ended March 31, 2023, and 2022, respectively.

10. Inventory

(in EUR 000)	As at	
	March 31, 2023	December 31, 2022
Raw materials	275	498
Work in progress	754	100
Finished goods	220	284
Total Inventory	1 249	882

The increase in inventory is due to increasing activities to prepare for the commercialization and further scale-up of the company in 2023. For the period ended March 31, 2023 and the year ended December 31, 2022 the Company did not recognize any expenses for inventory write-offs since the inventory level is expected to be sold in the foreseeable future.

11. Trade and Other receivables

(in EUR 000)	As at	
	March 31, 2023	December 31, 2022
Trade receivables	1 499	1 463
R&D incentive receivable (Australia)	356	346
VAT receivable	608	847
Current tax receivable	71	159
Foreign currency swaps	3	1
Other	381	422
Total trade and other receivables	2 918	3 238

The decrease of €320,000 in trade and other receivables is mainly due to decrease in VAT and current tax receivables.

The trade receivables as at March 31, 2023 are in line with the trade receivables as at December 31, 2022.

The Company can include unbilled receivables in its accounts receivable balance. Generally, these receivables represent earned revenue from products delivered to customers, which will be billed in the next billing cycle. All amounts are considered collectible and billable. As at December 31, 2022 and March 31, 2023, there were no unbilled receivables included in the trade receivables.

R&D incentive receivables relates to incentives received in Australia as support to the clinical trials and the development of the Genio[®] system.

The current tax receivable relates to excess payment of corporate income tax in Israel and in Belgium.

We refer to note 21 for more details on the foreign currency swaps.

12. Other current assets

The increase of €379,000 in other current assets as at March 31, 2023 is mainly due to a general increase in prepaid expenses and to a payment of €250,000 towards the Educational Grant with SMR Holding UG (Dr. Sommers). We refer to note 27 for more details.

13. Cash and cash equivalents

(in EUR 000)	As at	
	March 31, 2023	December 31, 2022
Short term deposit	4 635	36
Current accounts	29 029	17 852
Total cash and cash equivalents	33 664	17 888

The increase of current accounts by €11.2 million and the increase of short term deposits by €4.6 million is due to a decrease in term accounts of €14.6 million recorded as financial assets (we refer to note 14 for more details).

14. Financial assets

Current financial assets relate to term accounts with an initial maturity longer than 3 months but less than 12 months measured at amortized costs.

In 2023, the Company entered into USD term deposits at a well-established Belgian financial institution for a total amount \$US 15.0 million (€14.0 million) and €3.0 million. During the period ended as at March 31, 2023, \$US 25 million (€23.4 million) and €8.0 million reached maturity and is subsequently held as cash.

The investments in USD and EUR term deposits are made with excess cash, to optimize the Company's return and thus benefit the cash management whereby negative returns on cash balances are decreased.

As per March 31, 2023, the current financial assets consists of \$US 20.0 million (€18.4 million), which could generate a foreign currency exchange gain or loss in the financial results in accordance with the fluctuations of the USD/EUR exchange rate as the Company's functional currency is EUR, and €44.0 million. The total amount of term deposits as per March 31, 2023, amounts to €62.4 million.

15. Capital, Share Premium, Reserves

15.1. Capital and share premium

The number of shares and the par value in the paragraph below take into account resolutions adopted by the shareholders' meeting of February 21, 2020. All existing preferred shares were converted into common shares, and then a share split of 500:1 was approved by the shareholders' meeting. The tables and comments below reflect the number of shares after the share split of 500:1 as of January 1, 2020.

As part of the IPO on September 21, 2020, the Company incurred direct-attributable transaction costs of €6.5 million which have been deducted from the share premium.

As of March 31, 2023, the share capital of the Company amounts to €4.9 million represented by 28,286,985 shares, and the share premium amounts to €257.9 million (before deduction of the transaction costs).

Evolution of the share capital and share premium over the three months ended March 31, 2023 and 2022:

(Number of shares except otherwise stated)	Common shares	Total of shares	Par value (EUR)	Share capital	Share premium
January 1, 2022	25 772 359	25 772 359	0.17	4 427	242 198
February 10, 2022 - Exercise warrants	25 000	25 000	0.17	4	125
March 31, 2022	25 797 359	25 797 359	0.17	4 431	242 323
June 8, 2022 - Capital increase in cash	38 920	38 920	0.17	7	-
September 30, 2022 - Exercise warrants	10 000	10 000	0.17	2	117
December 31, 2022	25 846 279	25 846 279	0.17	4 440	242 440
March 29, 2023 - Capital increase in cash	393 162	393 162	0.17	68	2 481
March 30, 2023 - Capital increase in cash	2 047 544	2 047 544	0.17	351	12 999
March 31, 2023	28 286 985	28 286 985	0.17	4 859	257 920

On March 29, 2023, the Company issued 393,162 new shares for an aggregate capital increase of €2.5 million (including share premium). The Company raised \$2.8 million in gross proceeds pursuant to the Company's \$50 million at-the-market ("ATM") program established on December 22, 2022 at an issue price equal to the market price on the Nasdaq Global Market at the time of the sale. The shares were purchased by historical Nyxoah shareholder Cochlear Limited, and the proceeds will be used for general corporate purposes.

On March 30, 2023, the Company raised €13.35 million private placement financing from the sale of 2,047,544 new ordinary shares at a price per share of €6.52 (approximately U.S. \$7.10 at current exchange rates), the closing price on Euronext Brussels on March 23, 2023. Gross proceeds total €13.35 million (approximately U.S. \$15 million at current exchange rates) and will be used for general corporate purposes.

As part of both capital increases, the Company incurred direct-attributable transaction costs of €267,000 which have been deducted from the share premium. The proceeds from the capital increase net of transaction costs amounted to €15.6 million.

15.2. Reserves

The reserves include the share-based payment reserve (see note 16), other comprehensive income and the retained loss. Retained loss is comprised of primarily accumulated losses, other comprehensive income is comprised of currency translation reserves and remeasurements of post-employment benefit obligations.

The movement in other comprehensive income for the three months ended March 31, 2023 and 2022 is detailed in the table below:

(in EUR 000)	Currency translation reserve	Post- employment benefit obligations	Total
Opening value at January 1, 2022	270	(68)	202
Currency translation differences	(102)	-	(102)
Total other comprehensive income at March 31, 2022	168	(68)	100
Opening value at January 1, 2023	174	2	176
Currency translation differences	(28)	-	(28)
Total other comprehensive income at March 31, 2023	146	2	148

16. Share-Based compensation

Equity-settled share-based payment transactions

As of March 31, 2023, the Company has four outstanding equity-settled share-based incentive plans, including (i) the 2016 warrants plan (the 2016 Plan), (ii) the 2018 warrants plan (the 2018 Plan), (iii) the 2020 warrants plan (the 2020 Plan) and (iv) the 2021 warrants plan (the 2021 plan). The Company had an extraordinary shareholders' meeting on February 21, 2020 where it was decided to achieve a share split in a ratio of 500:1. Per warrant issued before February 21, 2020, 500 common shares will be issuable. For presentation purposes the tables and comments below reflect the number of shares the warrants give right to across all plans.

In accordance with the terms of the various plans, all warrants that had not yet vested before, vested on September 7, 2020, i.e. ten business days prior to the closing of the IPO on September 21, 2020.

On December 28, 2022, the Board of Directors, within the framework of the authorized capital, issued 700.000 warrants, giving each the right to subscribe to one common share of the Company. By consequence, the Company can issue up to 700.000 common shares if all warrants are exercised. As per March 31, 2023, no warrants of the 2022 Plan have been granted by the Company.

The changes of the period for the equity-settled warrant plans are as follows:

Number of shares (after share split) warrants give right to across all plans	2023	2022
Outstanding at January 1	1 416 490	993 490
Granted	200 862	214 000
Forfeited/Cancelled	(62 625)	(2 500)
Exercised	-	(25 000)
Outstanding as at March 31	1 554 727	1 179 990
Exercisable as at March 31	875 336	714 810

On March 24, 2023, 200,862 warrants were granted from the 2021 plan.

The following tables provide the input to the Black-Scholes model for warrants granted in 2018, 2020, 2021, 2022 and 2023 related to the 2016 warrant plan, the 2018 warrant plan, the 2020 warrant plan and the 2021 warrant plan. The tables and notes uses as a basis, the number of shares the warrants give right to across all plans.

	Plan 2016 (grant 2018)	Plan 2018 (grant 2018)	Plan 2018 (grant 2020)	Plan 2020 (grant 2020)	Plan 2021 (grant Sept 17 2021)
Return Dividend	0%	0%	0%	0%	0%
Expected volatility	66.92%	56.32%	56.32%	56.32%	51.30%
Risk-free interest rate	0.35%	-0.20%	-0.20%	-0.20%	-0.36%
Expected life	3	3	3	3	3
Exercise price	5.17	6.52	11.94	11.94	25.31
Stock price	1.09	10.24	10.20	10.20	25.75
Fair value	0.10	5.30	3.31	3.31	9.22

	Plan 2021 (grant Oct 27 2021)	Plan 2021 (grant Feb 21 2022)	Plan 2021 (grant Feb 21 2022)	Plan 2021 (grant Feb 21 2022)	Plan 2021 (grant May 14 2022)
Return Dividend	0%	0%	0%	0%	0%
Expected volatility	51.50%	49.80%	49.80%	49.80%	49.80%
Risk-free interest rate	-0.18%	0.37%	0.37%	0.50%	1.06%
Expected life	3	3	3	4	3
Exercise price	25.31	17.76	25.31	17.76	13.82
Stock price	20.50	17.50	17.50	17.50	13.82
Fair value	5.94	6.05	4.15	6.90	4.94

	Plan 2021 (grant June 8 2022)	Plan 2021 (grant Aug 8 2022)	Plan 2021 (grant Aug 8 2022)	Plan 2021 (grant March 24 2023)
Return Dividend	0%	0%	0%	0%
Expected volatility	52.60%	53.71%	53.97%	52.00%
Risk-free interest rate	1.60%	1.39%	1.45%	3.20%
Expected life	3	3	4	3
Exercise price	12.95	9.66	9.66	5.42
Stock price	13.34	9.75	9.75	6.70
Fair value	5.21	3.79	4.32	3.09

On March 24, 2023, the Company reduced the exercise price of 75% of the warrants previously granted to warrant holders under the 2021 Warrants Plan to 5.42 EUR to reflect the decrease in the company's share price. For the remaining 25% of the warrants previously granted under the 2021 Warrants Plan, the exercise price will remain unchanged. All other terms and conditions of the re-priced warrants remain unchanged to the original option agreement. The Company determined the fair value of the options at the date of the modification (March 24, 2023). The incremental fair value of the re-priced warrants will be recognised as an expense over the period from the modification date to the end of the vesting period. For the warrants already vested at the date of modification, the incremental fair value is fully recognised in P&L at date of modification. The expense for the original option grant will continue to be recognised as if the terms had not been modified.

The fair value of the modified warrants was determined using the same models and principles as described above, with the following model inputs:

	Plan 2021 (grant Sept 17 2021)	Plan 2021 (grant Oct 27 2021)	Plan 2021 (grant Feb 21 2022)	Plan 2021 (grant Feb 21 2022)
Return Dividend	0%	0%	0%	0%
Expected volatility	52.00%	52.00%	52.00%	52.00%
Risk-free interest rate	3.25%	3.25%	3.17%	3.36%
Expected life	2	2	2	2
Exercise price	5.42	5.42	5.42	5.42
Stock price	6.68	6.68	6.68	6.68
Fair value	2.48	2.52	2.67	2.49
Incremental Fair value	2.38	2.40	2.23	2.38

	Plan 2021 (grant Feb 21 2022)	Plan 2021 (grant May 14 2022)	Plan 2021 (grant Aug 8 2022)	Plan 2021 (grant Aug 8 2022)
Return Dividend	0%	0%	0%	0%
Expected volatility	52.00%	52.00%	52.00%	52.00%
Risk-free interest rate	3.03%	3.13%	3.13%	2.98%
Expected life	3	2	3	4
Exercise price	5.42	5.42	5.42	5.42
Stock price	6.68	6.68	6.68	6.68
Fair value	3.05	2.75	2.87	3.21
Incremental Fair value	2.23	1.92	1.28	1.19

The Company has recognized €1.0 million share-based payment expense for the three months ended March 31, 2023 (2022: €0.7 million) of which €484,000 is related to the incremental fair value of the re-priced warrants.

17. Financial Debt

Financial debt consists of recoverable cash advances and other loans. Related amounts can be summarized as follows:

(in EUR 000)	As at	
	March 31, 2023	December 31, 2022
Recoverable cash advances - Non-current	8 339	8 126
Recoverable cash advances - Current	307	305
Total Recoverable cash advances	8 646	8 431
Other loan - Non-current	42	63
Other loan - Current	83	83
Total Other loan	125	146
Non-current	8 381	8 189
Current	390	388
Total Financial Debt	8 771	8 577

Financial debt related to recoverable cash advances

Recoverable cash advances received

As at March 31, 2023, the details of recoverable cash advances received can be summarized as follows:

(in EUR 000)	Contractual advances	Advances received	Amounts reimbursed
Sleep apnea device (6472)	1 600	1 600	480
First articles (6839)	2 160	2 160	494
Clinical trial (6840)	2 400	2 400	210
Activation chip improvements (7388)	1 467	1 467	44
Total	7 627	7 627	1 228

During the three months ended March 31, 2023, the Company made no reimbursements and did not receive any new amounts.

Based on expected timing of sales and after discounting, the financial debt related to the recoverable cash advances is as follows:

(in EUR 000)	As at	
	March 31, 2023	December 31, 2022
Contract 6472	1 617	1 571
Contract 6839	2 275	2 214
Contract 6840	2 863	2 790
Contract 7388	1 891	1 856
Total recoverable cash advances	8 646	8 431
Non-current	8 339	8 126
Current	307	305
Total recoverable cash advances	8 646	8 431

The amounts recorded under “Current” caption correspond to the sales-independent amounts (fixed repayment) and sales-dependent reimbursements (variable repayment) estimated to be repaid to the Walloon Region in the next 12-month period. The estimated sales-independent (fixed repayment) as well as sales-dependent reimbursements (variable repayment) beyond 12 months are recorded under “Non-current” liabilities.

Changes in the recoverable cash advances can be summarized as follows:

(in EUR 000)	2023	2022
As at January 1	8 431	8 127
Advances reimbursed (excluding interests)	-	-
Initial measurement and re-measurement	(33)	(16)
Discounting impact	248	231
As at March 31	8 646	8 342

18. Trade payables

(in EUR 000)	As at	
	March 31, 2023	December 31, 2022
Payables	1 455	1 873
Invoices to be received	3 557	3 112
Total Trade payables	5 012	4 985

The increase in total trade payables of €27,000 as at March 31, 2023 is due to an increase in invoices to be received of €445,000 which is compensated by the decrease in trade payables of €418,000. The increase in invoices to be received is due to effect of higher clinical, R&D activities and manufacturing activities.

19. Income taxes and deferred taxes

(in EUR 000)	For the three months ended March 31	
	2023	2022
Current tax income/(expense)	(187)	(692)
Deferred tax income/(expense)	5	484
Total Income Tax Income/(Expense)	(182)	(208)

The current tax expense mainly relates to (i) income tax paid or payable by certain of the Company's subsidiaries for an amount of €139,000 (2022: €631,000), and (ii) an additional accrual of the liability for uncertain tax positions for an amount of €48,000 (2022: €61,000). The uncertain tax position was recorded following certain public rulings and guidance issued by tax authorities in one of the jurisdictions that the Company operates in. The current tax liability of €3.6 million also relates to a liability for uncertain tax positions for an amount of €2.0 million.

As of January 1, 2022, new tax regulations are in place in the US. In order to fully comply with internal revenue requirements, R&D expenses can no longer be deducted when incurred but instead they will be capitalized only for tax purposes and they will be amortized over a 5 year period. The current tax liability amount to €1.5 million for the subsidiary in the United States. As the subsidiary is not expecting to generate significant profits in the near future, no deferred tax assets on temporary differences have been recognized at this stage.

20. Other payables

(in EUR 000)	As at	
	March 31, 2023	December 31, 2022
Holiday pay accrual	719	612
Salary	1 309	2 186
Accrued expenses	2 305	2 228
Foreign currency option - current	108	10
Other	162	131
Total other payables	4 603	5 167

The decrease of €0.6 million in other payables as at March 31, 2023, compared to December 31, 2022, is the result of a decrease of €0.9 million in salary payables partly offset by an increase of €98,000 in the fair value of the foreign currency option, an increase of €77,000 in accrued expenses related to an increase in clinical and R&D activities and an increase in holiday pay accrual of €107,000.

21. Derivatives

The Company is exposed to currency risk primarily due to the expected future USD, AUD and NIS expenses that will be incurred as part of the ongoing and planned marketing, clinical trials and other related expenses. A financial risk management policy has been approved to i) generate yields on liquidity and ii) reduce the exposure to currency fluctuations with a timeline up to 24 months and by means of foreign currency swaps.

The Company has entered into several foreign currency swaps for which the notional amounts are detailed in the table below:

(in EUR 000)	As at	
	March 31, 2023	December 31, 2022
Foreign currency swaps EUR - NIS (in EUR)	4 919	542
Foreign currency swaps EUR - NIS (in NIS)	19 000	2 000
Foreign currency swaps EUR - AUD (in EUR)	186	379
Foreign currency swaps EUR - AUD (in AUD)	300	600
Foreign currency swaps EUR - USD (in EUR)	650	-
Foreign currency swaps EUR - USD (in USD)	604	-
Foreign currency swaps USD - EUR (in USD)	1 000	-
Foreign currency swaps USD - EUR (in EUR)	928	-

The following table shows the carrying amount of derivative financial instruments measured at fair value in the statement of the financial position including their levels in the fair value hierarchy:

(in EUR 000)	As at March 31, 2023			
	Level I	Level II	Level III	Total
Financial assets				
Foreign currency swaps	-	3	-	3
Financial liabilities				
Foreign currency swaps	-	108	-	108

The fair value is determined by the financial institution and is based on foreign currency swaps rates and the maturity of the instrument. All foreign currency swaps are classified as current as their maturity date is within the next twelve months.

The change in the balance of the financial assets is detailed as follows:

(in EUR 000)	2023	2022
Financial asset		
Opening value at January 1	1	-
Fair value adjustments	2	47
Closing value at March 31	3	47

The change in the balance of the financial liabilities is detailed as follows:

(in EUR 000)	2023	2022
Financial liability		
Opening value at January 1	10	654
Fair value adjustments	98	365
Closing value at March 31	108	1 019

22. Results of operation

Revenue and cost of goods sold

In the three months ended March 31, 2023, the Company generated revenue for the amount of €441,000 (2022: €0.7 million).

Revenue is recognized at a point in time upon satisfaction of the performance obligation, being the moment control over the Genio[®] system is transferred to the customer, which is in general at delivery at customer site or a predefined location in the country of the customer. For certain customers, control may be transferred upon shipment to the customer in case the incoterms are Ex-Works. The revenue from the Genio[®] system consists of a kit of products delivered at the same point in time, and as such revenue does not need to be allocated over the different products. The revenue is then recognized at an amount that reflects the consideration to which the Company expects to be entitled in exchange of the Genio[®] system. In determining the transaction price for the sale of the Genio[®] system, the Company considers the effects of variable consideration.

For the three month period ended March 31, 2023 the sales (based on country of customer) were generated in Germany (€306,000), Switzerland (€94,000) and Austria (€41,000) (2022: Germany: €0.6 million, Finland: €40,000). For the three month period ended March 31, 2023, the Company has two customers with individual sales larger than 10% of the total revenue (2022: three customers).

Cost of goods sold for the three months ended March 31, 2023 and 2022:

(in EUR 000)	For the three months ended March 31	
	2023	2022
Purchases of goods and services	542	244
Inventory movement	(367)	45
Total cost of goods sold	175	289

Operating expenses

The tables below detail the operating expenses for the three months ended March 31, 2023 and 2022:

(in EUR 000)	Total cost	Capitalized	Operating expense for the period
Research and development	8 870	(2 713)	6 157
Selling, general and administrative expenses	5 551	-	5 551
Other income and expenses	(46)	-	(46)
For the three months ended March 31, 2023	14 375	(2 713)	11 662

(in EUR 000)	Total cost	Capitalized	Operating expense for the period
Research and development	7 040	(3 445)	3 595
Selling, general and administrative expenses	4 193	-	4 193
Other income and expenses	(169)	33	(136)
For the three months ended March 31, 2022	11 064	(3 412)	7 652

Research and Development expenses

(in EUR 000)	For the three months ended	
	March 31	
	2023	2022
Staff costs	3 995	2 495
Consulting and contractors' fees	804	692
Q&A regulatory	36	73
IP costs	130	102
Depreciation and amortization expense	313	251
Travel	279	122
Manufacturing and outsourced development	1 184	1 448
Clinical studies	1 376	1 610
Other expenses	431	247
IT	322	-
Capitalized costs	(2 713)	(3 445)
Total research and development expenses	6 157	3 595

Before capitalization of €2.7 million for the three months ended March 31, 2023 and €3.4 million for the three months ended March 31, 2022, research and development expenses increased by €1.8 million or 26 %, from €7.0 million for the three months ended March 31, 2022, to €8.9 million for the three months ended March 31, 2023, due to the combined effect of higher clinical, R&D activities and manufacturing expenses and also due to a start of new ERP system implementation. This increase is mainly in staff and consulting costs to support those activities.

Selling, General and Administrative expenses

(in EUR 000)	For the three months ended	
	March 31	
	2023	2022
Staff costs	2 413	1 682
Consulting and contractors' fees	1 578	1 000
Legal fees	229	234
Rent	88	75
Depreciation and amortization expense	242	211
IT	248	99
Travel	243	281
Insurance fees	287	409
Other	223	202
Total selling, general and administrative expenses	5 551	4 193

Selling, general and administrative expenses increased by €1.4 million or 32 % from €4.2 million for the three months ended March 31, 2022 to €5.6 million for the three months ended March 31, 2023, mainly due to an increase of costs to support the commercialization of Genio® system in Europe, scale up of the Company and also due to a start of new ERP system implementation.

Other operating expenses

The Company had other operating income of €46,000 for the three months ended March 31, 2023 compared to other operating expenses of €136,000 for the three months ended March 31, 2022.

(in EUR 000)	For the three months ended March 31	
	2023	2022
Recoverable cash advances		
Initial measurement and re-measurement	33	16
R&D incentives (Australia)	21	95
Capitalization of R&D incentive	-	(33)
Other income/(expenses)	(8)	58
Total Other Operating Income/(Expenses)	46	136

23. Employee benefits

(in EUR 000)	For the three months ended March 31	
	2023	2022
Salaries	4 510	2 902
Social charges	326	233
Fringe benefits	9	15
Defined contribution plan	77	70
Holiday pay	150	58
Share-based payment	1 009	665
Other	327	234
Total employee benefits	6 408	4 177

(in EUR 000)	For the three months ended March 31	
	2023	2022
Selling, general and administrative expenses	2 413	1 682
Research & Development expenses	3 995	2 495
Total employee benefits	6 408	4 177

24. Financial income

(in EUR 000)	For the three months ended March 31	
	2023	2022
Interests	413	-
Exchange differences	208	1 529
Other	4	47
Total financial income	625	1 576

For the three month period ended March 31, 2022, exchange gains amount €1.5 million, mainly due to the revaluation of both the Company's USD cash balance and USD financial assets (note 14). This was related to a decrease in the rate of EUR/USD compared to December 31, 2021. For the three month period ended March 31, 2023, exchange gains amount to €0.2 million. We refer to note 25 for more details on the revaluation of both the Company's USD cash balance and USD financial assets as per March 31, 2023.

For the three month period ended March 31, 2023, the total interest income amounted to €413,000. This interest income relates to the term accounts.

25. Financial expense

(in EUR 000)	For the three months ended March 31	
	2023	2022
Fair value adjustment	96	318
Recoverable cash advances, Accretion of interest	248	231
Interest and bank charges	27	87
Interest on lease liabilities	30	22
Exchange differences	554	83
Other	3	47
Total Financial expense	958	788

The fair value adjustment relates to the fair value adjustment on financial instruments. More information can be found in note 21.

The discounting impact of the recoverable cash advances is further detailed in note 17 above.

For the three month period ended March 31, 2023, exchange losses amount to €0.6 million, mainly due to the revaluation of both the Company's USD cash balance and USD financial assets (note 14). For the year ended December 31, 2022, the closing rate of EUR/USD amounted to 1.07265, while as at March 31, 2023, the rate of EUR/USD increased to 1.0868, resulting in unrealized exchange losses on the USD balances.

The Company holds its USD cash balances and term deposits as they expect to incur cash-outflows in the US relating to both clinical costs (DREAM and ACCESS) and to the commercial launch of the Genio[®] system.

26. Loss Per Share (EPS)

The Basic Earnings Per Share and the Diluted Earnings Per Share are calculated by dividing earnings for the year by the weighted average number of shares outstanding during the year. As the Company is incurring net losses, outstanding warrants have no dilutive effect. As such, there is no difference between the Basic and Diluted EPS.

EPS for March 2023 has been presented in the income statement taking into account resolutions adopted by the shareholders' meeting of February 21, 2020. All existing preferred shares were converted into common shares, and then a share split of 500:1 was approved by the shareholders' meeting.

	For the three months ended March 31,	
	2023	2022
<i>As at March 31, after conversion and share split</i>		
Outstanding common shares at period-end	28 286 985	25 797 359
Weighted average number of common shares outstanding	25 878 120	25 786 123
Number of shares resulting of the exercise of outstanding warrants	2 516 125	1 968 000

Basic and Diluted EPS for the three month period ended March 31, 2023 and 2022 based on weighted average number of shares outstanding after conversion and share split are as follows:

	For the three months ended March 31,	
	2023	2022
Loss of year attributable to equity holders (in EUR)	(11 911 000)	(6 701 000)
Weighted average number of common shares outstanding (in units)	25 878 120	25 786 123
Basic earnings per share in EUR (EUR/unit)	(0.460)	(0.260)
Diluted earnings per share in EUR (EUR/unit)	(0.460)	(0.260)

27. Other commitments

The Company has granted in 2022 an amount of €0.5 million towards the Educational Grant with SMR Holding UG (Dr. Sommers) for the period starting on January 1, 2023 until December 31, 2024. The first installment of €250,000 is paid by the Company in January 2023, the second installment of €250,000 is due in January 2024.

28. Related Party Transactions

Transactions between the Company and its subsidiaries have been eliminated in consolidation and are not disclosed in the notes. Related party transactions are disclosed below.

Remuneration of Key Management

The remuneration of the senior management consists of the remuneration of the CEO of the Company for the three months ended March 31:

(in EUR 000)	For the three months ended March 31	
	2023	2022
Short-term remuneration & compensation	187	145
Share based payment	66	35
Total	253	180

Transactions with Non-Executive Directors and Shareholders:

	For the three months ended March 31, 2023			For the three months ended March 31, 2022		
	R&D Collaboration	Consulting services	Board Remuneration	R&D Collaboration	Consulting services	Board Remuneration
(in EUR 000)						
Cochlear	141	-	-	793	-	-
MINV SA	-	60	-	-	60	-
Donald Deyo	-	-	-	-	-	8
Robert Taub	-	-	36	-	-	26
Kevin Rakin	-	-	16	-	-	15
Pierre Gianello	-	-	18	-	-	14
Jan Janssen	-	-	-	-	-	32
Jurgen Hambrecht	-	-	15	-	-	15
Rita Mills	-	-	15	-	-	14
Giny Kirby	-	-	14	-	-	-
Wildman Venturees LLC	-	-	17	-	-	-
Total	141	60	131	793	60	124
Amounts outstanding at period-end	1 385	60	110	-	60	98

The Company and Cochlear Limited, or Cochlear, have entered into a collaboration agreement, dated November 2018, under which they agreed to collaborate to further develop and progress commercialization of implantable treatments for sleep disordered breathing conditions. A new Statement of Work was entered into on June 8, 2020. Under this agreement, Cochlear is working with the Company in developing and enhancing the next generation implantable stimulator. This collaboration agreement led to a financial impact of €141,000 and €0.8 million for the three months ended March 31, 2022 and 2023 respectively.

29. Events after the Balance-Sheet Date

On April 17, 2023, the Company issued 375,000 shares pursuant to the Company's \$50 million at-the-market ("ATM") program established on December 22, 2022 at an issue price equal to the market price on the Nasdaq Global Market at the time of the sale. Consequently, on the date of this Annual Report, the Company's registered capital amounts to €4,923,807.45, represented by 28,661,985 shares.

RESPONSIBILITY STATEMENT

We certify that, to the best of our knowledge,

- a) the condensed consolidated interim financial statement, prepared in accordance with the applicable standards for financial statements, give a true and fair view of the assets, liabilities, financial position and results of the Company and the undertakings included in the consolidation taken as a whole; and
- b) this interim management report provides a true and fair overview of the development, results and the position of the Company and the undertakings included in the consolidation taken as a whole, as well as a description of the principal risks and uncertainties that they face.

Mont-Saint-Guibert, May 16, 2023.

On behalf of the board of directors

Robert Taub, Chairman

Olivier Taelman, CEO