



**INTERIM FINANCIAL REPORT
THIRD QUARTER 2023**

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INTERIM FINANCIAL REPORT

THIRD 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. The co-primary effectiveness endpoints are 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, and 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 have undergone a Genio® implantation procedure. The company presented 12-month efficacy data on the first 34 DREAM patients and safety data, as of March 14, 2023, on all DREAM patients demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in-line with expectations. These data are preliminary and not conclusive of final DREAM success. 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. The Company anticipates having 12-month clinical data in the first half of 2024 and, as of the date of this report, has submitted the first three modules in the modular PMA.

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 clinical sites are being activated, and the first patients have undergone a Genio® implantation procedure.

B. EUROPEAN COMMERCIALIZATION

During the first nine months of 2023, Nyxoah recognized total revenue of €2.5 million, primarily in Germany. After securing DRG reimbursement in Germany during the first quarter of 2021, Nyxoah built and expanded its German commercial organization to a total of 14 full time employees.

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 September 30, 2023, the Company has activated 46 Tier 1 sites across Germany.

The Company has also focused on entering new European markets. The Company has secured DRG reimbursement in Switzerland, state reimbursement in Austria, and is looking into additional opportunities to enter several other countries. Nyxoah has also generated revenue in Switzerland, Austria and Spain, and the Company expects to expand into other European countries.

2. FINANCIAL HIGHLIGHTS

Revenue was €2.5 million for the nine months ended September 30, 2023, compared to €1.8 million for the nine months ended September 30, 2022 with strong acceleration in Q3 2023.

Cost of goods sold was €0.9 million for the nine months ended September 30, 2023, compared to €0.7 million cost for the nine months ended September 30, 2022.

Selling, general and administrative expenses increased by €3.3 million or 24 % from €13.5 million for the nine months ended September 30, 2022 to €16.8 million for the nine months ended September 30, 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 €7.0 million for the nine months ended September 30, 2023 and €11.9 million for the nine months ended September 30, 2022, research and development expenses increased by €3.1 million or 13 %, from €23.2 million for the nine months ended September 30, 2022, to €26.3 million for the nine months ended September 30, 2023, due to the combined effect of higher clinical, R&D activities and manufacturing expenses. This increase is mainly in staff, consulting costs and in manufacturing and outsourced development to support those activities, these increases were offset by a decrease of €2.7 million in clinical study activities due to Dream Study.

Nyxoah realized a net financial income of €0.8 million for the nine months ended September 30, 2023 primarily driven by the exchange rate depreciation of dollar versus euro and by interest income related to term accounts. This compares to a net positive financial result of €5.9 million for the nine months ended September 30, 2022, during which dollar appreciated versus euro.

Nyxoah realized a net loss of €32.3 million for the nine months ended September 30, 2023, compared to a net loss of €17.9 million for the nine months ended September 30, 2022.

Cash and cash equivalents

On September 30, 2023, cash and cash equivalents and financial assets totaled €72.5 million, compared to €94.9 million on December 31, 2022. The decrease in cash and cash equivalents resulted mainly from net cash used in operating activities of €33.1 million and net cash from investing activities of €11.2 million and offset by net cash flows from financial activities of €17.9 million due to capital increase. See note 16.

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, continue to enroll the ACCCESS IDE study for CCC patients and begin preparations to enter the US market with regulatory, manufacturing, commercial and market access readiness.

4. RISK FACTORS

We refer to the description of risk factors in the Company's 2022 annual report, pp. 60-83. 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 NINE MONTHS ENDED SEPTEMBER 30, 2023 –
INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(unaudited)

(in thousands)

	Notes	As at	
		September 30 2023	December 31 2022
ASSETS			
Non-current assets			
Property, plant and equipment	7	4 328	2 460
Intangible assets	8	45 720	39 972
Right of use assets	9	3 602	3 159
Deferred tax asset		47	47
Other long-term receivables	10	668	173
		€ 54 365	€ 45 811
Current assets			
Inventory	11	1 709	882
Trade receivables	12	1 918	1 463
Other receivables	12	2 437	1 775
Other current assets	13	1 683	1 284
Financial assets	15	59 239	76 968
Cash and cash equivalents	14	13 250	17 888
		€ 80 236	€ 100 260
Total assets		€ 134 601	€ 146 071
EQUITY AND LIABILITIES			
Capital and reserves			
Capital	16	4 926	4 440
Share premium	16	246 130	228 275
Share based payment reserve	17	7 468	5 645
Other comprehensive income	16	88	176
Retained loss		(150 070)	(118 212)
Total equity attributable to shareholders		€ 108 542	€ 120 324
LIABILITIES			
Non-current liabilities			
Financial debt	18	8 407	8 189
Lease liability	9	2 990	2 586
Pension liability		75	–
Provisions		125	59
Deferred tax liability		6	–
		€ 11 603	€ 10 834
Current liabilities			
Financial debt	18	769	388
Lease liability	9	788	719
Trade payables	19	4 480	4 985
Current tax liability	20	2 367	3 654
Other payables	21	6 052	5 167
		€ 14 456	€ 14 913
Total liabilities		€ 26 059	€ 25 747
Total equity and liabilities		€ 134 601	€ 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 NINE MONTHS ENDED SEPTEMBER 30, 2023 -
INTERIM CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS

(unaudited)
(in thousands)

	Notes	For the three months ended September 30		For the nine months ended September 30	
		2023	2022	2023	2022
Revenue	23	976	182	2 524	1 777
Cost of goods sold	23	(336)	(63)	(930)	(685)
Gross profit		€ 640	€ 119	€ 1 594	€ 1 092
Research and Development Expense	23	(6 568)	(4 221)	(19 330)	(11 286)
Selling, General and Administrative Expense	23	(5 058)	(4 763)	(16 794)	(13 492)
Other income/(expense)		–	87	265	237
Operating loss for the period		€ (10 986)	€ (8 778)	€ (34 265)	€ (23 449)
Financial income	25	2 178	5 127	3 592	11 372
Financial expense	26	(1 033)	(2 524)	(2 765)	(5 473)
Loss for the period before taxes		€ (9 841)	€ (6 175)	€ (33 438)	€ (17 550)
Income taxes	20	2 229	(65)	1 119	(379)
Loss for the period		€ (7 612)	€ (6 240)	€ (32 319)	€ (17 929)
Loss attributable to equity holders		€ (7 612)	€ (6 240)	€ (32 319)	€ (17 929)
Other comprehensive loss					
Items that may be subsequently reclassified to profit or loss (net of tax)					
Currency translation differences		(10)	100	(88)	(14)
Total comprehensive loss for the year, net of tax		€ (7 622)	€ (6 140)	€ (32 407)	€ (17 943)
Loss attributable to equity holders		€ (7 622)	€ (6 140)	€ (32 407)	€ (17 943)
Basic Loss Per Share (in EUR)	27	€ (0.266)	€ (0.242)	€ (1.166)	€ (0.695)
Diluted Loss Per Share (in EUR)	27	€ (0.266)	€ (0.242)	€ (1.166)	€ (0.695)

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 NINE MONTHS ENDED, SEPTEMBER 30 2023 -
INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(unaudited)

(in thousands)

	Attributable to owners of the parent					Total
	Common shares	Share premium	Share based payment reserve	Other comprehensive income	Retained loss	
Balance at January 1, 2023	€ 4 440	€ 228 275	€ 5 645	€ 176	€ (118 212)	120 324
Loss for the period	-	-	-	-	(32 319)	(32 319)
Other comprehensive loss for the period	-	-	-	(88)	-	(88)
Total comprehensive loss for the period	-	-	-	€ (88)	€ (32 319)	€ (32 407)
Equity-settled share-based payments						
Granted during the period	-	-	2 284	-	-	2 284
Forfeited during the period	-	-	(461)	-	461	-
Transaction cost	-	(337)	-	-	-	(337)
Issuance of shares for cash	486	18 192	-	-	-	18 678
Total transactions with owners of the company recognized directly in equity	486	17 855	1 823	-	461	20 625
Balance at September 30, 2023	€ 4 926	€ 246 130	€ 7 468	€ 88	€ (150 070)	€ 108 542

	Attributable to owners of the parent					Total
	Common shares	Share premium	Share based payment reserve	Other comprehensive income	Retained loss	
Balance at January 1, 2022	€ 4 427	€ 228 033	€ 3 127	€ 202	€ (87 167)	€ 148 622
Loss for the period	-	-	-	-	(17 929)	(17 929)
Other comprehensive income for the period	-	-	-	(14)	-	(14)
Total comprehensive loss for the period	-	-	-	€ (14)	€ (17 929)	€ (17 943)
Equity-settled share-based payments						
Granted during the period	-	-	2 136	-	-	2 136
Exercised during the period	6	242	(38)	-	38	248
Issuance of shares for cash	7	-	-	-	-	7
Total transactions with owners of the company recognized directly in equity	13	242	2 098	-	38	2 391
Balance at September 30, 2022	€ 4 440	€ 228 275	€ 5 225	€ 188	€ (105 058)	€ 133 070

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 NINE MONTHS ENDED SEPTEMBER 30, 2023 –
INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Notes	For the nine months ended September 30	
		2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax for the year		€ (33 438)	€ (17 550)
Adjustments for			
Finance income		(3 592)	(11 372)
Finance expenses		2 765	5 473
Depreciation and impairment of property, plant and equipment and right-of-use assets	7, 9	916	832
Amortization of intangible assets	8	720	607
Share-based payment transaction expense	17	2 284	2 136
Increase/(Decrease) in provisions		141	36
Other non-cash items		4	(353)
Cash generated before changes in working capital		€ (30 200)	€ (20 191)
Changes in working capital			
Decrease/(Increase) in inventory	11	(827)	(248)
(Increase)/Decrease in trade and other receivables	12	(627)	1 100
Increase/(Decrease) in trade and other payables	19,21	(929)	1 265
Cash generated from changes in operations		€ (32 583)	€ (18 074)
Income tax paid		(517)	(314)
Net cash from / (used in) operating activities		€ (33 100)	€ (18 388)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	7	(2 264)	(484)
Capitalization of intangible assets	8	(6 961)	(11 774)
Purchase of financial assets - current	15	(71 535)	(44 032)
Proceeds from sale of financial assets - current	15	90 623	24 582
Interest income on financial assets		1 384	63
Net cash from / (used in) investing activities		€ 11 247	€ (31 645)
CASH FLOWS FROM FINANCING ACTIVITIES			
Payment of principal portion of lease liabilities	9	(620)	(497)
Repayment of other loan		(63)	(62)
Interests paid		(26)	(185)
Repayment of recoverable cash advance	18	–	(220)
Proceeds from issuance of shares, net of transaction costs	16	18 341	255
Other financial costs		(56)	(55)
Net cash from / (used in) financing activities		€ 17 576	€ (764)
Movement in cash and cash equivalents		€ (4 277)	€ (50 797)
Effect of exchange rates on cash and cash equivalents		(361)	5 165
Cash and cash equivalents at January 1	14	€ 17 888	€ 135 509
Cash and cash equivalents at September 30	14	€ 13 250	€ 89 877

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 four 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), Nyxoah Inc. since May 14, 2020 (located in the USA) and Nyxoah GmbH since July 26, 2023 (located in Germany).

The interim condensed consolidated financial statements of Nyxoah SA and its subsidiaries (collectively, the Group) as of September 30, 2023 and for the three and nine months ended September 30, 2023, have been authorized for issue on November 8, 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) and as endorsed by the European Union. 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.

Going concern principle

The Unaudited Interim Condensed Consolidated Financial Statements have been prepared on a going concern basis. As at September 30, 2023, the Company had cash and cash equivalents of €13.3 million and financial assets of €59.2 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.

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)
- Amendments to IAS 12 Income taxes: International Tax Reform – Pillar Two Model Rules (effective immediately – disclosures are required for annual periods beginning on or after 1 January 2023). The Group will not be subject to Pillar Two Model rules.

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 September 30, 2023	As at December 31, 2022	As at September 30, 2023	As at December 31, 2022
Financial Assets				
Other long-term receivables (level 3)	668	173	668	173
Trade and other receivables (level 3)	4 334	3 237	4 334	3 237
Foreign currency forwards (level 2)	21	1	21	1
Other current assets (level 3)	1 683	1 284	1 683	1 284
Cash and cash equivalents (level 1)	13 250	17 888	13 250	17 888
Financial assets (level 1)	59 239	76 968	59 239	76 968

(in EUR 000)	Carrying value		Fair value	
	As at September 30, 2023	As at December 31, 2022	As at September 30, 2023	As at December 31, 2022
Financial liabilities				
Financial debt (level 3)	84	146	80	138
Foreign currency option (level 2)	1 013	10	1 013	10
Recoverable cash advances (level 3)	9 092	8 431	9 092	8 431
Trade and other payables (level 1 and 3)	9 519	10 142	9 519	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.

In July 2023, the Company acquired Nyxoah GmbH, a German company located in Eschborn with a share capital of EUR 25,000. Nyxoah GmbH was incorporated on May 11, 2023. Except for the minimum capital of EUR 25,000, Nyxoah GmbH has no assets or liabilities and no business had been conducted by it. The Company owns 100% of the shares of Nyxoah GmbH.

7. Property, Plant and Equipment

The total acquisitions for the nine months ended September 30, 2023 amount to €2.3 million (2022: €484,000) and were mainly related to laboratory equipment, 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 €350,000 in 2023 and to €296,000 in 2022 for the nine months ended September 30.

8. Intangible assets

(in EUR 000)	Development cost	Patents and licenses	Total
Cost			
Opening value at January 1, 2022	25 609	591	26 200
Additions	11 774	–	11 774
Cost at September 30, 2022	37 383	591	37 974
Opening value at January 1, 2023	41 073	591	41 664
Additions	6 961	–	6 961
Other	(493)	–	(493)
Cost at September 30, 2023	47 541	591	48 132
Amortization			
Opening amortization at January 1, 2022	(837)	(42)	(879)
Amortization	(575)	(32)	(607)
Amortization at September 30, 2022	(1 412)	(74)	(1 486)
Opening amortization at January 1, 2023	(1 608)	(84)	(1 692)
Amortization	(688)	(32)	(720)
Amortization at September 30, 2023	(2 296)	(116)	(2 412)
Net book value at September 30, 2022	35 971	517	36 488
Net book value at September 30, 2023	45 245	475	45 720

There is only one development project: The Genio[®] system. The Company started amortizing the first-generation Genio[®] system in 2021. The amortization amounted to €0.7 million for the nine months ended September 30, 2023 (2022: €0.6 million) 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 €7.0 million and €11.8 million for the nine months ended September 30, 2023, and 2022, respectively.

The line Other relates to R&D tax incentive in Belgium. We refer to note 10 for more details.

9. Right of use assets and lease liabilities

For the nine months ended September 30, 2023, the Company entered into new lease agreements for €321,000 (2022: €0.7 million). On top of that an existing lease contract has been extended, resulting in an increase of the RoU asset and lease liability with €0.8 million. The repayments of lease liabilities amounted to €0.6 million (2022: €497,000). The depreciations on the right of use assets amounted to €0.6 million and €0.5 million for the nine months ended September 30, 2023, and 2022, respectively.

10. Other long-term receivables

The increase in other long-term receivables is due to an R&D tax incentive in Belgium for an amount of 493,000 € in relation to certain development activities and clinical trials. The Company recognizes the research and development incentive as a long-term receivable (expected to be received in cash in 2026) and as a deduction from the carrying amount of the intangible asset.

11. Inventory

(in EUR 000)	As at	
	September 30, 2023	December 31, 2022
Raw materials	534	498
Work in progress	930	100
Finished goods	245	284
Total Inventory	1 709	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 September 30, 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.

12. Trade and Other receivables

(in EUR 000)	As at	
	September 30, 2023	December 31, 2022
Trade receivables	1 918	1 463
R&D incentive receivable (Australia)	681	346
VAT receivable	706	847
Current tax receivable	626	159
Foreign currency swaps	21	1
Other	403	422
Total trade and other receivables	4 355	3 238

The increase of €1.1 million in trade and other receivables is mainly due to an increase in trade receivables by €455,000, an increase in current tax receivable by €467,000 and an increase in R&D incentive receivables by €335,000 which is partially offset with a decrease by €141,000 in VAT receivable.

The Company may 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 September 30, 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, US and Belgium. The increase by €188,000 in US can be explained by the finalization of the R&D tax credit study during Q3 2023. We refer to note 20 for more details. On top of that the increase in Belgium by €347,000 is explained by an increase in withholding tax on interest for term deposit accounts.

Other mainly relates advance payments and withholding tax to be received related to Belgian R&D employees.

13. Other current assets

The increase of €399,000 in other current assets as at September 30, 2023 is due to increase in accrued interest on the term deposits by €0,6 million which is partly offset by a decrease in prepaid expenses by €230,000.

14. Cash and cash equivalents

(in EUR 000)	As at	
	September 30, 2023	December 31, 2022
Short term deposit	6 033	36
Current accounts	7 217	17 852
Total cash and cash equivalents	13 250	17 888

Cash and cash equivalents decreased to €13.3 million as at September 30, 2023, compared to €17.9 million as at December 31, 2022 with a decrease of current accounts by €10.6 million which is partially offset by an increase of short term deposits (less than 3 months) by €6.0 million

15. 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 and US Treasury bills for a total amount \$US 66.0 million (€60.5 million) and €11.0 million. During the period ended as at September 30, 2023, \$US 47.0 million (€43.6 million) and €47.0 million reached maturity and is subsequently held as cash.

As per September 30, 2023, the current financial assets consists of \$US 48.9 million (€46.2 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 €13.0 million. The total amount of term deposits as per September 30, 2023, amounts to €59.2 million.

16. Capital, Share Premium, Reserves

16.1. 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 part of the IPO on July 7, 2021, the Company incurred direct-attributable transaction costs of €7.6 million which have been deducted from the share premium.

As of September 30, 2023, the share capital of the Company amounts to €4.9 million represented by 28,673,985 shares, and the share premium amounts to €260.6 million (before deduction of the transaction costs).

Evolution of the share capital and share premium over the nine months ended September 30, 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
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
September 30, 2022	25 846 279	25 846 279	0.17	4 440	242 440
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
April 13, 2023 - Capital increase in cash	375 000	375 000	0.17	65	2 651
July 14, 2023 - Exercise warrants	2 000	2 000	0.17	–	10
August 29, 2023 - Exercise warrants	10 000	10 000	0.17	2	50
September 30, 2023	28 673 985	28 673 985	0.17	4 926	260 631

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.

On April 13, 2023, the Company issued 375,000 new shares for an aggregate capital increase of €2.7 million (including share premium). The Company raised \$3.0 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 proceeds will be used for general corporate purposes.

As part of above capital increases, the Company incurred direct-attributable transaction costs of €337,000 which have been deducted from the share premium. The proceeds from the capital increase net of transaction costs amounted to €18.3 million.

On July 14, 2023, pursuant to the exercise of warrants, the Company issued 2,000 new shares for an aggregate capital increase of €10,000 (including share premium).

On August 29, 2023, pursuant to the exercise of warrants, the Company issued 10,000 new shares for an aggregate capital increase of €52,000 (including share premium).

16.2. Reserves

The reserves include the share-based payment reserve (see note 17), 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 nine months ended September 30, 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	(14)	-	(14)
Total other comprehensive income at September 30, 2022	256	(68)	188
Opening value at January 1, 2023	174	2	176
Currency translation differences	(88)	-	(88)
Total other comprehensive income at September 30, 2023	86	2	88

17. Share-Based compensation

Equity-settled share-based payment transactions

As of September 30, 2023, the Company has five 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), (iv) the 2021 warrants plan (the 2021 plan) and (v) the 2022 warrants plan (the 2022 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.

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	475 862	461 500
Forfeited/Cancelled	(182 500)	(14 125)
Exercised	(12 000)	(25 000)
Outstanding as at September 30	1 697 852	1 415 865
Exercisable as at September 30	1 043 771	779 966

The followings warrants from the 2021 warrant plan have been granted in 2023:

- March 24, 2023: 200,862 warrants;
- April 12, 2023: 100,000 warrants;
- June 14, 2023: 161,398 warrants.

On June 14, 2023, 13,602 warrants were granted from the 2022 warrant 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, the 2021 warrant plan and the 2022 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)	Plan 2021 (grant April 12 2023)
Return Dividend	0%	0%	0%	0%	0%
Expected volatility	52.60%	53.71%	53.97%	52.00%	52.00%
Risk-free interest rate	1.60%	1.39%	1.45%	3.20%	3.24%
Expected life	3	3	4	3	3
Exercise price	12.95	9.66	9.66	5.42	6.36
Stock price	13.34	9.75	9.75	6.70	7.08
Fair value	5.21	3.79	4.32	3.09	3.04

	Plan 2021 (grant June 14 2023)	Plan 2022 (grant June 14 2023)
Return Dividend	0%	0%
Expected volatility	51.28%	51.28%
Risk-free interest rate	3.36%	3.36%
Expected life	3	3
Exercise price	7.19	7.19
Stock price	7.10	7.10
Fair value	2.75	2.75

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 as an expense at date of modification.

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 €2.3 million share-based payment expense for the nine months ended September 30, 2023 (2022: €2.1 million) of which €0.8 million is related to the incremental fair value of the re-priced warrants.

18. Financial Debt

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

(in EUR 000)	As at	
	September 30, 2023	December 31, 2022
Recoverable cash advances - Non-current	8 407	8 126
Recoverable cash advances - Current	685	305
Total Recoverable cash advances	9 092	8 431
Other loan - Non-current	–	63
Other loan - Current	84	83
Total Other loan	84	146
Non-current	8 407	8 189
Current	769	388
Total Financial Debt	9 176	8 577

Financial debt related to recoverable cash advances

Recoverable cash advances received

As at September 30, 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

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	
	September 30, 2023	December 31, 2022
Contract 6472	1 669	1 571
Contract 6839	2 404	2 214
Contract 6840	3 019	2 790
Contract 7388	2 000	1 856
Total recoverable cash advances	9 092	8 431
Non-current	8 407	8 126
Current	685	305
Total recoverable cash advances	9 092	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)	–	(220)
Advances payable	(108)	–
Initial measurement and re-measurement	25	(77)
Discounting impact	744	694
As at September 30	9 092	8 524

During the nine months ended September 30, 2023, the Company received a payment invitation for €108,000 from the Walloon Region which was not yet paid per as at September 30, 2023 . During the nine months ended September 30, 2022, the Company made €220,000 reimbursements. The Company did not receive any new amounts during the nine months ended September 30, 2023.

19. Trade payables

(in EUR 000)	As at	
	September 30, 2023	December 31, 2022
Payables	2 148	1 873
Invoices to be received	2 332	3 112
Total Trade payables	4 480	4 985

The decrease in total trade payables of €0.5 million as at September 30, 2023 is due to a decrease in invoices to be received of €0.8 million which is compensated by the increase in trade payables of €275,000.

20. Income taxes and deferred taxes

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Current tax income/(expense)	2 236	(944)	1 121	(2 579)
Deferred tax income/(expense)	(7)	879	(2)	2 200
Total Income Tax Income/(Expense)	2 229	(65)	1 119	(379)

As of January 1, 2022, new tax regulations are in place in the US in which R&D expenses could no longer be deducted when incurred but instead they should be capitalized only for tax purposes and amortized over a 5 year period. A current tax liability as well as a deferred tax asset were recognized. This deferred tax asset was reversed as per December 31, 2022. During the three months ended September 30, 2023, the Company finalized its R&D tax credit study and reached the conclusion that R&D expenses can be deducted when incurred. The R&D tax credit study concluded that taking into account that the research and development by the US subsidiary was done under the direction of the parent in Belgium and benefited Belgian parent' business, the expenditures in the US should be deducted when incurred. As a result the current tax liability amounting to €2.2 million was reversed during the three months ended September 30, 2023.

The current tax liability of €2.4 million includes a liability for uncertain tax positions for an amount of €2.3 million and an income tax liability for an amount of €56,000. 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. For the nine months ended September 30, 2023, an additional accrual of the liability for uncertain tax positions was recorded for an amount of €363,000 (2022: €69,000).

21. Other payables

(in EUR 000)	As at	
	September 30, 2023	December 31, 2022
Holiday pay accrual	692	612
Salary	1 845	2 186
Accrued expenses	2 274	2 228
Foreign currency option - current	1 013	10
Other	228	131
Total other payables	6 052	5 167

The increase of €0.9 million in other payables as at September 30, 2023, compared to December 31, 2022, is the result of an increase of €1 million in the fair value of the foreign currency option and an increase in holiday pay accrual of €80,000 partly offset by a decrease of €0.3 million in salary payables.

22. 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 and foreign currency forwards for which the notional amounts are detailed in the table below:

(in EUR 000)	<u>As at</u>	
	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Foreign currency swaps EUR - NIS (in EUR)	3 877	542
Foreign currency swaps EUR - NIS (in NIS)	15 500	2 000
Foreign currency forwards EUR - NIS (in EUR)	249	–
Foreign currency forwards EUR - NIS (in NIS)	1 000	–
Foreign currency swaps EUR - AUD (in EUR)	92	379
Foreign currency swaps EUR - AUD (in AUD)	150	600
Foreign currency swaps USD - EUR (in USD)	24 393	–
Foreign currency swaps USD - EUR (in EUR)	22 000	–

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)	<u>As at September 30, 2023</u>			
	<u>Level I</u>	<u>Level II</u>	<u>Level III</u>	<u>Total</u>
<i>Financial assets</i>				
Foreign currency swaps	–	21	–	21
<i>Financial liabilities</i>				
Foreign currency swaps	–	1 011	–	1 011
Foreign currency forwards	–	2	–	2

The fair value is determined by the financial institution and is based on foreign currency swaps rates, foreign currency forward rates and the maturity of the instrument. All foreign currency swaps and forwards 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)	<u>2023</u>	<u>2022</u>
<i>Financial asset</i>		
Opening value at January 1	<u>1</u>	<u>–</u>
Fair value adjustments	20	66
Closing value at September 30	<u>21</u>	<u>66</u>

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

(in EUR 000)	2023	2022
<i>Financial liability</i>		
Opening value at January 1	10	654
Fair value adjustments	1 003	2 558
Exchange rate difference	–	(80)
Closing value at September 30	1 013	3 132

23. Results of operation

Revenue and cost of goods sold

In the nine months ended September 30, 2023, the Company generated revenue for the amount of €2.5 million (2022: €1.8 million). In the three months ended September 30, 2023, the Company generated revenue for the amount of €1.0 million (2022: €182,000).

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 nine month period ended September 30, 2023 the sales (based on country of customer) were generated in Germany (€2.1 million), Switzerland (€324,000), Austria (€102,000) and Spain (€12,000) (2022: Germany: €1.6 million, Switzerland : €167,000 and Finland: €40,000). For the nine month period ended September 30, 2023, the Company has one customer with individual sales larger than 10% of the total revenue (2022: two customers).

For the three month period ended September 30, 2023 the sales (based on country of customer) were generated in Germany (€0.7 million), Switzerland (€207,000), Austria (€20,000) and Spain (€12,000) (2022: Germany: €15,000 and Switzerland: €167,000).

Cost of goods sold for the three and nine months ended September 30, 2023 and 2022:

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Purchases of goods and services	898	151	1 757	933
Inventory movement	(562)	(88)	(827)	(248)
Total cost of goods sold	336	63	930	685

Operating expenses

The tables below detail the operating expenses for the nine months ended September 30, 2023 and 2022:

(in EUR 000)	Total cost	Capitalized	Operating expense for the period
Research and development	26 302	(6 972)	19 330
Selling, general and administrative expenses	16 794	-	16 794
Other income and expenses	(769)	504	(265)
For the nine months ended September 30, 2023	42 327	(6 468)	35 859

(in EUR 000)	Total cost	Capitalized	Operating expense for the period
Research and development	23 177	(11 891)	11 286
Selling, general and administrative expenses	13 492	-	13 492
Other income and expenses	(354)	117	(237)
For the nine months ended September 30, 2022	36 315	(11 774)	24 541

The tables below detail the operating expenses for the three months ended September 30, 2023 and 2022:

(in EUR 000)	Total cost	Capitalized	Operating expense for the period
Research and development	8 539	(1 971)	6 568
Selling, general and administrative expenses	5 058	-	5 058
Other income and expenses	(496)	496	-
For the three months ended September 30, 2023	13 101	(1 475)	11 626

(in EUR 000)	Total cost	Capitalized	Operating expense for the period
Research and development	8 360	(4 139)	4 221
Selling, general and administrative expenses	4 763	-	4 763
Other income and expenses	(102)	15	(87)
For the three months ended September 30, 2022	13 021	(4 124)	8 897

Research and Development expenses

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Staff costs	3 255	2 592	10 636	7 682
Consulting and contractors' fees	592	802	2 286	2 107
Q&A regulatory	51	77	196	203
IP costs	144	131	385	353
Depreciation and amortization expense	264	320	895	816
Travel	325	327	896	655
Manufacturing and outsourced development	2 039	1 424	5 165	3 765
Clinical studies	1 263	2 325	3 829	6 577
Other expenses	303	362	1 029	1 017
IT	303	-	985	2
Capitalized costs	(1 971)	(4 139)	(6 972)	(11 891)
Total research and development expenses	6 568	4 221	19 330	11 286

Before capitalization of €7.0 million for the nine months ended September 30, 2023 and €11.9 million for the nine months ended September 30, 2022, research and development expenses increased by €3.1 million or 13 %, from €23.2 million for the nine months ended September 30, 2022, to €26.3 million for the nine months ended September 30, 2023, due to the combined effect of higher clinical, R&D activities and manufacturing expenses. This increase is mainly in staff, consulting costs and in

manufacturing and outsourced development to support those activities, this increase was offset by a decrease of €2.7 million in clinical study activities due to Dream Study.

Before capitalization of €2.0 million for the three months ended September 30, 2023 and €4.1 million for the three months ended September 30, 2022, research and development expenses increased by €0.2 million or 2 %, from €8.4 million for the three months ended September 30, 2022, to €8.5 million for the three months ended September 30, 2023, due to the combined effect of higher clinical, R&D activities and manufacturing expenses. This increase is mainly in staff and consulting costs to support those activities and manufacturing and outsourced development.

Selling, General and Administrative expenses

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Staff costs	2 321	2 055	7 123	5 384
Consulting and contractors' fees	1 277	928	5 133	3 032
Legal fees	117	145	603	560
Rent	74	245	269	447
Depreciation and amortization expense	254	179	737	619
IT	368	109	856	361
Travel	247	367	677	914
Insurance fees	274	404	850	1 239
Other	126	331	546	936
Total selling, general and administrative expenses	5 058	4 763	16 794	13 492

Selling, general and administrative expenses increased by €3.3 million or 24 % from €13.5 million for the nine months ended September 30, 2022 to €16.8 million for the nine months ended September 30, 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.

Selling, general and administrative expenses increased by €0.3 million or 6 % from €4.8 million for the three months ended September 30, 2022 to €5.1 million for the three months ended September 30, 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 income / (expenses)

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Recoverable cash advances				
Initial measurement and re-measurement	(64)	50	(25)	77
R&D incentives	556	55	845	192
Capitalization of R&D incentive	(496)	(15)	(504)	(117)
Other income/(expenses)	4	(3)	(51)	85
Total Other Operating Income/(Expenses)	–	87	265	237

The Company had other operating income of €265,000 for the nine months ended September 30, 2023 compared to other operating income of €237,000 for the nine months ended September 30, 2022.

The Company had no operating income/(expenses) for the three months ended September 30, 2023 compared to other operating income of €87,000 for the three months ended September 30, 2022.

The other operating income contains the R&D Incentive (Australia) that relates to an incentive to be received on development expenses incurred by the subsidiary in Australia. The R&D incentive for the period of nine months ended September 30, 2023 includes a correction for 2022.

24. Employee benefits

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Salaries	4 193	3 133	12 905	9 221
Social charges	312	242	966	742
Fringe benefits	10	(33)	26	44
Defined contribution plan	72	69	224	205
Holiday pay	100	162	324	200
Share-based payment	527	845	2 284	2 137
Other	362	229	1 030	517
Total employee benefits	5 576	4 647	17 759	13 066

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Selling, general and administrative expenses	2 321	2 055	7 123	5 384
Research & Development expenses	3 255	2 592	10 636	7 682
Total employee benefits	5 576	4 647	17 759	13 066

25. Financial income

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Interests	831	79	1 815	192
Exchange differences	1 322	4 955	1 752	11 045
Other	25	93	25	135
Total financial income	2 178	5 127	3 592	11 372

For the nine month period ended September 30, 2023, the total interest income amounted to €1.8 million (three month period ended September 30, 2023: €0.8 million). This interest income relates to the term accounts.

For the nine month period ended September 30, 2023, exchange gains amount to €1.8 million (three month period ended September 30, 2023: €1.3 million). For the year ended December 31, 2022, the closing rate of EUR/USD amounted to 1.07265, while as at September 30, 2023, the rate of EUR/USD decreased to 1.05803, resulting in unrealized exchange gains on the USD balances.

For the nine month period ended September 30, 2022, exchange gains amount €11.0 million (three month period ended September 30, 2022: €5.0 million), mainly due to the revaluation of both the Company's USD cash balance and USD financial assets (note 15). This was related to a decrease in the rate of EUR/USD compared to December 31, 2021.

For the nine month period ended September 30, 2022, other financial income mainly to consists of premiums received on foreign currency options. No premium were received in 2023.

26. Financial expense

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Fair value adjustment	587	609	1 003	2 558
Recoverable cash advances, Accretion of interest	248	231	743	694
Interest and bank charges	34	21	79	124
Interest on lease liabilities	31	26	91	73
Exchange differences	133	1 632	848	2 020
Other	–	5	1	4
Total Financial expense	1 033	2 524	2 765	5 473

The fair value adjustment relates to the fair value adjustment on financial instruments. More information can be found in note 22.

The discounting impact of the recoverable cash advances is further detailed in note 18 above.

For the nine month period ended September 30, 2023, exchange losses amount to €0.8 million (three month period ended September 30, 2023: €133,000), mainly due to the revaluation of both the Company's USD cash balance and USD financial assets (note 15). 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 September 30, 2023.

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.

27. 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 September 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 September 30		For the nine months ended September 30	
	2023	2022	2023	2022
<i>As at September 30, after conversion and share split</i>				
Outstanding common shares at period-end	28 673 985	25 846 279	28 673 985	25 846 279
Weighted average number of common shares outstanding	28 667 159	25 836 279	27 729 401	25 809 995
Number of shares resulting of the exercise of outstanding warrants	2 384 250	1 916 125	2 384 250	1 916 125

Basic and Diluted EPS for the three and nine month period ended September 30, 2023 and 2022 based on weighted average number of shares outstanding after conversion and share split are as follows:

	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Loss of year attributable to equity holders (in EUR)	(7 612 000)	(6 240 000)	(32 319 000)	(17 929 000)
Weighted average number of common shares outstanding (in units)	28 667 159	25 836 279	27 729 401	25 809 995
Basic earnings per share in EUR (EUR/unit)	(0.266)	(0.242)	(1.166)	(0.695)
Diluted earnings per share in EUR (EUR/unit)	(0.266)	(0.242)	(1.166)	(0.695)

28. Other commitments

The Company has granted in 2022 an amount of €0.5 million for educational grant starting on January 1, 2023 until December 31, 2024. The first installment of €250,000 is paid in January 2023, the second installment of €250,000 is due in January 2024.

29. 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 and nine months ended September 30:

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2023	2022	2023	2022
Short-term remuneration & compensation	260	120	656	391
Share based payment	33	47	134	102
Total	293	167	790	493

Transactions with Non-Executive Directors and Shareholders:

(in EUR 000)	For the nine months ended September 30, 2023			For the nine months ended September 30, 2022		
	R&D Collaborat ion	Consulting services	Board Remunera tion	R&D Collaborat ion	Consulting services	Board Remunera tion
Cochlear	182	–	–	1 749	–	–
MINV SA	–	–	–	–	60	–
Ray Cohen	–	–	–	–	–	20
Donald Deyo	–	–	–	–	–	21
Robert Taub	–	–	97	–	–	61
Kevin Rakin	–	–	47	–	–	33
Pierre Gianello	–	–	51	–	–	36
Jan Janssen	–	–	–	–	–	24
Jurgen Hambrecht	–	–	44	–	–	38
Rita Mills	–	–	49	–	–	28
Giny Kirby	–	–	47	–	–	15
Wildman Ventures LLC	–	–	56	–	–	–
Total	182	–	391	1 749	60	276
Amounts outstanding at period-end	–	–	110	970	60	126

(in EUR 000)	For the three months ended September 30, 2023			For the three months ended September 30, 2022		
	R&D Collaboration	Consulting services	Board Remuneration	R&D Collaboration	Consulting services	Board Remuneration
Cochlear	–	–	–	413	–	–
Ray Cohen	–	–	–	–	–	16
Donald Deyo	–	–	–	–	–	7
Robert Taub	–	–	31	–	–	19
Kevin Rakin	–	–	15	–	–	8
Pierre Gianello	–	–	19	–	–	1
Jan Janssen	–	–	–	–	–	5
Jurgen Hambrecht	–	–	15	–	–	14
Rita Mills	–	–	15	–	–	5
Giny Kirby	–	–	13	–	–	12
Wildman Ventures LLC	–	–	16	–	–	–
Total	–	–	124	413	–	87
Amounts outstanding at period-end	–	–	110	970	60	126

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 €182,000 and €1.7 million for the nine months ended September 30, 2023 and 2022 respectively. In April 2023, the project came to its end after development milestones were reached.

On September 28, 2023, the Company announced a partnership with ResMed in Germany to increase OSA awareness and therapy penetration in the German market. The Company and ResMed Germany will establish a continuum of care that will educate and guide OSA patients in the German market from diagnosis through treatment. Together, the companies will work to accelerate patient identification and better support patient set-up on the appropriate therapy.

30. Events after the Balance-Sheet Date

The Company confirms that despite the conflict between Israel and Hamas, operations are continuing notably regarding R&D and production with no major impact and the assets are currently safeguarded. The Company is not suffering impact of this conflict.

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, November 8, 2023.

On behalf of the board of directors

Robert Taub, Chairman

Olivier Taelman, CEO