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## INTERIM FINANCIAL REPORT

### THIRD QUARTER 2022

#### 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/m<sup>2</sup>, 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 110 patients had undergone a Genio® implantation procedure. The remaining implants are being scheduled, and the Company anticipates having 12-month clinical data in the fall of 2023. 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/m<sup>2</sup> 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 are expected to be implanted during the fourth quarter of 2022.

### ***B. EUROPEAN COMMERCIALIZATION***

During the first nine months of 2022, Nyxoah recognized total revenue of €1.8 million, primarily in Germany, representing a substantial increase over the first nine months of 2021. After securing DRG reimbursement in Germany during the first quarter of 2021, Nyxoah built and expanded its German commercial organization to a total of 15 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, 2022, the Company has activated 32 Tier 1 sites across Germany, up from 12 as of December 31, 2021.

The company has also focused on entering new European markets. The Company has secured DRG reimbursement in Switzerland, hospital reimbursement in Spain, and is awaiting reimbursement decisions in several other countries, including Belgium, Italy, and the Netherlands. In the first nine months of 2022, Nyxoah also generated revenue in Finland, Switzerland, and the Netherlands, and the Company expects sales in other European countries in 2022.

## **2. FINANCIAL HIGHLIGHTS**

Revenue was €1.8 million for the nine months ending September 30, 2022, compared to €557,000 for the nine months ending September 30, 2021. The increase in revenue was attributable to the Company's commercialization of the Genio® system mainly in Germany.

Cost of goods sold was €0.7 million for the nine months ending September 30, 2022, compared to €198,000 cost for the nine months ending September 30, 2021. The increase in cost of goods sold was attributable to the sales of the Genio® system in Europe.

Selling, general and administrative expenses increased by 25 % from €10.8 million for the nine months ending September 30, 2021 to €13.5 million for the nine months ending September 30, 2022, mainly due to an increase in consulting and contractors' fees to support the company in legal, finance, tax and IT matters as well as insurances following the listing of the company in the United States.

Consulting and contractors' fees include variable compensations for an amount of €1.9 million for the nine months ending September 30, 2021 related to a cash settled share-based payment transaction.

Before capitalization of €11.9 million for the nine months ending September 30, 2022 and €7.7 million for the nine months ending September 30, 2021, research and development expenses increased 39 % from €16.7 million for the nine months ending September 30, 2021 to €23.2 million for the nine months ending September 30, 2022, 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. This was offset by a decrease in patent fees and related expenses due to the payment for in-licensing agreement with Vanderbilt University during the first nine months ended September 30, 2021.

Nyxoah realised a net positive financial result of €5.9 million for the nine months ending September 30, 2022 primarily driven by the exchange rate appreciation of dollar versus euro. This compares to a net loss of €1.4 million for the nine months ending September 30, 2021.

Nyxoah realized a net loss of €17.9 million for the nine months ending September 30, 2022, compared to a net loss of €21.3 million for the nine months ending September 30, 2021.

#### *Cash and cash equivalents*

On September 30, 2022, cash and cash equivalents and financial assets totalled €115.4 million, compared to €135.5 million on December 31, 2021. The decrease in cash and cash equivalents resulted mainly from net cash flows used in operating activities of €18.5 million and net cash used in investing activities of €31.5 million. See note 13.

### **3. 2022 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 expects to complete implants in the DREAM IDE trial and to have the first patients implanted in the ACCESS IDE study for CCC patients in US.

Nyxoah looks forward to opening its manufacturing facility in Belgium to further scale-up production capacity.

Following the capital increase related to the Nasdaq IPO and based on the current objectives of the Company's business plan, Nyxoah expects that its existing cash and cash equivalents will fund planned operating and capital expense requirements in line with the Company's strategic priorities (European commercialization, US market entry, clinical data building, driving innovation/pipeline and scaling-up the organisation).

### **4. RISK FACTORS**

We refer to the description of risk factors in the Company's 2021 annual report, pp. 65-90. 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 2021 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, 2022 –  
INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

**(unaudited)**

**(in thousands)**

	Notes	As at	
		September 30 2022	December 31 2021
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	7	€ 2 216	€ 2 020
Intangible assets	8	36 488	25 322
Right of use assets	9	3 413	3 218
Deferred tax asset	19	2 423	46
Other long-term receivables		188	164
		<b>€ 44 728</b>	<b>€ 30 770</b>
<b>Current assets</b>			
Inventory	10	594	346
Trade receivables	11	757	226
Other receivables	11	2 022	2 286
Other current assets	12	587	1 693
Financial assets	14	25 505	–
Cash and cash equivalents	13	89 877	135 509
		<b>€ 119 342</b>	<b>€ 140 060</b>
<b>Total assets</b>		<b>€ 164 070</b>	<b>€ 170 830</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Capital and reserves</b>			
Capital	15	4 440	4 427
Share premium	15	228 275	228 033
Share based payment reserve	16	5 225	3 127
Other comprehensive income	15	188	202
Retained loss		(105 058)	(87 167)
<b>Total equity attributable to shareholders</b>		<b>€ 133 070</b>	<b>€ 148 622</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Financial debt	17	8 035	7 802
Lease liability	9	2 831	2 737
Pension liability		80	80
Provisions		47	12
Deferred tax liability		–	5
		<b>€ 10 993</b>	<b>€ 10 636</b>
<b>Current liabilities</b>			
Financial debt	17	656	554
Lease liability	9	722	582
Trade payables	18	5 346	3 995
Current tax liability	19	5 391	2 808
Other payables	20	7 892	3 633
		<b>€ 20 007</b>	<b>€ 11 572</b>
<b>Total liabilities</b>		<b>€ 31 000</b>	<b>€ 22 208</b>
<b>Total equity and liabilities</b>		<b>€ 164 070</b>	<b>€ 170 830</b>

*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 AND NINE MONTHS ENDED SEPTEMBER 30, 2022 -  
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	
		2022	2021	2022	2021
Revenue	22	€ 182	€ 203	€ 1 777	€ 557
Cost of goods sold	22	(63)	(82)	(685)	(198)
<b>Gross profit</b>		<b>€ 119</b>	<b>€ 121</b>	<b>€ 1 092</b>	<b>€ 359</b>
Research and Development Expense	22	(4 221)	(3 517)	(11 286)	(9 009)
Selling, General and Administrative Expense	22	(4 763)	(4 496)	(13 492)	(10 775)
Other income/(expense)		87	(178)	237	(274)
<b>Operating loss for the period</b>		<b>€ (8 778)</b>	<b>€ (8 070)</b>	<b>€ (23 449)</b>	<b>€ (19 699)</b>
Financial income	24	5 127	29	11 372	72
Financial expense	25	(2 524)	(585)	(5 473)	(1 484)
<b>Loss for the period before taxes</b>		<b>€ (6 175)</b>	<b>€ (8 626)</b>	<b>€ (17 550)</b>	<b>€ (21 111)</b>
Income taxes	19	(65)	(136)	(379)	(260)
<b>Loss for the period</b>		<b>€ (6 240)</b>	<b>€ (8 762)</b>	<b>€ (17 929)</b>	<b>€ (21 371)</b>
<b>Loss attributable to equity holders</b>		<b>€ (6 240)</b>	<b>€ (8 762)</b>	<b>€ (17 929)</b>	<b>€ (21 371)</b>
<b>Other comprehensive loss</b>					
<b>Items that may be subsequently reclassified to profit or loss (net of tax)</b>					
Currency translation differences		100	(54)	(14)	138
<b>Total comprehensive loss for the year, net of tax</b>		<b>€ (6 140)</b>	<b>€ (8 816)</b>	<b>€ (17 943)</b>	<b>€ (21 233)</b>
<b>Loss attributable to equity holders</b>		<b>€ (6 140)</b>	<b>€ (8 816)</b>	<b>€ (17 943)</b>	<b>€ (21 233)</b>
Basic Loss Per Share (in EUR)	26	€ (0.242)	€ (0.348)	€ (0.695)	€ (0.923)
Diluted Loss Per Share (in EUR)	26	€ (0.242)	€ (0.348)	€ (0.695)	€ (0.923)

*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 2021, 2022 -  
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	
<b>Balance at January 1, 2022</b>	€ 4 427	€ 228 033	€ 3 127	€ 202	€ (87 167)	€ 148 622
Loss for the period	-	-	-	-	(17 929)	(17 929)
Other comprehensive loss for the period	-	-	-	(14)	-	(14)
<b>Total comprehensive loss for the period</b>	-	-	-	€ (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
<b>Total transactions with owners of the company recognized directly in equity</b>	<b>13</b>	<b>242</b>	<b>2 098</b>	<b>-</b>	<b>38</b>	<b>2 391</b>
<b>Balance at September 30, 2022</b>	<b>€ 4 440</b>	<b>€ 228 275</b>	<b>€ 5 225</b>	<b>€ 188</b>	<b>€ (105 058)</b>	<b>€ 133 070</b>

	Attributable to owners of the parent					Total
	Common shares	Share premium	Share based payment reserve	Other comprehensive income	Retained loss	
<b>Balance at January 1, 2021</b>	€ 3 796	€ 150 936	€ 2 650	€ 149	€ (60 341)	€ 97 190
Loss for the period	-	-	-	-	(21 371)	(21 371)
Other comprehensive income for the period	-	-	-	138	-	138
<b>Total comprehensive loss for the period</b>	-	-	-	€ 138	€ (21 371)	€ (21 233)
Equity-settled share-based payments						
Granted during the period	-	-	784	-	-	784
Exercised during the period	33	1 160	(165)	-	165	1 193
Issuance of shares for cash	560	82 058	-	-	-	82 618
Transaction cost	-	(7,587)	-	-	-	(7,587)
<b>Total transactions with owners of the company recognized directly in equity</b>	<b>593</b>	<b>75,631</b>	<b>619</b>	<b>-</b>	<b>165</b>	<b>77,008</b>
<b>Balance at September 30, 2021</b>	<b>€ 4 389</b>	<b>€ 226 567</b>	<b>€ 3 269</b>	<b>€ 287</b>	<b>€ (81 547)</b>	<b>€ 152 965</b>

*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, 2022 –**  
**INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**  
**(in thousands)**

	Notes	For the nine months ended September 30	
		2022	2021
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
<b>Loss before tax for the year</b>		<b>€ (17 550)</b>	<b>€ (21 111)</b>
Adjustments for			
Finance income		(11 372)	(72)
Finance expenses		5 473	1 484
Depreciation and impairment of property, plant and equipment and right-of-use assets	7, 9	832	558
Amortization of intangible assets	8	607	653
Share-based payment transaction expense	16	2 136	784
Increase/(Decrease) in provisions		36	4
Other non-cash items		(353)	247
<b>Cash generated before changes in working capital</b>		<b>€ (20 191)</b>	<b>€ (17 453)</b>
Changes in working capital			
Decrease/(Increase) in inventory	10	(248)	(33)
(Increase)/Decrease in trade and other receivables	11	1 100	(2 876)
Increase/(Decrease) in trade and other payables	18, 20	1 265	2 563
<b>Cash generated from changes in operations</b>		<b>€ (18 074)</b>	<b>€ (17 799)</b>
Income tax paid		(314)	(205)
<b>Net cash used in operating activities</b>		<b>€ (18 388)</b>	<b>€ (18 004)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchases of property, plant and equipment	7	(484)	(1 257)
Capitalization of intangible assets	8	(11 774)	(7 219)
Purchase of financial assets - current	14	(44 032)	–
Proceeds from sale of financial assets - current	14	24 582	–
Interest income on financial assets		63	–
<b>Net cash used in investing activities</b>		<b>€ (31 645)</b>	<b>€ (8 476)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Payment of principal portion of lease liabilities	9	(497)	(358)
Repayment of other loan		(62)	(63)
Interests paid		(185)	(324)
Repayment of recoverable cash advance	15	(220)	(280)
Proceeds from issuance of shares, net of transaction costs	15	255	76 070
Other financial costs		(55)	(7)
<b>Net cash used in financing activities</b>		<b>€ (764)</b>	<b>€ 75 038</b>
<b>Movement in cash and cash equivalents</b>		<b>€ (50 797)</b>	<b>€ 48 558</b>
Effect of exchange rates on cash and cash equivalents	24	5 165	56
<b>Cash and cash equivalents at January 1</b>	13	<b>€ 135 509</b>	<b>€ 92 300</b>
<b>Cash and cash equivalents at September 30</b>	13	<b>€ 89 877</b>	<b>€ 140 914</b>

*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 September 30, 2022 and for the three and nine months ended September 30, 2022 have been authorized for issue on November 8, 2022 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, 2021.

Except for the application of standards, interpretations and amendments being mandatory as of January 1, 2022, and the new accounting policies mentioned in the relevant notes 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, 2021.

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).

Certain reclasses to comparatives have been made to be consistent with current year presentation.

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, 2021.

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 September 30, 2022, the Company had cash and cash equivalents of €89.9 million. Based on cash flow forecasts for the remaining period of 2022 and 2023, 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 COVID-19 or the Ukraine conflict will have an impact on the Company's activity. The company does not have business relationships with Russia. There is no direct nor indirect impact of the conflict on the day to day business of the Company.

#### ***New and amended standards and interpretations applicable***

*Effective for the annual periods beginning on January 1, 2022*

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 2022, but do not have an impact on the interim condensed consolidated financial statements of the Company:

- Amendments to IFRS 3 Business Combinations; IAS 16 Property, Plant and Equipment; IAS 37 Provisions, Contingent Liabilities and Contingent Assets as well as Annual Improvements, effective January 1, 2022

### **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 2021 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, 2022	As at December 31, 2021	As at September 30, 2022	As at December 31, 2021
<b>Financial Assets</b>				
Other long-term receivables (level 3)	188	164	188	164
Trade and other receivables (level 3)	2 713	2 512	2 713	2 512
Foreign currency forwards (level 2)	66	–	66	–
Other current assets (level 3)	587	1 693	587	1 693
Cash and cash equivalents (level 1)	89 877	135 509	89 877	135 509
Financial assets (level 1)	25 505	–	25 505	–

(in EUR 000)	Carrying value		Fair value	
	As at September 30, 2022	As at December 31, 2021	As at September 30, 2022	As at December 31, 2021
<b>Financial liabilities</b>				
Financial debt (level 3)	167	229	138	194
Foreign currency option (level 2)	3 132	654	3 132	654
Recoverable cash advances (level 3)	8 524	8 127	8 524	8 127
Trade and other payables (level 1 and 3)	10 106	6 974	10 106	6 974

## 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 nine months ended September 30, 2022 amount to €484,000 (2021: €1.3 million) and were mainly related to furniture and office equipment and laboratory equipment.

The depreciation charge amounts to €296,000 in 2022 and to €145,000 in 2021 for the nine months ended September 30.

## 8. Intangible assets

There is only one development project : The Genio® system.

(in EUR 000)	Development cost	Patents and licenses	Total
<b>Cost</b>			
Opening value at January 1, 2021	15 262	591	15 853
Additions	7 219	–	7 219
Exchange difference	–	–	–
<b>Cost at September 30, 2021</b>	<b>22 481</b>	<b>591</b>	<b>23 072</b>
Opening value at January 1, 2022	25 609	591	26 200
Additions	11 774	–	11 774
Exchange difference	–	–	–
<b>Cost at September 30, 2022</b>	<b>37 383</b>	<b>591</b>	<b>37 974</b>
<b>Amortization</b>			
Opening amortization at January 1, 2021	–	–	–
Amortization	(647)	(6)	(653)
Exchange difference	–	–	–
<b>Amortization at September 30, 2021</b>	<b>(647)</b>	<b>(6)</b>	<b>(653)</b>
Opening amortization at January 1, 2022	(837)	(42)	(879)
Amortization	(575)	(32)	(607)
Exchange difference	–	–	–
<b>Amortization at September 30, 2022</b>	<b>(1 412)</b>	<b>(74)</b>	<b>(1 486)</b>
<b>Net book value at September 30, 2021</b>	<b>21 834</b>	<b>585</b>	<b>22 419</b>
<b>Net book value at September 30, 2022</b>	<b>35 971</b>	<b>517</b>	<b>36 488</b>

The Company started amortizing the first-generation Genio® system in 2021. The amortization amounted to €0.6 million for the nine months ended September 30, 2022 (2021: €0.7 million) and is included in research and development expense.

The Company continues to incur in 2022 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 €11.8 million and €7.2 million for the nine months ended September 30, 2022, and 2021, respectively.

## 9. Right of use assets and lease liabilities

For the nine months ended September 30, 2022, the Company did enter into new lease agreements for €0.7 million (2021: €187,000). The repayments of lease liabilities amounted to €497,000 (2021: €358,000). The depreciations on the right of use assets amounted to €0.5 million and €413,000 for the nine months ended September 30, 2022, and 2021, respectively.

## 10. Inventory

(in EUR 000)	As at	
	September 30, 2022	December 31, 2021
Work in progress	286	83
Finished goods	308	263
<b>Total Inventory</b>	<b>594</b>	<b>346</b>

The increase in inventory is due to increasing activities. For the period ended September 30, 2022 and the year ended December 31, 2021 the Company did not recognize any expenses for inventory write-offs since the inventory level as per period end respectively year end is expected to be sold in the foreseeable future.



## 11. Trade and Other receivables

(in EUR 000)	As at	
	September 30, 2022	December 31, 2021
Trade receivables	757	226
R&D incentive receivable (Australia)	935	1 616
VAT receivable	458	524
Current tax receivable	132	71
Foreign currency swaps	66	–
Other	431	75
<b>Total trade and other receivables</b>	<b>2 779</b>	<b>2 512</b>

The increase of €0.5 million in trade receivables as at September 30, 2022 is due to generated revenue by the Company.

The Company includes 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, 2021 and September 30, 2022, 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<sup>®</sup> system. The decrease of €0.7 million in the R&D incentive receivable (Australia) is due to the fact that the Company received payments relating to the R&D incentives during 2022.

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

The increase in Others mainly due to increase in prepaid payment to vendors

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

## 12. Other current assets

The decrease of €1.1 million in other current assets as at September 30, 2022 is mainly due to the partial decrease in the advance payment of €1.1 million for Directors & Officers insurance following the initial public offering in the United States.

## 13. Cash and cash equivalents

(in EUR 000)	As at	
	September 30, 2022	December 31, 2021
Short term deposit	38	38
Current accounts	89 839	135 471
<b>Total cash and cash equivalents</b>	<b>89 877</b>	<b>135 509</b>

The decrease of current accounts by €45.6 million is due to an increase in term accounts of €25.5 million recorded as financial assets (we refer to note 14 for more details) and a decrease due to cash used in operations.

## 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 2022, the Company entered into USD term deposits at a well established financial institution for a total amount 50.0 million USD. As at August 16, 2022, 25.0 million USD reached maturity and is subsequently held as cash. The investments in USD 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.

The current financial assets consists of 25.0 million USD, 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.

The total amount of term deposits as per September 30, 2022, amounts to €25.5 million.

## 15. Capital, Share Premium, Reserves

### 15.1. Capital and share premium

Evolution of the share capital and share premium over the nine months ended September 30, 2022 and 2021:

(Number of shares <sup>(1)</sup> except otherwise stated)	Common shares	Par value (EUR)	Share capital	Share premium
<b>January 1, 2021</b>	<b>22 097 609</b>	<b>0.17</b>	<b>3 796</b>	<b>157 514</b>
February 22, 2021 - Exercise warrants	10 000	0.17	2	50
June 23, 2021 - Exercise warrants	60 000	0.17	10	300
July 7, 2021 - IPO	2 835 000	0.17	487	71 355
July 9, 2021 - IPO	425 250	0.17	73	10 703
July 9, 2021 - Exercise warrants	10 000	0.17	2	118
September 10, 2021 - Exercise warrants	82 500	0.17	14	558
September 30, 2021 - Exercise warrants	27 000	0.17	5	135
<b>September 30, 2021</b>	<b>25 547 359</b>	<b>0.17</b>	<b>4 389</b>	<b>240 733</b>
October 11, 2021 - Exercise warrants	110 000	0.17	19	755
November 4, 2021 - Exercise warrants	90 000	0.17	15	585
November 25, 2021 - Exercise warrants	25 000	0.17	4	125
<b>December 31, 2021</b>	<b>25 772 359</b>	<b>0.17</b>	<b>4 427</b>	<b>242 198</b>
February 10, 2022 - Exercise warrants	25 000	0.17	4	125
June 8, 2022 - Capital increase in cash	38 920	0.17	7	–
September 30, 2022 - Exercise warrants	10,000	0.17	2	117
<b>September 30, 2022</b>	<b>25 846 279</b>	<b>0.17</b>	<b>4 440</b>	<b>242 440</b>

<sup>1</sup> The numbers for the common shares have been retrospectively adjusted for the stock split.

On February 10, 2022, pursuant to the exercise of warrants, the Company issued 25,000 new shares for an aggregate capital increase of €129,000 (including share premium).

On June 8, 2022, the Company issued 38,920 new shares for an aggregate capital increase of €7,000 (there was no share premium).

On September 30, 2022, pursuant to the exercise of warrants, the Company issued 10,000 new shares for an aggregate capital increase of €119,000 (including share premium).

### 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 nine months ended September 30, 2022 and 2021 is detailed in the table below:

(in EUR 000)	Currency translation reserve	Post-employment benefit obligations	Total
Opening value at January 1, 2021	149	-	149
Currency translation differences	138	-	138
<b>Total other comprehensive income at September 30, 2021</b>	<b>287</b>	<b>-</b>	<b>287</b>
Opening value at January 1, 2022	270	(68)	202
Currency translation differences	(14)	-	(14)
Remeasurements of post-employment benefit obligations	-	-	-
<b>Total other comprehensive income at September 30, 2022</b>	<b>256</b>	<b>(68)</b>	<b>188</b>

## 16. Share-Based compensation

### *Equity-settled share-based payment transactions*

As of September 30, 2022, the Company had 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.

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.

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

<b>Number of shares (after share split) warrants give right to across all plans</b>	<b>2022</b>	<b>2021</b>
Outstanding at January 1	993 490	1 007 500
Granted	536 500	401 240
Forfeited/Cancelled	(41 125)	-
Exercised	(35 000)	(189 500)
<b>Outstanding as at September 30</b>	<b>1 453 865</b>	<b>1 219 240</b>
<b>Exercisable as at September 30</b>	<b>783 995</b>	<b>918 310</b>

On February 21, 2022, 219,000 warrants were granted from which 5,000 warrants were not accepted. On May 14, 2022 and June 8, 2022 respectively 72,500 and 175,000 warrants were granted which were all accepted. On August 8, 2022, 75,000 warrants were granted which were all accepted.

The following tables provide the input to the Black-Scholes model for warrants granted in 2018, 2019, 2020, 2021 and 2022 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.

	<b>Plan 2016 (grant 2018)</b>	<b>Plan 2018 (grant 2018)</b>	<b>Plan 2013 (grant 2018)</b>	<b>Plan 2018 (grant 2020)</b>	<b>Plan 2020 (grant 2020)</b>
Return Dividend	0%	0%	0%	0%	0%
Expected volatility	66.92%	56.32%	56.32%	56.32%	56.32%
Risk-free interest rate	0.35%	-0.20%	-0.20%	-0.20%	-0.20%
Expected life	3	3	3	3	3
Exercise price	5.17	6.52	11.94	11.94	11.94
Stock price	1.09	10.24	10.20	10.20	10.20
Fair value	0.10	5.30	3.31	3.31	3.31

	<b>Plan 2021 (grant Sept 17 2021)</b>	<b>Plan 2021 (grant Oct 27 2021)</b>	<b>Plan 2021 (grant Feb 21 2022)</b>	<b>Plan 2021 (grant Feb 21 2022)</b>	<b>Plan 2021 (grant Feb 21 2022)</b>
Return Dividend	0%	0%	0%	0%	0%
Expected volatility	51.30%	51.50%	49.80%	49.80%	49.80%
Risk-free interest rate	-0.36%	-0.18%	0.37%	0.37%	0.50%
Expected life	3	3	3	3	4
Exercise price	25.31	25.31	17.76	25.31	17.76
Stock price	25.75	20.50	17.50	17.50	17.50
Fair value	9.22	5.94	6.05	4.15	6.90

	<b>Plan 2021 (grant May 14 2022)</b>	<b>Plan 2021 (grant June 8 2022)</b>	<b>Plan 2021 (grant Aug 8 2022)</b>	<b>Plan 2021 (grant Aug 8 2022)</b>
Return Dividend	0%	0%	0%	0%
Expected volatility	49.80%	52.60%	53.71%	53.97%
Risk-free interest rate	1.06%	1.60%	1.39%	1.45%
Expected life	3	3	3	4
Exercise price	13.82	12.95	9.66	9.66
Stock price	13.82	13.34	9.75	9.75
Fair value	4.94	5.21	3.79	4.32

The Company has recognized €2.1 million share-based payment expense for the nine months ended September 30, 2022 (2021: €0.8 million).

## 17. Financial Debt

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

(in EUR 000)	<b>As at</b>	
	<b>September 30, 2022</b>	<b>December 31, 2021</b>
Recoverable cash advances - Non-current	7 972	7 656
Recoverable cash advances - Current	552	471
<b>Total Recoverable cash advances</b>	<b>8 524</b>	<b>8 127</b>
Other loan - Non-current	63	146
Other loan - Current	104	83
<b>Total Other loan</b>	<b>167</b>	<b>229</b>
Non-current	8 035	7 802
Current	656	554
<b>Total Financial Debt</b>	<b>8 691</b>	<b>8 356</b>

### *Financial debt related to recoverable cash advances*

#### *Recoverable cash advances received*

As at September 30, 2022, the details of recoverable cash advances received can be summarized as follows:

(in EUR 000)	<b>Contractual advances</b>	<b>Advances received</b>	<b>Amounts reimbursed</b>
Sleep apnea device (6472)	1 600	1 600	480
First articles (6839)	2 160	2 160	284
Clinical trial (6840)	2 400	2 400	210
Activation chip improvements (7388)	1 467	1 467	44
<b>Total</b>	<b>7 627</b>	<b>7 627</b>	<b>1 018</b>

During the nine months ended September 30, 2022, the Company made reimbursements totaling €220,000 (2021: €280,000). The Company did not receive any new amounts during the nine months ended September 30, 2022.

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

(in EUR 000)	<b>As at</b>	
	<b>September 30, 2022</b>	<b>December 31, 2021</b>
Contract 6472	1 536	1 452
Contract 6839	2 403	2 333
Contract 6840	2 754	2 630
Contract 7388	1 831	1 712
<b>Total recoverable cash advances</b>	<b>8 524</b>	<b>8 127</b>
Non-current	7 972	7 656
Current	552	471
<b>Total recoverable cash advances</b>	<b>8 524</b>	<b>8 127</b>

The amounts recorded under “Current” caption correspond to the sales-independent amounts (fixed repayment) as well as 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)	<b>2022</b>	<b>2021</b>
As at January 1	8 127	7 910
Advances reimbursed (excluding interests)	(220)	(280)
Initial measurement and re-measurement	(77)	254
Discounting impact	694	661
<b>As at September 30</b>	<b>8 524</b>	<b>8 545</b>

## 18. Trade payables

(in EUR 000)	As at	
	September 30, 2022	December 31, 2021
Payables	2 667	2 395
Invoices to be received	2 679	1 600
<b>Total Trade payables</b>	<b>5 346</b>	<b>3 995</b>

The increase in total trade payables of €1.4 million as at September 30, 2022 is mainly due to the increase in invoices to be received. This increase 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 September 30		For the nine months ended September 30	
	2022	2021	2022	2021
Current tax income/(expense)	(944)	(136)	(2 579)	(268)
Deferred tax income/(expense)	879	–	2 200	8
<b>Total Income Tax Income/(Expense)</b>	<b>(65)</b>	<b>(136)</b>	<b>(379)</b>	<b>(260)</b>

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. Due to this new regulation, there is an increase in current tax expense and current tax liability by €2.4 million and €2.5 million respectively, and also an increase in deferred tax asset and deferred tax income of €2.4 million and €2.2 million respectively. The deferred tax asset is recognized because the Company expects the US subsidiary will be able to recover the deferred tax asset in the foreseeable future.

The current tax liability of €5.4 million also relates to a liability for uncertain tax positions for an amount of €2.8 million. This current tax liability was recorded following certain public rulings and guidance recently issued by tax authorities in one of the jurisdictions that the Company operates in. The current tax expense related to this current tax liability for the nine months period ended September 30, 2022 amounts to €77,000.

## 20. Other payables

(in EUR 000)	As at	
	September 30, 2022	December 31, 2021
Holiday pay accrual	551	493
Salary	794	870
Accrued expenses	3 007	1 485
Foreign currency option - current	3 132	654
Other	408	131
<b>Total other payables</b>	<b>7 892</b>	<b>3 633</b>

The increase of €4.3 million in other payables as at September 30, 2022, compared to December 31, 2021, is mainly due to an increase of €2.5 million in the fair value of the foreign currency option and due to an increase of €1.5 million in accrued expenses related to an increase in clinical and R&D activities. The item Other includes €397,000 social liabilities.

## 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 forwards or options.

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

	<u>As at</u>	
	<u>September 30, 2022</u>	<u>December 31, 2021</u>
(in EUR 000)		
call USD (in USD)	22 800	34 350
put USD (in USD)	–	(3 000)
call EUR (in EUR)	–	2 500
put EUR (in EUR)	(20 000)	(30 000)

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

	<u>As at</u>	
	<u>September 30, 2022</u>	<u>December 31, 2021</u>
(in EUR 000)		
Foreign currency swaps EUR - NIS (in EUR)	1 230	–
Foreign currency swaps EUR - NIS (in NIS)	4 500	–

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:

	<u>As at September 30, 2022</u>			
	<u>Level I</u>	<u>Level II</u>	<u>Level III</u>	<u>Total</u>
(in EUR 000)				
<i>Financial assets</i>				
Foreign currency forwards	–	66	–	66
<i>Financial liabilities</i>				
Foreign currency option	–	3 132	–	3 132

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 put and call options and 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:

	<u>2022</u>	<u>2021</u>
(in EUR 000)		
<i>Financial asset</i>		
<b>Opening value at January 1</b>	<u>–</u>	<u>–</u>
New contracts	–	–
Fair value adjustments	66	–
<b>Closing value at September 30</b>	<u>66</u>	<u>–</u>

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

	<u>2022</u>	<u>2021</u>
<b>Opening value at January 1</b>	<b>654</b>	<b>–</b>
New contracts	–	343
Fair value adjustments	2 558	146
Exchange rate difference	(80)	–
<b>Closing value at September 30</b>	<b>3 132</b>	<b>489</b>

## 22. Results of operation

### *Revenue and cost of goods sold*

In the nine months ended September 30, 2022, the Company generated revenue for the amount of €1.8 million (2021: €0.6 million). In the three months ended September 30, 2022, the company generated revenue for the amount of €182,000 (2021: €203,000).

In the three months ended September 30, 2022, the Company had experienced a delay in sales due to product availability from component supplier due to over malfunctioning. Those malfunctioning were remediated, and the Company will have sufficient manufacturing capacity to meet all commercial demands.

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, 2022 the sales (based on country of customer) were generated in Germany (€1.6 million), Switzerland (€167,000) and Finland (€40,000) (2021: Germany: €0.5 million, Spain: €20,000 and Belgium: €40,000). For the nine month period ended September 30, 2022, the Company has two customers with individual sales larger than 10% of the total revenue (2021: three customers).

For the three month period ended September 30, 2022 the sales (based on country of customer) were generated in Germany (€15,000) and Switzerland (€167,000) (2021: Germany: €203,000).

Cost of goods sold for the three and nine months ended September 30, 2022 and 2021:

(in EUR 000)	<u>For the three months ended September 30</u>		<u>For the nine months ended September 30</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Purchases of goods and services	151	143	933	231
Inventory movement	(88)	(61)	(248)	(33)
<b>Total cost of goods sold</b>	<b>63</b>	<b>82</b>	<b>685</b>	<b>198</b>



### *Operating expenses*

The tables below detail the operating expenses for the nine months ended September 30, 2022 and 2021:

(in EUR 000)	<u>Total cost</u>	<u>Capitalized</u>	<u>Operating expense for the period</u>
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)
<b>For the nine months ended September 30, 2022</b>	<b><u>36 315</u></b>	<b><u>(11 774)</u></b>	<b><u>24 541</u></b>

(in EUR 000)	<u>Total cost</u>	<u>Capitalized</u>	<u>Operating expense for the period</u>
Research and development	16 726	(7 717)	9 009
Selling, general and administrative expenses	10 775	-	10 775
Other income and expenses	(224)	498	274
<b>For the nine months ended September 30, 2021</b>	<b><u>27 277</u></b>	<b><u>(7 219)</u></b>	<b><u>20 058</u></b>

The tables below detail the operating expenses for the three months ended September 30, 2022 and 2021:

(in EUR 000)	<u>Total cost</u>	<u>Capitalized</u>	<u>Operating expense for the period</u>
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)
<b>For the three months ended September 30, 2022</b>	<b><u>13 021</u></b>	<b><u>(4 124)</u></b>	<b><u>8 897</u></b>

(in EUR 000)	<u>Total cost</u>	<u>Capitalized</u>	<u>Operating expense for the period</u>
Research and development	7 131	(3 614)	3 517
Selling, general and administrative expenses	4 496	-	4 496
Other income and expenses	57	121	178
<b>For the three months ended September 30, 2021</b>	<b><u>11 684</u></b>	<b><u>(3 493)</u></b>	<b><u>8 191</u></b>

### Research and Development expenses

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2022	2021	2022	2021
Staff costs	2 592	2 240	7 682	5 367
Consulting and contractors' fees	802	2 481	2 107	3 150
Q&A regulatory	77	90	203	453
IP costs	131	143	353	934
Depreciation and amortization expense	320	239	816	694
Travel	327	253	655	298
Manufacturing and outsourced development	1 424	467	3 765	2 143
Clinical studies	2 325	1 118	6 577	2 826
Other expenses	362	100	1 019	861
Capitalized costs	(4 139)	(3 614)	(11 891)	(7 717)
<b>Total research and development expenses</b>	<b>4 221</b>	<b>3 517</b>	<b>11 286</b>	<b>9 009</b>

Before capitalization of €11.9 million for the nine months ended September 30, 2022 and €7.7 million for the nine months ended September 30, 2021, research and development expenses increased by €6.5 million or 39 %, from €16.7 million for the nine months ended September 30, 2021, to €23.2 million for the nine months ended September 30, 2022, 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. This was offset by a decrease in patent fees and related expenses due to the payment for in-licensing agreement with Vanderbilt University during the first nine months ended September 30, 2021.

Before capitalization of €4.1 million for the three months ended September 30, 2022 and €3.6 million for the three months ended September 30, 2021, research and development expenses increased by €1.2 million or 17 %, from €7.1 million for the three months ended September 30, 2021, to €8.4 million for the three months ended September 30, 2022, 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.

### Selling, General and Administrative expenses

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2022	2021	2022	2021
Staff costs	2 055	1 336	5 384	2 598
Consulting and contractors' fees	928	1 485	3 032	5 189
Legal fees	145	1	560	133
Rent	245	71	447	196
Depreciation and amortization expense	179	166	619	517
ICT	109	83	361	249
Travel	367	150	914	196
Insurance fees	404	523	1 239	523
Other	331	681	936	1 174
<b>Total selling, general and administrative expenses</b>	<b>4 763</b>	<b>4 496</b>	<b>13 492</b>	<b>10 775</b>

Selling, general and administrative expenses increased by €2.7 million or 25 % from €10.8 million for the nine months ended September 30, 2021 to €13.5 million for the nine months ended September 30, 2022, mainly due to an increase in staff costs to support the Company in its activities and an increase in insurance fees following the listing of the Company in the United States. This increase was offset by a decrease of €2.2 million in Consulting and contractors' fees due to variable compensations

for an amount of €1.9 million that were included in the nine months ended September 30, 2021 related to a cash settled share based payment transaction.

Selling, general and administrative expenses increased by €267,000 or 6 % from €4.5 million for the three months ended September 30, 2021 to €4.8 million for the three months ended September 30, 2022, mainly due to an increase in staff costs to support the Company in its activities. This increase was offset by a decrease of €0.6 million in Consulting and contractors' fees due to one time fee of € 0.4 million included in the three months ended September 30, 2021.

#### *Other operating expenses*

The Company had other operating income of €237,000 for the nine months ended September 30, 2022 compared to other operating expenses of €-274,000 for the nine months ended September 30, 2021.

The Company had other operating income of €87,000 for the three months ended September 30, 2022 compared to other operating expenses of €-178,000 for the three months ended September 30, 2021.

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2022	2021	2022	2021
Recoverable cash advances				
Initial measurement and re-measurement	50	(100)	77	(253)
R&D incentives (Australia)	55	136	192	572
Capitalization of R&D incentive	(15)	(121)	(117)	(498)
Other income/(expenses)	(3)	(93)	85	(95)
<b>Total Other Operating Income/(Expenses)</b>	<b>87</b>	<b>(178)</b>	<b>237</b>	<b>(274)</b>

### 23. Employee benefits

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2022	2021	2022	2021
Salaries	3 133	2 117	9 221	5 638
Social charges	242	267	742	599
Fringe benefits	(33)	66	44	221
Defined contribution plan	69	90	205	262
Holiday pay	162	189	200	287
Share-based payment	845	784	2 137	784
Other	229	63	517	174
<b>Total employee benefits</b>	<b>4 647</b>	<b>3 576</b>	<b>13 066</b>	<b>7 965</b>

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2022	2021	2022	2021
Selling, general and administrative expenses	2 055	1 336	5 384	2 598
Research & Development expenses	2 592	2 240	7 682	5 367
<b>Total employee benefits</b>	<b>4 647</b>	<b>3 576</b>	<b>13 066</b>	<b>7 965</b>

## 24. Financial income

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2022	2021	2022	2021
Interests	79	–	192	1
Exchange differences	4 955	15	11 045	57
Other	92	14	135	14
<b>Total financial income</b>	<b>5 126</b>	<b>29</b>	<b>11 372</b>	<b>72</b>

For the nine month period ended September 30, 2022, exchange gains amount to €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 14). For the year ended December 31, 2021, the closing rate of EUR/USD amounted to 1.13260, while as at September 30, 2022, the rate of EUR/USD decreased to 0.980200, resulting in unrealized exchange gains 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<sup>®</sup> system.

For the nine month period ended September 30, 2022, the total interest income amounted to €192,000 (three month period ended September 30, 2022 : €79,000). This interest income relates to the USD term accounts. Other financial income mainly consists of premiums received on foreign currency options.

## 25. Financial expense

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2022	2021	2022	2021
Fair value adjustment	609	146	2 558	146
Recoverable cash advances, Accretion of interest	231	220	694	661
Interest and bank charges	21	33	124	253
Interest on lease liabilities	26	22	73	67
Exchange differences	1 632	134	2 020	323
Other	4	29	4	34
<b>Total Financial expense</b>	<b>2 523</b>	<b>584</b>	<b>5 473</b>	<b>1 484</b>

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 nine month period ended September 30, 2022, exchange differences consists for €1,8 million out of realized losses on foreign currency options that reached maturity.

## 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 September 2022 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	
	2022	2021	2022	2021
<i>As at September 30, after conversion and share split</i>				
Outstanding common shares at period-end	25 846 279	25 547 359	25 846 279	25 547 359
Weighted average number of common shares outstanding	25 836 279	25 197 917	25 809 995	23 154 759
Number of shares resulting of the exercise of outstanding warrants	1 916 125	2 218 000	1 916 125	2 218 000

Basic and Diluted EPS for the three and nine month periods ended September 30, 2022 and 2021 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,	
	2022	2021	2022	2021
Loss of year attributable to equity holders (in EUR)	(6 240 000)	(8 762 000)	(17 929 000)	(21 371 000)
Weighted average number of common shares outstanding (in units)	25 836 279	25 197 917	25 809 995	23 154 759
Basic earnings per share in EUR (EUR/unit)	(0.242)	(0.348)	(0.695)	(0.923)
Diluted earnings per share in EUR (EUR/unit)	(0.242)	(0.348)	(0.695)	(0.923)

## 27. Other commitments

The Company has granted in October 2020 an amount of €0.5 million towards an institute under the Company's Sponsored Grant Program. The institute will have to perform over a total period of two years certain clinical and research activities and training and education activities. During the period ended September 30, 2022, the Company recognized €79,000 in Therapy Development expenses.

## 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 and nine months ended September 30:

(in EUR 000)	For the three months ended September 30		For the nine months ended September 30	
	2022	2021	2022	2021
Short-term remuneration & compensation	120	332	391	477
Share based payment	47	13	102	13
<b>Total</b>	<b>167</b>	<b>345</b>	<b>493</b>	<b>490</b>

The Company had the following related party transactions in 2021:

On July 15, 2021, the Board of Directors, based on the recommendation of the remuneration committee, approved an exceptional one-off bonus to Olivier Taelman, CEO, for the success of the Nasdaq IPO, for an amount of €150,000.

On August 27, 2021, the Board of Directors approved a revised remuneration package for Olivier Taelman, CEO, effective as of September 1, 2021.

The Company did not have any related party transactions for the three and nine months period ended September 30, 2022.

*Transactions with Non-Executive Directors and Shareholders:*

(in EUR 000)	For the nine months ended September 30, 2022			For the nine months ended September 30, 2021		
	R&D Collaborat ion	Consulting services	Board Remunera tion	R&D Collaborat ion	Consulting services	Board Remunera tion
Cochlear	1 749	–	–	1 450	–	–
MINV SA	–	60	–	–	69	–
Ray Cohen	–	–	20	–	–	–
Ginny Kirby	–	–	15	–	–	–
Donald Deyo	–	–	21	–	–	43
Robert Taub	–	–	61	–	–	54
Kevin Rakin	–	–	33	–	–	31
Pierre Gianello	–	–	36	–	–	28
Jan Janssen	–	–	24	–	–	28
Jurgen Hambrecht	–	–	38	–	–	31
Rita Mills	–	–	28	–	–	–
<b>Total</b>	<b>1 749</b>	<b>60</b>	<b>276</b>	<b>1 450</b>	<b>69</b>	<b>215</b>
<b>Amounts outstanding at period-end</b>	<b>970</b>	<b>60</b>	<b>126</b>	<b>–</b>	<b>69</b>	<b>215</b>

(in EUR 000)	For the three months ended September 30, 2022			For the three months ended September 30, 2021		
	R&D Collaborat ion	Consulting services	Board Remunera tion	R&D Collaborat ion	Consulting services	Board Remunera tion
Cochlear	413	–	–	1 450	–	–
MINV SA	–	–	–	–	52	–
Ray Cohen	–	–	16	–	–	–
Ginny Kirby	–	–	12	–	–	–
Donald Deyo	–	–	7	–	–	22
Robert Taub	–	–	19	–	–	13
Kevin Rakin	–	–	8	–	–	9
Pierre Gianello	–	–	1	–	–	7
Jan Janssen	–	–	5	–	–	7
Jurgen Hambrecht	–	–	14	–	–	9
Rita Mills	–	–	5	–	–	–
<b>Total</b>	<b>413</b>	<b>–</b>	<b>87</b>	<b>1 450</b>	<b>52</b>	<b>67</b>
<b>Amounts outstanding at period-end</b>	<b>970</b>	<b>60</b>	<b>126</b>	<b>–</b>	<b>69</b>	<b>215</b>

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 €1.7 million and €1.5 million for the nine months ended September 30, 2022 and 2021 respectively. For the three months ended September 30, the financial impact of the collaboration with Cochlear was of €413,000 in 2022 and €1.5 million in 2021.

## **29. Events after the Balance-Sheet Date**

No events after balance-sheet date took place.

## **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, 2022.

On behalf of the board of directors

Robert Taub, Chairman

Olivier Taelman, CEO