

# INTERIM FINANCIAL REPORT

FIRST HALF 2022

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#### **INTERIM FINANCIAL REPORT**

# FIRST HALF 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<sup>®</sup> system will be followed for five years post-implantation to assess the safety and efficacy of the Genio<sup>®</sup> 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 apneahypopnea index ("AHI") with hypopneas associated with a 4% oxyhemoglobin desaturation and a remaining AHI with hypopneas associated with a 4% oxyhemoglobin desaturation less than 20, together with a 25% reduction on the oxygen desaturation index ("ODI") between baseline and 12-month visits. Patients with moderate to severe OSA (AHI score between 15 and 65) and aged between 22 and 75 years are eligible for enrolment if they failed, did not tolerate or refused positive airway pressure ("PAP") treatment. Patients with a body mass index above 32 kg/m2, a complete concentric collapse ("CCC") observed during a drug induced sleep endoscopy and combined central and mixed AHI above 25% at baseline polysomnography are to be excluded.

Enrollment in the DREAM trial is now complete. 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/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.

#### ACCCESS 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 ACCCESS 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 first patient is expected to be implanted during the fourth quarter of 2022.

#### B. EUROPEAN COMMERCIALISATION

During the first half of 2022, Nyxoah recognized total revenue of €1.6 million, primarily in Germany, representing a substantial increase over the first half 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 13 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 June 30, 2022, the Company has activated 26 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 half 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  $\in 1.6$  million for the six months ending June 30, 2022, compared to  $\in 355,000$  for the six months ending June 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  $\notin 0.6$  million for the six months ending June 30, 2022, compared to  $\notin 115,000$  cost for the six months ending June 30, 2021. The increase in cost of goods sold was attributable to the sales of the Genio<sup>®</sup> system in Europe.

Selling, general and administrative expenses increased from  $\notin 6.3$  million for the six months ending June 30, 2021 to  $\notin 8.7$  million 2022 for the six months ending June 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  $\in 1.9$  million for the six months ending June 30, 2021 related to a cash settled share-based payment transaction.

Before capitalization of  $\notin$ 7.8 million for the six months ending June 30, 2022 and  $\notin$ 4.1 million for the six months ending June 30, 2021, research and development expenses increased from  $\notin$ 9.6 million for the six months ending June 30, 2021 to  $\notin$ 14.8 million for the six months ending June 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 six months ended June 30, 2021.

The financial result for the six months ending June 30, 2022 amount to  $\notin$ 3.3million due to the combined effect of  $\notin$ 5.7 million exchange gains driven by the revaluation of both the Company's USD cash balance and USD financial assets, partially offset by fair value adjustments on financial instruments (- $\notin$ 1.9million) and accretion of interests on recoverable cash advances ( $\notin$ -0.5million).

Nyxoah realized a net loss of  $\notin 11.7$  million for the six months ending June 30, 2022, compared to a net loss of  $\notin 12.6$  million for the six months ending June 30, 2021.

#### Cash and cash equivalents

On June 30, 2022, cash and cash equivalents and financial assets totalled  $\notin 123.3$  million, compared to  $\notin 135.5$  million on December 31, 2021. The decrease in cash and cash equivalents resulted mainly from net cash flows used in operating activities of  $\notin 9.7$  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 first patient implanted in ACCCESS 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 commercialisation, 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.

# UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION AS AT AND FOR THE SIX MONTHS ENDED JUNE 30, 2022 – INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(unaudited)

(in thousands)

		As at		
	Notes	June 30 2022	December 31 2021	
ASSETS				
Non-current assets				
Property, plant and equipment	7	€2111	€ 2 020	
Intangible assets	8	32 570	25 322	
Right of use assets	9	3 410	3 218	
Deferred tax asset	19	1 429	46	
Other long-term receivables		180	164	
		€ 39 700	€ 30 770	
Current assets				
Inventory	10	506	346	
Trade receivables	11	957	226	
Other receivables	11	1 548	2 286	
Other current assets	12	852	1 693	
Financial assets	14	47 717		
Cash and cash equivalents	13	75 602	135 509	
		€ 127 182	€ 140 060	
Total assets		€ 166 882	€ 170 830	
EQUITY AND LIABILITIES				
Capital and reserves				
Capital	15	4 438	4 427	
Share premium	15	228 158	228 033	
Share based payment reserve	16	4 411	3 127	
Other comprehensive income	15	88	202	
Retained loss		(98 850)	(87 167)	
Total equity attributable to shareholders		€ 138 245	€ 148 622	
		0 150 245	0140 022	
LIABILITIES				
Non-current liabilities				
Financial debt	17	8 089	7 802	
Lease liability	9	2 859	2 737	
Pension liability	)	80	80	
Provisions		44	12	
Deferred tax liability			5	
		€ 11 072	€ 10 636	
Current liabilities		£ 11 0/2	£ 10 030	
Financial debt	17	((1	554	
Lease liability		661	554	
Lease nability Trade payables	9 18	672	582	
	18	4 301	3 995	
Current tax liability		4 391	2 808	
Other payables	20	7 540	3 633	
		€ 17 565	€ 11 572	
Total liabilities		€ 28 637	€ 22 208	
Total equity and liabilities		€ 166 882	€ 170 830	

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

# UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION AS AT AND FOR THE SIX MONTHS ENDED JUNE 30, 2022 -INTERIM CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS

# (unaudited) (in thousands)

		For the six month 30	s ended June
	Notes	2022	2021
Revenue	22	€ 1 595	€ 355
Cost of goods sold	22	(623)	(115)
Gross profit		€ 972	€ 240
Research and Development Expense	22	(7 065)	(5 492)
Selling, General and Administrative Expense	22	(8 729)	(6 279)
Other income/(expense)		150	(97)
Operating loss for the period		€ (14 672)	€ (11 628)
Financial income	24	6 246	43
Financial expense	25	(2 950)	( 899)
Loss for the period before taxes		€ (11 376)	€ (12 484)
Income taxes	19	(315)	(124)
Loss for the period		€ (11 691)	€ (12 608)
Loss attributable to equity holders		€ (11 691)	€ (12 608)
Other comprehensive loss			
Items that may be subsequently reclassified to profit or loss (net of tax)			
Currency translation differences		(114)	192
Total comprehensive loss for the year, net of tax		€ (11 805)	€ (12 416)
Loss attributable to equity holders		€ (11 805)	€ (12 416)
Basic Loss Per Share (in EUR)	26	€ (0.453)	€ (0.570)
Diluted Loss Per Share (in EUR)	26	€ (0.453)	€ (0.570)

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

# UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION AS AT AND FOR THE SIX MONTHS ENDED JUNE 30, 2022 -INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(unaudited)

(in thousands)

	Attributable to owners of the parent					
	Common shares	Share premium	Share based payment reserve	Other comprehe nsive income	Retained loss	Total
Balance at January 1, 2022	€ 4 427	€ 228 033	€ 3 127	€ 202	€ (87 167)	€ 148 622
Loss for the period	-	-	_	_	(11 691)	(11 691)
Other comprehensive loss for the period		_	_	(114)	-	(114)
Total comprehensive loss for the period	-	-		€ (114)	€ (11 691)	€ (11 805)
Equity-settled share-based payments						
Granted during the period	-	-	1 292	-	-	1 292
Exercised during the period	4	125	(8)	-	8	129
Issuance of shares for cash	7	_	_		_	7
Total transactions with owners of the company recognized directly in equity	11	125	1 284		8	1 428
Balance at June 30, 2022	€ 4 438	€ 228 158	€ 4 411	€ 88	€ (98 850)	€ 138 245

	Common shares	Share premium	Share based payment reserve	Other comprehe nsive income	Retained loss	Total
Balance at January 1, 2021	€ 3 796	€ 150 936	€ 2 650	€ 149	€ (60 341)	€ 97 190
Loss for the period	-	-	-	-	(12 608)	(12 608)
Other comprehensive loss for the period	-	-	-	192	-	192
Total comprehensive loss for the period	-	-	-	€ 192	€ (12 608)	€ (12 416)
Equity-settled share-based payments						
Exercised during the period	12	350	_	_	_	362
Total transactions with owners of the company recognized directly in equity	12	350	_		_	362
Balance at June 30, 2021	€ 3 808	€ 151 286	€ 2 650	€ 341	€ (72 949)	€ 85 136

Attributable to owners of the parent

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

# UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION AS AT AND FOR THE SIX MONTHS ENDED JUNE 30, 2022 – INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

## (in thousands)

		For the six month 30	s ended June
	Notes	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax for the year		€ (11 376)	€ (12 484)
Adjustments for			
Finance income		(6 246)	(43)
Finance expenses		2 950	899
Depreciation and impairment of property, plant and equipment and right-of-use assets	7, 9	536	377
Amortization of intangible assets	8	402	428
Share-based payment transaction expense	16	1 292	-
Increase/(Decrease) in provisions		32	-
Other non-cash items		37	11
Cash generated before changes in working capital		€ (12 373)	€ (10 812)
Changes in working capital			
Decrease/(Increase) in inventory	10	(160)	(27)
(Increase)/Decrease in trade and other receivables	11	1 011	(3 463)
Increase/(Decrease) in trade and other payables	18, 20	2 053	6 061
Cash generated from changes in operations		€ (9 469)	€ (8 241)
Income tax paid		(254)	(111)
Net cash used in operating activities		€ (9 723)	€ (8 352)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	7	(302)	(795)
Capitalization of intangible assets	8	(7 650)	(3 726)
(Increase)/Decrease in financial assets - current	14	(44 032)	-
Net cash used in investing activities		€ (51 984)	€ (4 521)
CASH FLOWS FROM FINANCING ACTIVITIES	0		(22.0)
Payment of principal portion of lease liabilities	9	(317)	(236)
Repayment of other loan		(42)	(42)
Interests paid	1.5	(134)	(258)
Repayment of recoverable cash advance	15	-	(105)
Proceeds from issuance of shares, net of transaction costs	15	136	362
Other financial costs		( 8)	(10)
Net cash generated from financing activities		€ ( 365)	€ ( 289)
Movement in cash and cash equivalents		€ (62 072)	€ (13 162)
Effect of exchange rates on cash and cash equivalents	24	2 165	33
Cash and cash equivalents at January 1	13	€ 135 509	€ 92 300
Cash and cash equivalents at June 30	13	€ 75 602	€ 79 171

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

# 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<sup>®</sup> 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 June 30, 2022 and for the six months ended June 30, 2022 have been authorized for issue on August 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 ( $\in$ ) and all values are rounded to the nearest thousands, except when otherwise indicated (e.g.  $\in$  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 half-yearly 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 June 30, 2022, the Company had cash and cash equivalents of  $\notin$ 75.6 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.

	Carryin	Carrying value		Carrying value		value
(in EUR 000)	As at June 30, 2022	As at December 31, 2021	As at June 30, 2022	As at December 31, 2021		
Financial Assets						
Other long-term receivables (level 3)	180	164	180	164		
Trade and other receivables (level 3)	2 483	2 512	2 483	2 512		
Foreign currency forwards (level 2)	22	-	22	_		
Other current assets (level 3)	852	1 693	852	1 693		
Cash and cash equivalents (level 1)	75 602	135 509	75 602	135 509		
Financial assets (level 1)	47 717	-	47 717	_		

	Carrying value		Fair value		
(in EUR 000)	As at June 30, 2022	As at December 31, 2021	As at June 30, 2022	As at December 31, 2021	
Financial liabilities					
Financial debt (level 3)	188	229	157	194	
Foreign currency option (level 2)	2 631	654	2 631	654	
Recoverable cash advances (level 3)	8 562	8 127	8 562	8 127	
Trade and other payables (level 1 and 3)	9 210	6 974	9 210	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 six months ended June 30, 2022 amount to  $\notin$  302,000 (2021:  $\notin$  0.8 million) and were mainly related to furniture and office equipment and laboratory equipment.

The depreciation charge amounts to €198,000 in 2022 and to €104,000 in 2021 for the six months ended June 30.

# 8. Intangible assets

There is only one development project : The Genio<sup>®</sup> system.

(in EUR 000)	Development cost	Patents and licenses	Total
Cost			
Opening value at January 1, 2021	15 262	591	15 853
Additions	3 726	-	3 726
Exchange difference	166	_	166
Cost at June 30, 2021	19 154	591	19 745
Opening value at January 1, 2022	25 610	591	26 201
Additions	7 650	_	7 650
Exchange difference	_	-	_
Cost at June 30, 2022	33 260	591	33 851
Amortization			
Opening amortization at January 1, 2021	-	_	_
Amortization	( 428)	_	(428)
Exchange difference	(4)	-	(4)
Amortization at June 30, 2021	( 432)	-	( 432)
Opening amortization at January 1, 2022	(837)	(42)	( 879)
Amortization	(381)	(21)	(402)
Exchange difference	-	-	_
Amortization at June 30, 2022	(1 218)	( 63)	(1 281)
Net book value at June 30, 2021	18 722	591	19 313
Net book value at June 30, 2022	32 042	528	32 570

The Company started amortizing the first-generation Genio<sup>®</sup> system in 2021. The amortization amounted to  $\notin$ 402,000 for the six months ended June 30, 2022 (2021:  $\notin$ 428,000) 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<sup>®</sup> system and clinical trials to obtain additional regulatory approvals in certain countries or to be able to sell the Genio<sup>®</sup> System in certain countries. The total capitalized development expenses amounted to  $\notin$ 7.7 million and  $\notin$ 3.7 million for the six months ended June 30, 2022, and 2021, respectively.

# 9. Right of use assets and lease liabilities

For the six months ended June 30, 2022, the Company did enter into new lease agreements for  $\notin 0.6$  million (2021:  $\notin 55,000$ ). The repayments of lease liabilities amounted to  $\notin 317,000$  (2021:  $\notin 236,000$ ). The depreciations on the right of use assets amounted to  $\notin 338,000$  and  $\notin 273,000$  for the six months ended June 30, 2022, and 2021, respectively.

#### 10. Inventory

	As at		
(in EUR 000)	June 30, 2022	December 31, 2021	
Work in progress	387	83	
Finished goods	119	263	
Total Inventory	506	346	

The increase in inventory is due to increasing activities. For the period ended June 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

	As	at
(in EUR 000)	June 30, 2022	December 31, 2021
Trade receivables	957	226
R&D incentive receivable (Australia)	896	1 616
VAT receivable	392	524
Current tax receivable	96	71
Foreign currency forwards	22	-
Other	142	75
Total trade and other receivables	2 505	2 512

The increase of  $\notin 0.8$  million in trade receivables as at June 30, 2022 is due to generated revenue by the Company. As of December 31, 2021 and June 30, 2022, unbilled receivables included in the trade receivables were respectively  $\notin 0$  and  $\notin 400,000$ .

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.

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  $\notin 0.7$  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.

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

#### 12. Other current assets

The decrease of  $\notin 0.8$  million in other current assets as at June 30, 2022 is mainly due to the partial decrease in the advance payment of  $\notin 1.1$  million for Directors & Officers insurance following the initial public offering in the United States.

#### 13. Cash and cash equivalents

	As	at
(in EUR 000)	June 30, 2022	December 31, 2021
Short term deposit	37	38
Current accounts	75 565	135 471
Total cash and cash equivalents	75 602	135 509

The decrease of current accounts by  $\notin$  59.9 million is due to an increase in term accounts of  $\notin$  47.7 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. As at June 30, 2022, the Company holds USD term deposits at a well established financial institution for a total amount of 50.0 million USD. 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 50.0 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 June 30, 2022, amounts to €47.7 million.

#### 15. Capital, Share Premium, Reserves

#### 15.1. Capital and share premium

Evolution of the share capital and share premium over the six months ended June 30, 2022 and 2021:

(Number of shares <sup>(1)</sup> except otherwise stated)	Common shares	Total of shares	Par value (EUR)	Share capital	Share premium
January 1, 2021	22 097 609	22 097 609	0.17	3 796	157 514
February 22, 2021 - Exercise warrants	10 000	10 000	0.17	2	50
June 23, 2021 - Exercise warrants	60 000	60 000	0.17	10	300
June 30, 2021	22 167 609	22 167 609	0.17	3 808	157 864
July 7, 2021 - IPO	2 835 000	2 835 000	0.17	487	71 355
July 9, 2021 - IPO	425 250	425 250	0.17	73	10 703
July 9, 2021 - Exercise warrants	10 000	10 000	0.17	2	118
September 10, 2021 - Exercise warrants	82 500	82 500	0.17	14	558
September 30, 2021 - Exercise warrants	27 000	27 000	0.17	5	135
October 11, 2021 - Exercise warrants	110 000	110 000	0.17	19	755
November 4, 2021 - Exercise warrants	90 000	90 000	0.17	15	585
November 25, 2021 - Exercise warrants	25 000	25 000	0.17	4	125
December 31, 2021	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	_
June 30, 2022	25 836 279	25 836 279	0.17	4 438	242 323

<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).

# 15.2. Reserves

The reserves included 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 six months ended June 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	192	-	192
Remeasurements of post-employment benefit obligations			
Total other comprehensive income at June 30, 2021	341	_	341
Opening value at January 1, 2022	270	(68)	202
Currency translation differences	(114)	-	(114)
Remeasurements of post-employment benefit obligations		_	
Total other comprehensive income at June 30, 2022	156	(68)	88

#### 16. Share-Based compensation

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

As of June 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:

Number of shares (after share split) warrants give right to across all plans	2022	2021
Outstanding at January 1	993 490	1 007 500
Granted	461 500	-
Forfeited/Cancelled	(14 125)	-
Exercised	(25 000)	(70 000)
Outstanding as at June 30	1 415 865	937 500
Exercisable as at June 30	779 966	937 500

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.

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.

	Plan 2016 (grant 2018)	Plan 2018 (grant 2018)	Plan 2013 (grant 2018)	Plan 2018 (grant 2020)	Plan 2020 (grant 2020)
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

	Plan 2021 (grant Sept. 17 2021)	Plan 2021 (grant Oct. 27 2021)		Plan 2021 (grant Feb 21 2022)		Plan 2021 (grant May 14 2022)	Plan 2021 (grant June 8 2022)
Return Dividend	0%	0%	0%	0%	0%	0%	0%
Expected volatility	51.30%	51.50%	49.80%	49.80%	49.80%	49.80%	52.60%
Risk-free interest rate	-0.36%	-0.18%	0.37%	0.37%	0.50%	0.00%	1.60%
Expected life	3	3	3	3	4	3	3
Exercise price	25.31	25.31	17.76	25.31	17.76	13.82	12.95
Stock price	25.75	20.50	17.50	17.50	17.50	13.82	13.34
Fair value	9.22	5.94	6.05	4.15	6.90	4.94	5.21

The Company has recognized €1.3 million share-based payment expense for the six months ended June 30, 2022 (2021: €0)

# 17. Financial Debt

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

	As at	
(in EUR 000)	June 30, 2022	December 31, 2021
Recoverable cash advances - Non-current	8 005	7 656
Recoverable cash advances - Current	557	471
Total Recoverable cash advances	8 562	8 127
Other loan - Non-current	84	146
Other loan - Current	104	83
Total Other loan	188	229
Non-current	8 089	7 802
Current	661	554
Total Financial Debt	8 750	8 356

#### Financial debt related to recoverable cash advances

#### Recoverable cash advances received

As at June 30, 2022, 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	450
First articles (6839)	2 160	2 160	184
Clinical trial (6840)	2 400	2 400	135
Activation chip improvements (7388)	1 467	1 467	29
Total	7 627	7 627	798

During the six months ended June 30, 2022, the Company made reimbursements totaling  $\notin 0$  (2021:  $\notin 105,000$ ). The Company did not receive any new amounts during the six months ended June 30, 2022.

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

	As at	
(in EUR 000)	June 30, 2022	December 31, 2021
Contract 6472	1 537	1 452
Contract 6839	2 452	2 333
Contract 6840	2 767	2 630
Contract 7388	1 806	1 712
Total recoverable cash advances	8 562	8 127
Non-current	8 005	7 656
Current	557	471
Total recoverable cash advances	8 562	8 127

The amounts recorded under "Current" caption correspond to the sales-independent amounts (fixed repayment) estimated to be repaid to the Walloon Region in the next 12-month period. The estimated sales-independent (fixed repayment) beyond 12 months as well as sales-dependent reimbursements (variable repayment) are recorded under "Non-current" liabilities. Changes in the recoverable cash advances can be summarized as follows:

(in EUR 000)	2022	2021
As at January 1	8 127	7 910
Advances reimbursed (excluding interests)	_	(105)
Initial measurement and re-measurement	(28)	154
Discounting impact	463	441
As at June 30	8 562	8 400

# 18. Trade payables

	As at		
(in EUR 000)	June 30, 2022	December 31, 2021	
Payables	2 576	2 394	
Invoices to be received	1 725	1 601	
Total Trade payables	4 301	3 995	

The increase in total trade payables of €0.3 million as at June 30, 2022 is mainly due to the increase in invoices to be received.

## 19. Income taxes and deferred taxes

		For the six months ended June 30	
(in EUR 000)	2022	2021	
Current tax income/(expense)	(1 636)	(132)	
Deferred tax income/(expense)	1 321	8	
Total Income Tax Income/(Expense)	(315)	(124)	

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  $\notin$ 1.5 million, and also an increase in deferred taxed assets and deferred tax income of  $\notin$ 1.3 million. 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  $\notin$ 4.4 million also relates to a liability for uncertain tax positions for an amount of  $\notin$ 2.8 million. The current tax expense for the six month period ended June 30, 2022 amounts to  $\notin$ 69,000. 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.

#### 20. Other payables

	As	As at	
(in EUR 000)	June 30, 2022	December 31, 2021	
Holiday pay accrual	603	493	
Salary	634	870	
Accrued expenses	3 070	1 485	
Foreign currency option - current	2 631	654	
Other	602	131	
Total other payables	7 540	3 633	

The increase of  $\notin 3.9$  million in other payables as of June 30, 2022, compared to December 31, 2021, is mainly due to an increase of  $\notin 1.6$  million in accrued expenses related to an increase in clinical and R&D activities and due to an increase of  $\notin 2.0$  million in the fair value of the foreign currency option. The item Other includes  $\notin 449,000$  social debts towards the social agency.

#### 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:

	A	As at	
(in EUR 000)	June 30, 2022	December 31, 2021	
call USD (in USD)	34 350	34 350	
put USD (in USD)	_	(3 000)	
call EUR (in EUR)	-	2 500	
put EUR (in EUR)	(30 000)	(30 000)	

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

	A	As at	
(in EUR 000)	June 30, 2022	December 31, 2021	
Foreign currency forwards EUR - AUD (in AUD)	600	_	
Foreign currency forwards EUR - AUD (in EUR)	372	_	
Foreign currency forwards EUR - NIS (in NIS)	10 500	_	
Foreign currency forwards EUR - NIS (in EUR)	2 909	_	

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:

	As at June 30, 2022				
(in EUR 000)	Level I	Level II	Level III	Total	
Financial assets					
Foreign currency forwards		-	22	_	22
Financial liabilities					_
Foreign currency option		-	2 631	-	2 631

The fair value is determined by the financial institution and is based on foreign currency forwards rates and the maturity of the instrument. All foreign currency put and call options and foreign currency 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)	2022	2021
Opening value at January 1		
New contracts	_	_
Fair value adjustments	22	
Closing value at June 30	22	

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

	2022	2021
Opening value at January 1	654	_
New contracts	_	_
Fair value adjustments	1 949	_
Exchange rate difference	28	_
Closing value at June 30	2 631	_

#### 22. Results of operation

#### Revenue and cost of goods sold

In the six months ended June 30, 2022, the Company generated revenue for the amount of  $\notin 1.6$  million (2021:  $\notin 355,000$ ). Revenue is recognized at a point in time upon satisfaction of the performance obligation, being the moment control over the Genio<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> system. In determining the transaction price for the sale of the Genio<sup>®</sup> system, the Company considers the effects of variable consideration.

For the six month period ended June 30, 2022 the sales (based on country of customer) were generated in Germany ( $\notin$ 1.6 million) and Finland ( $\notin$ 40,000) (2021: Germany:  $\notin$ 310,000, Spain:  $\notin$ 24,000 and Belgium:  $\notin$ 20,000). For the six month period ended June 30, 2022, the Company has two customers with individual sales larger than 10% of the total revenue (2021: three customers).

Cost of goods sold for the six months ended June 30, 2022 and 2021:

	For the six months ended June 30	
(in EUR 000)	2022	2021
Purchases of goods and services	783	87
Inventory movement	(160)	28
Total cost of goods sold	623	115

#### **Operating expenses**

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

(in EUR 000)	Total cost	Capitalized	Operating expense for the period
Research and development	14 817	(7 752)	7 065
Selling, general and administrative expenses	8 729	-	8 729
Other income and expenses	(252)	102	(150)
For the six months ended June 30, 2022	23 294	(7 650)	15 644

(in EUR 000)	Total cost	Capitalized	Operating expense for the period
Research and development	9 596	(4 104)	5 492
Selling, general and administrative expenses	6 279	-	6 279
Other income and expenses	(281)	378	97
For the six months ended June 30, 2021	15 594	(3 726)	11 868

#### **Research and Development expenses**

	For the six months ended . 30	
(in EUR 000)	2022	2021
Staff costs	5 090	3 126
Consulting and contractors' fees	1 304	670
Q&A regulatory	125	363
IP costs	222	791
Depreciation and amortization expense	496	454
Travel	328	45
Manufacturing and outsourced development	2 341	1 677
Clinical studies	4 252	1 708
Other expenses	659	762
Capitalized costs	(7 752)	(4 104)
Total research and development expenses	7 065	5 492

Before capitalization of  $\notin 7.8$  million for the six months ended June 30, 2022 and  $\notin 4.1$  million for the six months ended June 30, 2021, research and development expenses increased by  $\notin 5.2$  million or 54 %, from  $\notin 9.6$  million for the six months ended June 30, 2021, to  $\notin 14.8$  million for the six months ended June 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 six months ended June 30, 2021.

# Selling, General and Administrative expenses

		For the six months ended June <u>30</u>	
(in EUR 000)	2022	2021	
Staff costs	3 329	1 262	
Consulting and contractors' fees	2 104	3 703	
Legal fees	415	132	
Rent	202	125	
Depreciation and amortization expense	440	351	
ICT	253	165	
Travel	547	46	
Insurance fees	835	_	
Other	604	495	
Capitalized costs		_	
Total selling, general and administrative expenses	8 729	6 279	

Selling, general and administrative expenses increased by  $\notin 2.5$  million or 39 % from  $\notin 6.3$  million for the six months ended June 30, 2021 to  $\notin 8.7$  million for the six months ended June 30, 2022, mainly due to an increase in staff costs to support the Company in its activities. The increase in other is largely due to an increase in insurance fees following the listing of the Company in the United States.

Consulting and contractors' fees includes variable compensations for an amount of  $\in 1.9$  million for the six months ended in June 30, 2021 related to a cash settled share based payment transaction.

## Other operating expenses

The Company had other operating income of  $\notin$ 150,000 for the six months ended June 30, 2022 compared to other operating expenses of  $\notin$ 97,000 for the six months ended June 30, 2021.

	For the six month 30	For the six months ended June <u>30</u>	
(in EUR 000)	2022	2021	
Recoverable cash advances			
Initial measurement and re-measurement	28	(153)	
R&D incentives (Australia)	137	435	
Capitalization of R&D incentive	(102)	(378)	
Other income/(expenses)	87	(1)	
Total Other Operating Income/(Expenses)	150	(97)	

# 23. Employee benefits

	For the six months ended June <b>30</b>		
(in EUR 000)	2022	2021	
Salaries	6 089	3 520	
Social charges	500	332	
Fringe benefits	78	155	
Defined contribution plan	136	172	
Holiday pay	38	98	
Share-based payment	1 292	-	
Other	286	111	
Total employee benefits	8 419	4 388	

	30	30		
(in EUR 000)	2022	2021		
Selling, general and administrative expenses	3 329	1 262		
Research & Development expenses	5 090	3 126		
Total employee benefits	8 419	4 388		

For the six months ended June

#### 24. Financial income

	For the six months ended June 30		
(in EUR 000)	2022	2021	
Interests	113	1	
Exchange differences	6 090	42	
Other	43	_	
Total financial income	6 246	43	

For the six month period ended June 30, 2022, exchange gains amount to  $\epsilon$ 6.1 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 June 30, 2022, the rate of EUR/USD decreased to 1.03870, 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.

# 25. Financial expense

		For the six months ended June 30	
(in EUR 000)	2022	2021	
Fair value adjustment	1 949	_	
Recoverable cash advances, Accretion of interest	463	441	
Interest and bank charges	103	220	
Interest on lease liabilities	47	44	
Exchange differences	388	189	
Other		5	
Total Financial expense	2 950	899	

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.

# 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 June 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.

	2022	2021
As at June 30, after conversion and share split		
Outstanding common shares at period-end	25 836 279	22 167 609
Weighted average number of common shares outstanding	25 796 560	22 108 001
Number of shares resulting of the exercise of outstanding warrants	1 953 125	937 500

Basic and Diluted EPS for the six-month periods ended June 30, 2022 and 2021 based on weighted average number of shares outstanding after conversion and share split are as follows:

		For the six months ended June 30,		
	2022	2021		
Loss of year attributable to equity holders (in EUR)	(11 691 000)	(12 608 000)		
Weighted average number of common shares outstanding (in units)	25 796 560	22 108 001		
Basic earnings per share in EUR (EUR/unit)	(0.453)	(0.570)		
Diluted earnings per share in EUR (EUR/unit)	(0.453)	(0.570)		

# 27. Other commitments

The Company has granted in October 2020 an amount of  $\notin 0.5$  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. The future payment commitments amount to  $\notin 50,000$  at June 30, 2022, which will be paid quarterly in instalments over the remaining period if the institute performs its activities. During the period ended June 30, 2022, the Company recognized  $\notin 78,000$  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 six months ended June 30:

	For the six months ended June 30		
(in EUR 000)	2022	2021	
Short-term remuneration & compensation	271	145	
Share based payment	55	_	
Total	326	145	

#### Transactions with Non-Executive Directors and Shareholders:

	For the six months ended June 30, 2022		For the six months ended June 30, 2021			
(** EUD 000)	R&D Collaborat					
(in EUR 000) Cochlear	<u>ion</u>	services	tion	ion	services	tion
MINV SA	1 336	- 60	_	_	- 17	_
Ray Cohen	-	-	4	-	-	_
Giny Kirby	_	-	3	-	-	_
Donald Deyo	-	_	14	-	-	21
Robert Taub	_	_	42	-	_	41
Kevin Rakin	-	_	25	-	-	22
Pierre Gianello	-	_	35	_	_	21
Jan Janssen	-	_	19	-	-	21
Jurgen Hambrecht	-	_	24	_	_	22
Rita Mills	-	_	23	-	-	_
Total	1 336	60	189		17	148
Amounts outstanding at period-end	559	60	78	_	_	_

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 financial impact of  $\notin$ 1.3 million for the six months ended June 30, 2022. No expenses for the six months ended June 30, 2021.

The Company also recognized a share-based payment expense of €55,000 for the six months ended June 30, 2022 for non-executive directors.

#### 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, August 8, 2022.

On behalf of the board of directors

Robert Taub, Chairman

Olivier Taelman, CEO