
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of August 2022

Commission File Number: **001-40552**

NYXOAH SA

(Translation of registrant's name into English)

Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Nyxoah SA

On August 8, 2022, Nyxoah SA (the “Company”) announced its unaudited first half-year results for 2022, which are further described in an H1 2022 report.

The information in the attached Exhibits 99.1 and 99.2 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

Exhibits

[99.1](#) [Press Release, dated August 8, 2022](#)

[99.2](#) [H1 Report 2022](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NYXOAH SA

Date: August 8, 2022

By: /s/ Loic Moreau

Name: Loic Moreau

Title: Chief Financial Officer



REGULATED INFORMATION

Nyxoah Reports Second Quarter and First Half 2022 Financial and Operating Results

DREAM enrollment complete, 12-month clinical data expected in fall of 2023

Mont-Saint-Guibert, Belgium – August 8, 2022, 10:05pm CET / 4:05pm ET – Nyxoah SA (Euronext Brussels/Nasdaq: NYXH) (“Nyxoah” or the “Company”), a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea (OSA), today reported financial and operating results for the second quarter and first half of 2022.

Second Quarter 2022 Financial and Operating Highlights

- Completed enrollment in DREAM U.S. pivotal trial; expect 12-month clinical data in the fall of 2023 and regulatory approval in the first half of 2024
- Generated revenue of €935,000 from the commercialization of Genio® in Europe, primarily in Germany, which represents growth of more than five times the amount achieved in the second quarter of 2021
- Activated 11 new implanting sites in Germany during the second quarter, bringing the total to 26 as of June 30, 2022; expecting to have at least 35 active implanting sites by the end of 2022
- Received FDA approval of IDE submission to commence the ACCCESS study to treat complete concentric collapse (CCC) patients in the U.S., with first patient implant expected in the fourth quarter of 2022
- Received FDA approval of the next generation Genio® 2.1 system for use in the DREAM study and CE mark for use in commercial patients in Europe; this improves patient comfort and compliance with a new smartphone application and upgraded external activation chip, which leverages Nyxoah’s scalable platform to continuously enhance patient comfort and therapy efficacy without requiring a new implant
- Partnered with Acurable to distribute the AcuPebble SA100 wearable home sleep test to OSA patients in Germany; launch is expected in the fourth quarter of 2022
- Included in the newly formed Euronext Tech Leaders Index, which is composed of 100+ innovative and high-growth technology companies with greater than €1 trillion in aggregate market capitalization

“We made significant progress on all of our key strategic priorities this quarter, including activating 11 new commercial sites in Germany, completing enrollment in our DREAM trial, and receiving approval for our ACCCESS IDE,” commented Olivier Taelman, Nyxoah’s Chief Executive Officer. “From a commercial standpoint, our second quarter performance showing 42% quarter-over-quarter growth strengthens our confidence that we will achieve market leadership status in Germany by the end of 2022.”



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“As the only commercially available hypoglossal nerve stimulation (HGNS) therapy approved for the treatment of CCC patients, we are encouraged by the first strong results from patients who are six months post-implantation. These results, combined with no longer having to perform a drug-induced sleep endoscopy (DISE) procedure prior to implant, are driving physicians to recommend Genio for their CCC and non-CCC patients,” continued Mr. Taelman.

Mr. Taelman concluded, “In the meantime, we have already begun investing in our U.S. market access organization. As for our ACCCESS study, we expect to implant the first patients before year end.”



REGULATED INFORMATION

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION – INTERIM CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS FOR THE THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2022 (in thousands)

Second Quarter and First Half 2022 Results

	For the three months ended June 30		For the six months ended June 30	
	2022	2021	2022	2021
Revenue	€ 935	€ 170	€ 1 595	€ 355
Cost of goods sold	€ (334)	€ (63)	€ (623)	€ (115)
Gross profit	€ 601	€ 107	€ 972	€ 240
Research and Development Expense	€ (3 470)	€ (2 398)	€ (7 065)	€ (5 492)
Selling, General and Administrative Expense	€ (4 536)	€ (3 913)	€ (8 729)	€ (6 279)
Other income/(expense)	€ 14	€ (101)	€ 150	€ (97)
Operating loss for the period	€ (7 391)	€ (6 305)	€ (14 672)	€ (11 628)
Financial income	€ 4 670	€ 39	€ 6 246	€ 43
Financial expense	€ (2 162)	€ (574)	€ (2 950)	€ (899)
Loss for the period before taxes	€ (4 883)	€ (6 840)	€ (11 376)	€ (12 484)
Income taxes	€ (107)	€ (99)	€ (315)	€ (124)
Loss for the period	€ (4 990)	€ (6 939)	€ (11 691)	€ (12 608)
Loss attributable to equity holders	€ (4 990)	€ (6 939)	€ (11 691)	€ (12 608)
Other comprehensive loss				
Items that may be subsequently reclassified to profit or loss (net of tax)				
Currency translation differences	€ (12)	€ 262	€ (114)	€ 192
Total comprehensive loss for the year, net of tax	€ (5 002)	€ (6 677)	€ (11 805)	€ (12 416)
Loss attributable to equity holders	€ (5 002)	€ (6 677)	€ (11 805)	€ (12 416)
Basic Loss Per Share (in EUR)	€ (0,193)	€ (0,314)	€ (0,453)	€ (0,570)
Diluted Loss Per Share (in EUR)	€ (0,193)	€ (0,314)	€ (0,453)	€ (0,570)



REGULATED INFORMATION

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION – INTERIM
CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT JUNE 30, 2022 (in thousands)

	As at	
	June 30 2022	December 31 2021
ASSETS		
Non-current assets		
Property, plant and equipment	€ 2 111	€ 2 020
Intangible assets	32 570	25 322
Right of use assets	3 410	3 218
Deferred tax asset	1 429	46
Other long-term receivables	180	164
	€ 39 700	€ 30 770
Current assets		
Inventory	506	346
Trade receivables	957	226
Other receivables	1 548	2 286
Other current assets	852	1 693
Financial assets	47 717	-
Cash and cash equivalents	75 602	135 509
	€ 127 182	€ 140 060
Total assets	€ 166 882	€ 170 830
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	4 438	4 427
Share premium	228 158	228 033
Share based payment reserve	4 411	3 127
Other comprehensive income	88	202
Retained loss	(98 850)	(87 167)
Total equity attributable to shareholders	€ 138 245	€ 148 622
LIABILITIES		
Non-current liabilities		
Financial debt	8 089	7 802
Lease liability	2 859	2 737
Pension liability	80	80
Provisions	44	12
Deferred tax liability	-	5
	€ 11 072	€ 10 636
Current liabilities		
Financial debt	661	554
Lease liability	672	582
Trade payables	4 301	3 995
Current tax liability	4 391	2 808
Other payables	7 540	3 633
	€ 17 565	€ 11 572
Total liabilities	€ 28 637	€ 22 208
Total equity and liabilities	€ 166 882	€ 170 830



REGULATED INFORMATION

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION - INTERIM CONSOLIDATED STATEMENTS OF
CASH FLOWS
AS AT JUNE 30, 2022 (in thousands)

	For the six months ended June30	
	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	536	377
Amortization of intangible assets	402	428
Share-based payment transaction expense	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	(160)	(27)
(Increase)/Decrease in trade and other receivables	1 011	(3 463)
Increase/(Decrease) in trade and other payables	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	(302)	(795)
Capitalization of intangible assets	(7 650)	(3 726)
(Increase)/Decrease in financial assets - current	(44 032)	-
Net cash used in investing activities	€ (51 984)	€ (4 521)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of principal portion of lease liabilities	(317)	(236)
Repayment of other loan	(42)	(42)
Interests paid	(134)	(258)
Repayment of recoverable cash advance	-	(105)
Proceeds from issuance of shares, net of transaction costs	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	2 165	33
Cash and cash equivalents at January 1	€ 135 509	€ 92 300
Cash and cash equivalents at June 30	€ 75 602	€ 79 171



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Revenue

Revenue was €935,000 for the second quarter ending June 30, 2022, compared to €170,000 for the second quarter ending June 30, 2021. Revenue for the first half of 2022 was €1.6 million, compared to €355,000 for the first half of 2021. The increase in revenue was attributable to the Company's commercialization of the Genio[®] system, primarily in Germany.

Cost of Goods Sold

Cost of goods sold was €334,000 for the three months ending June 30, 2022, representing a gross profit of €601,000, or gross margin of 64.3%. This compares to total cost of goods sold of €63,000 in the second quarter of 2021, for a gross profit of €107,000, or gross margin of 62.9%.

For the six months ending June 30, 2022, total cost of goods sold was €623,000, representing a gross profit of €972,000, or gross margin of 60.9%. This compares to total cost of goods sold of €115,000 in the first half of 2021, for a gross profit of €240,000, or gross margin of 67.6%.

Research and Development Expenses

Research and Development expenses were €3.5 million for the three months ending June 30, 2022, versus €2.4 million for the prior year period, reflecting the Company's investments in the development of next generation versions of the Genio[®] system as well as ongoing clinical studies, most notably DREAM in the U.S.

For the six months ending June 30, 2022, Research and Development expenses were €7.1 million, versus €5.5 million for the first half of 2021.

Selling, General and Administrative Expenses

Selling, General and Administrative expenses rose to €4.5 million for the second quarter of 2022, up from €3.9 million in the second quarter of 2021. This was due primarily to increased commercial efforts in Germany and other European markets, as well as investments in Nyxoaah's corporate infrastructure. The Company expects to continue adding headcount across the organization ahead of the U.S. commercial launch.

For the six months ending June 30, 2022, Selling, General and Administrative expenses were €8.7 million, up from €6.3 million in the first half of 2021 due to increased commercial efforts in Germany and investments in Nyxoaah's corporate infrastructure.

Operating Loss

Total operating loss for the second quarter and first half of 2022 was €7.4 million and €14.7 million, respectively, versus €6.3 million and €11.6 million in the second quarter and first half of 2021, respectively. This was driven by the acceleration in the Company's R&D spending, as well as ongoing commercial and clinical activities. Nyxoaah realized a net loss of €5.0 million and €11.8 million for the second quarter and first half of 2022, respectively, compared to a net loss of €6.7 million and €12.4 million for the second quarter and first half of 2021, respectively.



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Cash Position

As of June 30, 2022, cash and financial assets totaled €123.3 million, compared to €135.5 million on December 31, 2021. Total cash burn was approximately €2.0 million per month during the first half of 2022. Nyxoah expects monthly cash burn to increase in the second half of 2022 to account for the commencement of the ACCESS IDE trial in the U.S., and the current cash position provides ample liquidity to get to U.S. commercialization in 2024.

First Half 2022 Report

Nyxoah's financial report for the first half of 2022, including details of the audited consolidated results, are available on the investor page of Nyxoah's website (<https://investors.nyxoah.com/financials>).

Conference call and webcast presentation

Nyxoah will conduct a conference call open to the public today at 10:30 p.m. CET / 4:30 p.m. ET, which will also be webcast. To participate in the conference call, please access the following link to register for a dial-in number:

<https://register.vevent.com/register/BIfc3a52c9352e4e42958e9d816245b3b9>

A question-and-answer session will follow the presentation of the results. To access the live webcast, go to <https://investors.nyxoah.com/events>. The archived webcast will be available for replay shortly after the close of the call.

About Nyxoah

Nyxoah is a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea (OSA). Nyxoah's lead solution is the Genio[®] system, a patient-centered, leadless and battery-free hypoglossal neurostimulation therapy for OSA, the world's most common sleep disordered breathing condition that is associated with increased mortality risk and cardiovascular comorbidities. Nyxoah is driven by the vision that OSA patients should enjoy restful nights and feel enabled to live their life to its fullest.

Following the successful completion of the BLAST OSA study, the Genio[®] system received its European CE Mark in 2019. Nyxoah completed two successful IPOs: on Euronext Brussels in September 2020 and NASDAQ in July 2021. Following the positive outcomes of the BETTER SLEEP study, Nyxoah received CE mark approval for the expansion of its therapeutic indications to Complete Concentric Collapse (CCC) patients, currently contraindicated in competitors' therapy. Additionally, the Company is currently conducting the DREAM IDE pivotal study for FDA and US commercialization approval.

For more information, please visit <http://www.nyxoah.com/>.



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Caution – CE marked since 2019. Investigational device in the United States. Limited by U.S. federal law to investigational use in the United States.

Forward-looking statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations regarding the Genio[®] system; planned and ongoing clinical studies of the Genio[®] system; the potential advantages of the Genio[®] system; Nyxoah's goals with respect to the development, regulatory pathway and potential use of the Genio[®] system; the utility of clinical data in potentially obtaining FDA approval of the Genio[®] system; and the Company's results of operations, financial condition, liquidity, performance, prospects, growth and strategies. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. Additionally, these risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the "Risk Factors" section of the Company's Annual Report on Form 20-F for the year ended December 31, 2021, filed with the Securities and Exchange Commission ("SEC") on March 24, 2022, and subsequent reports that the Company files with the SEC. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.

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INTERIM FINANCIAL REPORT

FIRST 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® system will be followed for five years post-implantation to assess the safety and efficacy of the Genio® system in patients with moderate-to-severe OSA.

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

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

Enrollment in the DREAM trial is now complete. 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.

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 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 €1.6 million for the six months ending June 30, 2022, compared to €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 €0.6 million for the six months ending June 30, 2022, compared to €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® system in Europe.

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

Before capitalization of €7.8 million for the six months ending June 30, 2022 and €4.1 million for the six months ending June 30, 2021, research and development expenses increased from €9.6 million for the six months ending June 30, 2021 to €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 €3.3million due to the combined effect of €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 (-€1.9million) and accretion of interests on recoverable cash advances (€-0.5million).

Nyxoah realized a net loss of €11.7 million for the six months ending June 30, 2022, compared to a net loss of €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 €123.3 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 €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.

NYXOAH SA

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	€ 2 111	€ 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
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			
Financial debt	17	661	554
Lease liability	9	672	582
Trade payables	18	4 301	3 995
Current tax liability	19	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.

NYXOAH SA

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)

	Notes	For the six months ended June 30	
		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

NYXOAH SA

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 comprehensive income	Retained loss	Total
Balance at January 1, 2022	€ 4 427	€ 228 033	€ 3 127	€ 202	€ (87 167)	€ 148 622
Loss for the period	-	-	-	-	(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

	Attributable to owners of the parent					
	Common shares	Share premium	Share based payment reserve	Other comprehensive 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

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 SIX MONTHS ENDED JUNE 30, 2022 –
INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

		For the six months ended June 30	
	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			
Payment of principal portion of lease liabilities	9	(317)	(236)
Repayment of other loan		(42)	(42)
Interests paid		(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.

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 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). 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 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 €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.

(in EUR 000)	Carrying value		Fair value	
	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	-

(in EUR 000)	Carrying value		Fair value	
	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 €302,000 (2021: €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[®] 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[®] system in 2021. The amortization amounted to €402,000 for the six months ended June 30, 2022 (2021: €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[®] system and clinical trials to obtain additional regulatory approvals in certain countries or to be able to sell the Genio[®] System in certain countries. The total capitalized development expenses amounted to €7.7 million and €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 €0.6 million (2021: €55,000). The repayments of lease liabilities amounted to €317,000 (2021: €236,000). The depreciations on the right of use assets amounted to €338,000 and €273,000 for the six months ended June 30, 2022, and 2021, respectively.

10. Inventory

(in EUR 000)	As at	
	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

(in EUR 000)	As at	
	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 €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 €0 and €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[®] 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.

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

12. Other current assets

The decrease of €0.8 million in other current assets as at June 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	
	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 €59.9 million is due to an increase in term accounts of €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 ⁽¹⁾ 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

¹ 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 Feb 21 2022)	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:

(in EUR 000)	As at	
	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 €0 (2021: €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:

(in EUR 000)	As at	
	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

(in EUR 000)	As at	
	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

(in EUR 000)	For the six months ended June 30	
	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 €1.5 million, and also an increase in deferred taxed assets and deferred tax income of €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 €4.4 million also relates to a liability for uncertain tax positions for an amount of €2.8 million. The current tax expense for the six month period ended June 30, 2022 amounts to €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

(in EUR 000)	As at	
	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 €3.9 million in other payables as of June 30, 2022, compared to December 31, 2021, is mainly due to an increase of €1.6 million in accrued expenses related to an increase in clinical and R&D activities and due to an increase of €2.0 million in the fair value of the foreign currency option. The item Other includes € 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:

(in EUR 000)	As at	
	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:

(in EUR 000)	As at	
	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:

(in EUR 000)	As at June 30, 2022			
	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 €1.6 million (2021: €355,000). Revenue is recognized at a point in time upon satisfaction of the performance obligation, being the moment control over the Genio[®] system is transferred to the customer, which is in general at delivery at customer site or a predefined location in the country of the customer. For certain customers, control may be transferred upon shipment to the customer in case the incoterms are Ex-Works. The revenue from the Genio[®] system consists of a kit of products delivered at the same point in time, and as such revenue does not need to be allocated over the different products. The revenue is then recognized at an amount that reflects the consideration to which the Company expects to be entitled in exchange of the Genio[®] system. In determining the transaction price for the sale of the Genio[®] system, the Company considers the effects of variable consideration.

For the six month period ended June 30, 2022 the sales (based on country of customer) were generated in Germany (€1.6 million) and Finland (€40,000) (2021: Germany: €310,000, Spain: €24,000 and Belgium: €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:

(in EUR 000)	For the six months ended June 30	
	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

(in EUR 000)	For the six months ended June 30	
	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 €7.8 million for the six months ended June 30, 2022 and €4.1 million for the six months ended June 30, 2021, research and development expenses increased by €5.2 million or 54 %, from €9.6 million for the six months ended June 30, 2021, to €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

(in EUR 000)	For the six months ended June 30	
	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 €2.5 million or 39 % from €6.3 million for the six months ended June 30, 2021 to €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 €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 €150,000 for the six months ended June 30, 2022 compared to other operating expenses of €97,000 for the six months ended June 30, 2021.

(in EUR 000)	For the six months ended June 30	
	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

(in EUR 000)	For the six months ended June 30	
	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

(in EUR 000)	For the six months ended June 30	
	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

24. Financial income

(in EUR 000)	For the six months ended June 30	
	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 €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[®] system.

25. Financial expense

(in EUR 000)	For the six months ended June 30	
	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
<i>As at June 30, after conversion and share split</i>		
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 €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 €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 €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:

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

Transactions with Non-Executive Directors and Shareholders:

(in EUR 000)	For the six months ended June 30, 2022			For the six months ended June 30, 2021		
	R&D Collaboration	Consulting services	Board Remuneration	R&D Collaboration	Consulting services	Board Remuneration
Cochlear	1 336	-	-	-	-	-
MINV SA	-	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 €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