

Annual report 2023

# The path to restful nights

Nyxoah 



# The path to restful nights

Nyxoah 

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# Annual Report 2023



This Annual Report contains all required information as per the Belgian Code of Companies and Associations ("CCA"). It was approved by the Board of Director of Nyxoah SA on March 20, 2024.

In this Annual Report, Nyxoah SA and its affiliates will be collectively referred to as the "Company", the "Group", "Nyxoah", "we" or "us".

## Language of the Annual Report

The Company publishes its Annual Report in French (in accordance with Belgian law) and English. In case of an inconsistency between the French and the English version, the French version shall prevail. The French version in the European single electronic format (ESEF) of the Annual Report shall prevail over any other version.

## Availability of the Annual Report

To obtain a copy of this Annual Report free of charge, please contact: [ir@nyxoah.com](mailto:ir@nyxoah.com).

An electronic version of this Annual Report is available on the Company website:

<https://investors.nyxoah.com/financials>

## Forward-looking statements

In addition to historical facts and statements of current condition, this Annual Report contains "forward-looking statements" within the meaning of the securities laws of certain jurisdictions. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates", "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should" or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. Forward-looking statements include statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, its results of operations, prospects, growth, strategies and the industry in which it operates.

By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance. No undue reliance should be placed on these forward-looking statements. Any forward-looking statements are made only as of the date of this Annual Report and the Company does not intend, and does not assume any obligation, to update forward-looking statements set forth in this Annual Report, unless required by law.

Many factors may cause the results of operations, financial condition, liquidity and the development of the industries in which the Company competes to differ materially from those expressed or implied by the forward-looking statements contained in this Annual Report. Factors that might cause such a difference include, but are not limited to, those discussed in the section "Risk Factors". The risks described under "Risk Factors" are not exhaustive. New risks can emerge from time to time, and it is not possible for the Company to predict all such risks, nor can it assess the impact of all such risks on the business or the extent to which any risks, or combination of risks and other factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, forward-looking statements cannot be relied upon as a prediction of actual results.



**1**

# Report of the Board of Directors

# Report of the Board of Directors to the Shareholders for the Financial Year ending December 31, 2023

Dear Shareholders,

We are pleased to present to you the 2023 Annual Report relating to Nyxoah's consolidated financial statements as of December 31, 2023 prepared in accordance with International Financing Reporting Standards (IFRS) as endorsed by the European Union. The companies included in the consolidated financial statements are Nyxoah SA, Nyxoah Ltd, Nyxoah Pty Ltd, Nyxoah Inc and Nyxoah GmbH.

## 1.1 Business overview

We are 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 neurostimulation, or HGNS, therapy for the treatment of moderate to severe 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. Our innovative technology platform is a first-of-its-kind HGNS device designed to treat OSA through bilateral stimulation, by maintaining an open airway for a restful night's sleep. We started generating revenue from the sale of the Genio system in Europe in July 2020, and we are currently conducting our DREAM pivotal trial designed to support marketing authorization in the United States. We are developing a significant body of clinical evidence to further support the strong value proposition of the Genio system and its ability to improve the health and quality of life of OSA patients.

OSA occurs due to the relaxation of the soft tissue, throat and tongue muscles in a patient's airway, which causes an obstruction that temporarily prevents breathing during sleep. In patients with OSA, the airway repeatedly becomes partially or completely blocked, thereby limiting the airflow reaching the lungs from sufficiently oxygenating the blood. Approximately 425 million people between the ages of 30 and 69 globally suffer from moderate to severe OSA. This chronic disease negatively affects a patient's health and quality of life.

Published scientific literature estimates that there are currently approximately 23.8 million individuals with moderate to severe OSA in our initial target markets in Europe. Based on published scientific literature, we estimate that approximately 2.6 million patients are diagnosed annually in those countries and that approximately 80% of diagnosed patients are prescribed a continuous positive airway pressure, or CPAP, device. Published scientific literature reports non-compliance rates to CPAP between 29% and 83%. Based on these data, and for purposes of calculating the total addressable market in Europe for the Genio system, we estimate that approximately 35% of patients that are prescribed CPAP in those countries are not compliant with the therapy. Additionally, certain patients possess anatomical characteristics, including higher body-mass-index or increased tongue fat deposition that make them

ineligible for HGNS. Taking that into account, we estimate that approximately 70% of those non-compliant patients are eligible for HGNS based on their anatomical characteristics. As a result, we believe the total addressable market in Europe for the Genio system is at least 515,000 patients which represents an estimated annual market opportunity of approximately \$10 billion based on our current pricing for the Genio system. We also plan to enter the United States market, assuming we obtain marketing authorization in the United States, where published scientific literature estimates that there are approximately 23.7 million individuals with moderate to severe OSA. Based on the same assumptions set out above, we estimate a target market of approximately 510,000 patients in the United States, which represents an estimated annual total addressable market of approximately \$10 billion based on our current pricing for the Genio system.

The standard of care first-line therapy for patients with moderate to severe OSA is CPAP. CPAP is a treatment whereby air, at a constant or automated pressure, is pushed into the upper airway via a facial or nasal mask that the patient must wear during sleep. Despite its proven efficacy, CPAP has been associated with many limitations, making compliance a serious challenge. Second-line treatments, such as mandibular oral devices, are more suitable to treat mild-to-moderate OSA, and other therapies, such as anatomical surgical procedures, are highly invasive. In recent years, neurostimulation technology has emerged as a viable second-line therapy to treat patients suffering from moderate to severe OSA. This technology is centered on stimulating the hypoglossal nerve, which activates the genioglossus muscle resulting in a forward protrusion of the tongue. HGNS therapies have proven to be a safe and effective treatment for those suffering from moderate to severe OSA. Systems competing with our Genio system consist of multiple incisions and implantable components, including an implantable pulse generator with a battery and one or more leads. In addition, competing systems exclude a substantial subset of the OSA patient population. OSA patients diagnosed with complete concentric collapse at the level of the soft palate, or CCC, are currently contraindicated for other HGNS OSA therapies. Unlike other HGNS technologies indicated for treating OSA that provide unilateral stimulation of the hypoglossal nerve, our Genio system provides bilateral stimulation that we believe results in a stronger muscle contraction, a more symmetric tongue movement and a wider opening of the airway, which we believe has the potential to provide better clinical outcomes. Further, we believe that bilateral stimulation enables the Genio system to potentially address moderate to severe OSA patients with CCC, who are currently contraindicated for, or unable to be treated with, existing HGNS OSA therapies.

In order to diagnose CCC, a drug induced sleep endoscopy, or DISE, procedure is required. During this procedure, the patient receives propofol and/or midazolam to artificially induce sleep, and the pharyngeal collapse patterns are visualized using a flexible fiber optic nasopharyngoscope, a soft and flexible endoscope which is inserted in the patient's nose to visualize the pharyngeal area and assess the level, direction and degree of the collapsed area. Currently, the only HGNS therapy approved in the United States requires all patients seeking HGNS OSA therapy to undergo a DISE procedure. It is estimated that approximately 35% of moderate to severe OSA patients are affected by CCC and are therefore unable to receive currently available neurostimulation treatment in the United States.

Our Genio system includes the first battery-free, leadless and minimally invasive neurostimulator, capable of delivering bilateral HGNS for moderate to severe OSA patients who did not tolerate, have failed or refused conventional positive airway pressure, or PAP, therapy. We developed the Genio system with a patient-centric approach, designed for comfort and safety, to increase compliance and improve quality of life. The Genio system includes a single implanted device that can be placed through a minimally invasive, single-incision surgery under the chin. The power source for the stimulator is external. Unlike competing HGNS therapies, the lack of an implantable battery or additional leads limits the need for complex tunneling and only requires a single incision for implantation. This minimally invasive procedure is typically completed in approximately one hour and allows patients to recover quickly and resume normal activities typically within a week. Patients return to the physician approximately six weeks later for device titration, which typically involves an in-lab sleep trial to analyze breathing frequency. Further, the external activation chip eliminates the need for additional surgical procedures to

replace depleted batteries and enables software, firmware or external hardware updates and upgrades to be implemented without the need for surgical intervention thereby limiting potential infection risk due to an additional procedure.

We continue to develop a substantial body of clinical evidence on the Genio system. In 2019, we completed our BiLateral hypoglossal nerve STimulation for treatment of Obstructive Sleep Apnea, or BLAST OSA, trial, a prospective, open label, non-randomized, single arm treatment trial involving 27 implanted participants. Twenty-two patients completed the protocol, and the trial met all primary, secondary and exploratory endpoints. In the six-month data, the mean individual reduction in the Apnea-Hypopnea Index, or AHI, events per hour was 47.3%. Participants' AHI decreased from  $23.7 \pm 12.2$  to  $12.9 \pm 10.1$ , representing a mean change of 10.8 events per hour. The results of the trial were published in the European Respiratory Journal in October 2019 and were the basis for receiving CE-Mark on the Genio system.

We are seeking to expand indications of the Genio system by obtaining clinical evidence through our ongoing multicenter, prospective, open-label Bilateral Hypoglossal Nerve StimulaTion for TreatmEnt of ObstrUctive SLEEP Apnoea With and Without Complete Concentric Collapse clinical trial in Australia and New Zealand, or the BETTER SLEEP trial, to evaluate the effectiveness of the Genio system for patients suffering from CCC. We believe that positive results from this trial may eliminate the need for Genio system patients to be selected based on a DISE procedure prior to implantation of the Genio system, thereby leading to a potential indication expansion in Europe. In June 2021, we announced initial top-line results from the six-month data for the BETTER SLEEP trial. Based on this data, in October 2021, the EU Notified Body granted CE-Marked indication to include OSA patients with CCC for the Genio system in Europe, which should eliminate the need for a DISE procedure. Additionally, in September 2021, we received breakthrough device designation in the United States for the Genio system from the Food and Drug Administration, or FDA, for the treatment of OSA with CCC, based on the initial clinical evidence from the BETTER SLEEP trial. We plan to continue to obtain authorization in additional target markets and are currently conducting our Dual-sided Hypoglossal neRvE stimulaTion for the treatMent of Obstructive Sleep Apnea clinical trial, or DREAM trial, a multicenter, prospective, open-label, pivotal Investigational Device Exemption, or IDE, trial designed to support marketing authorization in the United States. Additionally, we presented 12-month data on the first 34 DREAM patients reaching 12-month follow-up as a late-breaking abstract at SLEEP 2023, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in line with expectations. These data are preliminary and not conclusive of final success of the DREAM trial. On March 19, 2024, we issued a press release announcing that the DREAM trial met its primary endpoints. More information can be found in the press release. We expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in late 2024.

In July 2022, we announced that the FDA approved an IDE to enable us to initiate a clinical trial, called ACCESS, to evaluate the use of the Genio system for the treatment of adult patients with moderate-to-severe OSA with CCC that have failed, did not tolerate, or refused PAP. In the ACCESS trial, we plan to implant up to 106 subjects with co-primary efficacy endpoints of AHI responder rate, per the Sher criteria, and ODI responder rate, both assessed at twelve months post-implant. The first enrolled subjects have been implanted.

We are initially targeting markets in Europe where we have identified a country-specific reimbursement pathway or execution strategy. We began our commercial launch in Germany in July 2020. After obtaining reimbursement approval in Germany through the existing HGNS special innovation funding program, or NUB, we generated our first revenue in the second half of 2020. In 2021, we successfully obtained reimbursement in Germany under a dedicated DRG code for HGNS and obtained reimbursement under an OSA-specific DRG code in Switzerland from the Federal Statistic Office, or BFS. The reimbursement coverage in both Germany and Switzerland includes the cost of the Genio



system, implant procedure, hospital stay and follow-up care. In 2021, we began marketing products in Switzerland and also secured first revenue in Spain and we began commercialization in Finland in 2022. We generated our first revenue in Austria in 2023. Based on market access activities conducted by us over the past several years, we have developed tailored reimbursement strategies using assessments of the local requirements of target countries. In countries where there is existing reimbursement coverage in place, we plan to piggyback on existing coding and reimbursement, acting as a fast follower. In countries where there is no existing reimbursement coverage, we will seek to be the first in that market to obtain reimbursement coverage. In countries without existing reimbursement coverage, the strategy could include (i) making the Genio system commercially available for patients through country specific innovation funding pathways for procedures and products that would not yet be covered by an existing code, (ii) supporting case-by-case funding submission in focus hospitals that can use their budget to fund the therapy, (iii) entering into specific commercial deals with privately funded hospital groups, or (iv) out-of-pocket payment.

We have established a systematic approach to commercializing the Genio system in our target markets, focusing on active engagement, education and market development across patients, physicians and hospitals. We currently market our therapy to physicians and hospitals where ear, nose, and throat doctors, or ENTs, sleep doctors and general practitioners see, diagnose and treat patients with OSA. We are actively expanding our current European sales and marketing organization with country-specific sales teams established in connection with obtaining reimbursement. Our sales teams are focused on prioritizing high volume ENT centers and sleep centers, and on building long-standing relationships with key physicians such as sleep doctors, ENTs and general practitioners who have strong connections to the OSA patient population that may be eligible for our therapy. We also seek to establish long-term partnerships with key opinion leaders, or KOLs, and patient associations that are oriented towards the needs of our patients. Our sales and marketing organization is focused on building physician awareness through referral network development, education, targeted KOL development and training, and direct-to-consumer marketing.

In addition to our ongoing clinical studies, we are also committed to continuing our research and development efforts related to the Genio system, with an emphasis on improving clinical outcomes, optimizing patient adoption and comfort, increasing access for a greater number of patients, and allowing more physicians to perform the implantation procedure. The primary focus of our research and development efforts in the near-term will be the continued technological advancement of the Genio system. Some of these improvements include features aimed at enhancing a physician's ability to monitor patient compliance and therapeutic efficacy. The Genio 2.1 system further reflects such improvements and is designed to improve patient comfort and compliance with a new smartphone application and an upgraded external activation chip. The Genio 2.1 system offers patients daily feedback on therapy usage and the autonomy to adjust stimulation amplitude within pre-defined boundaries. Physicians can also fine-tune stimulation amplitude to determine the optimal level of comfort for patients without compromising therapy efficacy. In the long term, including through our partnership with Vanderbilt University, we intend to provide new neurostimulation technologies for OSA patients. We continue to enhance our scalable technology platform to allow for quick and streamlined release of new features and functionalities through software, firmware and hardware updates and upgrades and therapy enhancement.

## 1.2 Our competitive strengths

We are focused on transforming the lives of patients who suffer from moderate to severe OSA by continuing to develop, clinically validate, manufacture and commercialize our innovative Genio system. We believe the Genio system offers a compelling solution for a large and significantly underpenetrated global patient population and that our focus and experience in treating patients with OSA, combined with the following strengths, will allow us to build our business and potentially expand our market opportunity:

### ***Disruptive, patient-centric neurostimulation solution to treat moderate to severe OSA***

We specifically designed the Genio system with the goal of advancing a therapy to treat moderate to severe OSA and providing a safe and effective patient-centric solution offering significant benefits to address the unmet needs of patients. The Genio system includes the first battery-free, leadless, neurostimulator designed to be implanted in a minimally invasive procedure using a single incision. The Genio system delivers bilateral HGNS for patients who suffer from moderate to severe OSA and did not tolerate, failed or refused standard first-line therapy, including CPAP. We believe that bilateral stimulation could lead to better therapeutic performance and address more therapeutic indications compared to other HGNS-based technologies. While other commercially available neurostimulation platforms require implantation of leads and a pulse generator containing a battery, our Genio system only requires implantation of a battery-free neurostimulator. Due to its unique design, the Genio system's implantable stimulator is the only neurostimulation-based OSA therapy that has received CE-Mark conditional labeling for 1.5T and 3T full-body MRI scans. CE-Mark conditional labeling for MRI scans have become more and more important for physicians and patients due to the growing need and incidence of MRI scans. Implantable medical devices that have not been tested and approved with MR conditional labeling are considered as MR unsafe, and MR scans are contra-indicated for these patients. We believe our Genio system technology has the potential to become the leading neurostimulation solution for many of the estimated 425 million diagnosed and undiagnosed OSA patients worldwide suffering from moderate to severe OSA.

### ***Growing body of clinical data and long-term clinical strategy***

The Genio system is predicated on a well-established mechanism of action of electrically stimulating the hypoglossal nerve. Our BLAST OSA trial provided positive data for the Genio system, demonstrating that treatment with the Genio system resulted in statistically significant improvements in sleep apnea symptoms and quality of life measures. These data results were also associated with high therapy compliance. The trial's results supported receipt of the CE-Mark in 2019 and have been published in peer-reviewed journals, including the European Respiratory Journal. We are continuing our clinical research to evaluate the efficacy of the Genio system on a longer-term basis through our post-market clinical trial for the treatment of OSA in adults, or the EliSA trial. In December 2020, we implanted the first patient in the DREAM trial, which is designed to support marketing authorization in the United States. In addition, in June 2021, we announced initial top-line results from the six-month data for the BETTER SLEEP trial. Based on this data, in October 2021, we expanded the CE-Marked indication to include OSA patients with CCC, which should eliminate the need for a DISE procedure. In September 2021, we received breakthrough device designation in the United States for the Genio system from the FDA for the treatment of OSA with CCC, based on the initial clinical evidence from the BETTER SLEEP trial. Further, in June 2022, we announced that the FDA approved the use of our next generation Genio 2.1 system for use in the DREAM trial. In June 2023, we presented 12-month data on the first 34 DREAM patients reaching 12-month follow-up as a late-breaking abstract at SLEEP 2023, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in line with expectations. These data are preliminary and not conclusive of final success of the DREAM trial. Additionally, in July 2022, we announced that the FDA approved an IDE to enable us to initiate a clinical trial, called ACCCESS, to evaluate the use of the Genio system for the treatment of adult patients with moderate-to-severe OSA with CCC that have failed, did not tolerate, or refused PAP.

### ***Significant product development and new indication pipeline***

The Genio system is a scalable-technology platform that allows for future external hardware, software and firmware updates to enhance therapeutic capabilities without requiring additional surgical procedures. We continue to invest in improving the Genio system to develop next generation products with features designed to improve patient comfort and compliance, efficacy and patient and market acceptance. Some of these improvements include features aimed at enhancing the physician's ability to monitor patient compliance and therapeutic efficacy, including sensor technology to monitor a patient's sleep position. We are also committed to expanding current treatment options for moderate to severe OSA patients by developing next generation neurostimulation-based technologies. We previously entered into a licensing agreement with Vanderbilt University pursuant to which we are exploring additional neurostimulation technologies. Under the agreement, we have an exclusive, worldwide license to make, use, sell or distribute products for treating sleep disordered breathing covered by certain patent rights owned, or that may be owned, by Vanderbilt. We will also work together with Vanderbilt University to continue prosecution of patent applications made by Vanderbilt.

### ***Platform technology protected by comprehensive and broad intellectual property***

Our platform technology is supported by a strong and growing portfolio of intellectual property rights, which includes utility and design patents, know-how and trade secrets, including therapy protocols, electrodes and methods. As of December 31, 2023, we had 199 granted or pending patent applications (with 54 issued or allowed U.S. patents), and 40 pending patent applications, ten of which are U.S. pending patent applications and hold six trademark registrations (with three U.S. trademark registrations). Additionally, we operate a manufacturing facility responsible for silicone overmolding and select assembly of external components, which provides us with enhanced proprietary know-how and control of the supply chain to meet future demand.

### ***Strong and experienced team***

Our senior management team has many years of experience in the healthcare and medical device industry. Specifically, our team has extensive operating experience in product development, clinical, regulatory approval and commercialization activities as well as established relationships with industry leaders in the academic, clinical and commercial neuromodulation industries. Members of our management team have served in leadership positions with well-regarded medical technology companies such as St. Jude Medical Inc., Medtronic Inc., Stryker Corp and Nevro Corp. Since our founding, we have been supported by a seasoned Board of Directors with extensive industry and public company experience and a Scientific Advisory Committee that consists of industry-relevant KOLs.

## **1.3 Our strategy**

Our mission is to become a global leader in providing innovative, clinically proven solutions to treat patients suffering from OSA. The key elements of our strategy to achieve this goal and promote future growth include:

### ***Obtaining marketing authorization in the United States***

We are conducting clinical trials to further evaluate the efficacy and safety of the Genio system for treating patients with moderate to severe OSA. We are currently conducting the DREAM trial, a pivotal trial designed to support marketing authorization for the Genio system in the United States via a premarket approval, or PMA, application. The DREAM trial is a multicenter, prospective, open-label trial designed to enroll 115 patients in approximately 20 centers in the United States and internationally. The trial aims to evaluate the safety and effectiveness of the Genio system to treat patients with moderate to severe OSA who either did not tolerate, failed or refused first-line PAP therapy. In June 2022, we announced

that the FDA approved the use of our next generation Genio 2.1 system for use in the DREAM trial. On March 19, 2024, we issued a press release announcing that the DREAM trial met its primary endpoints. More information can be found in the press release. We expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in late 2024.

***Promoting awareness of the Genio system among physicians, patients and payors to accelerate market adoption***

We believe that the Genio system has the potential to become the leading neurostimulation solution for moderate to severe OSA patients. To accomplish this, we intend to raise market awareness and educate physicians, payors and patients on the negative impact of OSA and position the Genio system as a safe and effective treatment for moderate to severe OSA patients. We currently offer education and training programs to sleep centers and surgeons, which we believe provide a better understanding of the Genio system's benefits and increase surgeons' confidence implanting our technology. In addition, we provide programs targeted towards patients who use the Genio system to promote and increase their engagement, long-term observance, quality of life and well-being. We intend to establish long-term partnerships with KOLs, ENTs and sleep scientific societies and patient associations that are built on mutual trust and oriented towards the needs of OSA patients and their families. Finally, we intend to establish relationships with government and commercial payors to help reduce barriers to treating OSA by highlighting our clinical data, costs affiliated with untreated OSA patients and the clinical benefit of the Genio system. We plan to build upon this multi-pronged approach with direct-to-consumer marketing initiatives that help to educate patients and can frequently result in patient leads.

***Continuing to enhance the Genio system and expand its indications***

We continue to invest in our solutions and services to further improve the implantation procedure and enhance the patient experience and product features. Potential feature improvements could include design alterations, information driven integrated capabilities, diagnostics or monitoring, sleep apnea testing or various other technological advancements. We believe that bilateral stimulation could lead to better therapeutic performance and address more therapeutic indications compared to other hypoglossal nerve stimulation-based technologies. In June 2021, we announced initial top-line results from the six-month data for the BETTER SLEEP clinical trial. Based on this data, in October 2021, the EU Notified Body granted CE-Marked indication to include OSA patients with CCC for the Genio system in Europe. Currently, CCC patients are contraindicated for other HGNS OSA therapies. Further, in June 2022, we announced that the FDA approved the use of our next generation Genio 2.1 system for use in the DREAM trial. In July 2022, we obtained the CE-Mark for the Genio 2.1 system. In addition, we may look for strategic opportunities, including partnerships or collaborations, to broaden our capabilities and expertise in line with our patient-centric vision.

***Pursuing and establishing favorable reimbursement coverage of the Genio system***

While there is general consensus among physicians and payors of the medical necessity to treat OSA and increase the number of HGNS therapy coverage decisions, we continue to develop further clinical evidence intended to demonstrate a long-term meaningful improvement in health outcomes for patients meeting the specified criteria. We are initially targeting markets in Europe where we have identified a clear reimbursement pathway or execution strategy. In Germany, we have successfully obtained reimbursement under a dedicated DRG code for HGNS. In Switzerland, we obtained reimbursement under an OSA-specific DRG code by the Federal Statistic Office, or BFS. Each of these reimbursement coverages includes the cost of the Genio system, implant procedure, hospital stay and follow-up care. We expect that the outcomes of the ongoing pivotal DREAM trial, if positive, will support marketing authorization and reimbursement in the United States. We believe that establishing and maintaining reimbursement will be important in achieving broad acceptance of our system by healthcare providers in these markets.

### ***Continuing to build a commercial infrastructure in selected geographies***

We have grown our commercial team to include a sales and marketing organization of over a dozen representatives with substantial medical device sales, education and clinical experience to support commercialization of the Genio system. Our initial strategy is to employ a targeted approach to increase therapy penetration within specific physician practice groups instead of a broad outreach strategy to physicians in general. Our sales and marketing organization is focused on prioritizing high volume centers that are strategically located and building long-standing relationships with key physicians with strong connections to the population of OSA patients indicated for the Genio system. We are focusing our efforts on developing Centers of Excellence in each of our commercial markets, where we plan to invest in developing the Genio system as the preferred treatment option for indicated moderate to severe OSA patients. Using a direct commercialization model in most of our target countries, we plan to utilize account managers to support these Centers of Excellence to strengthen the referral physician network, guiding new patients to these Centers of Excellence. We expect to gradually scale up our commercial organization in line with market entry and access in the various countries that we are targeting. Based on our experience gained from the commercial roll-out in Europe, but also taking into account particular dynamics of the local markets, we will determine and prepare what we believe to be the optimal sales and marketing structure for commercial launch in the United States if we obtain marketing authorization.

## **1.4 Our solution**

We developed the Genio system to provide patients suffering from moderate to severe OSA with an alternative HGNS system that addresses their unmet needs. We believe our minimally invasive and clinically proven solution has the potential to become the leading neurostimulation solution for many patients suffering from moderate to severe OSA, including patients with CCC. The Genio system has obtained CE-Mark and we are currently pursuing FDA marketing authorization.

### **1.4.1 Overview of the Genio system**

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 HGNS. The system includes an implanted component that can be implanted in a minimally invasive procedure requiring only a single incision. We developed the system using a patient-centric approach to offer patients a convenient alternative design to overcome the limitations of competing neurostimulation devices.

### **1.4.2 Components of the Genio system**

#### ***Implantable stimulator***

The implantable stimulator consists of a saddle-like antenna with two legs, each containing two metal pads, called paddle electrodes. The paddle electrodes are placed in contact with both branches of the hypoglossal nerve and deliver bilateral stimulation to the hypoglossal nerve. Pulses from the stimulator trigger a slight forward movement of the posterior portion of the tongue in order to maintain an open airway throughout the night. The implantable stimulator is FDA and CE labeled as MR conditional for 1.5T and 3T full body MRI scans.

#### ***Activation chip***

The activation chip is a detachable, external power source for the implantable stimulator and is composed of a chipset, which provides the patient's personalized therapy program, and a rechargeable battery. The chipset is programmable, which allows us to make future updates and upgrades, or to provide additional services to the Genio system without having to replace the implantable stimulator during an additional surgery. We advise that patients charge the activation chip with the charging unit after use.

### ***Disposable patch***

The disposable patch is a single-use, medical grade adhesive patch, which also contains a transmitting coil. The patch is placed on the skin under the chin each time before the patient goes to sleep. The patient attaches the activation chip to the disposable patch, which then activates the implantable stimulator. After use, the patient detaches the activation chip from the chin, places it in the charging unit, and disposes of the patch.

### ***Charging unit***

The charging unit and its power adapter are used to charge the activation chip's battery. A fully depleted activation chip can be charged on the charging unit within 3 hours.

### ***External stimulator***

In addition to the patient-use components described above, the system includes an external stimulator which is a disposable single-use device that is used during the implantation procedure by the surgeon to test activation and function of the implantable stimulator.

## **1.4.3 Benefits of the Genio system**

We designed the Genio system to advance patient care and provide a convenient treatment option to the large and underpenetrated patient population suffering from OSA. We believe the following factors offer meaningful benefits for patients, physicians and payors that have the potential to drive broad adoption of our system:

### ***Patient-centric therapeutic option***

The results of our BLAST OSA trial demonstrated safety and effectiveness of the Genio system for patients suffering from moderate to severe OSA, and the data were sufficient to obtain a CE-Mark from the European Notified Body. These results showed significant benefits in the following patient-centered outcomes:

- ***Attractive safety profile.*** The results from the BLAST OSA trial demonstrated that the Genio system was well tolerated with no device-related serious adverse events, or SAEs, reported during the first 6 months of the trial.
- ***Compelling clinical data.*** Clinical data suggest that the Genio system is a clinically effective therapy for patients eligible for HGNS treatment. The BLAST OSA trial found a 47.3% reduction in mean individual AHI (p-value<0.0001) and a decrease in mean individual ODI of 43.3% (p-value<0.0001) at six months following implantation, compared to their baseline measurements, for patients using the Genio system. In statistics, a p-value is a number calculated from a statistical test. It provides the probability that a null hypothesis (e.g., there is no treatment effect) is true for the particular set of observations being tested. The smaller the p-value (typically p-value < 0.05), the stronger the evidence that the null hypothesis should be rejected in favor of an alternative hypothesis (e.g., there is a treatment effect greater than a given threshold). A p-value less than 0.05 is said to be statistically significant. It indicates strong evidence against the null hypothesis, as there is less than a 5% probability that the null hypothesis is correct.
- ***Convenient therapy leading to strong compliance.*** Our device is designed to be convenient for patients to use, once implanted and optimized, requiring no additional programming or therapy titration. The BLAST OSA data reported that 91% of patients used the system more than five nights per week over a period of six months following implantation.
- ***Improved quality of life.*** Results from the BLAST OSA trial demonstrated that patients' quality of life significantly improved as assessed using the FOSQ-10 questionnaire, with an increase in mean score by 1.9 units (p-value=0.0157) and a decrease on the Epworth Sleepiness Scale, or ESS, score, by a mean of 3.3 units (p-value=0.0113). Additionally, the number of sleep partners who reported that their partner did not snore, or snored only softly, increased from 4.2% at baseline to 65.0%.



### ***Bilateral hypoglossal nerve stimulation***

The Genio system was designed to provide bilateral stimulation of the hypoglossal nerve. We believe bilateral stimulation results in a stronger muscle contraction, a more symmetric tongue movement and a wider opening of the airway, which we believe has the potential to provide better clinical outcomes. We also believe that the bilateral stimulation of the Genio system has the potential to treat moderate to severe OSA in patients with CCC. These patients are currently contraindicated for other HGNS systems.

### ***Minimally invasive implant procedure and design***

The Genio system only has one implantable, low-profile component, which is leadless and battery-free, and only requires a single incision for implantation. The surgical implantation occurs during an outpatient procedure that lasts approximately one hour. Importantly, our system relies on our proprietary duty cycle stimulation algorithm to control the frequency and strength of the neurostimulation. As a result, our system does not require the implantation of a sensing lead to monitor breathing. We believe that the minimally invasive procedure enables patients to recover quickly and resume normal activities within a week. We also believe that our single-incision implantation process will facilitate adoption by a growing number of physicians and surgeons.

### ***External activation chip and battery***

The Genio system's power source is located in the external activation chip, requiring no battery to be implanted in the patient. Similarly, the external activation chip also includes the software for each user's personalized therapy and can be updated or upgraded without the need for an additional surgical intervention. By eliminating the need for additional surgeries to replace a depleted battery and by enabling updates without additional surgeries, we believe the Genio system may offer a potential reduction in systematic healthcare costs.

## **1.4.4 Treating patients with the Genio system**

### ***Patient selection***

Under CE-Mark approval, the Genio system is indicated for adult patients suffering from moderate to severe OSA with an AHI equal to or greater than 15, but less than 65 events/hour. The Genio system is intended as a second-line therapy for patients who do not tolerate, or who fail or refuse CPAP therapy.

A variety of considerations are required to assess if a patient is eligible for the Genio system. Patients may only have a body mass index, or BMI, of up to 35kg/m<sup>2</sup>. Additionally, patients cannot have any medical illness or condition that contraindicates a surgical procedure under general anesthesia or that would prevent the implantation. Current contraindications for the device include: major craniofacial abnormalities that narrow the airway or the implantation site or that would impair the functioning of the hypoglossal nerve stimulator and congenital malformations of the larynx, tongue and throat.

Once a patient is diagnosed with moderate to severe OSA and either fails, does not tolerate or refuses CPAP treatment, they become eligible for HGNS.

### ***Implantation***

A surgeon implants the implantable stimulator of the Genio system during a minimally invasive procedure that requires only one incision and typically lasts approximately one hour in an out-patient setting under general anesthesia. During implantation, the surgeon makes a small curvilinear incision approximately six centimeters in length under the chin to expose the genioglossus muscle and the left and right hypoglossal nerve branches through dissection of multiple muscle layers. The Genio system's specifically designed and unique paddle electrodes allow the surgeon to position the implant stimulator over both genioglossus muscles facing both medial left and right branches of the hypoglossal nerve to allow bilateral stimulation. During surgery, the surgeon applies the disposable, single use external stimulator to test activation and function of the implantable stimulator. Once function is verified, the

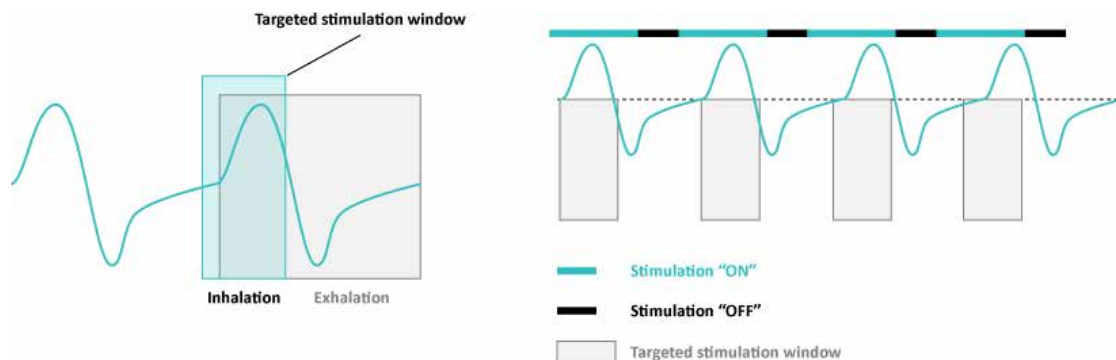
surgeon sutures the implantable stimulator to the muscle to secure fixation. After fixing the stimulator, the physician closes the incision. Patients are typically discharged the same day. While patients may experience mild discomfort or swelling at the incision site, often associated with minimally invasive procedures, this can be managed with over-the-counter pain medications. Patients can return home after completion of the procedure and generally recover within a few days and are able to resume normal activities within a week.

### **Therapy activation and optimization**

Within approximately six weeks following implantation, the patient returns to the physician for a follow-up visit where the physician activates the Genio system. The physician also provides appropriate patient training on how to use the different components of the device and to activate the therapy. Once activated, the patient can start using the Genio system during sleep.

The exact level of stimulation varies between patients based on the response of their hypoglossal nerve to the Genio system. Once activated, the patient enters the first phase of the therapy process, during which the device operates using low stimulation parameters that allow the patient to acclimate to the sensation and tongue movement of stimulation. Once the patient is acclimated to therapy, the second phase of therapy begins. This phase is designed to identify the patient's individual and specific therapeutic levels and patterns of stimulation during wakeful titration and studies performed in a sleep lab. The goal of the wakeful titration is to identify the optimal tongue contraction characteristics including direction and intensity using nasal endoscopy. Therapy titration is typically completed in one or two visits. The Genio system delivers stimulation at a programmed rate determined by the physician based on the patient's breathing frequency. To determine the appropriate rate, the patient's breathing frequency is initially analyzed during an in-lab sleep trial, and the stimulation pattern is adjusted using our proprietary duty cycle algorithm, which provides timely, alternative cycles of stimulation with patient-specific targeted therapy. Once the physician determines the desired titration and stimulation pattern, the physician programs the Genio activation chip to deliver patient-specific therapy based on those levels and patterns. At the optimal titration setting, the physician aims to keep the upper airway open during sleep resulting in blood oxygen saturation, and sleep continuity without waking the patient.

The figure below illustrates the algorithmic, alternating stimulation cycle that is designed to maximize the Genio system's efficacy.



### **Daily home stimulation and use**

Once the Genio system is activated and optimized, the patient uses the system at home while asleep to alleviate the symptoms of their moderate to severe sleep apnea. We recommend that the patient visit their physician once a year for a routine follow up where therapy efficacy can be evaluated and adjustments made as needed.



## 1.5 Clinical results and studies

We continue to invest in developing a substantial body of clinical evidence to support the safety and efficacy of the Genio system. Our clinical strategy consists of obtaining authorization in our target markets, demonstrating long-term clinical data for the Genio system and expanding authorized indications to reach a broader patient population, including patients with CCC. We have completed one clinical trial and are conducting three clinical trials globally with the goal of generating compelling and reproducible results with the Genio system for the large and underpenetrated population of patients with moderate to severe OSA.

### 1.5.1 BLAST OSA trial

#### **Overview**

The BLAST OSA trial was a prospective, open-label, non-randomized, multicenter, single-arm trial initiated in April 2017 with enrollment completed in February 2018. The objective of this trial was to evaluate and assess the safety, performance and efficacy of the Genio system in adult patients with moderate to severe OSA. The trial measured safety and efficacy endpoints at six months following five months of treatment. The primary safety endpoint was the incidence of device-related SAEs recorded during the trial over a period of six months post implantation. The primary efficacy endpoint was the mean change in the AHI score from baseline to six months post implantation measured by the number of apneas and hypopneas events per hour during an overnight sleep trial. The secondary performance endpoint was the change in the ODI score from baseline to six months post implantation. ODI score was measured by the number of desaturation episodes per hour during an overnight sleep trial. A desaturation period occurs when the patient stops breathing resulting in a decrease in blood oxygen.

Performance measures included changes in the sleep-related quality of life, evaluated by the level of daytime sleepiness using the Epworth Sleepiness Scale, or ESS, and the Functional Outcomes of Sleep Questionnaire, or FOSQ-10, as well as supplementary objective measures evaluated in an in-lab sleep trial, such as therapy response rate. The ESS measures the propensity for daytime sleepiness and the FOSQ-10 questionnaire measures sleep-related quality of life. Therapy response was defined based on the Sher success criteria as a reduction in AHI from baseline to six months of 50% or more, a remaining AHI score at six months of less than 20. The study also evaluated the change in the percentage of time spent at an oxygen desaturation state below 90% (SaO<sub>2</sub><90%). Response rate was a percentage of patients passing the Sher success criteria at six months. Sleep partner-reported snoring and nightly usage of the system were also evaluated.

In 2019, the BLAST OSA trial protocol was amended to include a long-term safety follow-up phase. All participants who received the Genio system were eligible to enroll in the long-term follow-up phase of the trial. While the long-term follow-up phase was not initiated, subjects were nevertheless followed up for an additional 36 months before the study was closed out.

#### **BLAST OSA results**

The BLAST OSA results were published in the European Respiratory Journal in October 2019. Screening exclusion criteria included in-lab sleep study test results, AHI that was above 60 or below 20 based on the 2014 American Academy of Sleep Medicine recommended scoring guidelines, or a patient having a non-supine AHI less than 10. Another 18% of patients were excluded from the trial due to CCC. A total of 27 participants underwent the implantation procedure of the Genio system. Of these participants, 63% (17/27) were men with a mean age of 55.9±12.0 years and a mean body mass index of 27.4±3.0 kg/m<sup>2</sup>. Twenty-two patients completed the protocol, and the trial met all primary, secondary and exploratory endpoints. In the six-month data, the mean individual reduction in AHI events per hour decreased 47.3%. Participants' AHI decreased from 23.7±12.2 to 12.9±10.1, representing a mean change of 10.8 events/ hour (p-value<0.0001). In statistics, a p-value is a number calculated from a statistical

test. It provides the probability that a null hypothesis (e.g., there is no treatment effect) is true for the particular set of observations being tested. The smaller the p-value (typically < 0.05), the stronger the evidence that the null hypothesis should be rejected in favor of an alternative hypothesis (e.g., there is a treatment effect greater than a given threshold). A p-value less than 0.05 is said to be statistically significant. It indicates strong evidence against the null hypothesis, as there is less than a 5% probability that the null hypothesis is correct.

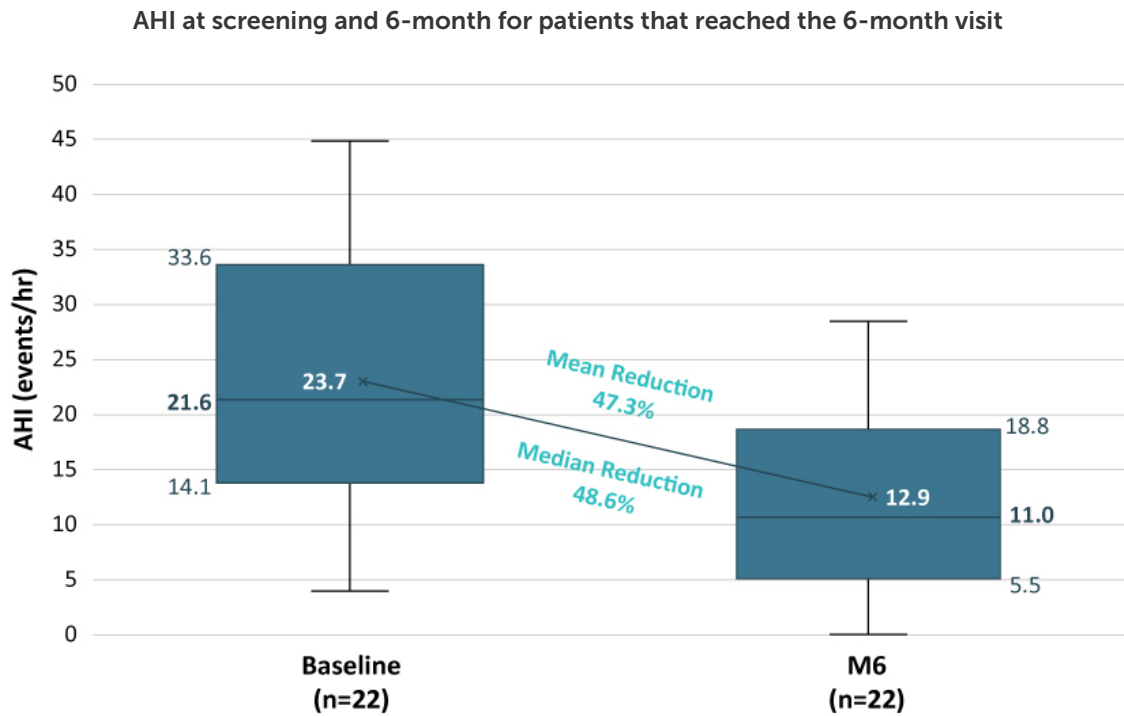
### **Safety results**

Four SAEs related to the surgical procedure (but not device-related) were reported in three of the 27 patients implanted during the six-month post-implantation period. These included two participants at the same hospital who developed local infections at the surgical site that resulted in removal of the implanted device. The fourth SAE was impaired swallowing, which led to one day prolongation of implantation-related hospitalization. Two patients were kept in the hospital for overnight observation. All SAEs were successfully resolved. The most frequent procedure-related adverse events, or AEs, that occurred in implanted patients were impairment or painful swallowing (30% of participants), dysarthria, or speech-slurring, (26% of participants), hematoma (19% of participants) and swelling or bruising around the incision site (19% of participants).

No device-related SAEs occurred during the six-month post-implantation period. The majority of device-related AEs were reported as mild and resolved within days. The most frequent device-related AE was a temporary and mild local skin irritation due to use of the disposable patch (30% of participants). This AE was generally resolved with the application of skin lotion to the irritated skin, and there was no discontinuation of therapy within implanted devices. Additional device related AEs that occurred in 11% of the patients included tongue abrasion, tongue fasciculation, discomfort due to electrical stimulation and abnormal scarring. The adverse reaction to stimulation discomfort was typically resolved by reprogramming the stimulation parameters.

### Trial performance results

Six months post-implantation, the mean individual reduction in AHI events per hour decreased 47.3%. Participants' mean AHI decreased from  $23.7 \pm 12.2$  to  $12.9 \pm 10.1$ , representing a mean change of 10.8 events/ hour ( $p$ -value $<0.0001$ ).



A reduction in the ODI score was demonstrated between baseline and six-month post-implantation, dropping from a mean of  $19.1 \pm 11.2$  to  $9.8 \pm 6.9$ , representing a mean change of 9.3 events/hour ( $p$ -value $<0.001$ ).

Both the propensity for daytime sleepiness, as measured by the Epworth Sleepiness Scale, and sleep-related quality of life, as assessed using FOSQ-10, significantly improved. The ESS decreased from  $11.0 \pm 5.3$  to  $8.0 \pm 5.4$ , representing a mean change of 3.3 units (95% CI 0.8-5.7,  $p$ -value=0.0113), whereas the FOSQ-10 score increased from  $15.3 \pm 3.3$  to  $17.2 \pm 3.0$ , representing a mean change of 1.9 units (95% CI 0.4-3.4,  $p$ -value=0.0157). The FOSQ-10 objective is to demonstrate a change in sleep-related quality of life at the 6-month visit compared to baseline. A FOSQ-10 score greater than 17 is considered clinically significant. A score below 8 for the Epworth Sleepiness Scale is considered clinically significant. Finally, the arousal index (measures shift from deep sleep to light sleep) significantly decreased from  $28.7 \pm 11.5$  to  $16.0 \pm 8.0$  ( $p$ -value $<0.0001$ ), representing a mean change of 12.7 events per hour.

The following chart sets forth the various outcome measures for the intent to treat patient population:

Outcome	Baseline (n=22)	6-months (n=22)	Mean Difference (95% CI)	P-value
AHI, events/hour	23.7 ± (12.2)	12.9 ± (10.1)	10.8 ± (14.6 to 7.0)	<0.0001
ODI, events/hour	19.1 ± (11.2)	9.8 ± (6.9)	9.3 ± (13.1 to 5.5)	<0.0001
FOSQ-10	15.3 ± (3.3)	17.2 ± (3.0)	1.9 ± (0.4 to 3.4)	0.0157
ESS	11.0 ± (5.3)*	8.0 ± (5.4)	3.0 ± (5.7 to 0.8)	0.0113
SaO <sub>2</sub> <90%, % time	5.0 ± (6.0)	2.1 ± (3.0)	2.9 ± (4.6 to 1.3)	0.0015
Arousal Index, events per hour	28.7 ± (11.5)	16.0 ± (8.0)	12.7 ± (16.6 to 8.9)	<0.0001
Sleep efficiency (%)	84.0 ± (10.8)	87.3 ± (8.9)	3.2 ± (0-01 to 6.4)	0.0494
Responder rate (Sher Criteria) at 6-month	11 patients out of 22 (50%)		NA	

Legend: Data are mean (Standard Deviation) unless otherwise specified. Arousal Index is the number of arousals and awakenings registered during the sleep trial. SaO<sub>2</sub> < 90% is the proportion of the night spent at an oxygen saturation below 90%. Sleep efficiency is the ratio of total time spent asleep in a night compared to the total amount of time spent in bed. ESS is the Epworth Sleepiness Scale. FOSQ10 is the 10 – item Functional Outcomes of Sleep Questionnaire. \* means n=21.

### Other metrics and outcomes

The reported snoring intensity was reduced, with 65.0% of patients' sleep partners reporting no snoring or soft snoring at the six-month post-implantation visit compared to only 4.2% at baseline. Additionally, 91% of patients reported using the Genio system more than five days a week, of whom 77% reported a nightly use of more than five hours per night.

The BLAST OSA trial demonstrated that the Genio system's therapy was well-tolerated, met its performance endpoints, and was associated with high compliance. The trial showed significant reduction of OSA severity and improvement of sleepiness and quality of life, while being well-tolerated.

## 1.5.2 BETTER SLEEP trial

We are currently conducting the 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 over a period of 36 months post-implantation. The BETTER SLEEP trial includes a subgroup of CCC patients, which is a patient population that is contraindicated for unilateral HGNS.

Patients with moderate to severe AHI scores ( $15 \leq \text{AHI} < 65$ ) and aged between 21 and 75 years were eligible for enrollment if they failed, refused or did not tolerate PAP treatment. Patients with a body mass index above 32 kg/m<sup>2</sup> were excluded. The trial has been authorized by the Australian and New Zealand regulatory authorities and is being conducted in eight local medical centers.

In the BETTER SLEEP trial, 42 patients were implanted with the Genio system, 18 of which have CCC (or 42.9% of the total implanted population) and 24 who were classified as non-CCC. Three patients in each arm did not complete their six-month polysomnography, and as a result, the analysis was calculated based on 36 patients (15 CCC, 21 non-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 primary safety endpoint included the incidence of device-related serious adverse events (SAEs) from consent to 6 months post-implant.

Primary and exploratory efficacy endpoints were defined as a mean reduction in AHI (4% oxygen desaturation AHI4) at six months post-implant for the entire cohort and for the CCC subgroup,

respectively. Scoring followed the American Academy of Sleep Medicine 2014 acceptable guidelines. Secondary efficacy endpoints included the oxygen desaturation index scored at 4% desaturation (ODI4). Statistical significance was assessed at  $p < 0.05$  using paired t-tests.

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, no device-related SAEs up to six months post-implant were reported by the site investigators. The clinical events committee (CEC) identified two device-related SAEs (device migration, infection). Final review and adjudication of SAEs and AEs have not yet been completed by an independent CEC and as a result the characterization of SAEs or AEs could be subject to change.

We expect to announce additional data with respect to the trial as further analyses are conducted and we seek 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, we will continue to monitor patients in the evaluable patient population and plan to continue evaluating over the course of three years following implantation.

In October 2021, Nyxoah received CE-mark indication approval to treat OSA patients with CCC, based on clinical evidence from the BETTER SLEEP trial.

Additionally, in September 2021, we received breakthrough device designation in the United States for the Genio system from the FDA for the treatment of OSA with CCC, based on the initial clinical evidence from the BETTER SLEEP trial.

### **1.5.3 EliSA trial**

After having obtained certification in Europe for the Genio system in March 2019, we initiated the EliSA post-marketing trial in Europe for the treatment of OSA in adult patients with moderate to severe OSA. The primary objective of this trial is to evaluate the long-term safety and clinical efficacy of the Genio system in adult patients suffering from moderate to severe OSA. The trial is expected to follow patients over a five-year period. EliSA is a multicenter prospective single-arm post market clinical follow-up trial and is expected to enroll at least 110 patients across approximately 25 investigational centers in Europe.

### **1.5.4 Pivotal DREAM trial**

In June 2020, the FDA approved our IDE application, allowing us to commence our pivotal DREAM trial of the Genio system. In June 2022, we announced that the FDA approved the use of the Genio 2.1 system in our DREAM trial. Our DREAM trial is a multicenter, prospective, open-label trial in which each participant who undergoes implantation of the Genio system will be followed for five years post-implantation to assess the safety and efficacy of the system in patients with moderate to severe OSA. We initiated the DREAM trial as an IDE pivotal trial to support an application seeking FDA marketing authorization and ultimately, reimbursement in the United States for bilateral HGNS for the treatment of moderate to severe OSA. The trial enrolled 115 patients who have all been implanted as of the date of this Annual Report, with 12-month effectiveness and safety primary endpoints. We have identified 20 centers for the trial, including 15 in the United States. Fifteen of them were active and enrolling patients as of December 2023.

The primary safety endpoint is incidence of device-related SAEs at 12-months post implantation. One of the co-primary effectiveness endpoints is the percentage of responders with at least a 50% reduction in 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 of 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 enrollment if they failed, did not tolerate or refused PAP treatment. Patients with a body mass index above  $32 \text{ kg/m}^2$ , a

CCC observed during a drug induced sleep endoscopy and combined central and mixed AHI above 25% at baseline polysomnography are to be excluded. We presented 12-month data on the first 34 DREAM patients reaching 12-month follow-up as a late-breaking abstract at SLEEP 2023, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in line with expectations. These data are preliminary and not conclusive of final success of the DREAM trial.

On March 19, 2024, we issued a press release announcing that the DREAM trial met its primary endpoints. More information can be found in the press release.

### 1.5.5 ACCESS trial

In July 2022, we announced that the FDA approved an IDE to enable us to initiate a clinical trial, called ACCESS, to evaluate the use of the Genio system for the treatment of adult patients with moderate-to-severe OSA with CCC that have failed, did not tolerate, or refused PAP. In the ACCESS trial, we plan to implant up to 106 subjects with co-primary efficacy endpoints of AHI responder rate, per the Sher criteria, and ODI responder rate, both assessed at twelve months post-implant. The first enrolled subjects have been implanted, and we anticipate completing implantation in late 2024.

## 1.6 Sales and marketing

We have grown our commercial team to more than 15 individuals, including sales representatives, field engineers and marketing professionals, who collectively bring substantial medical device sales, education and clinical experience to support commercialization of the Genio system. We are initially targeting markets in Europe where we have identified a clear reimbursement pathway or execution strategy. In Germany, we have successfully obtained reimbursement under a dedicated DRG code for HGNS, and, in Switzerland, we recently obtained reimbursement under an OSA-specific DRG code by the BFS. Each of these reimbursement coverages includes the cost of the Genio system, implant procedure, hospital stay and follow-up care. We began our commercial launch of the Genio system in July 2020. Our sales team in Germany consists of one country director and several representatives and field engineers, with support provided by our corporate team. We began marketing products in Switzerland and also secured first revenue in Spain in 2021 and we began commercialization in Finland in 2022 and in Austria in 2023.

We have established a systematic approach to commercializing the Genio system in select European countries which centers on active engagement and market development across patients, physicians and hospitals. Our Genio System has CE-Mark for OSA in patients with moderate to severe OSA in Europe. We market our Genio System to physicians and hospitals where ENTs, sleep doctors and general practitioners who see, diagnose and treat patients with OSA. We have developed a methodical marketing strategy to educate and develop the market and a commercial strategy tailored to suit local market needs in order to maximize therapy penetration and patient base expansion.

Our initial strategy is to employ a targeted approach to increase therapy penetration within specific physician practice groups instead of a broad outreach strategy to physicians. Our sales and marketing organization is focused on prioritizing high volume centers that are strategically located and building long-standing relationships with key physicians with strong connectivity to the population of OSA patients indicated for the Genio system. We are focusing our efforts on developing "Centers of Excellence", where we plan to invest in developing the Genio system as the preferred treatment option for appropriate moderate to severe OSA patients in need of an alternative to conventional first-line therapies. Using a direct commercialization model in most of our target countries, we plan to utilize account managers to support the Centers of Excellence to strengthen the referral physician network, guiding new patients to these Centers of Excellence. We expect to gradually scale up in line with market entry and access in the various countries that we are targeting. Based on our experience we will have gained from our initial commercial roll-out in Europe, but also taking into account particular aspects of local markets, we will determine and prepare what we believe to be the optimal sales and marketing structure for commercial launch in the United States if we obtain U.S. marketing authorization.

Our direct sales representatives and field engineers, which we refer to as our market development team, generally have substantial experience, specifically with patients, physicians and payors in the ENT or neurostimulation space. Our market development team is focused on prioritizing high volume ENT centers, sleep centers, and building long-standing relationships with key physicians such as sleep doctors, ENT and general practitioners who have strong connectivity to the OSA patient population that may be eligible for the Genio system. Additionally, we target cardiac electrophysiologists, cardiologists, cardiovascular surgeons and dentists, which are a second OSA patient referral base for ENT physicians. We support our physicians through all aspects of the patient journey, starting from initial diagnosis through surgical support and post implantation patient follow-up.

We seek to establish long-term partnerships with key opinion leaders and patient associations that are built on mutual trust and oriented towards the needs of our patients and customers. Our marketing organization is focused on building physician awareness through referral network development, education, and targeted KOL development and training. Additionally, we have established and implemented a dedicated direct-to-patient marketing strategy aligned with local regulations in selected countries. Through targeted digital and offline media campaigns, we are raising awareness, engaging and driving patients eligible to the Genio system to our active centers of excellence. We have developed dedicated education and training programs leading to a certification delivered by an approved proctor. These education and training programs offer sleep centers and implanting surgeons excellent training pertaining to the Genio system technology, the latest and most up-to-date insights on the implantation procedure and on therapy optimization as well as on the subject of HGNS science. Additionally, these education and training programs promote a better understanding of OSA, which we believe will result in maximizing outcomes for Genio users, a better understanding of the technology's benefits and risks and increasing confidence in the safety of the technology.

Additionally, we build awareness of the Genio system through digital social networks. The objective of this outreach is to target these patients and make them aware of our education webinars and website, where they can find a wealth of information on OSA and the purpose and benefits of the Genio system, based on our approved labeling. In addition to driving broad awareness and increasing physician and patient education, our marketing team has developed the in-house resources necessary to assist patients and physicians in the process of obtaining reimbursement approval for their procedures.

## 1.7 Research and development

In addition to our ongoing clinical studies, we are also committed to continuing our research and development efforts related to the Genio system, with an emphasis on improving clinical outcomes, optimizing patient adoption and comfort, increasing access for a greater number of patients and allowing more physicians to perform the procedure. The primary focus of our research and development efforts in the near-term will be the continued technological advancement of the Genio system. Some of these improvements include features aimed at enhancing a physician's ability to monitor patient compliance and therapy efficacy. We continue to enhance our scalable technology platform to potentially enable quick and streamlined release of new features and functionalities through software, firmware, hardware updates and upgrades and therapy enhancement. In January 2021, we entered into an exclusive license agreement with Vanderbilt University in order to further develop new neurostimulation technologies for the treatment of sleep disordered breathing conditions. We expect that these potential new treatments will focus on stimulating the ansa cervicalis, the efferent fiber of the glossopharyngeal nerve or nerves that innervate the palatoglossus and/or the palatopharyngeus muscle. Additionally, in June 2022, we announced that the FDA approved the use of our next generation Genio 2.1 system, which is designed to improve patient comfort and compliance with a new smartphone application and an upgraded external activation chip, for use in the DREAM trial. In July 2022, we obtained the CE-Mark for the Genio 2.1 system.



Further improvements or a next generation product may also bring additional features or services to the Genio system, potentially opening opportunities to generate revenue from data collected. For example, we expect the future generation of our products to focus on the capability to assess variables related to the patient's sleep quality including monitoring patient respiratory flow, snoring, movement and sleep position as well as the ability for the Genio system to be connected to the cloud. We believe this information may enable us to monitor and better understand the patient's quality of sleep and respiratory status, which we could consider sharing with key stakeholders. For example, we are considering developing solutions designed to enhance patient compliance by letting patients follow up regularly regarding the quality of the treatment received with healthcare connectivity tools. We are also exploring future tools that would provide sleep specialists with access to detailed patient therapy status via a digital care management platform, enabling them, on a remote and potentially reimbursable basis, to assess patient status and adjust Genio system treatment parameters. We believe the Genio system's location close to the airway is optimal for detection and analysis of sleep and respiratory variables.

We intend to build a scalable technology platform allowing quick and streamlined release of new features and functionalities through software, firmware, hardware updates and upgrades and therapy enhancement. We believe that the external Genio system Activation Chip could allow for external enhancements to the Genio system without the need for additional surgical intervention.

## 1.8 Manufacturing and supply

We rely on third-parties to manufacture and supply all the components of the Genio system to our specifications. Most components are supplied by single-source suppliers. Our principal suppliers of components are Meko, Medistri SA, Resonetics, VSI Parylene, Reinhardt Microtech GmbH (Cicor), Abatec (previously Lust Hybrid), Specialty Coating Systems (SCS), VSI Parylene, Resonetics, Medistri SAMeko, and S&D Tech SRL. The raw materials used by our suppliers are purchased in the open market. We continue to look for additional or replacement suppliers for the currently single-source components and we plan to maintain a sufficient level of inventory of such components to enable continued production for a limited period, such as during a supplier transition phase.

We work with third parties to manufacture and supply the components of the implantable stimulator and external stimulator. The initial assembly of the different electronics components is done by different external suppliers. The final assembly of the external stimulator and the final manufacturing step of the implantable stimulator, the silicone molding, are done internally by our manufacturing teams in the clean rooms at our facilities in Tel Aviv, Israel, and Milmort, Belgium. The capacity of our facilities in Tel Aviv and Milmort is expected to cover our expected clinical and European commercial product demand for 2024. We are working with a U.S. third party manufacturer to cover our expected future U.S. commercial product demand.

We work with third parties to manufacture and supply the electronic and plastic components of the activation chip and charging unit. In Tel Aviv, the final assembly of these parts is done by our manufacturing team in our facility. In Belgium, we have outsourced the assembly of the activation chip and charging unit to an external supplier. The manufacturing of the disposable patch is fully outsourced to the third party-supplier based in Israel.

## 1.9 Post balance sheet events

On March 6, 2024, the Company issued 8,650 shares pursuant to an exercise of 2,400 2020 ESOP Warrants and 6,250 2021 ESOP Warrants. Consequently, on the date of this Annual Report, the Company's registered capital amounts to EUR 4,927,355.12, represented by 28,682,635 shares.



## 1.10 Financial review of the year ending December 31, 2023

### 1.10.1 Analysis of the consolidated statements of loss and other comprehensive loss

The table below sets forth the Company's audited consolidated income statement, ending up with a €43.2 million net loss for the year ended December 31, 2023, and comparative information for the year 2022.

(in EUR 000)	For the year ended December 31	
	2023	2022
Revenue	4 348	3 084
Cost of goods sold	(1 656)	(1 150)
<b>Gross Profit</b>	<b>2 692</b>	<b>1 934</b>
Research and development expense	(26 651)	(15 861)
Selling, general and administrative expense	(21 687)	(18 855)
Other income/(expense)	544	283
<b>Operating loss for the period</b>	<b>(45 102)</b>	<b>(32 499)</b>
Financial income	4 174	6 763
Financial expense	(3 729)	(4 320)
<b>Loss for the period before taxes</b>	<b>(44 657)</b>	<b>(30 056)</b>
Income taxes	1 445	(1 169)
<b>Loss for the period</b>	<b>(43 212)</b>	<b>(31 225)</b>
Basic and diluted Loss Per Share (in EUR)	(1.545)	(1.209)

For the year ended December 31, 2023, the Company generated revenue for the amount of €4.3 million compared to €3.1 million for the year ended December 31, 2022. The sales were generated in Germany, Spain, Austria and Switzerland. The total cost of goods sold is amount of €1.7 million compared to €1.2 million for the year ended December 31, 2022.

The increase of operating loss from €32.5 million in 2022 to €45.1 million in 2023, or a change by €6.3 million, is due to the increase of activities in all departments. The Company is currently conducting four clinical trials to continue gathering clinical data and obtain regulatory approvals. The Company continues investing in research and development to improve and develop the next generation of the Genio system and preparing for scaling-up of production capacities.

Research and development expenses consist primarily of product development, engineering to develop and support our products, testing, consulting services and other costs associated with the next generation of the Genio system. These expenses primarily include employee compensation, consulting and contractor's fees and outsourced development expenses. Before capitalization of €8.5 million for the year ended December 31, 2023 and €15.6 million for the year ended December 31, 2022, research and development expenses increased by €3.7 million or 11.7 % from €31.4 million for the year ended December 31, 2022, to € 35.1 million for the year ended December 31, 2023, due to the combined

effect of higher manufacturing and R&D activities and clinical expenses. This increase is mainly in staff and consulting costs and in manufacturing and outsourced development to support those activities, and was partly offset by a decrease in clinical study activities. The IT costs amounting to €1.8 million consist of €1.6 million related to the start of a new ERP implementation. See note 22 to the Consolidated Financial Statements.

Selling, general and administrative expenses consist primarily of payroll and personnel related costs, consulting and spending related to support the commercialization of the Genio system in Europe and to finance, information technology and human resource functions. Other general and administrative expenses include travel expenses, professional services fees, audit fees, insurance costs and general corporate expenses, including facilities-related expenses. Selling, General and Administrative expenses increased by €2.8 million, or 15.0 % from €18.9 million for the year ended December 31, 2022 to €21.7 million for the year ended December 31, 2023 mainly due to an increase of costs to support the commercialization of the Genio system in Europe, the scale-up of the Company and also due to €0.5 million related to the start of a new ERP implementation. This increase was partly offset by a decrease in insurance and legal fees. See note 23 to the Consolidated Financial Statements.

### 1.10.2 Analysis of the consolidated balance sheets

The table below sets forth the Company's audited consolidated balance sheet for the year ended December 31, 2023, and comparative information as at December 31, 2022.

(in EUR 000)	As of December 31	
	2023	2022
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant and equipment	4 188	2 460
Intangible assets	46 608	39 972
Right of use assets	3 788	3 159
Deferred tax asset	56	47
Other long-term receivables	1 166	173
	<b>55 806</b>	<b>45 811</b>
<b>Current assets</b>		
Inventory	3 315	882
Trade receivables	2 758	1 463
Other receivables	3 212	1 775
Other current assets	1 318	1 284
Financial assets	36 138	76 968
Cash and cash equivalents	21 610	17 888
	<b>68 351</b>	<b>100 260</b>
<b>Total assets</b>	<b>124 157</b>	<b>146 071</b>

As of December 31

(in EUR 000)	2023	2022
<b>EQUITY AND LIABILITIES</b>		
<b>Capital and reserves</b>		
Capital	4 926	4 440
Share premium	246 127	228 275
Share based payment reserve	7 661	5 645
Other comprehensive income	128	176
Retained Earnings	(160 829)	(118 212)
<b>Total equity attributable to shareholders</b>	<b>98 022</b>	<b>120 324</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	8 373	8 189
Lease liability	3 116	2 586
Employee benefits	9	–
Provisions	185	59
Deferred tax liability	9	–
	<b>11 692</b>	<b>10 834</b>
<b>Current liabilities</b>		
Financial debt	364	388
Lease liability	851	719
Trade payables	6 155	4 985
Current tax liability	1 988	3 654
Other payables	5 085	5 167
	<b>14 443</b>	<b>14 913</b>
<b>Total liabilities</b>	<b>26 135</b>	<b>25 747</b>
<b>Total equity and liabilities</b>	<b>124 157</b>	<b>146 071</b>

The Company started recognizing the development expenditure as an asset since March 2019 triggered by obtaining CE mark and as from July 2020, the Company started recognizing the development expenditure as an asset for the improved second generation of the Genio system. Development costs primarily include employee compensation and outsourced development expenses. Amortization for the first generation of the Genio system started in 2021 and is recognized in the R&D department. In 2023 and 2022, the Company has capitalized developments costs for an amount of €7.6 million and €15.5 million, respectively. The net book value of the capitalized development costs in 2023 is €46.6 million. See note 8 to the Consolidated Financial Statements.

Property, plant & equipment shows a total additional net book value of €1.7 million at balance sheet date consequently to laboratory equipment followed by furniture and office equipment. See note 7 to the Consolidated Financial Statements.

Right of use assets shows a total additional increase by €0.6 million due to lease modifications mainly related to the extension of the contracts of buildings in Belgium and Israel, which is offset by depreciation. See note 9 to the Consolidated Financial Statements.

Cash, cash equivalents and financial assets (term deposits) amount to €57.7 million as of December 31, 2023 compared to €94.9 million as at December 31, 2022. Cash and cash equivalents show a total increase of €3.7 million mainly due to cash generated in investing activities of €32.0 million and in cash generated in financing activities of €16.9 million and offset by cash used in operating activities by €44.8 million. See notes 13 and 14 to the Consolidated Financial Statements.

The share capital and the share premium show a total increase of €18.3 million mainly due to capital increases in cash (including as a result of the exercise of warrants). See note 15 to the Consolidated Financial Statements.

Lease liabilities show a total increase by €0.7 million due to lease modifications mainly related to the extension of the contracts of buildings in Belgium and Israel. See note 9 to the Consolidated Financial Statements.

The increase in total trade payables of €1.2 million as at December 31, 2023 is due to an increase in payables of €2.2 million which is compensated by the decrease in invoices to be received of €1.1 million. See note 18 to the Consolidated Financial Statements.

Other current payables have decreased by €82,000 from €5.2 million to €5.1 million mainly due to a decrease of €206,000 mainly in payroll related liabilities. The decrease is partly offset by an increase of €80,000 in the fair value of foreign currency options. See notes 19 and 19.1 to the Consolidated Financial Statements.

### 1.10.3 Analysis of the consolidated net cash burn rate

The net cash burn rate is the net amount of cash and cash equivalents which have decreased over the year. The net cash burn rate equals the change in the cash and cash equivalents between December 31, 2022 and 2023.

The table below summarizes the net cash burn rate of the Company for the year 2023.

(in EUR 000)	For the year ended December 31	
	2023	2022
Net cash used in operating activities	(44 778)	(28 756)
Net cash from investing activities	32 011	(89 946)
Net cash from financing activities	16 858	(983)
Effects of exchange rate changes	(369)	2 064
<b>Change in Cash and cash equivalents</b>	<b>3 722</b>	<b>(117 621)</b>

The net cash burn rate for 2023 is a net cash inflow amounting to €3.7 million compared to a net cash outflow of €117.6 million for 2022.

The cash outflow resulting from operating activities amounted to €44.8 million in 2023 compared to €28.8 million in 2022. The increase of cash used in operations of €16.0 million was primarily due to higher losses of €14.6 million that were mainly attributable to increased research and development expenses and selling, general and administrative general expenses, as described in more detail above. This increase was offset by a negative variation in the working capital and other non-cash adjustments.

Cash flow from investing activities represented a net cash inflow of €32.0 million for 2023. The change of €122.0 million compared to 2022 is mainly due to a decrease in the purchase of term accounts by €22.6 million and an increase in term accounts that reached their maturity by €91.7 million (after which the term deposit is held as cash). See note 14 to the Consolidated Financial Statements.

The increase in cash inflow from financing activities is primarily derived from several capital increases during 2023. See note 15 to the Consolidated Financial Statements.

## 1.11 Personnel

As at December 31, 2023, the Nyxoah Group employed 146.8 full-time equivalents, including white-collar employees and consultants. The following table presents a breakdown of the Company's full-time equivalents as at December 31, 2023.

Sales, General & Administration	40.4
Research & Development	106.4
<b>Total</b>	<b>146.8</b>

As at December 31, 2023, the Nyxoah Group had 61.4 full-time equivalents located in Europe, 46.4 full-time equivalents located in Israel, 4 full-time equivalents located in Australia and 35 full-time equivalents located in the United States.

## 1.12 Environment

The Company is committed to providing a safe and healthy work environment for all its employees, contractors and visitors. This commitment also extends to ensuring that its operations do not place local communities or the environment at risk of injury, illness or damage. The Company has not been the subject of any significant environmental prosecutions for violating environmental regulations, licenses or other requirements in recent years.

## 1.13 Risks and uncertainties

Reference is made to section 2.9 ("Description of the principal risks associated with the activities of the Company").

## 1.14 Going concern

The Company has consistently operated with deficits and sustained negative cash flows since its inception considering the significant research and development expenses incurred for the development and regulatory approval of the Genio device. As of December 31, 2023, the Company's statement of financial position includes an accumulated loss of € 160.8 million and total assets of € 124.2 million. Current assets as of December 31, 2023 total €68.4 million, comprising €21.6 million in available cash and cash equivalents, and €36.1 million in marketable securities, primarily derived from previous public offerings.

The Company's current operating plan indicates that it will continue to incur losses from operations and generate negative cash flows from operating activities given ongoing expenditures related to the completion of its clinical trials only partially offset by the Company's revenue generating activities outside the U.S (which were €4.3 million in 2023 in the EU). Substantial revenue generation is expected to start following the launch of the Genio product in the U.S., which is dependent on obtaining marketing authorization in the United States for the Genio product from the FDA.

The Company projects that its existing cash and cash equivalents and marketable securities should be sufficient to fund operations until the beginning of the fourth quarter of 2024. To meet the Company's future working capital needs, management is actively exploring different financing avenues, including the public or private issuance of equity and debt financing. Additional funds are pivotal for diverse activities, in particular to launch the Genio product in the U.S. and the ongoing progression of research and development projects. This raises, however, a material uncertainty in respect of going concern as the current funds are not sufficient to cover a period of 12 months following the date of the Annual Report.

Although the additional funds have not been raised yet, given the positive outcome from the DREAM trial, the Company is confident that raising sufficient funding to continue its operations for at least 12 months following the date of the Annual Report should not pose significant challenges.

The accompanying consolidated financial statements have therefore been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

## 1.15 Events and circumstances that could have a significant impact on the future development of the Company

The Company has not identified any events or circumstances that could have a significant impact on the future development of the Company in addition to the risks described in section 2.9 ("Description of the principal risks associated with the activities of the Company").



2

# Corporate Governance

# Corporate Governance

## 2.1 General

This section gives an overview of the rules and principles on the basis of which the corporate governance of the Company is organized pursuant to the Belgian CCA, the Company's Articles of Association and the Company's Corporate Governance Charter adopted in accordance with the Belgian Code on Corporate Governance published by the Belgian Corporate Governance Committee on May 9, 2019 (the "2020 Code").

The Articles of Association and the Corporate Governance Charter are available on the Company's website ([www.nyxoah.com](http://www.nyxoah.com)) under the Investors/Corporate Governance tab.

The text of the 2020 Code is available on the website of the Corporate Governance Committee at: <https://www.corporategovernancecommittee.be/en/over-de-code-2020/2020-belgian-code-corporate-governance>.

The Company is committed to following the ten corporate governance principles listed in the 2020 Code, but in view of the activities of the Company, its size and the specific circumstances in which it operates, the Board is of the opinion that the Company can justify its deviation from certain provisions of the 2020 Code. These deviations are further detailed in section 2.6.

## 2.2 Board of Directors

### 2.2.1 Composition of the Board of Directors

The Company has a "one tier" governance structure whereby the Board of Directors is the ultimate decision making body, with the overall responsibility for the management and control of the Company, and is authorized to carry out all actions that are considered necessary or useful to achieve the Company's purpose. The Board of Directors has all powers except for those reserved to the general shareholders' meeting by law or the Articles of Association. The Board of Directors acts as a collegiate body.

Pursuant to the Company's Corporate Governance Charter, the role of the Board of Directors is to pursue the long term success of the Company by providing entrepreneurial leadership and enabling risks to be assessed and managed. The Board of Directors decides on the Company's values and strategy, its risk appetite and key policies.

Pursuant to the Belgian CCA and the Articles of Association, the Board of Directors must consist of at least three directors. The Company's Corporate Governance Charter provides that the composition of the Board of Directors should ensure that decisions are made in the corporate interest. It should be determined on the basis of diversity, as well as complementary skills, experience and knowledge. Pursuant to the 2020 Code, a majority of the directors must be non-executive and at least three directors must be independent in accordance with the criteria set out in the 2020 Code. By January 1, 2026, at least one third of the members of the Board of Directors must be of the opposite gender.

The directors are elected by the Company's general shareholders' meeting. The term of the directors' mandates cannot exceed four years. Resigning directors can be re-elected for a new term. Proposals by the Board of Directors for the appointment or re-election of any director must be based on a recommendation by the nominating and corporate governance committee. In the event the office



of a director becomes vacant, the remaining directors can appoint a successor temporarily filling the vacancy until the next general shareholders' meeting.

The general shareholders' meeting can dismiss the directors at any time.

The Board of Directors shall meet as frequently as the interest of the Company requires and at least four times per year, or at the request of two or more directors. The decisions of the Board of Directors are made by a simple majority of the votes cast. In case votes are tied, the chairperson of the Board of Directors will have a casting vote.

As at the date of this Annual Report, the Board of Directors consists of eight members, one of which is an executive director (the Chief Executive Officer) and seven of which are non-executive directors, including five independent directors, as detailed in the table below.

<b>Name</b>	<b>Position</b>	<b>Start of Term</b>	<b>End of Term</b>
Robert Taub	Non-executive Director / Chairman of the Board of Directors	2020	Annual general shareholders' meeting of 2024
Jürgen Hambrecht	Independent Non-executive Director	2020	Annual general shareholders' meeting of 2024
Kevin Rakin	Independent Non-executive Director	2020	Annual general shareholders' meeting of 2024
Rita Johnson-Mills	Independent Non-executive Director	2021	Annual general shareholders' meeting of 2024
Virginia Kirby	Independent Non-executive Director	2022	Annual general shareholders' meeting of 2024
Wildman Ventures LLC (represented by Danial Wildman)	Independent Non-executive Director	2023	Annual general shareholders' meeting of 2024
Pierre Gianello	Non-executive Director	2020	Annual general shareholders' meeting of 2024
Olivier Taelman	Executive Director / CEO	2020	Annual general shareholders' meeting of 2024

The following paragraphs contain brief biographies of each of the directors.

**Robert Taub** is the founder of our company and has served as Chairman of our Board of Directors since our inception in July 2009. He also served as our Chief Executive Officer from July 2009 to September 2016. Mr. Taub is an entrepreneur, investing in the pharmaceutical and medical fields. Prior to founding our Company, he co-founded and co-managed Octapharma AG, a human plasma protein company, from 1983 to 1995. He also founded and managed Omrix Biopharmaceuticals, Inc. through its initial public offering and listing on Nasdaq and its acquisition by Johnson & Johnson in 2008. Prior to that, Mr. Taub held various general management and sales and marketing positions with The Monsanto Company, Baxter Travenol Laboratories and the Revlon Health Care Group. Mr. Taub holds an MBA at INSEAD. Currently, Robert is the Chairman of Aya Gold and Silver (TSX: AYA.TO).

**Dr. Jürgen Hambrecht**, Ph.D. served as a non-executive director from 2016 to 2017, and re-joined our Board of Directors in 2020. Dr. Hambrecht served BASF SE, a German company, in various responsibilities around the world for almost 45 years, lastly as CEO then Chairman of the Supervisory Board until 2020. He has been member of the Supervisory Boards of Daimler AG, Daimler Truck AG, Fuchs Petrolub SE, Trumpf SE, Bilfinger SE and Lufthansa AG a.o. Dr. Hambrecht is a member of the Board of Aya Gold & Silver Inc (TSX: AYA.TO). He earned his doctorate in Chemistry from the University of Tuebingen, Germany.

**Kevin Rakin** has served as a non-executive director since June 2016. Since October 2013, Mr. Rakin has been a co-founder and partner of HighCape Capital and he brings more than 30 years of experience as an executive and investor in the life sciences industry. He served as the President of Shire Regenerative Medicine, Inc. from June 2011 to November 2012. Mr. Rakin was the chairman and chief executive officer of Advanced BioHealing from 2007 until its acquisition by Shire in 2011. Before that, he served as an Executive-in-Residence at Canaan Partners, a venture capital firm. Until its merger with Clinical Data in 2005, Mr. Rakin was the co-founder, President and Chief Executive Officer of Genaissance Pharmaceuticals, Inc., a pharmacogenomics company. He is currently on the boards of a number of private companies as well as Aziyo Biologics, Inc. (NASDAQ: AZYO), where he serves as the chairman of the board, Oramed Pharmaceuticals, Inc (NASDAQ: ORMP) and Quantum-SI (NASDAQ: QSI). Mr. Rakin received an MBA from Columbia University and a B.Com. (Hons) from the University of Cape Town, South Africa.

**Rita Johnson-Mills** has served as a non-executive director since August 2021. Since January 2018, Ms. Johnson-Mills has been a founder and Chief Executive Officer of consulting firm RJM Enterprises and she brings a combined 30 years of direct health care experience from the federal, state and private industry, 15 years of which she was directly responsible for profitability and growth of healthcare organizations. She served as President and Chief Executive Officer of UnitedHealthcare Community Plan of Tennessee from August 2014 to December 2017, after having previously served as Senior Vice President, Performance Excellence and Accountability for UnitedHealthcare Community & State since 2006. Before that, she served as the Director of Medicaid Managed Care for the Centers for Medicare and Medicaid Services and as Chief Executive Officer of Managed Health Services Indiana and Buckeye Health Plan, wholly owned subsidiaries of Centene Corporation. She currently serves on the Board of Directors of Quest Analytics, LLC, Ellipsis Health Inc., and Ownes & Minor, Inc. and previously served on the Board of Directors of Brookdale Senior Living Inc. Ms. Johnson-Mills received dual Master's degrees from Ohio State University, Master of Public Policy and Master of Labor/Human Resources. She is also a Hogan certified executive coach and a National Association of Corporate Directors Governance Fellow.

**Virginia Kirby** has served as a non-executive director since June 8, 2022. Ms. Kirby is currently a consultant with Virginia M. Kirby Consulting, a strategic consulting company that provides advisory services in regulatory strategy and operations, and has served in such role since April 2013. Additionally, Ms. Kirby is an Executive-in-Residence for the Officer of Technology Commercialization, Discovery Launch Pad at the University of Minnesota, and has served in such role since March 2020. Prior to serving in such roles, she served as the Senior Vice President of Clinical and Regulatory Affairs for Huinno, Inc. from March 2016 to October 2017, the Vice President of Clinical and Regulatory Affairs at Apnex Medical, Inc. from 2007 to 2013, and the Vice President of Clinical Affairs and Reimbursement at both EnteroMedics, Inc. from 2005 to 2006, and at ev3, Inc. from 2003 to 2005. She also held various roles of increasing seniority at Medtronic, Inc. (NYSE: MDT) from 1997 to 2003, and at 3M Company (NYSE: MMM) from 1983 to 1996. Ms. Kirby currently serves as a member of the Board of Directors of the Minneapolis Heart Institute Foundation, a non-profit cardiovascular research and education foundation, and has served in such role since April 2021. Ms. Kirby received a Bachelor of Science degree in Speech and Hearing Science from the University of Minnesota, a Master of Science degree in Psychoacoustics/Audiology from Purdue University and a Master of Science degree in Management of Technology from the University of Minnesota, Carlson School of Management/Institute of Technology.

**Wildman Ventures LLC**, as represented by **Daniel Wildman**, has served as a non-executive director since January 8, 2023. Mr. Wildman is currently the President and Chief Executive Officer of Wildman Ventures, LLC, a strategic consulting company that provides advisory services to several medical device and pharmaceutical companies, and has served in such role since January 2019. Additionally, Mr. Wildman is the Chairman of the Board of Progenerative Medical, Inc., where he has served in such role since March 2022, and also currently serves as a Strategic Advisor for PanTher Therapeutics, Inc., where he has served in such role since February 2022. Prior to serving in such roles, Mr. Wildman served in various roles at Johnson & Johnson (NYSE: JNJ), or J&J, from 2000 to January 2019, where

he most recently led the Digital Surgery Strategy Initiative that developed an integrated strategy for robotic surgery. From 1990 to 2000, Mr. Wildman served in a variety of sales, marketing, operations and strategic planning roles at Boston Scientific Corporation (NYSE: BSX). Mr. Wildman has served as a member of the Board of Directors of Urogen Pharma, Ltd. (NASDAQ: URGN) since November 2022 and previously served as an Independent Director of Precision Healing, Inc. from June 2020 to April 2022. Mr. Wildman received a Bachelor of Arts degree in Economics from St. Lawrence University.

**Pierre Gianello**, M.D. has served as a non-executive director since 2018, and as a medical advisor to the Company since 2010. Dr. Gianello is the general coordinator of Research of the Health Sciences Sector at the Université Catholique de Louvain, Brussels, or UCL, and councilor of the vice-rector in research and international relationships between UCL and others international universities for student exchange at the UCL. In 1997, Dr. Gianello became head of the Laboratory of Experimental Surgery and Transplantation at Université Catholique de Louvain and in 2005, he obtained the title of full Professor. From 2006 to 2009, he served as Dean of Research and from 2009 to 2011 as Vice-Rector. Professor Gianello has received ten scientific awards, including the Horlait-Dapsens Foundation (1986), Association "Professor Jean Morelle" Award (1989), "Claude Simon" Award (1989), Eurolover Foundation Prize (2001), Saint-Luc "Foundation" (2012). He is the author of more than 200 published manuscripts in peer reviewed scientific journals. Dr. Gianello was awarded a Doctor in Medicine, Surgery and Obstetrics at the Université Catholique de Louvain (Belgium) and completed his post-doc training at the Massachusetts General Hospital, Harvard Medical School in the Transplant Biology Research Centre managed by Prof. David Sachs.

**Olivier Taelman** has served as an executive director since September 2020 and our Chief Executive Officer since November 2019. Mr. Taelman joined our company in July 2019 as Chief Operating and Commercial Officer. Prior to joining our Company, Mr. Taelman was Vice President Europe at Autonomic Technologies, Inc., a U.S. medical device company, where he focused on clinical, market access and commercialization of SPG Neuromodulation to treat patients with severe headache and developed strong relationships with global key opinion leaders and managed investor relations. Prior to that, Mr. Taelman was Business Director, Neuromodulation at Nevro, Corp. (NYSE: NVRO) a neuromodulation company, where he led the development of the company's European commercial structure. Prior to Nevro, Mr. Taelman served for 10 years in various roles at Medtronic plc (NYSE: MDT), leading the neuromodulation department in Western European countries. Mr. Taelman holds an executive MBA from the Wharton University and a bachelor's degree in Biology and Physics from Hasselt University.

## 2.2.2 Director Independence

In accordance with article 7:87 of the Belgian CCA, a director of a listed company is considered as independent if he does not entertain a relation with the Company or an important shareholder of the Company the nature of which could put his independence at risk. If the director is a legal entity, the independence must be assessed both in respect of the legal entity and its permanent representative. In order to verify if a candidate director fulfils those conditions, the independence criteria set out in provision 3.5 of the 2020 Code are applied, which can be summarized as follows:

- a) Not be an executive, or exercising a function as a person entrusted with the daily management of the company or a related company or person, and not have been in such a position for the previous three years before their appointment. Alternatively, no longer enjoying stock options of the company related to this position.
- b) Not have served for a total term of more than twelve years as a non-executive board member.
- c) Not be an employee of the senior management (as defined in article 19,2° of the law of September 20, 1948 regarding the organization of the business industry) of the company or a related company or person, and not have been in such a position for the previous three years before their appointment. Alternatively, no longer enjoying stock options of the company related to this position.

- d) Not be receiving, or having received during their mandate or for a period of three years prior to their appointment, any significant remuneration or any other significant advantage of a patrimonial nature from the company or a related company or person, apart from any fee they receive or have received as a non-executive board member.
- e) Not hold shares, either directly or indirectly, either alone or in concert, representing globally one tenth or more of the company's capital or one tenth or more of the voting rights in the company at the moment of appointment.
- f) Not having been nominated, in any circumstances, by a shareholder fulfilling the conditions covered under e).
- g) Not maintain, nor have maintained in the past year before their appointment, a significant business relationship with the company or a related company or person, either directly or as partner, shareholder, board member, member of the senior management (as defined in article 19, 2° of the law of September 20, 1948 regarding the organization of the business industry) of a company or person who maintains such a relationship.
- h) Not be or have been within the last three years before their appointment, a partner or member of the audit team of the company or person who is, or has been within the last three years before their appointment, the external auditor of the company or a related company or person.
- i) Not be an executive of another company in which an executive of the company is a non-executive board member, and not have other significant links with executive board members of the company through involvement in other companies or bodies.
- j) Not have, in the company or a related company or person, a spouse, legal partner or close family member to the second degree, exercising a function as board member or executive or person entrusted with the daily management or employee of the senior management (as defined in article 19, 2° of the law of September 20, 1948 regarding the organization of the business industry), or falling in one of the other cases referred to in a) to i) above, and as far as point b) is concerned, up to three years after the date on which the relevant relative has terminated their last term.

Jürgen Hambrecht, Kevin Rakin, Rita Johnson-Mills, Virginia Kirby and Wildman Ventures LLC (represented by Daniel Wildman) are the Company's independent directors.

The Company is of the view that the independent directors (including their permanent representatives, if applicable) comply with each of the criteria of the Belgian CCA and 2020 Code.

### 2.2.3 Committees within the Board of Directors

The Board of Directors has established four board committees, which are responsible for assisting the Board of Directors and making recommendations in specific fields: (a) the audit committee (in accordance with article 7:99 of the Belgian CCA and provisions 4.10 and following of the 2020 Code), (b) the remuneration committee (in accordance with article 7:100 of the Belgian CCA and provisions 4.17 and following of the 2020 Code), (c) the nominating and corporate governance committee (in accordance with provisions 4.19 and following of the 2020 Code) and (d) the science & technology committee. The terms of reference of these board committees are primarily set out in the Company's Corporate Governance Charter.

### ***Audit committee***

The audit committee consists of three directors. According to the Belgian CCA, all members of the audit committee must be non-executive directors, and at least one member must be independent within the meaning of provision 3.5 of the 2020 Code. The 2020 Code requires that a majority of the members of the audit committee are independent.

As at the date of this Annual Report, the following directors are the members of the audit committee: Kevin Rakin (chair), Jürgen Hambrecht and Wildman Ventures LLC (represented by Daniel Wildman), all independent non-executive directors.

The members of the audit committee must have a collective competence in the business activities of the Company as well as in accounting, auditing and finance, and at least one member of the audit committee must have the necessary competence in accounting and auditing. According to the Board of Directors, the members of the audit committee satisfy this requirement, as evidenced by the different senior management and director mandates that they have held in the past and currently hold.

The role of the audit committee is to:

- inform the Board of Directors of the result of the audit of the financial statements and the manner in which the audit has contributed to the integrity of the financial reporting and the role that the audit committee has played in that process;
- monitor the financial reporting process, and to make recommendations or proposals to ensure the integrity of the process;
- monitor the effectiveness of the internal control and risk management systems, and the Company's internal audit process and its effectiveness;
- monitor the audit of the financial statements, including the follow-up questions and recommendations by the statutory auditor;
- assess and monitor the independence of the statutory auditor, in particular with respect to the appropriateness of the provision of additional services to the Company. More specifically, the audit committee analyses, together with the statutory auditor, the threats for the statutory auditor's independence and the security measures taken to limit these threats, when the total amount of fees exceeds the criteria specified in article 4 §3 of Regulation (EU) No 537/2014; and
- make recommendations to the Board of Directors on the selection, appointment and remuneration of the statutory auditor of the Company in accordance with article 16 §2 of Regulation (EU) No 537/2014.

The audit committee meets at least four times a year.

### ***Remuneration committee***

The remuneration committee consists of at least three directors. In line with the Belgian CCA and the 2020 Code (i) all members of the remuneration committee are non-executive directors, (ii) the remuneration committee consists of a majority of independent directors and (iii) the remuneration committee is chaired by the chairperson of the Board of Directors or another non-executive director appointed by the committee.

As at the date of this Annual Report, the following directors are the members of the remuneration committee: Robert Taub (chair), Rita Johnson-Mills and Wildman Ventures LLC (represented by Daniel Wildman). Robert Taub is non-executive director and chairman of the Board of Directors. Rita Johnson-Mills and Wildman Ventures LLC (represented by Daniel Wildman) are both independent non-executive directors.

Pursuant to the Belgian CCA, the remuneration committee must have the necessary expertise in terms of remuneration policy, which is evidenced by the experience and previous roles of its current members.

The role of the remuneration committee is to make recommendations to the Board of Directors with regard to the remuneration of directors and members of the executive management and, in particular, to:

- make proposals to the Board of Directors on the remuneration policy of directors, the persons in charge of the management, and the persons in charge of the daily management, as well as, where applicable, the resulting proposals that the Board of Directors must submit to the general shareholders' meeting;
- make proposals to the Board of Directors on the individual remuneration of the directors, the other persons in charge of the management, and the persons in charge of day-to-day management, including variable remuneration and long-term performance premiums, whether or not tied to shares, in the form of stock options or other financial instruments, and of severance payments, and where applicable, the resulting proposals that the Board of Directors must submit to the general shareholders' meeting;
- prepare the remuneration report; and
- explain the remuneration report at the annual general shareholders' meeting.

The remuneration committee meets at least twice a year.

#### ***Nominating and corporate governance committee***

The nominating and corporate governance committee consists of at least three directors. In line with the 2020 Code (i) the nominating and corporate governance committee consists of a majority of independent directors and (ii) the nominating and corporate governance committee is chaired by the chairperson of the Board of Directors or another non-executive director appointed by the committee.

As at the date of this Annual Report, the following directors are the members of the nominating and corporate governance committee: Rita Johnson-Mills (chair), Robert Taub and Jürgen Hambrecht. Robert Taub is non-executive director and chairman of the Board of Directors. Jürgen Hambrecht and Rita Johnson-Mills are both independent non-executive directors.

The role of the nominating and corporate governance committee is to:

- make recommendations to the Board of Directors with regard to the appointment of directors and members of the executive management;
- make recommendations to the Board in relation to the assignment of responsibilities to the executives;
- prepare plans for the orderly succession of board members;
- lead the re-appointment process of board members;
- ensure that sufficient and regular attention is paid to the succession of executives;
- ensure that appropriate talent development programs and programs to promote diversity in leadership are in place.

The nominating and corporate governance committee meets at least twice a year.

### **Science & technology committee**

The science & technology committee consists of at least three directors.

The following directors are the members of the science & technology committee: Pierre Gianello (chair), Robert Taub and Virginia Kirby.

The role of science & technology committee is to assist the Board in all matters:

- relating to strategic direction of the Company's technology, research and product development programs;
- relating to monitoring and evaluating existing and future trends in technology that may affect the Company's strategic plans, including monitoring of overall industry trends;
- relating to the innovation and technology acquisition process to assure ongoing business growth;
- relating to IT risk management and cyber security strategy;
- relating to measurement and tracking systems in place to monitor the performance of the Company's technology in support of overall business strategy and to achieve successful innovation.

The science & technology committee meets at least twice a year.

## **2.2.4 Meetings of the Board and the committees**

### **Meetings of the Board of Directors**

In 2023, the Board of Directors held nine (9) meetings.

<b>Board members</b>	<b>3 Mar 2023</b>	<b>22 Mar 2023</b>	<b>23 Mar 2023</b>	<b>16 May 2023</b>	<b>26 Jun 2023</b>	<b>8 Aug 2023</b>	<b>25 Sep 2023</b>	<b>7 Nov 2023</b>	<b>13 Dec 2023</b>
Robert Taub	Present	Excused	Present	Present	Present	Present	Present	Present	Present
Jürgen Hambrecht	Present	Present	Present	Present	Present	Present	Present	Excused	Present
Kevin Rakin	Present	Present	Present	Present	Present	Present	Present	Present	Present
Rita Johnson-Mills	Present	Present	Present	Present	Present	Present	Present	Present	Present
Virginia Kirby	Present	Present	Present	Present	Present	Present	Present	Present	Present
Wildman Ventures LLC (Daniel Wildman) (1)	Present	Present	Present	Present	Present	Present	Present	Present	Present
Pierre Gianello	Present	Present	Present	Present	Present	Present	Present	Excused	Present
Olivier Taelman	Present	Present	Present	Present	Present	Present	Present	Present	Present

(1) board member as of January 8, 2023

**Meetings of the Board committees**

In 2023, the audit committee held four (4) meetings.

<b>Audit committee members</b>	<b>21 Mar 2023</b>	<b>15 May 2023</b>	<b>8 Aug 2023</b>	<b>6 Nov 2023</b>
Kevin Rakin (chair)	Present	Present	Present	Present
Jürgen Hambrecht	Present	Present	Present	Present
Wildman Ventures LLC (Daniel Wildman) (1)	Present	Present	Present	Present

(1) member as of January 8, 2023

In 2023, the remuneration committee held one (1) meeting.

<b>Remuneration committee members</b>	<b>2 Mar 2023</b>
Robert Taub (chair) (1)	Present
Rita Johnson-Mills	Present
Wildman Ventures LLC (Daniel Wildman) (2)	Present

(1) chair as of January 8, 2023

(2) member as of January 8, 2023

In 2023, the nominating and corporate governance committee held one (1) meeting.

<b>Nominating and corporate governance committee members</b>	<b>24 Apr 2023</b>
Robert Taub	Present
Jürgen Hambrecht	Present
Rita Johnson-Mills (chair)	Present

In 2023, the science & technology committee held three (3) meetings.

<b>Science &amp; technology committee members</b>	<b>2 Mar 2023</b>	<b>15 Jun 2023</b>	<b>25 Sep 2023</b>
Robert Taub	Present	Present	Present
Virginia Kirby	Present	Present	Present
Pierre Gianello (chair)	Present	Present	Present



## 2.3 Executive Management

The executive management is charged with running the Company in accordance with the values, strategies, policies, plans and budgets endorsed by the Board. The executive management has all powers except for the determination of the Company's strategy, the supervision of the executive management, and the powers reserved to the Board of Directors and the general shareholders' meeting by law, the Articles of Association and the Company's Corporate Governance Charter.

The executive management shall meet at least once a month.

At the date of this Annual Report, the executive management of the Company consists of the following members:

Name	Position
Olivier Taelman	CEO
Loïc Moreau	CFO

The Chief Executive Officer is responsible for the day-to-day management of the Company. He may be granted additional well-defined powers by the Board of Directors. He has direct operational responsibility for the Company and oversees the organization and day-to-day management of subsidiaries, affiliates and joint ventures. The Chief Executive Officer is responsible for the execution and management of the outcome of all decisions of the Board of Directors.

The Chief Executive Officer leads the executive management within the framework established by the Board of Directors and under its ultimate supervision. The Chief Executive Officer is appointed and removed by the Board of Directors and reports directly to it.

The following paragraphs contain brief biographies of the current members of the executive management or in case of a legal entity being a member of executive management, its permanent representative.

**Olivier Taelman** – Reference is made to section 2.2.1.

**Loïc Moreau** has served as our Chief Financial Officer since January 2022. From 2009 through 2021, he held various senior roles at GlaxoSmithKline plc. (GSK), including roles in Mergers and Acquisitions, Corporate Development and Country-Chief Financial Officer across different geographies. Prior to GSK, Mr. Moreau built his career at Ernst & Young Global Limited (External Audit) and PricewaterhouseCoopers (Corporate Finance). Mr. Moreau holds an Executive Master from the École Supérieure des Sciences Commerciales d'Angers School of Management, France, and a Master of Finance from Solvay University, Belgium.

## 2.4 Conflicts of Interest

Directors and members of executive management are expected to arrange their personal and business affairs so as to avoid conflicts of interest with the Company. Any director with a conflicting financial interest (as contemplated by article 7:96 of the Belgian CCA) on any matter before the Board of Directors must bring it to the attention of the fellow directors, and take no part in any deliberation or voting related thereto. The Corporate Governance Charter contains the procedure for transactions between the Company and directors or members of executive management which are not covered by the legal provisions on conflicts of interest.

In 2023, two conflicts of interests were declared, as set out below.

**Extract from the written resolutions of the Board of Directors dated February 13, 2023:**

"Prior to the circulation of these written resolutions, Mr. Olivier Taelman declared to the Board that he has a conflict of interest in the sense of article 7:96 CCA. Since Mr. Olivier Taelman is a director of the Company and, in that capacity, has an direct interest of a financial nature in relation to item 1 on the agenda pursuant to which his performance-based bonus for 2022 will be determined, he cannot vote on this item on the agenda and will sign these written resolutions for acknowledgement only as regards that item on the agenda.

The other members of the Board declare by signing these written resolutions that they have no financial interest that directly or indirectly conflicts with decisions to be taken by the Board, in the sense of article 7:96 CCA.

**Context**

Reference is made to a meeting of the remuneration committee of the Company held on 2 January 2023, where the performance of Mr. Olivier Taelman and Mr. Loïc Moreau, in their capacity of CEO and CFO of the Company, respectively, was discussed to determine the amount of their performance-based bonus in relation to financial year 2022. The remuneration committee proposed to determine the performance-based bonuses of Mr. Olivier Taelman and Mr. Loïc Moreau as further detailed in the documents attached hereto in Schedule 1 (Proposal bonus to Mr. Olivier Taelman) and Schedule 2 (Proposal bonus to Mr. Loïc Moreau).

**Decisions**

1. Determining the performance-based bonus to Mr. Olivier Taelman in relation to financial year 2022

Mr. Olivier Taelman does not vote on this item and signs these written resolutions for acknowledgement only as regards this item.

Upon the recommendation of the remuneration committee, the Board resolved that the performance based bonus for Mr. Olivier Taelman in relation to financial year amounts to EUR 153,000, as further detailed in Schedule 1 (Proposal bonus to Mr. Olivier Taelman)."

**Extract from the written resolutions of the Board of Directors dated March 24, 2023:**

"Prior to the circulation of these written resolutions:

- Olivier Taelman (director and CEO of the Company) declared to the Board that he has a conflict of interest of a financial nature in the sense of article 7:96 CCA in relation to the proposed re-pricing of warrants previously granted under the 2021 Warrants Plan (item 1 of the agenda) and the proposed grant of warrants under the 2021 Warrants Plan (item 3 of the agenda). Therefore, he cannot vote on items 1 and 3 of the agenda and will sign these written resolutions for acknowledgement only with regard to these items on the agenda.

- The other directors discussed and acknowledged that they are of the opinion that the proposed re-pricing of 75% of the warrants previously granted to Olivier Taelman under the 2021 Warrants Plan and the proposed grant of 25,000 additional warrants under the 2021 Warrant Plan to Olivier Taelman, in both cases at a (revised) exercise price set in accordance with clause 4.3.1 of the 2021 Warrants Plan<sup>1</sup> is justified and in the interest of the Company (a) in view of Olivier Taelman's role within the Company and the efforts that are requested from him, and (b) because upon the exercise of warrants, Olivier Taelman will have to pay an exercise price for the warrants in cash to the Company, which will increase the Company's net equity and liquidities.

The other members of the Board declare by signing these written resolutions that they have no financial interest that directly or indirectly conflicts with decisions to be taken by the Board, in the sense of Article 7:96 CCA.

### **Resolutions**

1. Re-pricing of warrants previously granted under the 2021 Warrants Plan to the CEO and determination of the exercise price and of other terms and conditions of the re-priced warrants
  - Approval of the re-pricing of 75% of the warrants previously granted to Olivier Taelman under the 2021 Warrants Plan to the lowest of (a) the last closing price of the Company's share on Euronext Brussels prior to the effective date of these resolutions, and (b) the average closing price of the Company's share on Euronext Brussels over the thirty (30) day period preceding the effective date of these resolutions (in accordance with clause 4.3.1 of the 2021 Warrants Plan).  
For the remaining 25% of the warrants previously granted to Olivier Taelman, the exercise price will remain unchanged.
  - Approval that, for the re-priced warrants, the exercise restriction provided for in the relevant warrant agreement stipulating that the warrants can only be exercised prior to the fifth anniversary of the date on which the warrants were granted, will be modified to stipulate that the warrants can only be exercised prior to the fifth anniversary of the date of the re-pricing (i.e. the effective date of these resolutions).
  - Confirmation that all other terms and conditions of the re-priced warrants will remain unchanged.
2. (...)
3. Grant of warrants under the 2021 Warrants Plan to the CEO and determination of the exercise price and of other terms and conditions of the granted warrants
  - Approval of the grant of 25,000 warrants under the 2021 Warrants Plan to Olivier Taelman.
  - Determination of the exercise price of the granted warrants at the lowest of (a) the last closing price of the Company's share on Euronext Brussels prior to the effective date of these resolutions, and (b) the average closing price of the Company's share on Euronext Brussels over the thirty (30) day period preceding the effective date of these resolutions (in accordance with clause 4.3.1 of the 2021 Warrants Plan).
  - Confirmation that the other terms and conditions of the granted warrants shall be in accordance with the 2021 Warrants Plan."

## 2.5 Related Party Transactions

In 2023, no announcements were made pursuant to article 7:97, §4/1 of the Belgian CCA in respect of related party transactions.

## 2.6 Deviations from the Belgian Code on Corporate Governance

The Company applies the ten corporate governance principles contained in the 2020 Code and complies with the corporate governance provisions set forth in the 2020 Code, except in relation to the following:

- 1 In deviation of provision 4.14 of the 2020 Code, no independent internal audit function has been established. This deviation is explained by the size of the Company. The Audit Committee will regularly assess the need for the creation of an independent internal audit function and, where appropriate, will call upon external persons to conduct specific internal audit assignments and will inform the Board of Directors of their outcome.
- 2 In the past, including in 2023, share options have been granted to non-executive directors and the Company does not exclude to award share-based incentives to the non-executive directors, upon advice of the remuneration committee, in the future. This is contrary to provision 7.6 of the 2020 Code that provides that no stock options should be granted to non-executive board members. The Company believes that this provision of the 2020 Code is not appropriate and adapted to take into account the realities of companies in the life sciences industry that are still in a development phase. Notably, the ability to remunerate non-executive directors with share options allows the Company to limit the portion of remuneration in cash that the Company would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. The Company is of the opinion that granting non-executive directors the opportunity to be remunerated in part in share-based incentives rather than all in cash strengthens the alignment of their interests with the interests of the Company's shareholders. This is in the interest of the Company and its stakeholders. Furthermore, this is customary for directors active in companies in the life sciences industry.
- 3 In deviation of provision 7.6 of the 2020 Code, the non-executive members of the Board of Directors do not systematically receive part of their remuneration in the form of shares. This deviation is explained by the fact that the interests of the non-executive members of the Board of Directors are considered to be sufficiently oriented to the creation of long-term value for the Company, taking into account that some of them will from time to time hold shares or share options, the value of which is based on the value of the shares. Therefore, the (regular) payment in the form of existing shares is not deemed necessary.
- 4 Pursuant to article 7:91 of the Belgian CCA and provisions 7.6 and 7.11 of the 2020 Code, shares should not vest and share options should not be exercisable within three years as of their granting. The Company's Board of Directors has been explicitly authorized in the Company's Articles of Association to deviate from this rule in connection with stock based incentive plans, compensations, awards and issuances to employees, directors and service providers of the Company and/or its subsidiaries (from time to time). The Company is of the opinion that this allows for more flexibility when structuring share-based awards.
- 5 In deviation of provision 7.9 of the 2020 Code, no minimum threshold of shares to be held by members of the executive management team is set. This deviation is explained by the fact that the interests of the members of the executive management team are considered to be sufficiently oriented to the creation of long-term value for the Company, taking into account that some of them will from time to time hold shares or share options, the value of which is based on the value of the shares. Therefore, setting a minimum threshold of shares to be held by them is not deemed necessary.

6 In deviation of provision 7.12 of the 2020 Code, the board of directors does not include, in the contracts with the CEO and other members of executive management, provisions that would enable the Company to recover variable remuneration paid, or withhold the payment of variable remuneration, and specify the circumstances in which it would be appropriate to do so, insofar as enforceable by law. The Company believes that this provision of the 2020 Code is not appropriate and adapted to take into account the realities of companies in the life sciences industry that are still in a development phase nor considers that it is necessary, except as provided in the Company's Clawback Policy pursuant to applicable U.S. securities laws, to apply claw-back provisions as (i) the pay-out of the short-term variable remuneration, based on the achievement of one or more individual objectives and one or more Company objectives as set by the board of directors, is paid only upon achievement of those objectives, and (ii) the Company does not apply any other performance-based remuneration or variable compensation. Furthermore, the ESOP warrant plans set up by the Company contain bad leaver provisions that can result in the unexercised share options, whether vested or not, automatically and immediately becoming null and void if the agreement or other relationship between the holder and the (relevant subsidiary of the) Company is terminated for "cause". Notwithstanding the Company's position that warrants are not to be qualified as variable remuneration (when not depending on performance criteria), the board of directors is of the opinion that such bad leaver provisions sufficiently protect the Company's interests and that it is therefore currently not necessary to provide for additional contractual provisions that give the Company a contractual right to reclaim any (variable) remuneration from the members of the executive management. For those reasons, there are no contractual provisions in place between the Company and the members of the executive management that give the Company a contractual right to reclaim from said executives any variable remuneration that would be awarded.

## 2.7 Diversity policy

The Company has not adopted a diversity policy. This is explained by the size of the Company. As the Company will grow and become more mature over time, the Board will assess whether and when it will be deemed appropriate to adopt a diversity policy.

As far as gender diversity is concerned, one fourth of the members of the Company's management team are women and, as of December 31, 2023, 49% of the total work force of the Company were women.

At the level of the Board of Directors, two of our eight board members are currently female. By January 1, 2026, at least one third of the members of the Board of Directors must be of the opposite gender. The Board (and in particular the nominating and corporate governance committee within the Board) will take appropriate action to ensure to timely comply with this requirement.

## 2.8 Remuneration report

### 2.8.1 Introduction

In line with the Company's remuneration policy, non-executive directors receive a fixed annual remuneration in cash in consideration for their membership of the Board of Directors, regardless of the number of meetings that are held in a certain year. In addition, non-executive directors who are members of one or more committees of the Board of Directors may receive a fixed annual remuneration for their membership of such committee(s).

Non-executive directors do not receive a variable remuneration in cash. They may receive share-based remuneration in the form of a grant of warrants. In addition, the Company may from time to time offer non-executive directors the opportunity to subscribe to newly issued shares in the Company at a subscription price that may be substantially lower than the market value of the shares at that time, subject to conditions as set out in the Company's remuneration policy.

Finally, non-executive directors are entitled to reimbursement of reasonable out-of-pocket expenses (including travel and hotel expenses).

Executive directors do not receive any remuneration in consideration for their membership of the Board of Directors. They will receive remuneration as members of the executive management.

Board fees applicable to 2023 are included in the tables below.

Directors		
Remuneration component	Short description of main provisions	
Base remuneration	Chairperson of the Board – Non-executive director	Annual fixed fee of €82,000
	Non-executive directors	Annual fixed fee of €45,000
	Chairperson of the audit committee	Annual fixed fee of €18,000
	Members of the audit committee	Annual fixed fee of €9,000
	Chairpersons of the remuneration committee, the nominating and corporate governance committee and the science & technology committee	Annual fixed fee of €9,000
	Members of the remuneration committee, the nominating and corporate governance committee and the science & technology committee	Annual fixed fee of €4,500
	Executive directors	Not remunerated for mandate as executive director; remunerated as member of executive management
Fringe benefits	Non-executive directors	Reimbursement of reasonable out-of-pocket expenses (including travel and hotel expenses)

The remuneration of the members of executive management consists of three main elements: (a) a fixed annual base remuneration, (b) a short-term variable remuneration (or short-term incentive, "STI") consisting of a cash bonus, and (c) a long-term incentive ("LTI") consisting of warrants.

The target proportion of these three elements is: 1/3 fixed base remuneration, 1/3 STI and 1/3 LTI.

More detail regarding the remuneration of the members of executive management is out in the table below.

#### Members of executive management

Remuneration component	Short description of main provisions
Base remuneration	Fixed amount
Fringe benefits	Company car, laptop, phone, representation allowance
Age and risk provisions	Pension plan (fixed contribution); health insurance; life insurance (CEO only)
Short term incentive (STI)	Yearly performance bonus, as further detailed below
Long term incentive (LTI)	Participation in share option plans, as further detailed below

#### Short term incentive plan: yearly performance bonus

Main provisions	Short description
Performance cycle	One calendar year
Target bonus	NA
Performance criteria and corresponding payout levels	<p>One or more individual or Company performance criteria (objectives) are determined. For each objective, a target and corresponding payout level are determined:</p> <ul style="list-style-type: none"> <li>• If objective is 100% achieved: full payout of targeted payout level</li> <li>• If objective is achieved &lt;75%: in principle no payout (but Board can decide otherwise)</li> <li>• If objective is achieved &gt;75% and &lt;125%: payout between 75% and 125%, based on linear calculation</li> <li>• If objective is achieved &gt;125%: board can decide payout &gt;125%</li> </ul>
Calculation of bonus	The total bonus is composed of the sum of the payout levels related to the various performance criteria (if more than one)
Payment modalities	Payment in cash or equivalent (but not in Company warrants) 100% of the bonus is paid at once

**Long term incentive plan: share option plans**

Main provisions	Short description
Frequency of offer	No pre-set frequency
Performance cycle	NA
Target number of offered share options	NA
Exercise price	Value of underlying shares at date of offer of share options
Exercise period	Five years from date of offer of share options
Performance criteria and corresponding offering levels	NA
Calculation of number of offered share options	NA
Vesting	<p>Options issued prior to 2021: vesting in three tranches:</p> <ul style="list-style-type: none"> <li>• 1/3 of offered share options vests upon offer</li> <li>• 1/3 of offered share options vests on first anniversary of offer</li> <li>• 1/3 of offered share options vests on second anniversary of offer</li> </ul> <p>Options issued since 2021: vesting in four tranches:</p> <ul style="list-style-type: none"> <li>• 1/4 of offered share options vests upon offer</li> <li>• 1/4 of offered share options vests on first anniversary of offer</li> <li>• 1/4 of offered share options vests on second anniversary of offer</li> <li>• 1/4 of offered share options vests on third anniversary of offer</li> </ul>
Retention	NA

As the Company only became a listed company in September 2020, and therefore the obligation to draw up a remuneration report pursuant to Article 3:6, §3 CCA (as amended effective as of May 16, 2020) was not applicable to the Company before such time, the Company does not have readily available the information for the financial years prior to 2020. Hence, in this remuneration report, only a comparison to 2020, 2021 and 2022 is made. As from next year, the remuneration report will include information relating to additional years prior to the reported year (with a maximum of five years prior to the reported year and with the year 2020 being the earliest year in the comparison).



## 2.8.2 Total remuneration

### Total remuneration of the directors

Table 1 - Total remuneration directors

Name, position	Fixed remuneration			Variable remuneration				Total remuneration (f)	Proportion of fixed and variable remuneration	
	Base remuneration	Attendance fees	Fringe benefits	One-year variable	Multi-year variable (e)	Extra-ordinary items	Pension expense			
Robert Taub Non-executive director, Chairman	100 000 <sup>(a)</sup>	0	27 633 <sup>(c)</sup>	0	0	0	0	127 633	Fixed: 100%	Variable: 0%
Jürgen Hambrecht Non-executive director	58 500 <sup>(a)</sup>	0	0	0	0	0	0	58 500	Fixed: 100%	Variable: 0%
Kevin Rakin Non-executive director	63 000 <sup>(a)</sup>	0	5 593 <sup>(c)</sup>	0	0	0	0	68 593	Fixed: 100%	Variable: 0%
Rita Johnson-Mills Non-executive director	58 500 <sup>(a)</sup>	0	5 121 <sup>(c)</sup>	0	0	0	0	63 621	Fixed: 100%	Variable: 0%
Virginia Kirby Non-executive director	49 500 <sup>(a)</sup>	0	9 718 <sup>(c)</sup>	0	0	0	0	59 218	Fixed: 100%	Variable: 0%
Wildman Ventures LLC Non-executive director	58 500 <sup>(a)</sup>	0	12 778 <sup>(c)</sup>	0	0	0	0	71 278	Fixed: 100%	Variable: 0%
Pierre Gianello - Employee	110 447 <sup>(b)</sup>	0	567 <sup>(d)</sup>	0	0	0	0	111 014		
- Non-executive director	54 000 <sup>(a)</sup>	0	10 620 <sup>(c)</sup>	0	0	0	0	64 620		
Pierre Gianello TOTAL	164 447	0	11 187	0	0	0	0	175 634	Fixed: 100%	Variable: 0%
Olivier Taelman (*) Executive director, CEO	0	0	0	0	0	0	0	0		

Notes:

(\*)Olivier Taelman is not remunerated for the performance of his mandate as executive director as such; he is remunerated as member of the executive committee (see below).

(a) Fixed board fees composed as set out in the following table:

2023 board fees											
	Chair of the board	Non-executive director	AC chair	AC member	RC chair	RC member	NCGC chair	NCGC member	STC chair	STC member	Total
Robert Taub	82 000				9 000			4 500		4 500	100 000
Jürgen Hambrecht		45 000		9 000				4 500			58 500
Kevin Rakin		45 000	18 000								63 000
Rita Johnson-Mills		45 000				4 500	9 000				58 500
Virginia Kirby		45 000								4 500	49 500
Wildman Ventures LLC		45 000		9 000		4 500					58 500
Pierre Gianello		45 000							9 000		54 000

**Key:**

AC = Audit committee

RC = Remuneration committee

NCGC = Nominating and corporate governance committee

STC = Science & technology committee

(b) Salary pursuant to employment agreement between Pierre Gianello and the Company for the role of Pierre Gianello as medical director of the Company one day per week.

(c) Fringe benefits consist of the reimbursement of out-of-pocket expenses (mostly travel related).

(d) Meal vouchers.

(e) The "multi-year variable" remuneration corresponds to the "surplus value" as calculated in Table 4 below. Where the surplus value is negative, the multi-year variable remuneration is deemed zero.

(f) The numbers included in this column may differ from the numbers included in Note 32.2 to the Consolidated Financial Statements due to accounting rules applied for purposes of the Consolidated Financial Statements.

## Total remuneration of the members of executive management

Table 2 - Total remuneration members of executive management (\*)

Name, position	Fixed remuneration			Variable remuneration				Total remuneration	Proportion of fixed and variable remuneration	
	Base remuneration	Attendance fees	Fringe benefits (a)	One-year variable (b)	Multi-year variable (c)	Extra-ordinary items	Pension expense (d)			
Olivier Taelman CEO	436 351	NA	36 057	301 500	23 996	0	33 188	831 092	Fixed: 60.84%	Variable: 39.16%
Loïc Moreau CFO	258 877	NA	10 253	183 807	0	0	15 750	468 687	Fixed: 60.78%	Variable: 39.22%

Notes:

- (\*) The numbers included in this table may differ from the numbers included in Note 32.1 to the Consolidated Financial Statements due to accounting rules applied for purposes of the Consolidated Financial Statements.
- (a) Fringe benefits consist of: company car, laptop, mobile phone, representation allowance, health insurance, life insurance (CEO only), sectoral premium and eco-vouchers (CFO only) and meal vouchers.
- (b) The "one-year variable" remuneration corresponds to the yearly performance bonus as detailed in Table 3 below.
- (c) The "multi-year variable" remuneration corresponds to the "surplus value" as calculated in Table 4 below. Where the surplus value is negative, the multi-year variable remuneration is deemed zero.
- (d) Defined contribution pension plan.

## Table with notes regarding the performance

Table 3 - Performance (one-year variable remuneration)

	Description of performance criteria and type of applicable remuneration	Relative weight of performance criteria	a) Measured performance b) Corresponding remuneration (EUR)	
Olivier Taelman CEO	Company objectives: operational	55%	a) 49%	b) 121 275
	Company objectives: strategic/financial	45%	a) 89%	b) 180 225
	<b>Total</b>			<b>301 500</b>
Loïc Moreau CFO	Company objectives: operational/ strategic/financial	50%	a) 67%	b) 86 726
	Finance objectives	50%	a) 75%	b) 97 081
	<b>Total</b>			<b>183 807</b>

## 2.8.3 Share based remuneration

Table 4 - Remuneration in share options

Name, position	Main conditions of the share option plans						Information regarding the reported financial year			
							Opening balance	During the year		Closing balance
	Identifi- cation of the plan	Date of offer	Date of vesting of last tranche	End of holding period	Exercise period (from - to)	Exercise price	Number of share options held but not yet vested at the beginning of the year	a) Number of share options offered b) Value of underlying shares @ date of offer	a) Number of share options vested b) Value of underlying shares @ date of vesting c) Value @ exercise price d) Surplus value @ date of vesting	Share options not yet vested
Robert Taub Non- executive director, Chairman	ESOP 2021	8 Jun 2022	14 Jun 2023	NA	14 Jun 2023 8 Jun 2027	12.95	25 000	a)0 b)0	a)25 000 b)177 500 c)323 750 d)-146 250	0
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7.19	0	a)25 000 b)177 500	a)0 b)0 c)0 d)0	25 000
Jürgen Hambrecht Non- executive director	ESOP 2021	8 Jun 2022	14 Jun 2023	NA	14 Jun 2023 8 Jun 2027	12.95	25 000	a)0 b)0	a)25 000 b)177 500 c)323 750 d)-146 250	0
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7.19	0	a)25 000 b)177 500	a)0 b)0 c)0 d)0	25 000
Kevin Rakin Non- executive director	ESOP 2021	8 Jun 2022	14 Jun 2023	NA	14 Jun 2023 8 Jun 2027	12.95	25 000	a)0 b)0	a)25 000 b)177 500 c)323 750 d)-146 250	0
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7.19	0	a)25 000 b)177 500	a)0 b)0 c)0 d)0	25 000
Rita Johnson- Mills Non- executive director	ESOP 2021	8 Jun 2022	14 Jun 2023	NA	14 Jun 2023 8 Jun 2027	12.95	25 000	a)0 b)0	a)25 000 b)177 500 c)323 750 d)-146 250	0
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7.19	0	a)25 000 b)177 500	a)0 b)0 c)0 d)0	25 000

<b>Virginia Kirby</b> Non-executive director	ESOP 2021	8 Jun 2022	14 Jun 2023	NA	14 Jun 2023 8 Jun 2027	12.95	25 000	a)0 b)0	a)25 000 b)177 500 c)323 750 d)-146 250	0
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7.19	0	a)25 000 b)177 500	a)0 b)0 c)0 d)0	25 000
<b>Wildman Ventures LLC</b> Non-executive director	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7.19	0	a)11 398 b)80 926	a)0 b)0 c)0 d)0	11 398
	ESOP 2022	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7.19	0	a)13 602 b)96 574	a)0 b)0 c)0 d)0	13 602
<b>Pierre Gianello</b> Non-executive director	ESOP 2021	8 Jun 2022	14 Jun 2023	NA	14 Jun 2023 8 Jun 2027	12.95	25 000	a)0 b)0	a)25 000 b)177 500 c)323 750 d)-146 250	0
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7.19	0	a)25 000 b)177 500	a)0 b)0 c)0 d)0	25 000
<b>Olivier Taelman</b> CEO	ESOP 2021	17 Sep 2021	17 Sep 2024	NA	17 Sep 2024 17 Sep 2026	25.31	8 310	a)0 b)0	a)0 b)0 c)0 d)0	8 310
	ESOP 2021	17 Sep 2021	17 Sep 2023	NA	17 Sep 2021 24 Mar 2028	5.42 (*)	8 310	a)0 b)0	a)8 310 b)61 162 c)45 040 d)16 121	0
	ESOP 2021	24 Mar 2023	24 Mar 2026	NA	24 Mar 2023 24 Mar 2028	5.42	0	a)25 000 b)167 000	a)6 250 b)41 750 c)33 875 d)7 875	18 750
<b>Loïc Moreau</b> CFO	ESOP 2021	21 Feb 2022	21 Feb 2025	NA	21 Feb 2022 24 Mar 2028	5.42 (*)	22 500	a)0 b)0	a)7 500 b)34 950 c)40 650 d)-5 700	15 000
	ESOP 2021	21 Feb 2022	21 Feb 2026	NA	21 Feb 2025 21 Feb 2027	17.76	15 000	a)0 b)0	a)0 b)0 c)0 d)0	15 000
	ESOP 2021	21 Feb 2022	21 Feb 2024	NA	21 Feb 2023 24 Mar 2028	5.42 (**)	15 000	a)0 b)0	a)7 500 b)34 950 c)40 650 d)-5 700	7 500
	ESOP 2021	24 Mar 2023	24 Mar 2026	NA	24 Mar 2023 24 Mar 2028	5.42	0	a)15 284 b)102 097	a)3 821 b)25 524 c)20 710 d)4 814	11 463

(\*) The initial exercise price was EUR 25,31. The exercise price was reset to EUR 5,42 on March 24, 2023.

(\*\*) The initial exercise price was EUR 17,76. The exercise price was reset to EUR 5,42 on March 24, 2023.

In addition to the information included in Table 4 above, during 2023:

- None of the directors or members of executive management exercised any share options, and
- No share options held by any of the directors or members of executive management expired.

The Company does not facilitate the entering into of derivative contracts related to share options, nor does the Company cover any risks related to share options.

The key features of the various share option plans are largely the same, and can be summarized as follows:

- Form of share options: registered form.
- Transfer of share options: unless the Board of Directors determines otherwise, the share options cannot be sold, assigned, transferred, pledged or otherwise encumbered by the holder of the share options.
- Number of shares to be issued upon exercise of share option:
  - ESOP 2018: each share option can be exercised for 500 new shares, taking into account the share split at a 500:1 ratio that was decided by an extraordinary shareholders' meeting on February 21, 2020.
  - ESOP 2020/ESOP 2021/ESOP 2022: each share option can be exercised for one new share.
- Stock split: in the event of a stock split of the shares, the number of shares to be issued upon the exercise of the share options shall be adjusted accordingly.
- Duration of the share options:
  - Ten years as of their issuance.
  - Contractual expiration period of five years as of the grant, which period shall in no case exceed the ten year period as from issuance.
- Vesting of share options:
  - ESOP 2018/ESOP 2020: unless the Board of Directors determines otherwise: vesting in three tranches: 1/3 of the share options granted vests upon the date of grant, 1/3 vests on the first anniversary date of the relevant share option agreement, 1/3 vests on the second anniversary date of the relevant share option agreement.
  - ESOP 2021/ESOP 2022: unless the Board of Directors determines otherwise: vesting in four tranches: 1/4 of the share options granted vests upon grant, 1/4 vests on the first anniversary of the grant, 1/4 vests on the second anniversary of the grant, 1/4 vests on the third anniversary of the grant.
  - ESOP 2021 granted to directors on June 8, 2022 and on June 14, 2023: vesting in one tranche: all share options granted vest on the first anniversary of the grant.
- Exercise of share options:
  - ESOP 2018/ESOP 2020/ESOP 2021/ESOP 2022: vested share options can be exercised during the following exercise periods: (i) March 1 until June 30; and (ii) September 1 until November 30 of each year during which the share options are valid and exercisable.
- Consequence of termination of relationship between the holder of the share options and the Company: the exercise period and/or vesting period of the share options may vary depending on the circumstances under which the relationship between the holder and the Company is terminated.
- Governing law of the terms and conditions of the share options: laws of Belgium.

#### 2.8.4 Severance payment

During 2023, no severance payments were due or paid to any director or member of executive management.

#### 2.8.5 Use of the right to reclaim

The Company does not have any right to reclaim variable remuneration, hence the Company did not use such right in 2023.

#### 2.8.6 Derogations from the remuneration policy

During 2023, no derogations were made from the Company's remuneration policy.

#### 2.8.7 Evolution of the remuneration and the performance of the Company

As set out in the introduction of this remuneration report, the Company does not have readily available the information related to previous financial years prior to 2020. Therefore, this remuneration report includes the information related to 2023, 2022, 2021 and 2020 only. Going forward, the remuneration report will each year include information relating to one additional previous year (with a maximum of five years prior to the reported year and with the year 2020 being the earliest year in the comparison).

#### **Yearly remuneration of the directors and the members of executive management**

<b>Yearly remuneration (*)</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>
<b>Non-executive directors</b>				
Total remuneration (all non-executive directors collectively) (**)	383 654	304 097	421 710	552 447
<b>Members of executive management</b>				
Fixed remuneration (all members of executive management collectively)	516 473	673 152	736 223	790 476
Variable remuneration (all members of executive management collectively) (***)	1 666 010	287 381	212 000	509 303
Total remuneration (all members of executive management collectively)	2 182 483	960 533	948 223	1 299 779

(\*) The information in this table is derived from the information in this section 2.8 ("Remuneration report").

(\*\*) The total remuneration for 2020 comprises: board fees (annualized for directors who were only entitled to receive board fees as from September 21, 2020), fee pursuant to consultant agreement between MINV SA and the Company, and salary pursuant to employment agreement between Pierre Gianello and the Company. The total remuneration for 2021, 2022 and 2023 comprises: board fees paid to directors (excluding, for the avoidance of doubt, reimbursement of out-of-pocket expenses) and salary pursuant to employment agreement between Pierre Gianello and the Company.

(\*\*\*) In addition, in 2021, Fabian Suarez Gonzalez (acting via ActuaRisk Consulting SRL) received an extraordinary variable compensation in the amount of €3,709,285.99 triggered by the Company's IPO on Euronext Brussels in September 2020.

**Yearly performance of the Company**

<b>Company performance</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>
Financial performance criteria (number out of total performance criteria)	0/2	1/6	1/5	2/6
Non-financial performance criteria (number out of total performance criteria)	2/2	5/6	4/5	4/6
Net profit (net loss) (consolidated) (KEUR)	(12 245)	(27 619)	(31 225)	(43 212)

**Yearly average remuneration of the employees of the Company**

<b>Average remuneration of employees on a full-time equivalent basis</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>
Employees of the consolidated group	86 550	90 799	111 699	120 419

The average remuneration is calculated as follows:

- Excluded from the calculation: directors (including the salary of Pierre Gianello in his capacity of employee of the Company, as this salary is included in the "yearly remuneration of the directors and the members of executive management"; see table above) and members of executive management.
- Based on the gross salary of employees (incl. bonuses, holiday pay, remuneration in kind, car allowance, as applicable) and the invoiced amounts (excl. VAT) of staff members who work through a management company.
- For employees/other staff members who do not work on a full-time basis, their salary/remuneration was prorated as if they were working full-time.
- For employees/other staff members who did not work a full year, their salary/remuneration was prorated as if they had been working the full year.

**Ratio highest and lowest remuneration**

<b>Ratio highest remuneration / lowest remuneration</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>
Highest remuneration of the members of executive management (*)	1 913 149	730 533	631 184	831 092
Lowest remuneration (in full-time equivalent) of the employees	30 587	27 645	21 639	39 910
Ratio highest remuneration / lowest remuneration	62.55	26.43	29.17	20.82

(\*) For 2021, not taking into account the extraordinary variable compensation received by Fabian Suarez Gonzalez (acting via ActuaRisk Consulting SRL) in the amount of €3,709,285.99 triggered by the Company's IPO on Euronext Brussels in September 2020.



## 2.9 Description of the principal risks associated with the activities of the Company

The principal risks associated with the Company's business include (without being limited to) the risks described below.

### 2.9.1 Risks related to our financial position

***We have a limited operating history, have incurred losses in each period since our inception and may not be able to achieve or maintain profitability in the future.***

We were incorporated in 2009, obtained certification (CE-Mark) for our Genio system in March 2019, and had our first commercial sales in Germany in July 2020. In 2023 we generated €4.3 million of sales from the Genio system compared to €3.1 million in 2022. We have incurred operating losses and negative operating cash flows in each period since we were incorporated in 2009, including operating losses of €45.1 million and €32.5 million and negative operating cash flows of €44.8 million and €28.8 million for each of the years ended December 31, 2023 and December 31, 2022, respectively. As of December 31, 2023, we had an accumulated deficit of €160.8 million. These losses have resulted primarily from costs incurred in the development of our Genio system, as well as from general and administrative costs associated with our operations and manufacturing.

We expect that our operating expenses will continue to increase as we fund the continued development of our technology and the Genio product line, seek to expand manufacturing and sales and marketing capabilities, seek further regulatory clearances, certifications, approvals and marketing authorizations, particularly in the United States, for the Genio system, and as we incur the additional costs associated with being a public company in the United States. In June 2020, we obtained approval from the FDA under an investigational device exemption, or IDE, to begin our pivotal trial, the dual-sided hypoglossal nerve stimulation for the treatment of obstructive sleep apnea, or DREAM, trial. The aim of the DREAM trial, if the data are positive, is to support market authorization of the Genio system in the United States, as well as to support obtaining coverage and reimbursement more generally. We also plan to conduct additional clinical trials, and as a result, we expect clinical expenses will increase significantly over the next several years.

As a result, we expect to continue to incur operating losses for the foreseeable future, and we may never achieve profitability, which could impair our ability to sustain operations or obtain any required additional funding. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability in the future, we may suffer net losses or negative operating cash flows in subsequent periods.

***Our future financial performance depends on the commercial acceptance of the Genio system in target markets.***

The Genio system is currently our only commercial product, which we market in certain European countries, and our success depends entirely upon its market acceptance and adoption by physicians, payors and patients. The Genio system may not gain commercial acceptance in target markets. If we fail to gain and maintain commercial market acceptance of the Genio system in our target markets, for instance, because of insufficient price and reimbursement levels from government and third-party payors, competition, or the inability to demonstrate the benefits and cost-effectiveness of the Genio system compared to other products available on the market, the amount of revenue generated from sales of the Genio system in the future could continue to be limited, and could even decrease over time. In addition, the Genio system has not received marketing authorization in the United States, and our future financial performance will depend on the successful completion of our DREAM pivotal trial, which is intended to support an application for market authorization to commercialize the Genio system in the United States.

These and other factors present obstacles to commercial acceptance of the Genio system in target markets and could lead to our failure, or a substantial delay, in gaining significant market acceptance of the Genio system in target markets, which could affect our ability to generate revenue. Any failure of the Genio system to achieve meaningful market acceptance will harm our business and future prospects.

***We will require additional capital in the future, which may not be available to us on commercially favorable terms, or at all. More specifically, there is material uncertainty about our ability to continue as a going concern for a period of at least twelve months from the date of this Annual Report and our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given as of the date of this Annual Report.***

We expect to incur significant expenses and operating losses over the next few years, and we may need to raise additional capital in the future. We have so far been financed primarily by funds invested by our shareholders, including in connection with our initial public offering on Euronext Brussels in September 2020 and the listing of our ordinary shares on the Nasdaq Global Market in July 2021. Based on our current operating plan and our existing cash and cash equivalents of €21.6 million and financial assets of €36.1 million as of December 31, 2023, we expect to be able to fund our operations until the fourth quarter of 2024. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our financial resources much faster than currently expected. Pursuant to the requirements of IAS 1.25-26, Presentation of Financial Statements - Going Concern, and as a result of our financial condition and other factors described herein, there is material uncertainty about our ability to continue as a going concern for a period of at least twelve months from the date of this Annual Report. See Section 1.14 ("Going concern"). Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. Our future success depends on our ability to raise capital and/or execute our current operating plan. Any future funding requirements will depend on many factors, including without limitation:

- acceptance of our Genio system by patients, physicians, government payors, private payors, and the market generally in our target markets;
- the scope, rate of progress and cost of current or future clinical trials;
- the cost and timing of obtaining additional regulatory clearances, approvals, classifications, certifications or other marketing authorizations for the Genio system;
- the cost and timing of establishing additional sales and marketing capabilities;
- the cost of research and development activities;
- the cost of filing and prosecuting patent applications and other intellectual property rights and defending and enforcing our patents or other intellectual property rights in various jurisdictions;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;
- the cost associated with any complications or side effects related to the use of the Genio system;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the costs of operating as a public company in Belgium and the United States.

Any additional equity or debt financing that we raise may contain terms that are not favorable to us or our shareholders. If we raise additional funds by selling additional ordinary shares or other securities convertible into or exercisable or exchangeable for ordinary shares, the issuance of such securities will result in dilution to our shareholders.

In addition, any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our ordinary shares, make certain investments and engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products, or grant licenses on terms that are not favorable to us.

Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. We have no committed source of additional capital other than our at-the-market facility. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third-parties the rights to commercialize products or technologies that we would otherwise seek to commercialize ourselves. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations.

***Any loss or decrease of subsidies, reimbursable cash advances and tax reductions may affect our financial resources.***

Since September 2011, we have received financial support from the Walloon Region in the form of recoverable cash advances and subsidies. In March 2018, in accordance with Section 27A of the Australian Industry Research and Development Act 1986, the Australian Government gave notice to Nyxoah Pty Ltd, our Australian subsidiary, of registration for the research and development, or R&D, tax incentive from the 2017/2018 income year. This incentive represents 43.5% of the yearly eligible R&D expenditure. In October 2023, we received confirmation from the Walloon Region that we can apply tax credits in Belgium on eligible R&D investments.

All these subsidies and reimbursable cash advances increased our financial resources to support R&D and clinical development projects. However, we cannot predict whether we or our subsidiaries will continue to benefit from such incentives and/or advantages and/or to what extent. The repayment obligations with respect to the financial support from the Walloon Region will also have the effect of reducing our profitability until fully repaid.

## **2.9.2 Risks related to development of our products and product candidates**

***Even though we have obtained certification, a CE-Mark, in Europe for the Genio system based on first positive clinical trial results, there is no guarantee that we will be able to maintain our current certification or to obtain additional certification or marketing authorizations in other jurisdictions, including the United States, or that the results from our ongoing and planned clinical trials will be sufficient for us to obtain or maintain such certifications or authorizations.***

Even though we have obtained certification (CE-Mark) in Europe for the Genio system based on positive results from our BiLateral hypoglossal nerve stimulation for treatment of Obstructive Sleep Apnea, or BLAST, clinical trial, there is no assurance that ongoing and future clinical trials we may conduct to support further marketing authorizations, certifications or clearances (or to maintain existing ones) will be successful and that the Genio system will perform as intended. We may be required to develop more clinical evidence than we currently anticipate before we are able to demonstrate to the satisfaction of the FDA or other regulatory authorities that the Genio system is safe and effective for its intended use, if ever. To obtain a certificate of conformity, manufacturers need to comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC), the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC) or Medical Device Regulation (EU) 2017/745 of the European Parliament, and in particular to demonstrate that devices are designed and manufactured in such a way that they will not compromise the clinical condition or safety of patients, or the safety and health of users and others (that the potential benefits outweigh potential risks). In addition, medical devices must achieve the performance intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. However, if the Genio system causes or contributes to consumer injuries or other harm or other serious issues arise as to the device's performance, it may be necessary to conduct further clinical trials to confirm the device can perform safely and effectively.

In particular, even if certification has been obtained in Europe, there is no guarantee for success in the United States of a pivotal trial to support a premarket submission to the FDA or for future U.S. marketing authorization. The FDA's standard of review differs from that required to obtain a CE-Mark in Europe, which only indicates that the device in question is in full compliance with European legislation. Medical devices certified for marketing in the European Union need notably to demonstrate that they are designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. On the other hand, before FDA approval of a medical device in the United States, a device must not only be shown to be safe, but also effective its intended use, or in the case of a 510(k) clearance, substantially equivalent to a predicate device.

***Our growth will depend, in part, on our ability to expand the indications for the Genio system, as well as to continue to development enhancements to the system and also develop and commercialize additional products.***

Expanding indications for our Genio system and developing new products is expensive and time-consuming and could divert management's attention away from our core business. We plan to continue to invest in pursuing additional indications for our Genio system and in improving the Genio system to develop next generation versions designed to improve patient comfort, efficacy and convenience. For example, in July 2022, we received FDA approval for an IDE to enable us to initiate a clinical trial, called ACCESS, to evaluate the use of the Genio system for the treatment of adult patients with moderate-to-severe OSA with complete concentric collapse (CCC).

The success of any such product development efforts will depend on several factors, including our ability to do the following:

- properly identify and anticipate physician and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- obtain necessary licenses from or reach commercial agreements with third parties owning proprietary technologies or solutions;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain the necessary regulatory authorizations and/or certifications for expanded indications, new products or product modifications;
- be fully compliant with requirements related to marketing of new devices or modified products;
- provide adequate training to potential users of our products;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- develop an effective and dedicated sales and marketing team.

If we are not successful in expanding indications and developing and commercializing new products and product enhancements, our ability to increase our revenue in the future may be impaired.

***Hesitation to change or to undertake special training and economic, social, psychological and other concerns among physicians may limit general acceptance and adoption of the Genio system.***

Even if the Genio system receives marketing authorization or certification from the appropriate regulatory authorities or Notified Bodies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Our efforts to educate the medical community and third-party payors regarding the benefits of the Genio system are expected to require significant resources and may not be successful.

Acceptance of the Genio system will depend on physicians being convinced of the distinctive characteristics, clinical performance, benefits, safety and cost-effectiveness of the device and being prepared to undertake special training in certain cases. Furthermore, physicians will likely only adopt the Genio system if they determine, based on experience, clinical data, and published peer-reviewed journal articles that the Genio system is an attractive treatment solution, and that third-party payors, such as government programs and private health insurance plans, will provide coverage and adequate reimbursement for its use. Regarding the Genio system, only two articles related to the BLAST OSA trial have been published in the European Respiratory Journal and Laryngoscope Investigative Otolaryngology.

The degree of market acceptance of the Genio system and any other product candidates we develop will depend on a number of social, psychological, economic and other factors and concerns, including:

- general conservatism about the adoption of new treatment practices and reluctance to switch their patients from existing therapies;
- personal history of adverse events and severe/serious adverse events;
- lack or perceived lack of long-term evidence supporting additional patient benefits;
- perceived liability risks associated with the use of new products and procedures;
- limited or lack of reimbursement and coverage within healthcare payment systems;
- costs associated with the purchase of new products and equipment;
- other procedures competing for physician time and attention;
- the fact that the Genio system contains an implantable device requiring surgery for implantation;
- the time commitment that may be required for special training;
- insufficient level of commercial attractiveness to physicians;
- the extent of ongoing support required by the clinician; and
- the extent of ongoing involvement of the patient in therapy.

***We may focus our financial and managerial resources on a particular market resulting in a failure to capitalize on markets that may be more profitable or for which there is a greater likelihood of success.***

Taking into account our current financial and managerial resources, we will have to carefully prioritize the order in which we address our target European markets for commercialization of the Genio system, based on parameters such as market size, market readiness, and competition, and then allocate our financial and managerial resources accordingly. In order to identify our primary target markets, we make projections on the number of people by target market. These projections are derived from a variety of sources, including, but not limited to, scientific literature, governmental statistics and market research, and are highly contingent on a number of variables that are difficult to predict and may prove to be too high. If as a result of these or other factors the market for the Genio system does not develop as currently anticipated, our ability to generate revenue could be materially adversely affected. Further, if we use our financial and managerial resources to promote a particular indication expansion that is not ultimately sufficiently commercially successful, this could result in a smaller population of patients who could benefit from the Genio system than we anticipate which would result in lower potential revenue.

***Competition from medical device companies and medical device subsidiaries of large healthcare and pharmaceutical companies is intense and expected to increase.***

The medical technology industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Our competitors have historically dedicated and will continue to dedicate significant resources to promoting their products or developing new products or methods to treat moderate to severe OSA. We compete as a second line therapy in the OSA treatment market for patients with moderate to severe OSA.

We consider other companies that have designed hypoglossal nerve stimulation technologies to treat OSA as direct competitors. We are aware of only one currently marketed nerve stimulation device for the treatment of OSA, the Inspire Medical system marketed by Inspire Medical Systems, Inc., and one other nerve stimulation system for the treatment of OSA currently not actively commercialized in Europe from ImThera/ LivaNova PLC. The Inspire Medical system is currently the only neuro stimulation system approved to treat moderate to severe OSA in the United States. Additionally, we also consider, as indirect competition, invasive surgical treatment options such as uvulopalatopharyngoplasty and maxillomandibular advancement surgery and, to a lesser extent, mandibular advancement devices, which are primarily used in the treatment of mild to moderate OSA.

In Europe, the Genio system is CE-Mark certified for use as a second-line therapy in the treatment of moderate to severe OSA in patients who do not tolerate, refused or failed positive airway pressure, or PAP, therapy. If one or more PAP device manufacturers successfully develop a PAP device that is better tolerated and demonstrates significantly higher compliance rates, or if improvements in other second-line therapies make them more effective, cost effective, easier to use or otherwise more attractive than the Genio system, these therapies could have a material adverse effect on our sales, financial condition and results of operations.

Companies against which we compete, directly or indirectly, may have competitive advantages with respect to primary competitive factors in the OSA treatment market, including:

- greater company, product and brand recognition;
- a more extensive body of clinical data demonstrating product reliability and durability;
- more effective marketing to and education of patients, physicians and sleep centers;
- greater product ease of use and patient comfort;
- more sales force experience and greater market access;
- better product support and service;
- more advanced technological innovation, product enhancements and speed of innovation;
- more effective pricing and revenue strategies;
- lower procedure costs to patients;
- more effective reimbursement teams and strategies;
- dedicated practice development; and
- more effective clinical training teams.

The commercial availability of any approved competing product could potentially inhibit recruitment and enrollment in our clinical trials. We may successfully conclude our clinical trials and obtain final regulatory authorization or certification, and nevertheless may fail to compete against competitors or alternative treatments that may be available or developed for the relevant indication. Alternative treatments include devices and surgery, as well as potential pharmacological treatments, among others. New treatment options may emerge yielding clinical results better than or equal to those achieved with the Genio system, possibly at a lower cost. Emergence of such new therapies may inhibit our ability to develop and grow the market for the Genio system. Furthermore, new entrants into the markets in which we operate could also decide to more aggressively compete on price, requiring us to reduce prices to maintain market share.

***A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, could materially and adversely affect our business and our financial results and cause a disruption to our research, development and commercialization efforts.***

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Notably, the COVID-19 pandemic continues to evolve. The extent to which COVID-19 impacts our operations or those of our collaborators, vendors and other material business relations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the virus and the actions to contain it or treat its impact, among others.

### **2.9.3 Risks related to our dependence on third parties and on key personnel**

***A loss or degradation in performance of the suppliers on which we depend for services and components used in the production and assembly of the Genio system could have a material effect on our business, financial condition and results of operations.***

The Genio system requires customized components and services that are currently available from a limited number of sources. If these suppliers decide not to supply, are unable to supply, or if they



provide us with components or services of insufficient quality, this could harm our reputation and business by affecting, for example, product availability and performance. Our suppliers might not be able or willing to continue to provide us with the components or services we need, at suitable prices or in sufficient quantity or quality. If any of our existing suppliers is unable or unwilling to meet our demand for components or services, or if the services or components that they supply do not meet quality and other specifications, clinical trials or sales of the Genio system could be delayed or halted, which could prevent us from achieving or maintaining profitability. For instance, we currently rely on a single source supplier for a number of critical components to the Genio system. We are seeking to qualify additional suppliers for certain of our components. The addition of a new supplier to the production process generally requires extensive evaluations, testing and regulatory approval, making it difficult and costly for us to diversify our exposure to single source suppliers. In addition, if we have to switch to a replacement supplier for any of our product components or for certain services required for the production and assembly of the Genio system such as, for example, the sterilization and coating of the product components, or if we have to commence our own manufacturing to satisfy market demand, we may face delays, and the manufacturing and delivery of the Genio system could be interrupted for an extended period of time, which could delay completion of our clinical trials or commercialization and prevent us from achieving or maintaining profitability. Alternative suppliers may be unavailable, may be unwilling to supply, may not have the necessary regulatory approvals or certifications, or may not have in place an adequate quality management system. Furthermore, modifications to a service or component made by a third-party supplier could require new approvals or certifications from the relevant regulatory authorities before the modified service or component may be used.

If we are required to change the manufacturer of a critical component of our implant systems, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality specifications and applicable regulatory requirements, which could further impede our ability to manufacture our implant systems in a timely manner. If we encounter demand for our system in excess of our inventory and we need to contract with these additional suppliers, we will face challenges in meeting that demand. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our implant systems or could require that we modify the design of those systems. If the change in manufacturer results in a significant change to any product, new marketing authorizations or certification from the FDA or similar regulatory authority may be necessary before we implement the change, which could cause substantial delays. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely or cost-effective manner.

In addition, our suppliers may discontinue their supply of components or services upon which we rely before the end of the product life of the Genio system. The timing of a discontinuation may not allow us sufficient time to develop and obtain any regulatory authorizations or certifications as required for replacement components or service before we exhaust our inventory. If suppliers discontinue their supply of components or services, we may have to pay premium prices to our suppliers to keep their production or service lines open or to obtain alternative suppliers, buy substantial inventory to last until the scheduled end of life of the Genio system or through such time as we have an alternative component developed and authorized by the regulatory authorities, or temporarily cease supplying the Genio system once our inventory of the affected component is exhausted.

Any of these interruptions to the supply of services or components could result in a substantial reduction in our available inventory and an increase in our production costs.

***We may be unable to attract and retain management and other personnel we need to succeed.***

Given our current state of the development, reliance on the expertise and experience of our board of directors, management and other key employees, as well as contractors, in management, engineering, manufacturing, clinical and regulatory matters, sales and marketing, and other functions is crucial.

The departure of any of these individuals without timely and adequate replacement or the loss of any of our senior management or other key employees would make it difficult for us to achieve our objectives in a timely manner, or at all. We might not be able to find and attract other individuals with similar levels of expertise and experience or similar relationships with commercial partners and other market participants. In addition, our competitive position could be compromised if a member of senior management transferred to a competitor.

We expect to expand our operations and grow our clinical development, manufacturing, administrative and commercial operations. This will require hiring a number of qualified clinical, scientific, commercial and additional administrative, sales and marketing personnel. Competition for skilled personnel is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Competitors may have greater financial and other resources, different risk profiles and a longer history than we do. If we are unable to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development, commercialization or growth. Failure to retain or attract key personnel could have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

***Third-party performance failure may increase our developments costs, delay granting of regulatory authorizations or certifications or delay or prevent commercialization.***

We rely, and may rely in the future, on third parties to conduct certain clinical trials, perform data collection and analysis and provide marketing, manufacturing, regulatory advice and other services that are crucial to our business. In particular, our technology and product development activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if the third parties do not devote a sufficient amount of time or effort to our activities or otherwise fail to successfully carry out their contractual duties or to meet regulatory obligations or expected deadlines; if we replace a third party; if the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons including the loss of data; or if the third party becomes bankrupt or enters into liquidation.

We may not always have the ability to control the performance of third parties in their conduct of their activities. Our agreements with these third parties generally allow the third party to terminate the agreement at any time, subject to standard notice terms. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or agreements with such third parties are terminated for any reason, we would be required to find a replacement third party to conduct the required activities. We may be unable to enter into a new agreement with another third party on commercially acceptable terms, if at all. Furthermore, if the quality or accuracy of the data obtained by the third party is compromised, or if data are otherwise lost, we would be required to repeat the affected trial. Third-party performance failures may therefore increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of the Genio system in target markets. In addition, our third-party agreements usually contain a clause limiting such third party's liability, such that we may not be able to obtain full compensation for any losses that we may incur in connection with the third party's performance failures.

***Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to supply our products on a timely basis.***

Expedited, reliable shipping is essential to our operations since the components of the Genio system are manufactured to our specifications by third-party suppliers in various jurisdictions. While the initial assembly of the different electronic components is done by different external suppliers, the final assembly is performed in our facilities in Israel and Belgium. As a result, we rely heavily on providers of transport services for reliable and secure point-to-point transport of the key components of the Genio system to our facility and for tracking of these shipments. Should a carrier encounter delivery



performance issues such as loss, damage or destruction of any components, it would be costly to replace such components in a timely manner and such occurrences, if they resulted in delays to the assembly and shipment of the completed Genio system to customers, may damage our reputation and lead to decreased demand for the Genio system and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for the Genio system on a timely basis.

#### 2.9.4 Risks related to manufacturing

***We may not be able to manufacture or outsource manufacturing of the Genio system in sufficient quantities, in a timely manner or at a cost that is economically attractive.***

Our revenue and other operating results will depend, in large part, on our ability to manufacture and sell the Genio system in sufficient quantities and quality, in a timely manner, and at a cost that is economically attractive.

We expect to be required to significantly increase manufacturing volumes as clinical trials on the Genio system are expanded and the Genio system is commercialized. The capacity of our manufacturing facilities in Tel Aviv, Israel, and Milmort, Belgium, along with our contract manufacturer in the United States, is expected to cover the Genio Implantable Stimulator and Genio External Stimulator demand for 2024. Manufacturing of the Genio Activation Chip and the Genio Charging Unit is mostly outsourced to a third party contract manufacturing organization. In order to support future demand for the Genio system, we may need to expand our manufacturing capacity, which could require opening a new facility or additional outsourcing to a third-party contract manufacturing organization. For example, if we obtain regulatory authorization to market the Genio system in the United States we would likely have to significantly increase our manufacturing capabilities in order to satisfy anticipated demand. We expect that this could include opening a manufacturing facility in the United States. Opening a new manufacturing facility could involve significant additional expenses, including for the construction of a new facility, the movement and installation of key manufacturing equipment, the modification of manufacturing processes and for the recruitment and training of new team members. In addition, we must also notify, and in most cases obtain approval from, regulatory authorities regarding any changes or modifications to our manufacturing facilities and processes, and the regulatory authorities might not authorize us to proceed or might delay the process significantly.

In addition, our current business expectation is that the cost of goods sold will decline over time as (i) internal efficiencies increase and (ii) the cumulative volume of Genio systems manufactured grows. However, we or our suppliers might not be able to increase yields and/or decrease manufacturing costs with time, and in fact costs may increase, which could prevent us from achieving or maintaining profitability.

***Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our Genio system and manage our inventory.***

To ensure adequate inventory supply of the Genio system in general and its components, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for the Genio system and its components. To date, we have only commercialized the Genio system in limited quantities, mostly in Germany, and our ability to accurately forecast demand for our Genio system could be negatively affected by many factors, including failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for the Genio system or for products of our competitors, failure to accurately predict customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in

excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of the Genio brand. Conversely, if we underestimate customer demand for the Genio system, our third-party contract manufacturers may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or third-party manufacturers might not be able to allocate sufficient capacity in order to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for the Genio system.

We intend to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions. As a result, we will be subject to the risk that a portion of our inventory will become obsolete or expire, which could affect our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

### 2.9.5 Risks related to legal and regulatory compliance matters

***The Genio system is still unapproved in certain significant markets, such as the United States market, and seeking and obtaining regulatory authorization or certification for active implantable medical devices can be a long, expensive and uncertain process.***

Applications for prior regulatory authorization in the countries where we intend to sell or market the Genio system and any other products we develop may require extensive non-clinical, clinical and performance testing, all of which must be undertaken in accordance with the requirements of regulations established by the relevant regulatory agencies, which are complex and have become more stringent over time. We may be adversely affected by potential changes in government policy or legislation applicable to implantable medical devices. At the date of this Annual Report, we have received certification to market the Genio system and the Genio 2.1 system in the EU member states through CE-Marking and Israeli Medical Devices and Accessories, or AMAR. CE-Marking is also valid in the European Economic Area, or EEA (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland).

In the United States, we are in the early stages of seeking FDA marketing authorization. We have received IDE approval from the FDA, which allows us to proceed with our DREAM and ACCESS clinical trials of the Genio system in the United States, and we are in the process of determining the appropriate regulatory pathway to pursue for seeking marketing authorization for the device from the FDA. Even though we have received approval IDEs, the Genio system may not successfully obtain marketing authorization. In addition, there may be substantial and unexpected delays in the process, for example in the initiation and completion of clinical trial testing and evaluation.

Since the Genio system is a wireless medical device, additional complications may arise with respect to obtaining marketing authorization in the United States. For example, the Federal Communications Commission must also determine that wireless medical devices, such as the Genio system, are compatible with other uses of the spectrum on which the device operates, and that power levels and the frequency spectrum of the wireless energy transfer comply with applicable regulations.

***Failure to comply with the significant regulations and approvals to which our manufacturing facilities and those of our third-party suppliers are subject to may affect our business.***

We currently manufacture the Genio system and have entered into relationships with third-party suppliers to manufacture and supply certain components of the Genio system. Our manufacturing practices and the manufacturing practices of our third-party suppliers are subject to ongoing regulation and periodic inspection. In the United States, the methods used in, and the facilities used for, the manufacture of medical devices must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, and

servicing of medical devices. Furthermore, we will be required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. The Genio system is also subject to similar state regulations and various laws and regulations of other countries governing manufacturing.

Any failure to follow and document the adherence to regulatory requirements (including having in place an adequate quality management system in line with the most up-to-date standards and regulations) by us or our third-party suppliers may lead to significant delays in the availability of the Genio system for commercial sale or clinical trials, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval or maintenance of marketing applications for the Genio system.

In the United States, the FDA and other federal and state agencies, including the U.S. Department of Justice, closely regulate compliance with all requirements governing medical device products, including requirements pertaining to marketing and promotion of devices in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients using our products;
- restrictions on our products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- untitled or warning letters;
- fines, restitution or disgorgement of profits or revenues;
- consent decrees;
- total or partial suspension or clinical hold of one or more of our clinical trials;
- total or partial suspension or withdrawal regulatory approvals;
- total or partial suspension of production or distribution;
- delay of or refusal to approve pending applications or supplements to approved applications or to provide future market authorizations, certifications or approvals;
- mandatory communications with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving us;
- withdrawal of the products from the market;
- mandatory product recalls or seizure of products;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation; or
- injunctions or the imposition of civil or criminal penalties.

Any of the foregoing actions could be detrimental to our reputation or result in significant costs or loss of revenues. Any of these actions could significantly and negatively affect supply of the Genio system, if authorized for sale by the FDA. If any of these events occurs, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

***Seeking, obtaining and maintaining certification in the EU under the MDR, with the CE-Mark to be re-certified before December 31, 2027, can be an uncertain process and Notified Bodies have limited resources and may experience backlogs.***

Devices such as our Genio system currently on the market in the EU that have been granted a CE-Mark under the AIMD Directive, will need to be re-evaluated and re-certified in accordance with the MDR. Any modification to an existing CE-Marked medical device will also require review and certification under the MDR.

The MDR also requires a re-designation of the Notified Bodies, the organizations designated by the EU member state in which they are based that are responsible for assessing whether medical devices and manufacturers of medical devices meet the applicable regulatory requirements in the EU. To be re-designated, Notified Bodies must demonstrate increased technical expertise in their scope of designation, as well as improved quality management systems. This re-designation process has caused backlogs in the assessment of medical devices and medical device manufacturers during the transition period leading up to May 26, 2021, the effective date of the MDR. In the European Union, currently 42 Notified Bodies have been re-designated, including one for Belgium.

To be able to continue to place our Genio device on the EU market, if we decide to do so, the CE-Mark obtained in 2019 for our Genio system will have to be re-certified under the MDR before the extended deadline of December 31, 2027. To benefit from the extended transitional period, the manufacturer or its authorized representative need to have submitted an application for MDR certification by May 26, 2024 and needs to have signed a written proposal/agreement with the Notified Body by September 26, 2024. The re-certification requires us to present documentation and other evidence demonstrating that the performance and the safety of the system has been maintained and that the system continues to meet existing regulations and standards. Otherwise, the marketing and sale of the Genio system in EU member states may be temporarily or permanently prohibited. Significant modifications to the Genio system, if any, will require certification under the MDR and cannot be implemented during the transition period from AIMDD to MDR.

The overall backlogs experienced by the Notified Bodies having already been re-designated (including the Dutch company DEKRA Certification B.V., which issued the CE-Mark and an ISO 13485:2016 certificate to us under the AIMD Directive) might have a negative impact on the re-certification of the Genio system. We believe, however, that we are on track to meet the new requirements by the deadlines set forth in the MDR.

Any third-party entities that we rely upon for distribution of our products in the EU, such as our local distributor in Spain, also need to be compliant with the MDR. If a distributor in the EU fails to meet the MDR requirements, on a timely basis or at all, the marketing and sale of our Genio products by such distributor may be temporarily or permanently prohibited.

Any delay or failure to comply with the MDR could result in the sale of our Genio products being temporarily or permanently prohibited in EU member states and affect our reputation, business, financial condition, results of operations and prospects.

***Compliance with regulations for quality systems for medical device companies is difficult, time consuming and costly.***

We have developed and maintains a quality management system for medical devices intended to ensure quality of our products and activities. The system is designed to be in compliance with regulations in many different jurisdictions, including the QSR mandated by the FDA in the United States and the requirements of the AIMD Directive in the European Union, including the international standard ISO13485 required by the member states in Europe that recognize the CE-Mark, as well as Israel, New Zealand and Australia. The FDA issued a Notice of Proposed Rulemaking in February 2022 describing revisions to the QSR to harmonize it with ISO13485. However, it is not clear when the FDA plans to issue a Final Rule to implement the harmonized regulations.

Compliance with regulations for quality management systems for medical device companies is time consuming and costly, and there are changes in such regulations from time to time. For example, the latest version of ISO13485, ISO13485:2016, aims to harmonize the requirements of ISO13485 with the requirements of the AIMD Directive. While management believes that we are compliant with existing quality management system regulations for medical device companies as of the date of this Annual Report, it is possible that we may be found to be noncompliant with new or existing regulations in the future. In addition, we may be found to be noncompliant as a result of future changes in, or interpretation of, the regulations for quality systems. If we do not achieve compliance or subsequently become noncompliant, the regulatory authorities may require that we take appropriate action to address non-conformance issues identified in a regulatory audit, and may, if we do not take such corrective actions in a timely manner, withdraw marketing clearance, or require product recall or take other enforcement action.

Our external vendors must, in general, also comply with the quality systems regulations and ISO13485. Any of our external vendors may become noncompliant with quality systems regulations or ISO13485, which could result in enforcement action by regulatory authorities, including, for example a warning letter from the FDA or a requirement to withdraw from the market or suspend distribution, or export or use of products manufactured by one or more of our vendors.

Any change or modification to a device (including changes to the manufacturing process) may require supplemental filings to regulatory authorities or new submissions for marketing authorization or certification (depending on the jurisdiction) and must be made in compliance with appropriate quality system regulations (such as the QSR for the United States and the AIMD Directive and the MDR for Europe), which may cause interruption to or delays in the marketing and sale of our products. Regulations and laws regarding the manufacture and sale of AIMDs are subject to future changes, as are administrative interpretation and policies of regulatory agencies. If we fail to comply with such laws and regulations where we would intend to market the Genio system, we could be subject to enforcement action including recall of our device, withdrawal of approval, authorization, certification or clearance and civil and criminal penalties. If any of these events occur, it may materially and adversely affect our business, financial condition, results of operations and prospects.

***Active implantable medical devices such as the Genio system carry risks associated with the surgical procedure for implant or removal of the device, use of the device, or the therapy delivered by the device.***

The Genio system is a medical device with complex electronic circuits and software and includes a component that is implanted in the patient through a surgical procedure. It is not possible to design and build electronic implantable medical devices that are 100% reliable, since all electronic devices carry a risk of failure. Furthermore, all surgical procedures carry risks, and the effectiveness of any medical therapy varies between patients. The consequences of failure of the Genio system include complications arising from product use and associated surgical procedures and could range from minor to life-threatening effects and even death.

All medical devices have associated risks. Regulatory authorities regard active implantable medical devices, or AIMDs, as the highest risk category of medical devices and, accordingly, AIMDs are subject to a high level of scrutiny when seeking regulatory approval or other marketing authorization. The Genio system was reviewed, classified and the certificate of conformity as an AIMD was issued by our European Notified Body allowing us to affix the CE-Mark. A CE-Mark in Europe indicates that the device in question is in full compliance with European legislation. Medical devices authorized for marketing in the European Union need to comply with the essential requirements laid down in the AIMD Directive and in particular to demonstrate that they are designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others (that the potential benefits outweigh potential risks). In addition, medical devices must achieve the performance intended by the manufacturer and be designed, manufactured, and

packaged in a suitable manner. Devices authorized first in the European Union may be associated with an increased risk of post-marketing safety alerts and recalls. On the other hand, before FDA premarket approval of a medical device in the United States, a device must be shown to be safe and effective per its intended use. The risks associated with medical devices and the therapy delivered by them, include, among others, risks associated with any surgical procedure, such as infection, allergic reaction, and consequences of anesthesia and risks associated with any implantable medical device such as device movement, electromagnetic interference, device failure, tissue damage including nerve damage, pain and psychological side effects associated with the therapy or the surgical procedure.

Adverse events associated with these risks may lead some patients to blame us, the physician or other parties for such occurrences. This may result in product liability lawsuits, medical malpractice lawsuits, investigations by regulatory authorities, adverse publicity, criminal charges or other harmful circumstances for us. Any of those circumstances may have a material adverse effect on our ability to conduct our business, to continue selling the Genio system, to achieve revenue objectives, or to develop future products.

***If our products are defective, or otherwise pose safety risks, the relevant governmental authorities could require their recall, or we may need to initiate a recall of our products voluntarily.***

AIMDs are characterized by a complex manufacturing process, requiring adherence to demanding product specifications. The Genio system uses many disciplines including electrical, mechanical, software, biomaterials, and other types of engineering. Device failures discovered during the clinical trial phase may lead to suspension or termination of the trial. In addition, device failures and malfunctions may result in a recall of the product, which may relate to a specific manufacturing lot or may affect all products in the field. Recalls may occur at any time during the life cycle of a device after regulatory authorization has been obtained for the commercial distribution of the device. For example, engineers employed by us undertaking development or manufacturing activities may make an incorrect decision or make a decision during the engineering phase without the benefit of long-term experience, and the impact of such wrong decisions may not be felt until well into a product's life cycle.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Recalls of the Genio system would divert managerial and financial resources and could result in damaged relationships with regulatory authorities and lead to loss of market share to competitors. In addition, any product recall may result in irreparable harm to our reputation. Any product recall could impair our ability to produce products in a cost-effective and timely manner in order to meet customer demand. We may also be required to bear other costs or take other actions that may have a negative impact on future revenue and could prevent us from achieving or maintaining profitability.

***We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.***

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. The Genio system is designed to be implanted in the body and to affect important bodily functions and processes. As with any other complex medical



device, there exists the reasonable certainty that, over time, one or more components of some Genio systems will malfunction. As a medical device manufacturer, we are exposed to the product liability claims arising from the Genio system failures and malfunctioning, product use and associated surgical procedures. This risk exists even if the Genio system is certified or authorized for commercial sale by regulatory authorities or Notified Bodies and manufactured in facilities licensed and regulated by the applicable regulatory authority or Notified Body. The medical device industry has historically been subject to extensive litigation over product liability claims, and we may face product liability suits if the Genio system causes, or merely appears to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise being exposed to the Genio system, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in one or more of the following:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize the Genio system or new products;
- decreased demand for the Genio system;
- damage to our reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of sales.

Although we maintain product liability and clinical trial liability insurance at levels we believe are appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities, including claims for amounts in excess of insured liabilities. As of the date of the Annual Report, there are no product liability claims against us.

***We bear the risk of warranty claims on the Genio system.***

We bear the risk of warranty claims on the Genio system. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer, and any such recovery from a vendor or supplier may be inadequate to fully compensate us. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. As of the date of the Annual Report, there are no warranty claims against us.

***We are and will be subject to healthcare fraud and abuse laws and other laws applicable to our business activities and if we are unable to comply with such laws, we could face substantial penalties.***

We are subject to various federal, state and local laws pertaining to healthcare fraud and abuse laws, including anti-kickback, false claims and transparency laws. Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities.

In addition, many EU member states have adopted national “Sunshine Acts” which impose reporting and transparency requirements (often on an annual basis) on medical device manufacturers, similar to the requirements in the United States. For instance, pursuant to the Belgian Act of December 18, 2016 and its implementing Royal Decree of June 14, 2017, which entered into force on June 23, 2017, manufacturers of medical devices are required to document and disclose all direct or indirect premiums and benefits granted to healthcare professionals, healthcare organizations and patient organizations with a practice or a registered office in Belgium. Also, under Article 10 of the Belgian Act of March 25, 1964, it is prohibited (subject to limited exceptions) in the context of the supply of medical devices to offer or grant any advantage or benefit in kind to amongst others healthcare professionals and healthcare organizations. In addition, certain countries also mandate implementation of commercial compliance programs.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our financial arrangements with physicians, some of whom receive compensation in the form of stock options, which could be viewed as influencing the purchase of or use of our products in procedures they perform and may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

Any action brought against us for violations of these laws or regulations, even if successfully defended, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. We may be subject to private qui tam actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act including mandatory treble damages and significant per-claim penalties. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

***Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.***

We and certain third parties that we rely on for our operations collect and store confidential and sensitive information, and our and their operations are highly dependent on information technology systems, including internet-based systems, which may be vulnerable to damage or interruption from earthquakes and hurricanes, fires, floods and other natural disasters, and attacks by computer viruses, unauthorized access, terrorism, and war, as well as telecommunication and electrical failures. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could also cause us to cease or delay our manufacturing of the Genio systems. If such an event were to occur and cause interruptions in our operations, it could have a material adverse effect on our business. For example, the loss of clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Since the Genio system is a wireless medical device, additional complications may arise with respect to the wireless, RF, technology used for the communication between the system parts. While we have reviewed and determined the integrity of the Genio system and the communication protocol, use of wireless technology imposes a risk that third parties might attempt to access our system. An additional risk is related to interruption or distortion of communication by other devices that might be used in the vicinity of the system, especially when in use by the user, which might have an effect on the effectiveness



of the therapy delivered by the system. Any disruption or security breach or other security incident that resulted in a loss of or damage to our data or applications, or the inappropriate access to or disclosure of personal, confidential, or proprietary information could delay our product development, clinical trials, or commercialization efforts, result in increased overhead costs and damage our reputation, all of which could negatively affect our business, financial condition and operating results.

## 2.9.6 Risks related to intellectual property

***The inability to fully protect and exploit our intellectual property and trade secrets may adversely affect our financial performance and prospects.***

Our success will depend significantly on our ability to protect our proprietary and licensed in rights, including in particular the intellectual property and trade secrets related to the Genio system. We rely on a combination of patent(s) (applications), trademarks, designs and trade secrets, and use non-disclosure, confidentiality and other contractual agreements to protect our technology. If we are unable to obtain and maintain sufficient intellectual property protection for the Genio system or other product candidates that we may identify, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize the Genio system and other product candidates that we may pursue may be impaired.

We generally seek patent protection where possible for those aspects of our technology and products that we believe provide significant competitive advantages. However, obtaining, maintaining, defending and enforcing pharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Under certain of our license or collaboration agreements, we may not have the right to control the preparation, filing, prosecution and maintenance of patent applications, or to maintain the rights to patents licensed to or from third parties. Further, we cannot be certain that patents will be issued with respect to our pending or future patent applications. In addition, we do not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or whether they will prevent the development of competitive patents or provide meaningful protection against competitors or against competitive technologies.

The patent position of medical device companies generally is uncertain, involves complex legal, technological and factual questions. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. The subject matter claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Therefore, our pending and future patent applications may not result in patents being issued in relevant jurisdictions that protect the Genio system or our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates, and even if our patent applications issue as patents in relevant jurisdictions, they may not issue in a form that will provide us with any meaningful protection for our product candidates or technology, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Additionally, our competitors may be able to circumvent our patents by developing similar or alternative product candidates or technologies in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others, or other proceedings in the USPTO or applicable foreign offices that challenge priority of invention or other features of patentability. An adverse determination in any such submission, proceeding or litigation could result in loss of exclusivity or freedom to operate, patent claims being narrowed, invalidated or held unenforceable, in whole or in part, limit the scope or duration of the patent protection of the Genio system or our product candidates, all of which could limit our ability to stop others from using or commercializing similar or identical product candidates or technology to compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates or approved products (if any) without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates, or could have a material adverse effect on our ability to raise funds necessary to continue our research programs or clinical trials. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, our intellectual property rights might be challenged, invalidated, circumvented or rendered unenforceable. Our competitors or other third parties may successfully challenge and invalidate or render unenforceable our issued patents, including any patents that may be issued in the future. This could prevent or limit our ability to stop competitors from marketing products that are identical or substantially equivalent to the Genio system. In addition, despite the broad definition of our concepts and inventions in our portfolio, as is common in technological progress, competitors may be able to design around our patents or develop products that provide outcomes that are comparable to the Genio system but that are not covered by our patents. Much of our value is in our intellectual property, and any challenge to our intellectual property portfolio (whether successful or not) may affect our value.

***We could become subject to intellectual property litigation.***

The medical device industry is characterized by rapidly changing products and technologies and there is intense competition to establish intellectual property and proprietary rights covering the use of these new products and the related technologies. This vigorous pursuit of intellectual property and proprietary rights has resulted and will continue to result in extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product and/or a process infringes a patent involves complex legal and factual issues, and the outcome of such disputes is often uncertain.

There may be existing patents of which we are unaware that are inadvertently infringed by the Genio system. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates.

We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market the Genio system and our product candidates.

Any infringement claim against us, even if without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources and/or divert the time and efforts of management from the conduct of our business. In addition, any intellectual property litigation could force us to do one or more of the following: (i) stop selling the Genio system or using technology that contains the allegedly infringing intellectual property; (ii) forfeit the opportunity to license our patented technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; (iii) pay substantial damages to the party whose intellectual property rights we may be found to be infringing; or (iv) redesign those products that contain or utilize the allegedly infringing intellectual property. As of the date of this Annual Report, there is no intellectual property litigation pending against us.

Additionally, competitors and other third parties may infringe or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

***If we are unable to protect the confidentiality of our proprietary information, our business and competitive position would be harmed.***

We rely upon unpatented confidential and proprietary information, including technical information, know-how, and other trade secrets to develop and maintain our competitive position with respect to the Genio system. While we generally enter into non-disclosure or confidentiality agreements with our employees and other third parties to protect our intellectual property and trade secrets, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our proprietary information. Further, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our product candidates that we consider proprietary. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary information will be effective. If any of our proprietary information is disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

***We depend on exclusive licenses and agreements with third parties, which might not provide adequate protection for our technology.***

We rely on licensing agreements providing us exclusivity in the field of our practice. While we have ensured through multiple robust agreements acquisition of exclusive licenses and freedom to operate for our technology, as with any agreement, under unexpected or unpredictable circumstances, these could be under a risk of being terminated despite companies' efforts and diligence in ensuring integrity of the agreement. Should the agreements be found invalid or licenses revoked and the licensor decide to sue us for infringement of its patents rights, this could expose us to risks of litigation. In addition, any intellectual property litigation could force us to do one or more of the following: (i) stop selling the Genio system or using technology that contains the allegedly infringing intellectual property; (ii) forfeit the opportunity to license our patented technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; (iii) pay substantial damages to the party whose intellectual property rights we may be found to be infringing; or (iv) redesign those products that contain or utilize the allegedly infringing intellectual property. The requirement to obtain licenses to third party intellectual property could also arise in the future. If we need to license in any third-party intellectual property, we could be required to pay lump sums or royalties on our products. In addition, if we are required to obtain licenses to third party intellectual property, we might not be able to obtain such licenses on commercially reasonable terms or at all.

We may be subject to claims by third parties asserting that we or our employees have infringed upon, misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

### **2.9.7 Risks related to the ordinary shares**

***The dual listing of our ordinary shares may adversely affect the liquidity and value of the ordinary shares.***

Our ordinary shares trade on both Euronext Brussels and the Nasdaq Global Market. Trading of the ordinary shares in these markets will take place in different currencies (U.S. dollars on the Nasdaq Global Market and € on Euronext Brussels), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Belgium). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on Euronext Brussels could cause a decrease in the trading price of the ordinary shares on the Nasdaq Global Market. Investors could seek to sell or buy our ordinary shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both the trading prices on one exchange and the ordinary shares available for trading on the other exchange. However, the dual listing of the ordinary shares may reduce the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ordinary shares in the United States.

***We intend to retain all available funds and any future earnings and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of the ordinary shares.***

We have never declared or paid any cash dividends on our shares, and we intend to retain all available funds and any future earnings to fund the development and expansion of our business. Therefore, you are not likely to receive any dividends on your ordinary shares for the foreseeable future and the success of an investment in ordinary shares will depend upon any future appreciation in their value. Consequently, investors may need to sell all or part of their holdings of ordinary shares after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ordinary shares will appreciate in value or even maintain the price at which our investors have purchased them. Investors seeking cash dividends should not purchase the ordinary shares.

***We or the third parties upon which we depend may be adversely affected by general political, unstable market and economic conditions and other events beyond our control and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

We have become increasingly subject to the risks arising from adverse changes in market and economic and political conditions, both domestically and globally, including trends toward protectionism and nationalism, other unfavorable changes in economic conditions as well as disruptions in global credit and financial markets, such as inflation, failures and instability in U.S. and international banking systems, downgrades of the U.S. credit rating, rising interest rates, slower economic growth or a recession, and other events beyond our control, such as natural disasters, pandemics such as the COVID-19 (coronavirus), epidemics, political instability, and armed conflicts and wars, including the ongoing conflict between Russia and Ukraine, the war between Israel and Hamas.

Increases in inflation could raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows. In response to high levels of inflation and recession fears, the U.S. Federal Reserve, the European Central Bank, and the Bank of England have raised, and may continue to raise, interest rates and implement fiscal policy interventions. Even if these interventions lower inflation, they may also reduce economic growth rates, create a recession, and have other similar effects.

If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult to secure, more costly or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could harm our growth strategy, financial performance and stock price and could require us to delay or abandon plans with respect to our business, including clinical development plans. Further, recent developments in the banking industry could adversely affect our business. We cannot predict the impact that the high market volatility and instability of the banking sector more broadly could have on economic activity and our business in particular. In addition, there is a risk that one or more of our current service providers, manufacturers or other third parties with which we conduct business may not survive difficult economic times, including the current global situation resulting from the COVID-19 pandemic, the ongoing conflict between Russia and Ukraine, the war between Israel and Hamas, the instability of the banking sector, and the uncertainty associated with current worldwide economic conditions, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our research and development facility and all manufacturing facilities are located in Tel Aviv, Israel. In addition, the majority of our employees and some officers are residents of Israel. Accordingly, political, economic and military conditions in Israel, including the ongoing conflict between Israel and Hamas,

may directly adversely affect our business. Any armed conflicts, terrorist activities, political instability in the region or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our business conditions in general and harm our results of operations. Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although Israeli legislation requires the Israeli government to cover the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure that this government coverage will be maintained, or if maintained, will be sufficient to fully compensate us if any damages are incurred. Any losses or damages incurred by us could have a material adverse effect on our business.

The effects of current and future economic and political conditions and other events beyond our control on us, patients, our third party vendors, including clinical trial sites, and our partners could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

***Investors resident in countries other than Belgium may suffer dilution if they are unable to participate in future preferential subscription rights offerings.***

Under Belgian law and our constitutional documents, shareholders have a waivable and cancellable preferential subscription right to subscribe pro rata to their existing shareholdings to the issuance, against a contribution in cash, of new ordinary shares or other securities entitling the holder thereof to new ordinary shares, unless such rights are limited or cancelled by resolution of our general shareholders' meeting or, if so authorized by a resolution of such meeting, our board of directors. The exercise of preferential subscription rights by certain shareholders not residing in Belgium (including those in the United States, Australia, Israel, Canada or Japan) may be restricted by applicable law, practice or other considerations, and such shareholders may not be entitled to exercise such rights, unless the rights and ordinary shares are registered or qualified for sale under the relevant legislation or regulatory framework. In particular, we may not be able to establish an exemption from registration under the U.S. Securities Act, and we are under no obligation to file a registration statement with respect to any such preferential subscription rights or underlying securities or to endeavor to have a registration statement declared effective under the U.S. Securities Act. Shareholders in jurisdictions outside Belgium who are not able or not permitted to exercise their preferential subscription rights in the event of a future preferential subscription rights, equity or other offering may suffer dilution of their shareholdings.



# 3

## Shares and Shareholders



# Shares and Shareholders

## 3.1 Group structure

The Group is composed of Nyxoah SA and its wholly owned subsidiaries:

- Nyxoah Ltd (Israeli subsidiary, incorporated on January 1, 2008 under the name M.L.G. Madaf G. Ltd and a subsidiary of Nyxoah SA since October 21, 2009), which conducts research and development and manufacturing activities, and the preparation of commercial activities.
- Nyxoah Pty Ltd (Australian subsidiary, incorporated on February 1, 2017), which conducts clinical activities.
- Nyxoah Inc. (U.S. subsidiary, incorporated on May 14, 2020), which conducts clinical activities and the preparation of commercial activities.
- Nyxoah GmbH (German subsidiary, incorporated on May 11, 2023 under the name Blitz F23-668 GmbH and a subsidiary of Nyxoah SA since July 26, 2023) which conducts commercial activities.

The following chart represents the Group's structure at the date of this Annual Report:



The Company does not carry out any activities through a branch office.

## 3.2 Share capital and shares

### 3.2.1 Capital increases and issuance of shares in 2023

On January 1, 2023, the share capital of the Company amounted to EUR 4,440,069.16 and was represented by 25,846,279 shares.

On March 29, 2023, the Company issued 393,162 shares pursuant to a capital increase by way of contributions in cash in the framework of the Company's "at-the-market" ("ATM") facility.

On March 30, 2023, the Company issued 2,047,544 shares pursuant to a capital increase by way of contributions in cash in the framework of a private placement.

On April 17, 2023, the Company issued 375,000 shares pursuant to a capital increase by way of contributions in cash in the framework of the Company's ATM facility.

On July 14, 2023, the Company issued 2,000 shares pursuant to an exercise of subscription rights.

On August 29, 2023, the Company issued 10,000 shares pursuant to an exercise of subscription rights.

Consequently, on December 31, 2023, the Company's registered capital amounted to EUR 4,925,869.05, represented by 28,673,985 shares.



### 3.2.2 Outstanding subscription rights

The Company has currently outstanding ESOP Warrants (subscription rights) pursuant to four outstanding share based incentive plans, namely (i) the ESOP Warrants that were granted to employees, officers, directors, consultants and advisors of the Company and its Subsidiaries pursuant to the 2018 Warrants plan (the "2018 ESOP Warrants"), (ii) the ESOP Warrants that were granted to employees, officers, directors, consultants and advisors of the Company and its Subsidiaries pursuant to the 2020 Warrants plan (the "2020 ESOP Warrants"), (iii) the ESOP Warrants that were granted to employees, officers, directors, consultants and advisors of the Company and its Subsidiaries pursuant to the 2021 Warrants plan (the "2021 ESOP Warrants"), and (iv) the ESOP Warrants that were issued and/or granted to employees, officers, directors, consultants and advisors of the Company and its Subsidiaries pursuant to the 2022 Warrants plan (the "2022 ESOP Warrants").

The following table provides an overview of the ESOP Warrants that are outstanding (i.e. still exercisable) as of December 31, 2023.

Type of ESOP Warrants Plan	Number of ESOP Warrants issued	Number of ESOP Warrants lapsed, exercised or no longer available for grant	Number of ESOP Warrants outstanding	Issue date	Expiration date	Exercise Price ESOP Warrant (€)	Number and type of Shares issuable per ESOP Warrant	Aggregate number and type of Shares issuable upon exercise of outstanding ESOP Warrants
2018 ESOP Warrants	525	425	100	12 Dec 2018	12 Dec 2028	3 259.91 <sup>a</sup> 5 966.59 <sup>b</sup>	500 <sup>m</sup> common shares per ESOP Warrant	50 000 common shares
2020 ESOP Warrants	550 000	139 500	410 500	21 Feb 2020	21 Feb 2030	11.94	1 common share per ESOP Warrant	410 500 common shares
2021 ESOP Warrants	1 400 000	280 750	1 119 250	8 Sep 2021	8 Sep 2031	25.31 <sup>c</sup> 17.76 <sup>d</sup> 13.82 <sup>e</sup> 12.95 <sup>f</sup> 9.66 <sup>g</sup> 5.42 <sup>h</sup> 6.36 <sup>i</sup> 7.19 <sup>j</sup>	1 common share per ESOP Warrant	1 119 250 common shares
2022 ESOP Warrants	700 000	0	700 000	28 Dec 2022	28 Dec 2032	7.19 <sup>k</sup> 5.92 <sup>l</sup>	1 common share per ESOP Warrant	700 000 common shares
<b>Total</b>								<b>2 279 750 common shares</b>

Notes:

<sup>a</sup> For 67 2018 ESOP Warrants granted in July 2019. This results in a subscription price of € 6.52 (rounded) per new Share.

<sup>b</sup> For 33 2018 ESOP Warrants granted in April 2020. This results in a subscription price of € 11.93 (rounded) per new Share.

<sup>c</sup> For 25,185 2021 ESOP Warrants granted and accepted in 2021 and 2022.

<sup>d</sup> For 97,375 2021 ESOP Warrants granted and accepted in 2022.

<sup>e</sup> For 58,875 2021 ESOP Warrants granted and accepted in 2022.

<sup>f</sup> For 150,000 2021 ESOP Warrants granted and accepted in 2022.

<sup>g</sup> For 6,250 2021 ESOP Warrants granted and accepted in 2022.

<sup>h</sup> For 595,167 2021 ESOP Warrants granted and accepted in 2021, 2022 and 2023.

<sup>i</sup> For 25,000 2021 ESOP Warrants granted and accepted in 2023.

<sup>j</sup> For 161,398 2021 ESOP Warrants granted and accepted in 2023.

<sup>k</sup> For 13,602 2022 ESOP Warrants granted and accepted in 2023.

<sup>l</sup> For 42,254 2022 ESOP Warrants granted and accepted in 2023.

<sup>m</sup> Taking into account the Share Split at a ratio of 500:1 that was approved by an extraordinary shareholders' meeting on February 21, 2020.

### 3.2.3 Number, form and transferability of shares

Of the 28,673,985 shares of Nyxoah SA outstanding at the end of 2023, 17,814,212 shares were registered shares and 10,859,773 shares were dematerialized shares. All shares are fully paid up and are of the same class (common shares).

The articles of association of the Company do not contain any restriction on the transfer of the shares.

The Company is not aware of shareholders' agreements that may give rise to restrictions on the transfer of shares.

### 3.2.4 Rights attached to the shares

Each share (i) entitles its holder to one vote at Nyxoah SA's shareholders' meetings; (ii) has the same rights and obligations, (iii) equally shares in the profit of Nyxoah SA; and (iv) gives its holder a preferential subscription right to subscribe to new shares, convertible bonds or warrants in proportion to the part of the share capital represented by the shares already held. The preferential subscription right can be restricted or cancelled by a resolution approved by the shareholders' meeting, or by the Board of Directors subject to an authorization of the shareholders' meeting, in accordance with the provisions of the Belgian CCA and the Company's articles of association.

The articles of association of the Company do not contain any restriction on voting rights.

The Company is not aware of shareholders' agreements that may give rise to restrictions on the exercise of voting rights.

There are no holders of securities with special control rights in the Company, nor are there any control mechanisms in case of an employee shareholding system.

### 3.2.5 Procedure for changes in share capital

In principle, changes to the share capital are decided by the shareholders. The general shareholders' meeting may at any time decide to increase or reduce the share capital of the Company. Such resolution requires the presence or representation of at least 50% of the share capital of the Company and a majority of at least 75% of the votes cast (whereby abstentions are not included in the numerator nor in the denominator). In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented, but a resolution still requires a majority of at least 75% of the votes cast.

Subject to the same quorum and majority requirements, the general shareholders' meeting may authorize the board of directors, within certain limits, to increase the Company's share capital without any further approval of the shareholders. This is the so-called authorized capital (see below). This authorization needs to be limited in time (i.e. it can only be granted for a renewable period of maximum five years) and scope (i.e. the authorized capital may not exceed the amount of the registered capital at the time of the authorization).

### 3.2.6 The Company's authorised capital

On September 7, 2020, the Company's general shareholders' meeting authorized the Board of Directors to increase the share capital of the Company within the framework of the authorized capital with a maximum of 100% of its amount as at the closing of the IPO (i.e. EUR 3,680,297.39). The Company's general shareholders' meeting decided that the Board of Directors, when exercising its powers under the authorized capital, will be authorized to restrict or cancel the statutory preferential subscription rights of the shareholders (within the meaning of article 7:188 and following of the Belgian CCA). This authorization includes the restriction or cancellation of preferential subscription rights for the benefit of one or more specific persons (whether or not employees of the Company or its subsidiaries) and the authority to increase the Company's capital after having been notified by the FSMA that the Company is the subject of a public takeover bid.

The authorization is valid until November 10, 2025 (i.e. for a term of five years as from the date of the publication of the authorization in the Annexes to the Belgian State Gazette on November 10, 2020).

In 2023, the Company made use of the authorized capital on March 30, 2023, in connection with a private placement.

### 3.2.7 Purchase and sale of own shares

The Company may acquire, pledge and dispose of its own shares, profit certificates or associated certificates at the conditions provided for by articles 7:215 and following of the Belgian CCA. These conditions include a prior special shareholders' resolution approved by at least 75% of the votes validly cast at a general shareholders' meeting (whereby abstentions are not included in the numerator nor in the denominator) where at least 50% of the share capital and at least 50% of the profit certificates, if any, are present or represented. Furthermore, shares can only be acquired with funds that would otherwise be available for distribution as a dividend to the shareholders and the transaction must pertain to fully paid-up shares or associated certificates. Finally, an offer to purchase shares must be made by way of an offer to all shareholders under the same conditions. Shares can also be acquired by the Company without offer to all shareholders under the same conditions, provided that the acquisition of the shares is effected in the central order book of the regulated market of Euronext Brussels or, if the transaction is not effected via the central order book, provided that the price offered for the Shares is lower than or equal to the highest independent bid price in the central order book of the regulated market of Euronext Brussels at that time.

Generally, the general shareholders' meeting or the Articles of Association determine the amount of shares, profit certificates or certificates that can be acquired, the duration of such an authorization which cannot exceed five years as from the publication of the proposed resolution as well as the minimum and maximum price that the Board of Directors can pay for the shares.

The prior approval by the shareholders is not required if the Company purchases the shares to offer them to the Company's personnel, in which case the shares must be transferred within a period of 12 months as from their acquisition.

The Board of Directors may also expressly be authorised to dispose of the Company's own shares to one or more specific persons other than employees of the Company or its subsidiaries, in accordance with the provisions of the Belgian CCA.

The authorizations referred to above (if any) shall extend to the acquisition and disposal of shares of the Company by one or more of its direct subsidiaries, within the meaning of the legal provisions relating to the acquisition of shares in their parent company by subsidiaries.

The Company's general shareholders' meeting did not grant such authorization to the Board of Directors.

As of the date of this Annual Report, the Company does not hold any own Shares.

### 3.2.8 Anti-takeover provisions

Public takeover bids for shares and other securities giving access to voting rights (such as subscription rights or convertible bonds, if any) are subject to supervision by the FSMA. Any public takeover bid must be extended to all of the Company's voting securities, as well as all other securities giving access to voting rights. Prior to making a bid, a bidder must publish a prospectus which has been approved by the FSMA prior to publication.

The Belgian Act of April 1, 2007 on public takeover bids, as amended (the "Belgian Takeover Act") provides that a mandatory bid must be launched if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting for their account, directly or indirectly holds more than 30% of the voting securities in a company having its registered office in Belgium and of which at least part of the voting securities are traded on a regulated market or on a multilateral trading facility designated by the Belgian Royal Decree of April 27, 2007 on public takeover bids, as amended (the "Belgian Takeover Decree"). The mere fact of exceeding the relevant threshold through the acquisition of shares will give rise to a mandatory bid, irrespective of whether the price paid in the relevant transaction exceeds the current market price. The duty to launch a mandatory bid does not apply in certain cases set out in the Belgian Takeover Decree such as (i) in case of an acquisition if it can be shown that a third party exercises control over the Company or that such party holds a larger stake than the person holding 30% of the voting securities or (ii) in case of a capital increase with preferential subscription rights decided by the Company's general shareholders' meeting.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose significant shareholdings and merger control, that may apply towards the Company and which may create hurdles to an unsolicited tender offer, merger, change in management or other change in control. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of the shares. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their shares at a premium.

In addition, pursuant to Belgian company law, the board of directors of Belgian companies may in certain circumstances, and subject to prior authorization by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (pursuant to the "authorized capital") or through share buy-backs (i.e. purchase of own shares). In principle, the authorization of the Board of Directors to increase the share capital of the Company through contributions in kind or in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the securities of the Company. The general shareholders' meeting can, however, under certain conditions, expressly authorize the Board of Directors to increase the capital of the Company in such case by issuing shares in an amount of not more than 10% of the existing Shares at the time of such a public takeover bid.

On September 7, 2020, the Company's general shareholders' meeting expressly authorized the Board of Directors to increase the Company's capital after having been notified by the FSMA that the Company is the subject of a public takeover bid.

The Articles of Association do not provide for any other specific protective mechanisms against public takeover bids.

The Company did not enter into any agreement with its directors or employees providing for compensation when, as a result of a public takeover bid, the directors resign or have to resign without valid reason or the employment of employees is terminated.

### 3.2.9 Material contracts containing change of control clauses

On June 30, 2016, the Company entered into a loan agreement with Novallia SA in the amount of € 500,000 for a duration of eight years. The agreement is subject to a change of control provision pursuant to which Novallia SA may terminate the credit agreement and claim repayment of all outstanding amounts in the event of a change in the shareholder structure.

### 3.2.10 Procedure for amending the Company's articles of association

Amendments to the Company's articles of association (other than an amendment of the corporate purpose), require the presence or representation of at least 50% of the share capital of the Company and a majority of at least 75% of the votes cast (whereby abstentions are not included in the numerator nor in the denominator). An amendment of the Company's corporate purpose requires the approval of at least 80% of the votes cast at a general shareholders' meeting (whereby abstentions are not included in the numerator nor in the denominator), which can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting may validly deliberate and decide regardless of the number of Shares present or represented. The special majority requirements, however, remain applicable.

## 3.3 Shareholders

### 3.3.1 Major shareholders

Based on the transparency notifications received by the Company and relevant SEC filings in the U.S., the shareholders' structure of the Company (including all shareholders owning 3% or more of Nyxoah SA's shares) on December 31, 2023 was as follows:

Shareholder	Number of shares declared in most recent public filing (1)	% of shares based on denominator at time of triggering event (2)	% of shares (simulation) based on denominator on December 31, 2023 (3)
Cochlear Investments Pty Ltd (4)	5 090 779	19.40%	17.75%
Cooperatieve Gilde Healthcare III Sub-Holding UA + Cooperatieve Gilde Healthcare III Sub-Holding 2 UA (5)	3 153 822	14.72%	11.00%
Robert Taub + Robelga SRL (6)	3 390 514	11.99%	11.82%
Together Partnership (7)	2 948 285	10.42%	10.28%
Jürgen Hambrecht	1 047 029	4.89%	3.65%
Resmed Inc. (7)	1 619 756	5.73%	5.65%
Others (8)	11 423 800		39.85%
<b>Total (denominator) on December 31, 2023</b>	<b>28 673 985</b>		<b>100.00%</b>

(1) As a result of transactions that do not need to be disclosed to Nyxoah or filed with the SEC, the numbers mentioned in this column might not be the actual numbers of shares held by the relevant shareholders at the date of this Annual Report.

(2) Percentages based on number of shares and denominator at time of event that triggered transparency notification or SEC filing.

(3) Percentages based on number of shares at time of event that triggered transparency notification or SEC filing but on current denominator.

(4) Cochlear Investments Pty Ltd is 100% held by Cochlear Limited. Cochlear Limited is not controlled.

(5) Cooperatieve Gilde Healthcare III Sub-Holding UA and Cooperatieve Gilde Healthcare III Sub-Holding 2 UA hold the shares in Nyxoah. Gilde Healthcare III Management BV is the management company of these two entities and can -in the absence of specific instructions- exercise the voting rights at its discretion. Gilde Healthcare III Management BV is controlled by Gilde Healthcare Holding BV. Gilde Healthcare Holding BV is not controlled.

(6) Robelga SRL is 100% owned by BMI estate (a partnership (société simple) without legal personality). Robert Taub has 100% usufruct and Robert Taub's children have 100% bare ownership of BMI estate.

(7) Not controlled.

(8) Existing shareholders whose shareholding does not exceed 3%.

### 3.3.2 Agreements between shareholders of the Company

On the date of this Annual Report, the Company has no knowledge of the existence of any shareholders' agreements between its shareholders.

### 3.3.3 Agreements between the Company and major shareholders

#### ***Collaboration Agreement with Cochlear***

The Company and Cochlear Limited ("Cochlear") have entered into a collaboration agreement, dated November 7, 2018, under which the Company and Cochlear agree to collaborate to further develop and progress commercialization of implantable treatments for sleep disordered breathing conditions. Cochlear has significant expertise in the development of implantable devices and this agreement can therefore be considered as material.

The specific contributions and services to be used, applied and provided by both parties are further detailed in a document called "Statement of Work" that may be agreed upon by the parties from time to time. The initial Statement of Work was agreed upon by the Company and Cochlear on November 7, 2018. According to this Statement of Work, Cochlear would evaluate three packaging technologies (i.e. Titanium, Ceramic and Hybrid) and support the Company in the assessment of the Company's encapsulation technologies. The objectives of this initial Statement of Work have been met. Additional Statements of Work were entered into on June 8, 2020 and January 30, 2023 and were both completed in 2023.

As no new Statement of Work was entered into and parties do not currently have the intention to enter into additional Statements of Work, the collaboration agreement can be considered as ended.

#### ***Agreement with Man & Science SA (a company held and controlled by Robert Taub, TOGETHER Partnership, Jürgen Hambrecht and Noshaq SA)***

The Company, Man & Science SA (a company held and controlled by Robert Taub, TOGETHER Partnership, Jürgen Hambrecht and Noshaq SA), Cephalix SA<sup>1</sup>, Glucobel SA, Surgical Electronics SA and Dr. Adi Mashiach have entered into a multiparty agreement<sup>2</sup> regarding their respective ownership and licensing rights in relation to multiple inventions, including but not limited to inventions generally related to implantable flexible neuro-stimulators and inventions for specific medical indications including sleep disordered breathing, head pain, glucose monitoring, hypertension and other indications. This agreement provides that (i) the Company fully owns all rights in relation to the inventions specifically related to the sleep disordered breathing field and (ii) Man & Science SA is the owner of the generic inventions and granted a fully paid-up, exclusive and worldwide, license with respect to these inventions to several parties, including the Company in the field of sleep disordered breathing. On June 23, 2016, the Company, Cephalix SA, Surgical Electronics SA, and Man & Science SA entered into a confirmatory addendum, aiming to confirm that (i) the Company fully owns all rights in relation to the inventions specifically related to the sleep disordered breathing field as further detailed in the agreement, (ii) Man & Science SA granted an exclusive, worldwide, fully paid-up, royalty free and transferable license to the Company in the "Shared Patents" in the Sleep Disordered Breathing field inventions and (iii) the Company granted an exclusive, fully paid-up, royalty free, transferable license to use the patents as listed in the schedules to the agreement outside the sleep disordered breathing field, namely to Cephalix SA in the head pain field, Surgical Electronics SA in the hypertension field and Man & Science SA outside the head pain field and the hypertension field.

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<sup>1</sup> Pursuant to a notarial deed of December 19, 2018, Man & Science SA was merged into Cephalix SA, which resulted in a transfer under universal title of all assets and liabilities of Man & Science SA to Cephalix SA. At the same time Cephalix SA changed its corporate name to Man & Science SA.

<sup>2</sup> This agreement is undated.

In February 2020, the Company entered into a clarification of the confirmatory addendum with Man & Science SA. The clarification confirms that the license granted to the Company by Man & Science SA under the agreement and the confirmatory addendum are irrevocable, transferable, fully paid up, royalty-free and include the right to grant sublicenses in the sleep disordered breathing field, which are retroactive as from the filing date of the oldest of the patents and patent applications and will continue in effect until the last to expire patent, which is expected to occur in 2032 (excluding any potential patent term extension). The Company does not have current or future financial obligations to Man & Science SA pursuant to the agreement.





4

# Consolidated Financial Statements



# Consolidated Financial Statements as of December 31, 2023

## 4.1 Statement by the Board of Directors

The Board of Directors, represented by all its members, hereby certifies that, to the best of its knowledge,

a. the consolidated financial statements, 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

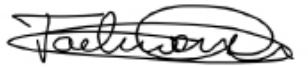
b. this Annual Report of the Board of Directors provides a true and fair overview of the development, results and the position of the Company and the undertakings included in the consolidation taken as a whole, as well as a description of the principal risks and uncertainties that they face.

Mont-Saint-Guibert, March 20, 2024

On behalf of the Board of Directors

Robert Taub, Chairman

Olivier Taelman, CEO



## 4.2 Consolidated balance sheets

(in thousands)	Notes	As at December 31	
		2023	2022
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	7	€ 4 188	€ 2 460
Intangible assets	8	46 608	39 972
Right of use assets	9	3 788	3 159
Deferred tax asset	29	56	47
Other long-term receivables	10	1 166	173
		<b>€ 55 806</b>	<b>€ 45 811</b>
<b>Current assets</b>			
Inventory	11	3 315	882
Trade receivables	12	2 758	1 463
Other receivables	12	3 212	1 775
Other current assets		1 318	1 284
Financial assets	14	36 138	76 968
Cash and cash equivalents	13	21 610	17 888
		<b>€ 68 351</b>	<b>€ 100 260</b>
<b>Total assets</b>		<b>€ 124 157</b>	<b>€ 146 071</b>

(in thousands)	Notes	As at December 31	
		2023	2022
<b>EQUITY AND LIABILITIES</b>			
<b>Capital and reserves</b>			
Capital	15	4 926	4 440
Share premium	15	246 127	228 275
Share based payment reserve	16	7 661	5 645
Other comprehensive income	15	137	176
Retained loss		(160 829)	(118 212)
<b>Total equity attributable to shareholders</b>		<b>€ 98 022</b>	<b>€ 120 324</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Financial debt	17	8 373	8 189
Lease liability	9	3 116	2 586
Pension liability	26	9	–
Provisions		185	59
Deferred tax liability	29	9	–
		<b>€ 11 692</b>	<b>€ 10 834</b>
<b>Current liabilities</b>			
Financial debt	17	364	388
Lease liability	9	851	719
Trade payables	18	6 155	4 985
Current tax liability	29	1 988	3 654
Other payables	19	5 085	5 167
		<b>€ 14 443</b>	<b>€ 14 913</b>
<b>Total liabilities</b>		<b>€ 26 135</b>	<b>€ 25 747</b>
<b>Total equity and liabilities</b>		<b>€ 124 157</b>	<b>€ 146 071</b>

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

### 4.3 Consolidated statements of loss and other comprehensive loss

(in thousands)	For the year ended December 31		
	Notes	2023	2022
Revenue	20	€ 4 348	€ 3 084
Cost of goods sold	20	(1 656)	(1 150)
<b>Gross profit</b>		<b>€ 2 692</b>	<b>€ 1 934</b>
Research and Development Expense	22	(26 651)	(15 861)
Selling, General and Administrative Expense	23	(21 687)	(18 855)
Other income/(expense)	24	544	283
<b>Operating loss for the period</b>		<b>(45 102)</b>	<b>(32 499)</b>
Financial income	27	4 174	6 763
Financial expense	28	(3 729)	(4 320)
<b>Loss for the period before taxes</b>		<b>(44 657)</b>	<b>(30 056)</b>
Income taxes	29	1 445	(1 169)
<b>Loss for the period</b>		<b>(43 212)</b>	<b>(31 225)</b>
<b>Loss attributable to equity holders</b>		<b>(43 212)</b>	<b>(31 225)</b>
<b>Other comprehensive income/(loss)</b>			
<b>Items that may not be subsequently reclassified to profit or loss (net of tax)</b>			
Remeasurements of post-employment benefit obligations, net of tax	26	81	70
<b>Items that may be subsequently reclassified to profit or loss (net of tax)</b>			
Currency translation differences		(120)	(96)
<b>Total other comprehensive income/(loss)</b>		<b>€ (39)</b>	<b>€ (26)</b>
<b>Total comprehensive loss for the year, net of tax</b>		<b>€ (43 251)</b>	<b>€ (31 251)</b>
<b>Loss attributable to equity holders</b>		<b>€ (43 251)</b>	<b>€ (31 251)</b>
Basic loss per share (in EUR)	30	€ (1.545)	€ (1.209)
Diluted loss per share (in EUR)	30	€ (1.545)	€ (1.209)

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

## 4.4 Consolidated statements of changes in equity

(in thousands)	Notes	Attributable to owners of the parent					Total
		Common shares	Share premium	Share based payment reserve	Other comprehensive income	Retained loss	
Balance at January 1, 2022		€ 4 427	€ 228 033	€ 3 127	€ 202	€ (87 167)	€ 148 622
Loss for the period		–	–	–	–	(31 225)	(31 225)
Other comprehensive loss for the period		–	–	–	(26)	–	(26)
Total comprehensive loss for the period		–	–	–	€ (26)	€ (31 225)	€ (31 251)
Equity-settled share-based payments							
Granted during the period	16	–	–	2 698	–	–	2 698
Exercised during the period	15	6	242	(180)	–	180	248
Issuance of shares for cash	15	7	–	–	–	–	7
Total transactions with owners of the company recognized directly in equity		13	242	2 518	–	180	2 953
Balance at December 31, 2022		€ 4 440	€ 228 275	€ 5 645	€ 176	€ (118 212)	€ 120 324

**Attributable to owners of the parent**

(in thousands)	Notes	Common shares	Share premium	Share based payment reserve	Other comprehensive income	Retained loss	Total
Balance at January 1, 2023		€ 4 440	€ 228 275	€ 5 645	€ 176	€ (118 212)	€ 120 324
Loss for the period		–	–	–	–	(43 212)	(43 212)
Other comprehensive income for the period		–	–	–	(39)	–	(39)
<b>Total comprehensive loss for the period</b>		–	–	–	€ (39)	€ (43 212)	€ (43 251)
Equity-settled share-based payments							
Granted during the period	16	–	–	2 611	–	–	2 611
Exercised during the period	16	2	60	(18)	–	18	62
Expired during the period	16	–	–	(577)	–	577	–
Transaction cost	15	–	(340)	–	–	–	(340)
Issuance of shares for cash	15	484	18 132	–	–	–	18 616
<b>Total transactions with owners of the company recognized directly in equity</b>		486	17 852	2 016	–	595	20 949
Balance at December 31, 2023		€ 4 926	€ 246 127	€ 7 661	€ 137	€ (160 829)	€ 98 022

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

## 4.5 Consolidated statements of cash flow

(in thousands)	For the year ended December 31		
	Notes	2023	2022
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Loss before tax for the year		€ (44 657)	€ (30 056)
Adjustments for			
Finance income	27	(4 174)	(6 763)
Finance expenses	28	3 729	4 320
Depreciation and impairment of property, plant and equipment and right-of-use assets	7,9	1 398	1 119
Amortization of intangible assets	8	962	813
Share-based payment transaction expense	16	2 611	2 698
Remeasurement of recoverable cash advances	17	(324)	(247)
Increase/(decrease) in provisions		216	37
Other non-cash items		(256)	(356)
<b>Cash generated before changes in working capital</b>		<b>€ (40 495)</b>	<b>€ (28 435)</b>
(Increase)/decrease in inventory		(2 433)	(536)
(Increase)/decrease in trade and other receivables		(1 540)	7
Increase/(decrease) in trade and other payables		479	615
<b>Cash generated from changes in operations</b>		<b>(43 989)</b>	<b>(28 349)</b>
Interests received		–	3
Income tax paid		(789)	(410)
<b>Net cash generated from / (used in) operating activities</b>		<b>(44 778)</b>	<b>(28 756)</b>



**For the year ended December 31**

(in thousands)	Notes	2023	2022
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchases of property, plant and equipment	7	(2 500)	(886)
Capitalization of intangible assets	8	(8 462)	(15 463)
Purchase of financial assets - current		(80 018)	(102 620)
Proceeds from sale of financial assets - current		120 681	28 913
Interest income on financial assets		2 310	110
<b>Net cash generated from / (used in) investing activities</b>		<b>€ 32 011</b>	<b>€ (89 946)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Payment of principal portion of lease liabilities	9	(757)	(772)
Repayment of other loan	17	(83)	(83)
Interests paid		(192)	(130)
Repayment of recoverable cash advance	17	(396)	(216)
Proceeds from issuance of shares, net of transaction costs	15	18 337	255
Other financial costs		(51)	(37)
<b>Net cash generated from / (used in) financing activities</b>		<b>16 858</b>	<b>(983)</b>
<b>Movement in cash and cash equivalents</b>		<b>4 091</b>	<b>(119 685)</b>
Effect of exchange rates on cash and cash equivalents		(369)	2 064
<b>Cash and cash equivalents at January 1</b>	<b>13</b>	<b>17 888</b>	<b>135 509</b>
<b>Cash and cash equivalents at December 31</b>	<b>13</b>	<b>€ 21 610</b>	<b>€ 17 888</b>

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





5

# Notes to the Consolidated Financial Statements

# Notes to the Consolidated Financial Statements

## 5.1 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. Nyxoah SA is registered with the legal entities register (Brabant Walloon) under enterprise number 0817.149.675. The Company’s registered office is in Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

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

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

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

Nyxoah SA has four wholly owned subsidiaries: Nyxoah Ltd, a subsidiary of the Company since October 21, 2009 (located in Israel and incorporated on January 10, 2008 under the name M.L.G. Madaf G. Ltd), Nyxoah Pty Ltd since February 1, 2017 (located in Australia), Nyxoah Inc. since May 14, 2020 (located in the USA) and Nyxoah GmbH since July 26, 2023 (located in Germany).

These consolidated financial statements have been authorized for issue on March 20, 2024 by the Board of Directors of the Company.

## 5.2 Material accounting policies

### 5.2.1 Basis of Preparation and Going Concern

#### ***Basis of Preparation***

The Company's consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board (IASB) and as endorsed by the European Union.

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

The preparation of the 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.

#### ***Going concern principle***

The consolidated financial statements have been prepared on a going concern basis. Please refer to note 5.1 for the detailed explanation of the going concern.

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

### 5.2.2 New and amended standards and interpretations applicable

#### ***Effective for the annual periods beginning on January 1, 2023***

The Company has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective. Several amendments and interpretations apply for the first time in 2023, but do not have an impact on the consolidated financial statements of the Company:

- IFRS 17 Insurance Contracts (applicable for annual periods beginning on or after January 1, 2023)
- Amendments to IFRS 17 Insurance contracts: Initial Application of IFRS 17 and IFRS 9 – Comparative Information (applicable for annual periods beginning on or after January 1, 2023)
- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates (applicable for annual periods beginning on or after January 1, 2023)
- Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction (applicable for annual periods beginning on or after January 1, 2023)
- Amendments to IAS 12 Income taxes: International Tax Reform – Pillar Two Model Rules (effective immediately – disclosures are required for annual periods beginning on or after 1 January 2023). The Company has adopted these amendments, however they are not yet applicable for the current reporting year as the Company's consolidated revenue is currently below the threshold of €750 million.

The following amendments have had an impact on the Company's disclosures of accounting policies, but not on the measurement, recognition or presentation of any items in the Company's financial statements:

- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting Policies (applicable for annual periods beginning on or after January 1, 2023)

### ***New standards not yet effective***

The standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Company's financial statements are disclosed below. The Company intends to adopt these standards and interpretations, if applicable, when they become effective.

- Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current and Non-current Liabilities with Covenants (applicable for annual periods beginning on or after 1 January 2024).
- Amendments to IFRS 16 Leases: Lease Liability in a Sale and Leaseback (applicable for annual periods beginning on or after January 1, 2024).
- Amendments to IAS 7 Statement of Cash Flows and IFRS 7 Financial Instruments: Disclosures: Supplier Finance Arrangements (applicable for annual periods beginning on or after 1 January 2024, but not yet endorsed in the EU).
- Amendments to IAS 21 The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability (applicable for annual periods beginning on or after 1 January 2025, but not yet endorsed in the EU).

None of the IFRS standards issued, but not yet effective are expected to have a material impact on the Company's financials.

### **5.2.3 Basis of Consolidation**

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries as at December 31, 2023 and 2022.

Subsidiaries are all entities (including structured entities) over which the Company has control. The Company controls an entity when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Company. They are deconsolidated from the date control ceases.

Inter-company transactions, balances and unrealized gains on transactions between group companies are eliminated.

### **5.2.4 Foreign Currency Translations**

The consolidated financial statements are presented in Euro, which is the Company's functional and presentation currency. For each subsidiary, the Company determines the functional currency. Items included in the financial statements of each subsidiary are measured using that functional currency.

Transactions in foreign currencies are recorded at their respective foreign exchange rate prevailing at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated at the foreign exchange rates prevailing at the closing date. Exchange differences arising on the settlement of monetary items or on reporting monetary items at rates different from those at which they were initially recorded during the period or in previous periods, are recognized in the consolidated income statement. Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates as at the date of the initial transactions.

On consolidation, the assets and liabilities of foreign operations are translated into euros at the rate of exchange prevailing at the reporting date and the income statement is translated at the average rate of the year. The exchange differences arising on the translation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognized in the income statement.

## 5.2.5 Intangible Assets

### **Patents**

Patents relate to direct attributable expenditure incurred for obtaining patent rights related to the Genio system and are carried at costs less accumulated amortization and accumulated impairment losses. Patents costs are amortized as from January 2021 together with the related Genio system capitalized development costs.

### **Research and Development Costs**

Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset when the Company can demonstrate:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The Company started recognizing the development expenditure as an asset since March 2019 triggered by obtaining CE mark for the first generation of the Genio system. As from July 2020, the Company started recognizing the development expenditure as an asset for the improved second generation of the Genio system. The asset is carried at cost less any accumulated amortization and accumulated impairment losses. Development costs include employee compensation and outsourced development expenses. Amortization of the asset begins when development is complete and the asset is available for use. The asset is depreciated on a straight-line basis over the estimated useful life of 14 years. During the period of development, the asset is tested for impairment annually. Amortization for the first generation of the Genio system started in 2021 and is recognized in the R&D and Clinical departments. See note 8.

## 5.2.6 Property, Plant and Equipment

Property, plant and equipment are initially recorded in the statement of financial position at their acquisition cost, which includes the costs directly attributable to the acquisition and installation of the asset.

Property, plant and equipment are subsequently measured at their historical cost less accumulated depreciation and impairment, if any.

Property, plant and equipment are depreciated on a straight-line basis over their estimated useful life. The estimated useful life of each category of property, plant and equipment is as follows:

- |                                  |  |
|----------------------------------|--|
| • IT equipment                   | 3 years                                |
| • Furniture and office equipment | 5 to 15 years                          |
| • Laboratory equipment           | 15 years                               |
| • Leasehold improvements         | The shorter of lease term and 10 years |

Assets under construction are not depreciated until the date that the asset is available for use.

Property, plant and equipment are derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset, which is the difference between the net disposal proceeds and the carrying amount of the asset, is included in the income statement when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.

### 5.2.7 Impairment of Intangible Assets and Property, Plant and Equipment

At each reporting date, the Company assesses whether there is an indication that property, plant and equipment and intangible assets with a definite useful life may be impaired. If an indication of impairment exists, or at least annually when impairment test is required in case of intangible assets with an indefinite useful life or intangible assets not yet for use, the Company estimates the asset's recoverable amount. The recoverable amount of an asset is the higher of the assets or cash-generating units (CGU) fair value less costs to sell and its value in use.

The recoverable amount is determined based on the value in use of the individual asset or the CGU. In assessing value in use, the estimated future pre-tax cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceeds the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the consolidated income statement.

### 5.2.8 Financial Assets

Financial assets include mainly other long-term receivables, trade receivables, other receivables, term accounts with an initial maturity longer than 3 months but less than 12 months and cash and cash equivalents, and are measured at amortized cost using the effective interest method, less impairment allowance. Interest income is recognized by applying the effective interest rate, except for short-term receivables when the effect of discounting is immaterial.

#### *Derecognition*

A financial asset is derecognized when the contractual rights to receive cash flows from the asset have expired or when the Company transferred its rights to receive cash flows and substantially all risks and rewards of ownership of the financial asset to another party.

#### *Impairment of Financial Assets*

For trade receivables and other receivables, the Company applies a simplified approach in calculating Expected Credit Losses ("ECL"). Therefore, the Company does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date. The Company has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

The carrying amount of the asset is reduced through the use of an allowance account and the loss is recognized in the income statement.

### 5.2.9 Financial Liabilities

The financial liabilities include financial debt, derivative liabilities, trade payables and other payables.

#### *Liabilities at amortized cost*

Those financial liabilities, except for the derivative liabilities, are measured at amortized cost using the effective interest rate method. Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The



effective interest rate amortization is included as financial cost in the consolidated income statement. When the estimated contractual cash flows are modified, the entity recalculates the gross carrying amount of the financial liability as the present value of the modified cash flows discounted at the original effective interest rate. The difference between the recalculated carrying amount and the initial carrying amount is included in other operating income & expense in the consolidated income statement.

#### ***Liabilities at fair value with changes in fair value through profit and loss***

The Company has derivative liabilities consisting of foreign currency options to hedge its contingency risk exposure to certain foreign currencies. Those derivative financial instruments are initially recorded at fair value and derivative financial instruments are subsequently remeasured at their fair value with changes in fair value recorded in the income statement under "Financial income/financial expenses". Any transactions costs incurred are immediately recognized in the consolidated income statement.

The Company does not apply hedge accounting to those derivative financial liabilities.

The fair value of a hedging derivative financial instrument is classified as a non-current liability when the remaining maturity of the hedged item is more than 12 months and as a current liability when the remaining maturity of the hedged item is less than 12 months. The fair value is recorded in the consolidated balance sheet under "Other payables".

#### ***Derecognition***

The Company derecognizes financial liabilities when, and only when, the Company's obligations are discharged, cancelled or they expire. The difference between the carrying amount of the financial liability derecognized and the consideration paid and payable is recognized in income statement.

### **5.2.10 Fair value measurement**

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Company. The fair value of an asset or liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that the market participants act in their economic best interest.

All assets and liabilities for which fair value is measured or disclosed in the consolidated financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 quoted (unadjusted) market prices in active markets for identical assets or liabilities;
- Level 2 valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable; and
- Level 3 valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

### **5.2.11 Inventory**

Inventories consist of raw materials, work-in-progress and finished goods of the Genio System and related components. Inventories are valued at the lower of cost and net realizable value. Costs incurred in bringing each product to its present location and condition are accounted for as follows: cost of direct materials and labor and a proportion of manufacturing overheads based on the normal operating capacity, but excluding borrowing costs. The cost is assigned using the FIFO ("first-in-first-out") method. Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

### 5.2.12 Cash and Cash Equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks, other short-term deposits with a maturity of or less than 3 months, and which are subject to an insignificant risk of changes in value.

### 5.2.13 Income Taxes

Income taxes include current income tax and deferred income tax.

#### ***Current Income Tax***

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the tax authorities. Tax rates and tax laws that are considered to determine the amount of tax assets or liabilities are those that are enacted or substantially enacted, at the reporting date.

The current income tax liability includes a liability for tax positions subject to uncertainty over income tax treatment when it is probable that an outflow of economic resources will occur. Measurement of the liability for tax positions subject to uncertainty over income tax treatment is based on either the most likely amount method or the expected value method based on the Company's best estimate of the underlying risk.

#### ***Deferred Income Tax***

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at reporting date. Deferred tax liabilities are recognized for all taxable temporary differences, except when the deferred tax liability arises from the initial recognition of an asset or liability in a transaction that at the time of the transaction affects neither the accounting profit nor taxable profit or loss.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilized, except when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that at the time of the transaction affects neither accounting profit nor taxable profit or loss.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and tax liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantially enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred taxes relate to the same taxation authority.

### 5.2.14 Employee Benefits

#### ***Short-Term Employee Benefits***

Short-term employee benefits include salaries and social security taxes, paid vacation and bonuses. They are recognized as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period are presented within current liabilities (other payables).

### ***Post-Employment Benefits***

Post-employment benefits include pensions and retirement benefits for employees, which are covered by contributions of the Company.

The Company has set up a pension plan for its employees which qualifies as Defined Benefit pension plan under IAS 19. In the view of the minimum legal returns guaranteed under such scheme, those plans qualify as Defined Benefits plans. Such pension scheme is treated in accordance with IAS 19 "Employee Benefits" as a defined benefit plan. For defined benefit plans, the amount recognized in the Statement of financial position as a net liability (asset) corresponds to the difference between the present value of future obligations and the fair value of the plan assets.

The present value of the obligation and the costs of services are determined by using the "projected unit credit method" and actuarial valuations are performed at the end of each reporting period. The actuarial calculation method implies the use of actuarial assumptions by the Company, involving the discount rate, evolution of wages, employee turnover and mortality tables. These actuarial assumptions correspond to the best estimations of the variables that will determine the final cost of post-employment benefits. The discount rate reflects the rate of return on high quality corporate bonds with a term equal to the estimated duration of the post-employment benefits obligations. The actuarial calculations of post-employment obligations are performed by independent actuaries.

Remeasurement, comprising actuarial gains and losses, the effect of the changes to the asset ceiling (if applicable) and the return on plan assets (excluding interest), is reflected immediately in the consolidated statement of financial position with a charge or credit recognized in other comprehensive income in the period in which they occur. Remeasurement recognized in other comprehensive income is reflected immediately in retained loss and will not be reclassified to profit or loss.

## **5.2.15 Share-Based Compensation**

### ***Equity-settled share-based compensation***

The Company operates an equity-based compensation plan, whereby warrants are granted to directors, management and selected employees and non-employees. The warrants are accounted for as equity-settled share-based payment plans since the Company has no legal or constructive obligation to repurchase or settle the warrants in cash.

Each warrant gives the beneficiaries the right to subscribe to one or several common share of the Company. The warrants are granted for free and have an exercise price which is determined by the Board of Directors of the Company.

The fair value of the employee services received in exchange for the grant of stock options or warrants is determined at the grant date using a Black & Scholes valuation model.

The costs of equity-settled transactions are recognized in employee benefit expense. The total amount to be expensed over the vesting period, if any, with a corresponding increase in the « share-based payment reserve » within equity, is determined by reference to the fair value of the stock options or warrants granted, excluding the impact of any non-market vesting conditions. The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the entity's best estimate of the number of equity instruments that will ultimately vest. At each closing date, the entity revises its estimates of the number of stock options that are expected to become exercisable. It recognizes the impact of the revision of original estimates, if any, in the income statement, and a corresponding adjustment to equity over the remaining vesting period.

The proceeds received net of any directly attributable transaction costs are credited to share capital when the stock options or the warrants are exercised. When warrants granted under a share-based compensation plan are exercised or when they are not exercised and have expired, the amount previously recognized under the share-based payment reserve is reclassified to the caption retained loss, within equity.

### 5.2.16 Provisions

A provision is set up by the Company if, at the reporting date, the Company has a present obligation, either legal or constructive, as a result of past events, when it is probable that an outflow of resources will be required to settle the obligation and when a reliable estimate of the amount can be made.

### 5.2.17 Leases

The Company assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

#### ***Right-of-use assets***

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Company is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated life and the lease term. Right-of-use assets are subject to impairment, but no impairment has been identified in fiscal year 2022 and 2023.

#### ***Lease liabilities***

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Company and payments of penalties for terminating a lease, if the lease term reflects the Company exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognized as expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

#### ***Short-term leases and leases of low-value assets***

The Company applies the short-term lease recognition exemption to its short-term leases of machinery, equipment and buildings (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment and bicycles that are considered of low value (i.e., below €5,000). Lease payments on short-term leases and leases of low-value assets are recognized as expense on a straight-line basis over the lease term. See note 31.2.

### 5.2.18 Revenue

The Company continues the commercialization of its Genio system in Europe, targeting customers primarily comprised of hospitals and distributors. Our internal sales force directly serves hospitals, while distributors are used in locations without a direct commercial presence. Revenue recognition aligns with the satisfaction of performance obligations under contractual agreements, with contracts having a single, short-term performance obligation.

Performance obligation is deemed fulfilled at a specific point in time when the customer gains control of the Genio system, either upon product shipment or delivery, per the terms outlined in contractual agreements. The Genio system, delivered as a kit of products simultaneously, is treated as a singular performance obligation.

#### ***Variable consideration including volume rebates***

Revenue undergoes adjustments for variable consideration and other factors influencing the transaction price. Notably, some contracts may entail a volume discount, offering a free Genio system for meeting or exceeding a specified purchase volume over a generally 12-month period. The Company allocates a portion of the transaction price to the free Genio system, determined by the relative standalone fair value, unless reasonably certain the purchase volume threshold won't be met. The Company only includes an amount of variable consideration, estimated in accordance with the most likely amount or expected value method, in the transaction price to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company provides customers with a limited right of return for products in case of non-conformity or performance issues. Since product returns have been historically de-minimis, we haven't factored in a revenue reduction related to variable considerations for returns.

#### ***Warranty obligations***

The Company provides a three-year warranty on the Genio system for general repairs of defects that existed at the time of sale. The assurance-type warranties are accounted for as warranty provisions which is currently not material.

### 5.2.19 Recoverable cash advances and other government grants

The Company received the support from a governmental agency, in this case the Walloon Region ("Region"), under the form of recoverable cash advances. Recoverable cash advances are aimed at supporting specific development programs. As part of this support, an agreement is concluded with the Region consisting in three distinct phases being a research phase, a decision phase and an exploitation phase. During the research phase, the Company receives funds from the Region based on eligible expenses incurred by the Company.

At the end of the research phase, there is a decision phase of six months, allowing the Company to decide whether or not it will use the results of the research phase.

- If the Company decides not to use the results of the research phase, it has to notify the Region and transfer to the Region the rights associated with the research phase. Accordingly, the advances received are not to be reimbursed.
- If the Company decides to use the results of the research phase, it will enter into the exploitation phase. In such a situation, the advances received become refundable through a fixed repayment part (30%) and a variable repayment scheme (0.224%-0.45%). The fix part is repayable unconditionally in accordance with a reimbursement plan. The variable part is dependent on the success of the project, i.e. based on a percentage on sales generated by the product that has benefited from the research.
- Reimbursements (fixed and variable) to be made by the Company (interests included) may represent up to 2 times the amount of cash advance received, depending on the level and the timing of the sales.

At inception, recoverable cash advances are recognized as financial liability at fair value when received. To determine the fair value of the cash advances received, the Company estimates future cash outflows considering (i) assumptions regarding the estimation of the timing and the probability of the future sales or (ii) the probability that the Company will notify the Walloon Region whether it will decide or not to use the results of the research phase and (iii) an appropriate discount rate.

At inception, if the fair value of the liability exceeds the amounts of the cash received, the difference is recognized in the income statement as operating expenses. If the amount of cash received would exceed the fair value of the liability, the difference would be considered as a government grant, being recognized in the income statement as operating income on a systematic basis in order to match the expenses incurred.

Subsequently, at each closing date, the financial liability is measured at amortized cost. When the estimated contractual cash flows are modified, the entity recalculates the gross carrying amount of the financial liability as the present value of the modified cash flows discounted at the original effective interest rate. The difference between the recalculated carrying amount and the initial carrying amount is included in the caption "other operating income/expenses" in the consolidated income statement and in the financial expenses for the impact of the discounting. When modifying the estimated contractual cash flows, the Company reviews if there are indicators, either positive or negative, influencing the estimation of the timing and level of the future sales of the products benefiting from the support of the Walloon Region.

When repayment of recoverable cash advances may be forgiven, the liability component of recoverable cash advances is treated as a government grant and taken to income only when there is reasonable assurance that the entity will meet the terms for forgiveness of the advance.

Government grants are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. When the grant relates to an asset, it is deducted from the carrying amount of the asset and is reflected in the income statement as a reduction in the amortization expense of the asset concerned on a systematic basis over the life of the asset.

## 5.2.20 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.

## 5.2.21 Significant events and transactions of the reporting period

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

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

On April 17, 2023, the Company issued 375,000 shares pursuant to the Company's \$50 million at-the-market ("ATM") program established on December 22, 2022 at an issue price equal to the market price on the Nasdaq Global Market at the time of the sale.

On July 14, 2023, the Company issued 2,000 shares pursuant to an exercise of subscription rights.

On August 29, 2023, the Company issued 10,000 shares pursuant to an exercise of subscription rights.

Consequently, on December 31, 2023, the Company's registered capital amounts to €4.9 million, represented by 28 673 985 shares.

### 5.3 Capital Management

The Company's objectives when managing capital are to maintain sufficient liquidity to meet its working capital requirements and fund capital investment in order to safeguard its ability to continue operating as a going concern. The capital structure of the Company consists of equity attributable to the shareholders, such as share capital, share premium, reserves and retained loss, and of borrowings. The capital of Nyxoah SA amounts to €4.9 million at December 31, 2023 (2022: €4.4 million). Total cash and cash equivalents amount to €21.6 million at December 31, 2023 (2022: €17.9 million). Term account amounts to €36.1 million at December 31, 2023 (2022: €77.0 million). The current cash situation and the anticipated cash generation are the most important parameters in assessing the capital structure. The Company's policy is to maintain a strong capital base in order to maintain investor confidence in its capacity to support the future development of its operations.

The Company monitors capital regularly to ensure that its ability to continue operating as a going concern (we refer to 5.1) and the legal capital requirements are met and may propose capital increases to the Shareholders' Meeting to ensure the necessary capital remains intact.

### 5.4 Management of Financial Risks

The Company's activities expose it to a variety of financial risks. The Company's finance department identifies and evaluates the financial risks in co-operation with the operating units.

#### 5.4.1 Market Risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market prices. The Company's activities may expose it to changes in foreign currency exchange rates and interest rates. The Company is not exposed to any equity price risk or commodity price risk as it does not invest in these classes of investments.

#### 5.4.2 Credit risk

The credit risk arises mainly from trade receivables, cash and cash equivalents and deposits with banks and financial institutions. The Company only works with international reputable commercial banks and financial institutions.

Furthermore, the Company is not exposed to any material credit risk from trade receivables or other receivables. Other receivables are mainly due by the tax incentive in Australia and Belgium and there is limited risk associated to this receivable.

### 5.4.3 Foreign Exchange Risk

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 does not hedge currently its operational FX risk (as already partly hedged with the contingency risk) and its risk on outstanding balances denominated in another currency than its functional currency.

Additionally, earnings variability arises from the translation of monetary assets and liabilities denominated in currencies other than the functional currency of the Company's subsidiaries at the rate of exchange at each closing date, the impact of which is reported as a foreign exchange gain or loss in the consolidated statements of comprehensive income.

Currency	2023 rates		2022 rates	
	Closing	Average	Closing	Average
NIS	3.97763	3.98960	3.78240	3.53440
AUD	1.62033	1.63002	1.57630	1.51430
USD	1.10377	1.08242	1.07270	1.05170

Based on the Company's foreign currency exposures at the level of the consolidated income statement, varying the above foreign exchange rates to reflect positive and negative changes of 5.0 % of the NIS, AUD and USD would have the following impact:

Change in foreign exchange rate	(in EUR 000)	Effect on loss (before tax)			Effect on pretax equity		
		NIS	USD	AUD	NIS	USD	AUD
2023	5%	29	-	33	56	54	352
	-5%	(29)	-	(36)	(59)	(60)	(389)
2022	5%	122	54	73	141	113	364
	-5%	(79)	(60)	(80)	(58)	(125)	(403)

### 5.4.4 Interest rate risk

The Company has a significant amount of cash in EUR and USD for which the EUR cash position may be subject to negative interest rates above a certain level. The EUR cash balance at December 31, 2023 amounts to €21.6 million. The hedging strategy as described in the section foreign currency risk does also bring benefits in terms of cash management whereby the option premium received exceeds the negative return on the EUR cash balance.

Without taking into account the impact of the FX vanilla options on the interest rate risk, an increase (decrease) in the interest rate by 5.0 %, would lead to an interest expense (gain) of €3 877 (€3 877).



### 5.4.5 Liquidity Risk

The Company's main sources of cash inflows are obtained through capital increases, recoverable cash advances and grants. Cash is invested in low risk investments such as short-term bank deposits or savings accounts. The Company mainly makes use of liquid investment in current accounts (in Euro) or short-term deposit accounts.

The ability of the Company to maintain adequate cash reserves to support its activities in the medium term is highly dependent on the Company's ability to raise additional funds. As a consequence, the Company is exposed to significant liquidity risk in the medium term.

Please refer to note 5.1 on going concern consideration.

Contractual undiscounted maturities of financial liabilities at December 31, are as follows:

	As at December 31					
	2023			2022		
(in EUR 000)	Lease Liability	Financial Debt	Trade & Other Payable	Lease Liability	Financial Debt	Trade & Other Payable
Less than 1 year	990	378	11 240	802	400	10 152
1 - 5 years	2 729	8 488	–	2 594	6 456	–
5+ years	748	4 608	–	134	7 115	–
<b>Total</b>	<b>4 467</b>	<b>13 474</b>	<b>11 240</b>	<b>3 530</b>	<b>13 971</b>	<b>10 152</b>

### 5.4.6 Fair Value

The carrying amount of cash and cash equivalents, trade receivables, other receivables, financial assets and other current 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. Please refer to note 2.9 for information on the valuation of non-current liabilities.

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

(in EUR 000)	Carrying value		Fair value	
	As at December 31		As at December 31	
	2023	2022	2023	2022
<b>Financial Assets</b>				
Other long-term receivables (level 3)	1 166	173	1 166	173
Trade and other receivables (level 3)	5 627	3 237	5 627	3 237
Foreign currency swaps (level 2)	343	1	343	1
Other current assets (level 3)	1 318	1 284	1 318	1 284
Cash and cash equivalents (level 1)	21 610	17 888	21 610	17 888
Financial Assets (level 1)	36 138	76 968	36 138	76 968
<b>Financial liabilities</b>				
Financial debt (level 3)	63	146	60	138
Foreign currency swaps (level 2)	90	10	90	10
Recoverable cash advances (level 3)	8 674	8 431	8 674	8 431
Trade and other payables (level 1 and 3)	11 150	10 142	11 150	10 142

## 5.5 Critical accounting estimates and assumptions

When preparing the consolidated financial statements, judgments, estimates and assumptions are made that affect the carrying amount of certain assets, liabilities and expenses. These include the going concern assessment, the share-based payment transactions, the accounting for research and development expenses, the recoverable cash advances and deferred taxes. These judgments, estimates and assumptions have been reviewed for each year and are reviewed on a regular basis, taking into consideration past experience and other factors deemed relevant under the then prevailing economic conditions. Changes in such conditions might accordingly result in different estimates in the Company's future consolidated financial statements.

### 5.5.1 Critical Judgments

#### *Going Concern*

The Company has consistently operated with deficits and sustained negative cash flows since its inception considering the significant research and development expenses incurred for the development and regulatory approval of the Genio device. As of December 31, 2023, the Company's statement of financial position includes an accumulated loss of € 160.8 million and total assets of € 124.2 million. Current assets as of December 31, 2023 total €68.4 million, comprising €21.6 million in available cash and cash equivalents, and €36.1 million in marketable securities, primarily derived from previous public offerings.

The Company's current operating plan indicates that it will continue to incur losses from operations and generate negative cash flows from operating activities given ongoing expenditures related to the completion of its clinical trials only partially offset by the Company's revenue generating activities outside the U.S. (which were €4.3 million in 2023 in the EU). Substantial revenue generation is expected to start following the launch of the Genio product in the U.S., which is dependent on obtaining marketing authorization in the United States for the Genio product from the FDA.

The Company projects that its existing cash and cash equivalents and marketable securities should be sufficient to fund operations until the beginning of the fourth quarter of 2024. To meet the Company's future working capital needs, management is actively exploring different financing avenues, including the public or private issuance of equity and debt financing. Additional funds are pivotal for diverse activities, in particular to launch the Genio product in the U.S. and the ongoing progression of research and development projects. This raises, however, a material uncertainty in respect of going concern as the current funds are not sufficient to cover a period of 12 months following the date of the Annual Report.

Although the additional funds have not been raised yet, given the positive outcome from the DREAM trial, the Company is confident that raising sufficient funding to continue its operations for at least 12 months following the date of the Annual Report should not pose significant challenges.

The accompanying consolidated financial statements have therefore been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

### ***Income tax***

The tax laws applicable to the Company are complex and are subject to changes in tax landscapes, new laws, guidance, and rulings issued by the tax authorities. The Company may need to make a significant judgment whether certain tax positions taken in the tax filings are uncertain and whether it is probable that those tax positions may be challenged by the tax authorities in case of a tax audit. In making this judgment, the Company considers also third-party tax advice it has obtained.

When measuring the tax liability for uncertain tax positions, the Company need to assess the likelihood that the tax position will be challenged and determine the most likely amount (or expected value amount) that may have to be paid when the tax position is not accepted, considering any penalties and late interests payable.

## **5.5.2 Critical Accounting Estimates and Assumptions**

### ***Recoverable Cash Advances***

The Company benefits from recoverable cash advances granted by the Walloon Region. These are in substance financial liabilities of the Company towards the Region. The determination of the amount of the financial liability is subject to a high degree of subjectivity and requires the Company to make estimates of the future sales it will derive in the future from the products that benefited from the support of the Region.

Based on these estimates, it may be concluded that the amount of the cash advance that the Company has received from the Region exceeds the amount of the financial liability estimated by the Company. In such a situation, the difference is considered as a government grant. Subsequent re-estimation of the timing of the cash outflows of the financial liability is accounted for in profit and loss.

Management estimates the fair value of the liability of the future payment to be made to the Walloon Region based on a forecasted volume of sales. The estimation of the fair value is dependent on the discount rate applied. The fixed part to be reimbursed has been discounted with a discount rate of 5.0% and the variable part (based on sales forecasts) with a discount rate of 12.5%. Refer also to note 17.1.

### ***Development Expenses capitalized and related impairment testing***

The Company capitalizes costs for product development projects. Initial capitalization of costs is based on management's judgement that technological and economic feasibility is confirmed, usually when a product development project has reached a defined milestone according to an established project management model.

At December 31, 2019, for the first time the Company capitalized amount of development costs for the first generation of the Genio System. This amount includes costs related to the development of the Genio System which received CE Mark approval in March 2019 and related improvements. Therefore, the Company is of the opinion that, from March 2019, development expenditures do meet capitalization criteria. The Company uses an estimate for certain research and development expenses related to the Genio System and related improvements to determine the amount to be capitalized or recorded as an expense. Accordingly, the costs incurred for the first generation of the Genio System have been recognized as development assets for a total amount of €11.4 million. No additional costs have been capitalized since July 2020. In addition, the Company started capitalizing the development costs for the improved second generation of the Genio System and additional clinical studies as from July 2020. The total capitalized cost for the improved second generation and the additional clinical studies amounts to €37.3 million as of December 31, 2023 (2022: €29.6 million). See note 8.

The development expenses capitalized have to be tested annually for impairment during the development period, prior to the start of its amortization. The Company performs the impairment test on the smallest group of assets to which it belongs for which there are separately identifiable cash flows: its cash-generating units ("CGU's"). Where the carrying value of an asset exceeds its recoverable amount (i.e. the higher of value in use and fair value less costs to sell), the asset is written down accordingly. The Company is a one product line company and the capitalized development expenses are only related to this product (Genio System). The Company determined that it has two cash generating units, Genio system launched in Europe and Genio system launched in the United States, for which a value in use analysis has been performed.

When performing the impairment test, management needs to make significant judgments, estimates and assumptions. The Company bases its impairment calculation on detailed budgets and forecast calculations generally covering a period of three years (since the Company is in an early commercial stage). For longer periods, a growth rate is calculated and applied to future cash flows projected. See note 8.

### **Share-Based Payments**

The Company has equity-settled share-based payment plans in place. Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which is dependent on the terms and conditions of the option plan. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them. The assumptions and models used for estimating the fair-value for share-based payment transactions are disclosed in note 16.

## **5.6 Subsidiaries**

For all years ended as at December 31, 2023 and 2022 respectively, 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.

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.

The Company also owns 100% of the shares of Nyxoah Inc, an American company located in Delaware that was incorporated in May 2020 and has a share capital of USD 1.

The Company also owns 100% of the shares of Nyxoah GmbH, a German company located in Eschborn that was acquired in July 2023 and has a share capital of EUR 25 000.

## 5.7 Property, Plant and Equipment

(in EUR 000)	Furniture and office equipment	Leasehold improvements	Laboratory equipment	Assets under construction	Total
<b>Cost</b>					
Opening Gross value January 1, 2022	858	555	858	691	2 962
Additions	255	184	420	27	886
Exchange differences	(33)	(35)	(28)	–	(96)
<b>Cost at December 31, 2022</b>	<b>1 080</b>	<b>704</b>	<b>1 250</b>	<b>718</b>	<b>3 752</b>
Additions	127	55	141	2 055	2 378
Transfers	–	578	140	(718)	–
Other	–	–	(7)	–	(7)
Exchange differences	(25)	(23)	(23)	–	(71)
<b>Cost at December 31, 2023</b>	<b>1 182</b>	<b>1 314</b>	<b>1 501</b>	<b>2 055</b>	<b>6 052</b>
<b>Depreciation</b>					
Opening accumulated depreciation January 1, 2022	(563)	(229)	(150)	–	(942)
Depreciation charge	(137)	(85)	(170)	–	(392)
Exchange differences	23	12	7	–	42
<b>Depreciation at December 31, 2022</b>	<b>(677)</b>	<b>(302)</b>	<b>(313)</b>	<b>–</b>	<b>(1 292)</b>
Depreciation charge	(160)	(145)	(297)	–	(602)
Exchange differences	17	8	5	–	30
<b>Depreciation at December 31, 2023</b>	<b>(820)</b>	<b>(439)</b>	<b>(605)</b>	<b>–</b>	<b>(1 864)</b>
<b>Net book value at December 31, 2022</b>	<b>403</b>	<b>402</b>	<b>937</b>	<b>718</b>	<b>2 460</b>
<b>Net book value at December 31, 2023</b>	<b>362</b>	<b>875</b>	<b>896</b>	<b>2 055</b>	<b>4 188</b>

In 2023, acquisitions were mainly related to the US production line under construction for an amount of €2.1 million, laboratory equipment for an amount of €0.1 million (2022: €420,000) and furniture and office equipment for an amount of €127,000 (2022: €255,000). Additions to leasehold improvements in 2023 amount to €55,000 (2022: €184,000). The total amount of purchases of property, plant and equipment in the consolidated statements of cash flow is higher than the additions due to the tax incentive relating to investments of 2023 amounting to €122,000.

There has been a transfer from asset under construction for an amount of €0.7 million to leasehold improvement (€0.6 million) and laboratory equipment (€140,000).

The line Other relates to tax incentive in Belgium on the investments of 2022. We refer to note 10 for more details.

The depreciation charge amounts to €0.6 million in 2023 and to €392,000 in 2022.

## 5.8 Intangible assets

(in EUR 000)	Development cost	Patents and licenses	Total
<b>Cost</b>			
Opening value at January 1, 2022	25 610	591	26 201
Additions	15 463	–	15 463
<b>Cost at December 31, 2022</b>	<b>41 073</b>	<b>591</b>	<b>41 664</b>
Additions	8 085	–	8 085
Other	(487)	–	(487)
<b>Cost at December 31, 2023</b>	<b>48 671</b>	<b>591</b>	<b>49 262</b>
<b>Amortization</b>			
Opening amortization at January 1, 2022	(837)	(42)	(879)
Amortization	(771)	(42)	(813)
<b>Amortization at December 31, 2022</b>	<b>(1 608)</b>	<b>(84)</b>	<b>(1 692)</b>
Amortization	(920)	(42)	(962)
<b>Amortization at December 31, 2023</b>	<b>(2 528)</b>	<b>(126)</b>	<b>(2 654)</b>
<b>Net book value at December 31, 2022</b>	<b>39 465</b>	<b>507</b>	<b>39 972</b>
<b>Net book value at December 31, 2023</b>	<b>46 143</b>	<b>465</b>	<b>46 608</b>

There is only one development project: The Genio system. The Company started amortizing the first-generation Genio system in 2021. The amortization amounted to €1.0 million for 2023 and is included in Research and development expenses. The remaining amortization period of this development asset is 11 years.

The Company continues to incur in 2023 development expenses with regard to the improved second-generation Genio system and clinical trials to obtain additional regulatory approvals in certain countries or to be able to sell the Genio System in certain countries. The total capitalized development expenses amounted to €8.1 million and €15.5 million for 2023 and 2022, respectively. The total amount of capitalization of intangible assets in the consolidated statements of cash flow is higher than the additions due to the tax incentive relating to investments of 2023 amounting to €377,000.

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

In accordance with the accounting principle, the intangible assets are tested annually for impairment during the development period. The Genio system is currently a unique product line developed by the Company and the Company determined that it has two cash generating units, Genio system in Europe and Genio system in the United States, for which a value in use analysis has been performed. The discount rates over the expected term that the assets will generate economic benefits are:

	Europe	US
Discount rate	11.9%	13.0%

The discount rates have been determined by reference to the analyst reports covering the Company which are available.

Based on the current operating budget as approved by the Board of Directors, the Company's management prepared cash flow forecasts, which covers a 3-year period and an appropriate extrapolation of cash flows beyond 2026. A sensitivity analysis has been performed concluding that a reasonable change in the WACC and/or forecasted growth rate would not lead to an impairment.

## 5.9 Right of use assets and lease liabilities

The Company has lease contracts for buildings and vehicles used in its operations. Leases of building have lease terms between six and eighteen years, while motor vehicles generally have lease terms between four and five years. The Company's obligations under its leases are secured by the lessor's title to the leased assets. Generally, the Company is restricted from assigning and subleasing the leased assets and some contracts require the Company to maintain certain financial ratios. The Company also has certain leases of office equipment and bicycles with low value and machinery, equipment and buildings for a short term. The Company applies the "short-term lease" and "lease of low-value assets" recognition exemptions for these leases. We refer to note 31.2 for the impact on income statement for these "short-term leases" and "leases of low-value assets".

The carrying amounts of right-of-use assets recognized and the movements during the period is as follows:

(in EUR 000)	Building	Motor vehicles	Total
<b>Cost</b>			
Opening value at January 1, 2022	3 443	670	4 113
Additions	368	433	801
Disposal	–	(94)	(94)
Exchange difference	(187)	–	(187)
<b>Cost at December 31, 2022</b>	<b>3 624</b>	<b>1 009</b>	<b>4 633</b>
Additions	–	396	396
Disposal	–	(34)	(34)
Lease modification	1 093	12	1 105
Exchange difference	(113)	–	(113)
<b>Cost at December 31, 2023</b>	<b>4 604</b>	<b>1 383</b>	<b>5 987</b>
<b>Depreciation</b>			
Opening accumulated depreciation at January 1, 2022	(688)	(207)	(895)
Depreciation charge	(530)	(198)	(728)
Disposal	–	94	94
Exchange difference	55	–	55
<b>Depreciation at December 31, 2022</b>	<b>(1 163)</b>	<b>(311)</b>	<b>(1 474)</b>
Depreciation charge	(535)	(261)	(796)
Disposal	–	34	34
Exchange difference	37	–	37
<b>Depreciation at December 31, 2023</b>	<b>(1 661)</b>	<b>(538)</b>	<b>(2 199)</b>
<b>Net book value at December 31, 2022</b>	<b>2 461</b>	<b>698</b>	<b>3 159</b>
<b>Net book value at December 31, 2023</b>	<b>2 943</b>	<b>845</b>	<b>3 788</b>

In 2023, the Company did enter into new lease agreements for €396,000 compared to €0.8 million in 2022. The lease modification amounted to €1.1 million (2022: no lease modification) and mainly related to the extension of the contract of buildings in Belgium and Israel. The repayments of lease liabilities amounted to €0.9 million (2022: €0.8 million). The depreciations on the right of use assets amounted to €0.8 million and €0.7 million for 2023 and 2022, respectively.

For the year ended December 31, 2023, the Company recognized no gain or loss on disposal (2022: no gain or loss on disposal).

The maturity analysis of lease liabilities is disclosed in note 4.5.

(in EUR 000)	2023	2022
<b>Lease debt at January 1</b>	<b>3 305</b>	<b>3 319</b>
New lease debts	397	798
Rent expense paid	(886)	(772)
Accretion of interest	129	98
Lease modification	1 105	—
Exchange differences	(83)	(138)
<b>Lease debt at December 31</b>	<b>3 967</b>	<b>3 305</b>

	<b>As at December 31</b>	
(in EUR 000)	2023	2022
Non-current lease liabilities	3 116	2 586
Current lease liabilities	851	719
<b>Total</b>	<b>3 967</b>	<b>3 305</b>

## 5.10 Other long-term receivables

The increase in other long-term receivables is due to a tax incentive in Belgium for an amount of €1.0 million mainly in relation to certain development activities and clinical trials. The Company recognizes the incentive as a long-term receivable and as a deduction from the carrying amount of the (in)tangible asset.

The incentive recorded as at December 31, 2023 relates to 2022 as well as 2023 investments both on tangible and intangible assets. The amount related to investments made in 2022 mainly related to intangible assets and is expected to be received in cash in 2027. The amount related to investments made in 2023 mainly related to intangible assets and is expected to be received in cash in 2028.

## 5.11 Inventory

	<b>As at December 31</b>	
(in EUR 000)	2023	2022
Raw materials	1 329	498
Work in progress	1 530	100
Finished goods	456	284
<b>Total Inventory</b>	<b>3 315</b>	<b>882</b>



The increase in inventory is due to increasing activities to prepare for the commercialization and further scale-up of the Company in 2024. For the year ended December 31, 2023 and 2022 the Company did not recognize any expenses for inventory write-offs since the inventory level as per year-end is expected to be sold in the foreseeable future.

## 5.12 Trade and Other receivables

(in EUR 000)	As at December 31	
	2023	2022
Trade receivables	2 758	1 463
R&D incentive receivable (Australia)	723	346
VAT receivable	850	847
Current tax receivable	808	159
Foreign currency swaps	343	1
Other	488	422
<b>Total trade and other receivables</b>	<b>5 970</b>	<b>3 238</b>

The increase of €2.7 million in trade and other receivables as at December 31, 2023 is mainly due to an increase in trade receivables of €1.3 million as a result of an increase in revenue by the Company. The increase in other receivables is mainly due to an increase in current tax receivable of €0.6 million, an increase in R&D incentive receivables by €377,000 and an increase in foreign currency swaps of €342,000.

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

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

The current tax receivable relates to excess payment of corporate income tax in Israel, US and Belgium. The increase can mainly be explained by an increase in Belgium by €0.6 million due to an increase in withholding tax on interest for term deposit accounts.

We refer to note 19.1 for more details on the foreign currency swaps.

## 5.13 Cash and cash equivalents

(in EUR 000)	As at December 31	
	2023	2022
Short term deposit	9 158	36
Current accounts	12 452	17 852
<b>Total cash and cash equivalents</b>	<b>21 610</b>	<b>17 888</b>

Cash and cash equivalents increased to €21.6 million as at December 31, 2023, compared to €17.9 million as at December 31, 2022 with an increase of short term deposits by €9.1 million which is partially offset by a decrease of current accounts by €5.4 million. The short term deposits relate to term accounts with an initial maturity less than 3 months measured at amortized costs.

## 5.14 Financial assets

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

In 2023, the Company entered into USD term deposits and US Treasury bills for a total amount \$US 75.1 million (€69.0 million) and €11.0 million. During the period ended as at December 31, 2023, \$US 70.8 million (€65.7 million) and €55.0 million reached maturity and is subsequently held as cash.

The current financial assets consists of \$US 34.4 million (€31.1 million), which could generate a foreign currency exchange gain or loss in the financial results in accordance with the fluctuations of the USD/EUR exchange rate as the Company's functional currency is EUR, and €5.0 million. The total amount of term deposits as at December 31, 2023, amounts to €36.1 million.

## 5.15 Capital, Share Premium, Reserves

### 5.15.1 Capital and share premium

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

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

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

As of December 31, 2022, the share capital of the Company amounts to €4.4 million represented by 25,846,279 shares, and the share premium amounts to €242.4 million (before deduction of the transaction costs).

As of December 31, 2023, the share capital of the Company amounts to €4.9 million represented by 28,673,985 shares, and the share premium amounts to €260.6 million (before deduction of the transaction costs).

Evolution of the share capital and share premium ended December 31, 2023 and 2022:

(Number of shares except otherwise stated)	Common shares	Total of shares	Par value (in EUR)	Share capital (in EUR 000)	Share premium (in EUR 000)
January 1, 2022	25 772 359	25 772 359	0.17	4 427	242 198
February 10, 2022 - Exercise warrants	25 000	25 000	0.17	4	125
June 8, 2022 - Capital increase in cash	38 920	38 920	0.17	7	–
September 30, 2022 - Exercise warrants	10 000	10 000	0.17	2	117
<b>December 31, 2022</b>	<b>25 846 279</b>	<b>25 846 279</b>	<b>0.17</b>	<b>4 440</b>	<b>242 440</b>
March 29, 2023 - Capital increase in cash	393 162	393 162	0.17	68	2 481
March 30, 2023 - Capital increase in cash	2 047 544	2 047 544	0.17	351	12 999
April 17, 2023 - Capital increase in cash	375 000	375 000	0.17	65	2 651
July 14, 2023 - Exercise warrants	2 000	2 000	0.17	–	10
August 29, 2023 - Exercise warrants	10 000	10 000	0.17	2	50
<b>December 31, 2023</b>	<b>28 673 985</b>	<b>28 673 985</b>	<b>0.17</b>	<b>4 926</b>	<b>260 631</b>

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

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

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

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

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

On April 17, 2023, the Company issued 375,000 new shares for an aggregate capital increase of €2.7 million (including share premium). The Company raised \$3.0 million in gross proceeds pursuant to the Company's \$50 million at-the-market ("ATM") program established on December 22, 2022 at an issue price equal to the market price on the Nasdaq Global Market at the time of the sale. The proceeds will be used for general corporate purposes.

As part of above capital increases, the Company incurred direct-attributable transaction costs of €340,000 which have been deducted from the share premium. The proceeds from the capital increase net of transaction costs amounted to €18.3 million.

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

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

### 5.15.2 Reserves

The reserves include the share-based payment reserve (see note 16), other comprehensive income and the retained loss. Retained loss is comprised of primarily of 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 year ended December 31, 2023 and 2022 is detailed in the table below:

(in EUR 000)	Currency translation reserve	Post- employment benefit obligations	Total
Opening value at January 1, 2022	270	(68)	202
Currency translation differences	(96)	–	(96)
Remeasurements of post-employment benefit obligations	–	70	70
<b>Total other comprehensive income at December 31, 2022</b>	<b>174</b>	<b>2</b>	<b>176</b>
Currency translation differences	(120)	–	(120)
Remeasurements of post-employment benefit obligations	–	81	81
<b>Total other comprehensive income at December 31, 2023</b>	<b>54</b>	<b>83</b>	<b>137</b>

### 5.16 Share-Based compensation

As per December 31, 2023, the Company has four outstanding equity-settled share-based incentive plans, including (i) the 2018 warrants plan (the 2018 Plan), (ii) the 2020 warrants plan (the 2020 plan), (iii) the 2021 warrants plan (the 2021 plan) and (iv) the 2022 warrants plan (the 2022 plan). The Company had an extraordinary shareholders' meeting on February 21, 2020, where it was decided to achieve a share split in a ratio of 500:1. Per warrant issued before February 21, 2020, 500 common shares will be issuable. For presentation purposes the tables and comments below reflect the number of shares the warrants give right to across all plans.

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

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

<b>Number of shares (after share split) warrants give right to across all plans</b>	<b>2023</b>	<b>2022</b>
Outstanding at January 1	1 416 490	993 490
Granted	518 116	536 500
Forfeited	(165 125)	(42 750)
Exercised	(12 000)	(35 000)
Expired	(121 875)	(35 750)
<b>Outstanding at December 31</b>	<b>1 635 606</b>	<b>1 416 490</b>
<b>Exercisable at December 31</b>	<b>1 034 835</b>	<b>795 745</b>

### 5.16.1 Description of the equity-settled share-based incentive plans

#### **2016 Plan**

On November 3, 2016, the shareholders' meeting of the Company approved the issuance of 1,500 warrants, giving each the right to subscribe to one common share of the Company before share split (500 shares after the share split). Under this plan, up to 1,500 warrants can be issued. By consequence, the Company can issue up to 1,500 common shares before share split (750,000 shares after the share split) if all warrants are exercised.

The total amount of warrant holders under the 2016 Plan cannot exceed 150 persons. Unless the Board of Directors determines otherwise, the 2016 ESOP Warrants are not transferable inter vivos once they have been granted to a holder of 2016 ESOP Warrants, and may not be pledged or encumbered with any security, pledge or right in rem in any other way, either voluntarily, by operation of law or otherwise. The exercise price of each warrant cannot be less than €2,585.32. Taking into consideration the share split, this would result in an exercise price of €5.17 per share. The key features of the warrants granted under the 2016 Plan are as follows (i) each warrant could be exercised for one share before share split (500 shares after the share split), (ii) the warrants are granted for free, (iii) the warrants have a term of maximum ten years since the issue date, (iv) the only vesting condition is that the holder is still an employee of the Company at the vesting date, and (v) unless the Board of Directors determines otherwise, the warrants vest as follows: 34.0 % at the grant date, 33.0 % at the first anniversary of the grant date, 33.0 % at the second anniversary. Accordingly, the fair value of the plan is expensed over the vesting period. All 1 500 warrants were granted throughout the years 2016, 2017 and 2018. As a result of the IPO, 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 status of the 2016 warrant plan at December 31 is as follows:

<b>Number of shares (after share split) warrants give right to for Plan 2016</b>	<b>2023</b>	<b>2022</b>
Outstanding at January 1	27 500	52 500
Granted	-	-
Forfeited	-	-
Exercised	(10 000)	(25 000)
Expired	(17 500)	-
<b>Outstanding at December 31</b>	<b>-</b>	<b>27 500</b>
<b>Exercisable at December 31</b>	<b>-</b>	<b>27 500</b>

With respect to the warrants exercised in 2023, a total of 20 warrants representing 10,000 shares were exercised. A total of 35 warrants representing 17,500 shares expired in 2023 because the warrants were not exercised by employees within 3 months after having left the company. There are no outstanding warrants as per December 31, 2023.

**2018 Plan**

On December 12, 2018, the shareholders' meeting of the Company approved the issuance of 525 warrants, giving each the right to subscribe to one common share of the Company before share split (500 shares after the share split). Under this plan, up to 525 warrants can be issued. By consequence, the Company can issue up to 525 common shares before the share split (262,500 shares after the share split) if all warrants are exercised.

The total amount of warrant holders under the 2018 Plan cannot exceed 150 individuals. Unless the Board of Directors determines otherwise, the 2018 ESOP Warrants are not transferable inter vivos once they have been granted to a holder of 2018 ESOP Warrants, and may not be pledged or encumbered with any security, pledge or right in rem in any other way, either voluntarily, by operation of law or otherwise. The exercise price of each warrant cannot be less than €3,259.91. Taking into consideration the share split, this would result in an exercise price of €6.52 per share. The key features of the warrants granted under the 2018 Plan are as follows (i) each warrant could be exercised for one share before share split (500 shares after the share split), (ii) the warrants are granted for free, (iii) the warrants have a term of maximum ten years since the issue date, (iv) the only vesting condition is that the holder is still an employee of the Company at the vesting date, and (v) unless the Board of Directors determines otherwise, the warrants vest as follows: 34.0 % at the grant date, 33.0 % at the first anniversary of the grant date, 33.0 % at the second anniversary. Accordingly, the fair value of the plan is expensed over the vesting period. As a result of the IPO, 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.

In April 2020, 33 warrants were granted under the 2018 Plan with an exercise price of €5,966.59 (exercise price of €11.93 per share after the share split) while the previous warrants of the 2018 Plan have an exercise price of €3,259.91 (exercise price of €6.52 per share after the share split).

The status of the 2018 warrant plan at December 31 is as follows:

<b>Number of shares (after share split) warrants give right to for Plan 2018</b>	<b>2023</b>	<b>2022</b>
Outstanding at January 1	50 000	50 000
Granted	-	-
Forfeited	-	-
Exercised	-	-
Expired	-	-
<b>Outstanding at December 31</b>	<b>50 000</b>	<b>50 000</b>
<b>Exercisable at December 31</b>	<b>50 000</b>	<b>50 000</b>

No warrants have been exercised in 2023. Since the 2018 warrant plan prescribes that each warrant gives right to 500 shares and our table above presents the impact on the number of shares, the actual remaining number of warrants as per December 31, 2023 equals 100 representing 50,000 shares.

**2020 Plan**

On April 7, 2020, the shareholders' meeting of the Company approved the issuance of 550,000 warrants, giving each the right to subscribe to one common share of the Company. Under this plan, up to 550,000 warrants can be issued. By consequence, the Company can issue up to 550,000 common shares if all warrants are exercised.

The total number of warrant holders under the 2020 Plan cannot exceed 150 persons. Unless the Board of Directors determines otherwise, the 2020 ESOP Warrants are not transferable inter vivos once they have been granted to a holder of 2020 ESOP Warrants, and may not be pledged or encumbered with any security, pledge or right in rem in any other way, either voluntarily, by operation of law or otherwise. The key features of the warrants granted under the 2020 Plan are as follows (i) each warrant could be exercised for one share, (ii) the warrants are granted for free, (iii) the warrants have a term of maximum ten years since the issue date, (iv) the only vesting condition is that the holder is still an employee of the Company at the vesting date, and (v) unless the Board of Directors determines otherwise, the warrants vest as follows: 34.0 % at the grant date, 33.0 % at the first anniversary of the grant date, 33.0 % at the second anniversary. Accordingly, the fair value of the plan is expensed over the vesting period. As a result of the IPO, 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 exercise price of each warrant amounts to €11.94.

The status of the 2020 warrant plan at December 31 is as follows:

<b>Number of shares/warrants give right to for Plan 2020</b>	<b>2023</b>	<b>2022</b>
Outstanding at January 1	450 500	490 500
Granted	-	-
Forfeited	-	-
Exercised	-	(10 000)
Expired	(40 000)	(30 000)
<b>Outstanding at December 31</b>	<b>410 500</b>	<b>450 500</b>
<b>Exercisable at December 31</b>	<b>410 500</b>	<b>450 500</b>

A total of 40,000 warrants expired in 2023 because the warrants were not exercised by employees within 3 months after having left the company. The remaining number of warrants as per December 31, 2023 equals 410,500 representing 410,500 shares.

### **2021 Plan**

On September 8, 2021, the Board of Directors, within the framework of the authorized capital, issued 1,400,000 warrants, giving each the right to subscribe to one common share of the Company. By consequence, the Company can issue up to 1,400,000 common shares if all warrants are exercised. On September 17, 2021, 319,240 warrants were granted from which 29,500 warrants were not accepted. On October 27, 2021 111,500 warrants were granted which were all accepted.

The total number of warrant holders under the 2021 Plan cannot exceed 150 persons. Unless the Board of Directors determines otherwise, the 2021 ESOP Warrants are not transferable inter vivos once they have been granted to a holder of 2021 ESOP Warrants, and may not be pledged or encumbered with any security, pledge or right in rem in any other way, either voluntarily, by operation of law or otherwise. The key features of the warrants granted under the 2021 Plan are as follows (i) each warrant could be exercised for one share, (ii) the warrants are granted for free, (iii) the warrants have a term of maximum ten years since the issue date, (iv) the only vesting condition is that the holder is still an employee of the Company at the vesting date, and (v) unless the Board of Directors determines otherwise, the warrants vest as follows: 25.0 % at the grant date, 25.0 % at the first anniversary of the grant date, 25.0 % at the second anniversary of the grant date, 25.0 % at the third anniversary of the grant date. Accordingly, the fair value of the plan is expensed over the vesting period. The exercise price of the 2021 ESOP Warrants granted in 2021 amounts to €25.31.

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

On March 24, 2023, the Company reduced the exercise price of 75% of the warrants previously granted to warrant holders under the 2021 Warrants Plan to 5.42 EUR to reflect the decrease in the company's share price. For the remaining 25% of the warrants previously granted under the 2021 Warrants Plan, the exercise price will remain unchanged. All other terms and conditions of the re-priced warrants remain unchanged to the original option agreement.

On March 24, 2023, 200,862 warrants were granted which were all accepted. On April 12, 2023 and June 14, 2023 respectively 100,000 and 161,398 warrants were granted which were all accepted.

The status of the 2021 warrant plan at December 31 is as follows:

Number of shares/warrants give right to for Plan 2021	2023	2022
Outstanding at January 1	888 490	400 490
Granted	462 260	536 500
Forfeited	(165 125)	(42 750)
Exercised	(2 000)	–
Expired	(64 375)	(5 750)
<b>Outstanding at December 31</b>	<b>1 119 250</b>	<b>888 490</b>
<b>Exercisable at December 31</b>	<b>563 771</b>	<b>267 745</b>

In 2023, a total of 2,000 warrants were exercised, 165,125 warrants have been forfeited because the warrants were not vested by employees leaving the company and 64,375 warrants expired because the warrants were not exercised by employees within 3 months after having left the company. The remaining number of warrants as per December 31, 2023 equals 1,119,250 representing 1,119,250 shares.

### 2022 Plan

On December 28, 2022, the Board of Directors, within the framework of the authorized capital, issued 700,000 warrants, giving each the right to subscribe to one common share of the Company. By consequence, the Company can issue up to 700,000 common shares if all warrants are exercised.

The total number of warrant holders under the 2022 Plan cannot exceed 150 persons. Unless the Board of Directors determines otherwise, the 2022 ESOP Warrants are not transferable inter vivos once they have been granted to a holder of 2022 ESOP Warrants, and may not be pledged or encumbered with any security, pledge or right in rem in any other way, either voluntarily, by operation of law or otherwise. The key features of the warrants granted under the 2022 Plan are as follows (i) each warrant could be exercised for one share, (ii) the warrants are granted for free, (iii) the warrants have a term of maximum ten years since the issue date, (iv) the only vesting condition is that the holder is still an employee of the Company at the vesting date, and (v) unless the Board of Directors determines otherwise, the warrants vest as follows: 25.0 % at the grant date, 25.0 % at the first anniversary of the grant date, 25.0 % at the second anniversary of the grant date, 25.0 % at the third anniversary of the grant date. Accordingly, the fair value of the plan is expensed over the vesting period.



On June 14, 2023 and October 20, 2023 respectively 13,602 and 42,254 warrants were granted from which all were accepted.

The status of the 2022 warrant plan at December 31 is as follows:

<b>Number of shares/warrants give right to for Plan 2022</b>	<b>2023</b>	<b>2022</b>
Outstanding at January 1	–	–
Granted	55 856	–
Forfeited	–	–
Exercised	–	–
Expired	–	–
<b>Outstanding at December 31</b>	<b>55 856</b>	<b>–</b>
<b>Exercisable at December 31</b>	<b>10 564</b>	<b>–</b>

No warrants have been exercised in 2023. The number of warrants as per December 31, 2023 equals 55,856 representing 55,856 shares.

### 5.16.2 Accounting for Equity-settled Share-Based Payment

The fair value of the plan is expensed over the vesting period. As a result of the exercise price reduction on March 24, 2023 of the warrants previously granted to warrant holders under the 2021 Warrants Plan, the Company determined the fair value of the options at the date of the modification (March 24, 2023). The incremental fair value of the re-priced warrants is recognised as an expense over the period from the modification date to the end of the vesting period. For the warrants already vested at the date of modification, the incremental fair value is fully recognised as an expense at date of modification.

The share-based compensation expense for all vested warrants recognized in the income statement was €2.6 million for the year ended December 31, 2023, of which €0.8 million is related to the incremental fair value of the re-priced warrants. For the year ended December 31, 2022 the share-based compensation expense amounted to €2.7 million. The table below details the number of exercisable (vested) warrants and their weighted average exercised price. For presentation purposes the table reflect the number of shares the warrants give right to across all plans.

<b>Total</b>	<b>2023</b>	<b>2022</b>
Exercisable Warrants at December 31	984,935	718,400
Shares representing the Exercisable Warrants at December 31	1,034,835	795,745
Weighted average exercise price per share	10.70	15.09
Weighted average share price at the date of exercise	7.25	15.03

### 5.16.3 Fair value

The fair value of each option or subscription right is estimated on the date of grant using the Black & Scholes model based on the following:

- The dividend return is estimated by reference to the historical dividend payment of the Group. Currently, this is estimated to be zero as no dividend have been paid since inception;
- Expected volatility is estimated based on a sample of similar companies based on the healthcare products sector of the Damodaran dataset;
- Risk-free interest rate is based on the yield of EUR bonds with an equivalent term to liquidation event;
- The expected life of the share options is based on current expectations and is not necessarily indicative of exercise patterns that may occur.

Fair value of the shares is estimated based on the market approach using publicly traded companies and acquisitions of private held companies within the same industry as Nyxoah. (Prior to the initial public offering)

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

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

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

	Plan 2021 (grant Jun 8 2022)	Plan 2021 (grant Aug 8 2022)	Plan 2021 (grant Aug 8 2022)	Plan 2021 (grant Mar 24 2023)	Plan 2021 (grant Apr 12 2023)
Return Dividend	0%	0%	0%	0%	0%
Expected volatility	52.60%	53.71%	53.97%	52.00%	52.00%
Risk-free interest rate	1.60%	1.39%	1.45%	3.20%	3.24%
Expected life	3	3	4	3	3
Exercise price	12.95	9.66	9.66	5.42	6.36
Stock price	13.34	9.75	9.75	6.70	7.08
Fair value	5.21	3.79	4.32	3.09	3.04

	<b>Plan 2021 (grant Jun 14 2023)</b>	<b>Plan 2022 (grant Jun 14 2023)</b>	<b>Plan 2022 (grant Oct 20 2023)</b>
Return Dividend	0%	0%	0%
Expected volatility	51.28%	51.28%	50.00%
Risk-free interest rate	3.36%	3.36%	3.55%
Expected life	3	3	3
Exercise price	7.19	7.19	5.92
Stock price	7.10	7.10	5.60
Fair value	2.75	2.75	2.07

As a result of the exercise price reduction on March 24, 2023 of the warrants previously granted to warrant holders under the 2021 Warrants Plan, the Company determined the fair value of the options at the date of the modification (March 24, 2023). The fair value of the modified warrants was determined using the same models and principles as described above, with the following model inputs:

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

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

The weighted average fair value of warrants granted during the year was €2.85 in 2023 and €5.29 in 2022. The weighted average remaining contractual life for the share options outstanding as at December 31 was 2.9 in 2023 and 3.4 in 2022.

## 5.17 Financial Debt

Financial debt consists of recoverable cash advances, and other loans. The related amounts as at December 31, 2023 and 2022, can be summarized as follows:

(in EUR 000)	As at December 31	
	2023	2022
Recoverable cash advances - Non-current	8 373	8 126
Recoverable cash advances - Current	301	305
<b>Total Recoverable cash advances</b>	<b>8 674</b>	<b>8 431</b>
Other loan - Non-current	–	63
Other loan - Current	63	83
<b>Total other loans</b>	<b>63</b>	<b>146</b>
Non-current	8 373	8 189
Current	364	388
<b>Total Financial Debt</b>	<b>8 737</b>	<b>8 577</b>

## 5.17.1 Financial debt related to recoverable cash advances

### **Recoverable cash advances received**

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

(in EUR 000)	Contractual advances	Advances received	Fixed reimbursements*	Variable reimbursements*
Sleep apnea device (6472)	1 600	1 600	588	7
First articles (6839)	2 160	2 160	561	11
Clinical trial (6840)	2 400	2 400	360	13
Activation chip improvements (7388)	1 467	1 467	66	18
<b>Total</b>	<b>7 627</b>	<b>7 627</b>	<b>1 575</b>	<b>49</b>

\* Excluding interests

- The Convention 6472 "Sleep apnea device" for a total amount of €1.6 million was signed in 2011. The total amount of the advance has been received before January 1, 2015. The Company has notified his intention to exploit the results of this project before 2015. At December 31, 2023, the Company repaid all fixed reimbursements amounting to €0.6 million (excluding interests). The turnover dependent reimbursement is based on 0.224% of the sales achieved by June 2037. The Company made a reimbursement of a variable part amounting to €7,000 for the year ended December 31, 2023.
- The Convention 6839 "First Articles" for a total amount of €2.2 million was signed on December 5, 2012. As at December 31, 2023, the advance received amounted to €2.2 million. The turnover dependent reimbursement is based on 0.3% of the sales achieved by June 2037. The Company notified to the Region its decision about the exploitation of the results during 2017, therefore fixed reimbursement started in 2018. As at December 31, 2023, cumulated reimbursements amount to €0.6 million (excluding interests) out of which €79,000 was reimbursed in 2023 and €96,000 in 2022.
- The Convention 6840 "Clinical Trial" for a total amount of €2.4 million was signed on December 6, 2012. As at December 31, 2023, the advance received amounted to €2.4 million. The turnover dependent reimbursement is based on 0.336% of the sales achieved by June 2029. The Company has notified to the Region its decision about the exploitation of the results in the course of 2018. As at December 31, 2023, cumulated fixed reimbursements amount to €360,000 (excluding interests) out of which €163,000 was reimbursed in 2023 and €75,000 in 2022.
- The Convention 7388 "Implant for Obstructive Sleep Apnea, "Activation Chip Improvements" for a total amount of €1.5 million was signed in December 2015. As at December 31, 2023, the advance received amounted to €1.5 million. The turnover dependent reimbursement is based on 0.45% of the sales achieved to June 2039. In 2019, the Company has notified to the Region its decision about the exploitation of the results. As at December 31, 2023, cumulated fixed reimbursements amount to €66,000 (excluding interests) out of which €40,000 was reimbursed in 2023 and €15,000 in 2022.

### **Evolution of the financial debt in the financial statements**

The determination of the amount to be reimbursed to the Walloon Region under the signed agreements is subject to a degree of uncertainty as it depends on the amount of the future sales that the Company will generate or not in the future. To determine the fair value of those advances, management of the Company has considered the possible outcomes of the program currently benefiting from the support of the Walloon Region. Management has considered that the probability to have to reimburse the 30% non-revocable repayment has a probability of 100% to occur. The reimbursement of the variable part, the fair value of which is determined on the basis of the sales forecasts largely depends on external factors such as CE marking, social security programs, post-market studies and expected timing and level of sales.

The Management performed an initial recognition of the financial debt for the variable part using a discount rate of 12.5 %.

The table below details the remaining undiscounted cash flows resulting from the reimbursement of the recoverable cash advances. The initial recognition of the liability reflects a reimbursement up to 2 times the amount of cash advance received.

(in EUR 000)	<b>As at December 31</b>	
	<b>2023</b>	<b>2022</b>
Recoverable cash advances received	7 627	7 627
Amounts to be reimbursed	15 254	15 254
Amounts reimbursed at year-end (interests included)	(1 843)	(1 429)
<b>Total Recoverable cash advances (undiscounted)</b>	<b>13 411</b>	<b>13 825</b>

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

(in EUR 000)	<b>As at December 31</b>	
	<b>2023</b>	<b>2022</b>
Contract 6472	1 629	1 571
Contract 6839	2 290	2 214
Contract 6840	2 818	2 790
Contract 7388	1 937	1 856
Total recoverable cash advances	8 674	8 431
Non-current	8 373	8 126
Current	301	305
<b>Total recoverable cash advances</b>	<b>8 674</b>	<b>8 431</b>

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

(in EUR 000)	<b>2023</b>	<b>2022</b>
<b>As at January 1</b>	<b>8 431</b>	<b>8 127</b>
Advances reimbursed (excluding interests)	(396)	(350)
Interests paid	(27)	(24)
Initial measurement and re-measurement	(324)	(247)
Discounting impact	990	925
<b>As at December 31</b>	<b>8 674</b>	<b>8 431</b>

The discounting impact is included and presented in the financial expenses and amounted to €1.0 million (2022: €0.9 million). The initial measurement and re-measurement are included in other operating income and amounted to €324,000 for the year ended December 31, 2023 (2022: €247,000).

A sensitivity analysis of the carrying amount of recoverable cash advances has been done to assess the impact of a change in assumptions. The Company tested reasonable sensitivity to changes in revenue projections of +/- 25% and in the discount rates of +/- 25%. The table hereunder details the sensitivity results:

Fair Value of Liabilities as of end of 2023 (in EUR 000)	Variation of revenue projections		
	Variation of discount rates *	-25%	0%
-25%	9 224	9 604	9 879
0%	8 234	8 674	8 997
25%	7 388	7 868	8 223

\* A change of -25% in the discount rates implies that the discount rate used for the fixed part of the recoverable cash advances is 3.8 % instead of 5.0 % while the one used for the variable part is 9.4 % instead of 12.5%. An increase of 25% of revenue projections implies, if discount rates does not change, an increase of the expected liability as repayment of the liability is accelerated.

An increase of 25% of the discount rate decreases the expected liability if revenue projections remain unchanged.

### 5.17.2 Other Loans

The Company has contracted a loan of €0.5 million on June 29, 2016 with a maturity of 8 years, repayable as from June 30, 2018 and bearing interest of 1.284 % p.a. The loan has a carrying amount of €63,000 at December 31, 2023 and €146,000 at December 31, 2022. The payments have been postponed for three months due to COVID-19 during 2021 so the maturity date of the loan has been extended until June 30, 2024. The total repayments for the year ended December 31, 2023, amounted to €83,000 (2022: €83,000).

## 5.18 Trade payables

(in EUR 000)	As at December 31	
	2023	2022
Payables	4 102	1 873
Invoices to be received	2 053	3 112
<b>Total trade payables</b>	<b>6 155</b>	<b>4 985</b>

The increase in total trade payables of €1.2 million as at December 31, 2023 is due to an increase in payables of €2.2 million which is compensated by a decrease in invoices to be received of €1.1 million. The increase in payables is explained by significant R&D/Manufacturing invoices received into the month of December for which payments have been processed in 2024. The decrease of the invoices to be received is explained by the fact that the Cochlear project has ended in 2023 which means there is no provision related to Cochlear as at December 31, 2023.

The Company normally settles its trade payables in 30 days.

## 5.19 Other payables

(in EUR 000)	As at December 31	
	2023	2022
Holiday pay accrual	791	612
Salary	1 801	2 186
Accrued expenses	2 203	2 228
Foreign currency option - current	90	10
Other	200	131
<b>Total other payables</b>	<b>5 085</b>	<b>5 167</b>

The decrease of €82,000 in other payables as at December 31, 2023, compared to December 31, 2022, is due to a decrease of €206,000 mainly in payroll related liabilities. The decrease is partly offset by a increase of €80,000 in the fair value of the foreign currency options. We refer to note 19.1.

### 5.19.1 Derivatives

The Company is exposed to currency risk primarily due to the expected future USD, AUD and NIS expenses that will be incurred as part of the ongoing and planned marketing, clinical trials and other related expenses. A financial risk management policy has been approved to i) generate yields on liquidity and ii) reduce the exposure to currency fluctuations with a timeline up to 24 months and by means of foreign currency swaps. There have not been any transfers of level 3 categories during the year.

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

(in EUR 000)	As at December 31	
	2023	2022
Foreign currency swaps EUR - NIS (in EUR)	847	542
Foreign currency swaps EUR - NIS (in NIS)	3 500	2 000
Foreign currency swaps NIS - EUR (in NIS)	14 000	–
Foreign currency swaps NIS - EUR (in EUR)	3 334	–
Foreign currency swaps EUR - USD (in EUR)	18 000	379
Foreign currency swaps EUR - USD (in USD)	19 787	600



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)	<b>As at December 31, 2023</b>			
	<b>Level I</b>	<b>Level II</b>	<b>Level III</b>	<b>Total</b>
<i>Financial assets</i>				
Foreign currency swaps	–	343	–	343
<i>Financial liabilities</i>				
Foreign currency swaps	–	90	–	90

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

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

(in EUR 000)	<b>2023</b>	<b>2022</b>
Opening value at January 1	1	–
Settled contracts	(1)	–
Fair value adjustments	343	1
<b>Closing value at December 31</b>	<b>343</b>	<b>1</b>

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

(in EUR 000)	<b>2023</b>	<b>2022</b>
Opening value at January 1	10	654
Fair value adjustments	90	2 721
Settled contracts	(10)	–
Exchange rate difference	–	30
Settlement foreign currency put and call contracts	–	(3 027)
Recognition premium income	–	(368)
<b>Closing value at December 31</b>	<b>90</b>	<b>10</b>

## 5.20 Revenue and cost of goods sold

For the year ended December 31, 2023, the Company generated revenue for the amount of €4.3 million compared to €3.1 million for the year ended December 31, 2022. 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.

The sales based on country of customer for the year ended December 31, 2023 and 2022:

(in EUR 000)	For the year ended December 31	
	2023	2022
Sales Germany	3 816	2 805
Sales Finland	–	41
Sales Spain	37	24
Sales Switzerland	373	214
Sales Austria	122	–
Sales Belgium	–	–
<b>Total sales</b>	<b>4 348</b>	<b>3 084</b>

For the year ended December 31, 2023, the Company has no customers with individual sales larger than 10% of the total revenue (2022: 1 customer).

Cost of goods sold for the year ended December 31, 2023 and 2022:

(in EUR 000)	For the year ended December 31	
	2023	2022
Purchases of goods and services	4 089	1 686
Inventory movement	(2 433)	(536)
<b>Total cost of goods sold</b>	<b>1 656</b>	<b>1 150</b>

## 5.21 Operating expenses

The tables below detail the operating expenses for the year ended December 31, 2023 and 2022:

(in EUR 000)	Total cost	Capitalized	Operating expense for the year
Research and development	35 125	(8 474)	26 651
Selling, general and administrative expenses	21 687	–	21 687
Other income and expenses	(1 549)	1 005	(544)
<b>For the year ended December 31, 2023</b>	<b>55 263</b>	<b>(7 469)</b>	<b>47 794</b>

(in EUR 000)	Total cost	Capitalized	Operating expense for the year
Research and development	31 448	(15 587)	15 861
Selling, general and administrative expenses	18 855	–	18 855
Other income and expenses	(406)	123	(283)
<b>For the year ended December 31, 2022</b>	<b>49 897</b>	<b>(15 464)</b>	<b>34 433</b>

## 5.22 Research and Development expenses

Research and development expenses consist primarily of product development, engineering to develop and support our products, testing, consulting services and other costs associated with the next generation of the Genio system. These expenses primarily include employee compensation, consulting and contractor's fees and outsourced development expenses.

(in EUR 000)	For the year ended December 31	
	2023	2022
Staff costs	13 803	11 074
Consulting and contractors' fees	2 762	2 623
Q&A regulatory	263	263
Depreciation and amortization expense	1 314	1 014
Travel	1 179	862
Manufacturing and outsourced development	6 458	4 986
Clinical studies	4 929	8 568
Other expenses	1 674	1 618
IP costs	941	440
IT	1 802	–
Capitalized costs	(8 474)	(15 587)
<b>Total research and development expenses</b>	<b>26 651</b>	<b>15 861</b>

Before capitalization of €8.5 million for the year ended December 31, 2023 and €15.6 million for the year ended December 31, 2022, research and development expenses increased by €3.7 million or 11.7% from €31.4 million for the year ended December 31, 2022, to € 35.1 million for the year ended December 31, 2023, due to the combined effect of higher manufacturing and R&D activities and clinical expenses. This increase is mainly in staff and consulting costs and in manufacturing and outsourced development to support those activities, this increase was partly offset by a decrease in clinical study activities due to Dream Study . The IT costs amounting to €1.8 million consist of €1.6 million related to the start of a new ERP implementation.

### 5.23 Selling, General and Administrative expenses

Selling, general and administrative expenses consist primarily of payroll and personnel related costs, and spending related to finance, information technology and human resource functions. Other general and administrative expenses include travel expenses, professional services fees, audit fees, insurance costs and general corporate expenses, including facilities-related expenses.

(in EUR 000)	For the year ended December 31	
	2023	2022
Staff costs	8 738	7 811
Consulting and contractors' fees	6 801	4 526
Legal fees	776	1 033
Rent	317	440
Facilities	209	226
Depreciation and amortization expense	1 042	914
IT	1 190	517
Travel	934	1 097
Insurance fees	985	1 504
Recruitment	207	245
Other	488	542
<b>Total selling, general and administrative expenses</b>	<b>21 687</b>	<b>18 855</b>

Selling, General and Administrative expenses increased by €2.8 million, or 15.0 % from €18.9 million for the year ended December 31, 2022 to €21.7 million for the year ended December 31, 2023 mainly due to an increase of costs to support the commercialization of Genio system in Europe, scale up of the Company and also due to €0.5 million related to the start of a new ERP implementation. This increase was partly offset by decrease in insurance and legal fees.

## 5.24 Other operating income and expenses

The Company had other operating income of €0.5 million for the year ended December 31, 2023 compared to €283,000 for the year ended December 31, 2022. The impact of the recoverable cash advances is further detailed in note 17.1.

(in EUR 000)	For the year ended December 31	
	2023	2022
Recoverable cash advances		
Initial measurement and re-measurement	324	247
R&D incentives	1 376	86
Capitalization of R&D incentive	(1 005)	(123)
Other income/(expenses)	(151)	73
<b>Total Other Operating Income</b>	<b>544</b>	<b>283</b>

The other operating income contains the R&D Incentive in Australia and as from 2023 the tax incentive in Belgium as well. The incentives to be received relate to development expenses incurred by the subsidiary in Australia and Belgium. Refer to note 10 for more information on the tax incentive in Belgium. For the year ended December 31, 2023, €1.0 million has been deducted from the expenses capitalized and for the year ended December 31, 2022, €123,000 has been deducted from the expenses capitalized in relation to this R&D Incentive. The R&D incentive (Australia) for the year ended December 31, 2022 includes a correction for 2021 due to change in estimation taken into account.

## 5.25 Employee Benefits

(in EUR 000)	For the year ended December 31	
	2023	2022
Salaries	16 400	13 530
Social charges	1 363	1 077
Fringe benefits	33	48
Defined contribution plan	296	264
Holiday pay	485	340
Share-based payment (see note 16)	2 611	2 697
Other	1 353	929
<b>Total employee benefits</b>	<b>22 541</b>	<b>18 885</b>

(in EUR 000)	For the year ended December 31	
	2023	2022
Selling, general and administrative expenses	8 738	7 811
Research & Development expenses	13 803	11 074
<b>Total employee benefits</b>	<b>22 541</b>	<b>18 885</b>

As at December 31, 2023, the Company employed 146.8 (2022: 137.5) full-time equivalents, including white-collar employees and consultants. The following table presents a breakdown of the Company's full-time equivalents as at December, 2023 and 2022:

(in FTE's)	<b>As at December 31</b>	
	<b>2023</b>	<b>2022</b>
Selling, General & Administration	40.4	34.9
Research & Development	106.4	102.6
<b>Total</b>	<b>146.8</b>	<b>137.5</b>

As at December 31, 2023, the Company had 47.9 full-time equivalents located in Belgium (2022: 55.9), 46.4 full-time equivalents located in Israel (2022: 44.6), 4.0 full-time equivalents located in Australia (2022: 6.0), 35.0 full-time equivalents located in USA (2022: 31.0) and 13.5 full-time equivalents located in Germany (2022: 0.0).

## 5.26 Pension Schemes

### 5.26.1 Defined contribution plan

The Company offers Defined Contribution Plan funded through group insurances to its employees of the Israel entity. The total expense recognized in the consolidated income statement for contributions under this plan amounts to €210,000 (2022: €260,000).

### 5.26.2 Defined benefit plan

The Company offers a pension plan with a minimum return guaranteed by law to its employees of the Belgian entity. The contributions to this plan amount to minimum 7 % of the salary, partly paid by the employer and partly by the employees. As explained hereafter, this pension plan qualifies as Defined Benefit Plan under IFRS. As a result, a provision of €9,000 (2022: €0,000) has been recorded for the net benefit obligation in 2023.

As a consequence of the law of December 18, 2015, minimum returns guaranteed by the employers are as follows:

- For the contributions paid as from January 1, 2016, a new variable return based on OLO rates comprised between 1.75 % and 3.75 %. The rate is currently set to 1.75 %.
- For the contributions paid until end December 2015, the previously applicable legal returns of 3.75 % on employee contributions and 3.25 % on employer contributions continue to apply until retirement date of the participants.

The insurance companies managing these plans for the Company also guarantee a minimum return on the reserves as well as on future contributions for some portions of the plan. They have evolved as follows: 4.75 % until 1998, 3.25 % from 1999 till 2012 and between 0.50 % and 2.25 % since 2013. They are currently set between 0.50 % and 1.50 %. The assets of the plan are entirely managed by external insurance companies "qualifying third party" which do not have any link with the Company.

The weighted average duration until the pension age for the Belgian plan is 16 years as at December 31, 2023. In view of the minimum legal returns guaranteed, this pension Plan qualifies as Defined Benefit Plan under IFRS. Indeed, it induces a financial risk for the Company during periods of declining market interest rates when the returns guaranteed by the insurance companies are lower than the minimum legal returns, which is currently the case. In this case, the intervention of the insurance company is limited, and the Company shall fund the balance between the return delivered by the insurance company and the legal return.

A complete actuarial calculation has been performed for this plan by external actuaries based on the "Projected Unit Credit Method without future contribution" according to the IAS 19,115 as follows:

- Projection of the minimum return guaranteed by the law till the retirement date and discounting of this amount with the discount rate used for the valuation (rate of high-quality corporate bonds);
- The discounted net obligation is the maximum between this discounted projection and the projection of the accrued reserves discounted at the discount rate used for the valuation (rate of high-quality corporate bonds).

The net defined benefit obligation was established at €9,000 as of December 31, 2023 (2022: €0,000):

(in EUR 000)	2023	2022
Net defined benefit liability at January 1	–	80
Defined benefit cost included in profit or loss	284	166
Total remeasurement included in OCI	(81)	(70)
Employer contributions	(194)	(176)
<b>Net defined benefit liability at December 31</b>	<b>9</b>	<b>–</b>

The gross defined benefit liability is as follows:

(in EUR 000)	2023	2022
Gross defined benefit liability at January 1	583	494
Current service cost	287	166
Interest cost	24	7
Administrative expenses	(3)	(3)
Taxes on contributions	(8)	(7)
Insurance premiums for risk benefits	(9)	(10)
Actuarial gain due to change in financial assumptions	4	(69)
Actuarial loss due to change in experience assumptions	(114)	5
<b>Gross defined benefit liability at December 31</b>	<b>764</b>	<b>583</b>

The fair value of the plan assets is as follows:

(in EUR 000)	2023	2022
Fair value plan assets at January 1	583	414
Interest income	27	7
Employer contributions	194	176
Administrative expenses	(3)	(3)
Taxes on contributions	(8)	(7)
Insurance premiums for risk benefits	(9)	(10)
Actuarial gain on fair value of the plan assets	(29)	6
<b>Fair value plan assets at December 31</b>	<b>755</b>	<b>583</b>

The number of members and the average age of the members is as follows:

	<b>For the year ended December 31</b>	
	<b>2023</b>	<b>2022</b>
Active members	40	35
Average age	39	40

All plan assets are invested in an insurance contract with guaranteed interest rate (branch 21 product). The defined benefit calculation has been performed based on the below assumptions:

	<b>For the year ended December 31</b>	
	<b>2023</b>	<b>2022</b>
Discount rate	3.4%	4.2%
Inflation rate	2.2%	2.2%
Salary increase (in excess of inflation)	1.0%	1.0%
Withdrawal rate based on age (minimum)	0.0%	0.0%
Withdrawal rate based on age (maximum)	12.0%	12.0%

The discount rate was derived from the EIOPA term structure on each valuation date, considering the weighted average duration of liabilities. The inflation rate is based on the long-term objective of the European Central Bank. Retirement age assumption is in line with current legal requirements. The withdrawal rate and the salary increase rate reflect the expectations of the company on a long-term basis.

A sensitivity with reasonable possible changes on the discount rate will impact the net defined benefit liability as follows (positive = increase net defined benefit liability / negative = decrease of net defined benefit liability):

	<b>For the year ended December 31</b>	
	<b>2023</b>	<b>2022</b>
Increase of 0.25% in the discount rate	(2)	–
Decrease of 0.25% in the discount rate	3	–

The expected employer contributions for the year 2024 amount to €200,000.

The total expected benefit payments are:

(in EUR 000)	<b>As at December 31, 2023</b>
In the next 12 months	14
Between 2 and 5 years	90
Between 6 and 10 years	58
<b>Expected total benefit payments</b>	<b>162</b>



## 5.27 Financial income

(in EUR 000)	For the year ended December 31	
	2023	2022
Interests	2 571	372
Exchange differences	1 254	6 041
Fair value adjustment	343	1
Other	6	349
<b>Total financial income</b>	<b>4 174</b>	<b>6 763</b>

The financial income decreased by €2.6 million from €6.8 million for the year ended December 31, 2022 to €4.2 million for the year ended December 31, 2023 mainly due to a decrease in exchange differences which is offset by an increase in interests. For the year ended December 31, 2022, exchange losses amount to €6.0 million, mainly due to the revaluation of both the Company's USD cash balance and USD financial assets (note 14). For the year ended December 31, 2021, the closing rate of USD/EUR amounted to 1.13260, while as at December 31, 2022, the rate of USD/EUR decreased to 1.072650, resulting in unrealized exchange gains on the USD balances. We refer to note 28 for more details on the revaluation of both the Company's USD cash balance and USD financial assets as per December 31, 2023.

For the year ended December 31, 2023, the total interest income amounted to €2.6 million. This interest income relates to the term accounts.

The fair value adjustment relates to the fair value adjustment on financial instruments. More information can be found in note 19.1.

For the year ended December 31, 2022 other financial income mainly to consists of premiums received on foreign currency options. No premium were received in 2023.

## 5.28 Financial Expense

(in EUR 000)	For the year ended December 31	
	2023	2022
Fair value adjustment	90	2 721
Recoverable cash advances, Accretion of interest	990	925
Interest and bank charges	88	139
Interest on lease liabilities	129	98
Exchange differences	2 432	437
Other	–	–
<b>Total Financial expense</b>	<b>3 729</b>	<b>4 320</b>

The financial expenses decreased by €0.6 million from €4.3 million for the year ended December 31, 2022 to €3.7 million for the year ended December 31, 2023 mainly due to a decrease in fair value adjustments (note 19.1) which is offset by an increase in exchange differences. For the year ended December 31, 2023, exchange losses amount to €2.4 million, mainly due to the revaluation of both the Company's USD cash balance and USD financial assets (note 14). For the year ended December 31, 2022, the closing rate of USD/EUR amounted to 1.072650, while as at December 31, 2023, the rate of USD/EUR increased to 1.103765, resulting in unrealized exchange losses on the USD balances.

The discounting impact of the recoverable cash advances is further detailed in note 17.1 above.

## 5.29 Income taxes and deferred taxes

The major components of income tax expense for the years ended December 31, 2023 and 2022 are as follows:

(in EUR 000)	For the year ended December 31	
	2023	2022
Current tax income/(expense)	1 442	(1 179)
Deferred tax income/(expense)	3	10
<b>Total Income tax income/(expense)</b>	<b>1 445</b>	<b>(1 169)</b>

As of January 1, 2022, new tax regulations are in place in the US in which R&D expenses could no longer be deducted when incurred but instead they should be capitalized only for tax purposes and amortized over a 5 year period. A current tax liability was recognized. During 2023, more information became available on the new tax law and the Company finalized its R&D tax credit study and reached the conclusion that R&D expenses can be deducted when incurred. The R&D tax credit study concluded that taking into account that the research and development by the US subsidiary was done under the direction of the parent in Belgium and benefited Belgian parent' business, the expenditures in the US should be deducted when incurred. As a result the current tax liability which was outstanding as at December 31, 2022 amounting to €1.6 million was reversed.

The current tax income mainly relates to (i) reversal of tax liability in US for an amount of €1.6 million (see more details above) (ii) income tax paid or payable by certain of the Company's subsidiaries for an amount of €185,000 (2022: €1.8 million), and (iii) a reversal of accrual of the liability for uncertain tax positions for an amount of €41,000 (2022: a reversal of €0.6 million).

The current tax liability of €2.0 million includes a liability for uncertain tax positions for an amount of €1.9 million and an income tax liability for an amount of €52,000. The uncertain tax position was recorded following certain public rulings and guidance issued by tax authorities in one of the jurisdictions that the Company operates in.

The deferred tax relates to a subsidiary where some payroll accruals are temporary differences in the determination of the taxable income. These temporary differences generate deferred tax income/(expense) of € 3,000 in 2023 and € 10,000 in 2022.

The income tax expenses can be reconciled to the Company's Belgian statutory income tax rate of 25% (25% in 2022) as follows:

(in EUR 000)	<b>For the year ended December 31</b>	
	<b>2023</b>	<b>2022</b>
Loss for the period before taxes	(44 657)	(30 056)
Company statutory income tax rate	25.00%	25.00%
Income tax at company statutory tax rate	11 164	7 514
Foreign tax rate differential	93	69
Unrecognized DTA on tax losses and temporary differences	(10 660)	(9 058)
Non deductible expenses	(387)	(566)
Share based payments	(653)	(674)
Income not subject to tax	112	974
Tax adjustments to the previous period	1 622	–
Local income taxes	46	601
Other	108	(29)
<b>Income tax at company effective tax rate</b>	<b>1 445</b>	<b>(1 169)</b>
Company effective income tax rate	3.24%	(3.89%)

The tax adjustments to the previous period relates to the reversal of the current tax liability in the US subsidiary due to the R&D tax credit study (see above for more information).

The local income taxes in the effective tax rate reconciliation mainly relates to the theoretical tax exposure on R&D costs in the Australian subsidiary.

The Belgian entity, the Australian entity and German entity have historical losses that can be carried forward to future taxable income. The Belgian entity has tax losses for €153.6 million as at December 31, 2023 (2022: €108.2 million). The Australian entity has tax losses for €1.8 million as at December 31, 2023 (2022: €2.6 million). The German entity has tax losses for €7,000 as at December 31, 2023. Due to the fact that these entities are not expected to generate significant profits in the near future, no deferred tax assets on tax losses carried forward and temporary differences have been recognized at this stage.

Deferred tax assets and liabilities are detailed below by nature of temporary differences for the year ended December 31, 2023 and 2022:

(in EUR 000)	As at December 31, 2023		
	Assets	Liabilities	Net
Intangible assets	1 064	–	1 064
Property, plant and equipment	6	–	6
Right-of-use assets	–	(805)	(805)
Other current assets	–	(71)	(71)
Financial debt (Recoverable Cash Advances and derivatives)	1 948	–	1 948
Lease liabilities	839	–	839
Retirement benefit obligations	2	–	2
Other current liabilities	49	(30)	19
Tax-losses carried forward	38 886	–	38 886
<b>Total gross deferred tax assets/(liabilities)</b>	<b>42 794</b>	<b>(906)</b>	<b>41 888</b>
Netting by tax entity	(897)	897	–
Unrecognized deferred tax assets	(41 841)	–	(41 841)
<b>Total deferred tax assets/(liabilities)</b>	<b>56</b>	<b>(9)</b>	<b>47</b>

(in EUR 000)	As at December 31, 2022		
	Assets	Liabilities	Net
Intangible assets	4 125	–	4 125
Property, plant and equipment	–	(7)	(7)
Right-of-use assets	–	(634)	(634)
Other current assets	13	–	13
Financial debt (Recoverable Cash Advances and derivatives)	1 827	(44)	1 783
Lease liabilities	660	–	660
Other current liabilities	–	(29)	(29)
Tax-losses carried forward	27 744	–	27 744
<b>Total gross deferred tax assets/(liabilities)</b>	<b>34 369</b>	<b>(714)</b>	<b>33 655</b>
Netting by tax entity	(714)	714	–
Unrecognized deferred tax assets	(33 608)	–	(33 608)
<b>Total deferred tax assets/(liabilities)</b>	<b>47</b>	<b>–</b>	<b>47</b>

The Company accumulates tax losses that are carried forward indefinitely for offset against future taxable profits of the Company. As stated above, the entities accumulating tax losses are not expected to generate significant profits in the near future so no deferred tax assets on tax losses carried forward and temporary differences have been recognized at this stage. The recognized deferred tax assets and liabilities in the consolidated balance sheets of the Company are positions that arise from temporary differences between statutory and IFRS account balances in the subsidiary in Israel and US.

## 5.30 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.

	2023	2022
<b>As at December 31, after conversion and share split</b>		
Outstanding common shares at period-end	28 673 985	25 846 279
Weighted average number of common shares outstanding	27 968 142	25 819 165
Potential number of shares resulting from the exercise of warrants	2 279 750	2 578 750

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

	<b>For the period ended December 31</b>	
	2023	2022
Loss of year attributable to common holders (in EUR)	(43 212 000)	(31 225 000)
Loss of year attributable to preferred holders (in EUR)	–	–
Loss of year attributable to equity holders (in EUR)	(43 212 000)	(31 225 000)
Weighted average number of common shares outstanding (in units)	27 968 142	25 819 165
Basic earnings per share in EUR (EUR/unit)	(1.545)	(1.209)
Diluted earnings per share in EUR (EUR/unit)	(1.545)	(1.209)

## 5.31 Other commitments

### 5.31.1 Capital commitments

There are no commitments related to capital expenditures at the closing date.

### 5.31.2 Lease expenses

The lease expense recognized in the income statement related to low-value leases and short-term leases amounts to:

	<b>For the year ended December 31</b>	
(in EUR 000)	2023	2022
Expense	202	240
<b>Total</b>	<b>202</b>	<b>240</b>

### 5.31.3 Other commitments

The Company has granted in 2022 an amount of €0.5 million for educational grant starting on January 1, 2023 until December 31, 2024. The first installment of €250,000 is paid in January 2023, the second installment of €250,000 is planned to be paid during Q1 2024.

## 5.32 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.

### 5.32.1 Remuneration of Key Management

The remuneration of the senior management consists of the remuneration of the CEO of the Company for the period ended December 31:

(in EUR 000)	For the period ended December 31	
	2023	2022
Short-term remuneration & compensation	732	777
Post-employment benefits	33	29
Share based payment	143	118
<b>Total</b>	<b>908</b>	<b>924</b>

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

(in EUR 000)	For the period ended December 31, 2023			For the period ended December 31, 2022		
	R&D Collaboration	Consulting services	Board Remuneration	R&D Collaboration	Consulting services	Board Remuneration
Cochlear	766	–	–	2 021	–	–
Robelga SRL (formerly MINV SA)	–	–	–	–	60	–
Donald Deyo	–	–	–	–	–	21
Robert Taub	–	–	129	–	–	76
Kevin Rakin	–	–	68	–	–	48
Pierre Gianello	–	–	65	–	–	42
Jan Janssen	–	–	–	–	–	12
Jurgen Hambrecht	–	–	58	–	–	46
Rita Mills	–	–	64	–	–	47
Giny Kirby	–	–	59	–	–	28
Raymond Cohen	–	–	–	–	–	23
Wildman Venturees LLC	–	–	86	–	–	–
<b>Total</b>	<b>766</b>	<b>–</b>	<b>529</b>	<b>2 021</b>	<b>60</b>	<b>343</b>
Amounts outstanding at year-end	–	–	110	1 243	60	95

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 € 182,000 for the year ended December 31, 2023, compared to €2.0 million for the year ended December 31, 2022. In January 2023 parties signed an additional statement of work related to the transfer of assets and related support for the setting up of a production line in the US. This additional statement scope of work led to a financial impact of €0,6 million for the year ended December 31, 2023 and was recognized as part of assets under construction. All statements of work were completed in 2023.

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

### **5.32.3 Transactions with related parties**

The following is a description of related party transactions we have entered into with any members of our board of directors or executive officers or the holders of more than 3% of our share capital.

#### ***Consulting Agreement with Olivier Taelman***

Effective September 1, 2021, the Company and Olivier Taelman decided by mutual agreement to terminate the employment contract of Olivier Taelman with the Company and to enter into an agreement, pursuant to which Mr. Taelman will perform his functions as CEO of the Company on a self-employed basis going forward. Pursuant to the terms of this agreement, Mr. Taelman will be entitled to receive an annual fee equal to the euro equivalent of \$450,000, as well as a short term incentive and a long term incentive (in the form of the grant of warrants) in accordance with the Company's remuneration policy as approved from time to time by the shareholders' meeting of the Company. Mr. Taelman will continue to benefit from a company car, a laptop, a mobile phone, an occupational pension scheme and a hospitalization insurance. The consulting agreement has an indefinite term and can be terminated by either us or Mr. Taelman at any time subject to a notice period of three months, supplemented with one month per completed year of services under the Agreement, with a maximum total notice period of nine months. We can immediately terminate the consulting agreement in case of serious cause.

#### ***Employment Agreement with Loïc Moreau***

We are party to an employment agreement, dated October 8, 2021, with Loïc Moreau, our chief financial officer since January 1, 2022. Pursuant to the terms of his employment agreement, Mr. Moreau receives a base salary of €259,000 and is eligible to receive an annual cash bonus of up to €184,000 based on performance criteria established by our remuneration committee and board of directors. The employment agreement has an indefinite term and can be terminated by either us or Mr. Moreau at any time subject to prior notice in accordance with Belgian law. We can immediately terminate the employment agreement in case of serious cause.

### Consulting Arrangements

#### Robelga SRL (formerly MINV SA) Consulting Agreements

On June 9, 2021, we entered into a consulting agreement with MINV SA, pursuant to which MINV SA (i) assisted our executive management during investor meetings in connection with our initial public offering on Nasdaq and (ii) provided various consultancy services, including to support our executive management in business development activities. On June 23, 2021, pursuant to a “merger by absorption” of MINV SA by Robelga SRL, all rights and obligations of MINV SA were transferred to Robelga SRL. For the year ended December 31, 2023, we paid Robelga SRL a total fee of €60,000 for said services rendered during 2022 until the expiration of the agreement on June 8, 2022.

#### Warrants to Our Board Directors and Executive Management

We have granted warrants to certain members of our board of directors and executive management.

#### Policies and Procedures for Related Person Transactions

We have adopted a related person transaction policy requiring that all related person transactions required to be disclosed by a foreign private issuer pursuant to the Exchange Act be approved by the audit committee or another independent body of our board of directors.

### 5.33 Events after the Balance-Sheet Date

On March 6, 2024, the Company issued 8,650 shares pursuant to an exercise of 2,400 2020 ESOP Warrants and 6,250 2021 ESOP Warrants. Consequently, on the date of this Annual Report, the Company’s registered capital amounts to EUR 4,927,355.12, represented by 28,682,635 shares.

On March 19, 2024, the Company issued a press release announcing that the Company’s DREAM pivotal trial met its primary endpoints. More information can be found in the press release.

### 5.34 Statutory Auditor Services and Performance of Exceptional Activities or Execution of Special Instructions Performed by the Auditor

EY Réviseurs d’Entreprises SRL, organized and existing under the laws of Belgium, with registered office at Kouterveldstraat 7b bus 001, 1831 Diegem, Belgium has been appointed as the statutory auditor of the Company for a term of 3 years ending immediately at the approval by the shareholders’ meeting of the financial statements for the year ended 31 December 2024.

The fees are broken down as follows:

(in EUR 000)	For the year ended December 31	
	2023	2022
Audit fees	433	567
Audit-related fees <sup>1</sup>	80	45
Tax fees <sup>2</sup>	20	21
All other fees <sup>3</sup>	13	18
<b>Total</b>	<b>546</b>	<b>651</b>

<sup>1</sup> Audit-related Fees are primarily services related to SEC filings, including comfort letters, consents and comment letters.

<sup>2</sup> Tax Fees are the aggregate fees billed for professional services rendered by the principal accountant for tax compliance, tax advice and tax planning related services.

<sup>3</sup> All other fees include products and/or services provided by the principal accountant, other than the services reported in the above.



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# Statutory Auditors Report



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## Independent auditor's report to the general meeting of Nyxoah SA for the year ended 31 December 2023

In the context of the statutory audit of the Consolidated Financial Statements of Nyxoah SA (the "Company") and its subsidiaries (together the "Group"), we report to you as statutory auditor. This report includes our opinion on Consolidated Balance Sheets as at 31 December 2023, Consolidated Statements of Loss and Other Comprehensive Loss, Consolidated Statements of Changes in Equity, Consolidated Statements of Cash Flow for the year ended 31 December 2023 and the disclosures including material accounting policy information (all elements together the "Consolidated Financial Statements") as well as our report on other legal and regulatory requirements. These two reports are considered one report and are inseparable.

We have been appointed as statutory auditor by the shareholders' meeting of 8 June 2022, in accordance with the proposition by the Board of Directors following recommendation of the Audit Committee. Our mandate expires at the shareholders' meeting that will deliberate on the Consolidated Financial Statements for the year ending 31 December 2024. We performed the audit of the Consolidated Financial Statements of the Group during 8 consecutive years.

### Report on the audit of the Consolidated Financial Statements

#### Unqualified opinion

We have audited the Consolidated Financial Statements of Nyxoah SA, that comprise of Consolidated Balance Sheets on 31 December 2023, Consolidated Statements of Loss and Other Comprehensive Loss, Consolidated Statements of Changes in Equity, Consolidated Statements of Cash Flow of the year and the disclosures, including material accounting policy information, which show a consolidated balance sheet total of € 124.157 thousand and of which the consolidated income statement shows a loss for the year of € 43.212 thousand.

In our opinion, the Consolidated Financial Statements give a true and fair view of the consolidated net equity and financial position as at 31 December 2023, and of its consolidated results for the year then ended, prepared in accordance with the International Financial Reporting Standards as adopted by the European Union ("IFRS") and with applicable legal and regulatory requirements in Belgium.

#### Basis for the unqualified opinion

We conducted our audit in accordance with International Standards on Auditing ("ISA's") applicable in Belgium. In addition, we have applied the ISA's approved by the International Auditing and Assurance Standards Board ("IAASB") that apply at the current year-end date and have not yet been approved at national level.

Our responsibilities under those standards are further described in the "Our responsibilities for the audit of the Consolidated Financial Statements" section of our report.

We have complied with all ethical requirements that are relevant to our audit of the Consolidated Financial Statements in Belgium, including those with respect to independence.

We have obtained from the Board of Directors and the officials of the Company the explanations and information necessary for the performance of our audit and we believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Material uncertainty related to going concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 5.1 to the financial statements, the Company has suffered recurring losses from operations, sustained negative cash flows since its inception, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 5.1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Besloten vennootschap  
Société à responsabilité limitée  
RPR Brussel - RPM Bruxelles - BTW-TVA BE0446.334.711-IBAN N° BE71 2100 9059 0069  
\*handelend in naam van een vennootschap/agissant au nom d'une société

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## Key audit matters

### Description of the key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period. In addition to the matter described in the Material Uncertainty Related to Going Concern section, we have determined the matters described below to be the key audit matters to be communicated in our report.

These matters were addressed in the context of our audit of the Consolidated Financial Statements as a whole and in forming our opinion thereon, and consequently we do not provide a separate opinion on these matters.

### Valuation of recoverable government cash advances and intangible assets related to the Genio® system

As at 31 December 2023, the financial liability associated with recoverable government advances and the Genio® System intangible assets representing capitalized costs for the development of the system amounted to approximately €8,7 million and €46,6 million respectively. As detailed in notes 17 and 8 of the Consolidated Financial Statements, the financial liability related to recoverable advances must be revalued each period (in line with IFRS 9 - Financial Instruments) and the intangible assets under development must be tested annually for impairment (in line with IAS 36 - Impairment of Assets). The fair value of liabilities and assets is determined using assumptions, of which the most significant are revenue growth and discount rate.

The audit of these assumptions is complex as they are determined by management and are subjective and sensitive in nature. We note that the Genio® System has been approved in the EU but not yet in other markets, such as the US market. Although the company has recently received positive feedback from ongoing clinical trials in the US, the receipt of the formal regulatory approval may take longer to obtain than expected. As a result, the revenue growth assumption is sensitive to a higher level of management subjectivity. The audit of the discount rate used by management is also complex, as it depends on the inherent risk of the industry in which the Company operates, as well as the uncertainty associated with the outcome of the research and development process.

### Summary of the procedures performed

- We obtained an understanding of management's process for determining significant assumptions, model selection, and the evaluation of the data used to develop these assumptions.
- With the assistance of our internal specialists, we tested the significant assumptions as described above (revenue growth and discount rate), by comparing these assumptions with market and industry data, and verifying the clerical accuracy of the model provided by management.
- We performed an independent sensitivity test on these assumptions, again with the help of our internal specialists.
- We tested all revenue growth assumptions against the business plan prepared by management, publicly available industry data and other internal information to assess their consistency.
- We read and assessed the minutes of the Board of Directors, including its appendices, to confirm the estimated revenue growth.
- Finally, we read and assessed the Notes 17 and 8 to the Consolidated Financial Statements to verify the completeness of the information described therein.

### Responsibilities of the Board of Directors for the preparation of the Consolidated Financial Statements

The Board of Directors is responsible for the preparation of the Consolidated Financial Statements that give a true and fair view in accordance with IFRS and with applicable legal and regulatory requirements in Belgium and for such internal controls relevant to the preparation of the Consolidated Financial Statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of Consolidated Financial Statements, the Board of Directors is responsible for assessing the Company's ability to continue as a going concern, and provide, if applicable, information on matters impacting going concern. The Board of Directors should prepare the financial statements using the going concern basis of accounting, unless the Board of Directors either intends to liquidate the Company or to cease business operations, or has no realistic alternative but to do so.



**Audit report dated 20 March 2024 on the Consolidated Financial Statements  
of Nyxoah SA as of and  
for the year ended 31 December 2023 (continued)**

### **Our responsibilities for the audit of the Consolidated Financial Statements**

Our objectives are to obtain reasonable assurance whether the Consolidated Financial Statements are free from material misstatement, whether due to fraud or error, and to express an opinion on these Consolidated Financial Statements based on our audit. Reasonable assurance is a high level of assurance, but not a guarantee that an audit conducted in accordance with the ISA's will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these Consolidated Financial Statements.

In performing our audit, we comply with the legal, regulatory and normative framework that applies to the audit of the Consolidated Financial Statements in Belgium. However, a statutory audit does not provide assurance about the future viability of the Company and the Group, nor about the efficiency or effectiveness with which the board of directors has taken or will undertake the Company's and the Group's business operations. Our responsibilities with regards to the going concern assumption used by the board of directors are described below.

As part of an audit in accordance with ISA's, we exercise professional judgment and we maintain professional skepticism throughout the audit. We also perform the following tasks:

- identification and assessment of the risks of material misstatement of the Consolidated Financial Statements, whether due to fraud or error, the planning and execution of audit procedures to respond to these risks and obtain audit evidence which is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting material misstatements resulting from fraud is higher than when such misstatements result from errors, since fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- obtaining insight in the system of internal controls that are relevant for the audit and with the objective to design audit procedures that are appropriate in the circumstances, but not for the

purpose of expressing an opinion on the effectiveness of the Company's internal control;

- evaluating the selected and applied accounting policies, and evaluating the reasonability of the accounting estimates and related disclosures made by the Board of Directors as well as the underlying information given by the Board of Directors;
- conclude on the appropriateness of the Board of Directors' use of the going-concern basis of accounting, and based on the audit evidence obtained, whether or not a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's or Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the Consolidated Financial Statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the Company to cease to continue as a going-concern;
- evaluating the overall presentation, structure and content of the Consolidated Financial Statements, and evaluating whether the Consolidated Financial Statements reflect a true and fair view of the underlying transactions and events.

We communicate with the Audit Committee within the Board of Directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the audits of the subsidiaries. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities.

We provide the Audit Committee within the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Audit Committee within the Board of Directors, we determine those matters that were of most significance in the audit of the Consolidated Financial Statements of the current

period and are therefore the key audit matters. We describe these matters in our report, unless the law or regulations prohibit this.

## Report on other legal and regulatory requirements

### Responsibilities of the Board of Directors

The Board of Directors is responsible for the preparation and the content of the Board of Directors' report on the Consolidated Financial Statements.

### Responsibilities of the auditor

In the context of our mandate and in accordance with the additional standard to the ISA's applicable in Belgium, it is our responsibility to verify, in all material respects, the Board of Directors' report on the Consolidated Financial Statements, as well as to report on these matters.

### Aspects relating to Board of Directors' report

In our opinion, after carrying out specific procedures on the Board of Directors' report, the Board of Directors' report is consistent with the Consolidated Financial Statements and has been prepared in accordance with article 3:32 of the Code of companies and associations.

In the context of our audit of the Consolidated Financial Statements, we are also responsible to consider whether, based on the information that we became aware of during the performance of our audit, the Board of Directors' report contain any material inconsistencies or contains information that is inaccurate or otherwise misleading. In light of the work performed, there are no material inconsistencies to be reported.

### Independence matters

Our audit firm and our network have not performed any services that are not compatible with the audit of the Consolidated Financial Statements and have remained independent of the Company during the course of our mandate.

The fees related to additional services which are compatible with the audit of the Consolidated Financial Statements as referred to in article 3:65 of the Code of companies and associations were duly itemized and valued in the notes to the Consolidated Financial Statements.

### European single electronic format ("ESEF")

In accordance with the standard on the audit of the conformity of the financial statements with the European single electronic format (hereinafter "ESEF"), we have carried out the audit of the compliance of the ESEF format with the regulatory technical standards set by the European Delegated Regulation No 2019/815 of 17 December 2018 (hereinafter: "Delegated Regulation").

The board of directors is responsible for the preparation, in accordance with the ESEF requirements, of the consolidated financial statements in the form of an electronic file in ESEF format in the official French language (hereinafter 'the digital consolidated financial statements') included in the annual financial report available on the portal of the FSMA (<https://www.fsma.be/fr/stori>) in the official French language.

It is our responsibility to obtain sufficient and appropriate supporting evidence to conclude that the format and markup language of the digital consolidated financial statements comply in all material respects with the ESEF requirements under the Delegated Regulation.

Based on the work performed by us, we conclude that the format and tagging of information in the digital consolidated financial statements of Nyxoah SA per 31 December 2023 included in the annual financial report available on the portal of the FSMA (<https://www.fsma.be/fr/stori>) in the official French language are, in all material respects, in accordance with the ESEF requirements under the Delegated Regulation.



Audit report dated 20 March 2024 on the Consolidated Financial Statements  
of Nyxoah SA as of and  
for the year ended 31 December 2023 (continued)

**Other communications.**

- This report is consistent with our supplementary declaration to the Audit Committee as specified in article 11 of the regulation (EU) nr. 537/2014.

Diegem, 20 March 2024

EY Bedrijfsrevisoren BV  
Statutory auditor  
Represented by

Carlo-Sébastien D'Addario \*  
Partner  
\*Acting on behalf of a BV/SRL

Unique sequential number of EY reports tracking database

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# Statutory Accounts

# Statutory Accounts as of December 31, 2023

## 7.1 Balance sheet

<b>Assets</b>	<b>Notes</b>	<b>Codes</b>	<b>Period</b>	<b>Preceding period</b>
Formation expenses	6.1	20	6 374 645	8 896 154
Fixed assets		21/28	49 023 448	39 407 922
Intangible fixed assets	6.2	21	45 388 058	37 729 099
Tangible fixed assets	6.3	22/27	3 583 499	1 655 932
Land and buildings		22		
Plant, machinery and equipment		23	724 535	661 943
Furniture and vehicles		24	159 727	181 811
Leasing and other similar rights		25		
Other tangible fixed assets		26	644 607	94 484
Assets under construction and advance payments		27	2 054 630	717 694
<b>Financial fixed assets</b>	<b>6.4 / 6.5.1</b>	<b>28</b>	<b>51 891</b>	<b>22 891</b>
Affiliated Companies	6.15	280/1	29 064	64
Participating interests		280	29 064	64
Amounts receivable		281		
Other companies linked by participating interests	6.15	282/3		
Participating interests		282		
Amounts receivable		283		
Other financial fixed assets		284/8	22 827	22 827
Shares		284		
Amounts receivable and cash guarantees		285/8	22 827	22 827



	Notes	Codes	Period	Preceding Period
<b>Current assets</b>		29/58	62 996 339	93 898 353
Amount receivable after more than one year		29	1 107 072	
Trade debtors		290		
Other amounts receivable		291	1 107 072	
<b>Stocks and contracts in progress</b>		3	3 315 191	881 981
Stocks		30/36	3 315 191	881 981
Raw material and consumables		30/31	1 328 765	498 585
Work in progress		32	1 530 363	99 541
Finished goods		33	456 062	283 855
Goods purchased for resale		34		
Immovable property intended for sale		35		
Advance payments		36		
Contracts in progress		37		
<b>Amount receivable within one year</b>		40/41	4 305 830	2 539 183
Trade debtors		40	2 914 721	1 575 659
Other amounts receivable		41	1 391 109	963 524
<b>Current investments</b>	6.5.1 / 6.6	50/53	45 262 431	76 968 116
Own shares		50		
Other investments		51/53	45 262 431	76 968 116
<b>Cash at bank and in hand</b>		54/58	7 738 387	12 250 184
<b>Accruals and deferred income</b>	6.6	490/1	1 267 428	1 258 889
<b>Total Assets</b>		20/58	118 394 432	142 202 429

## Statutory Accounts

	Notes	Codes	Period	Preceding Period
<b>Equity and liabilities</b>				
Equity		10/15	108 601 388	134 695 009
Contributions	6.7.1	10/11	265 557 552	246 880 354
Capital		10	4 925 869	4 440 069
Issued capital		100	4 925 869	4 440 069
Uncalled capital		101		
Beyond capital		11	260 631 682	242 440 285
Share premium account		1100/10	260 631 682	242 440 285
Other		1109/19		
Revaluation surpluses		12		
Reserves (+)/(-)		13		
Reserves not available		130/1		
Legal reserve		130		
Reserves not available statutorily		1311		
Purchase of own shares		1312		
Financial support		1313		
Other		1319		
Untaxed reserves		132		
Available reserves		133		
Accumulated profits (losses) (+)/(-)		14	-156 956 164	-112 185 345
Capital subsidies		15		
Advance to shareholders on the distribution of net assets		19		
Provisions and deferred taxes		16	185 252	59 017
Provisions for liabilities and charges		160/5	185 252	59 017
Pensions and similar obligations		160		
Taxes		161		
Major repairs and maintenance		162		
Environmental obligations		163		
Other liabilities and charges	6.8	164/5	185 252	59 017
Deferred taxes		168		

	Notes	Codes	Period	Preceding period
Amounts payable		17/49	9 607 792	7 448 403
Amounts payable after more than one year	6.9	17	642 624	923 472
Financial debt		170/4	642 624	923 472
Subordinated loans		170		
Unsubordinated debentures		171		
Leasing and other similar obligations		172		
Credit institutions		173		
Other loans		174	642 624	923 472
Trade debts		175		
Suppliers		1750		
Bills of exchange payable		1751		
Advance payments on contracts in progress		176		
Other amounts payable		178/9		
Amounts payable within one year	6.9	42/48	8 650 151	6 253 118
Current portion of amounts payable after more than one year falling due within one year		42	301 681	343 347
Financial debt		43		
Credit institutions		430/8		
Other loans		439		
Trade debts		44	3 850 620	4 039 150
Suppliers		440/4	3 850 620	4 039 150
Bills of exchange payable		441		
Advance payments on contracts in progress		46		
Taxes, remuneration and social security	6.9	45	1 848 616	1 528 161
Taxes		450/3	183 267	183 463
Remuneration and social security		454/9	1 665 349	1 344 698
Other amounts payable		47/48	2 649 233	342 460
Accruals and deferred income	6.9	492/3	315 017	271 813
Total liabilities		10/49	118 394 432	142 202 429

## 7.2 Profit and loss account

	Notes	Codes	Period	Preceding period
<b>Operating income</b>		<b>70/76A</b>	<b>17 014 138</b>	<b>18 950 378</b>
Turnover	6.10	70	4 378 149	3 095 389
Stock on finished goods and work in progress: increase (decrease)	(+)/(-)	71	3 737 884	37 398
Produced fixed assets		72	8 437 145	15 402 040
Other operating income	6.10	74	460 960	415 551
Non-recurring operating income	6.12	76A		
<b>Operating charges</b>		<b>60/66A</b>	<b>63 611 420</b>	<b>51 500 500</b>
Goods for resale, raw materials and consumables		60	1 992 410	1 198 786
Purchases		600/8	4 089 124	1 697 371
Stock: decrease (increase)	(+)/(-)	609	-2 096 715	-498 585
Services and other goods		61	46 813 833	40 992 066
Remuneration, social security and pensions	6.10	62	7 093 200	5 117 754
Amortizations of and other amounts written down on formation expenses, intangible and tangible fixed assets		630	4 058 350	3 830 345
Amounts written down on stocks, contracts in progress and trade debtors: additions (write-backs)	6.10	631/4	3 401 389	29 043
Provisions for liabilities and charges: appropriations (uses and write-backs)	6.10	635/8	126 235	47 370
Other operating charges	6.10	640/8	126 005	285 136
Operating charges reported as assets under restructuring costs		649		
Non-recurring operating charges	6.12	66A		
<b>Operating profit (loss)</b>	<b>(+)/(-)</b>	<b>9901</b>	<b>-46 597 282</b>	<b>-32 550 122</b>

	Notes	Codes	Period	Preceding Period
<b>Financial income</b>		<b>75/76B</b>	<b>4 077 994</b>	<b>7 086 262</b>
Recurring financial income		75	4 077 994	7 086 262
Income from financial fixed assets		750	329 639	305 556
Income from current assets		751	2 570 782	736 983
Other financial income	6.11	752/9	1 177 572	6 043 723
Non-recurring financial income	6.12	76B		
<b>Financial charges</b>	<b>6.11</b>	<b>65/66B</b>	<b>3 343 857</b>	<b>4 146 338</b>
Recurring financial charges		65	2 707 268	3 103 953
Debt charges		650	108 640	82 614
Amounts written down on current assets other than stocks, contracts in progress and trade debtors: additions (write-backs) (+)/(-)		651		
Other financial charges		652/9	2 598 629	3 021 339
Non-recurring financial charges	6.12	66B	636 588	1 042 385
<b>Profit (Loss) for the period before taxes (+)/(-)</b>		<b>9903</b>	<b>-45 863 145</b>	<b>-29 610 198</b>
Transfer from deferred taxes		780		
Transfer to deferred taxes		680		
<b>Income taxes on the result (+)/(-)</b>	<b>6.13</b>	<b>67/77</b>	<b>1 092 326</b>	<b>15 621</b>
Taxes		670/3		35 558
Adjustment of income taxes and write-back of tax provisions		77	1 092 326	19 937
<b>Profit (Loss) of the period (+)/(-)</b>		<b>9904</b>	<b>-44 770 819</b>	<b>-29 625 819</b>
Transfer from untaxed reserves		789		
Transfer to untaxed reserves		689		
<b>Profit (Loss) of the period available for appropriation (+)/(-)</b>		<b>9905</b>		
			<b>-44 770 819</b>	<b>-29 625 819</b>

### 7.3 Appropriation account

		Notes	Codes	Period	Preceding period
Profit (Loss) to the appropriated	(+)/(-)		9906	-156 956 164	-112 185 345
Profit (Loss) of the period available for appropriation	(+)/(-)		(9905)	-44 770 819	-29 625 819
Profit (Loss) of the preceding period brought forward	(+)/(-)		14P	-112 185 345	-82 559 526
<b>Transfer from equity</b>			<b>791/2</b>		
From contributions			791		
From reserves			792		
<b>Appropriations to equity</b>			<b>691/2</b>		
To contributions			691		
To legal reserve			6920		
To other reserves			6921		
Profit (loss) to be carried forward	(+)/(-)		(14)	-156 956 164	-112 185 345
Shareholders' contribution in respect of losses			794		
<b>Profit to be distributed</b>			<b>694/7</b>		
Compensation for contributions			694		
Directors or managers			695		
Employees			696		
Other beneficiaries			697		

## 7.4 Valuation rules

The statutory annual accounts have been drawn up in accordance with the Royal Decree of April 29, 2019 regarding the implementation of the Code of Companies and Associations.

The annual accounts give a true and fair view of the assets, liabilities, financial position and results of the Company. The amounts relating to the financial year are established in a consistent way with those of the previous financial year.

Assets and liabilities are valued in accordance with article 3:108 of the Royal Decree of April 29, 2019 on the assumption that the Company will continue as a going concern.

Each component of the assets and liabilities is valued separately. Depreciations, write-off and revaluations are specific to each asset to which they relate. Provisions for liabilities and charges are individualized. Valuations, depreciations, write-off and provisions for liabilities and charges meet the requirements of prudence, sincerity and good faith.

### ***Formation expenses***

Formation expenses will be amortized over a period of 5 years as from the finalization of the capital round.

### ***Intangible assets***

Intangible fixed assets are stated at net book value, i.e. the acquisition value less depreciations and write-downs recorded. If they were set up by the Company itself, they are recorded at the lower of cost or production cost, or at a conservative estimate of their value in use, with an estimate of future yield acting as a ceiling.

Intangible assets are amortized on a straight-line basis. The following amortization percentage applies: 20%

### ***Research and development expenses - Patents***

The development costs are capitalized as intangible asset on the balance sheet if the potential profitability is identifiable and probable. Development expenses will be capitalized for the first time in the year in which the CE mark is obtained.

### ***Research and development expenses - Device treating Obstructive Sleep Apnea***

The development costs are capitalized as intangible asset on the balance sheet if the potential profitability is identifiable and probable. Part of the capitalization will stop following the sales made. Nevertheless, part of the capitalization will continue, i.e.: indirect and direct costs of clinical studies conducted in Europe, the United States and Australia; development costs incurred in Israel.

Research and development costs are amortized over the estimated life of the Genio system based on the expiration of the last patent of this technology. The Company concludes that the useful life of the technology and related improvements is at least 14 years from January 1, 2021.

### ***Property, plant and equipment***

Fixed assets are stated at net book value, i.e. the acquisition value less depreciations and impairments.

Fixed assets are depreciated using the straight-line method. Additional costs are immediately recognized in the income statement. The following depreciation percentages apply:

- Computer hardware: 33%.
- Fitting-out of rented buildings: 20%
- Machinery and tools: 20%.
- Furniture: 10%

Interest expenses are not included in the acquisition value.

Property, plant and equipment that are no longer in use or that have no planned use on a long-term basis for the Company's business are, where applicable, subject to exceptional depreciation or impairment to bring their valuation into line with their probable realizable value.

### ***Long-term financial assets***

Financial fixed assets are valued at their acquisition cost and impairments are accounted for in case sustainable minus values are identified considering applicable circumstances, considering expected profitability or perspectives for which the investment or shares are held.

Guarantees are booked at their nominal value.

Write-offs are applied to receivables included in financial fixed assets in the event of uncertainty regarding the payment of those on the due date.

### ***Receivables***

Receivables are recorded in the balance sheet at their nominal value. Receivables are subject to write-off in the event of uncertainty as to the payment of all or part of the receivable on the due date.

Receivables are recorded in the balance sheet at their nominal value taking into consideration liabilities recorded in accruals and deferred income on the basis of pro rata temporis of interest:

- a. interest conventionally included in the nominal value of the receivables;
- b. the difference between the acquisition value and the nominal value of the receivables;
- c. the discounting of non-interest-bearing or abnormally low-interest receivables,

### ***Cash and cash equivalents***

Cash and cash equivalents are recorded at their nominal value. Write-offs are applied if their realizable value is lower than their nominal value on the closing date of the financial year. Additional write-offs are booked in the same way as for investments.

### ***Accrued charges and deferred income***

Income and expenses relating to the financial year or to the previous financial years are taken into account, regardless of the date of payment or collection of such income and expenses, unless the actual collection of such income is uncertain. If income or expenses are significantly influenced by income or expenses attributable to another financial year, this is mentioned in the notes to the accounts.



### ***Recoverable advances***

Recoverable advances contracted with the Direction Générale d'Aide à la Recherche de la Région Wallonne (DGO6) are recognized as other operating income in the fiscal year in which the Company obtains confirmation of the settlement of the DGO6's claims. When the Company decides to use the results of the research or development project (decision subject to written notification by the Company to DGO6), the portion of the recoverable cash advance that is repayable at the time of the decision to start using the results of the research or development project independently of sales (i.e. 30% of the recoverable advance) will be recognized as a debt on the balance sheet. The remaining 70% of the amount of the recoverable advance, which is repayable based on sales, will be recorded as an off-balance sheet item.

### ***Accrued charges and deferred revenues***

These debts are valued at their nominal value. These debts do not include any long-term debts, either interest-free or with a low interest rate. If this is the case, a discount must be applied to these debts that should be capitalized.

### ***Transactions in foreign currencies***

Transactions in foreign currencies are translated at the exchange rate applicable at the date of the transaction.

Non-current assets and shareholders' equity are translated into euros at the historical exchange rate.

Other assets and liabilities in foreign currencies are translated into euros at the exchange rate applicable at the balance sheet date. Realized and unrealized exchange differences are immediately recognized in the income statement.

### ***Cash flow hedges***

The effects of changes in the fair value of cash flow hedges are recognized as off-balance sheet commitments and disclosed in the notes to the financial statements. In the case of cash flow hedges (Call & Put; Swaps); premiums received are recorded in an accrual account; changes in financial instruments are recorded in the income statement.

### ***Income and expense recognition***

Income and expenses related to the disposal of an asset will be recognized in the year in which the main risks and rewards on the asset are transferred to the purchaser. In principle, the transfer of the main risks and rewards correspond to the transfer of ownership of the asset or, if it is separated from it, to the transfer of the risks of loss or deterioration of the asset.

With respect to the provision of services, the income and expenses related to the provision of services will be allocated to the financial year in which the essential part of the service is performed.

Expenses will be recognized as they are incurred. Invoiced expenses that are related to the following financial year will be accounted for on a deferred charges account on the assets side of the balance sheet.





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