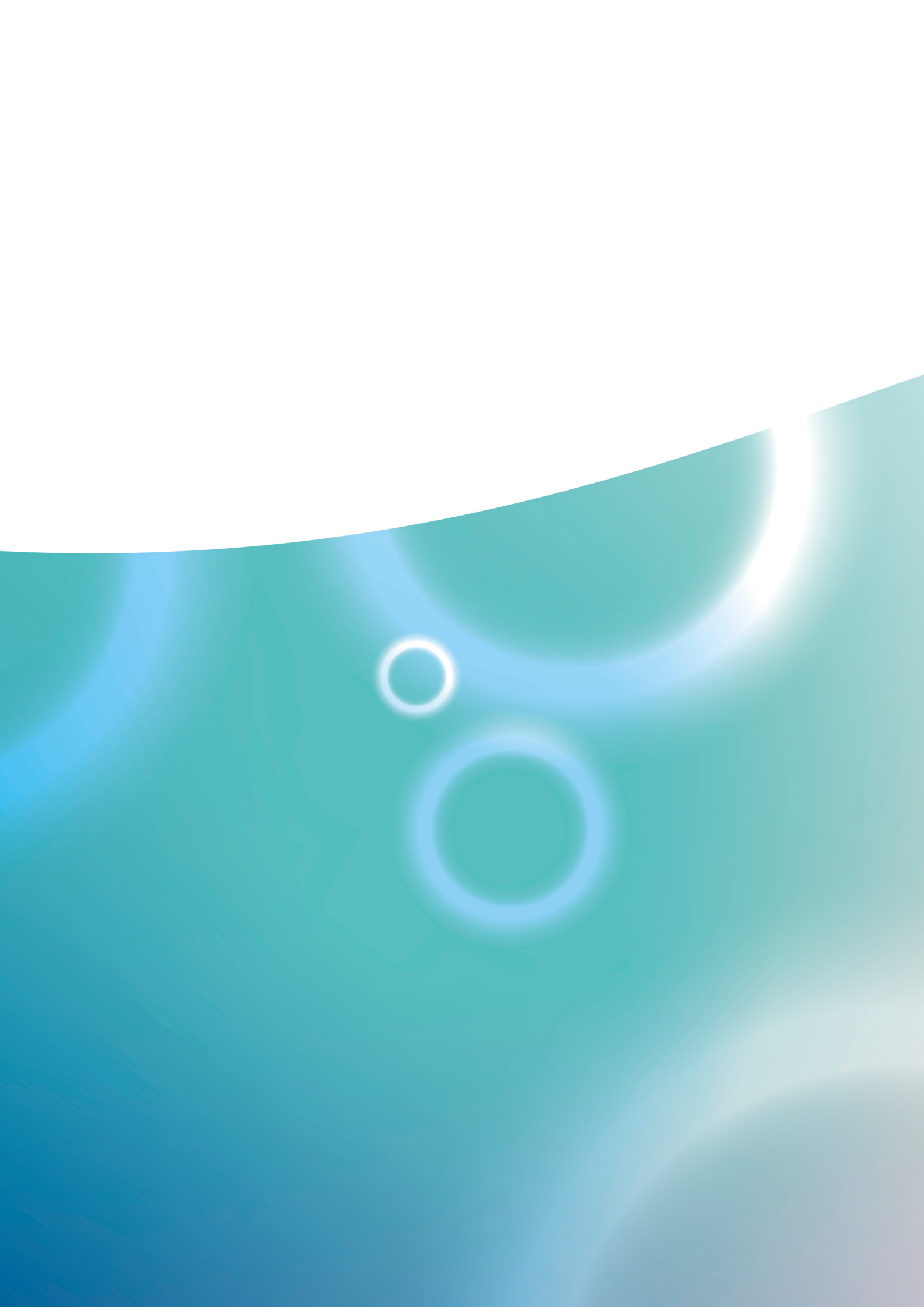




# The path to restful nights

Annual report 2021



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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 24], 2022.

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 has prepared its Annual Report in English. The Company also provides a French translation of the Annual Report, in accordance with Belgian laws. Both the English version and the French version of the Annual Report are legally binding. Without prejudice to the responsibility of the Company for inconsistencies between the different language versions of the Annual Report, in case of discrepancies between the language versions, the English version shall prevail.

## 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.

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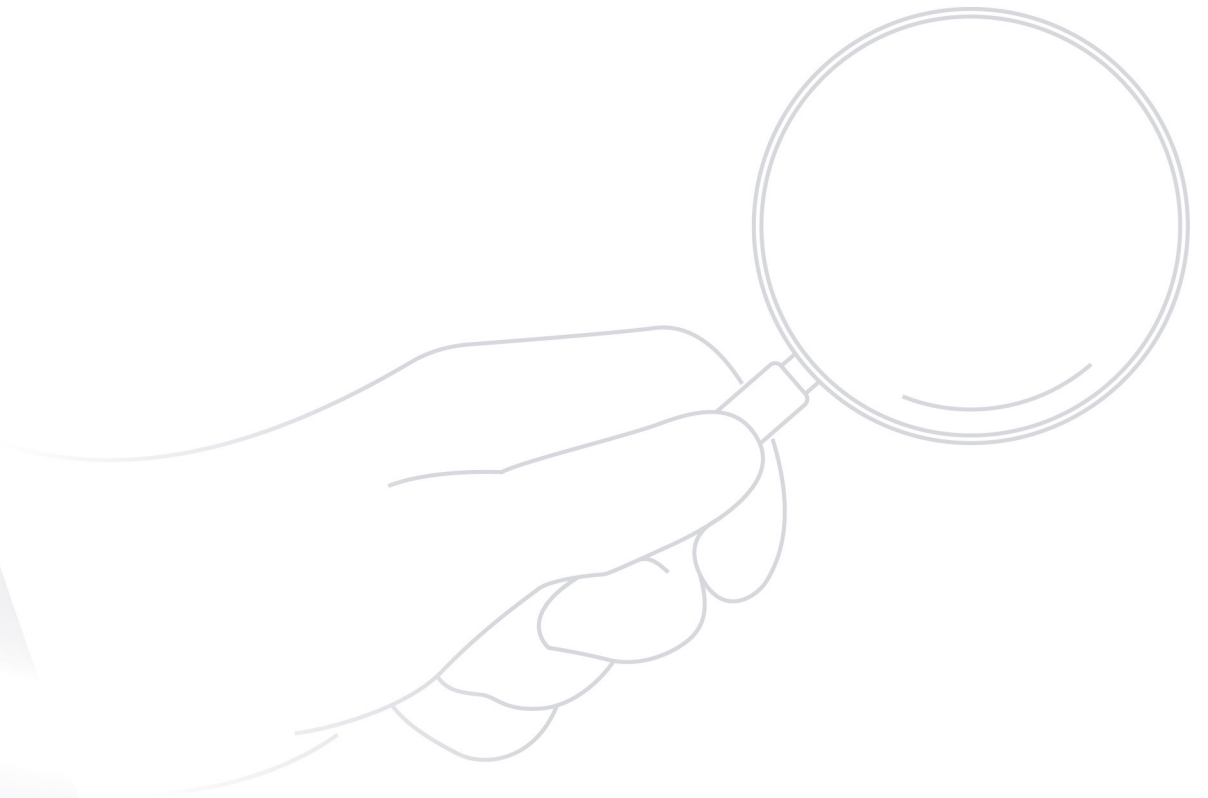
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**1**

# **Report of the Board of Directors**

# Report of the Board of Directors to the Shareholders for the Financial Year Ending December 31, 2021

Dear Shareholders,

We are pleased to present to you the 2021 Annual Report relating to Nyxoah's consolidated financial statements as of December 31, 2021 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 and Nyxoah Inc.

## 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 24.5 million individuals with moderate to severe OSA in our initial target markets in Europe, Australia and New Zealand. Based on published scientific literature, we estimate that approximately 2.7 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, Australia and New Zealand 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, Australia and New Zealand for the Genio system is at least 520,000 patients which represents an estimated annual market opportunity of approximately \$11 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 physi-

cian 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. We anticipate initial 12-month data for the DREAM trial will be available by the second quarter of 2023. Assuming a positive outcome from the DREAM trial, we expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in the first half of 2024.

We are initially targeting markets in Europe, Australia and New Zealand 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 also recently 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 expect to begin commercialization in the Netherlands and Finland in 2022. 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 avail-

able 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 support physicians using the Genio system through all aspects of the patient's journey, starting from initial diagnosis through surgical support and post-implantation patient follow-up. 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 and customers. 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. 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 sys-

tem 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. 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.

### **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. In January 2021, we 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, 2021, we had 186 granted or pending patent applications (with 53 issued or allowed U.S. patents), and 46 pending patent applications, eleven 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 either a premarket approval, or PMA, application or a De Novo request. The DREAM trial is a multicenter, prospective, open-label trial designed to enroll 134 patients in approximately 25 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. We anticipate initial 12-month data for the DREAM trial will be available by the second quarter of 2023. Assuming a positive outcome from the DREAM trial, we expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in the first half of 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 ap-

nea 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. 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, Australia and New Zealand 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**

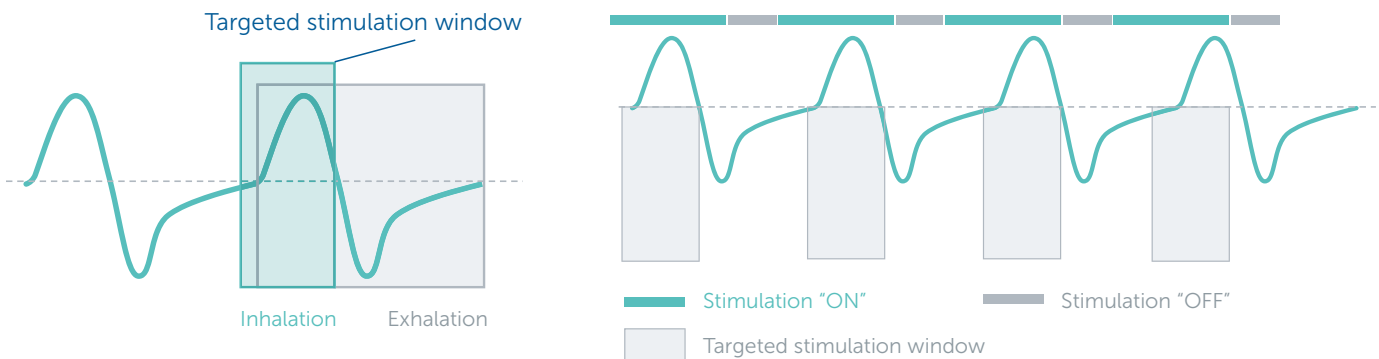
A surgeon implants the implantable stimulator of the Genio system during a minimally invasive procedure that requires only one incision and typically lasts approximately one hour in an out-patient setting under general anesthesia. During implantation, the surgeon makes a small curvilinear incision approximately 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**

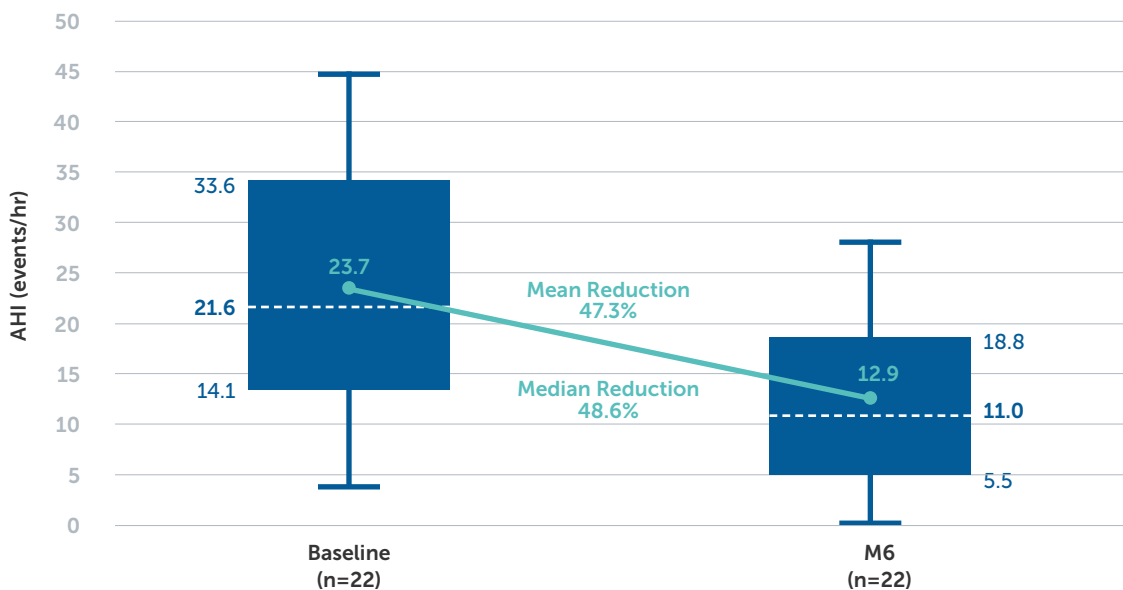
Four SAEs related to the surgical procedure (but not device-related) were reported in three of the 27 patients implanted during the six-month post-implantation period. These included two participants at the same hospital who developed local infections at the surgical site that resulted in removal of 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±12.2 to 12.9±10.1, representing a mean change of 10.8 events/ hour (p-value<0.0001).

*AHI at screening and 6-month for patients that reached the 6-month visit*





A reduction in the ODI score was demonstrated between baseline and six-month post-implantation, dropping from a mean of 19.1±11.2 to 9.8±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±5.3 to 8.0±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±3.3 to 17.2±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±11.5 to 16.0±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
SaO2<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. SaO2 < 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  $32 \text{ kg/m}^2$  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. 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 is expected to enroll 134 patients who will undergo implantation procedure with 12-month effectiveness and safety primary endpoints. As of December 2021, 26 patients have been implanted. We have identified 25 centers for the trial, including 16 in the United States. Fifteen of them were active and enrolling patients as of December 2021.

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 kg/m<sup>2</sup>, 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 anticipate initial 12-month data will be available in the first half of 2023. Four SAEs have been reported to date.

## 1.6 Sales and marketing

We have grown our commercial team to more than a dozen 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, Australia and New Zealand 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 expect to begin commercialization in the Netherlands and Finland in 2022.

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.

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 Medistri SA, Resonetics, VSI Parylene, Reinhardt Microtech GmbH (Cicor), Lust Hybrid, Meko, 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 team in the clean room at our facility in Tel Aviv, Israel. The capacity of our facility in Tel Aviv is expected to cover our expected product demand for 2022. We are finalizing our plan to establish a manufacturing facility in Liège, Belgium that is expected to provide us with additional capacity for the assembly of implantable stimulators and external stimulators as we progress our commercialization plans.

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 Nasdaq IPO

In July 2021, the Company raised \$97.8 million as a result of the initial public offering of 3,260,250 new shares of the Company on Nasdaq, at a price to the public of \$30 per share.

## 1.10 Post balance sheet events

On February 10, 2022, the Company issued 25,000 shares pursuant to an exercise of 50 2016 ESOP Warrants (each giving right to 500 shares). Consequently, on the date of this Annual Report, the Company's registered capital amounts to EUR 4,431,664.69, represented by 25,797,359 shares.

## 1.11 Financial review of the year ending December 31, 2021

### 1.11.1 Analysis of the consolidated income statement

The table below sets forth the Company's audited consolidated income statement, ending up with a €27.6 million net loss for the year ended December 31, 2021, and comparative information for the year 2020.

(in EUR 000)	For the year ended December 31	
	2021	2020
Revenue	852	69
Cost of goods sold	(303)	(30)
<b>Gross Profit</b>	<b>549</b>	<b>39</b>
General and administrative expenses	(11,113)	(7,522)
Research and development expenses	(2,353)	(473)
Clinical expenses	(2,706)	(1,053)
Manufacturing expenses	(4,760)	(460)
Quality assurance and regulatory expenses	(1,463)	(227)
Patents Fees & Related	(1,062)	(123)
Therapy Development expenses	(3,599)	(1,864)
Other operating income / (expenses)	265	459
<b>Operating loss for the period</b>	<b>(26,242)</b>	<b>(11,224)</b>
Financial income	3,675	62
Financial expense	(2,072)	(990)
<b>Loss for the period before taxes</b>	<b>(24,639)</b>	<b>(12,152)</b>
Taxes	(2,980)	(93)
<b>Loss for the period</b>	<b>(27,619)</b>	<b>(12,245)</b>
Basic and diluted Loss Per Share (in EUR)	(1.161)	(0.677)

For the first time since its inception, the Company started generating revenue as of July 2020. The revenue for the amount of €0.9 million was generated under the existing HGNS NUB coding in Germany. In addition, in 2021 the Company has generated revenues in Spain and Belgium as well. The total cost of goods sold amounts to €303,000.

The increase of operating loss from €11.2 million in 2020 to €26.2 million in 2021, or a change of by €15 million, is due to the increase of activities in all departments. The Company is currently conducting three clinical trials to continue gathering clinical data and obtain regulatory approvals. In June 2020 the Company obtained FDA approval to start the DREAM study in the US. In line with its strategy, 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.

General and administrative expenses increased by €3.6 million, or 47.7 % from €7.5 million for the year ended December 31, 2020 to €11.1 million for the year ended December 31, 2021 mainly due to an increase in consulting and contractors' fees and insurance. The increase in consulting and contractors' fees includes variable compensations of €2.0 million for the year ended December 31, 2020 and €1.9 million for the year ended December 31, 2021 related to a cash-settled share based payment transaction. There was also an increase of consultant services to support the company in legal, finance, tax and IT matters due to company growth and an increase in an insurance expense by €1.0 million, compared to the year ended December 31, 2020 due to Directors & Officers insurance following initial public offering in the United States. The increase in other expenses was mainly due to increase in recruitment fees and board members remuneration. This increase was offset by a decrease in staff cost for the year ended December 31, 2021 due to decrease in share-based payment to CEO of the Company. See note 21.

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 and outsourced development expenses. Before capitalization of €3.5 million in 2021 and €2.6 million in 2020, research and development expenses increased by €2.8 million or 90.3% from €3.1 million in 2020, to €5.8 million in 2021, due to an increase in staff to support our R&D activities and in outsourced developments. The Company started as of January 2021 to amortize its intangible assets. This explains the significant increase of depreciation expenses in 2021. See note 22.

Clinical expenses consist primarily of clinical studies related to the development of our Genio® system, consulting services and other costs associated with clinical activities. These expenses include employee compensation, clinical trial management and monitoring, payments to clinical investigators, data management and travel expenses for our various clinical trials. Before capitalization of €6.8 million in 2021, and €3.3 million in 2020, clinical expenses increased by €5.2 million, or 120 %, from €4.3 million in 2020 to €9.5 million in 2021. The increase in the expenses was mainly due to an increase in staff, consulting and study activities of the on-going DREAM IDE in the United States, completion of the BETTER SLEEP trial implantations and continuous recruitment for the EliSA trial. See note 23.

Manufacturing expenses consist primarily of employee compensation, acquisition costs of the components of the Genio® system, as well as distribution-related expenses such as logistics and shipping costs for non-commercial units of the Genio® system. Before capitalization of €0.3 million in 2021, and €3.3 million in 2020, manufacturing expenses increased by €1.2 million, or 33 % from €3.8 million in 2020 to €5.0 million in 2021. The increase in the expenses was mainly due to an increase in staff, in production and engineering team to support capacity and yield improvement. In addition, manufacturing expenses increased in 2021, compared to 2020 due to the increase in demand of our Genio® system for non-commercial purposes (clinical trials, development activities, etc.) and, therefore, the increase of production costs associated. See note 24.

Quality assurance and regulatory expenses consist primarily of quality control, quality assurance and regulatory expenses for activities non-related to the production of commercial units of the Genio® system. These expenses include employee compensation, consulting, testing and travel expenses related to the QA/RA department. Before capitalization of €359,000 in 2021 and €1.2 million in 2020, quality assurance and regulatory expenses increased by €348,000, or 24 % from €1.5 million in 2020 to €1.8 million in 2021. The increase in the expenses was mainly due to an increase in staff, consulting and QA & regulatory activities to support manufacturing scaling up process. See note 25.

Therapy development expenses consist primarily of compensation for personnel, spending related to direct sale force, market access and reimbursement activities. Other therapy development expenses include training physicians, travel expenses, conferences, market research, advertising and public relations. Therapy development expenses increased by €1.7 million or 93.1 % from €1.9 million in 2020 to €3.6 million in 2021. The increase in the expenses was mainly due to an increase in staff and consulting, to support the ongoing commercialization in Europe. See note 27.



### 1.11.2 Analysis of the consolidated statements of financial position

The table below sets forth the Company's audited consolidated balance sheet for the year ended December 31, 2021, and comparative information as at December 31, 2020.

(in EUR 000)

As of December 31

	2021	2020
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant and equipment	2,020	713
Intangible assets	25,322	15,853
Right of use assets	3,218	3,283
Deferred tax asset	46	32
Other long-term receivables	164	91
	<b>30,770</b>	<b>19,972</b>
<b>Current assets</b>		
Inventory	346	55
Trade receivables	226	-
Other receivables	2,286	1,644
Other current assets	1,693	109
Cash and cash equivalents	135,509	92,300
	<b>140,060</b>	<b>94,108</b>
<b>Total assets</b>	<b>170,830</b>	<b>114,080</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Capital and reserves</b>		
Capital	4,427	3,796
Share premium	228,033	150,936
Share based payment reserve	3,127	2,650
Other comprehensive income	202	149
Retained Earnings	(87,167)	(60,341)
<b>Total equity attributable to shareholders</b>	<b>148,622</b>	<b>97,190</b>

(in EUR 000)	As of December 31	
	2021	2020
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	7,802	7,607
Lease liability	2,737	2,844
Employee benefits	80	37
Provisions	12	-
Deferred tax liability	5	-
	<b>10,636</b>	<b>10,488</b>
<b>Current liabilities</b>		
Financial debt	554	616
Lease liability	582	473
Trade payables	3,995	1,190
<b>Current tax liability</b>	<b>2,808</b>	-
Other payables	3,633	4,123
	<b>11,572</b>	<b>6,402</b>
<b>Total liabilities</b>	<b>22,208</b>	<b>16,890</b>
<b>Total equity and liabilities</b>	<b>170,830</b>	<b>114,080</b>

The Company started recognizing the development expenditure as an asset since March 2019 triggered by obtaining CE mark. Development costs primarily include employee compensation and outsourced development expenses. In 2021 and 2020, the Company has capitalized developments costs for an amount of €10.3 million and €10.1 million, respectively. The net book value of the capitalized development costs in 2021 is €25.3 million. In addition, intangible assets include patents and licenses for an amount of €0.5 million, a decrease of €42,000 in 2021 compared to 2020. See note 8.

Property, plant & equipment shows a total additional net book value of €1.3 million at balance sheet date consequently to assets under constructions related to the constructions of new clean rooms and to leasehold improvements in Company's offices in Belgium and Israel. See note 2.6.

Right of use assets shows a total additional decrease by €65,000 due to higher depreciation in 2021, directly linked to the high additions of new leases in 2020. See note 9.

Cash and cash equivalents show a total additional increase €43.2 million mainly due to capital increase for a total amount €77.7 million, net of transaction costs in July 2021 in connection with the Company's Initial Public Offering ("IPO") on Nasdaq, compensated by cash used in the operating activities by €25.3 million and cash used in the investing activities of €11.8 million.

The share capital and the share premium have increased by respectively €0.6 million and €77.1 million due to the capital increases in cash in 2021 for a total amount €77.7 million, net of transaction costs.

Lease liabilities shows a total additional insignificant increase of €2,000. See note 9.

The increase in total trade payables of €2.8 million as at December 31, 2021 is due to the increase in trade payables of €1.6 million and an increase in invoices to be received of €1.2 million.

Other non-current and current payables have decreased by €490,000 from €4.1 million to €3.6 million mainly due to the payment of the variable compensation of a cash-settled share-based payment transaction for an executive member in 2021. This decrease was offset by an increase of €0.6 million in salary and holiday pay expenses due to the growth of the company personnel in 2021 and the fair value of the foreign currency option which was entered into by the company during 2021.

### 1.11.3 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, 2020 and 2021.

The table below summarizes the net cash burn rate of the Company for the year 2021.

(in EUR 000)	For the year ended December 31	
	2021	2020
Net cash used in operating activities	(25,336)	(6,864)
Net cash from investing activities	(11,817)	(10,693)
Net cash from financing activities	76,472	104,025
Effects of exchange rate changes	3,890	(23)
<b>Change in Cash and cash equivalents</b>	<b>43,209</b>	<b>86,445</b>

The net cash burn rate for 2021 is a net cash inflow amounting to €43.2 million compared to a net cash inflow of €86.4 million for 2020.

The cash outflow resulting from operating activities amounted to €25.3 million in 2021 compared to €6.9 million in 2020. The increase of cash used in operations of €18.4 million was primarily due to higher losses of €12.5 million that were mainly attributable to increased general and administrative expenses, Manufacturing expenses and Research and development expenses as described in more detail above. Additionally, non-operating cash adjustments has decreased with €3.2 mainly due to increase in net financial income of €2.6 million derived from the revaluation of the Company's USD cash balance. Furthermore, there was a negative variation in the working capital of €2.6 million due to an increase in Other current assets of €1.6 million mainly from an advance payment to DNO insurance and increase of €0.9 million in Trade and other receivables mainly due the additional R&D incentives obtained during 2021.

Cash flow from investing activities represented a net cash outflow of €11.8 million for 2021. An increase of €1.1 million compared to 2020 mainly explained by increase in Purchases of property, plants, and equipment, which are in line with the company growth, and in addition higher capitalization of development expenses in 2021.

The decrease in cash inflow from financing activities is primarily derived from the lower capital raise from the Nasdaq IPO in 2021, compared to the capital raise from the Euronext IPO in 2020.

## 1.12 Personnel

As at December 31, 2021, the Nyxoah Group employed 105.8 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, 2021.

General & Administration	15.8
IP & Trademark	1
Research & Development	17
Clinical Affairs	22.2
Quality Assurance & Regulatory Affairs	14
Operations	24
Therapy Development (including the sales team)	11.8
<b>Total</b>	<b>105.8</b>

As at December 13, 2021, the Nyxoah Group had 37.8 full-time equivalents located in Europe, 46 full-time equivalents located in Israel, 7 full-time equivalents located in Australia and 15 full-time equivalents located in the United States.

### 1.13 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.

### 1.14 Risks and uncertainties

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

### 1.15 Going concern

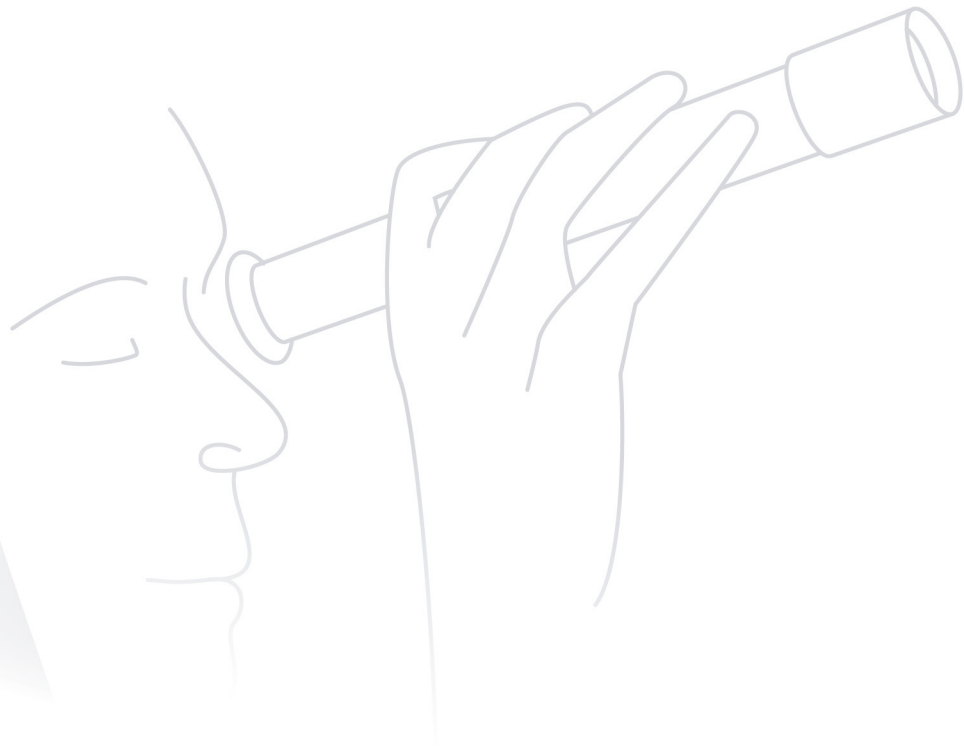
As at December 31, 2021, the Company had cash and cash equivalents of KEUR 135,509. Based on cash flow forecasts for the years 2022 and 2023, which include significant expenses and cash outflows in relation to -among others- the ongoing clinical trials, the continuation of research and development projects, and the scaling-up of the Company's manufacturing facilities, the Company believes that this cash position will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of this Annual Report. The Company does not believe that COVID-19 will have an impact on the Company's going concern.

In view of the above, and notwithstanding a loss brought forward of KEUR 87,167 as of December 31, 2021, the Board of Directors has decided, after due consideration, that the application of the valuation rules in the assumption of a "going concern" is justified.

### 1.16 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 four independent directors, as detailed in the table below.

Name	Position	Start of Term	End of Term
Robert Taub	Non-executive Director / Chairman of the Board of Directors	2020	Annual general shareholders' meeting of 2024
Kevin Rakin	Independent Non-executive Director	2020	Annual general shareholders' meeting of 2024
Donald Deyo	Independent Non-executive Director	2020	Annual general shareholders' meeting of 2024
Jürgen Hambrecht	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
Pierre Gianello	Non-executive Director	2020	Annual general shareholders' meeting of 2024
Jan Janssen	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).

**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 Genaisance 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.

**Donald Deyo** has served as a non-executive director since June 2016. Mr. Deyo is the Chairman and Chief Executive Officer of LindaCare NV, or LindaCare, a company that specializes in developing and providing advanced remote digital health solutions for chronic disease. Prior to LindaCare, Mr. Deyo served as Chief Executive Officer and a member of the board of directors for FemPulse Corporation, a company focused on developing bioelectronic medicine (neuromodulation) therapies for women's health concerns, and as Chief Executive Officer and a member of the board of directors of Medallion Therapeutics, Inc. Prior to that, he spent 30 years at Medtronic plc (NYSE: MDT), or Medtronic, a medical device company, where he served in various executive leadership roles, including Vice President of Research & Development for Neuromodulation, Vice President of Product Development & Technology for Cardiac Rhythm Management and Vice President and General Manager for Medtronic Pacerart. He also founded the executive consultancy MedTech Execs, which provides strategic and operational services to medical device and pharmaceutical companies through a global network of experienced executives. Mr. Deyo serves on the Board of Directors for LindaCare, where he is chairman of the board. Mr. Deyo holds a B.Sc. in Computer Engineering from Iowa State University and an MBA from University of St. Thomas.

**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 Chairman of the Supervisory Board from 2014 until 2020. He has been member of the Supervisory Boards of Daimler AG, Daimler Truck AG, Fuchs Petrolub SE and Lufthansa a.o. Dr. Hambrecht is Chairman of the Supervisory Board of Trumpf GmbH & Co. KG and a member of the Supervisory Boards of Daimler AG and Daimler Truck AG as well as of Aya Gold & Silver Inc (TSX: AYA.TO). He earned his doctorate in Chemistry from the University of Tübingen, Germany.

**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 Brookdale Senior Living Inc. and Quest Analytics, LLC. 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.

**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), EuroLiver 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.

**Jan Janssen** has served as a non-executive director since November 2018. Mr. Janssen is the chief technology officer at Cochlear Limited (OTCMKTS: CHEOY), or Cochlear, a global company developing implantable hearing devices, where he oversees the development of new technologies and commercial products and quality and regulatory affairs. Mr. Janssen joined Cochlear in 2000 as Head of the Cochlear Technology Centre based in Belgium, having previously worked with Philips Electronics where he was involved in research and development in the fields of high-tech electronics and cochlear implants. Mr. Janssen was promoted to Senior Vice President, Design and Development at Cochlear in 2005 and appointed Chief Technology Officer in 2017. Mr. Janssen earned a M.Sc. in Micro-Electronics Engineering from Karel de Grote' Hogeschool Antwerpen and a M.Sc. in Telecommunication Engineering from Katholieke Universiteit Leuven.

**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.

Kevin Rakin, Donald Deyo, Jürgen Hambrecht and Rita Johnson-Mills are the Company's independent directors.

The Company is of the view that the independent directors comply with each of the criteria of the Belgian CCA and 2020 Code.

The Company is indeed of the opinion that, for the purposes of assessing the independence of Donald Deyo, the fees paid on a yearly basis to MedTech Execs LLC (director of the Company until September 2020, permanently represented by Donald Deyo) for its membership in the project steering committee of Cochlear do not constitute a significant remuneration within the meaning of the independence criteria mentioned under d) above.

### 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), Donald Deyo and Jürgen Hambrecht, 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), Jürgen Hambrecht and Rita Johnson-Mills. 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.

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: Donald Deyo (chair), Pierre Gianello and Jan Janssen.

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 2021, the Board of Directors held ten (10) meetings.

Board members	14/02/21	1/04/21	8/04/21	21/05/21	4/06/21	25/06/21	27/08/21	8/09/21	17/09/21	19/11/21
Robert Taub	Present	Present	Present	Present	Present	Present	Present	Present	Present	Present
Janke Dittmer (1)	Present	Present	Present	Present	Present	Present	N/A	N/A	N/A	N/A
Kevin Rakin	Present	Present	Present	Present	Present	Repres.	Present	Repres.	Repres.	Present
Jürgen Hambrecht	Present	Present	Present	Present	Present	Repres.	Present	Repres.	Present	Present
Donald Deyo	Present	Present	Present	Present	Present	Repres.	Present	Repres.	Repres.	Present
Rita Johnson-Mills (2)	N/A	N/A	N/A	N/A	N/A	N/A	Present	Repres.	Repres.	Present
Pierre Gianello	Present	Present	Present	Present	Present	Repres.	Present	Repres.	Repres.	Present
Jan Janssen	Present	Present	Present	Present	Present	Repres.	Present	Repres.	Repres.	Present
Olivier Taelman	Present	Present	Present	Present	Present	Present	Present	Present	Present	Present

(1) board member until July 7, 2021

(2) board member as of August 27, 2021

### Meetings of the Board committees

In 2021, the audit committee held five (5) meetings.

<b>Audit committee members</b>	<b>08/04/2021</b>	<b>15/04/2021</b>	<b>15/06/2021</b>	<b>06/08/2021</b>	<b>15/12/2021</b>
Kevin Rakin	Present	Present	Present	Present	Present
Jürgen Hambrecht	Present	Present	Present	Present	Present
Donald Deyo	Present	Present	Present	Present	Present

In 2021, the remuneration committee held five (5) meetings.

<b>Remuneration committee members</b>	<b>2/04/2021</b>	<b>22/06/2021</b>	<b>17/09/2021</b>	<b>3/11/2021</b>	<b>15/11/2021</b>
Robert Taub	Present	Present	Present	Present	Present
Jürgen Hambrecht	Present	Present	Present	Absent	Present
Donald Deyo (1)	Present	Present	Present	N/A	N/A
Rita Johnson-Mills (2)	N/A	N/A	N/A	Present	Present

(1) member of the remuneration committee until August 27, 2021

(2) member of the remuneration committee as of August 27, 2021

In 2021, the nominating and corporate governance committee held five (5) meetings.

<b>Nominating and corporate governance committee members</b>	<b>2/04/2021</b>	<b>22/06/2021</b>	<b>17/09/2021</b>	<b>24/09/2021</b>	<b>12/11/2021</b>
Robert Taub	Present	Present	Present	Present	Present
Jürgen Hambrecht	Present	Present	Present	Present	Absent
Donald Deyo (1)	Present	Present	Present	N/A	N/A
Rita Johnson-Mills (2)	N/A	N/A	N/A	Present	Present

(1) member of the nominating and corporate governance committee until August 27, 2021

(2) member of the nominating and corporate governance committee as of August 27, 2021

## 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:

<b>Name</b>	<b>Position</b>
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 2021, certain directors declared a conflict of interest. The following declarations were made in that respect.

**Extract from the minutes of the Board of Director's meeting of June 4, 2021:**

"In accordance with article 7:96 of the Belgian Code of Companies and Associations ("CCA"), prior to the deliberation and resolution by the board, the following statements were made: Robert Taub has a conflict of interest of a financial nature, within the meaning of Article 7:96 CCA, with the proposed approval by the board of directors of the consultancy agreement between the Company and MINV SA, a company controlled by Robert Taub. Therefore, Robert Taub will not participate in the deliberation or vote on the resolution regarding the approval of this consultancy agreement.

The proposed consultancy agreement with MINV SA gives the Company access to the expertise and experience of MINV SA and its representative (Robert Taub), in particular in relation to building result oriented teams, leading cross cultural global organizations, and executing acquisitions, fund raisings, divestitures, partnerships, joint ventures and license agreements globally.

The proposed consultancy agreement with MINV SA is for a period of 12 months and provides for a total consultancy fee of up to EUR 120,000.

The board of directors is of the opinion that the proposed consultancy agreement with MINV SA is justified and in the interest of the Company because of MINV SA's experience and expertise which will be very useful to support the business development activities of the Company and to actively help management during the investor roadshows the Company is planning during the coming weeks.

After discussion, the board of directors decides to approve the proposed consultancy agreement with MINV SA. Robert Taub did not participate in the deliberation or vote on the approval of this consultancy agreement."

**Extract from the written unanimous resolutions of the Board of Directors dated July 15, 2021:**

"The remuneration committee of Nyxoah met yesterday and recommends that the board of directors approves an exceptional one-off bonus to Olivier Taelman, CEO, for the success of the Nasdaq IPO, in an amount of EUR 150,000.

In accordance with Article 7:95 of the Belgian Code of Companies and Associations ("CCA"), it is proposed that this resolution of the board of directors is adopted by unanimous written consent of the directors.

By way of preliminary statement, it is noted that Olivier Taelman has a conflict of interest of a financial nature, within the meaning of Article 7:96 CCA, with the resolution which is proposed to be adopted by the board. Therefore, Olivier Taelman will not participate in the vote regarding this resolution.

As regards the proposed bonus for Olivier Taelman, the board of directors is of the opinion that this bonus is justified in view of Olivier Taelman's role in the Nasdaq IPO and the efforts that were and will be requested from him."

### Extract from the minutes of the Board of Director's meeting of August 27, 2021:

"Prior to discussing and resolving on the next item on the agenda, in accordance with Article 7:96 of the CCA, Olivier Taelman, CEO, stated that he has a conflict of interest of a financial nature, within the meaning of Article 7:96 CCA, with the proposed approval by the board of directors of certain changes to his remuneration package to be effective as of 1 September 2021. Therefore, Olivier Taelman did not participate in the deliberation or vote on the resolutions regarding the approval of his new remuneration package, his New Agreement (as defined below) and the potential remuneration split.

It is proposed that the following elements of the remuneration package of Olivier Taelman, in his capacity as CEO of the Company, are changed as follows:

- (i) as of 1 September 2021: a fixed annual base remuneration equal to the EUR equivalent of USD 450,000 (compared to a fixed annual base remuneration of EUR 300,000 previously), and
- (ii) as of 1 January 2022: a short-term variable remuneration (or short-term incentive, "STI") consisting of a cash bonus equal to 100% of the fixed annual base remuneration (compared to an STI of 40% of the fixed annual base remuneration previously) in case the yearly objectives as set by the board are achieved for 100% (it being understood that (x) for an achievement below 75% of the yearly objectives, in principle no STI will be due (unless the board, upon the proposal of the remuneration committee, decides at its discretion to nevertheless grant an STI of maximum 75%); (y) for an achievement between 75% and 125% of the yearly objectives, an STI between 75% and 125% shall be due, based on a linear calculation; and (z) for an achievement of more than 125% of the yearly objectives, the board, upon the proposal of the remuneration committee, may decide at its discretion to grant an STI of more than 125%).

This new remuneration package is part of a broader reorganization of the way in which the Company and Olivier Taelman collaborate. Indeed, in light of the continuous expansion and the increasing importance of the international activities of the Company, and to allow a more flexible work organization, it is proposed that the Company and Olivier Taelman mutually agree to terminate the existing employment contract of Olivier Taelman with the Company and that the Company and Olivier Taelman enter into an agreement pursuant to which Olivier Taelman will perform his functions as CEO of the Company on a self-employed basis going forward (the "New Agreement"). It is further proposed that under the New Agreement, in addition to the fixed annual base remuneration and the STI as set out above, Olivier Taelman will be entitled to receive a long term incentive ("LTI") 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, and that Olivier Taelman will continue to benefit from a company car, a laptop, a mobile phone, an occupational pension scheme and a hospitalization insurance.

Finally, it is noted that in view of said internationalization of the Company, a remuneration split between the US and Belgium may be put in place for Olivier Taelman in the future (as a result of which part of his remuneration may be borne by other companies of the Nyxoah group).

The board of directors is of the opinion that the proposed new remuneration package (i.e. the proposed fixed annual base remuneration and the proposed STI), as well as the proposed New Agreement and potential remuneration split, are justified and in the interest of the Company (a) in view of the internationalisation of the Company, Olivier Taelman's role within the Company and the efforts that are requested from him, (b) because the proposed remuneration package is in line with market practice as confirmed by a benchmarking exercise done by the remuneration

committee and (c) because a remuneration split is in line with market practice in a group with international activities. In addition, an STI of 100% of the base remuneration in case the agreed upon objectives are achieved for 100% is in line with the Company's remuneration policy, as is the LTI provided for in the New Agreement.

After discussion, the board of directors (excluding Olivier Taelman) decided unanimously to approve Olivier Taelman's proposed new fixed annual base remuneration, his new STI and his eligibility for an LTI, as well as the termination in mutual agreement of his current employment contract, the entering into by the Company of the New Agreement and a possible future remuneration split between the US and Belgium.

The board (excluding Olivier Taelman) further resolved unanimously to grant a power of attorney to Robert Taub (i) to prepare, finalize and sign an agreement to terminate the existing employment contract of Olivier Taelman with the Company and the proposed New Agreement, (ii) to prepare, finalize, amend and sign any agreement or other documents (including any amendment of the New Agreement) as may be required or useful to put in place a remuneration split between the US and Belgium for Olivier Taelman, and (iii) to prepare, finalize and sign any other (contractual) documentation required to reflect or implement the above resolutions and changes."

#### **Extract from the minutes of the Board of Director's meeting of September 17, 2021:**

"Prior to discussing and resolving on the first item on the agenda, in accordance with Article 7:96 CCA, Olivier Taelman, CEO, stated that he has a conflict of interest of a financial nature, within the meaning of Article 7:96 CCA, with the proposed grant of warrants to him by the board of directors. Therefore, Olivier Taelman did not participate in the deliberation or vote on the resolution regarding the grant of warrants to him.

Based on a recent Black-Scholes illustration of the value of a warrant, it is proposed that 33,240 warrants are granted to Olivier Taelman, as further explained in a document submitted to this meeting.

It is further proposed that:

- In accordance with Clause 4.3.1 of the 2021 Warrant Plan, the exercise price of the warrants granted to Olivier Taelman amounts to EUR 25.31 per warrant (which is the average closing price of the Company's share on Euronext Brussels over the thirty (30) day period preceding today's date (i.e. the date of the offer of the warrants to Olivier Taelman) and which was lower than the last closing price of the Company's share on Euronext Brussels prior to today's date), and
- The other terms and conditions of the warrants granted to Olivier Taelman shall be in accordance with the 2021 Warrants Plan.

The board of directors is of the opinion that the proposed grant of 33,240 warrants under the 2021 Warrant Plan at an exercise price of EUR 25.31 per warrant 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, (b) because the proposed grant of warrants is in line with the Company's remuneration policy as approved by the shareholders' meeting on 9 June 2021, and (c) because upon exercise of all such warrants Olivier Taelman will have to pay an exercise price of in aggregate EUR 841,304.40 in cash to the Company, which will increase the Company's net equity and liquidities.

After discussion, the board of directors (excluding Olivier Taelman) decided unanimously to approve the grant of 33,240 warrants under the 2021 Warrant Plan to Olivier Taelman at an exercise price of EUR 25.31 per warrant.”

## 2.5 Related Party Transactions

In 2021, 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 Previously, 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 enables the non-executive directors to link their effective remuneration to the performance of the Company and to strengthen 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. In any event, the Company intends that the portion of the remuneration payable in share options will be limited.
- 3 In deviation of provision 7.6 of the 2020 Code, the non-executive members of the Board of Directors do not 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 currently considered to be sufficiently oriented to the creation of long-term value for the Company, also considering the fact that some of them already hold shares and some of them already held share options, the value of which is based on the value of the shares. Therefore, the payment in 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. For example, it is customary for share incentive plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.

- 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 currently considered to be sufficiently oriented to the creation of long-term value for the Company, also considering the fact that some of them already hold shares and some of them already hold 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.

## 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, 2021, 50% of the total work force of the Company were women.

At the level of the Board of Directors, one of our eight board members is 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.

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 2021 are included in the table below.

#### Directors

Remuneration component	Short description of main provisions	
Base remuneration	Chairman of the Board – Non-executive director	Annual fixed fee of €50,000
	Independent non-executive directors	Annual fixed fee of €25,000
	Other non-executive directors	Annual fixed fee of €25,000
	Chairman of the audit committee	Annual fixed fee of €5,000
	Members of audit committee	Annual fixed fee of €2,500
	Members of remuneration committee	Annual fixed fee of €2,500
	Members of science & technology committee	Annual fixed fee of €2,500
	Members of the nominating and corporate governance committee	No fee
	Members of Cochlear project steering committee	Annual fixed fee of €10,000
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
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 pursuant to 2021 plan: 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 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 directors

Table 1 - Total Remuneration Directors

Name, position	Fixed remuneration			Variable remuneration		Extra-ordinary items	Pension expense	Total remuneration	Proportion of fixed and variable remuneration
	Base remuneration	Attendance fees	Fringe benefits	One-year variable	Multi-year variable				
Robert Taub Non-executive chairman	52,500.00 <sup>(a)</sup>	0.00	9,130.54 <sup>(e)</sup>	0.00	0.00	0.00	0.00	61,630.54	Fixed: 100.00% Variable: 0.00%
Janke Dittmer Non-executive director	0.00 <sup>(b)</sup>	0.00	0.00	0.00	0.00	0.00	0.00	0.00	Fixed: N/A Variable: N/A
Jürgen Hambrecht Non-executive director	30,000.00 <sup>(a)</sup>	0.00	0.00	0.00	0.00	0.00	0.00	30,000.00	Fixed: 100.00% Variable: 0.00%
Kevin Rakin Non-executive director	30,000.00 <sup>(a)</sup>	0.00	0.00	0.00	0.00	0.00	0.00	30,000.00	Fixed: 100.00% Variable: 0.00%
Donald Deyo Non-executive director	40,833.33 <sup>(a)</sup>	0.00	0.00	0.00	0.00	0.00	0.00	40,833.33	Fixed: 100.00% Variable: 0.00%
Rita Johnson-Mills Non-executive director	9,166.67 <sup>(c)</sup>	0.00	0.00	0.00	0.00	0.00	0.00	9,166.67	Fixed: 100.00% Variable: 0.00%
Pierre Gianello Employee	86,596.68 <sup>(d)</sup>	0.00	0.00	0.00	0.00	0.00	0.00	86,596.68	
Non-executive director	27,500.00 <sup>(a)</sup>	0.00	0.00	0.00	0.00	0.00	0.00	27,500.00	
Pierre Gianello TOTAL	114,096.68	0.00	0.00	0.00	0.00	0.00	0.00	114,096.68	Fixed: 100.00% Variable: 0.00%
Jan Janssen Non-executive director	27,500.00 <sup>(a)</sup>	0.00	0.00	0.00	0.00	0.00	0.00	27,500.00	Fixed: 100.00% Variable: 0.00%
Olivier Taelman (*) Executive director, CEO	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	

#### 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) Board fees composed as set out in the following table:

## 2021 Board Fees

	Fixed annual fees								Total
	Non-executive chairman	Independent non-executive director	Other non-executive director	Chairman of audit committee	Member of audit committee	Member of remuneration committee	Member of science & technology committee	Member of Cochlear project steering committee	
Robert Taub	50,000.00					2,500.00			52,500.00
Janke Dittmer									0.00
Jürgen Hambrecht		25,000.00			2,500.00	2,500.00			30,000.00
Kevin Rakin		25,000.00		5,000.00					30,000.00
Donald Deyo		25,000.00			2,500.00	1,666.67	2,500.00	9,166.67	40,833.33
Rita Johnson-Mills		8,333.33				833.33			9,166.67
Pierre Gianello			25,000.00				2,500.00		27,500.00
Jan Janssen			25,000.00				2,500.00		27,500.00

(b) Janke Dittmer renounced to receive any board fees.

(c) Fee for the period as of August 27, 2021; composed as set out in the table under (a) above.

(d) 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.

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

## Total remuneration of members of executive management

Table 2 - Total remuneration members of executive management

Name, position	Fixed remuneration			Variable remuneration		Extra-ordinary items	Pension expense	Total remuneration	Proportion of fixed and variable remuneration
	Base remuneration	Attendance fees	Fringe benefits	One-year variable	Multi-year variable				
Olivier Taelman CEO	412,722.16	NA	17,747.61 <sup>a</sup>	287,381.14 <sup>b</sup>	0.00	0.00	12,682.00 <sup>d</sup>	730,532.91	Fixed: 60.66% Variable: 39.34%
Fabian Suarez Gonzalez <sup>(*)</sup> CFO (until December 31, 2021)	230,000.04	NA	0.00	0.00	0.00	3,709,285.99 <sup>e</sup>	0.00	3,939,286.03	Fixed: 5.84% Variable: 94.16%

### Notes:

(\*) Acting via ActuaRisk Consulting SRL.

(a) Fringe benefits consist of: company car (€8,467.99), laptop and mobile phone (€156), representation allowance (€4,200), health insurance (€2,904.84), sectoral premium and eco-vouchers (€517.64) and meal vouchers (€1,501.14).

(b) The "one-year variable" remuneration of Olivier Taelman consists of (i) an exceptional one-off bonus of €150,000 in relation to the successful Nasdaq IPO in July 2021, and (ii) the yearly performance bonus as further detailed in Table 3 below.

(c) The "multi-year variable" remuneration corresponds to the "surplus value" as calculated in Table 4 below.

(d) Defined contribution pension plan.

(e) As a result of the Euronext Brussels IPO in September 2020 (which was one possible "Exit" for purposes of the extraordinary variable compensation described in this note), ActuaRisk Consulting SRL was entitled to an extraordinary variable compensation that would become payable by the Company when ActuaRisk Consulting SRL would invoice such compensation. ActuaRisk Consulting SRL could not invoice the Company prior to March 18, 2021 (i.e. six months following the Euronext Brussels IPO), and issued the invoice on July 12, 2021. The extraordinary variable compensation amounted to €3,709,285.99, based on the principles set out in the following table:

Exit Value (€)	Variable compensation (in % of the Exit Value, excl. VAT)
< 65,000,000	0%
≥ 65,000,000 < 300,000,000	0.35%
≥ 300,000,000	0.50%

whereby the Exit Value equals the closing trading price of the shares of the Company at the time ActuaRisk Consulting SRL invoices the Company, multiplied by the number of then outstanding shares of the Company. Specifically, the Exit Value amounted to €741,857,197, based on (a) 25,437,859 outstanding shares of the Company on the date of the invoice, (b) a closing trading price of the shares of the Company on Nasdaq on the date of the invoice of US\$ 34.62, and (c) a US\$/€ exchange rate on the date of the invoice of 1.1871, which led to an extraordinary variable compensation of €3,709,285.99.

## 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	Clinical objectives	33%	a) 90% b) 45,290.49
	Commercial objectives	33%	a) 60% b) 30,193.66
	Operational objectives	33%	a) 125% b) 61,897.00
	<b>Total</b>		<b>137,381.15</b>
Fabian Suarez Gonzalez (*) CFO	None	N/A	a) N/A b) N/A
	<b>Total</b>		<b>N/A</b>

Notes:

(\*)Acting via ActuaRisk Consulting SRL.

## 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				
	Identification of the plan	Date of offer	Date of vesting of last tranche	End of holding period	Exercise period (from - to)	Exercise price	Opening balance	During the year			Closing balance
							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 chairman	NA										
Janke Dittmer Non-executive director	NA										
Jürgen Hambrecht Non-executive director	NA										
Kevin Rakin Non-executive director	ESOP 2016	3/11/16	3/11/18	NA	3/11/16 3/11/21	2,585.32	0	a) 0	a) 0	0	
Donald Deyo Non-executive director	ESOP 2016	3/11/16	3/11/18	NA	3/11/16 3/11/21	2,585.32	0	a) 0	a) 0	0	
Rita Johnson-Mills Non-executive director	NA										
Pierre Gianello Non-executive director	ESOP 2016	9/12/16	9/12/18	NA	9/12/16 9/12/21	2,585.32	0	a) 0	a) 0	0	
Jan Janssen Non-executive director	NA										
Olivier Taelman CEO	ESOP 2013	7/04/20	7/04/20	NA	7/04/20 23/12/24	5,966.59	0	a) 0 b) 0	a) 0 b) 0 c) 0 d) 0	0	
	ESOP 2018	29/07/19	29/07/21	NA	29/07/19 29/07/24	3,259.91	0	a) 0 b) 0	a) 0 b) 0 c) 0 d) 0	0	
	ESOP 2018	7/04/20	7/04/22	NA	7/04/20 7/04/25	5,966.59	0	a) 0 b) 0	a) 0 b) 0 c) 0 d) 0	0	
	ESOP 2020	7/04/20	7/04/22	NA	7/04/20 7/04/25	11.94	0	a) 0 b) 0	a) 0 b) 0 c) 0 d) 0	0	
	ESOP 2021	17/09/21	17/09/24	NA	17/09/21 17/09/26	25.31	0	a) 33,240 b) 841,304.40	a) 8,310 b) 210,326.10 c) 210,326.10 d) 0.00	24,930	
<b>Total</b>							0	a) 33,240 b) 841,304.40	a) 8,310 b) 210,326.10 c) 210,326.10 d) 0.00	24,930	
Fabian Suarez Gonzalez (*) CFO	ESOP 2016	13/06/17	13/06/19	NA	13/06/17 13/06/22	2,585.32	0	a) 0	a) 0	0	

Notes:

(\*) Acting via ActuaRisk Consulting SRL, but holding the share options personally.

(\*\*) Share options held/granted/vested under the ESOP 2013, ESOP 2016 and ESOP 2018 plans each give right to 500 common shares; share options held/granted/vested under the ESOP 2020 and ESOP 2021 plans each give right to 1 common share.

In addition to the information included in Table 4 above, during 2021:

- Kevin Rakin exercised 54 ESOP 2016 share options,
- Donald Deyo exercised 54 ESOP 2016 share options,
- Pierre Gianello exercised 12 ESOP 2016 share options,
- Olivier Taelman exercised 1 ESOP 2013 share option and 199 ESOP 2018 share options,
- None of the other 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 2013/ESOP 2016/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: 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 2013/ESOP 2016/ESOP 2018/ESOP 2020: unless the Board of Directors determines otherwise: vesting in three tranches: 1/3 (or 34% in the case of ESOP 2013) of the share options granted vests upon the date of grant, 1/3 (or 33% in the case of ESOP 2013) vests on the first anniversary date of the relevant share option agreement, 1/3 (or 33% in the case of ESOP 2013) vests on the second anniversary date of the relevant share option agreement.
  - ESOP 2021: 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.

- Exercise of share options:
  - ESOP 2013: vested share options can be exercised at any time during the year.
  - ESOP 2016/ESOP 2018/ESOP 2020/ESOP 2021: 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 2021, 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 2021.

#### **2.8.6 Derogations from the remuneration policy**

During 2021, no derogations were made from the Company's remuneration policy in respect of the remuneration of the directors.

In respect of the remuneration of the members of executive management, the remuneration policy provides that such remuneration consists of three main elements, being (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. In other words, the target remuneration package includes a target STI equal to 100% of the fixed annual base remuneration as well as an LTI having a value equal to 100% of the fixed annual base remuneration.

In respect of 2021, the target STI of the Company's CEO, Olivier Taelman, only amounted to 40% of his fixed annual base remuneration. However, this "ordinary" STI, was complemented with an exceptional one-off bonus of €150,000 in relation to the successful Nasdaq IPO in July 2021, bringing the total STI for 2021 to 70% of the 2021 fixed annual base remuneration.

The Company's CFO in 2021, Fabian Suarez Gonzalez (acting via ActuaRisk Consulting SRL), did not receive any STI or LTI for 2021. However, in 2021 he 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.

#### **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 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>2021</b>	<b>2020</b>
<b>Non-executive directors</b>		
Total remuneration (all non-executive directors collectively) (*)	331,560.55	383,653.86
<b>Members of executive management</b>		
Fixed remuneration (all members of executive management collectively)	673,151.81	516,472.57
Variable remuneration (all members of executive management collectively) (**)	287,381.14	1,666,010.00
Total remuneration (all members of executive management collectively)	960,532.95	2,182,482.57

(\*) 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 comprises: board fees (annualized for directors who were only entitled to receive board fees for part of the year), and salary pursuant to employment agreement between Pierre Gianello and the Company.

(\*\*) 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>2021</b>	<b>2020</b>
Financial performance criteria (number out of total performance criteria)	1/6	0/2
Non-financial performance criteria (number out of total performance criteria)	5/6	2/2
Net profit (net loss) (consolidated) (KEUR)	(25,301)	(12,245)

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

<b>Average remuneration of employees on a full-time equivalent basis</b>	<b>2021</b>	<b>2020</b>
Employees of the consolidated group	90,798.95	86,550.49

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 change in the 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

Ratio highest remuneration / lowest remuneration	2021	2020
Highest remuneration of the members of executive management (*)	730,532.91	1,913,149.21
Lowest remuneration (in full-time equivalent) of the employees	27,644.91	30,586.50
Ratio highest remuneration / lowest remuneration	26.43	62.55

(\*) 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 relating to clinical development

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

Even though the Company has obtained certification (CE-Mark), in Europe for the Genio® system based on positive results from the BiLateral hypoglossal nerve STimulation for treatment of Obstructive Sleep Apnea, or BLAST clinical trial, there is no assurance that ongoing and future clinical trials the Company 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. The Company may be required to develop more clinical evidence than currently anticipated before the Company is 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 U.S. pivotal trial 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.

***Attracting patients to perform clinical trials and meeting clinical trial objectives can be more costly and time-consuming than expected, has already been adversely impacted by the ongoing COVID-19 pandemic, and could be adversely affected by another health crisis.***

In order to conduct its clinical trials, the Company must recruit, screen and enroll eligible patients. Patients may be identified from the investigator's own clinical practice or hospital or may be referred by another physician. Potential clinical trial participants must provide informed consent before undergoing certain clinical tests that are used to determine patient eligibility based on inclusion/exclusion criteria. As a result, at the time of informed consent, the Company does not know if a patient will be eligible to participate in the trial. For example, patients with CCC are excluded from the DREAM trial, and the Company cannot determine eligibility until after the patient has consented and undergone a drug-induced sleep endoscopy. To that end, the Company will need to screen many more patients than it intends to enroll in order to meet the enrollment criteria. After a patient is determined to be eligible and is enrolled in the clinical trial, they must comply with the trial requirements and undergo periodic time-consuming tests, including a sleep test in a sleep lab. Not all patients who undergo screening will ultimately be eligible for the enrollment in the clinical trials. Moreover, some of the enrolled participants may not comply with the requirements of the trial, thereby leading to poor or unusable data, or some may withdraw from the trial, which may compromise the results of the clinical trial.

The Company may not be able to initiate, continue and/or complete in a timely manner clinical trials if it is unable to locate and enroll a sufficient number of eligible patients within the planned recruitment period to participate in these trials as required by the applicable regulatory authorities in the United States, Europe and any other applicable jurisdictions.

Delays in subject enrollment or failure of trial subjects to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial. Patient enrollment in the clinical trials may be affected by many factors including:

- the fact that the Genio<sup>®</sup> system is an implantable device requiring clinical trial subjects to undergo surgery,
- the existence of a competing device with FDA marketing authorization and long-term data supporting its safety and efficacy;
- clinicians' and patients' perceptions as to the potential advantages and risks of the Genio<sup>®</sup> system in relation to other available therapies, including any new product candidates that may be approved for the indications the Company is investigating;
- the severity of the condition, moderate to severe OSA, under investigation and clinicians' and patients' perceptions as to the potential advantages and risks of the Genio<sup>®</sup> system in relation to other available therapies, including any new product candidates that may be approved for this indication;
- the size and nature of the patient population;
- the severity of the disease under investigation
- the eligibility criteria for the trial in question;
- subject compliance with the trial protocol;
- the design of the clinical trial;
- the referral practices of physicians,
- limitations placed on enrollment by regulatory authorities or other bodies;
- the ability to monitor trial subjects adequately during and after treatment,
- the proximity and availability of clinical trial sites for prospective subjects,
- the approval of other devices or therapeutics for the target indications,
- efforts to facilitate timely enrollment;
- other clinical trials competing for the same target patients as those of the Company; and
- the necessity for the trial subjects to dedicate their time to multiple visits to the clinic and/or sleep lab for tests, including a sleep test in a lab, forming part of the clinical trials.

In addition, as a result of the COVID-19 pandemic, and related "shelter in place" or "quarantine" orders and other public health guidance measures, the Company has experienced and may experience in the future disruptions that could materially impact the ability to recruit patients to participate in the trials or otherwise disrupt normal functioning of the healthcare system which could impair the ability of the Company to conduct its clinical trials and business in general as planned. Initial delays were due to COVID-lockdown, sites being activated sequentially, relying on remote proctoring and lack of a reliable patient recruitment mechanism. Currently, a targeted patient add campaign with secondary screeners is helping to accelerate enrolment in the study while proctorship issues have largely been addressed.

Potential causes of disruptions include but are not limited to:

- delay of surgeon training due to the limitations of traveling for surgeons to be trained, proctors and the Company's staff;
- delay of surgeon training due to the closing or restricted use of cadaver lab facilities hosting the training sessions;
- limitations of number of implants due to COVID-19 and recommendations from regulatory or health authorities to limit elective surgeries;
- delays in site initiation and subject enrollment due to diversion of healthcare resources away from the conduct of clinical trials, including the unavailability, diversion or reallocation of resources and facilities of hospitals serving as the Company's clinical trial sites and hospital staff supporting the conduct of the Company's clinical trials;
- delays or difficulties in enrolling subjects in the Company's clinical trials because COVID-19 in some cases has reduced the willingness of patients to participate or continue to participate in clinical trials, resulting in the need to recruit new potential participants and go through new screening processes;
- increased rates of subjects withdrawing from the Company's clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- potential non-compliance of subjects with clinical trial protocols if quarantine impedes patient movement or interrupts or restricts healthcare services; and
- delays in data verification processes, database cleaning, analysis and reporting activities due to limited access to the hospitals, site staff and patient clinical files (source documentation).

Any difficulties in enrolling a sufficient number of subjects for any of the Company's clinical trials, or any subjects withdrawing from the clinical trials or not complying with the trial protocols could result in significant delays and could require the Company to abandon one or more clinical trials altogether. If the Company's trial sites are restricted in performing elective surgeries or following up with their trial subjects, this may lead to missing information and may potentially impact clinical trial data quality and integrity. Enrollment delays and other issues with the Company's clinical trials may result in increased research and development costs that may exceed the resources available to the Company and in delays to commercially launch the Genio<sup>®</sup> system in target markets, if authorized for sale in such markets.

***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<sup>®</sup> system.***

Even if the Genio<sup>®</sup> 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. The Company's efforts to educate the medical community and third-party payors regarding the benefits of the Genio<sup>®</sup> system are expected to require significant resources and may not be successful.

Acceptance of the Genio<sup>®</sup> system will depend on physicians being convinced of the distinctive characteristics, clinical performance, benefits, safety and cost-effectiveness of the Genio<sup>®</sup> system 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 which will be developed 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.

***Long-term growth depends on the Company's ability to enhance its technology, expand indications and develop and commercialize additional products.***

Expanding indications for the Genio® system and developing new products is expensive and time-consuming and could divert management's attention away from the Company's core business. The Company continues to invest in pursuing additional indications for the Genio® system and in improving the Genio® system to develop next generation versions designed to improve patient comfort, efficacy and convenience. The success of any such product development efforts will depend on several factors, including the Company's 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 trials 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 the Company's products;
- receive adequate coverage and reimbursement for procedures performed with the Company's products; and
- develop an effective and dedicated sales and marketing team.

If the Company is not successful in expanding indications (such as for instance treating complete concentric collapse patients) and developing and commercializing new products and product enhancements, its ability to increase its revenue in the future may be impaired.

## 2.9.2 Risks relating to commercialization and reimbursement

***The Company's future financial performance depends on the commercial acceptance of the Genio® system in target markets.***

The Genio® system is currently the only commercial product on the market by the Company. It is marketed in certain European countries, and its 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 the Company fails to gain and maintain commercial market acceptance of the Genio® system in its 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 the Company's future financial performance will depend on the successful completion of its 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 the Company's failure, or a substantial delay, in gaining significant market acceptance of the Genio® system in target markets, which could affect the Company's ability to generate revenue. Any failure of the Genio® system to achieve meaningful market acceptance will harm the Company's business and future prospects.

***The Company's success is largely contingent on third-party payments from government providers, healthcare insurance providers or other public or private sources, and its product may not be accepted for reimbursement by such payers.***

The existence of coverage and adequate reimbursement for the Company's products by government and/or private payers will be critical for market adoption of the Genio® system. Physicians and hospitals are unlikely to use the Genio® system at all or to a great extent, if they do not receive adequate reimbursement for the procedures utilizing the Company's product, and potential patients may be unable or unwilling to pay for the Genio® system themselves if appropriate reimbursement by government or private payers is not available.

In many countries, payment for the Genio® system will be dependent on obtaining a "reimbursement code" for the procedure and product. Obtaining a reimbursement code can be a time-consuming process (taking from months to years), that varies from country to country and that could require the Company to provide supporting scientific, clinical and cost-effectiveness data for the use of its products. Following the grant of a reimbursement code payers (e.g. national healthcare systems or health insurance companies) have to agree to provide coverage for the procedure(s) that use the Genio® system, which could be an additional hurdle for the Company. Increasingly, third-party payers are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. The Company may not be able to provide data sufficient to satisfy governmental and third-party payers that procedures using its products should be covered and reimbursed.

With global pressure on healthcare costs, payers are attempting to contain costs by, for example, limiting coverage of and the level of reimbursements for new therapies. Generally, hospitals, governments and third-party payers are increasingly exerting downward pressure and reviewing the cost-effectiveness of medical products, therapies and services. These payers may not view the Genio system or any other product candidates, if authorized for marketing, as cost-effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our product candidates, if authorized for marketing, to be sold on a competitive basis. Securing adequate or attractive reimbursement often depends on the successful outcome of a medical economics study, which is a clinical study designed to demonstrate the cost effectiveness of a product or procedure. Such studies are time-con-

suming and costly. It is uncertain if the results of such studies will be sufficient to support a reimbursement application. The Company might therefore not be able to obtain reimbursement at satisfactory levels or at all.

Although there is a general consensus about the medical necessity to treat OSA and notwithstanding the increasing number of hypoglossal nerve stimulation therapy coverage decisions (as evidenced by the Inspire case), the Company:

- is currently in discussions and negotiations to secure reimbursement coverage
- is at risk of currently not having sufficient evidence to determine that the Genio therapy results demonstrate a meaningful improvement in net health outcomes for patients meeting the specified criteria. If so, further evidence might be necessary, while in the meantime the Company will make the Genio® system available through country-specific innovation funding pathways.

At this stage of development and penetration of hypoglossal nerve stimulation therapy in the OSA field, there are no large clinical trials available (yet) to confirm the long-term cost effectiveness of hypoglossal nerve stimulation.

Additionally, besides CPAP, as a first-line treatment, other second-line treatments, such as mandibular advancement devices, are not widely covered by healthcare systems and reimbursement differs significantly from one country to another.

The downward pressure on healthcare costs has become particularly intense in Europe, and as a result, increasingly high barriers are being erected to the entry of new products (e.g. the Genio® system).

The price that the Company may receive for, and the marketability of, the Genio® system for which the Company receives regulatory approval may suffer significantly if the government and/or third-party payers fail to provide adequate coverage and reimbursement or if further governmental cost containment or other health reform initiatives are adopted or implemented.

As a result, the Company could fail to support a commercial infrastructure or realize an appropriate return on its investment in product development.

***If the Company is unable to expand its sales, marketing and distribution capabilities for the Genio® system or to partner with suitable third parties to provide these services, the Company may not be successful in commercializing the Genio® system in its target markets, if and when they are approved.***

The Company only has limited experience in marketing and selling our Genio system. To achieve commercial success the Company will need on the one hand to keep expanding its internal sales and marketing organization to commercialize the Genio® system in markets that the Company will target directly, which may entail risks as set out above. On the other hand, the Company may decide to target certain other markets indirectly via distributors or other arrangements. If the Company is unable to find suitable distribution partners, loses these distribution partners or if the Company's distribution partners fail to sell its products in sufficient quantities, on commercially viable terms or in a timely manner, the commercialization of the Genio® system could be materially harmed, which could prevent the Company from achieving or maintaining profitability.

Another factor that may inhibit the Company's efforts to commercialize the Genio® system in target markets is the lack of complementary products to be offered by sales personnel, which may put the Company at a competitive disadvantage relative to companies with more products.

If the Company is unable to expand its own sales, marketing and distribution capabilities or enter into arrangements with other third parties to perform these services, the Company would not be able to successfully commercialize its products in these markets.

***The occurrence of a pandemic, epidemic or other health crisis, including the ongoing COVID-19 pandemic, could have a negative impact on the Company's product development and manufacturing activities, the recruitment and conduct of its clinical trials and its ability to source required funding, which could delay or prevent it from executing its strategy as planned.***

The Company's business and the business of its development and manufacturing partners and suppliers could be materially adversely affected by the effects of pandemics, epidemics or other health crises, including the ongoing COVID-19 pandemic. The ultimate impact of the COVID-19 outbreak or any similar health pandemic or epidemic is highly uncertain and subject to rapid change.

The Company has experienced certain impacts and may experience others which could have material adverse effects on our operations and the execution of our business plans. Examples of these include the following:

- The Company has experienced some delays in the conduct of its current clinical trials, as individuals with moderate to severe OSA defer seeking treatments, physicians have fewer in-person meetings to recruit and enroll patients, and recruited patients are hindered by restrictions in traveling to and accessing clinical sites. In addition, resources at hospitals have been diverted to dealing with the pandemic, pausing certain elective procedures and causing delays in scheduling screening evaluations, implant procedures, and follow-up monitoring visits. As a result of the foregoing factors, the expected timeline for data readouts of our clinical trials may be negatively impacted, which would adversely affect our business.
- The Company relies on independent clinical investigators other third-party service providers to assist us in managing, monitoring and otherwise carrying out our nonclinical studies and clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs.
- The Company also relies on third party suppliers and contract manufacturers to produce and assemble certain components of the Genio system. We could experience supply chain delays or shortages of these system components, which could impact both our ability to meet current timetables for our clinical trials and also hamper our ability to fulfill commercial orders for the system.
- The Company temporarily closed its executive offices and implemented various governmental safety guidelines, including work-from-home policies for most employees. The effects of government orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.
- The Company has instituted work-from-home policies for certain of our employees, and this could adversely affect our operations, the productivity of our employees and our ability to conduct and complete our nonclinical studies and clinical trials.
- In our initially targeted European markets, the pandemic could cause delays in pursuing and obtaining governmental and other third-party reimbursement decisions, as the work of these organizations may be slowed due to personnel work-from-home measures and travel and other scheduling constraints.
- In Germany, where reimbursement is available for our Genio system, COVID-19 has caused delays in activating centers and implanting patients particularly in the last quarter of 2021.
- The COVID-19 pandemic also presents a number of challenges for our sales and marketing efforts, including, among others, the impact on our marketing and sales team in Europe due to travel limitations and government-mandated work-from-home or shelter-in-place orders, potential decreased product demand due to reduced numbers of in-person meetings with prescribers, and patient visits with physicians, potential delays in scheduling DISE and implant treatments, as well as increased unemployment resulting in lower new prescriptions.



- In addition, the ability of the U.S. Food and Drug Administration, or FDA, and other regulatory authorities or other bodies to engage in routine regulatory and oversight activities, such as the review and authorization or certification of new products and the inspection of manufacturing and clinical trial sites, may be affected by the COVID-19 pandemic. The FDA and other regulatory authorities or other bodies may have slower response times or be under-resourced. If the global health concerns continue to disrupt or prevent regulatory authorities from conducting their regular reviews, inspections, or other regulatory activities, it could significantly impact the timely review and process our marketing applications, clinical trial authorizations, or other regulatory submissions, which could have a material adverse effect on our business.
- The near- and longer-term future impacts of the COVID-19 pandemic on global and national economies, and related impacts on the availability of investment capital in financial markets, continues to be uncertain. Continued economic disruptions could cause a contraction in equity capital and debt markets, making access to financing unavailable on acceptable terms or at all.

While the ultimate overall economic impact caused by the COVID-19 pandemic may be difficult to assess or predict, it is currently resulting in significant disruption to the global financial markets. If the resulting disruptions are sustained or recurrent, they could make it more difficult for the Company to access capital, which could in the future negatively affect its ability to source required funding, which could delay or prevent it from executing its strategy as planned.

Although the Company is monitoring developments relating to the COVID-19 situation closely, the impact of COVID-19 on the Company's business is uncertain at this time and will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions taken to contain it or address its impact, among other things. Therefore, the Company does not yet know the full extent of the impact on its business (including its supply chains, its clinical trials and its access to the capital required to execute its business strategy).

***The Company may focus its limited 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 its current limited financial and managerial resources, the Company will have to carefully prioritize the order in which it addresses of the target European markets for commercialization of the Genio<sup>®</sup> system, based on parameters such as market size, market readiness, and competition, and then allocate its financial and managerial resources accordingly.

In order to identify its primary target markets, the Company makes 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<sup>®</sup> system does not develop as currently anticipated, the Company's ability to generate revenue could be materially adversely affected. Further, the Company uses its limited 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<sup>®</sup> system than the Company anticipates which would result in lower potential revenue for the Company.



### 2.9.3 Risks relating to the Company's financial situation

***While in the opinion of the Company it has sufficient working capital for its present requirements, that is for at least the next 12 months following the date of this Annual Report, the Company could require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available.***

The Company believes that its existing cash, cash equivalents, short-term investments and revenue will be sufficient to meet its capital requirements and fund its operations for at least 12 months. However, the Company has based these estimates on assumptions that may prove to be incorrect, and the Company could spend its available financial resources much faster than currently expected. Any future funding requirements will depend on many factors, including without limitation:

- acceptance of the Genio® system by patients, physicians, government payors, private payors, and the market generally in the Company's 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 of research and development activities;
- the cost of filing and prosecuting patent applications and other intellectual property rights and defending and enforcing the Company's patents or other intellectual property rights in various jurisdictions;
- the cost of defending, in litigation or otherwise, any claims that the Company infringes 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 ;
- the cost and timing of establishing additional sales and marketing capabilities;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the extent to which the Company acquires or invest in products, technologies and businesses, although the Company 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 the Company raises may contain terms that are not favorable to the Company or its shareholders. If the Company raises additional funds by selling additional Shares or other securities convertible into or exercisable or exchangeable for Shares, the issuance of such securities will result in dilution to the Company's shareholders.

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

Furthermore, the Company cannot be certain that additional funding will be available on acceptable terms, if at all. While the ultimate overall economic impact caused by the COVID-19 pandemic may be difficult to fully assess or predict, it is currently resulting in significant disruption to the global financial markets. If the resulting disruptions are sustained or recurrent, they could make it more difficult for the Company to access capital, and could in the future negatively affect its ability to source required

funding, which could delay or prevent it from executing its strategy as planned. If it does not have, or is not able to obtain, sufficient funds, the Company may have to delay development or commercialization of its products or license to third-parties the rights to commercialize products or technologies that the Company would otherwise seek to commercialize. The Company also may have to reduce marketing, customer support or other resources devoted to its products or cease operations.

***The Company has a limited operating history, has incurred losses in each period since its inception and may not be able to achieve or maintain profitability in the future .***

The Company was incorporated in 2009, obtained certification (CE-Mark) for the Genio® system in March 2019, and had its first commercial sales in Germany in July 2020. Since commencing commercialization, the Company has generated only limited revenue from commercial sales of the Genio® system. The Company has incurred operating losses and negative operating cash flows in each period since it was incorporated. As of December 31, 2021, the Company has an accumulated deficit of €84.8 million. These losses have resulted primarily from costs incurred in the development of the Genio® system, as well as from general and administrative costs associated with the Company operations and manufacturing. The Company expects that its operating expenses will continue to increase as it funds the continued development of its technology and the Genio® product line, seeks to expand manufacturing and sales and marketing capabilities, seeks further regulatory clearances, certifications, approvals and marketing authorizations, particularly in the United States from the Food and Drug Administration ("FDA"), for the Genio® system, and as the Company incurs the additional costs associated with being a public company in the United States. In June 2020, the Company obtained approval from the FDA under an investigational device exemption ("IDE") trial, to begin the pivotal trial, the dual-sided hypoglossal nerve stimulation for the treatment of obstructive sleep apnea, or DREAM, trial. The aim of the study is to support a marketing authorization from the FDA in the United States, as well as to support product reimbursement more generally. The Company also plans to conduct additional clinical trials and as a result, management expects that clinical expenses will increase significantly over the next several years. These expenses, together with anticipated commercial/sales, R&D and general and administrative expenses, will likely result in the Company incurring further losses for at least the next few years.

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

***Any loss or decrease of subsidies, reimbursable cash advances and tax reductions may affect the Company's financial resources.***

Since September 2011, the Company has 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 the Company's 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.

All these subsidies and reimbursable cash advances increased the Company's financial resources to support R&D and clinical development projects. However, the Company cannot predict whether it or its 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 the Company's profitability until fully repaid.

#### 2.9.4 Risks relating to the Company's dependence on third parties and on key personnel

***A loss or degradation in performance of the suppliers on which the Company depends for services and components used in the production and assembly of the Genio® system could have a material effect on the Company's 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 the Company with components or services of insufficient quality, this could harm the Company's reputation and business by affecting, for example, product availability and performance. The Company's suppliers might not be able or willing to continue to provide the Company with the components or services it needs, at suitable prices or in sufficient quantity or quality. If any of the Company's existing suppliers are unable or unwilling to meet its 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 the Company from achieving or maintaining profitability. For instance, the Company currently relies on a single source supplier for a number of critical components to the Genio® system. The Company is seeking to qualify additional suppliers for certain of its 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 the Company to diversify its exposure to single source suppliers. In addition, if the Company has to switch to a replacement supplier for any of its product components or for certain services required for the production and assembly of the Genio® system (for example, the sterilization and coating of the product components), or if the Company has to commence its own manufacturing to satisfy market demand, it 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 its clinical trials or commercialization and prevent the Company 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.

In addition, the Company's suppliers may discontinue their supply of components or services upon which the Company relies before the end of the product life of the Genio® system. The timing of a discontinuation may not allow the Company sufficient time to develop and obtain any regulatory authorizations or certifications are required for replacement components or service before the Company exhausts its inventory. If suppliers discontinue their supply of components or services, the Company may have to pay premium prices to its 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 the Company has an alternative component developed and authorized by the regulatory authorities or temporarily cease supplying the Genio® system once its 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 the Company's available inventory and an increase in its production costs.

***The Company may be unable to attract and retain management and other personnel it needs to succeed.***

Given the current state of the development of the Company, reliance on the expertise and experience of the 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 from the Company without timely and adequate replacement or the loss of any of the Company's senior management or other key employees would make it difficult for the Company to achieve its objectives in a timely manner, or at all. The

Company 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, the Company's competitive position could be compromised if a member of senior management transferred to a competitor.

The Company expects to expand its operations and grow its 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 the Company's 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 the Company. If the Company is unable to identify, attract, retain and motivate these highly skilled personnel, it may be unable to continue its development, commercialization or growth. Failure to retain or attract key personnel could have a material adverse effect on the Company's business, results of operations, cash flows, financial condition and/or prospects. In addition, if, as a result of COVID-19, the employees are not able to come to work, then this could also have a material adverse effect on the business, results of operations, cash flows, financial condition and/or prospects.

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

The Company relies, 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 its business. In particular, the Company's technology and product development activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if (i) the third parties do not devote a sufficient amount of time or effort to the Company's activities or otherwise fail to successfully carry out their contractual duties or to meet regulatory obligations or expected deadlines, (ii) the Company replaces a third party, (iii) 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 (iv) the third party becomes bankrupt or enters into liquidation.

The Company may not always have the ability to control the performance of third parties in their conduct of their activities. The 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, the Company would be required to find a replacement third party to conduct the required activities. The Company may be unable to enter into a new agreement with another third party on commercially acceptable terms. Furthermore, if the quality or accuracy of the data obtained by the third party is compromised, or if data is otherwise lost, the Company would be required to repeat the affected study. Third-party performance failures may therefore increase the Company's development costs, delay the Company's ability to obtain regulatory approval, and delay or prevent the commercialization of the Genio® system in target markets. In addition, the Company's third-party agreements usually contain a clause limiting such third party's liability, such that the Company may not be able to obtain full compensation for any losses that the Company may incur in connection with the third party's performance failures.

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

Expedited, reliable shipping is essential to the Company's operations since the components of the Genio® system are manufactured to the Company's 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 done in the Company's facilities in Israel and Belgium. As a result, the Company relies heavily on providers of transport services for reliable and secure point-to-point transport of the key components of the Genio® system to the Company's 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 the Company's reputation and lead to decreased demand for the Genio® system and increased cost and expense to the Company's business. In addition, any significant increase in shipping rates could adversely affect the Company's operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services the Company uses would adversely affect the Company's ability to process orders for the Genio® system on a timely basis.

### 2.9.5 Risks relating to the markets and countries in which the Company operates

***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. The Company's 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. The Company competes as a second line therapy in the OSA treatment market for patients with moderate to severe OSA.

The Company considers other companies that have designed hypoglossal nerve stimulation technologies to treat OSA as direct competitors.

Additionally, the Company also considers, 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 ("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 the Company's sales, financial condition and results of operations.

Companies against which the Company competes, 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 the Company's clinical trials. The Company may successfully conclude its clinical trials and obtain final regulatory authorization or certification, and nevertheless may fail to compete against competitors (such as the CE-marked and FDA-approved device from Inspire and the CE-marked device from ImThera/LivaNova, currently running an IDE study in the United States) 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 the Company's ability to develop and grow the market for the Genio® system. Furthermore, new entrants into the markets in which the Company operates could also decide to more aggressively compete on price, requiring the Company to reduce prices to maintain market share.

***Significant parts of the Company's operations are located in Israel and, therefore, the Company's results may be adversely affected by political, economic and military instability in Israel.***

The Company is finalizing its plan to establish a manufacturing facility in Liège, Belgium, but the Company's research and development facility and all current manufacturing facilities are located in Tel Aviv, Israel. In addition, the majority of its employees and some officers are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly adversely affect the Company's 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 the Company's business conditions in general and harm its results of operations. The Company's 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, the Company cannot assure that this government coverage will be maintained, or if maintained, will be sufficient to fully compensate the Company for damages incurred. Any losses or damages incurred by the Company could have a material adverse effect on its business.

## 2.9.6 Risks related to manufacturing

***The Company 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.***

The Company's revenues and other operating results will depend, in large part, on its 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.

The Company expects 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 the Company's facility in Tel Aviv is expected to cover the IS demand and the ES demand up until the first half of 2022. 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, the Company would likely need to expand its manufacturing capacity, which could require opening a new facility or additional outsourcing to a third-party contract manufacturing organization. The Company is finalizing its plan to establish a manufacturing facility in Liège, Belgium, which is expected to be ready by the end of 2021 or Q1 2022 at the latest. The manufacturing facility in Liège is expected to provide the Company with additional capacity for the assembly of IS and ES as it progresses its commercialization plans. 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, the Company must also notify, and in



most cases obtain approval from, regulatory authorities regarding any changes or modifications to its manufacturing facilities and processes, and the regulatory authorities might not authorize the Company to proceed or might delay the process significantly.

In addition, the Company's 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<sup>®</sup> systems manufactured grows. However, the Company or its suppliers might not be able to increase yields and/or decrease manufacturing costs with time, and in fact costs may increase, which could prevent the Company from achieving or maintaining profitability.

***The Company's results of operations could be materially harmed if it is unable to accurately forecast customer demand for its Genio<sup>®</sup> system and manage its inventory.***

To ensure adequate inventory supply of the Genio<sup>®</sup> system in general and its components, the Company must forecast inventory needs and place orders with its suppliers based on its estimates of future demand for the Genio<sup>®</sup> system and/or its components. To date, the Company has only commercialized the Genio<sup>®</sup> system in limited quantities, mostly in Germany, and its ability to accurately forecast demand for its Genio<sup>®</sup> system could be negatively affected by many factors, including failure to accurately manage the Company's expansion strategy, product introductions by competitors, an increase or decrease in customer demand for the Genio<sup>®</sup> system or for products of the Company's 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 the Company's gross margin to be adversely affected and could impair the strength of the Genio<sup>®</sup> brand. Conversely, if the Company underestimates customer demand for the Genio<sup>®</sup> system, the Company third-party contract manufacturers may not be able to deliver products to meet the Company's requirements, and this could result in damage to the Company's reputation and customer relationships. In addition, if the Company experiences 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 the Company, or at all, or suppliers or third-party manufacturers might not be able to allocate sufficient capacity in order to meet the Company's increased requirements, which could have an adverse effect on the Company's ability to meet customer demand for the Genio<sup>®</sup> system.

The Company seeks to maintain sufficient levels of inventory in order to protect itself from supply interruptions. As a result, it is subject to the risk that a portion of its inventory will become obsolete or expire, which could affect the Company's earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

### **2.9.7 Legal and regulatory risks**

***The Genio<sup>®</sup> 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 the Company intends to sell or market the Genio<sup>®</sup> system and other products it develops 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. The Company may be adversely affected by potential changes in government policy or legislation applicable to implantable medical devices. At the date of this Annual Report, the Company has only received certification for the European Economic Area ("EEA") Member States and Israel (in both cases through CE-Marking) for its Genio<sup>®</sup> system.

In the United States, the Company is in the early stages of a process of seeking marketing authorization. The Company received an investigational device exemption ("IDE") approval from the FDA on June 23, 2020, which allows it to proceed with certain clinical testing of the Genio® system in the United States, and is in the process of determining the appropriate regulatory pathway to pursue for seeking marketing authorization for the device from the FDA. Even though it has received an IDE, 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 the Company's manufacturing facilities and those of its third-party suppliers are subject to may affect the Company's business.***

The Company currently manufactures the Genio® system and has entered into relationships with third party suppliers to manufacture and supply certain components of the Genio® system. The manufacturing practices of the Company and of its 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, the Company will be required to verify that its suppliers maintain facilities, procedures and operations that comply with its 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 QMS in line with the most up-to-date standards and regulations) by the Company or its 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 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 health care fraud and abuse laws as well as state consumer protection laws.

Failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with the Company's products, manufacturers or manufacturing processes, may yield various results, including:



- litigation involving patients using the Company's products;
- restrictions on the Company's 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 the Company's clinical trials;
- total or partial suspension or withdrawal of regulatory approvals;
- total or partial suspension of production or distribution;
- delay 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 the Company;
- 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 the Company's reputation; or
- injunctions or the imposition of civil or criminal penalties.

Any of the foregoing actions could be detrimental to the Company's reputation or result in significant costs or loss of revenues for the Company. 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, the Company could be exposed to product liability claims and could lose customers and experience reduced sales and increased costs.

***Seeking, obtaining and maintaining certification in the EEA under the new Medical Device Regulation, with the CE-mark to be re-certified before May 2024, can be an uncertain process and Notified Bodies have limited resources and may experience backlogs.***

Under the new Medical Device Regulation, devices currently on the market in the EEA having been granted a CE-Mark under Council Directive 90/385/EEC of June 20, 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (the "AIMD Directive") – such as the Company's Genio® system – will need to be re-evaluated and re-certified in accordance with the new Medical Device Regulation. Any modification to an existing CE-marked medical device will also require review and certification under the new Medical Device Regulation.

The new Medical Device Regulation also imposes a re-designation of the "Notified Bodies" (i.e. the organizations designated by the EEA Member State in which they are based, which are responsible for assessing whether medical devices and manufacturers of medical devices meet the applicable regulatory requirements in the EEA). 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 the May 2021 effective date of the new Medical Device Regulation. In the European Union, not all Notified Bodies have been re-designated so far and the COVID-19 pandemic has significantly slowed down their designation process. Without Medical Device Regulation designation, Notified Bodies may not yet start certifying devices in accordance with the new Regulation.

The CE-Mark obtained in 2019 for the Company's Genio® system will remain valid until March 2024 and it must be re-certified under the new Medical Device Regulation then. The recertification requires the company 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 EEA Member States may be temporarily or permanently prohibited. Significant modifications to the Genio® system, if any, will also require certification under the new Medical Device Regulation.

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 the Company under the AIMD Directive) might have a negative impact on the (re-)approval of the Genio® system. The Company believes, however, that it is on track to meeting the new requirements by the deadlines set forth in the new Medical Device Regulation.

Any third-party distributors relied upon by the Company in the EEA, such as its local distributor in Spain, also need to be compliant with the new Medical Device Regulation. If a distributor in the EEA fails to meet the requirements of the new Medical Device Regulation, on a timely basis or at all, the marketing and sale of the Genio® system by such distributor may be temporarily or permanently prohibited.

Any delay or failure to comply with the new Medical Device Regulation could result in the sale of the Genio® system being temporarily or permanently prohibited in EEA Member States and affect the Company's 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.***

The Company has developed and maintains a quality management system for medical devices intended to ensure quality of the Company's products and activities. The system is designed to be in compliance with regulations in many different jurisdictions, including the Quality Systems Regulations 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.

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, ISO13485:2019 (i.e. the latest version of ISO13485) aims to harmonize the requirements of ISO13485 with the requirements of the AIMD. While management believes that the Company is compliant with existing quality management system regulations for medical device companies at the date of this Annual Report, it is possible that the Company may be found to be non-compliant with new or existing regulations in the future. In addition, the Company may be found to be non-compliant as a result of future changes in, or interpretation of, the regulations for quality systems. If the Company does not achieve compliance or subsequently becomes non-compliant, the regulatory authorities may require that the Company takes appropriate action to address non-conformance issues identified in a regulatory audit, and may, if the Company does not take such corrective actions in a timely manner, withdraw marketing clearance, or require product recall or take other enforcement action.

The Company's external vendors must, in general, also comply with the quality systems regulations and ISO13485. Any of the Company's external vendors may become non-compliant 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 the Company's 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 quality systems regulations for the United States and the AIMD Directive and the new Medical Device Regulation for Europe), which may cause interruption to or delays in the marketing and sale of the Company's 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 the Company fails to comply with such laws and regulations where the Company would intend to market the Genio<sup>®</sup> system, the Company could be subject to enforcement action including recall of its 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 the Company's business, financial condition, results of operations and prospects.

***Active implantable medical devices such as the Genio<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 ("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<sup>®</sup> system was reviewed, classified and the CE-Mark was granted by the Company's European Notified Body as an AIMD. 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 (and 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 EU 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 US, 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 the Company, 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 the Company. Any of those circumstances may have a material adverse effect on the Company ability to conduct its business, to continue selling the Genio<sup>®</sup> system, to achieve revenue objectives, or to develop future products.

***If the Company's products are defective, or otherwise pose safety risks, the relevant governmental authorities could require their recall, or the Company may need to initiate a recall of its 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 the Company 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. The Company may also choose to voluntarily recall a product if any material deficiency is found. A government mandated or voluntary recall 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 the Company's reputation. Any product recall could impair the Company's ability to produce products in a cost-effective and timely manner in order to meet customer demand. The Company may also be required to bear other costs or take other actions that may have a negative impact on future revenue and could prevent the Company from achieving or maintaining profitability.

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

The business of the Company exposes it 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, the Company is 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 the Company 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 the Company's suppliers, such as those who provide the Company with components and raw materials, may be the basis for a claim against the Company. Product liability claims may be brought against the Company by patients, healthcare providers or others selling or otherwise being exposed to the Genio® system, among oth-

ers. If the Company cannot successfully defend itself against product liability claims, the Company 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 its primary business;
- the inability to commercialize the Genio® system or new products;
- decreased demand for the Genio® system;
- damage to the Company's 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 the Company maintains product liability and clinical trial liability insurance at levels it believes are appropriate, this insurance is subject to deductibles and coverage limitations. The Company current product liability insurance may not continue to be available to the Company on acceptable terms, if at all, and, if available, coverage may not be adequate to protect the Company against any future product liability claims. If the Company is unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, the Company could be exposed to significant liabilities, including claims for amounts in excess of insured liabilities. As of the date of this Annual Report, there are no product liability claims against the Company.

***The Company bears the risk of warranty claims on the Genio® system.***

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

***The Company is and will be subject to healthcare fraud and abuse laws and other laws applicable to its business activities and if it is unable to comply with such laws, it could face substantial penalties.***

The Company is subject to various federal, state and local laws pertaining to healthcare fraud and abuse laws.

For instance, pursuant to the Belgian Act of 18 December 2016 and its implementing Royal Decree of June 14, 2017 (the "Sunshine Act"), 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.

Upon the planned launch of operations in the United States, the Company's operations will be subject to various federal and state fraud and abuse laws. Such laws include the federal and state anti-kick-back statutes, physician payment transparency laws, false claims laws and sunshine laws. These laws may affect, among other things, the Company's proposed sales and marketing and education pro-

grams and require it to implement additional internal systems for tracking certain marketing expenditures and to report to governmental authorities. In addition, the Company may be subject to patient privacy and security regulations by both the federal government and the states in which the Company conducts its business.

Any action brought against the Company for violations of these laws or regulations, even if successfully defended, could cause us to incur significant legal expenses and divert the Company's management's attention from the operation of its business. The Company may be subject to private 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 the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, it 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 the Company's operations. If any of the physicians or other healthcare providers or entities with whom the Company expects 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 the Company's business, financial condition and results of operations.

***Security breaches and other disruptions could compromise the Company's information and expose the Company to liability, which would cause the Company's business and reputation to suffer.***

The Company and certain third parties that it relies on for its operations collect and store confidential and sensitive information, 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 the Company's corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could also cause the Company to cease or delay manufacturing of the Genio systems. If such an event were to occur and cause interruptions in the Company's operations, it could have a material adverse effect on the Company's business. For example, the loss of clinical trial data from completed, ongoing or planned trials could result in delays in the Company's regulatory approval efforts and significantly increase its 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 the Company has reviewed and determined the integrity of its system and the communication protocol, use of wireless technology imposes a risk that third parties might attempt to access the Company's 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 the Company's data or applications, or the inappropriate access to or disclosure of personal, confidential, or proprietary information could delay the Company's product development, clinical trials, or commercialization efforts, result in increased overhead costs and damage the Company's reputation, all of which could negatively affect its business, financial condition and operating results.



## 2.9.8 Risks relating to intellectual property

***The inability to fully protect and exploit the Company's intellectual property and trade secrets may adversely affect the Company's financial performance and prospects.***

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

The Company generally seeks patent protection where possible for those aspects of its technology and products that it believes provides significant competitive advantages. However, obtaining, maintaining, defending and enforcing pharmaceutical patents is costly, time consuming and complex, and the Company 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 the Company will fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection. Under certain of the Company's license or collaboration agreements, it 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, the Company cannot be certain that patents will be issued with respect to its pending or future patent applications. In addition, the Company does 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.

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

***The Company 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 the Company is unaware that are inadvertently infringed by the Genio<sup>®</sup> system.

Competitors may have or develop patents and other intellectual property that they assert are infringed by the Genio® system. Any infringement claim against the Company, even if without merit, may cause the Company to incur substantial costs, and could place a significant strain on the Company's financial resources and/or divert the time and efforts of management from the conduct of the Company's business. In addition, any intellectual property litigation could force the Company 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 the Company patented technology to others or to collect royalty payments based upon successful protection and assertion of its intellectual property rights against others; (iii) pay substantial damages to the party whose intellectual property rights the Company 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 the Company.

***The Company depends on confidentiality agreements with third parties, which might not provide adequate protection for its confidential information.***

The Company relies upon unpatented confidential and proprietary information, including technical information, know-how, and other trade secrets to develop and maintain its competitive position with respect to the Genio® system. While the Company generally enters into non-disclosure or confidentiality agreements with its employees and other third parties to protect its intellectual property and trade secrets, it cannot guarantee that it has entered into such agreements with each party that may have or has had access to the Company's proprietary information. Further, despite these efforts, any of these parties may breach the agreements and disclose the Company's proprietary information, and it may not be able to obtain adequate remedies for such breaches.

***The Company depends on exclusive licenses and agreements with third parties, which might not provide adequate protection for its technology.***

The Company relies on licensing agreements providing the Company exclusivity in the field of its practice. While the Company has ensured through multiple robust agreements acquisition of exclusive licenses and freedom to operate for its 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 the Company for infringement of its patents rights, this could expose the company to risks of litigation. In addition, any intellectual property litigation could force the Company 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 the Company patented technology to others or to collect royalty payments based upon successful protection and assertion of its intellectual property rights against others; (iii) pay substantial damages to the party whose intellectual property rights the Company 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 the Company needs to license in any third-party intellectual property, it could be required to pay lump sums or royalties on its products. In addition, if the Company is required to obtain licenses to third party intellectual property, it might not be able to obtain such licenses on commercially reasonable terms or at all.



## 2.9.9 Risks relating to the shares

### ***An active market for the Shares may not be sustained.***

An active trading market for the Shares may not develop and the existing active trading market for the Shares may not be sustained or may not be sufficiently liquid. If an active trading market is not developed or not sustained, the liquidity and trading price of the Shares could be adversely affected. The degree of liquidity of the Shares may negatively impact the price at which an investor can dispose of the Shares where the investor is seeking to achieve a sale within a short timeframe.

Trading of the Shares on Euronext Brussels and the Nasdaq Global Market will take place in different currencies (U.S. dollars on the Nasdaq Global Market and EUR 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 the Shares on these two markets may differ due to these and other factors. Any decrease in the price of the Shares on Euronext Brussels could cause a decrease in the trading price of the ordinary shares on the Nasdaq Global Market and vice versa. Investors could seek to sell or buy the 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 Shares available for trading on the other exchange. However, the dual listing of the 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 Shares in the United States and Belgium.

Further, publicly traded securities from time to time experience significant price and volume fluctuations that may be unrelated to the results of operations or the financial condition of the companies that have issued them. In addition, the market price of the Shares may prove to be highly volatile and may fluctuate significantly in response to a number of factors, many of which are beyond the Company's control, including the following:

- announcements of technological innovations, clinical data in relation to existing or new products or collaborations by the Company or its competitors;
- market expectations for the Company's financial performance;
- actual or anticipated fluctuations in the Company's business, results of operations and financial condition;
- changes in the estimates of the Company's results of operations, downgrades of recommendations, or cessation of publication of research reports on the Company by securities analysts;
- potential or actual sales of blocks of Shares in the market or short selling of Shares, future issues or sales of Shares, and stock market price and volume fluctuations in general;
- the entrance of new competitors or new products in the markets in which the Company operates;
- volatility in the market as a whole or investor perception of the Company's markets and competitors;
- changes in market valuation of similar companies;
- announcements by the Company or its competitors of significant contracts;
- acquisitions, strategic alliances, joint ventures, capital commitments or new products or services;
- additions or departures of key personnel;
- litigation;
- developments regarding intellectual property rights, including patents;
- regulatory, pricing and reimbursement developments in Europe, the United States and other jurisdictions, and new government regulation in general;
- general economic, financial and political conditions;
- disruptions of financial markets as result of a pandemic or other public health crisis, such as COVID-19; and
- the risk factors mentioned above.

The market price of the Shares may be adversely affected by most of the preceding or other factors regardless of the Company's actual results of operations and financial condition.

***The Company will likely not be in a capacity to pay dividends in the near future and intends to retain all earnings.***

The Company has not declared or paid dividends on its Shares in the past. In the near future, the Company's dividend policy will be determined and may change from time to time by determination of the Board of Directors. Any declaration of dividends will be based upon the Company's earnings, financial condition, capital requirements and other factors considered important by the Board of Directors.

Belgian law and the Articles of Association do not require the Company to declare dividends. Currently, the Board of Directors expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future.

***Certain significant shareholders of the Company may have different interests from the Company and may be able to control the Company, including the outcome of shareholder votes.***

The Company has a number of significant shareholders. For an overview of the Company's current significant shareholders see section 3.3.1.

The Company is not aware of shareholders entering into a shareholders' agreement or agreeing to act in concert. Nevertheless, they could, alone or together, have the ability to elect or dismiss directors, and, depending on how broadly the Company's other Shares are held, take certain other shareholders' decisions that require at least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such items are submitted to voting by the shareholders. Alternatively, to the extent that these shareholders have insufficient votes to impose certain shareholders' decisions, they could still have the ability to block proposed shareholders' resolutions that require at least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such decisions are submitted to voting by the shareholders. Any such voting by the shareholders may not be in accordance with the interests of the Company or the other shareholders of the Company.

***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 the Company's 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 Shares or other securities entitling the holder thereof to new Shares, unless such rights are limited or cancelled by resolution of the Company's general shareholders' meeting or, if so authorized by a resolution of such meeting, the Board of Directors. The exercise of preferential subscription rights by certain shareholders not residing in Belgium (including but not limited to 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 Shares are registered or qualified for sale under the relevant legislation or regulatory framework. In particular, the Company may not be able to establish an exemption from registration under the U.S. Securities Act, and the Company is 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

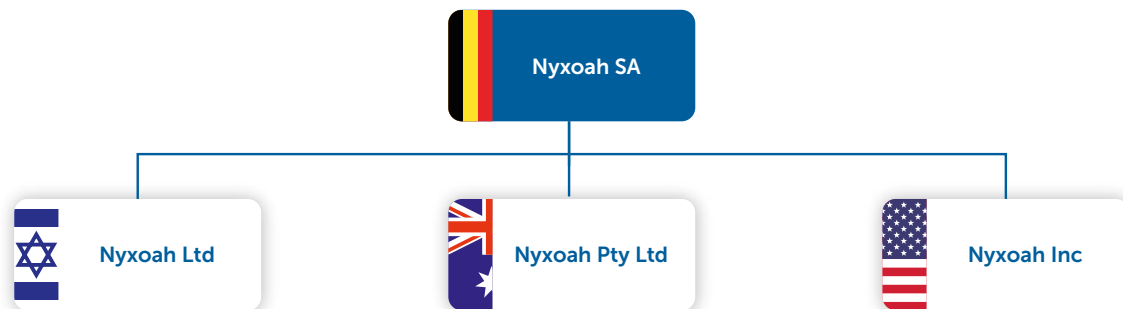
# Shares and Shareholders

## 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 and the preparation of commercial activities.
- Nyxoah Inc. (U.S. subsidiary, incorporated on May 14, 2020), which conducts clinical activities and the preparation of 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 2021

On January 1, 2021, the share capital of the Company amounted to EUR 3,796,047.64 and was represented by 22,097,609 shares.

On February 22, 2021, the Company issued 10,000 shares pursuant to an exercise of subscription rights.

On June 23, 2021, the Company issued 60,000 shares pursuant to an exercise of subscription rights.

On July 7, 2021, the Company issued 2,835,000 shares pursuant to a capital increase in cash at the occasion of the closing of the Nasdaq IPO.

On July 9, 2021, the Company issued (i) 425,250 shares pursuant to a capital increase in cash following the exercise of an option to purchase additional shares in connection with the Company's Nasdaq IPO, as well as (ii) 10,000 shares pursuant to an exercise of subscription rights.

On September 10, 2021, the Company issued 82,500 shares pursuant to an exercise of subscription rights.

On September 30, 2021, the Company issued 27,000 shares pursuant to an exercise of subscription rights.

On October 11, 2021, the Company issued 110,000 shares pursuant to an exercise of subscription rights.

On November 4, 2021, the Company issued 90,000 shares pursuant to an exercise of subscription rights.

On November 25, 2021, the Company issued 25,000 shares pursuant to an exercise of subscription rights.

Consequently, on December 31, 2021, the Company's registered capital amounted to EUR 4,427,369.69, represented by 25,772,359 shares.

In addition, on September 8, 2021, the Board of Directors, in the framework of the authorized capital, issued 1,400,000 subscription rights in the framework of the 2021 Warrants Plan (see below).

### 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 2016 Warrants plan (the "2016 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 2018 Warrants plan (the "2018 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 2020 Warrants plan (the "2020 ESOP Warrants"), and (vi) 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").

The following table provides an overview of the ESOP Warrants that are outstanding (i.e. still exercisable) as of December 31, 2021.

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
2016 ESOP Warrants	1,500	1,395	105	3/11/2016	3/11/2026	2,585.32 <sup>a</sup>	500 <sup>e</sup> common shares per ESOP Warrant	52,500 common shares
2018 ESOP Warrants	525	425	100	12/12/2018	12/12/2028	3,259.91 <sup>b</sup> 5,966.59 <sup>c</sup>	500 <sup>e</sup> common shares per ESOP Warrant	50,000 common shares
2020 ESOP Warrants	550,000	59,500	490,500	21/02/2020	21/02/2030	11.94	1 common share per ESOP Warrant	490,500 common shares
2021 ESOP Warrants	1,400,000	750	1,399,250	08/09/2021	08/09/2031	25.31 <sup>d</sup>	1 common share per ESOP Warrant	1,399,250 common shares
<b>Total</b>								<b>1,992,250 common shares</b>

## Notes:

<sup>a</sup> This results in a subscription price of €5.17 (rounded) per new Share.

<sup>b</sup> This results in a subscription price of €6.52 (rounded) per new Share.

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

<sup>d</sup> For 401,240 2021 ESOP Warrants granted and accepted in 2021.

<sup>e</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 25,772,359 shares of Nyxoah SA outstanding at the end of 2021, 13.365.686 shares were registered shares and 12,406,673 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 2021, the Company made use of the authorized capital when issuing the ESOP 2021 Warrants on September 8, 2021.

### 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 case of 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, the shareholders' structure of the Company (including all shareholders owning 3% or more of Nyxoah SA's shares) on December 31, 2021 was as follows:

Shareholder	Number of shares declared in most recent transparency notification (1)	% of shares at time of most recent transparency notification (2)	% of shares (simulation) based on denominator on December 31, 2021 (3)
Cochlear Investments Pty Ltd (4)	3,947,617	18.43%	15.32%
Cooperatieve Gilde Healthcare III Sub-Holding UA + Cooperatieve Gilde Healthcare III Sub-Holding 2 UA (5)	3,153,822	14.72%	12.24%
Robert Taub + Robelga SRL (6)	2,817,470	13.15%	10.93%
Together Partnership (7)	2,503,500	11.69%	9.71%
Jürgen Hambrecht	1,047,029	4.89%	4.06%
Deerfield Parnters (8)	899,300	3.60%	3.49%
Resmed Inc. (7)	794,235	3.71%	3.08%
Others (9)	10,609,386		41.17%
<b>Total (denominator) on December 31, 2021</b>	<b>25,772,359</b>		<b>100.00%</b>

(1) As a result of transactions that do not need to be disclosed to Nyxoah, 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 transparency notification.

(3) Percentages based on number of shares at time of transparency notification 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) Deerfield Partners, L.P. is controlled by (i) Deerfield Mgmt L.P., which is controlled by J.E. Flynn Capital, LLC and (ii) Deerfield Management Company, L.P., which is controlled by Flynn Management LLC. Both Flynn Management LLC and J.E. Flynn Capital, LLC are controlled by James E. Flynn.

(9) 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. A new Statement of Work was entered into on June 8, 2020 and the Company may decide to enter into other new Statements of Work with Cochlear to continue their collaboration.

The collaboration agreement will end on the date of completion of the last "Statement of Work" or may be terminated with a 30 days' prior written notice from a party to the other party provided that party concludes on reasonable grounds, and after consultation with the "project steering committee", that there is no reasonable prospect of the objectives of the project being achieved. Each party is also entitled to terminate the collaboration agreement with immediate effect upon the occurrence of specific events (e.g. material breach of the collaboration agreement or by a party, insolvency or bankruptcy, etc.). Depending on the project, the Company could pay a break-up fee, if the decision is made to stop the collaboration with Cochlear.

#### 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 Mashlach 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.

<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.



4

# Consolidated Financial Statements



# Consolidated Financial Statements as of December 31, 2021

## 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.

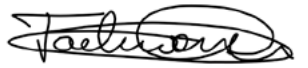
Mont-Saint-Guibert, March 24, 2022

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	
		2021	2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	7	€ 2 020	€ 713
Intangible assets	8	25 322	15 853
Right of use assets	9	3 218	3 283
Deferred tax asset	33	46	32
Other long-term receivables		164	91
		<b>€ 30 770</b>	<b>€ 19 972</b>
<b>Current assets</b>			
Inventory	10	346	55
Trade receivables	11	226	–
Other receivables	11	2 286	1 644
Other current assets	12	1 693	109
Cash and cash equivalents	13	135 509	92 300
		<b>€ 140 060</b>	<b>€ 94 108</b>
<b>Total assets</b>		<b>€ 170 830</b>	<b>€ 114 080</b>

		As at December 31	
	Notes	2021	2020
<b>EQUITY AND LIABILITIES</b>			
<b>Capital and reserves</b>			
Capital	14	4 427	3 796
Share premium	14	228 033	150 936
Share based payment reserve	14	3 127	2 650
Other comprehensive income	14	202	149
Retained loss	14	(87 167)	(60 341)
<b>Total equity attributable to shareholders</b>		<b>€ 148 622</b>	<b>€ 97 190</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Financial debt	16	7 802	7 607
Lease liability	9	2 737	2 844
Pension liability	30	80	37
Provisions		12	–
Deferred tax liability	33	5	–
		<b>€ 10 636</b>	<b>€ 10 488</b>
<b>Current liabilities</b>			
Financial debt	16	554	616
Lease liability	9	582	473
Trade payables	17	3 995	1 190
Current tax liability	33	2 808	–
Other payables	18	3 633	4 123
		<b>€ 11 572</b>	<b>€ 6 402</b>
<b>Total liabilities</b>		<b>€ 22 208</b>	<b>€ 16 890</b>
<b>Total equity and liabilities</b>		<b>€ 170 830</b>	<b>€ 114 080</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	2021	2020
Revenue	19	€ 852	€ 69
Cost of goods sold	19	( 303)	( 30)
<b>Gross profit</b>		<b>€ 549</b>	<b>€ 39</b>
General and administrative expenses	21	(11 113)	(7 522)
Research and development expenses	22	(2 353)	(473)
Clinical expenses	23	(2 706)	(1 053)
Manufacturing expenses	24	(4 760)	(460)
Quality assurance and regulatory expenses	25	(1 463)	(227)
Patents fees & Related	26	(1 062)	(123)
Therapy development expenses	27	(3 599)	(1 864)
Other operating income / (expenses)	28	265	459
<b>Operating loss for the period</b>		<b>€ (26 242)</b>	<b>€ (11 224)</b>
Financial income	31	3 675	62
Financial expense	32	(2 072)	(990)
<b>Loss for the period before taxes</b>		<b>€ (24 639)</b>	<b>€ (12 152)</b>
Income taxes	33	(2 980)	(93)
<b>Loss for the period</b>		<b>€ (27 619)</b>	<b>€ (12 245)</b>
<b>Loss attributable to equity holders</b>		<b>€ (27 619)</b>	<b>€ (12 245)</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	30	(68)	–
<b>Items that may be subsequently reclassified to profit or loss (net of tax)</b>			
Currency translation differences		121	(58)
<b>Total other comprehensive income/(loss)</b>		<b>€ 53</b>	<b>€ (58)</b>
<b>Total comprehensive loss for the year, net of tax</b>		<b>€ (27 566)</b>	<b>€ (12 303)</b>
<b>Loss attributable to equity holders</b>		<b>€ (27 566)</b>	<b>€ (12 303)</b>
Basic loss per share (in EUR)	34	€ (1.161)	€ (0.677)
Diluted loss per share (in EUR)	34	€ (1.161)	€ (0.677)

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

## 4.4 Consolidated Statements Of Changes In Equity

(in thousands)

	Attributable to owners of the parent						
	Common shares	Preferred shares	Share premium	Share based payment reserve	Other comprehensive income	Retained loss	Total
Balance at January 1, 2020	€ 1 122	€ 1 359	€ 47 668	€ 420	€ 207	€ (48 415)	€ 2 361
Loss for the period	-	-	-	-	-	(12 245)	(12 245)
Other comprehensive loss for the period	-	-	-	-	(58)	-	(58)
Total comprehensive loss for the period	-	-	-	-	€ (58)	€ (12 245)	€ (12 303)
Equity-settled share-based payments							
Granted during the period	-	-	-	2 549	-	-	2 549
Exercised during the period	11	-	340	(319)	-	319	351
Conversion of preferred shares to common shares	1 359	(1 359)	-	-	-	-	-
Issuance of shares for cash	1 293	-	108 517	-	-	-	109 810
Transaction cost	-	-	(6 578)	-	-	-	(6 578)
Conversion convertible loan	11	-	989	-	-	-	1 000
Total transactions with owners of the company recognized directly in equity	2 674	(1 359)	103 268	2 230	-	319	107 132
Balance at December 31, 2020	€ 3 796	-	€ 150 936	€ 2 650	€ 149	€ (60 341)	€ 97 190

Attributable to owners of the parent

	Common shares	Preferred shares	Share premium	Share based payment reserve	Other com- prehensive income	Retained loss	Total
Balance at January 1, 2021	€ 3 796	-	€ 150 936	€ 2 650	€ 149	€ (60 341)	€ 97 190
Loss for the period	-	-	-	-	-	(27 619)	(27 619)
Other comprehensive in- come for the period	-	-	-	-	53	-	53
<b>Total comprehensive loss for the period</b>	-	-	-	-	€ 53	€ (27 619)	€ (27 566)
Equity-settled share-based payments							
Granted during the period	-	-	-	1 270	-	-	1 270
Exercised during the period	71	-	2 626	(793)	-	793	2 697
Issuance of shares for cash	560	-	82 058	-	-	-	82 618
Transaction cost	-	-	(7 587)	-	-	-	(7 587)
<b>Total transactions with owners of the company recognized directly in equity</b>	631	-	77 097	477	-	793	78 998
Balance at December 31, 2021	€ 4 427	-	€ 228 033	€ 3 127	€ 202	€ (87 167)	€ 148 622

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	2021	2020
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Loss before tax for the year		€ (24 639)	€ (12 152)
Adjustments for			
Finance income	31	(3 675)	(62)
Finance expenses	32	2 072	990
Depreciation and impairment of property, plant and equipment and right-of-use assets	7,9	783	620
Amortization of intangible assets	8	879	–
Share-based payment transaction expense	15	1 270	2 549
Increase/(decrease) in provisions		( 13)	7
Other non-cash items		(595)	(134)
<b>Cash generated before changes in working capital</b>		<b>€ (23 918)</b>	<b>€ (8 182)</b>
Changes in working capital			
(Increase) in inventory	10	(291)	(55)
(Increase)/decrease in trade and other receivables	11	(2 523)	365
Increase/(decrease) in trade and other payables	17,18	1 670	1 109
<b>Cash generated from changes in operations</b>		<b>€ (25 062)</b>	<b>€ (6 763)</b>
Interests received		–	3
Income tax paid	33	(274)	(104)
<b>Net cash used in operating activities</b>		<b>€ (25 336)</b>	<b>€ (6 864)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchases of property, plant and equipment	7	(1 469)	(562)
Capitalization of intangible assets	8	(10 348)	(10 118)
Increase of long-term deposits		–	(13)
<b>Net cash used in investing activities</b>		<b>€ (11 817)</b>	<b>€ (10 693)</b>

**For the year ended December 31**

	<b>Notes</b>	<b>2021</b>	<b>2020</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Payment of principal portion of lease liabilities	9	(500)	(479)
Repayment of other loan	16	(83)	(63)
Interests paid		(385)	(151)
Repayment of recoverable cash advance	16	(280)	(55)
Proceeds from convertible loan	14	–	1 000
Proceeds from issuance of shares, net of transaction costs	14	77 728	103 583
Other financial costs		(8)	–
Recoverable cash advances received		–	190
<b>Net cash generated from financing activities</b>		<b>€ 76 472</b>	<b>€ 104 025</b>
<b>Movement in cash and cash equivalents</b>		<b>€ 39 319</b>	<b>€ 86 468</b>
Effect of exchange rates on cash and cash equivalents		3 890	(23)
<b>Cash and cash equivalents at January 1</b>	<b>13</b>	<b>€ 92 300</b>	<b>€ 5 855</b>
<b>Cash and cash equivalents at December 31</b>	<b>13</b>	<b>€ 135 509</b>	<b>€ 92 300</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 established three wholly owned subsidiaries: Nyxoah Ltd, a subsidiary of the Company since October 21, 2009 (located in Israel and incorporated on January 10, 2008 under the name M.L.G. Madaf G. Ltd), Nyxoah Pty Ltd since February 1, 2017 (located in Australia) and Nyxoah Inc. since May 14, 2020 (located in the USA).

These consolidated financial statements have been authorized for issue on March 24, 2022 by the Board of Directors of the Company.



## 5.2 Significant 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).

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

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 5.5.1 for the detailed explanation of the going concern.

The Company does not believe that COVID-19 or the Ukraine conflict will have an impact on the Company's activity. The Company does not have business relationships with Russia.

### 5.2.2 New and amended standards and interpretations applicable

#### Effective for the annual periods beginning on January 1, 2021

The Group has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective.

Several amendments and interpretations apply for the first time in 2021, but do not have an impact on the interim condensed consolidated financial statements of the Company:

- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform – Phase 2 (applicable for annual periods beginning on or after January 1, 2021)
- Amendments to IFRS 4 Insurance Contracts – deferral of IFRS 9, effective January 1, 2021
- Amendment to IFRS 16 Leases covid-19-Related Rent Concessions beyond June 30, 2021 (effective April 1, 2021, with early application permitted)

#### New standards not yet effective

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

- a. Amendments to IAS 1 'Presentation of Financial Statements: Classification of Liabilities as current or non-current', effective January 1, 2023
- b. Amendments to IFRS 3 Business Combinations; IAS 16 Property, Plant and Equipment; IAS 37 Provisions, Contingent Liabilities and Contingent Assets as well as Annual Improvements, effective January 1, 2022
- c. Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies, effective January 1, 2023

- d. IFRS 17 'Insurance contracts', effective January 1, 2023
- e. Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates, effective January 1, 2023
- f. Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction, effective January 1, 2023

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, 2021 and 2020.

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 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 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. 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 Equity Instruments**

Equity instruments issued by the Company are recorded at the fair value of the proceeds received, net of transaction costs.

### Convertible loan

The Company has issued a convertible loan on June 26, 2020 (which was converted on September 21, 2020) for a total amount of €1.0 million. The Company identified two components included in the convertible loan agreement: a host loan and an embedded derivative failing the equity classification. The Company has applied the simplification method called the "fair value option". Under this approach, a contract that contains one or more embedded derivatives that would normally be required to be accounted for separately can instead be accounted for jointly with its host instrument at fair value through income statement. Until conversion and at each reporting date, the Company revaluates the fair value of the convertible loan. Upon subsequent evaluation, the element of gains or losses attributable to changes in credit risk should be recognized in other comprehensive income with the remainder recognized in profit or loss. The estimation of the fair value of the convertible loan on initial or subsequent recognition is dependent on the discount rate and maturity date. The fair value measurement of the convertible loan is classified as level 3. The Company used a discount rate of 5.0 % for the initial recognition of the convertible loan.

### 5.2.14 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.

## **5.2.15 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.

## **5.2.16 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 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.

#### **Cash-settled share-based payment transaction**

The Company has two cash-settled share-based payment arrangements in place granted to contracts in return for services delivered. A liability is recognized for the fair value of cash-settled transactions. The fair value is measured initially and at each reporting date up to and including the settlement date, with changes in fair value recognized in general and administrative expenses. The fair value is expensed over the period until the vesting date with recognition of a corresponding liability. The fair value is determined by reference to the pre-money valuation of the Company or the share-price as the cash-settled share-based payment transactions have an exercise price of zero. The cash-settled share-based payment liability has been fully settled during 2021.

#### **5.2.17 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.

#### **5.2.18 Leases**

The Group 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 Group 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 useful life and the lease term. Right-of-use assets are subject to impairment, but no impairment has been identified in fiscal years 2020 and 2021.



### **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 Group 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 Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (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 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 35.

## **5.2.19 Revenue**

The Company has started commercializing the Genio® system in Europe. The Company sells The Genio® system to hospitals and distributors. Revenue from selling the Genio® system is recognized at a point in time when 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. 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 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.

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

Some contracts may include a volume discount in the form of a free Genio® system when a certain purchase volume over a predefined period (generally 12-months) is met or exceeded. The Company will allocate a portion of the transaction price to the free Genio® system based on the relative stand-alone fair value of the Genio® system unless it is reasonably certain that the purchase volume threshold will not be met (considering the constraining estimates of variable consideration).

Some contracts may include a volume discount in the form of a free Genio® system when a certain purchase volume over a predefined period (generally 12-months) is met or exceeded. The Company will apply the most likely amount method or the expected value method to estimate the variable consideration in the contract. The Company will then apply the requirements on constraining estimates of variable consideration in order to determine the amount of the variable consideration that can be included in the transaction price and recognized as revenue.

The contracts with customers do not have right of 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.

#### 5.2.20 Recoverable cash advances and other government grants

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 recognized as income in equal amounts over the expected useful life of the related asset.

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.

The Company also has received research and development incentives in Australia in relation to certain development activities and clinical trials. The Company recognizes the research and development incentives as another receivable and other operating income when it is reasonably certain that all conditions (which are limited and only protective in nature such as having an entity in Australia, conducting R&D activities in Australia) are satisfied and the incentive will be received, which is when the development activities and clinical trials are being performed. See note 11 and 16.1.

### **5.2.21 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.

### **5.2.22 Significant events and transactions of the reporting period**

The company started generating its first commercial sales in July 2020. In the year ended December 31, 2021, the Company generated revenue in Germany, Spain and Belgium. See note 19.

For the year ended December 31, 2021, the Company entered into an exclusive license agreement with Vanderbilt University. This agreement allows the Company to develop new neurostimulation technologies for the treatment of sleep disordered breathing conditions based on inventions and patents owned by Vanderbilt University, which will potentially expand the Company's future pipeline. Under the agreement, the Company paid to Vanderbilt an upfront license issue fee of approximately \$US0.7 million. The Company may be required to make minimum annual royalty payments to Vanderbilt of up to \$US 300,000 in 2024 and 2025, up to \$US 0.5 million in 2026 and 2027, and up to \$US1.0 million in 2028 and each year thereafter, which are creditable against the earned payments of up to an aggregate of \$US13.8 million in connection with patent issuance, clinical studies, regulatory approvals and net sales milestones. The Company may also be required to pay Vanderbilt a low to mid double digit percentage, not to exceed 40.0 %, of any non-royalty sublicensing revenue that the Company receives. The Vanderbilt Agreement, including the royalty obligations thereunder, will continue on a licensed product-by-licensed product and country-by-country basis until the expiration date of the last-to-expire licensed patent in each country. Either the Company or Vanderbilt may terminate the Vanderbilt Agreement in the event the Company fails to make a payment to Vanderbilt, breach of default the Company's diligence obligations or breach or default on any other material term, and if the Company fail to make such payment or cure such breach or default within 60 days of written notice from Vanderbilt. The Company may terminate the agreement by providing 120 days advance notice to Vanderbilt. For the year ended December 31, 2021, the upfront license issue for and past patenting costs relating to this agreement were expensed as occurred. See note 26.

On July 7, 2021, the Company closed its initial public offering in the United States (the "Offering") of 2,835,000 ordinary shares at a price to the public of US\$30 per share for total gross proceeds of US\$85.1 million before deducting underwriting discounts and commissions and estimated offering expenses. In addition, the underwriters of the Offering exercised their option to purchase additional shares in full. The option to purchase additional shares granted to the underwriters was for the purchase of up to an additional 425,250 new ordinary shares, at the public offering price of US\$30

per share, before underwriting discounts and commissions. On July 9, 2021, the Company closed the exercise of this option. This exercise brought the total gross proceeds of the Offering to US\$97.8 million before deducting underwriting discounts and commissions and estimated offering expenses. As part of the IPO, the Company incurred direct-attributable transaction costs of €7.6 million which have been deducted from the share premium. The proceeds from the IPO net of transaction costs amounted to €75.0 million. See note 14.

### 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 €4.4 million at December 31, 2021 (2020: €3.8 million). Total cash and cash equivalents amount to €135.5 million at December 31, 2021 (2020: €92.3 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 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 as other receivables are mainly due by the governments in Australia and the Walloon Region and there is limited risk associated to this receivable.

#### 5.4.3 Foreign Exchange Risk

The Company is exposed to currency risk primarily on USD and AUD currency from the expected future USD and AUD expenses that will be incurred as part of the ongoing and planned marketing, clinical trials and other related expenses. The Company has limited exposure on the NIS currency. A financial risk management policy has been approved whereby the Company decided to hedge its contingency risk exposure on the USD and AUD with a hedging ratio up to 100 %, a hedging timeline up to 24 months and by means of FX forwards, vanilla options (buy and sell), vanilla options combina-

tions without leverage and time is money contracts. 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	2021 rates		2020 rates	
	Closing	Average	Closing	Average
NIS	3.51590	3.82077	3.92758	3.92330
AUD	1.56150	1.57494	1.58636	1.65548
USD	1.13260	1.18274	1.22239	1.15189

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:

(in EUR 000)

Change in foreign exchange rate	Effect on loss (before tax)			Effect on pretax equity			
	NIS	USD	AUD	NIS	USD	AUD	
2021	5%	18	4	64	37	13	284
	-5%	(18)	(5)	(71)	(39)	(14)	(314)
2020	5%	12	(4)	55	83	(7)	208
	-5%	(12)	4	(61)	(91)	8	(230)

#### 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, 2021 amounts to €135.5 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 €14,000 (€-14,000 ).

#### 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.

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

	(in EUR 000)					
				As at December 31		
	2021			2020		
	Lease Liability	Financial Debt	Trade & Other Payable	Lease Liability	Financial Debt	Trade & Other Payable
Less than 1 year	665	578	7 628	560	632	5 313
1 - 5 years	2 441	6 770	–	2 185	4 987	–
5+ years	485	7 262	–	895	4 620	–
<b>Total</b>	<b>3 591</b>	<b>14 610</b>	<b>7 628</b>	<b>3 640</b>	<b>10 239</b>	<b>5 313</b>

### 5.4.6 Fair Value

The carrying amount of cash and cash equivalents, trade receivables, other receivables 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 which consist of foreign currency options are measured at fair value through profit and loss. Fair value is determined by the financial institution and is based on foreign currency forwards rates and the maturity of the instrument.

	(in EUR 000)			
	Carrying value		Fair value	
	As at December 31		As at December 31	
	2021	2020	2021	2020
<b>Financial Assets</b>				
Other long-term receivables (level 3)	164	91	164	91
Trade and other receivables (level 3)	2 512	1 644	2 512	1 644
Other current assets (level 3)	1 693	109	1 693	109
Cash and cash equivalents (level 1)	135 509	92 300	135 509	92 300
<b>Financial liabilities</b>				
Financial debt (level 3)	229	313	194	250
Foreign currency option (level 2)	654	–	654	–
Recoverable cash advances (level 3)	8 127	7 910	8 127	7 910
Trade and other payables (level 1 and 3)	6 974	5 313	6 974	5 313

## 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

As at December 31, 2021, the Company had cash and cash equivalents of €135.5 million. Based on cash flow forecasts for the years 2022 and 2023, which include significant expenses and cash outflows in relation to -among others- the ongoing clinical trials, the continuation of research and development projects, and the scaling-up of the Company's manufacturing facilities, the Company believes that this cash position will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of this Consolidated Financial Statements. In view of the above, and notwithstanding a loss brought forward of €87.2 million as of December 31, 2021, the Board of Directors has decided, after due consideration, that the application of the valuation rules in the assumption of a "going concern" is justified.

#### 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 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 16.1.

### **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 €14.2 million as of December 31, 2021 (2020: €14.2 million). In addition, the Company started capitalizing the development costs for the improved second generation of the Genio® System as from July 2020 for a total amount of €11.4 million (2020: €1.0 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).

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 seven (since the Company is in an early commercial stage) years. For longer periods, a long-term growth rate is calculated and applied to future cash flows projected after the terminal year. 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.

In addition, the Company had two cash-settled share-based payment plans in place, both vested by the end of the reporting period. Estimating the fair value of those cash-settled share-based payment plans require the Company to estimate (i) the pre-money valuation of the Company at December 31, 2019 and (ii) to estimate the vesting period considering the most likely date when an Exit event may occur. The assumptions and models used for estimating the fair-value for share-based payment transactions are disclosed in note 15.



## 5.6 Subsidiaries

For all years ended as at December 31, 2021 and 2020 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 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.

## 5.7 Property, Plant and Equipment

(in EUR 000)	Furniture and office equipment	Leasehold improve- ments	Laboratory equipment	Assets under construction	Total
<b>Cost</b>					
Opening Gross value January 1, 2020	484	192	138	–	814
Additions	178	358	26	–	562
Exchange differences	(2)	–	–	–	(2)
<b>Cost at December 31, 2020</b>	<b>661</b>	<b>550</b>	<b>164</b>	<b>–</b>	<b>1 375</b>
Additions	143	25	667	634	1 469
Transfers	–	(57)	–	57	–
Exchange differences	54	37	27	–	118
<b>Cost at December 31, 2021</b>	<b>858</b>	<b>555</b>	<b>858</b>	<b>691</b>	<b>2 962</b>
<b>Depreciation</b>					
Opening accumulated depreciation January 1, 2020	(347)	(96)	(49)	–	(492)
Depreciation charge	(83)	(74)	(12)	–	(169)
Exchange differences	–	–	–	–	–
<b>Depreciation at December 31, 2020</b>	<b>(430)</b>	<b>(170)</b>	<b>(61)</b>	<b>–</b>	<b>(661)</b>
Depreciation charge	(95)	(41)	(77)	–	(213)
Exchange differences	(38)	(18)	(12)	–	(68)
<b>Depreciation at December 31, 2021</b>	<b>(563)</b>	<b>(229)</b>	<b>(150)</b>	<b>–</b>	<b>(942)</b>
<b>Net book value at December 31, 2020</b>	<b>231</b>	<b>380</b>	<b>103</b>	<b>–</b>	<b>713</b>
<b>Net book value at December 31, 2021</b>	<b>295</b>	<b>326</b>	<b>708</b>	<b>691</b>	<b>2 020</b>

In 2021, acquisitions were mainly related to furniture and office equipment for a total amount of €143,000 (2020: €178,000), to assets under construction for €0.6 million (2020: €0) and to leasehold improvements and laboratory equipment for an amount of €0.7 million (2020: €384,000). The investment in assets under construction relates to the construction of new clean rooms.

The depreciation charge amounts to €213,000 in 2021 and to €169,000 in 2020.

## 5.8 Intangible assets

(in EUR 000)	Development cost	Patents and licenses	Total
<b>Cost</b>			
Opening value at January 1, 2020	5 311	335	5 646
Additions	9 874	256	10 130
Exchange difference	77	–	77
<b>Cost at December 31, 2020</b>	<b>15 262</b>	<b>591</b>	<b>15 853</b>
Additions	10 348	–	10 348
Exchange difference	–	–	–
<b>Cost at December 31, 2021</b>	<b>25 610</b>	<b>591</b>	<b>26 201</b>
<b>Amortization</b>			
Opening amortization at January 1, 2021	–	–	–
Amortization	(837)	(42)	(879)
Exchange difference	–	–	–
<b>Amortization at December 31, 2021</b>	<b>(837)</b>	<b>(42)</b>	<b>(879)</b>
<b>Net book value at December 31, 2020</b>	<b>15 262</b>	<b>591</b>	<b>15 853</b>
<b>Net book value at December 31, 2021</b>	<b>24 773</b>	<b>549</b>	<b>25 322</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 €0.9 million for 2021 and is included in Research and development expenses (€0.8 million) and in Clinical expenses (€125,000). The remaining amortization period of this development asset is 13 years.

The Company continues to incur in 2021 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 €10.3 million and €10.1 million for 2021 and 2020, respectively.

In accordance with the accounting principle, the intangible assets are tested annually for impairment during the development period, prior to the start of its amortization. The Genio® system is currently the unique product line developed by the Company and the Company determined that it has only one cash generating unit for which a value in use analysis has been performed. The discount rate and long-term growth rate applied over the expected term that the asset will generate economic benefits are 11.0 % and 3.5 %, respectively. The discount has 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 seven-year period and an appropriate extrapolation of cash flows beyond 2028. A sensitivity analysis has been performed concluding that a reasonable change in the WACC and/or the long-term 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 generally have lease terms between four and nine years, while motor vehicles generally have lease terms of 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 with low value. The Company applies the "short-term lease" and "lease of low-value assets" recognition exemptions for these leases. We refer to note 35 for the impact on income statement for these "short-term leases" and "leases of low-value assets".

The future cash outflows to which the Company is potentially exposed that are not reflected in the measurement of lease liabilities only consist of leases not yet commenced to which the Company is committed. The impact is \$US 0.7 million.

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, 2020	1 207	192	1 399
Additions	3 194	233	3 427
Disposal	(1 207)	(23)	(1 230)
Exchange difference	(5)	–	(5)
<b>Cost at December 31, 2020</b>	<b>3 189</b>	<b>402</b>	<b>3 591</b>
Additions	24	290	314
Disposal	(13)	(22)	(35)
Exchange difference	243	–	243
<b>Cost at December 31, 2021</b>	<b>3 443</b>	<b>670</b>	<b>4 113</b>
<b>Depreciation</b>			
Opening accumulated depreciation at January 1, 2020	(281)	(52)	(333)
Depreciation charge	(383)	(68)	(451)
Disposal	470	11	481
Exchange difference	(5)	–	(5)
<b>Depreciation at December 31, 2020</b>	<b>(199)</b>	<b>(109)</b>	<b>(308)</b>
Depreciation charge	(453)	(117)	(570)
Disposal	2	19	21
Exchange difference	(38)	–	(38)
<b>Depreciation at December 31, 2021</b>	<b>(688)</b>	<b>(207)</b>	<b>(895)</b>
<b>Net book value at December 31, 2020</b>	<b>2 990</b>	<b>293</b>	<b>3 283</b>
<b>Net book value at December 31, 2021</b>	<b>2 755</b>	<b>463</b>	<b>3 218</b>

In 2021, the Company did enter into new lease agreements for €314,000, which are mainly related to cars, compared to €3.4 million in 2020. The repayments of lease liabilities amounted to €0.5 million (2020: €479,000). The depreciations on the right of use assets amounted to €0.6 million and €451,000 for 2021 and 2020, respectively.

For the year ended December 31, 2021, the Company recognized a gain on disposal of €11,000 (2020: loss on disposal of €6,000).

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

(in EUR 000)	<b>2021</b>	<b>2020</b>
<b>Lease debt at January 1</b>	<b>3 317</b>	<b>1 075</b>
New lease debts	314	3 427
Rent expense paid	(591)	(479)
Accretion of interest	91	47
Disposal	(25)	(743)
Exchange differences	213	(10)
<b>Lease debt at December 31</b>	<b>3 319</b>	<b>3 317</b>

(in EUR 000)	<b>As at December 31</b>	
	<b>2021</b>	<b>2020</b>
Non-current lease liabilities	2 737	2 844
Current lease liabilities	582	473
<b>Total</b>	<b>3 319</b>	<b>3 317</b>

## 5.10 Inventory

(in EUR 000)	<b>As at December 31</b>	
	<b>2021</b>	<b>2020</b>
Work in progress	83	42
Finished goods	263	13
<b>Total Inventory</b>	<b>346</b>	<b>55</b>

The increase in inventory is due to increasing activities. For the year ended December 31, 2021 and 2020, 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.

## 5.11 Trade and Other receivables

(in EUR 000)	As at December 31	
	2021	2020
Trade receivables	226	–
R&D incentive receivable (Australia)	1 616	951
VAT receivable	524	607
Current tax receivable	71	(3)
Other	75	89
<b>Total trade and other receivables</b>	<b>2 512</b>	<b>1 644</b>

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

The increase of €226,000 in trade receivables as at December 31, 2021 is due to generated revenue by the Company in Germany, Spain and Belgium. The increase of €0.7 million in the R&D incentive receivable (Australia) relates to additional R&D incentives claimed during 2021. The current tax receivable relates to excess payment of corporate income tax in Israel.

## 5.12 Other current assets

The increase of €1.6 million in other current assets between 2021 and 2020 is mainly due to an advance payment of €1.1 million for Directors & Officers insurance following initial public offering in the United States (period 25/06/21-18/09/22). In addition, the Company has granted an amount of €160,000 towards an institute under Company's Donation agreement. As of December 31, 2021 the full amount was paid. The institute will have to perform research activities over one year period. In 2021, the Company recognized €16,000 in Therapy Development expenses and an amount of €144,000 will be recognized in 2022.

## 5.13 Cash and cash equivalents

(in EUR 000)	As at December 31	
	2021	2020
Short term deposit	38	34
Current accounts	135 471	92 266
<b>Total cash and cash equivalents</b>	<b>135 509</b>	<b>92 300</b>

## 5.14 Capital, Share Premium, Reserves

### 5.14.1 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 of December 31, 2021, the share capital of the Company amounts to €4.4 million represented by 25,772,359 shares, and the share premium amounts to €242.2 million (before deduction of the transaction costs).

As of December 31, 2020, the share capital of the Company amounts to €3.8 million represented by 22,097,609 shares, and the share premium amounts to €157.5 million (before deduction of the transaction costs).

Evolution of the share capital and share premium ended December 31, 2021 and 2020:

(Number of shares <sup>(1)</sup> except otherwise stated)	Common shares	Preferred shares	Total of shares	Par value (in EUR)	Share capital (in EUR 000)	Share premium (in EUR 000)
January 1, 2020 (adjusted for share split in 2020)	6 728 500	8 150 500	14 879 000	0.17	2 481	47 668
February 21, 2020 - Conversion of preferred shares to common shares	8 150 500	(8 150 500)	–	–	–	–
February 21, 2020 - Capital increase	2 100 000	–	2 100 000	0.21	436	24 624
September 7, 2020 - Exercise warrants	44 500	–	44 500	0.17	8	222
September 21, 2020 - IPO	4 335 000	–	4 335 000	0.17	745	72 950
September 21, 2020 - Convertible loan	65 359	–	65 359	0.17	11	989
September 29, 2020 - Exercise over-allotment warrants	650 250	–	650 250	0.17	112	10 943
October 28, 2020 - Exercise warrants	23 500	–	23 500	0.17	4	117
<b>January 1, 2021 (adjusted for share split in 2020)</b>	<b>22 097 609</b>	<b>–</b>	<b>22 097 609</b>	<b>0.17</b>	<b>3 796</b>	<b>157 514</b>
February 22, 2021 - Exercise warrants	10 000	–	10 000	0.17	2	50
June 23, 2021 - Exercise warrants	60 000	–	60 000	0.17	10	300
July 7, 2021 - IPO	2 835 000	–	2 835 000	0.17	487	71 355

1 The numbers for the common and preferred shares have been retrospectively adjusted for the stock split

July 9, 2021 - IPO	425 250	–	425 250	0.17	73	10 703
July 9, 2021 - Exercise warrants	10 000	–	10 000	0.17	2	118
September 10, 2021 - Exercise warrants	82 500	–	82 500	0.17	14	558
September 30, 2021 - Exercise warrants	27 000	–	27 000	0.17	5	135
October 11, 2021 - Exercise warrants	110 000	–	110 000	0.17	19	755
November 4, 2021 - Exercise warrants	90 000	–	90 000	0.17	15	585
November 25, 2021 - Exercise warrants	25 000	–	25 000	0.17	4	125
<b>December 31, 2021</b>	<b>25 772 359</b>	<b>–</b>	<b>25 772 359</b>	<b>0.17</b>	<b>4 427</b>	<b>242 198</b>

On February 21, 2020, the Company, its shareholders and a new investor (ResMed Inc.) signed a subscription agreement with respect to an aggregate capital increase in the Company of €25.1 million (including share premium) in exchange for 2,100,000 (after conversion) new shares in the Company.

Pursuant to the terms and conditions of the subscription agreement, the shareholders' meeting adopted on February 21, 2020 the following resolutions:

- the conversion of all preferred shares into common shares,
- the cancellation of the outstanding Series B Anti-Dilution Warrants and Series B2 Anti-Dilution Warrants
- share split at a 500:1 ratio to reduce the value per individual share of the Company, and
- the amount of preferred and common shares above are adjusted for share split of 500:1.

On September 7, 2020, pursuant to the exercise of warrants, the aggregate capital of the Company increased with €230,000 (including share premium) in exchange for 44,500 new shares in the Company.

On September 21, 2020, the Company acknowledged the following transactions that were conditionally approved by the shareholders' meeting on September 7, 2020:

The Initial Public Offering (IPO) resulted in an aggregate capital increase in the Company of €73.7 million (including share premium) in exchange for 4,335,000 new shares in the Company at the price of EUR 17 per share. The conversion of a convertible loan of €1.0 million in shares resulted (triggered by the IPO) in an aggregate capital increase in the Company of €1.0 million (including share premium) in exchange for 65,359 new shares in the Company. The convertible loan was entered into between the Company and Noshaq SA ("Noshaq") on June 26, 2020 for an amount of €1.0 million. The convertible loan had a non-compounding interest rate of 2.5 % per annum. The trigger events for a mandatory conversion were (i) an initial public offering, (ii) qualifying financing and (iii) a trade sale. If no mandatory conversion has taken place on or prior to the second anniversary of date of the loan, the Company will be able to opt for an optional conversion to force Noshaq to convert the entire outstanding Principal Amount at nominal value into new shares. The convertible loan was accounted for prior to conversion at fair value with changed in fair value through the profit or loss. Change in fair value of this conversion feature between the issue date and the conversion date is immaterial.

As part of the IPO, the Company incurred direct-attributable transaction costs of €6.5 million which have been deducted from the share premium. The proceeds from the IPO net of transaction costs amounted to €67.2 million. For the other capital increases the transaction costs amounted to €96,000.

On September 29, 2020, pursuant to the exercise of the "Over-allotment Warrant" that was conditionally issued on September 7, 2020, the aggregate capital of the company increased with €11.1 million (including share premium) in exchange for 650,250 new shares in the Company.

On October 28, 2020, pursuant to the exercise of warrants, the aggregate capital of the Company increased with €122,000 (including share premium) in exchange for 23,500 new shares in the Company.

On February 22, 2021, pursuant to the exercise of warrants, the Company issued 10,000 new shares for an aggregate capital increase of €52,000 (including share premium).

On June 23, 2021, pursuant to the exercise of warrants, the Company issued 60,000 new shares for an aggregate capital increase of €310,000 (including share premium).

On July 7, 2021, the Company closed its initial public offering in the United States (the "Offering") of 2,835,000 ordinary shares at a price to the public of US\$30 per share for total gross proceeds of US\$85.1 million before deducting underwriting discounts and commissions and estimated offering expenses. In addition, the underwriters of the Offering exercised their option to purchase additional shares in full. The option to purchase additional shares granted to the underwriters was for the purchase of up to an additional 425,250 new ordinary shares, at the public offering price of US\$30 per share, before underwriting discounts and commissions. On July 9, 2021, the Company closed the exercise of this option. This exercise brought the total gross proceeds of the Offering to US\$97.8 million before deducting underwriting discounts and commissions and estimated offering expenses. As part of the IPO, the Company incurred direct-attributable transaction costs of €7.6 million which have been deducted from the share premium. The proceeds from the IPO net of transaction costs amounted to €75.0 million.

On July 9, 2021, pursuant to the exercise of warrants, the Company issued 10,000 new shares for an aggregate capital increase of €120,000 (including share premium).

On September 10, 2021, pursuant to the exercise of warrants, the Company issued 82,500 new shares for an aggregate capital increase of €0.6 million (including share premium).

On September 30, 2021, pursuant to the exercise of warrants, the Company issued 27,000 new shares for an aggregate capital increase of €140,000 (including share premium).

On October 11, 2021, pursuant to the exercise of warrants, the Company issued 110,000 new shares for an aggregate capital increase of €0.8 million (including share premium).

On November 4, 2021, pursuant to the exercise of warrants, the Company issued 90,000 new shares for an aggregate capital increase of €0.6 million (including share premium).

On November 25, 2021, pursuant to the exercise of warrants, the Company issued 25,000 new shares for an aggregate capital increase of €129,000 (including share premium).

#### 5.14.2 Reserves

The reserves included the share-based payment reserve (see note 15), 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, 2021 and 2020 is detailed in the table below:

(in EUR 000)	Currency translation reserve	Post-employment benefit obligations	Total
Opening value at January 1, 2020	207	-	207
Currency translation differences	(58)	-	(58)
<b>Total other comprehensive income at December 31, 2020</b>	<b>149</b>	<b>-</b>	<b>149</b>
Currency translation differences	121	-	121
Remeasurements of post-employment benefit obligations	-	(68)	(68)
<b>Total other comprehensive income at December 31, 2021</b>	<b>270</b>	<b>(68)</b>	<b>202</b>

## 5.15 Share-Based compensation

The Company has five outstanding equity-settled share-based incentive plans, including (i) the 2013 warrants plan (the 2013 Plan), (ii) the 2016 warrants plan (the 2016 Plan), (iii) the 2018 warrants plan (the 2018 Plan), (iv) the 2020 warrants plan (the 2020 plan) and (v) the 2021 warrants plan (the 2021 plan). The Company had an extraordinary shareholders' meeting on February 21, 2020, where it was decided to achieve a share split in a ratio of 500:1. Per Warrant issued before February 21, 2020, 500 common shares will be issuable. 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:

Number of shares (after share split) warrants give right to across all plans	2021	2020
Outstanding at January 1	1 007 500	1 143 500
Granted	401 240	567 000
Forfeited/Cancelled	(750)	(635 000)
Exercised	(414 500)	(68 000)
<b>Outstanding at December 31</b>	<b>993 490</b>	<b>1 007 500</b>
<b>Exercisable at December 31</b>	<b>693 310</b>	<b>1 007 500</b>

In addition, the Company had one cash-settled share-based payment transaction which is explained further below.

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

#### 2013 Plan

On May 3, 2013, the shareholders' meeting of the Company approved the issuance of 340 warrants, giving each the right to subscribe to one common share of the Company before share split (500 shares after the share split). These warrants are valid until May 3, 2023. In addition, on December 23, 2014, the shareholders' meeting of the Company issued 300 additional warrants under the 2013 Plan.

The Shareholders' Meeting granted a special proxy to the Board of Directors of the Company in order to (i) identify the beneficiaries, (ii) offer the issued warrants to workers of the Company, and (iii) determine the exercise price of the concerned warrants.

The exercise price of each warrant is €2,585.51 before share split for warrants granted before April 2020. Taking into consideration the share split, this would result in an exercise price of €5.17 per share. The exercise price of each warrant is €5,966.59 before share split for warrants granted in April 2020. Taking into consideration the share split, this would result in an exercise price of €11.94 per share. The key features of the warrants granted under the 2013 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 five 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. 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, 1 warrant was granted under the 2013 Plan with an exercise price of €5,966.59 (€11.94 per share after the share split).

The status of the 2013 warrant plan at December 31, is as follows:

<b>Number of shares (after share split) warrants give right to for Plan 2013</b>	<b>2021</b>	<b>2020</b>
Outstanding at January 1	80 500	208 000
Granted	-	500
Forfeited/Cancelled	-	(83 500)
Exercised	(80 500)	(44 500)
<b>Outstanding at December 31</b>	<b>-</b>	<b>80 500</b>
<b>Exercisable at December 31</b>	<b>-</b>	<b>80 500</b>

With respect to the warrants exercised in 2021, a total of 161 warrants representing 80,500 shares after share split, were exercised. There are no outstanding warrants as per December 31, 2021.

## 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>2021</b>	<b>2020</b>
Outstanding at January 1	217 500	742 500
Granted	-	-
Forfeited/Cancelled	-	(501 500)
Exercised	(165 000)	(23 500)
<b>Outstanding at December 31</b>	<b>52 500</b>	<b>217 500</b>
<b>Exercisable at December 31</b>	<b>52 500</b>	<b>217 500</b>

With respect to the warrants exercised in 2021, a total of 330 warrants representing 165,000 shares were exercised. Since the 2016 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, 2021 equals 105 representing 52,500 shares.

## 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 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>2021</b>	<b>2020</b>
Outstanding at January 1	159 500	193 000
Granted	-	16 500
Forfeited/Cancelled	-	(50 000)
Exercised	(109 500)	-
<b>Outstanding at December 31</b>	<b>50 000</b>	<b>159 500</b>
<b>Exercisable at December 31</b>	<b>50 000</b>	<b>159 500</b>

With respect to the warrants exercised in 2021, a total of 219 warrants representing 109,500 shares were exercised. 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, 2021 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>2021</b>	<b>2020</b>
Outstanding at January 1	550 000	-
Granted	-	550 000
Forfeited/Cancelled	-	-
Exercised	(59 500)	-
<b>Outstanding at December 31</b>	<b>490 500</b>	<b>550 000</b>
<b>Exercisable at December 31</b>	<b>490 500</b>	<b>550 000</b>

With respect to the warrants exercised in 2021, a total of 59,500 warrants representing 59,500 shares were exercised. The remaining number of warrants as per December 31 2021 equals 490,500 representing 490,500 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.

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

Number of shares/warrants give right to for Plan 2021	2021	2020
Outstanding at January 1	-	-
Granted	401 240	-
Forfeited/Cancelled	(750)	-
Exercised	-	-
Outstanding at December 31	400 490	-
Exercisable at December 31	100 310	-

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

The fair value of the plan is expensed over the vesting period. The share-based compensation expense for all vested warrants recognized in the income statement was €1.3 million for the year ended December 31, 2021 and €2.5 million for the year ended December 31, 2020. 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.

Total	2021	2020
Exercisable Warrants at December 31	591 015	550 915
Shares representing the Exercisable Warrants at December 31	693,310	1,007,500
Weighted average exercise price per share	13.10	9.17
Weighted average share price at the date of exercise	21.45	-

### 5.15.3 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, 2019, 2020 and 2021 related to the 2013 warrant plan, the 2016 warrant plan, the 2018 warrant plan, the 2020 warrant plan and the 2021 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 2013 (grant 2018)	Plan 2018 (grant 2020)	Plan 2020 (grant 2020)	Plan 2021 (grant Sept. 17 2021)	Plan 2021 (grant Oct. 27 2021)
Return Dividend	0%	0%	0%	0%	0%	0%	0%
Expected volatility	66.92%	56.32%	56.32%	56.32%	56.32%	51.30%	51.50%
Risk-free interest rate	0.35%	-0.20%	-0.20%	-0.20%	-0.20%	-0.36%	-0.18%
Expected life	3	3	3	3	3	3	3
Exercise price	5.17	6.52	11.94	11.94	11.94	25.31	25.31
Stock price	1.09	10.24	10.20	10.20	10.20	25.75	20.50
Fair value	0.10	5.30	3.31	3.31	3.31	9.22	5.94

The weighted average fair value of warrants granted during the year was €8.31 in 2021 and €3.31 in 2020. The weighted average remaining contractual life for the share options outstanding as at December 31 was 3.7 in 2021 and 3.4 in 2020.

### 5.15.4 Cash-settled share-based payment transactions

The Company has signed a service agreement with ActuaRisk Consulting SRL in 2014 and amended afterwards for an indefinite period which includes a variable compensation for the services delivered under the service agreement. The variable compensation will become payable upon an "Exit of the Company" ("Exit"), unless ActuaRisk Consulting SRL becomes a bad leaver as defined in the service agreement prior to the Exit. The variable compensation can be invoiced by ActuaRisk Consulting SRL, as from the 6th month following an Exit at an amount equal to the closing trading of the Shares of the company at the time of invoice multiplied by the number of the then outstanding shares adjusted with then outstanding warrants and multiplied by a variable % between 0.0% and 0.5% depending on the

exit value. The exercise period has no maturity. The vesting period is variable and starts at the signing date of the service agreement and the expected date of an Exit. The vesting term was estimated at December 31, 2019 at 82 months. The IPO completed on September 21, 2020 qualifies as an Exit under the service agreement and as such the rights are vested at December 31, 2020.

This arrangement qualifies as a cash-settled share-based payment transaction. The arrangement with ActuaRisk Consulting SRL has vested in full on September 21, 2020 and was exercised on July 12, 2021 for an amount of €3.7 million. The liability for the cash-settled share-based payment arrangements amounts to €1.8 million at December 31, 2020 with an expense recognized in general and administrative expense of €1.9 million (2020: €2.0 million).

## 5.16 Financial Debt

Financial debt consists of recoverable cash advances, and other loans. The related amounts as at December 31, 2021 and 2020, can be summarized as follows :

(in EUR 000)	As at December 31	
	2021	2020
Recoverable cash advances - Non-current	7 656	7 419
Recoverable cash advances - Current	471	491
<b>Total Recoverable cash advances</b>	<b>8 127</b>	<b>7 910</b>
Other loan - Non-current	146	188
Other loan - Current	83	125
Foreign currency option - current	654	–
<b>Total other loans</b>	<b>229</b>	<b>313</b>
Non-current	7 802	7 607
Current	554	616
<b>Total Financial Debt</b>	<b>8 356</b>	<b>8 223</b>

### 5.16.1 Financial debt related to recoverable cash advances

#### Recoverable cash advances received

As at December 31, 2021, the details of recoverable cash advances received can be summarized as follows:

(in EUR 000)	Contractual advances	Advances received	Amounts reimbursed
Sleep apnea device (6472)	1 600	1 600	450
First articles (6839)	2 160	2 160	184
Clinical trial (6840)	2 400	2 400	135
Activation chip improvements (7388)	1 467	1 467	29
<b>Total</b>	<b>7 627</b>	<b>7 627</b>	<b>798</b>

- 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 turnover dependent reimbursement is based on 0.224% of the sales achieved by June 2037. The Company has notified his intention to exploit the results of this project before 2015. As a result, cumulated fixed reimbursements amount to €450,000 (excluding interests) out of which €30,000 was reimbursed in 2021 and €40,000 in 2020.
- The Convention 6839 "First Articles" for a total amount of €2.2 million was signed on December 5, 2012. At January 1, 2015, the advance received amounted to €1.9 million. The outstanding amount of €226,000 has been received in 2018. 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. The Region has informed the Company that the fixed reimbursement related to 2019 and 2020 will be due in 2021. As at December 31, 2021, cumulated fixed reimbursements amount to €184,000 (excluding interests) out of which €100,000 was reimbursed in 2021 and €0 in 2020.
- The Convention 6840 "Clinical Trial" for a total amount of €2.4 million was signed on December 6, 2012. As at December 31, 2021, the advance received amounted to €2.4 million. The turnover dependent reimbursement is based on 0.336% of the sales achieved by December 2038. The Company has notified to the Region its decision about the exploitation of the results in the course of 2018. Fixed reimbursements for this convention started in 2021 and amount to €135,000 (excluding interests) as at December 31, 2021.
- 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, 2021, the advance received amounted to €1.5 million. The turnover dependent reimbursement is based on 0.45% of the sales achieved to December 2038. In 2019, the Company has notified to the Region its decision about the exploitation of the results. As at December 31, 2021, cumulated fixed reimbursements amount to €29,000 (excluding interests) out of which €14,000 was reimbursed in 2021 and €15,000 in 2020.

### 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%.



As the period for reimbursements is up to 2037/2038, the initial recognition of the liability reflects a reimbursement of the recoverable cash advances which represents 2 times the amount received as detailed in the table below:

(in EUR 000)	<b>As at December 31</b>	
	<b>2021</b>	<b>2020</b>
Recoverable cash advances received	7 627	7 627
Amounts to be reimbursed (2 times)	15 254	15 254
Amounts reimbursed at year-end (interests included)	(873)	(582)
<b>Total Recoverable cash advances (undiscounted)</b>	<b>14 381</b>	<b>14 672</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>2021</b>	<b>2020</b>
Contract 6472	1 452	1 421
Contract 6839	2 333	2 214
Contract 6840	2 630	2 592
Contract 7388	1 712	1 683
<b>Total recoverable cash advances</b>	<b>8 127</b>	<b>7 910</b>
Non-current	7 656	7 419
Current	471	491
<b>Total recoverable cash advances</b>	<b>8 127</b>	<b>7 910</b>

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

(in EUR 000)	<b>2021</b>	<b>2020</b>
As at January 1	7 910	7 148
Advances received	-	190
Advances reimbursed (excluding interests)	(280)	(55)
Initial measurement and re-measurement	(385)	(145)
Accretion of interest	882	772
<b>As at December 31</b>	<b>8 127</b>	<b>7 910</b>

The discounting impact is included and presented in the financial expenses and amounted to €0.9 million (2020: €0.8 million). The initial measurement and re-measurement are included in other operating income and amounted to €385,000 for the year ended December 31, 2021 (2020: €145,000).

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 2021 (in EUR 000)	Variation of revenue projections		
	Variation of discount rates *	-25%	0%
-25%	8 363	9 275	9 509
0%	7 300	8 127	8 392
25%	6 417	7 168	7 449

\* 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.

### 5.16.2 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 €229,000 at 31 December 2021 and €313,000 at 31 December 2020. The payments have been postponed for three months due to COVID-19 during 2020 so the maturity date of the loan has been extended until June 30, 2024. The total repayments for the year ended December 31, 2021, amounted to €83,000 (2020: €63,000).

## 5.17 Trade payables

(in EUR 000)	As at December 31	
	2021	2020
Payables	2 394	815
Invoices to be received	1 601	375
<b>Total Trade payables</b>	<b>3 995</b>	<b>1 190</b>

The increase in total trade payables of €2.8 million as at December 31, 2021 is due to the increase in trade payables of €1.6 million and an increase in invoices to be received of €1.2 million.

The increase in invoices to be received largely relates to the increase in operating and R&D activities. The company normally settles its trade payables in 30 days.

## 5.18 Other payables

(in EUR 000)	As at December 31	
	2021	2020
Holiday pay accrual	493	376
Salary	870	382
Accrued expenses	1 485	1 244
Foreign currency option - current	654	-
Other	131	2 121
<b>Total other payables</b>	<b>3 633</b>	<b>4 123</b>

The decrease of other payables as at December 31, 2021, compared to December 31, 2020, is mainly due to the decrease of liability due to the payment of the variable compensation of a cash-settled share-based payment transaction for an executive member. On July 12, 2021, ActuaRisk Consulting SRL issued an invoice related to its variable compensation for a total amount of €3.7 million, of which €1.8 million was included in other payables as at December 31, 2020.

This decrease was offset by an increase of €0.6 million in salary and holiday pay expenses due to the growth of the company personnel in 2021 and the fair value of the foreign currency option which was entered into by the company during 2021.

### 5.18.1 Derivatives

The Company is exposed to currency risk primarily on USD and AUD currency from the expected future USD and AUD expenses that will be incurred as part of the ongoing and planned marketing, clinical trials and other related expenses. The Company has limited exposure on the NIS currency. A financial risk management policy has been approved whereby the Company decided to hedge its contingency risk exposure on the USD and AUD with a hedging ratio up to 100 %, a hedging timeline up to 24 months and by means of FX forwards, vanilla options (buy and sell), vanilla options combinations without leverage and time is money contracts.

As at December 31, 2021, the Company has entered into several FX vanilla options (buy and sell) for which the notional amounts are detailed in the table below:

(in EUR 000)	As at December 31	
	2021	2020
call USD (in USD)	34 350	-
put USD (in USD)	(3 000)	-
call EUR (in EUR)	2 500	-
put EUR (in EUR)	(30 000)	-

The following table shows the carrying amount of derivative financial instruments measured at fair value in the statement of the financial position including their levels in the fair value hierarchy:

(in EUR 000)	As at December 31, 2021			
	Level I	Level II	Level III	Total
Foreign currency option	–	654	–	654
<b>Total</b>	–	654	–	654

Fair value is determined by the financial institution and is based on foreign currency forwards rates and the maturity of the instrument. All FX vanilla options are classified as current liabilities as their maturity date is within the next twelve months

The change in the balance is detailed as follows:

(in EUR 000)	2021	2020
Opening value at January 1	–	–
New contracts	338	–
Fair value adjustments	316	–
<b>Closing value at December 31</b>	<b>654</b>	–

The fair value of above options amount to €0.7 million as per December 31, 2021 with a financial loss recognized in the consolidated income statement of €316,000.

## 5.19 Revenue and cost of goods sold

For the year ended December 31, 2021, the Company generated revenue for the amount of €0.9 million compared to €69,000 for the year ended December 31, 2020. 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 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) were generated in Germany (€0.8 million, 2020: €69,000), Spain (€24,000) and Belgium (€20,000). For the year ended December 31, 2021, the Company has five customers with individual sales larger than 10% of the total revenue (2020: one customer).

Cost of goods sold for the year ended December 31, 2021 and 2020:

(in EUR 000)	For the year ended December 31	
	2021	2020
Purchases of goods and services	594	85
Inventory movement	(291)	(55)
<b>Total cost of goods sold</b>	<b>303</b>	<b>30</b>

## 5.20 Operating expenses

The tables below detail the operating expenses for the year ended December 31, 2021 and 2020:

(in EUR 000)	Total cost	Capitalized	Operating expense for the year
General and administrative expenses	11 113	–	11 113
Research and development	5 834	(3 481)	2 353
Clinical expenses	9 547	(6 841)	2 706
Manufacturing expenses	5 042	(282)	4 760
Quality assurance and regulatory expense	1 822	(359)	1 463
Patents fees & related expenses	1 062	–	1 062
Therapy development expenses	3 599	–	3 599
Other operating expenses/(income)	(880)	615	(265)
<b>For the year ended December 31, 2021</b>	<b>37 139</b>	<b>(10 348)</b>	<b>26 791</b>

(in EUR 000)	Total cost	Capitalized	Operating expense for the year
General and administrative expenses	7 522	–	7 522
Research and development expenses	3 066	(2 593)	473
Clinical expenses	4 316	(3 263)	1 053
Manufacturing expenses	3 802	(3 342)	460
Quality assurance and regulatory expenses	1 474	(1 247)	227
Patents fees & related	379	(256)	123
Therapy development expenses	1 864	–	1 864
Other operating expenses/(income)	(1 032)	573	(459)
<b>For the year ended December 31, 2020</b>	<b>21 391</b>	<b>(10 128)</b>	<b>11 263</b>

## 5.21 General and Administrative expenses

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	
	2021	2020
Staff costs	2 132	3 015
Consulting and contractors' fees	6 001	2 883
Legal fees	402	201
Rent	247	89
Facilities	141	116
Depreciation and amortization expense	710	599
ICT	363	234
Travel	158	134
Other	959	251
<b>Total general and administrative expenses</b>	<b>11 113</b>	<b>7 522</b>

General and administrative expenses increased by €3.6 million, or 47.7 % from €7.5 million for the year ended December 31, 2020 to €11.1 million for the year ended December 31, 2021 mainly due to an increase in consulting and contractors' fees and insurance. The increase in consulting and contractors' fees includes variable compensations of €2.0 million for the year ended December 31, 2020 and €1.9 million for the year ended December 31, 2021 related to a cash-settled share based payment transaction. There was also an increase of consultant services to support the company in legal, finance, tax and IT matters due to company growth and an increase in an insurance expense by €1.0 million, compared to the year ended December 31, 2020 due to Directors & Officers insurance following initial public offering in the United States. The increase in other expenses was mainly due to increase in recruitment fees and board members remuneration. This increase was offset by a decrease in staff cost for the year ended December 31, 2021 due to decrease in share based payment to CEO of the Company. See note 36.

## 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 and outsourced development expenses.

(in EUR 000)	For the year ended December 31	
	2021	2020
Staff costs	2 099	1 304
Outsourced developments	2 754	1 717
Consulting and contractors' fees	56	–
Depreciation and amortization expense	827	20
Travel	55	4
Other	43	21
Capitalized costs	(3 481)	(2 593)
<b>Total research and development expenses</b>	<b>2 353</b>	<b>473</b>

Before capitalization of €3.5 million for the year ended December 31, 2021 and €2.6 million for the year ended December 31, 2020, research and development expenses increased by €2.8 million or 90.3 % from €3.1 million for the year ended December 31, 2020, to €5.8 million for the year ended December 31, 2021, due to an increase in staff to support our R&D activities and in outsourced developments. The Company started as of January 2021 to amortize its intangible assets. This explains the significant increase of depreciation expenses for the year ended December 31, 2021.

## 5.23 Clinical expenses

Clinical expenses consist primarily of clinical studies related to the development of our Genio® system, consulting services and other costs associated with clinical activities. These expenses include employee compensation, clinical trial management and monitoring, payments to clinical investigators, data management and travel expenses for our various clinical trials.

(in EUR 000)	For the year ended December 31	
	2021	2020
Staff costs	3 431	1 531
Consulting and contractors' fees	1 187	748
Clinical studies	3 923	1 731
Depreciation and amortization expense	125	–
Travel	358	51
Other	523	255
Capitalized costs	(6 841)	(3 263)
<b>Total clinical expenses</b>	<b>2 706</b>	<b>1 053</b>

Before capitalization of €6.8 million for the year ended December 31, 2021, and €3.3 million for the year ended December 31, 2020, clinical expenses increased by €5.2 million, or 121.2 %, from €4.3 million for the year ended December 31, 2020 to €9.5 million for the year ended December 31, 2021. The increase in the expenses was mainly due to an increase in staff, consulting and study activities of the on-going DREAM IDE in the United States, completion of the BETTER SLEEP trial implantations and continuous recruitment for the EliSA trial. Other clinical expenses for the year ended December 31, 2021 mainly increased due to recruitment and training costs.

## 5.24 Manufacturing expenses

(in EUR 000)	For the year ended December 31	
	2021	2020
Staff costs	1 625	1 211
Consulting and contractors' fees	279	–
Manufacturing	2 693	2 427
Travel	36	25
Other	409	139
Capitalized costs	(282)	(3 342)
<b>Total manufacturing expenses</b>	<b>4 760</b>	<b>460</b>

Manufacturing expenses consist primarily of employee compensation, acquisition costs of the components of the Genio® system, as well as distribution-related expenses such as logistics and shipping costs for non-commercial units of the Genio® system.

Before capitalization of €282,000 for the year ended December 31, 2021, and €3.3 million for the year ended December 31, 2020, manufacturing expenses increased by €1.2 million, or 32.6 % from €3.8 million in 2020 to €5.0 million for the year ended December 31, 2021. The increase in the expenses was mainly due to an increase in staff, in production and engineering team to support capacity and yield improvement. In addition, manufacturing expenses increased for the year ended December 31, 2021, compared to the year ended December 31, 2020 due to the increase in demand of our Genio® system for non-commercial purposes (clinical trials, development activities, etc.) and, therefore, the increase of production costs associated.

Manufacturing costs (including material and supplier costs only, staff costs excluded) are as follows:

(in EUR 000)	For the year ended December 31	
	2021	2020
Implantable stimulator	2 224	1 660
Activation chip	165	228
Disposable patch	243	102
External stimulator	84	69
Other	(23)	368
Capitalized costs	(202)	(2 254)
<b>Total</b>	<b>2 491</b>	<b>173</b>



## 5.25 Quality assurance and Regulatory expenses

Quality assurance and regulatory expenses consist primarily of quality control, quality assurance and regulatory expenses for activities non-related to the production of commercial units of the Genio® system. These expenses include employee compensation, consulting, testing and travel expenses related to the QA/RA department.

(in EUR 000)	For the year ended December 31	
	2021	2020
Staff costs	826	641
Consulting and contractors' fees	440	291
QA & Regulatory	511	542
Travel	6	0
Other	39	–
Capitalized costs	(359)	(1 247)
<b>Total quality assurance and regulatory expenses</b>	<b>1 463</b>	<b>227</b>

Before capitalization of €359,000 for the year ended December 31, 2021 and €1.2 million for the year ended December 31, 2020, quality assurance and regulatory expenses increased by €348,000, or 23.6 % from €1.5 million for the year ended December 31, 2020 to €1.8 million for the year ended December 31, 2021. The increase in the expenses was mainly due to an increase in staff, consulting and QA & regulatory activities to support manufacturing scaling up process.

## 5.26 Patents fees and related expenses

Patents fees and related expenses consist primarily of compensation for personnel, spending related to the protection of company's intellectual property, prosecution costs and travel expenses.

(in EUR 000)	For the year ended December 31	
	2021	2020
Staff costs	4	53
Legal fees	1 054	320
Other	4	6
Capitalized costs	–	(256)
<b>Total IP, trademark &amp; innovations expenses</b>	<b>1 062</b>	<b>123</b>

Before capitalization of €0 for the year ended December 31, 2021 and €256,000 for the year ended December 31, 2020, patent fees and related expenses increased by €0.7 million, or 180.1 % from €379,000 for the year ended December 31, 2020, to €1.1 million for the year ended December 31, 2021, due to expenses related the in-licensing agreement with Vanderbilt University.

## 5.27 Therapy development expenses

Therapy development expenses consist primarily of compensation for personnel, spending related to direct sale force, market access and reimbursement activities. Other therapy development expenses include training physicians, travel expenses, conferences, market research, advertising and public relations.

(in EUR 000)	For the year ended December 31	
	2021	2020
Staff costs	1 586	696
Consulting and contractors' fees	1 464	813
Facilities	8	8
Clinical studies	–	150
Travel	174	123
Other	367	74
<b>Total therapy development expenses</b>	<b>3 599</b>	<b>1 864</b>

Therapy development expenses increased by €1.7 million or 93.1 % from €1.9 million for the year ended December 31, 2020 to €3.6 million for the year ended December 31, 2021. The increase in the expenses was mainly due to an increase in staff and consulting, to support the ongoing commercialization in Europe. Other therapy development expenses for the year ended December 31, 2021 mainly increased due to increased recruitment costs.

## 5.28 Other operating expenses

The Company had other operating expenses of €265,000 for the year ended December 31, 2021 compared to €459,000 for the year ended December 31, 2020, the evolution being mainly due to the impact of the initial measurement and re-measurement of the financial debt. The impact of the recoverable cash advances is further detailed in note 16.1.

(in EUR 000)	For the year ended December 31	
	2021	2020
Recoverable cash advances		
Initial measurement and re-measurement	385	147
R&D incentives (Australia)	645	1 000
Capitalization of R&D incentive	(615)	(573)
Other income/(expenses)	(150)	(115)
<b>Total Other Operating Income/(Expenses)</b>	<b>265</b>	<b>459</b>

The other operating expenses contain the R&D Incentive (Australia) that relates to an incentive to be received on development expenses incurred by the subsidiary in Australia. For the year ended December 31, 2021, €0.6 million has been deducted from the expenses capitalized and for the year ended December 31, 2020, €0.6 million has been deducted from the expenses capitalized in relation to this R&D Incentive.

The R&D Incentive (Australia) relates to incentive to be received on development expenses incurred by the subsidiary in Australia. The R&D incentive of €0.6 million for the year ended December 31, 2020 has been deducted from the clinical expenses capitalized.

## 5.29 Employee Benefits

(in EUR 000)	For the year ended December 31	
	2021	2020
Salaries	8 373	4 577
Social charges	793	562
Fringe benefits	297	104
Defined contribution plan	335	249
Holiday pay	390	273
Share-based payment (see note 15)	1 270	2 548
Other	246	138
<b>Total employee benefits</b>	<b>11 704</b>	<b>8 451</b>

(in EUR 000)	For the year ended December 31	
	2021	2020
General and administrative expenses	2 132	3 015
Research & Development expenses	2 099	1 304
Clinical expenses	3 431	1 531
Operation & Manufacturing expenses	1 625	1 211
QA expenses	826	641
Other expenses (therapy development, patents, etc.)	1 591	749
<b>Total employee benefits</b>	<b>11 704</b>	<b>8 451</b>

As at December 31, 2021, the Company employed 105.8 (2020: 71.9) 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, 2021 and 2020:

(in FTE's)	As at December 31	
	2021	2020
General & Administration	15.8	9.0
IP & Trademark	1.0	0.0
Research & Development	17.0	10.8
Clinical & Regulatory Affairs	22.2	23.2
Quality Assurance & Regulatory	14.0	7.9
Operations	24.0	15.0
Therapy Development (including the sales team)	11.8	6.0
<b>Total</b>	<b>105.8</b>	<b>71.9</b>

As at December 31, 2021, the Company had 37.8 full-time equivalents located in Belgium (2020: 20.2), 46.0 full-time equivalents located in Israel (2020: 36.7), 7.0 full-time equivalents located in Australia (2020: 5.0), and 15.0 full-time equivalents located in USA (2020: 10.0).

## 5.30 Pension Schemes

### 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 amount to €260,000 (2020: €171,000).

### 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 €80,000 (2020: €37,000) has been recorded for the net benefit obligation in 2021.

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 17 years as at December 31, 2021. 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 €80,000 as of December 31, 2021 (2020: €37,000):

(in EUR 000)	2021	2020
Net defined benefit liability at January 1	37	30
Defined benefit cost included in profit or loss	95	93
Total remeasurement included in OCI	68	–
Employer contributions	(120)	(77)
Transfer reserves (terminated participants)	–	(9)
<b>Net defined benefit liability at December 31</b>	<b>80</b>	<b>37</b>

The gross defined benefit liability is as follows:

(in EUR 000)	2021	2020
Gross defined benefit liability at January 1	248	209
Current service cost	95	90
Interest cost	0	1
Administrative expenses	(1)	–
Taxes on contributions	(14)	(8)
Transfer reserves (terminated participants)	–	(60)
Actuarial gain due to change in financial assumptions	(87)	–
Actuarial loss due to change in experience assumptions	253	16
<b>Gross defined benefit liability at 31 December</b>	<b>494</b>	<b>248</b>

The fair value of the plan assets is as follows:

(in EUR 000)	<b>2021</b>	<b>2020</b>
Fair value plan assets at January 1	211	179
Interest income	0	2
Employer contributions	120	77
Administrative expenses	(1)	–
Taxes on contributions	(14)	(8)
Transfer reserves (terminated participants)	–	(55)
Actuarial gain on fair value of the plan assets	98	16
<b>Fair value plan assets at December 31</b>	<b>414</b>	<b>211</b>

The number of members and the average age of the members is as follows:

	<b>For the year ended December 31</b>	
	<b>2021</b>	<b>2020</b>
Active members	24	14
Average age	41	43

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>2021</b>	<b>2020</b>
Discount rate	1.4%	0.1%
Inflation rate	2.0%	2.0%
Salary increase (in excess of inflation)	1.0%	0.0%
Withdrawal rate based on age (minimum)	0.0%	1.5%
Withdrawal rate based on age (maximum)	12.0%	8.5%

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>2021</b>	<b>2020</b>
Increase of 0.25% in the discount rate	(17)	(2)
Decrease of 0.25% in the discount rate	18	2

The expected employer contributions for the year 2022 amounts to €166,000.

The total expected benefit payments are:

(in EUR 000)	<b>As at December 31, 2021</b>
In the next 12 months	5
Between 2 and 5 years	53
Between 6 and 10 years	79
<b>Expected total benefit payments</b>	<b>137</b>

## 5.31 Financial income

(in EUR 000)	<b>For the year ended December 31</b>	
	<b>2021</b>	<b>2020</b>
Interests	1	3
Exchange differences	3 648	59
Other	26	–
<b>Total financial income</b>	<b>3 675</b>	<b>62</b>

For the year ended December 31, 2021, exchange gains amount to €3.6 million, mainly due to the revaluation of the Company's USD cash balance.

## 5.32 Financial Expense

(in EUR 000)	<b>For the year ended December 31</b>	
	<b>2021</b>	<b>2020</b>
Recoverable cash advances, Accretion of interest	882	772
Interest and bank charges	296	151
Interest on lease liabilities	90	47
Exchange differences	448	20
Other	356	–
<b>Total Financial expense</b>	<b>2 072</b>	<b>990</b>

For the year ended December 31, 2021, the other financial expenses mainly relate to the fair value adjustment on financial instruments for €316,000. More information can be found in note 16.3.

The discounting impact of the recoverable cash advances is further detailed in note 18.1 above.

### 5.33 Income taxes and deferred taxes

The major components of income tax expense for the years ended December 31, 2021 and 2020 are as follows:

(in EUR 000)	For the year ended December 31	
	2021	2020
Current tax	(2 984)	(104)
Deferred tax Income/(Expense)	4	11
<b>Total Income Tax Expenses</b>	<b>(2 980)</b>	<b>(93)</b>

The current tax expense mainly relates to (i) income tax paid or payable by certain of the Company's subsidiaries for an amount of €366,000, and (ii) a liability for uncertain tax positions for an amount of €2.6 million. The latter was recorded following certain public rulings and guidance recently issued by tax authorities in one of the jurisdictions that the Company operates in.

The deferred tax also relates to these two subsidiaries where some payroll accruals are temporary differences in the determination of the taxable income. These temporary differences generate deferred tax income/(expense) of €4,000 in 2021 and €11,000 in 2020.

The income tax expenses can be reconciled to the Company's Belgian statutory income tax rate of 25.00% as follows:

(in EUR 000)	For the year ended December 31	
	2021	2020
Loss for the period before taxes	(24 639)	(12 152)
Company Statutory Income Tax Rate	25.00%	25.00%
Income Tax at Company Statutory Tax Rate	6 160	3 038
Foreign Tax Rate Differential	8	58
Unrecognized DTA on tax losses and temporary differences	(5 650)	(2 681)
Non deductible expenses	(555)	(488)
Share based payments	(317)	-
Tax adjustments to the previous period	(57)	-
Local income taxes	(2 618)	-
Other	49	(20)
Income Tax at Company Effective Tax Rate	(2 980)	(93)
Company Effective Income Tax Rate	(12.09%)	(0.77%)



As mentioned above, the subsidiaries in Israel and the United States are paying income taxes and recognized deferred tax on some temporary differences. 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 and the Australian entity both have historical losses that can be carried forward to future taxable income. The Belgian entity has tax losses for €79.0 million as at December 31, 2021 (2020: €56.3 million). The Australian entity has tax losses for €1.2 million as at December 31, 2021 (2020: €0.8 million). 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, 2021 and 2020:

(in EUR 000)	<b>As at December 31, 2021</b>		
	<b>Assets</b>	<b>Liabilities</b>	<b>Net</b>
Intangible assets	3 034	(580)	2 454
Right-of-use assets	-	(636)	(636)
Financial debt (Recoverable Cash Advances and derivatives)	1 655	(65)	1 590
Lease liabilities	654	-	654
Retirement benefit obligations	20	-	20
Other current liabilities	-	(41)	(41)
Tax-losses carried forward	20 218	-	20 218
<b>Total gross deferred tax assets/(liabilities)</b>	<b>25 581</b>	<b>(1 322)</b>	<b>24 259</b>
Netting by tax entity	(1 317)	1 317	-
Unrecognized deferred tax assets	(24 218)	-	(24 218)
<b>Total deferred tax assets/(liabilities)</b>	<b>46</b>	<b>(5)</b>	<b>41</b>

(in EUR 000)	<b>As at December 31, 2020</b>		
	<b>Assets</b>	<b>Liabilities</b>	<b>Net</b>
Intangible assets	1 395	(202)	1 193
Right-of-use assets	-	(643)	(643)
Other current assets	58	-	58
Financial debt (Recoverable Cash Advances and derivatives)	1 535	(47)	1 488
Lease liabilities	649	-	649
Retirement benefit obligations	9	-	9
Other current liabilities	-	(99)	(99)
Tax-losses carried forward	13 978	-	13 978
<b>Total gross deferred tax assets/(liabilities)</b>	<b>17 624</b>	<b>(991)</b>	<b>16 633</b>
Netting by tax entity	(991)	991	-
Unrecognized deferred tax assets	(16 601)	-	(16 601)
<b>Total deferred tax assets/(liabilities)</b>	<b>32</b>	<b>-</b>	<b>32</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 statutory in the subsidiaries in Israel and the United States.

### 5.34 Loss Per Share (EPS)

The Basic Earnings Per Share and the Diluted Earnings Per Share are calculated by dividing earnings for the year by the weighted average number of shares outstanding during the year. As the Company is incurring net losses, outstanding warrants have no dilutive effect. As such, there is no difference between the Basic and Diluted EPS.

EPS for December 2021 has been presented in the income statement taking into account resolutions adopted by the shareholders' meeting of February 21, 2020. All existing preferred shares were converted into common shares, and then a share split of 500:1 was approved by the shareholders' meeting.

	2021	2020
<b>As at December 31, after conversion and share split</b>		
Outstanding common shares at period-end	25 772 359	22 097 609
Weighted average number of common shares outstanding	23 792 693	18 097 988
Number of shares resulting of the exercise of outstanding warrants	1 993 000	1 007 500

Basic and Diluted EPS for the periods ended December 31, 2021 and 2020 based on weighted average number of shares outstanding after conversion and share split are as follows:

	<b>For the period ended December 31</b>	
	2021	2020
Loss of year attributable to common holders (in EUR)	(27 618 903)	(12 245 000)
Loss of year attributable to preferred holders (in EUR)	-	-
Loss of year attributable to equity holders (in EUR)	(27 618 903)	(12 245 000)
Weighted average number of common shares outstanding (in units)	23 792 693	18 097 988
<b>Basic earnings per share in EUR (EUR/unit)</b>	<b>(1.161)</b>	<b>(0.677)</b>
<b>Diluted earnings per share in EUR (EUR/unit)</b>	<b>(1.161)</b>	<b>(0.677)</b>

## 5.35 Other commitments

### 5.35.1 Capital commitments

There are no commitments related to capital expenditures at the closing date.

### 5.35.2 Lease expenses

The lease expense recognized in the income statement related to low-value leases and short-term leases amounts to:

(in EUR 000)	For the year ended December 31	
	2021	2020
Expense	75	89
Total	75	89

### 5.35.3 Other commitments

The Company has granted in October 2020 an amount of €0.5 million towards an institute under the Company's Sponsored Grant Program. The institute will have to perform over a total period of two years certain clinical and research activities and training and education activities. The future payment commitments amount to €150,000 at December 31, 2021 which will be paid quarterly in instalments over the remaining period if the institute performs its activities. During the period ended December 31, 2021, the Company recognized €250,000 in Therapy Development expenses.

## 5.36 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.

### 5.36.1 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	
	2021	2020
Short-term remuneration & compensation	576	337
Share based payment	117	1 576
Total	693	1 913

In the period between 2014 and December 2021, Mr. Fabian Suarez Gonzalez (acting via ActuaRisk Consulting SRL) served as the Company's CFO. On November 08, 2021, the Company announced that Mr. Loïc Moreau will join the Company as CFO as of January 1, 2022.

For the year ended December 31, 2021 and 2020, ActuaRisk Consulting, a company owned by a member of the executive management, invoiced Nyxoah SA for an amount of €230,000 and €309,000, respectively, for consulting services. The Company also recognized a share-based payment expense of €1.9 million for the year ended December 31, 2021, and €1.8 million for the year ended December 31, 2020, respectively to a cash-settled share-based payment transaction.

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

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

For the year ended December 31, 2020, a loan of €9,000 was granted by Nyxoah SA to Olivier Taelman in connection with the payment of taxes due following the acceptance of warrants. No other loans or other guarantees have been given to a member of the executive management team. The loan was reimbursed in the first half of 2021.

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

(in EUR 000)	For the period ended December 31, 2021			For the period ended December 31, 2020		
	R&D Collaboration	Consulting services	Board Remuneration	R&D Collaboration	Consulting services	Board Remuneration
Cochlear	2 050	–	–	1 300	–	–
Noshaq	–	–	–	–	10	–
MINV SA	–	120	–	–	50	–
Man & Science SA	–	–	–	–	44	–
Gilde Healthcare	–	–	–	–	–	–
Christopher Smith	–	–	–	–	–	–
Medtech execs LLC	–	–	–	–	–	9
Donald Deyo	–	–	41	–	–	12
Robert Taub	–	–	58	–	–	28
Janke Dittmer	–	–	–	–	–	8
Kevin Rakin	–	–	38	–	–	8
Pierre Gianello	–	–	22	–	–	8
Jan Janssen	–	–	35	–	–	8
Jurgen Hambrecht	–	–	28	–	–	9
Rita Mills	–	–	7	–	–	–
<b>Total</b>	<b>2 050</b>	<b>120</b>	<b>229</b>	<b>1 300</b>	<b>104</b>	<b>90</b>
Amounts outstanding at year-end	565	60	47	–	–	46

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 lead to financial impact of €2.1 million for the year ended December 31, 2021, compared to €1.3 million for the year ended December 31, 2020.

### **5.36.3 Transactions with related parties**

The following is a description of related party transactions we have entered into since January 1, 2021 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 of €382,263, 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 €225,000 and is eligible to receive an annual cash bonus of up to €100,000 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**

##### **MINV 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) will provide various consultancy services, including to support our executive management in business development activities. We will pay MINV SA a total fee of €120,000 for said services to be rendered over a period from the effective date of the agreement for a duration of 12 months.

##### **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.

### 5.37 Events after the Balance-Sheet Date

On February 10, 2022, the Company issued 25,000 shares pursuant to an exercise of subscription rights. Consequently, on the date of this Annual Report, the Company's registered capital amounts to €4,431,664.69, represented by 25,797,359 shares.

### 5.38 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 De Kleetlaan 2, 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 2018. Re-appointment of the statutory auditor has been decided by the General Assembly of Shareholders dated 23 May 2019. The new mandate of 3 years ends at the approval by the shareholders' meeting of the financial statements for the year ended 31 December 2021.

The fees are broken down as follows:

- Audit fee for statutory and consolidated financials: €305,000 in 2021 and €458,000 in 2020
- Tax consulting services: €2,000 in 2021 and €3,000 in 2020
- IPO, Capital increase and other related reports: €232,000 in 2021 and €357,000 in 2020
- Training: €10,000 in 2020

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# Statutory Auditors Report



EY Bedrijfsrevisoren  
EY Réviseurs d'Entreprises  
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## Independent auditor's report to the general meeting of Nyxoah SA for the year ended 31 December 2021

As required by law and the Company's articles of association, we report to you as statutory auditor of Nyxoah SA (the "Company") and its subsidiaries (together the "Group"). This report includes our opinion on the consolidated balance sheets as at 31 December 2021, the consolidated statements of loss and other comprehensive loss, changes in equity, and cash flows for the year ended 31 December 2021 and the disclosures (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 23 May 2019, 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 2021. We performed the audit of the Consolidated Financial Statements of the Group during 6 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 the consolidated balance sheets on 31 December 2021, the consolidated statements of loss and other comprehensive loss, changes in equity, and cash flows of the year and the disclosures, which show a consolidated balance sheet total of € 170.830.000 and of which the consolidated income statement shows a loss for the year of € 27.619.000.

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 2021, 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 ("ISAs"). 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.

#### Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the Consolidated Financial Statements of the current reporting period.

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

##### Description of the key audit matter

As at 31 December 2021, 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 €8.1 million and €25.3 million respectively. As detailed in notes 7 and 16.1 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 not yet been approved in some important markets, such as the US market, and 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 the process used by management to determine the significant assumptions, the choice of model, 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), comparing these assumptions with market and industry data, and the completeness and accuracy of the data used;
- We performed a sensitivity test on these assumptions, again with the help of our internal specialists.
- We tested all assumptions for revenue growth 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 annexes, to confirm the estimated revenue growth. Finally, we read and assessed the notes in Notes 7 and 16.1 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.

#### **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 ISAs 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.



**Audit report dated 24 March 2022 on the Consolidated Financial Statements  
of Nyxoah SA as of and  
for the year ended 31 December 2021 (continued)**

As part of an audit in accordance with ISAs, 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 ISAs applicable in Belgium, it is our responsibility to verify, in all material respects, the Board of Directors' report on the



**Audit report dated 24 March 2022 on the Consolidated Financial Statements of Nyxoah SA as of and for the year ended 31 December 2021 (continued)**

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 contains 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")**

English is not an official language in Belgium

**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, 24 March 2022

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, 2021

## 7.1 Balance sheet

	Notes	Codes	Period	Preceding period
<b>Assets</b>				
Formation expenses	6.1	20	11,709,906	6,149,881
<b>Fixed assets</b>		21/28	24,642,950	14,796,654
Intangible fixed assets	6.2	21	23,085,979	14,485,404
<b>Tangible fixed assets</b>	6.3	22/27	1,532,807	293,159
Land and buildings		22		
Plant, machinery and equipment		23	609,316	37,397
Furniture and vehicles		24	100,288	61,198
Leasing and other similar rights		25		
Other tangible fixed assets		26	131,725	194,564
Assets under construction and advance payments		27	691,478	
<b>Financial fixed assets</b>	6.4 to 6.5.1	28	24,163	18,091
Affiliated Companies	6.15	280/1	64	62
Participating interests		280	64	62
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	24,099	18,029
Shares		284		
Amounts receivable and cash guarantees		285/8	24,099	18,029

	Notes	Codes	Period	Preceding period
<b>Current assets</b>		29/58	133,871,124	91,294,625
Amount receivable after more than one year		29		
Trade debtors		290		
Other amounts receivable		291		
<b>Stocks and contracts in progress</b>		3	345,998	55,435
Stocks		30/36	345,998	55,435
Raw material and consumables		30/31		
Work in progress		32	83,440	41,903
Finished goods		33	262,558	13,532
Goods purchased for resale		34		
Immovable property intended for sale		35		
Advance payments		36		
Contracts in progress		37		
Amount receivable within one year		40/41	632,770	695,238
Trade debtors		40	228,045	234,090
Other amounts receivable		41	404,725	461,148
<b>Current investments</b>		50/53		
Own shares		50		
Other investments		51/53		
<b>Cash at bank and in hand</b>		54/58	131,247,463	90,446,826
<b>Accruals and deferred income</b>		490/1	1,644,893	97,126
<b>Total assets</b>		20/58	170,223,980	112,241,160

## Statutory Accounts

	Notes	Codes	Period	Preceding period
<b>Equity and Liabilities</b>				
<b>Equity</b>		10/15	164,065,475	105,771,637
<b>Contributions</b>	6.7.1	10/11	246,625,001	161,309,852
Capital		10	4,427,370	3,796,048
Issued capital		100	4,427,370	3,796,048
Uncalled capital		101		
Beyond capital		11	242,197,632	157,513,804
Share premium account		1100/1	242,197,632	157,513,804
Other		1109/1		
<b>Revaluation surpluses</b>		12		
<b>Reserves</b>	(+)/(-)	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		
<b>Accumulated profits (losses)</b>		14	-82,559,526	-55,538,215
<b>Capital subsidies</b>	(+)/(-)	15		
<b>Advance to shareholders on the distribution of net assets</b>		19		
<b>Provisions and deferred taxes</b>		16	11,647	3,270
<b>Provisions for liabilities and charges</b>		160/5	11,647	3,270
Pensions and similar obligations		160		
Taxes		161		
Major repairs and maintenance		162		
Environmental obligations		163		
Other liabilities and charges	6.8	164/5	11,647	3,270
<b>Deferred taxes</b>		168		



	Notes	Codes	Period	Preceding period
<b>Amounts payable</b>		17/49	6,146,858	6,466,253
<b>Amounts payable after more than one year</b>	6.9	17	1,275,843	1,537,177
Financial debt		170/4	1,275,843	1,537,177
Subordinated loans		170		
Unsubordinated debentures		171		
Leasing and other similar obligations		172		
Credit institutions		173		
Other loans		174	1,275,843	1,537,177
Trade debts		175		
Suppliers		1750		
Bills of exchange payable		1751		
Advance payments on contracts in progress		176		
Other amounts payable		178/9		
<b>Amounts payable within one year</b>	6.9	42/48	3,866,733	4,574,574
Current portion of amounts payable after more than one year falling due within one year		42	443,000	544,667
Financial debt		43		
Credit institutions		430/8		
Other loans		439		
Trade debts		44	2,470,070	2,806,379
Suppliers		440/4	2,470,070	2,806,379
Bills of exchange payable		441		
Advance payments on contracts in progress		46		
Taxes, remuneration and social security		45	566,584	479,345
Taxes		450/3	707	204,036
Remuneration and social security		454/9	560,114	275,309
Other amounts payable		47/48	387,079	744,183
<b>Accruals and deferred income</b>		492/3	1,004,282	354,502
<b>Total liabilities</b>		10/49	170,223,980	112,241,160

## 7.2 Profit and loss account

	Notes	Codes	Period	Preceding period
<b>Operating income</b>		<b>70/76A</b>	<b>11,636,220</b>	<b>10,482,876</b>
Turnover	6.10	70	862,860	69,160
Stock on finished goods and work in progress: increase (decrease) (+)/(-)		71	290,563	55,435
Produced fixed assets		72	9,502,672	9,381,248
Other operating income		74	980,125	977,033
Non-recurring operating income	6.10	76A		
<b>Operating charges</b>		<b>60/66A</b>	<b>39,461,323</b>	<b>19,460,013</b>
Goods for resale, raw materials and consumables		60	303,485	85,515
Purchases		600/8	303,485	85,515
Stock : decrease (increase) (+)/(-)		609		
Services and other goods		61	39,737,036	23,374,090
Remuneration, social security and pensions	6.10	62	3,931,748	1,968,510
Amortizations of and other amounts written down on formation expenses, intangible and tangible fixed assets		630	3,046,551	440,339
Amounts written down on stocks, contracts in progress and trade debtors : additions (write-backs) (+)/(-)	6.10	631/4		
Provisions for liabilities and charges : appropriations (uses and write-backs) (+)/(-)	6.10	635/8	8,376	3,270
Other operating charges	6.10	640/8	21,387	69,789
Operating charges reported as assets under restructuring costs(-)		649		
Non-recurring operating charges	6.12	66A	7,587,260	-6,481,501
<b>Operating profit (loss) (+)/(-)</b>		<b>9901</b>	<b>-27,825,103</b>	<b>-8,977,137</b>

	Notes	Codes	Period	Preceding period
<b>Financial income</b>		<b>75/76B</b>	<b>3,669,662</b>	<b>115,404</b>
Recurring financial income		75	3,669,662	115,404
Income from financial fixed assets		750	77,097	49,948
Income from current assets		751	1,424	2,072
Other financial income	6.11	752/9	3,591,141	63,384
Non-recurring financial income	6.12	76B		
<b>Financial charges</b>		<b>65/66B</b>	<b>2,855,365</b>	<b>2,263,321</b>
Recurring financial charges		65	1,036,497	1,300,805
Debt charges		650	305,017	123,847
Amounts written down on current assets other than stocks, contracts in progress and trade debtors : additions (write-backs) (+)/(-)		651		846,916
Other financial charges		652/9	731,481	330,042
Non-recurring financial charges	6.12	66B	1,818,868	962,516
<b>Profit (Loss) for the period before taxes (+)/(-)</b>		<b>9903</b>	<b>-27,010,807</b>	<b>-11,125,054</b>
Transfer from deferred taxes		780		
Transfer to deferred taxes		680		
<b>Income taxes on the result (+)/(-)</b>		<b>67/77</b>	<b>10,504</b>	<b>621</b>
Taxes	6.13	670/3	10,504	621
Adjustment of income taxes and write-back of tax provisions		77		
<b>Profit (Loss) of the period (+)/(-)</b>		<b>9904</b>	<b>-27,021,311</b>	<b>-11,125,675</b>
Transfer from untaxed reserves		9975		
Transfer to untaxed reserves				
<b>Profit (Loss) of the period available for appropriation (+)/(-)</b>		<b>99762</b>	<b>-27,021,311</b>	<b>-11,125,675</b>

### Appropriation account

		Notes	Codes	Period	Preceding period
Profit (Loss) to the appropriated	(+)/(-)		9906	-82,559,526	-55,538,215
Profit (Loss) of the period available for appropriation	(+)/(-)		(9905)	-27,021,311	-11,125,675
Profit (Loss) of the preceding period brought forward	(+)/(-)		14P	-55,538,215	-44,412,540
Transfer from equity			791/2		
From contributions			791		
From reserves			792		
Appropriations to equity			691/2		
To contributions			691		
To legal reserve			6920		
To other reserves			6921		
Profit (loss) to be carried forward	(+)/(-)		(14)	-82,559,526	-55,538,215
Shareholders' contribution in respect of losses			794		
Profit to be distributed			694/7		
Compensation for contributions			694		
Directors or managers			695		
Employees			696		
Other beneficiaries			697		

## 7.3 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.

The valuation rules have been modified compared to the previous financial year for the following areas:

- Intangible assets
- Cash Flow hedges

There is no impact on the annual accounts related to these modifications to mention.

### **Formation expenses amortized over a period of 5 years**

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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