Report of the board of directors to the shareholders' meeting of Nyxoah SA regarding the statutory annual accounts as of 31 December 2021

Dear Shareholders,

We are pleased to present to you our report regarding the financial year which ended on 31 December 2021 and to submit to you for your approval the statutory annual accounts for the financial year which ended on 31 December 2021.

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 physician approximately six weeks later for device titration, which typically involves an in-lab sleep trial to analyze breathing frequency. Further, the external activation chip eliminates the need for additional surgical procedures to replace depleted batteries and enables software, firmware or external hardware updates and upgrades to be implemented without the need for surgical intervention thereby limiting potential infection risk due to an additional procedure.

We continue to develop a substantial body of clinical evidence on the Genio system. In 2019, we completed our BiLAteral hypoglossal nerve STimulation for treatment of Obstructive Sleep Apnea, or BLAST OSA, trial, a prospective, open label, non-randomized, single arm treatment trial involving 27 implanted participants. Twenty-two patients completed the protocol, and the trial met all primary, secondary and exploratory endpoints. In the six-month data, the mean individual reduction in the Apnea-Hypopnea Index, or AHI, events per hour was 47.3%. Participants' AHI decreased from 23.7±12.2 to 12.9±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 available for patients through country specific innovation funding pathways for procedures and products that would not yet be covered by an existing code, (ii) supporting case-by-case funding

submission in focus hospitals that can use their budget to fund the therapy, (iii) entering into specific commercial deals with privately funded hospital groups, or (iv) out-of-pocket payment.

We have established a systematic approach to commercializing the Genio system in our target markets, focusing on active engagement, education and market development across patients, physicians and hospitals. We currently market our therapy to physicians and hospitals where ear, nose, and throat doctors, or ENTs, sleep doctors and general practitioners see, diagnose and treat patients with OSA. We are actively expanding our current European sales and marketing organization with country-specific sales teams established in connection with obtaining reimbursement. Our sales teams are focused on prioritizing high volume ENT centers and sleep centers, and on building long-standing relationships with key physicians such as sleep doctors, ENTs and general practitioners who have strong connections to the OSA patient population that may be eligible for our therapy. We 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.

2. Our competitive strengths

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

- ***Disruptive, patient-centric neurostimulation solution to treat moderate to severe OSA***. We specifically designed the Genio system with the goal of advancing a therapy to treat moderate to severe OSA and providing a safe and effective patient-centric solution offering significant benefits to address the unmet needs of patients. The Genio system includes the first battery-free, leadless, neurostimulator designed to be implanted in a minimally invasive procedure using a single incision. The Genio system delivers bilateral HGNS for patients who suffer from moderate to severe OSA and did not tolerate, failed or refused standard first-line therapy, including CPAP. We believe that bilateral stimulation could lead to better therapeutic performance and address more therapeutic indications compared to other HGNS-based technologies. While other commercially available neurostimulation platforms require

implantation of leads and a pulse generator containing a battery, our Genio system only requires implantation of a battery-free neurostimulator. Due to its unique design, the Genio system's implantable stimulator is the only neurostimulation-based OSA therapy that has received CE-Mark conditional labeling for 1.5T and 3T full-body MRI scans. CE-Mark conditional labeling for MRI scans have become more and more important for physicians and patients due to the growing need and incidence of MRI scans. Implantable medical devices that have not been tested and approved with MR conditional labeling are considered as MR unsafe, and MR scans are contra-indicated for these patients. We believe our Genio system technology has the potential to become the leading neurostimulation solution for many of the estimated 425 million diagnosed and undiagnosed OSA patients worldwide suffering from moderate to severe OSA.

- ***Growing body of clinical data and long-term clinical strategy.*** The Genio system is predicated on a well-established mechanism of action of electrically stimulating the hypoglossal nerve. Our BLAST OSA trial provided positive data for the Genio system, demonstrating that treatment with the Genio system resulted in statistically significant improvements in sleep apnea symptoms and quality of life measures. These data results were also associated with high therapy compliance. The trial's results supported receipt of the CE-Mark in 2019 and have been published in peer-reviewed journals, including the European Respiratory Journal. We are continuing our clinical research to evaluate the efficacy of the Genio system on a longer-term basis through our post- market clinical trial for the treatment of OSA in adults, or the EliSA trial. In December 2020, we implanted the first patient in the DREAM trial, which is designed to support marketing authorization in the United States. In addition, in June 2021, we announced initial top-line results from the six-month data for the BETTER SLEEP trial. Based on this data, in October 2021, we expanded the CE-Marked indication to include OSA patients with CCC, which should eliminate the need for a DISE procedure. 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.

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 apnea testing or various other technological advancements. We believe that bilateral stimulation could lead to better therapeutic performance and address more therapeutic indications compared to other hypoglossal nerve stimulation-based technologies. In June 2021, we announced initial top-line results from the six-month data for the BETTER SLEEP clinical trial. Based on this data, in October 2021, the EU Notified Body granted CE-Marked indication to include OSA patients with CCC for the Genio system in Europe. Currently, CCC patients are contraindicated for other HGNS OSA therapies. 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.

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.

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.

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.

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 Epsworth 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.

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/m². 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

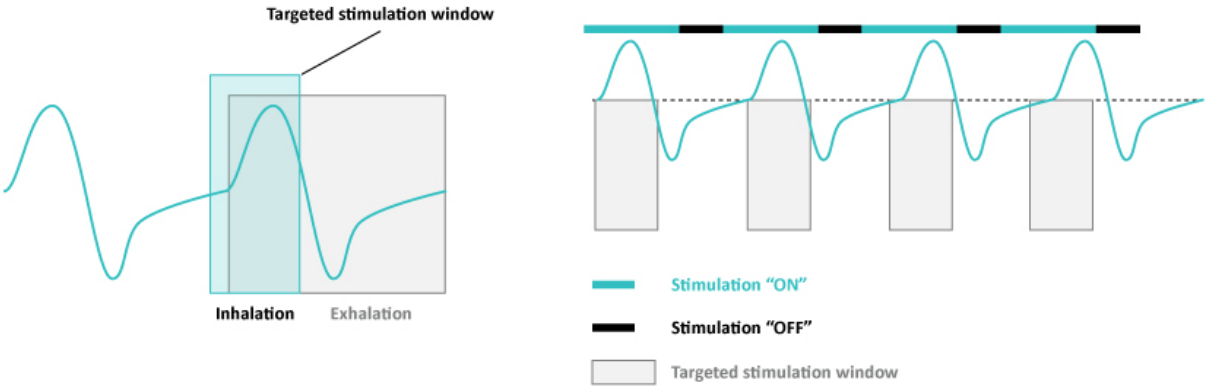
day. While patients may experience mild discomfort or swelling at the incision site, often associated with minimally invasive procedures, this can be managed with over-the-counter pain medications. Patients can return home after completion of the procedure and generally recover within a few days and 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.

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.

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% (SaO2<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/m2. 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

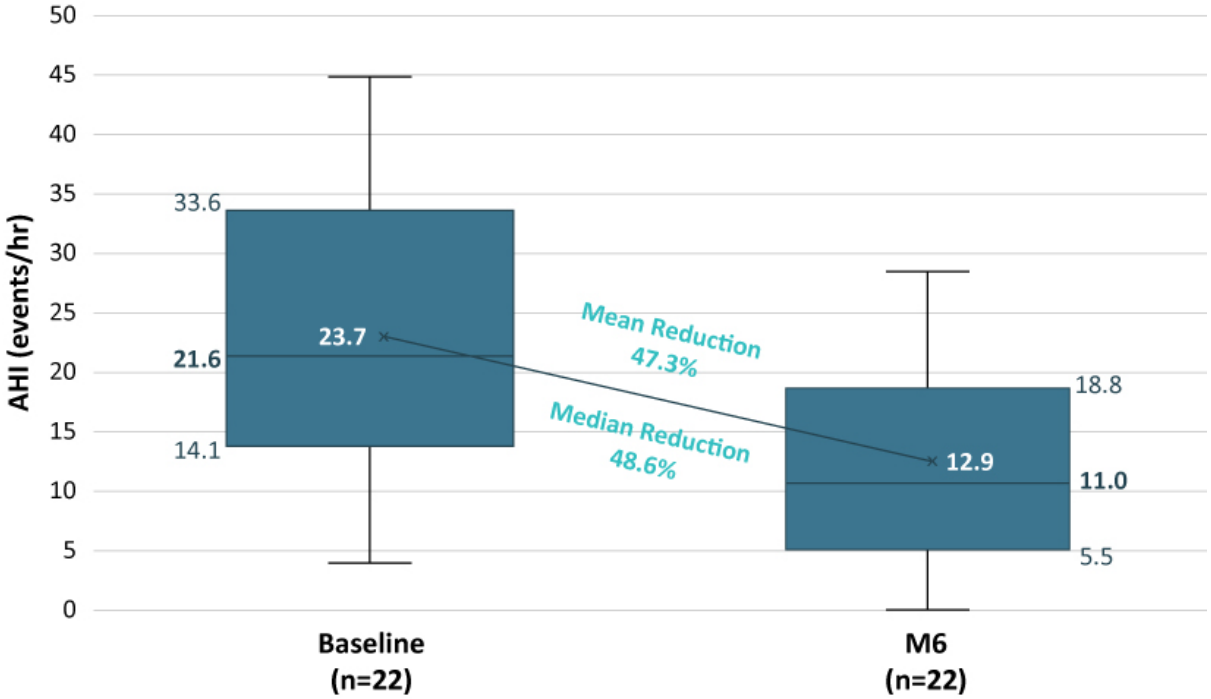
Four SAEs related to the surgical procedure (but not device-related) were reported in three of the 27 patients implanted during the six-month post-implantation period. These included two participants at the same hospital who developed local infections at the surgical site that resulted in removal of 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

Outcome	Baseline (n=22)	6-months (n=22)	Mean Difference (95% CI)	P-value
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.

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 ≤ AHI < 65) and aged between 21 and 75 years were eligible for enrollment if they failed, refused or did not tolerate PAP treatment. Patients with a body mass index above 32 kg/m² were excluded. 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.

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.

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/m², 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.

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.

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.

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.

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.

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.

11.Analysis of the statutory balance sheet and the results of the year

11.1. Assets

Nyxoah SA's asset position as at 31 December 2021, including a comparison with the previous financial year, is detailed in the table below.

	As of 31 December			
	2021	**2020**	**Variation**	**Variation (%)**
ASSETS				
Formation expenses	**11,709,906**	**6,149,881**	**5,560,025**	**90%**
Fixed assets				
Intangible assets	23,085,979	14,485,404	8,600,575	50%
Property, plant & equipment	1,532,807	293,159	1,239,648	423%
Financial assets	24,164	18,091	6,073	34%
	24,642,950	**14,796,654**	**9,846,296**	**67%**
Current assets				
Stock	345,998	55,435	290,563	524%
Receivable	632,770	695,238	-62,468	-9%
	978,768	**750,673**	**228,095**	**30%**
Cash	**131,247,463**	**90,446,826**	**40,800,637**	**45%**
Prepaid charges	**1,644,893**	**97,126**	**1,547,767**	**1,594%**
Total assets	**170,223,980**	**112,241,160**	**57,982,820**	**52%**

11.1.1. *Formation expenses*

On July 02, 2021, the Company completed its IPO on the Nasdaq Stock Market. This represents the second public offering after the one successfully achieved on the Euronext last year. Costs related to the IPO, and recorded as formation expenses, are lawyers' fees, costs related to financial institutions and auditor's fees. These expenses have been capitalized and will be depreciated over five years starting on the first day of listing on the stock market.

The variation of the year can be explained by the 2021 Nasdaq IPO additions (KEUR 7,587) and the current depreciations (KEUR 2,027).

11.1.2. *Fixed assets*

Fixed assets are composed of three categories: intangible assets, tangible assets (i.e., property, plant and equipment) and financial assets. The change in fixed assets can be explained as follows:

In 2021, development costs related to clinical and R&D projects have been capitalized for an additional amount of KEUR 9.503. As from January 01, 2021, amortization of development expenses has started, to reach an amount of KEUR 902. Intangible assets are amortized on a

straight-line basis over a period of 14 years based on the useful life of the patents as from the completion of the development stage of each project.

The increase in property, plant and equipment is explained by two elements linked to the production line in Liège. On one hand, the Company has invested in laboratory equipment to support the manufacturing of components in Liège and to support projects under development stage. On the other hand, investments were made to fit out the new manufacturing facilities in Liège with regulatory and quality requirements.

11.1.3. *Current assets*

Nyxoah continues to support the growth of commercial activities in Europe. Therefore, to support the sales, the Company has improved its production capabilities to have sufficient commercial inventories of which value at the date of the closing of the annual accounts amounted to KEUR 346. On the other hand, current assets increase compared to 2020, following multiples sales performed in December 2021. Trade receivables amount to KEUR 228 in 2021 (KEUR 234 in 2020).

11.1.4. *Cash*

The Company's treasury position amounts to KEUR 131,247 at year-end which represents an increase of KEUR 40,800 compared to prior year-end. This increase is explained by the IPO completed on July 02, 2021, and the 2021 cash flow of the year.

11.1.5. *4.1.5. Prepaid charges*

The increase of prepaid charges as at December 31, 2021, compared to December 31, 2020, is mainly due to recognition of invoices dealing with several accounting periods such as D&O insurances (KEUR 1,068) and the donation agreement with Mannheim institute (KEUR 144).

11.2. Liabilities

Nyxoah SA's liabilities position as at 31 December 2021, including a comparison with the previous financial year, is detailed in the table below.

	As of 31 December			
	2021	**2020**	**Variation**	**Variation (%)**
EQUITY AND LIABILITIES				
Equity	**164,065,475**	**105,771,637**	**58.293.838**	**55%**
Provisions and deferred taxes	**11,647**	**3,270**	**8,377**	**256%**
Long term debt	**1,275,843**	**1,537,177**	**-261,334**	**-17%**
Short term debt				
Short term debt	443,000	544,667	-101,667	-19%
Account payable	2,470,070	2,806,379	-336,309	-12%
Remuneration	566,584	479,345	87,239	18%
Other debt	387,079	744,183	-357,104	-48%
	3,866,733	**4,574,574**	**-707,841**	**-15%**
Accrual and deferred income	**1,004,282**	**354,502**	**649,779**	**184%**
Total equity and liabilities	**170,223,980**	**112,241,160**	**57,982,820**	**52%**

11.2.1. *Capital*

In 2021, as a result of the above-mentioned Public Offering and warrants exercises, the share capital and the share premium increased by KEUR 631 and KEUR 84,684 respectively. These increases were compensated by the loss of the year of KEUR 27,021 resulting in an increase of KEUR 58,304 of the equity.

11.2.2. *Long term debt*

Long term debt is composed of the Novallia loan and the recoverable cash advances from the Walloon Region. The decrease of KEUR 261 corresponds to the portion of the debt transferred from long term to current liabilities as they will fall due in 2022, if requested by the Walloon Region. For a situation including the short and the long term part, we refer to the table below.

Agreement	***Amount (Contract)***	***Amount received***	***Initial Debt***	***Amount reimbursed***	***LT Debt***	***ST Debt***
6472	1,600,000.00	1,600,000.00	480,000.00	450,000.00	0.00	30,000.00
6839	2,160,000.00	2,160,000.00	648,000.00	184,000.00	224,000.00	240,000.00
6840	2,400,000.00	2,400,000.00	720,000.00	135,000.00	510,000.00	75,000.00
7388	1,466,701.00	1,466,701.00	440,010.00	29,334.00	396,009.00	14,667.00
Total	***7,626,701.00***	***7,626,701.00***	***2,288,010.00***	***798,334.00***	***1,130,009.00***	***359,667.0***

11.2.3. *Short term debt*

Short term debt, or current liabilities, include trade payables and payables to affiliated companies. Trade payables in 2021 were smaller than 2020 due to the payment of the “exit fee” in connection with the Euronext IPO payable to the CFO of the Company and calculated based on the current value of the Company. This is compensated by the current liabilities towards research and development projects and clinical studies conducted.

Debts with affiliated companies are decreasing due to, among other things, the intercompany movements between the Company and its subsidiaries.

Given that the liabilities are mainly explained by the agreements with the Walloon Region, the above table details the current situation of the recoverable cash advances.

11.2.4. *Accruals and deferred income*

Accruals and deferred income were higher in 2021 due to the fair value measurement and the premium of the derivatives (Call/Put) held by the Company to manage the cash. This amounts respectively to KEUR 334 and KEUR 334.

11.3. Profit & Loss

The table below sets forth Nyxoah SA's income statement, ending up with a KEUR 27,021 net loss for the year ended 31 December 2021, and comparative information for the year 2020.

	As of 31 December			
	2021	**2020**	**Variation**	**Variation (%)**
Income statement				
Revenue				
Turnover	862,860	69,160	793,700	1,148%
Increase (decrease) in stock and in contracts in progress	290,563	55,435	235,128	424%
Other operating income	980,125	977,033	3,092	0%
Produced fixed assets	9,502,672	9,381,248	121,424	1%
	11,636,220	**10,482,876**	**1,153,344**	**11%**
Operating costs				
COGS	-303,485	-30,080	-273,405	909%
Work In Progress	0,00	-55,435	55,435	-100%
Research and development costs	-23,530,444	-14,253,789	-9,276,655	65%
- Services and other goods	-22,285,873	-13,147,814	-9,138,059	70%
- Remuneration, social security and pensions	-1,244,521	-1,105,975	-138,546	13%
Overhead costs	-20,138,389	-11,088,813	-9,049,576	82%
- Services and other goods	-17,451,163	-10,226,276	-7,224,887	71%
- Remuneration, social security and pensions	-2,687,226	-862,537	-1,824,689	212%
Depreciation	-3,046,552	-440,339	-2,606,213	592%
Provisions for liabilities and charges	-8,376	-3,270	-5,106	156%
Other operating costs	-21,387	-69,789	48,404	-69%
Non recurring operating or financial charges	7,587,260	6,481,501	1,105,759	17%
Operating loss	**-27,825,103**	**-8,977,137**	**-18,847,966**	**210%**
Financial income	**3,669,661**	**115,404**	**3,554,257**	**3080%**
Financial charges	**-2,855,365**	**-2,263,321**	**-592,044**	**26%**
Income taxes	**-10,504**	**-621**	**-9,883**	**1592%**
Loss of the period	**–27,021,311**	**-11,125,675**	**-15,895,636**	**140%**

11.3.1. *Revenue*

The Company continues its growth on the existing HGNS NUB coding in Germany, generating revenues of KEUR 809 in 2021 (KEUR 69 in 2020). The remaining part of sales have been generated in Spain and Belgium.

To support the sales growth, the manufacturing of devices intended for sale follows the same trend which has a P&L impact on the stock variation account.

Other income decreased following the last remaining payment received from the Walloon Region in 2020 related to the 6840 reimbursable cash advance agreement (see table above). Moreover, intercompany movements with the subsidiary in Australia decreased given the current stage of the clinical studies.

Non-recurring operating income increase following an intercompany reinvoicing towards the Israeli and American subsidiaries.

11.3.2. *Operating Costs*

Operating costs show a significant increase compared to 2020. This is explained by several factors:

- Production costs increased because of the production of the devices sold in 2021.
- Research and development costs raised as a result of an increase of the R&D and clinical projects, respectively, managed by Nyxoah LTD and Nyxoah INC, whose costs are charged to Nyxoah SA. Research and development costs also include an amount of KEUR 2,050 relating to the development of the Genio® system with Cochlear. Finally, clinical trial costs in 2021 increased significantly compared to 2020 due to the various clinical trials conducted in Australia, Europe and mainly in the U.S.
- Overhead costs increased due to the growth of the Company's activities and its internal projects managed by consultants and members of the organization.
- Salary costs increased due to additional recruitment in both the R&D and the G&A department. This reflects the expansion of the Company's activities.
- Depreciation increased due to the capitalization of both IPO costs and the acquisition of equipment to support the manufacturing process of implantable stimulator. Some intangible assets started to be amortized as of January 01, 2021.
- Capitalization of development costs increased due to clinical trial activities performed in Europe, Australia and in the U.S., and the reinvoicing of costs by the Israeli and American subsidiaries.
- Non-recurring operating expenses decreased because capitalization of Nasdaq IPO costs have been deducted from the overhead expenses. Non-recurring operating charges include an intercompany reinvoicing towards the Israeli and American subsidiaries.

11.3.3. *Financial income*

Financial income increased following the year-end re-evaluation of the USD cash at bank balance.

11.3.4. *Financial charges*

Financial charges increased significantly in 2021 compared to 2020 which is explained as follows:

- Banks are charging the Company with negative interests for cash at bank. In order to manage cash, the Company proceeds to investment strategies according to the current/future needs in Euros and foreign currencies. The Company has Call & Put contracts which have been measured at fair value and recognized under financial charges at the end of the fiscal year.

- The Company has written off all cash transfer transactions to its Australian subsidiary. Cash transferred in 2021 was significatively higher than in 2020.
- Exchange rate differences are an important factor as well because the Company is dealing more and more with foreign companies.

11.3.5. *Loss of the year*

The loss of the year amounts to KEUR 27,021 compared to a loss of the year of KEUR 11,126 for 2020.

The Board of Directors proposes to carry forward the loss of the year as follows:

Profit (loss) of the year:	(27,021,311)
Profit (loss) of previous years:	(55,538,215)
Loss to be carried forward:	***(82,549,526)***

12.Use of financial instruments

The Company uses financial investments to hedge its foreign exchange risk in connection with the transfer of funds to subsidiaries of the group. In connection with these investments, the Company uses strategies called Call & Put/Swaps on currencies. Derivatives are initially recorded at fair value; transaction costs are recognized in the income statement; premiums received are recorded in a suspense account until the contract conclusion. Financial instruments are subsequently re-measured at fair value.

13.Risks and uncertainties

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

13.1. 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 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® 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® 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® 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 trail 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® 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® system.

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

Acceptance of the Genio® system will depend on physicians being convinced of the distinctive characteristics, clinical performance, benefits, safety and cost-effectiveness of the Genio® 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.

13.2. 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-consuming 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® 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® 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® system than the Company anticipates which would result in lower potential revenue for the Company.

13.3. 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 the 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.

13.4. 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.

13.5. 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.

13.6. 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® 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® system and manage its inventory.

To ensure adequate inventory supply of the Genio® 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® system and/or its components. To date, the Company has only commercialized the Genio® system in limited quantities, mostly in Germany, and its ability to accurately forecast demand for its Genio® 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® 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® brand. Conversely, if the Company underestimates customer demand for the Genio® 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® 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.

13.7. Legal and regulatory risks

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

Applications for prior regulatory authorization in the countries where the Company intends to sell or market the Genio® 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® 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® 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® system carry risks associated with the surgical procedure for implant or removal of the device, use of the device, or the therapy delivered by the device.

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

All medical devices have associated risks. Regulatory authorities regard active implantable medical devices ("AIMDs") as the highest risk category of medical devices and accordingly AIMDs are subject to a high level of scrutiny when seeking regulatory approval or other marketing authorization. The Genio® system was reviewed, classified and the 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® 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 others. 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.

or 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-kickback 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 programs 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.

13.8. 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® 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® 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® 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® 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® 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® 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.

13.9. Risks relating to the ownership of 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.

14.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.

15.Corporate governance statement

15.1. 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) 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 15.6.

15.2. Board of Directors

15.2.1. *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 Genaissance Pharmaceuticals, Inc., a pharmacogenomics company. He is currently on the boards of a number of private companies as well as Aziyo Biologics, Inc. (NASDAQ: AZYO), where he serves as the chairman of the board, Oramed Pharmaceuticals, Inc (NASDAQ: ORMP) and Quantum-SI (NASDAQ: QSI). Mr. Rakin received an MBA from Columbia University and a B.Com. (Hons) from the University of Cape Town, South Africa.

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 Paceart. 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 Tubingen, 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.

15.2.2. *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.

15.2.3. *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.

15.2.4. *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	14/02/2021	01/04/2021	08/04/2021	21/05/2021	04/06/2021	25/06/2021	27/08/2021	08/09/2021	17/09/2021	19/11/2021
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	Represented	Present	Represented	Represented	Present
Jürgen Hambrecht	Present	Present	Present	Present	Present	Represented	Present	Represented	Present	Present
Donald Deyo	Present	Present	Present	Present	Present	Represented	Present	Represented	Represented	Present
Rita Johnson-Mills (2)	N/A	N/A	N/A	N/A	N/A	N/A	Present	Represented	Represented	Present
Pierre Gianello	Present	Present	Present	Present	Present	Represented	Present	Represented	Represented	Present
Jan Janssen	Present	Present	Present	Present	Present	Represented	Present	Represented	Represented	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.

Audit committee members	08/04/2021	15/04/2021	15/06/2021	06/08/2021	15/12/2021
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.

Remuneration committee members	02/04/2021	22/06/2021	17/09/2021	03/11/2021	15/11/2021
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.

Nominating and corporate governance committee members	02/04/2021	22/06/2021	17/09/2021	24/09/2021	12/11/2021
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

15.3. Executive management

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

The executive management shall meet at least once a month.

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

Name	Position
Olivier Taelman	CEO
Loïc Moreau	CFO

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

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

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

Olivier Taelman – Reference is made to section 15.2.1.

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.

15.4. 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."

15.5. 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.

15.6. 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.

15.7. 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.

15.8. Remuneration report

15.8.1. *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	One or more individual or Company performance criteria (objectives) are determined. For each objective, a target and corresponding payout level are determined: - If objective is 100% achieved: full payout of targeted payout level - If objective is achieved <75%: in principle no payout (but Board can decides otherwise) - If objective is achieved >75% and <125%: payout between 75% and 125%, based on linear calculation - If objective is achieved >125%: board can decide payout >125%
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	Options issued prior to 2021: vesting in three tranches: - 1/3 of offered share options vests upon offer - 1/3 of offered share options vests on first anniversary of offer - 1/3 of offered share options vests on second anniversary of offer Options issued pursuant to 2021 plan: vesting in four tranches: - 1/4 of offered share options vests upon offer - 1/4 of offered share options vests on first anniversary of offer - 1/4 of offered share options vests on second anniversary of offer - 1/4 of offered share options vests on third anniversary of offer
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).

15.8.2. *Total remuneration*

Total remuneration of directors

TABLE 1 - TOTAL REMUNERATION DIRECTORS									
	Fixed remuneration			Variable remuneration					
Name, position	**Base remunera-tion**	**Attendance fees**	**Fringe benefits**	**One-year variable**	**Multi-year variable**	**Extra-ordinary items**	**Pension expense**	**Total remuneration**	**Proportion of fixed and variable remuneration**
Robert Taub *Non-executive chairman*	52.500,00 *(a)*	0,00	9.130,54 *(e)*	0,00	0,00	0,00	0,00	61.630,54	Fixed: 100,00% Variable: 0,00%
Janke Dittmer *Non-executive director*	0,00 *(b)*	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 *(a)*	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 *(a)*	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 *(a)*	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 *(c)*	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 *(d)*	0,00	0,00	0,00	0,00	0,00	0,00	86.596,68	
- Non-executive director	27.500,00 *(a)*	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 *(a)*	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 fee for non-executive chairman	Fixed annual fee for independent non-executive director	Fixed annual fee for other non-executive director	Fixed annual fee for chairman of audit committee	Fixed annual fee for member of audit committee	Fixed annual fee for member of remuneration committee	Fixed annual fee for member of science & technology committee	Fixed annual fee for member of Cochlear project steering committee	**Total**
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									
	Fixed remuneration			Variable remuneration					
Name, position	Base remunera-tion	Attendance fees	Fringe benefits	One-year variable	Multi-year variable	Extra-ordinary items	Pension expense	Total remuneration	Proportion of fixed and variable remuneration
Olivier Taelman *CEO*	412.722,16	NA	17.747,61 *(a)*	287.381,14 *(b)*	0,00 *(c)*	0,00	12.682,00 *(d)*	730.532,91	Fixed: 60,66% Variable: 39,34%
Fabian Suarez Gonzalez (*) *CFO (until December 31, 2021)*	230.000,04	NA	0,00	0,00	0,00	3.709.285,99 *(e)*	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
	TOTAL			**137.381,15**
Fabian Suarez Gonzalez (*) *CFO*	None	N/A	a)	N/A
			b)	N/A
	TOTAL			**N/A**

Notes:

(*) Acting via ActuaRisk Consulting SRL.

15.8.3. *Share based remuneration*

TABLE 4 - REMUNERATION IN SHARE OPTIONS										
	Main conditions of the share option plans						Information regarding the reported financial year			
							Opening balance	During the year		Closing balance
Name, position	Identification of the plan	Date of offer	Date of vesting of last tranche	End of holding period	Exercise period (from - to)	Exercise price	Number of share options held but not yet vested at the beginning of the year (**)	a) Number of share options offered b) Value of underlying shares @ date of offer (**)	a) Number of share options vested b) Value of underlying shares @ date of vesting c) Value @ exercise price d) Surplus value @ date of vesting (**)	Share options not yet vested
Robert Taub *Non-executive chairman*	NA									
Janke Dittmer *Non-executive director*	NA									
Jürgen Hambrecht *Non-executive director*	NA									
Kevin Rakin *Non-executive director*	ESOP 2016	03/11/2016	03/11/2018	NA	03/11/2016 03/11/2021	2.585,32	0	a) 0	a) 0	0
Donald Deyo *Non-executive director*	ESOP 2016	03/11/2016	03/11/2018	NA	03/11/2016 03/11/2021	2.585,32	0	a) 0	a) 0	0
Pierre Gianello *Non-executive director*	ESOP 2016	09/12/2016	09/12/2018	NA	09/12/2016 09/12/2021	2.585,32	0	a) 0	a) 0	0
Rita Johnson-Mills *Non-executive director*	NA									
Jan Janssen *Non-executive director*	NA									
Olivier Taelman *CEO*	ESOP 2013	07/04/2020	07/04/2020	NA	07/04/2020 23/12/2024	5.966,59	0	a) 0 b)	a) 0 b) c) d)	0
	ESOP 2018	29/07/2019	29/07/2021	NA	29/07/2019 29/07/2024	3.259,91	0	a) 0 b)	a) 0 b) c) d)	0
	ESOP 2018	07/04/2020	07/04/2022	NA	07/04/2020 07/04/2025	5.966,59	0	a) 0 b)	a) 0 b) c) d)	0
	ESOP 2020	07/04/2020	07/04/2022	NA	07/04/2020 07/04/2025	11,94	0	a) 0 b)	a) 0 b) c) d)	0
	ESOP 2021	17/09/2021	17/09/2024	NA	17/09/2021 17/09/2026	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
TOTAL							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	13/06/2017	13/06/2019	NA	13/06/2017 13/06/2022	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 sharse 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.

15.8.4. *Severance payment*

During 2021, no severance payments were due or paid to any director or member of executive management.

15.8.5. *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.

15.8.6. *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.

15.8.7. *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

Yearly remuneration	2021	2020
Non-executive directors		
Total remuneration (all non-executive directors collectively) (*)	331.560,55	383.653,86
Members of executive management		
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

Company performance	2021	2020
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

Average remuneration of employees on a full-time equivalent basis	2021	2020
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.

15.9. 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%
Total (denominator) on December 31, 2021	**25,772,359**		**100,00%**

(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%.

15.10. Share capital and shares

15.10.1. *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 and12,406,673 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.

15.10.2. *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.

15.10.3. *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).

15.10.4. *The Company's authorized 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.

15.10.5. *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.

15.10.6. *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.

15.10.7. *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.

15.10.8. *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.

16.Subsidiaries and branches

The company has the following subsidiaries :

Entity name	*Country*	*Field of activity*	*Participation*
Nyxoah Ltd	Israel	R&D center	100%
Nyxoah Pty Ltd	Australia	Clinical study center	100%
Nyxoah Inc	United States	Clinical study center	100%

The Company does not have any branches.

17.Research and development

The Company has invested a lot in research and development. Total R&D costs since the Company was founded, amount to around EUR 63 million.

18.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 6 ("Description of the principal risks associated with the activities of the Company").

Mont-Saint-Guibert, 24 March 2022

On behalf of the Board of Directors.

Robert Taub, Chairman Olivier Taelman, CEO