



Report of the board of directors to the shareholders' meeting of Nyxoah SA regarding the statutory annual accounts as of December 31, 2023

Dear Shareholders,

We are pleased to present to you our report regarding the financial year which ended on December 31, 2023 and to submit to you for your approval the statutory annual accounts for the financial year which ended on December 31, 2023.

1. Business overview

We are a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea, or OSA. Our lead solution is the Genio system, a CE-Marked, patient-centric, minimally invasive, next generation hypoglossal neurostimulation, or HGNS, therapy for the treatment of moderate to severe OSA. OSA is the world's most common sleep disordered breathing condition and is associated with increased mortality risk and comorbidities including cardiovascular diseases, depression and stroke. Our innovative technology platform is a first-of-its-kind HGNS device designed to treat OSA through bilateral stimulation, by maintaining an open airway for a restful night's sleep. We started generating revenue from the sale of the Genio system in Europe in July 2020, and we are currently conducting our DREAM pivotal trial designed to support marketing authorization in the United States. We are developing a significant body of clinical evidence to further support the strong value proposition of the Genio system and its ability to improve the health and quality of life of OSA patients.

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

Published scientific literature estimates that there are currently approximately 23.8 million individuals with moderate to severe OSA in our initial target markets in Europe. Based on published scientific literature, we estimate that approximately 2.6 million patients are diagnosed annually in those countries and that approximately 80% of diagnosed patients are prescribed a continuous positive airway pressure, or CPAP, device. Published scientific literature reports non-compliance rates to CPAP between 29% and 83%. Based on these data, and for purposes of calculating the total addressable market in Europe for the Genio system, we estimate that approximately 35% of patients that are prescribed CPAP in those countries are not compliant with the therapy. Additionally, certain patients possess anatomical characteristics, including higher body-mass-index or increased tongue fat deposition that make them ineligible for HGNS. Taking that into account, we estimate that approximately 70% of those non-compliant patients are eligible for HGNS based on their anatomical characteristics. As a result, we believe the total addressable market in Europe for the Genio system is at least 515,000 patients which represents an estimated annual market opportunity of approximately \$10 billion based on our current pricing for the Genio system. We also plan to enter the United States market, assuming we obtain marketing authorization in the United States, where published scientific literature estimates that there are approximately 23.7 million individuals with moderate to severe OSA. Based on the same

assumptions set out above, we estimate a target market of approximately 510,000 patients in the United States, which represents an estimated annual total addressable market of approximately \$10 billion based on our current pricing for the Genio system.

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

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

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

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

We continue to develop a substantial body of clinical evidence on the Genio system. In 2019, we completed our BiLateral hypoglossal nerve STimulation for treatment of Obstructive Sleep Apnea, or BLAST OSA, trial, a prospective, open label, non-randomized, single arm treatment trial involving 27 implanted participants. Twenty-two patients completed the protocol, and the trial met all primary, secondary and exploratory endpoints. In the six-month data, the mean individual reduction in the Apnea-Hypopnea Index, or AHI, events per hour was 47.3%. Participants' AHI decreased from 23.7 ± 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. Additionally, we presented 12-month data on the first 34 DREAM patients reaching 12-month follow-up as a late-breaking abstract at SLEEP 2023, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in line with expectations. These data are preliminary and not conclusive of final success of the DREAM trial. On March 19, 2024, we issued a press release announcing that the DREAM trial met its primary endpoints. More information can be found in the press release. We expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in late 2024.

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

We are initially targeting markets in Europe where we have identified a country- specific reimbursement pathway or execution strategy. We began our commercial launch in Germany in July 2020. After obtaining reimbursement approval in Germany through the existing HGNS special

innovation funding program, or NUB, we generated our first revenue in the second half of 2020. In 2021, we successfully obtained reimbursement in Germany under a dedicated DRG code for HGNS and obtained reimbursement under an OSA-specific DRG code in Switzerland from the Federal Statistic Office, or BFS. The reimbursement coverage in both Germany and Switzerland includes the cost of the Genio system, implant procedure, hospital stay and follow-up care. In 2021, we began marketing products in Switzerland and also secured first revenue in Spain and we began commercialization in Finland in 2022. We generated our first revenue in Austria in 2023. Based on market access activities conducted by us over the past several years, we have developed tailored reimbursement strategies using assessments of the local requirements of target countries. In countries where there is existing reimbursement coverage in place, we plan to piggyback on existing coding and reimbursement, acting as a fast follower. In countries where there is no existing reimbursement coverage, we will seek to be the first in that market to obtain reimbursement coverage. In countries without existing reimbursement coverage, the strategy could include (i) making the Genio system commercially available for patients through country specific innovation funding pathways for procedures and products that would not yet be covered by an existing code, (ii) supporting case-by-case funding submission in focus hospitals that can use their budget to fund the therapy, (iii) entering into specific commercial deals with privately funded hospital groups, or (iv) out-of-pocket payment.

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

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

functionalities through software, firmware and hardware updates and upgrades and therapy enhancement.

2. Our competitive strengths

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

- ***Disruptive, patient-centric neurostimulation solution to treat moderate to severe OSA.*** We specifically designed the Genio system with the goal of advancing a therapy to treat moderate to severe OSA and providing a safe and effective patient-centric solution offering significant benefits to address the unmet needs of patients. The Genio system includes the first battery-free, leadless, neurostimulator designed to be implanted in a minimally invasive procedure using a single incision. The Genio system delivers bilateral HGNS for patients who suffer from moderate to severe OSA and did not tolerate, failed or refused standard first-line therapy, including CPAP. We believe that bilateral stimulation could lead to better therapeutic performance and address more therapeutic indications compared to other HGNS-based technologies. While other commercially available neurostimulation platforms require implantation of leads and a pulse generator containing a battery, our Genio system only requires implantation of a battery-free neurostimulator. Due to its unique design, the Genio system's implantable stimulator is the only neurostimulation-based OSA therapy that has received CE-Mark conditional labeling for 1.5T and 3T full-body MRI scans. CE-Mark conditional labeling for MRI scans have become more and more important for physicians and patients due to the growing need and incidence of MRI scans. Implantable medical devices that have not been tested and approved with MR conditional labeling are considered as MR unsafe, and MR scans are contra-indicated for these patients. We believe our Genio system technology has the potential to become the leading neurostimulation solution for many of the estimated 425 million diagnosed and undiagnosed OSA patients worldwide suffering from moderate to severe OSA.
- ***Growing body of clinical data and long-term clinical strategy.*** The Genio system is predicated on a well-established mechanism of action of electrically stimulating the hypoglossal nerve. Our BLAST OSA trial provided positive data for the Genio system, demonstrating that treatment with the Genio system resulted in statistically significant improvements in sleep apnea symptoms and quality of life measures. These data results were also associated with high therapy compliance. The trial's results supported receipt of the CE-Mark in 2019 and have been published in peer-reviewed journals, including the European Respiratory Journal. We are continuing our clinical research to evaluate the efficacy of the Genio system on a longer-term basis through our post-market clinical trial for the treatment of OSA in adults, or the ELISA trial. In December 2020, we implanted the first patient in the DREAM trial, which is designed to support marketing authorization in the United States. In addition, in June 2021, we announced initial top-line results from the six-month data for the BETTER SLEEP trial. Based on this data, in October 2021, we expanded the CE-Marked indication to include OSA patients with CCC, which should eliminate the need for a DISE procedure. In September 2021, we received breakthrough device designation in the United States for the Genio system from the

FDA for the treatment of OSA with CCC, based on the initial clinical evidence from the BETTER SLEEP trial. Further, in June 2022, we announced that the FDA approved the use of our next generation Genio 2.1 system for use in the DREAM trial. In June 2023, we presented 12-month data on the first 34 DREAM patients reaching 12-month follow-up as a late-breaking abstract at SLEEP 2023, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in line with expectations. These data are preliminary and not conclusive of final success of the DREAM trial. Additionally, in July 2022, we announced that the FDA approved an IDE to enable us to initiate a clinical trial, called ACCCESS, to evaluate the use of the Genio system for the treatment of adult patients with moderate-to-severe OSA with CCC that have failed, did not tolerate, or refused PAP.

- **Significant product development and new indication pipeline.** The Genio system is a scalable-technology platform that allows for future external hardware, software and firmware updates to enhance therapeutic capabilities without requiring additional surgical procedures. We continue to invest in improving the Genio system to develop next generation products with features designed to improve patient comfort and compliance, efficacy and patient and market acceptance. Some of these improvements include features aimed at enhancing the physician's ability to monitor patient compliance and therapeutic efficacy, including sensor technology to monitor a patient's sleep position. We are also committed to expanding current treatment options for moderate to severe OSA patients by developing next generation neurostimulation-based technologies. We previously entered into a licensing agreement with Vanderbilt University pursuant to which we are exploring additional neurostimulation technologies. Under the agreement, we have an exclusive, worldwide license to make, use, sell or distribute products for treating sleep disordered breathing covered by certain patent rights owned, or that may be owned, by Vanderbilt. We will also work together with Vanderbilt University to continue prosecution of patent applications made by Vanderbilt.
- **Platform technology protected by comprehensive and broad intellectual property.** Our platform technology is supported by a strong and growing portfolio of intellectual property rights, which includes utility and design patents, know-how and trade secrets, including therapy protocols, electrodes and methods. As of December 31, 2023, we had 199 granted or pending patent applications (with 54 issued or allowed U.S. patents), and 40 pending patent applications, ten of which are U.S. pending patent applications and hold six trademark registrations (with three U.S. trademark registrations). Additionally, we operate a manufacturing facility responsible for silicone overmolding and select assembly of external components, which provides us with enhanced proprietary know-how and control of the supply chain to meet future demand.
- **Strong and experienced team.** Our senior management team has many years of experience in the healthcare and medical device industry. Specifically, our team has extensive operating experience in product development, clinical, regulatory approval and commercialization activities as well as established relationships with industry leaders in the academic, clinical and commercial neuromodulation industries. Members of our management team have served in leadership positions with well-regarded medical technology companies such as St. Jude Medical Inc., Medtronic Inc., Stryker Corp and Nevro Corp. Since our founding, we have been supported by a seasoned Board of Directors with extensive industry and public company experience and a Scientific Advisory Committee that consists of industry-relevant KOLs.

3. Our strategy

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

- ***Obtaining marketing authorization in the United States.*** We are conducting clinical trials to further evaluate the efficacy and safety of the Genio system for treating patients with moderate to severe OSA. We are currently conducting the DREAM trial, a pivotal trial designed to support marketing authorization for the Genio system in the United States via a premarket approval, or PMA, application. The DREAM trial is a multicenter, prospective, open-label trial designed to enroll 115 patients in approximately 20 centers in the United States and internationally. The trial aims to evaluate the safety and effectiveness of the Genio system to treat patients with moderate to severe OSA who either did not tolerate, failed or refused first-line PAP therapy. In June 2022, we announced that the FDA approved the use of our next generation Genio 2.1 system for use in the DREAM trial. On March 19, 2024, we issued a press release announcing that the DREAM trial met its primary endpoints. More information can be found in the press release. We expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in late 2024.
- ***Promoting awareness of the Genio system among physicians, patients and payors to accelerate market adoption.*** We believe that the Genio system has the potential to become the leading neurostimulation solution for moderate to severe OSA patients. To accomplish this, we intend to raise market awareness and educate physicians, payors and patients on the negative impact of OSA and position the Genio system as a safe and effective treatment for moderate to severe OSA patients. We currently offer education and training programs to sleep centers and surgeons, which we believe provide a better understanding of the Genio system's benefits and increase surgeons' confidence implanting our technology. In addition, we provide programs targeted towards patients who use the Genio system to promote and increase their engagement, long-term observance, quality of life and well-being. We intend to establish long-term partnerships with KOLs, ENTs and sleep scientific societies and patient associations that are built on mutual trust and oriented towards the needs of OSA patients and their families. Finally, we intend to establish relationships with government and commercial payors to help reduce barriers to treating OSA by highlighting our clinical data, costs affiliated with untreated OSA patients and the clinical benefit of the Genio system. We plan to build upon this multi-pronged approach with direct-to-consumer marketing initiatives that help to educate patients and can frequently result in patient leads.
- ***Continuing to enhance the Genio system and expand its indications.*** We continue to invest in our solutions and services to further improve the implantation procedure and enhance the patient experience and product features. Potential feature improvements could include design alterations, information driven integrated capabilities, diagnostics or monitoring, sleep apnea testing or various other technological advancements. We believe that bilateral stimulation could lead to better therapeutic performance and address more therapeutic indications compared to other hypoglossal nerve stimulation-based technologies. In June 2021, we announced initial top-line results from the six-month data for the BETTER SLEEP clinical trial. Based on this data, in October 2021, the EU Notified Body granted CE-Marked indication to include OSA patients with CCC for the Genio system in Europe. Currently, CCC patients are contraindicated for other HGNS OSA therapies. Further, in June 2022, we announced that the FDA approved the use of our next generation Genio 2.1 system for use in the DREAM trial. In July 2022, we obtained the CE-Mark for the Genio 2.1 system. In addition, we may look for

strategic opportunities, including partnerships or collaborations, to broaden our capabilities and expertise in line with our patient-centric vision.

- ***Pursuing and establishing favorable reimbursement coverage of the Genio system.*** While there is general consensus among physicians and payors of the medical necessity to treat OSA and increase the number of HGNS therapy coverage decisions, we continue to develop further clinical evidence intended to demonstrate a long-term meaningful improvement in health outcomes for patients meeting the specified criteria. We are initially targeting markets in Europe where we have identified a clear reimbursement pathway or execution strategy. In Germany, we have successfully obtained reimbursement under a dedicated DRG code for HGNS. In Switzerland, we obtained reimbursement under an OSA-specific DRG code by the Federal Statistic Office, or BFS. Each of these reimbursement coverages includes the cost of the Genio system, implant procedure, hospital stay and follow-up care. We expect that the outcomes of the ongoing pivotal DREAM trial, if positive, will support marketing authorization and reimbursement in the United States. We believe that establishing and maintaining reimbursement will be important in achieving broad acceptance of our system by healthcare providers in these markets.
- ***Continuing to build a commercial infrastructure in selected geographies.*** We have grown our commercial team to include a sales and marketing organization of over a dozen representatives with substantial medical device sales, education and clinical experience to support commercialization of the Genio system. Our initial strategy is to employ a targeted approach to increase therapy penetration within specific physician practice groups instead of a broad outreach strategy to physicians in general. Our sales and marketing organization is focused on prioritizing high volume centers that are strategically located and building long-standing relationships with key physicians with strong connections to the population of OSA patients indicated for the Genio system. We are focusing our efforts on developing Centers of Excellence in each of our commercial markets, where we plan to invest in developing the Genio system as the preferred treatment option for indicated moderate to severe OSA patients. Using a direct commercialization model in most of our target countries, we plan to utilize account managers to support these Centers of Excellence to strengthen the referral physician network, guiding new patients to these Centers of Excellence. We expect to gradually scale up our commercial organization in line with market entry and access in the various countries that we are targeting. Based on our experience gained from the commercial roll-out in Europe, but also taking into account particular dynamics of the local markets, we will determine and prepare what we believe to be the optimal sales and marketing structure for commercial launch in the United States if we obtain marketing authorization.

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 Epworth Sleepiness Scale, or ESS, score, by a mean of 3.3 units (p-value=0.0113). Additionally, the number of sleep partners who reported that their partner did not snore, or snored only softly, increased from 4.2% at baseline to 65.0%.
- ***Bilateral hypoglossal nerve stimulation.*** The Genio system was designed to provide bilateral stimulation of the hypoglossal nerve. We believe bilateral stimulation results in a stronger muscle contraction, a more symmetric tongue movement and a wider opening of the airway, which we believe has the potential to provide better clinical outcomes. We also believe that the bilateral stimulation of the Genio system has the potential to treat moderate to severe OSA in patients with CCC. These patients are currently contraindicated for other HGNS systems.
- ***Minimally invasive implant procedure and design.*** The Genio system only has one implantable, low-profile component, which is leadless and battery-free, and only requires a single incision for implantation. The surgical implantation occurs during an outpatient procedure that lasts approximately one hour. Importantly, our system relies on our proprietary duty cycle stimulation algorithm to control the frequency and strength of the neurostimulation. As a result, our system does not require the implantation of a sensing lead to monitor breathing. We believe that the minimally invasive procedure enables patients to recover quickly and resume normal activities within a week. We also believe that our single-incision implantation process will facilitate adoption by a growing number of physicians and surgeons.
- ***External activation chip and battery.*** The Genio system's power source is located in the external activation chip, requiring no battery to be implanted in the patient. Similarly, the external activation chip also includes the software for each user's personalized therapy and can be updated or upgraded without the need for an additional surgical intervention. By eliminating the need for additional surgeries to replace a depleted battery and by enabling updates without additional surgeries, we believe the Genio system may offer a potential reduction in systematic healthcare costs.

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.

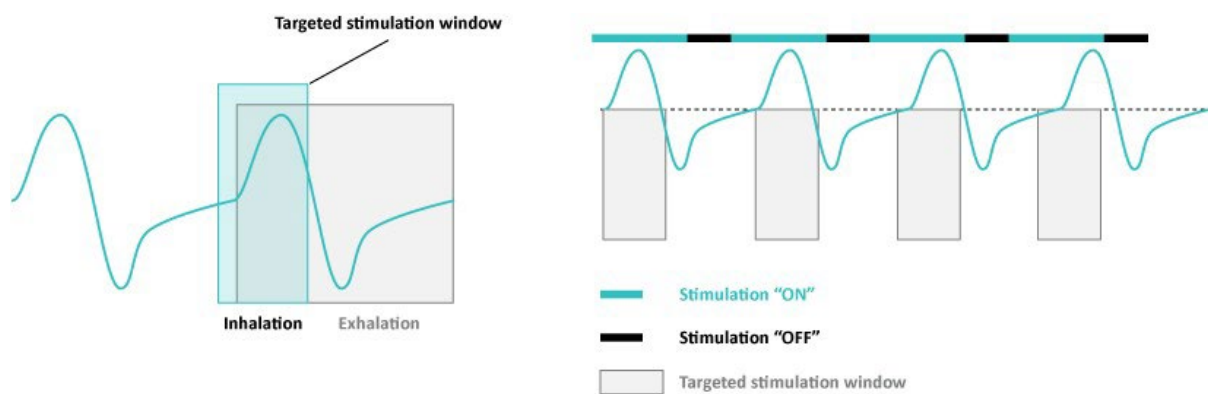
Therapy activation and optimization

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

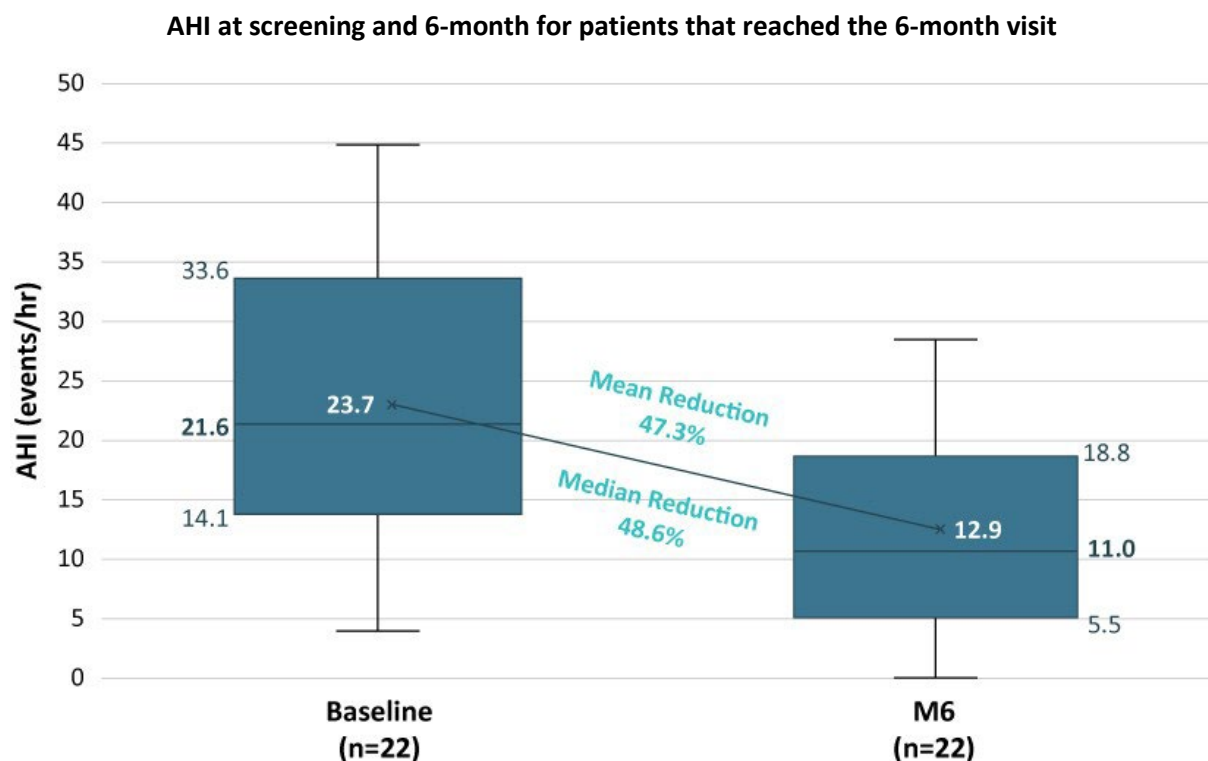
Four SAEs related to the surgical procedure (but not device-related) were reported in three of the 27 patients implanted during the six-month post-implantation period. These included two participants at the same hospital who developed local infections at the surgical site that resulted in removal of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



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

Both the propensity for daytime sleepiness, as measured by the Epworth Sleepiness Scale, and sleep-related quality of life, as assessed using FOSQ-10, significantly improved. The ESS decreased from 11.0±5.3 to 8.0±5.4, representing a mean change of 3.3 units (95% CI 0.8-5.7, p-value=0.0113), whereas the FOSQ-10 score increased from 15.3±3.3 to 17.2±3.0, representing a mean change of 1.9 units (95% CI 0.4-3.4, p-value=0.0157). The FOSQ-10 objective is to demonstrate a change in sleep-related quality of life at the 6-month visit compared to baseline. A FOSQ-10 score greater than 17 is

considered clinically significant. A score below 8 for the Epworth Sleepiness Scale is considered clinically significant. Finally, the arousal index (measures shift from deep sleep to light sleep) significantly decreased from 28.7±11.5 to 16.0±8.0 (p-value<0.0001), representing a mean change of 12.7 events per hour.

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

Outcome	Baseline (n=22)	6-months (n=22)	Mean Difference (95% CI)	P-value
AHI, events/hour	23.7 ± (12.2)	12.9 ± (10.1)	10.8 ± (14.6 to 7.0)	<0.0001
ODI, events/hour	19.1 ± (11.2)	9.8 ± (6.9)	9.3 ± (13.1 to 5.5)	<0.0001
FOSQ-10	15.3 ± (3.3)	17.2 ± (3.0)	1.9 ± (0.4 to 3.4)	0.0157
ESS	11.0 ± (5.3)*	8.0 ± (5.4)	3.0 ± (5.7 to 0.8)	0.0113
SaO2<90%, % time	5.0 ± (6.0)	2.1 ± (3.0)	2.9 ± (4.6 to 1.3)	0.0015
Arousal Index, events per hour	28.7 ± (11.5)	16.0 ± (8.0)	12.7 ± (16.6 to 8.9)	<0.0001
Sleep efficiency (%)	84.0 ± (10.8)	87.3 ± (8.9)	3.2 ± (0.01 to 6.4)	0.0494
Responder rate (Sher Criteria) at 6-month	11 patients out of 22 (50%)		NA	

Legend

Data are mean (Standard Deviation) unless otherwise specified. Arousal Index is the number of arousals and awakenings registered during the sleep trial. SaO2 < 90% is the proportion of the night spent at an oxygen saturation below 90%. Sleep efficiency is the ratio of total time spent asleep in a night compared to the total amount of time spent in bed. ESS is the Epworth Sleepiness Scale. FOSQ10 is the 10 – item Functional Outcomes of Sleep Questionnaire. * means n=21.

Other metrics and outcomes

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

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

5.2. BETTER SLEEP trial

We are currently conducting the BETTER SLEEP trial, a multicenter, prospective, open-label, two-group clinical trial, designed to assess the long-term safety and performance of the Genio system for the treatment of adult OSA patients with and without CCC over a period of 36 months post-implantation. The BETTER SLEEP trial includes a subgroup of CCC patients, which is a patient population that is contraindicated for unilateral HGNS.

Patients with moderate to severe AHI scores ($15 \leq \text{AHI} < 65$) and aged between 21 and 75 years were eligible for enrollment if they failed, refused or did not tolerate PAP treatment. Patients with a body mass index above 32 kg/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. In June 2022, we announced that the FDA approved the use of the Genio 2.1 system in our DREAM trial. Our DREAM trial is a multicenter, prospective, open-label trial in which each participant who undergoes implantation of the Genio system will be followed for five years post-implantation to assess the safety and efficacy of the system in patients with moderate to severe OSA. We initiated the DREAM trial as an IDE pivotal trial to support an application seeking FDA marketing authorization and ultimately, reimbursement in the United States for bilateral HGNS for the treatment of moderate to severe OSA. The trial enrolled 115 patients who have all been implanted as of the date of this Annual Report, with 12-month effectiveness and safety primary endpoints. We have identified 20 centers for the trial, including 15 in the United States. Fifteen of them were active and enrolling patients as of December 2023.

The primary safety endpoint is incidence of device-related SAEs at 12-months post implantation. One of the co-primary effectiveness endpoints is the percentage of responders with at least a 50% reduction in AHI with hypopneas associated with a 4% oxyhemoglobin desaturation and a remaining AHI with hypopneas associated with a 4% oxyhemoglobin desaturation less than 20, together with a 25% reduction of ODI between baseline and 12-month visits. Patients with moderate to severe OSA (AHI score between 15 and 65) and aged between 22 and 75 years are eligible for enrollment if they failed, did not tolerate or refused PAP treatment. Patients with a body mass index above 32 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 presented 12-month data on the first 34 DREAM patients reaching 12-month follow-up as a late-breaking abstract at SLEEP 2023, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in line with expectations. These data are preliminary and not conclusive of final success of the DREAM trial.

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

5.5. ACCESS trial

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

6. Sales and marketing

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

field engineers, with support provided by our corporate team. We began marketing products in Switzerland and also secured first revenue in Spain in 2021 and we began commercialization in Finland in 2022 and in Austria in 2023.

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

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

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

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

understanding of OSA, which we believe will result in maximizing outcomes for Genio users, a better understanding of the technology's benefits and risks and increasing confidence in the safety of the technology.

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

7. Research and development

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

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

We intend to build a scalable technology platform allowing quick and streamlined release of new features and functionalities through software, firmware, hardware updates and upgrades and therapy

enhancement. We believe that the external Genio system Activation Chip could allow for external enhancements to the Genio system without the need for additional surgical intervention.

8. Manufacturing and supply

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

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

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

9. Post balance sheet events

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

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

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

10.1. Assets

Nyxoah SA's asset position as at 31 December 2023, including a comparison with the previous financial year, is detailed in the table below.

	2023	As of 31 December		
		2022	Variation	Variation (%)
ASSETS				
Formation expenses	6,374,645	8,896,154	-2,521,509	-28%
Fixed assets				
Intangible assets	45,388,058	37,729,099	7,658,959	20%
Property, plant & equipment	3,583,499	1,655,932	1,927,567	116%

Financial assets	51,891	22,891	29,000	127%
	49,023,448	39,407,922	9,615,526	24%
Long Term Receivables	1,107,072.04	0.00	1,107,072.04	N/A
Current assets				
Stock	3,315,190	881,981	2,433,209	276%
Receivable	4,305,830	2,539,183	1,766,647	70%
	7,621,020	3,421,164	4,199,856	123%
Cash	53,000,818	89,218,301	-36,217,483	-41%
Prepaid charges	1,267,428	1,258,889	8,539	1%
Total assets	118,394,431	142,202,429	-23,807,999	-17%

10.1.1. Formation expenses

The variation of the year is explained by the annual depreciation (KEUR 2,861) and offset by the capital increase operations (ATM) for an amount of KEUR 340.

10.1.2. 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 2023, development costs related to clinical and R&D projects have been capitalized for an additional amount of KEUR 7,659. Amortization of Intangibles for the year 2023 is reaching an amount of KEUR 736. 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 the result of significant investments (KEUR 2,054) made to expand the production line in the United States. On the other hand, laboratory equipment was purchased to support local production and development projects.

10.1.3. Long Term Receivables

The increase in long term receivable is explained by the acceptance by the Belgian authorities of the tax credit on R&D costs submitted by Nyxoah for the years 2022 & 2023. As explanation, this credit is repayable in 5 years, starting from the year in which the tax return is submitted.

10.1.4. Current assets

Nyxoah continues to support the growth of commercial activities in Europe (Germany and Switzerland). 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 3,315. On the other hand, current assets increase compared to 2022, following significant sales performed in December 2023. Trade receivables amount to KEUR 2,774 in 2023 (KEUR 1,462 in 2022).

10.1.5. Cash

The Company's treasury position amounts to KEUR 53,000 at year-end which represents a decrease of KEUR 36,218 compared to prior year-end. This decrease is mainly driven by indirect and direct

expenses regarding clinical activities conducted worldwide, production costs, investments in fixed assets, R&D project costs and ERP implementation costs.

10.2. Liabilities

Nyxoah SA's liabilities position as at 31 December 2023, including a comparison with the previous financial year, is detailed in the table below.

	As of 31 December			
	2023	2022	Variation	Variation (%)
Capitaux propres et passif			0	
Capitaux propres	108,601,388	134,695,010	-26,093,622	-19%
Provisions et impôts différés	185,252	59,017	126,235	214%
Dettes à plus d'un an	642,624	923,472	-280,848	-30%
Dettes à un an au plus	0	0	0	0
Dettes à plus d'un an échéant dans l'année	301,681	343,348	-41,667	-12%
Dettes commerciales	3,850,619	4,039,149	-188,530	-5%
Dettes fiscales, sociales et salariales	1,848,616	1,528,161	320,455	21%
Autres dettes	2,649,233	342,460	2,306,774	674%
	8,650,150	6,253,117	2,397,032	38%
Compte de régularisation	315,017	271,813	43,204	16%
Total du passif	118,394,431	142,202,429	-23,807,999	-17%

10.2.1. Capital

The decrease in shareholders' equity is mainly explained by the loss for the year of KEUR 44,771. This decrease was offset by successive capital increases during the first quarter 2023.

10.2.2. Provisions and deferred taxes

The year's variation is explained by the increase in warranty provisions calculated on the number of Genio products sold in 2023.

10.2.3. 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 281 corresponds mainly to the portion of the debt transferred from long term to current liabilities as they will fall due in 2024, 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	480,000.00	0	0
6839	2,160,000.00	2,160,000.00	621,903.00	474,105.19	80,617.04	67,181.00
6840	2,400,000.00	2,400,000.00	720,000.00	360,000.00	210,000.00	150,000.00
7388	1,466,701.00	1,466,701.00	440,008.00	66,001.50	352,007.00	22,000.00
Total	7,626,701.00	7,626,701.00	2,261,911.00	1,380,106.69	642,624.04	239,181.00

10.2.4. Short term debt

Short term debt, or current liabilities, include trade payables and payables to affiliated companies. Trade payables in 2023 decreased slightly following invoices received and provisions set aside in December.

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

Remuneration increase due to holidays paid and yearly bonuses provisions following the significant increase of FTE during 2023 (37 average FTE vs 28.1).

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.

10.3. Profit & Loss

The table below sets forth Nyxoah SA's income statement, ending up with a KEUR 44,771 net loss for the year ended 31 December 2023, and comparative information for the year 2022.

	As of 31 December			
	2023	2022	Variation	Variation (%)
Income statement				
Revenue				
Turnover	4,378,149	3,095,389	1,282,759	41%
Increase (decrease) in stock and in contracts in progress	3,737,884	535,983	3,201,901	597%
Other operating income	460,960	415,551	45,409	11%
Produced fixed assets	8,437,145	15,402,040	-6,964,896	-45%
	17,014,137	19,448,964	-2,434,826	-13%
Operating costs				
COGS	-1,992,411	-1,149,517	-842,893	73%
Work In Progress	0	0	N/A	N/A
Research and development costs	-22,307,845	-23,816,750	1,508,905	-6%
- Services and other goods	-21,377,399	-22,944,777	1,567,378	-7%
- Remuneration, social security and pensions	-930,446	-871,973	-58,473	7%
Overhead costs	-31,599,188	-22,840,923	-8,758,264	38%
- Services and other goods	-25,436,434	-18,595,143	-6,841,291	37%
- Remuneration, social security and pensions	-6,162,754	-4,245,781	-1,916,973	45%
Depreciation	-7,459,738	-3,859,388	-3,600,351	93%
Provisions for liabilities and charges	-126,235	-47,371	-78,864	166%
Other operating costs	-126,005	-285,136	159,131	-56%
Non recurring operating or financial charges	0	0	0	N/A
Operating loss	-46,597,283	-32,550,121	-14,047,162	43%
Financial income	4,077,994	7,086,262	-3,008,268	-42%
Financial charges	-3,343,857	-4,146,339	802,482	-19%
Income taxes	1,092,326	-15,621	1,107,857	-7092%
Loss of the period	-44,770,819	-29,625,819	-15,145,000	51%

10.3.1. Revenue

The Company continues its growth mainly in Germany, generating revenues of KEUR 4,378 in 2023 (KEUR 3,095 in 2022). The remaining part of sales has been generated in Spain and Switzerland.

Other operating income is stable compared with 2022, and is made up mainly by the withholding tax exemption for employees working in the clinical field.

The decrease in capitalized expenses in 2023 is explained by the gradual completion of clinical trials, mainly in America, with the aim of obtaining FDA approval.

10.3.2. Operating Costs

Operating costs show a significant increase compared to 2022. This is explained by several factors:

- Production costs increased because of the production of the devices sold in 2023.
- Research and development costs decrease as a result of the reduction in clinical activities conducted mainly by Nyxoah INC. These costs are charged to Nyxoah SA.
- Overhead costs increased due to the growth of the Company's activities and its internal projects managed by consultants and members of the organization such as the implementation of a new ERP.
- 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 and write-off increased following the write-off of KEUR 3,401 on non-trading inventory.

10.3.3. Financial income

Financial income decreased following the year-end revaluation of our USD bank balances. This decrease was nevertheless offset by the increase in interest generated and provisioned on bank deposits and T-Bills (KEUR 1,834).

10.3.4. Financial charges

Financial charges decreased significantly in 2023 compared to 2022 which is explained as follows:

- The Company has written off all cash transfer transactions to its Australian subsidiary.
- Exchange rate differences are an important factor as well because the Company is dealing more and more with foreign currencies.

10.3.5. Loss of the year

The loss of the year amounts to KEUR 44,778 compared to a loss of the year of KEUR 27,021 for 2021.

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

Profit (loss) of the year:	(44,770,819)
Profit (loss) of previous years:	(112,185,345)
<u>Loss to be carried forward:</u>	<u>(156,956,164)</u>

11. 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.

Nyxoah also is using deposit term, with different maturity, to generate positive interests.

12. Risks and uncertainties

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

12.1. Risks related to our financial position

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

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

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

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

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

The Genio system is currently our only commercial product, which we market in certain European countries, and our success depends entirely upon its market acceptance and adoption by physicians, payors and patients. The Genio system may not gain commercial acceptance in target markets. If we fail to gain and maintain commercial market acceptance of the Genio system in our target markets, for instance, because of insufficient price and reimbursement levels from government and third-party

payors, competition, or the inability to demonstrate the benefits and cost-effectiveness of the Genio system compared to other products available on the market, the amount of revenue generated from sales of the Genio system in the future could continue to be limited, and could even decrease over time. In addition, the Genio system has not received marketing authorization in the United States, and our future financial performance will depend on the successful completion of our DREAM pivotal trial, which is intended to support an application for market authorization to commercialize the Genio system in the United States.

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

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

We expect to incur significant expenses and operating losses over the next few years, and we may need to raise additional capital in the future. We have so far been financed primarily by funds invested by our shareholders, including in connection with our initial public offering on Euronext Brussels in September 2020 and the listing of our ordinary shares on the Nasdaq Global Market in July 2021. Based on our current operating plan and our existing cash and cash equivalents of €21.6 million and financial assets of €36.1 million as of December 31, 2023, we expect to be able to fund our operations until the fourth quarter of 2024. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our financial resources much faster than currently expected. Pursuant to the requirements of IAS 1.25-26, Presentation of Financial Statements - Going Concern, and as a result of our financial condition and other factors described herein, there is material uncertainty about our ability to continue as a going concern for a period of at least twelve months from the date of this Annual Report. See Section 14 (“Going concern”). Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. Our future success depends on our ability to raise capital and/or execute our current operating plan. Any future funding requirements will depend on many factors, including without limitation:

- acceptance of our Genio system by patients, physicians, government payors, private payors, and the market generally in our target markets;
- the scope, rate of progress and cost of current or future clinical trials;
- the cost and timing of obtaining additional regulatory clearances, approvals, classifications, certifications or other marketing authorizations for the Genio system;
- the cost and timing of establishing additional sales and marketing capabilities;
- the cost of research and development activities;
- the cost of filing and prosecuting patent applications and other intellectual property rights and defending and enforcing our patents or other intellectual property rights in various jurisdictions;

- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;
- the cost associated with any complications or side effects related to the use of the Genio system;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the costs of operating as a public company in Belgium and the United States.

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

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

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

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

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

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

12.2. Risks related to development of our products and product candidates

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

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

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

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

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

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

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

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

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

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

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

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

- general conservatism about the adoption of new treatment practices and reluctance to switch their patients from existing therapies;

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

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

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

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

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

We consider other companies that have designed hypoglossal nerve stimulation technologies to treat OSA as direct competitors. We are aware of only one currently marketed nerve stimulation device for the treatment of OSA, the Inspire Medical system marketed by Inspire Medical Systems, Inc., and one other nerve stimulation system for the treatment of OSA currently not actively commercialized in Europe from ImThera/ LivaNova PLC. The Inspire Medical system is currently the only neuro

stimulation system approved to treat moderate to severe OSA in the United States. Additionally, we also consider, as indirect competition, invasive surgical treatment options such as uvulopalatopharyngoplasty and maxillomandibular advancement surgery and, to a lesser extent, mandibular advancement devices, which are primarily used in the treatment of mild to moderate OSA.

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

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

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

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

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

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

12.3. Risks related to our dependence on third parties and on key personnel

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

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

If we are required to change the manufacturer of a critical component of our implant systems, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality specifications and applicable regulatory requirements, which could further impede our ability to manufacture our implant systems in a timely manner. If we encounter demand for our system in excess of our inventory and we need to contract with these additional suppliers, we will face challenges in meeting that demand. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our implant systems or could require that we modify the design of those

systems. If the change in manufacturer results in a significant change to any product, new marketing authorizations or certification from the FDA or similar regulatory authority may be necessary before we implement the change, which could cause substantial delays. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely or cost-effective manner.

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

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

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

Given our current state of the development, reliance on the expertise and experience of our board of directors, management and other key employees, as well as contractors, in management, engineering, manufacturing, clinical and regulatory matters, sales and marketing, and other functions is crucial. The departure of any of these individuals without timely and adequate replacement or the loss of any of our senior management or other key employees would make it difficult for us to achieve our objectives in a timely manner, or at all. We might not be able to find and attract other individuals with similar levels of expertise and experience or similar relationships with commercial partners and other market participants. In addition, our competitive position could be compromised if a member of senior management transferred to a competitor.

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

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

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

compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons including the loss of data; or if the third party becomes bankrupt or enters into liquidation.

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

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

Expedited, reliable shipping is essential to our operations since the components of the Genio system are manufactured to our specifications by third-party suppliers in various jurisdictions. While the initial assembly of the different electronic components is done by different external suppliers, the final assembly is performed in our facilities in Israel and Belgium. As a result, we rely heavily on providers of transport services for reliable and secure point-to-point transport of the key components of the Genio system to our facility and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any components, it would be costly to replace such components in a timely manner and such occurrences, if they resulted in delays to the assembly and shipment of the completed Genio system to customers, may damage our reputation and lead to decreased demand for the Genio system and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for the Genio system on a timely basis.

12.4. Risks related to manufacturing

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

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

We expect to be required to significantly increase manufacturing volumes as clinical trials on the Genio system are expanded and the Genio system is commercialized. The capacity of our manufacturing facilities in Tel Aviv, Israel, and Milmort, Belgium, along with our contract manufacturer in the United States, is expected to cover the Genio Implantable Stimulator and Genio External Stimulator demand for 2024. Manufacturing of the Genio Activation Chip and the Genio Charging Unit is mostly outsourced to a third party contract manufacturing organization. In order to support future demand

for the Genio system, we may need to expand our manufacturing capacity, which could require opening a new facility or additional outsourcing to a third-party contract manufacturing organization. For example, if we obtain regulatory authorization to market the Genio system in the United States we would likely have to significantly increase our manufacturing capabilities in order to satisfy anticipated demand. We expect that this could include opening a manufacturing facility in the United States. Opening a new manufacturing facility could involve significant additional expenses, including for the construction of a new facility, the movement and installation of key manufacturing equipment, the modification of manufacturing processes and for the recruitment and training of new team members. In addition, we must also notify, and in most cases obtain approval from, regulatory authorities regarding any changes or modifications to our manufacturing facilities and processes, and the regulatory authorities might not authorize us to proceed or might delay the process significantly.

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

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

To ensure adequate inventory supply of the Genio system in general and its components, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for the Genio system and its components. To date, we have only commercialized the Genio system in limited quantities, mostly in Germany, and our ability to accurately forecast demand for our Genio system could be negatively affected by many factors, including failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for the Genio system or for products of our competitors, failure to accurately predict customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of the Genio brand. Conversely, if we underestimate customer demand for the Genio system, our third-party contract manufacturers may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or third-party manufacturers might not be able to allocate sufficient capacity in order to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for the Genio system.

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

12.5. Risks related to legal and regulatory compliance matters

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

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

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

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

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

We currently manufacture the Genio system and have entered into relationships with third-party suppliers to manufacture and supply certain components of the Genio system. Our manufacturing practices and the manufacturing practices of our third-party suppliers are subject to ongoing regulation and periodic inspection. In the United States, the methods used in, and the facilities used for, the manufacture of medical devices must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, and servicing of medical devices. Furthermore, we will be required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. The Genio system is also subject to similar state regulations and various laws and regulations of other countries governing manufacturing.

Any failure to follow and document the adherence to regulatory requirements (including having in place an adequate quality management system in line with the most up-to-date standards and regulations) by us or our third-party suppliers may lead to significant delays in the availability of the

Genio system for commercial sale or clinical trials, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval or maintenance of marketing applications for the Genio system.

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

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

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

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

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

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

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

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

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

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

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

We have developed and maintains a quality management system for medical devices intended to ensure quality of our products and activities. The system is designed to be in compliance with regulations in many different jurisdictions, including the QSR mandated by the FDA in the United States and the requirements of the AIMD Directive in the European Union, including the international

standard ISO13485 required by the member states in Europe that recognize the CE-Mark, as well as Israel, New Zealand and Australia. The FDA issued a Notice of Proposed Rulemaking in February 2022 describing revisions to the QSR to harmonize it with ISO13485. However, it is not clear when the FDA plans to issue a Final Rule to implement the harmonized regulations.

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

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

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

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

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

All medical devices have associated risks. Regulatory authorities regard active implantable medical devices, or AIMDs, as the highest risk category of medical devices and, accordingly, AIMDs are subject to a high level of scrutiny when seeking regulatory approval or other marketing authorization. The

Genio system was reviewed, classified and the certificate of conformity as an AIMD was issued by our European Notified Body allowing us to affix the CE-Mark. A CE-Mark in Europe indicates that the device in question is in full compliance with European legislation. Medical devices authorized for marketing in the European Union need to comply with the essential requirements laid down in the AIMD Directive and in particular to demonstrate that they are designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others (that the potential benefits outweigh potential risks). In addition, medical devices must achieve the performance intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. Devices authorized first in the European Union may be associated with an increased risk of post-marketing safety alerts and recalls. On the other hand, before FDA premarket approval of a medical device in the United States, a device must be shown to be safe and effective per its intended use. The risks associated with medical devices and the therapy delivered by them, include, among others, risks associated with any surgical procedure, such as infection, allergic reaction, and consequences of anesthesia and risks associated with any implantable medical device such as device movement, electromagnetic interference, device failure, tissue damage including nerve damage, pain and psychological side effects associated with the therapy or the surgical procedure.

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

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

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

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

Recalls of the Genio system would divert managerial and financial resources and could result in damaged relationships with regulatory authorities and lead to loss of market share to competitors. In

addition, any product recall may result in irreparable harm to our reputation. Any product recall could impair our ability to produce products in a cost-effective and timely manner in order to meet customer demand. We may also be required to bear other costs or take other actions that may have a negative impact on future revenue and could prevent us from achieving or maintaining profitability.

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

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

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

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

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

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

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

We are subject to various federal, state and local laws pertaining to healthcare fraud and abuse laws, including anti-kickback, false claims and transparency laws. Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities. In addition, many EU member states have adopted national “Sunshine Acts” which impose reporting and transparency requirements (often on an annual basis) on medical device manufacturers, similar to the requirements in the United States. For instance, pursuant to the Belgian Act of December 18, 2016 and its implementing Royal Decree of June 14, 2017, which entered into force on June 23, 2017, manufacturers of medical devices are required to document and disclose all direct or indirect premiums and benefits granted to healthcare professionals, healthcare organizations and patient organizations with a practice or a registered office in Belgium. Also, under Article 10 of the Belgian Act of March 25, 1964, it is prohibited (subject to limited exceptions) in the context of the supply of medical devices to offer or grant any advantage or benefit in kind to amongst others healthcare professionals and healthcare organizations. In addition, certain countries also mandate implementation of commercial compliance programs.

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

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

sanctions, including exclusions from government funded healthcare programs. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

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

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

12.6. Risks related to intellectual property

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

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

We generally seek patent protection where possible for those aspects of our technology and products that we believe provide significant competitive advantages. However, obtaining, maintaining, defending and enforcing pharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and

development output before it is too late to obtain patent protection. Under certain of our license or collaboration agreements, we may not have the right to control the preparation, filing, prosecution and maintenance of patent applications, or to maintain the rights to patents licensed to or from third parties. Further, we cannot be certain that patents will be issued with respect to our pending or future patent applications. In addition, we do not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or whether they will prevent the development of competitive patents or provide meaningful protection against competitors or against competitive technologies.

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

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

In addition, our intellectual property rights might be challenged, invalidated, circumvented or rendered unenforceable. Our competitors or other third parties may successfully challenge and invalidate or render unenforceable our issued patents, including any patents that may be issued in the future. This could prevent or limit our ability to stop competitors from marketing products that are identical or substantially equivalent to the Genio system. In addition, despite the broad definition of our concepts and inventions in our portfolio, as is common in technological progress, competitors may

be able to design around our patents or develop products that provide outcomes that are comparable to the Genio system but that are not covered by our patents. Much of our value is in our intellectual property, and any challenge to our intellectual property portfolio (whether successful or not) may affect our value.

We could become subject to intellectual property litigation.

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

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

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

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

Additionally, competitors and other third parties may infringe or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors. In addition,

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

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

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

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

We rely on licensing agreements providing us exclusivity in the field of our practice. While we have ensured through multiple robust agreements acquisition of exclusive licenses and freedom to operate for our technology, as with any agreement, under unexpected or unpredictable circumstances, these could be under a risk of being terminated despite companies' efforts and diligence in ensuring integrity of the agreement. Should the agreements be found invalid or licenses revoked and the licensor decide to sue us for infringement of its patents rights, this could expose us to risks of litigation. In addition, any intellectual property litigation could force us to do one or more of the following: (i) stop selling the Genio system or using technology that contains the allegedly infringing intellectual property; (ii) forfeit the opportunity to license our patented technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; (iii) pay substantial damages to the party whose intellectual property rights we may be found to be infringing; or (iv) redesign those products that contain or utilize the allegedly infringing intellectual property. The requirement to obtain licenses to third party intellectual property could also arise in the

future. If we need to license in any third-party intellectual property, we could be required to pay lump sums or royalties on our products. In addition, if we are required to obtain licenses to third party intellectual property, we might not be able to obtain such licenses on commercially reasonable terms or at all.

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

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

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

12.7. Risks related to the ordinary shares

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

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

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

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

which our investors have purchased them. Investors seeking cash dividends should not purchase the ordinary shares.

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

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

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

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

Our research and development facility and all manufacturing facilities are located in Tel Aviv, Israel. In addition, the majority of our employees and some officers are residents of Israel. Accordingly, political, economic and military conditions in Israel, including the ongoing conflict between Israel and Hamas, may directly adversely affect our business. Any armed conflicts, terrorist activities, political instability in the region or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our business conditions in general and harm our results of operations. Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although Israeli legislation requires the Israeli government to

cover the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure that this government coverage will be maintained, or if maintained, will be sufficient to fully compensate us if any damages are incurred. Any losses or damages incurred by us could have a material adverse effect on our business.

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

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

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

13. Justification of the application of the valuation rules in the assumption of continuity

Since the balance sheet shows a loss carried forward of €157.0 million, we hereby confirm, pursuant to Article 3.6 of the Code of Companies and Associations, the application of the valuation rules in the assumption of continuity. We believe that the application of the valuation rules in the assumption of continuity is justified because the loss carried forward is largely due to the significant research and development expenses incurred over the years for the development and regulatory approval of the Genio device. That being said, the Company is able to pay all its debt when they fall due.

14. Going concern

The Company has consistently operated with deficits and sustained negative cash flows since its inception considering the significant research and development expenses incurred for the

development and regulatory approval of the Genio device. As of December 31, 2023, the Company's statement of financial position includes an accumulated loss of €157.0 million and total assets of €118.4 million. Current assets as of December 31, 2023 total €63.0 million, comprising €7.7 million in available cash and cash equivalents, and €45.3 million in marketable securities, primarily derived from previous public offerings.

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

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

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

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

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 five 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
Jürgen Hambrecht	Independent Non-executive Director	2020	Annual general shareholders’ meeting of 2024
Kevin Rakin	Independent Non-executive Director	2020	Annual general shareholders’ meeting of 2024
Rita Johnson-Mills	Independent Non-executive Director	2021	Annual general shareholders’ meeting of 2024
Virginia Kirby	Independent Non-executive Director	2022	Annual general shareholders’ meeting of 2024

Wildman Ventures LLC (represented by Danial Wildman)	Independent Non-executive Director	2023	Annual general shareholders' meeting of 2024
Pierre Gianello	Non-executive Director	2020	Annual general shareholders' meeting of 2024
Olivier Taelman	Executive Director / CEO	2020	Annual general shareholders' meeting of 2024

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

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

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

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

Rita Johnson-Mills has served as a non-executive director since August 2021. Since January 2018, Ms. Johnson-Mills has been a founder and Chief Executive Officer of consulting firm RJM Enterprises and she brings a combined 30 years of direct health care experience from the federal, state and private industry, 15 years of which she was directly responsible for profitability and growth of healthcare organizations. She served as President and Chief Executive Officer of UnitedHealthcare Community Plan of Tennessee from August 2014 to December 2017, after having previously served as Senior Vice President, Performance Excellence and Accountability for UnitedHealthcare Community & State since 2006. Before that, she served as the Director of Medicaid Managed Care for the Centers for Medicare and Medicaid Services and as Chief Executive Officer of Managed Health Services Indiana and Buckeye Health Plan, wholly owned subsidiaries of Centene Corporation. She currently serves on the Board of Directors of Quest Analytics, LLC, Ellipsis Health Inc., and Ownes & Minor, Inc. and previously served

on the Board of Directors of Brookdale Senior Living Inc. Ms. Johnson-Mills received dual Master's degrees from Ohio State University, Master of Public Policy and Master of Labor/Human Resources. She is also a Hogan certified executive coach and a National Association of Corporate Directors Governance Fellow.

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

Wildman Ventures LLC, as represented by Daniel Wildman, has served as a non-executive director since January 8, 2023. Mr. Wildman is currently the President and Chief Executive Officer of Wildman Ventures, LLC, a strategic consulting company that provides advisory services to several medical device and pharmaceutical companies, and has served in such role since January 2019. Additionally, Mr. Wildman is the Chairman of the Board of Progenerative Medical, Inc., where he has served in such role since March 2022, and also currently serves as a Strategic Advisor for PanTher Therapeutics, Inc., where he has served in such role since February 2022. Prior to serving in such roles, Mr. Wildman served in various roles at Johnson & Johnson (NYSE: JNJ), or J&J, from 2000 to January 2019, where he most recently led the Digital Surgery Strategy Initiative that developed an integrated strategy for robotic surgery. From 1990 to 2000, Mr. Wildman served in a variety of sales, marketing, operations and strategic planning roles at Boston Scientific Corporation (NYSE: BSX). Mr. Wildman has served as a member of the Board of Directors of Urogen Pharma, Ltd. (NASDAQ: URGN) since November 2022 and previously served as an Independent Director of Precision Healing, Inc. from June 2020 to April 2022. Mr. Wildman received a Bachelor of Arts degree in Economics from St. Lawrence University.

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

training at the Massachusetts General Hospital, Harvard Medical School in the Transplant Biology Research Centre managed by Prof. David Sachs.

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

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.

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

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

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), Jürgen Hambrecht and Wildman Ventures LLC (represented by Daniel Wildman), all independent non-executive directors.

The members of the audit committee must have a collective competence in the business activities of the Company as well as in accounting, auditing and finance, and at least one member of the audit committee must have the necessary competence in accounting and auditing. According to the Board of Directors, the members of the audit committee satisfy this requirement, as evidenced by the

different senior management and director mandates that they have held in the past and currently hold.

The role of the audit committee is to:

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

The audit committee meets at least four times a year.

Remuneration committee

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

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

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

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

- make proposals to the Board of Directors on the remuneration policy of directors, the persons in charge of the management, and the persons in charge of the daily management, as well as,

where applicable, the resulting proposals that the Board of Directors must submit to the general shareholders' meeting;

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

The remuneration committee meets at least twice a year.

Nominating and corporate governance committee

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

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

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

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

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

Science & technology committee

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

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

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

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

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

15.2.4. Meetings of the Board and the committees

Meetings of the Board of Directors

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

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

(1) board member as of January 8, 2023

Meetings of the Board committees

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

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

(1) member as of January 8, 2023

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

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

(1) chair as of January 8, 2023

(2) member as of January 8, 2023

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

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

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

Science & technology committee members	2 Mar 2023	15 Jun 2023	25 Sep 2023
Robert Taub	Present	Present	Present
Virginia Kirby	Present	Present	Present
Pierre Gianello (chair)	Present	Present	Present

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

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

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

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

Context

Reference is made to a meeting of the remuneration committee of the Company held on 2 January 2023, where the performance of Mr. Olivier Taelman and Mr. Loïc Moreau, in their capacity of CEO and CFO of the Company, respectively, was discussed to determine the amount of their performance-based bonus in relation to financial year 2022. The remuneration committee proposed to determine

the performance-based bonuses of Mr. Olivier Taelman and Mr. Loïc Moreau as further detailed in the documents attached hereto in Schedule 1 (Proposal bonus to Mr. Olivier Taelman) and Schedule 2 (Proposal bonus to Mr. Loïc Moreau).

Decisions

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

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

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

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

"Prior to the circulation of these written resolutions:

- Olivier Taelman (director and CEO of the Company) declared to the Board that he has a conflict of interest of a financial nature in the sense of article 7:96 CCA in relation to the proposed re-pricing of warrants previously granted under the 2021 Warrants Plan (item 1 of the agenda) and the proposed grant of warrants under the 2021 Warrants Plan (item 3 of the agenda). Therefore, he cannot vote on items 1 and 3 of the agenda and will sign these written resolutions for acknowledgement only with regard to these items on the agenda.
- The other directors discussed and acknowledged that they are of the opinion that the proposed re-pricing of 75% of the warrants previously granted to Olivier Taelman under the 2021 Warrants Plan and the proposed grant of 25,000 additional warrants under the 2021 Warrant Plan to Olivier Taelman, in both cases at a (revised) exercise price set in accordance with clause 4.3.1 of the 2021 Warrants Plan¹ is justified and in the interest of the Company (a) in view of Olivier Taelman's role within the Company and the efforts that are requested from him, and (b) because upon the exercise of warrants, Olivier Taelman will have to pay an exercise price for the warrants in cash to the Company, which will increase the Company's net equity and liquidities.

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

Resolutions

1. Re-pricing of warrants previously granted under the 2021 Warrants Plan to the CEO and determination of the exercise price and of other terms and conditions of the re-priced warrants

- Approval of the re-pricing of 75% of the warrants previously granted to Olivier Taelman under the 2021 Warrants Plan to the lowest of (a) the last closing price of the Company's share on Euronext Brussels prior to the effective date of these resolutions, and (b) the average closing price of the Company's share on Euronext Brussels over the thirty (30) day period preceding the effective date of these resolutions (in accordance with clause 4.3.1 of the 2021 Warrants Plan).
For the remaining 25% of the warrants previously granted to Olivier Taelman, the exercise price will remain unchanged.
- Approval that, for the re-priced warrants, the exercise restriction provided for in the relevant warrant agreement stipulating that the warrants can only be exercised prior to the fifth anniversary of the date on which the warrants were granted, will be modified to stipulate that

the warrants can only be exercised prior to the fifth anniversary of the date of the re-pricing (i.e. the effective date of these resolutions).

- Confirmation that all other terms and conditions of the re-priced warrants will remain unchanged.

2. (...)

3. **Grant of warrants under the 2021 Warrants Plan to the CEO and determination of the exercise price and of other terms and conditions of the granted warrants**

- Approval of the grant of 25,000 warrants under the 2021 Warrants Plan to Olivier Taelman.
- Determination of the exercise price of the granted warrants at the lowest of (a) the last closing price of the Company's share on Euronext Brussels prior to the effective date of these resolutions, and (b) the average closing price of the Company's share on Euronext Brussels over the thirty (30) day period preceding the effective date of these resolutions (in accordance with clause 4.3.1 of the 2021 Warrants Plan).
- Confirmation that the other terms and conditions of the granted warrants shall be in accordance with the 2021 Warrants Plan.”

15.5. Related party transactions

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

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. In the past, including in 2023, share options have been granted to non-executive directors and the Company does not exclude to award share-based incentives to the non-executive directors, upon advice of the remuneration committee, in the future. This is contrary to provision 7.6 of the 2020 Code that provides that no stock options should be granted to non-executive board members. The Company believes that this provision of the 2020 Code is not appropriate and adapted to take into account the realities of companies in the life sciences industry that are still in a development phase. Notably, the ability to remunerate non-executive directors with share options allows the Company to limit the portion of remuneration in cash that the Company would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. The Company is of the opinion that granting non-executive directors the opportunity to be remunerated in part in share-based incentives rather than all in cash strengthens the alignment of their interests with the interests of the Company's shareholders. This is in the interest of the Company and its stakeholders. Furthermore, this is customary for directors active in companies in the life sciences industry.
3. In deviation of provision 7.6 of the 2020 Code, the non-executive members of the Board of Directors do not systematically receive part of their remuneration in the form of shares. This deviation is explained by the fact that the interests of the non-executive members of the Board of Directors are considered to be sufficiently oriented to the creation of long-term value

for the Company, taking into account that some of them will from time to time hold shares or share options, the value of which is based on the value of the shares. Therefore, the (regular) payment in the form of existing shares is not deemed necessary.

4. Pursuant to article 7:91 of the Belgian CCA and provisions 7.6 and 7.11 of the 2020 Code, shares should not vest and share options should not be exercisable within three years as of their granting. The Company's Board of Directors has been explicitly authorized in the Company's Articles of Association to deviate from this rule in connection with stock based incentive plans, compensations, awards and issuances to employees, directors and service providers of the Company and/or its subsidiaries (from time to time). The Company is of the opinion that this allows for more flexibility when structuring share-based awards.
5. In deviation of provision 7.9 of the 2020 Code, no minimum threshold of shares to be held by members of the executive management team is set. This deviation is explained by the fact that the interests of the members of the executive management team are considered to be sufficiently oriented to the creation of long-term value for the Company, taking into account that some of them will from time to time hold shares or share options, the value of which is based on the value of the shares. Therefore, setting a minimum threshold of shares to be held by them is not deemed necessary.
6. In deviation of provision 7.12 of the 2020 Code, the board of directors does not include, in the contracts with the CEO and other members of executive management, provisions that would enable the Company to recover variable remuneration paid, or withhold the payment of variable remuneration, and specify the circumstances in which it would be appropriate to do so, insofar as enforceable by law. The Company believes that this provision of the 2020 Code is not appropriate and adapted to take into account the realities of companies in the life sciences industry that are still in a development phase nor considers that it is necessary, except as provided in the Company's Clawback Policy pursuant to applicable U.S. securities laws, to apply claw-back provisions as (i) the pay-out of the short-term variable remuneration, based on the achievement of one or more individual objectives and one or more Company objectives as set by the board of directors, is paid only upon achievement of those objectives, and (ii) the Company does not apply any other performance-based remuneration or variable compensation. Furthermore, the ESOP warrant plans set up by the Company contain bad leaver provisions that can result in the unexercised share options, whether vested or not, automatically and immediately becoming null and void if the agreement or other relationship between the holder and the (relevant subsidiary of the) Company is terminated for "cause". Notwithstanding the Company's position that warrants are not to be qualified as variable remuneration (when not depending on performance criteria), the board of directors is of the opinion that such bad leaver provisions sufficiently protect the Company's interests and that it is therefore currently not necessary to provide for additional contractual provisions that give the Company a contractual right to reclaim any (variable) remuneration from the members of the executive management. For those reasons, there are no contractual provisions in place between the Company and the members of the executive management that give the Company a contractual right to reclaim from said executives any variable remuneration that would be awarded.

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, 2023, 49% of the total work force of the Company were women.

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

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. In addition, the Company may from time to time offer non-executive directors the opportunity to subscribe to newly issued shares in the Company at a subscription price that may be substantially lower than the market value of the shares at that time, subject to conditions as set out in the Company's remuneration policy.

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

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

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

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

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

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

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

Members of executive management	
Remuneration component	Short description of main provisions
Base remuneration	Fixed amount
Fringe benefits	Company car, laptop, phone, representation allowance
Age and risk provisions	Pension plan (fixed contribution); health insurance; life insurance (CEO only)
Short term incentive (STI)	Yearly performance bonus, as further detailed below
Long term incentive (LTI)	Participation in share option plans, as further detailed below
Short term incentive plan: yearly performance bonus	
Main provisions	Short description
Performance cycle	One calendar year
Target bonus	NA
Performance criteria and corresponding payout levels	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 decide 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 since 2021: 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, 2021 and 2022 is made. As from next year, the remuneration report will include

information relating to additional years prior to the reported year (with a maximum of five years prior to the reported year and with the year 2020 being the earliest year in the comparison).

15.8.2. Total remuneration

Total remuneration of directors

Table 1 - Total remuneration directors										
Name, position	Fixed remuneration			Variable remuneration		Extra-ordinary items	Pension expense	Total remuneration (f)	Proportion of fixed and variable remuneration	
	Base remuneration	Attendance fees	Fringe benefits	One-year variable	Multi-year variable (e)					
Robert Taub Non-executive director, Chairman	100 000 (a)	0	27 633 (c)	0	0	0	0	127 633	Fixed: 100%	Variable: 0%
Jürgen Hambrecht Non-executive director	58 500 (a)	0	0	0	0	0	0	58 500	Fixed: 100%	Variable: 0%
Kevin Rakin Non-executive director	63 000 (a)	0	5 593 (c)	0	0	0	0	68 593	Fixed: 100%	Variable: 0%
Rita Johnson-Mills Non-executive director	58 500 (a)	0	5 121 (c)	0	0	0	0	63 621	Fixed: 100%	Variable: 0%
Virginia Kirby Non-executive director	49 500 (a)	0	9 718 (c)	0	0	0	0	59 218	Fixed: 100%	Variable: 0%
Wildman Ventures LLC Non-executive director	58 500 (a)	0	12 778 (c)	0	0	0	0	71 278	Fixed: 100%	Variable: 0%
Pierre Gianello - Employee	110 447 (b)	0	567 (d)	0	0	0	0	111 014		
- Non-executive director	54 000 (a)	0	10 620 (c)	0	0	0	0	64 620		
Pierre Gianello TOTAL	164 447	0	11 187	0	0	0	0	175 634	Fixed: 100%	Variable: 0%
Olivier Taelman (*) Executive director, CEO	0	0	0	0	0	0	0	0		

Notes:

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

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

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

Key:

AC = Audit committee

RC = Remuneration committee

NCGC = Nominating and corporate governance committee

STC = Science & technology committee

- (b) Salary pursuant to employment agreement between Pierre Gianello and the Company for the role of Pierre Gianello as medical director of the Company one day per week.
- (c) Fringe benefits consist of the reimbursement of out-of-pocket expenses (mostly travel related).
- (d) Meal vouchers.
- (e) The “multi-year variable” remuneration corresponds to the “surplus value” as calculated in Table 4 below. Where the surplus value is negative, the multi-year variable remuneration is deemed zero.
- (f) The numbers included in this column may differ from the numbers included in Note 32.2 to the Consolidated Financial Statements due to accounting rules applied for purposes of the Consolidated Financial Statements.

Total remuneration of the members of executive management

Table 2 - Total remuneration members of executive management (*)										
Name, position	Fixed remuneration			Variable remuneration		Extra-ordinary items	Pension expense (d)	Total remuneration	Proportion of fixed and variable remuneration	
	Base remuneration	Attendance fees	Fringe benefits (a)	One-year variable (b)	Multi-year variable (c)					
Olivier Taelman CEO	436 351	NA	36 057	301 500	23 996	0	33 188	831 092	Fixed: 60.84%	Variable: 39.16%
Loïc Moreau CFO	258 877	NA	10 253	183 807	0	0	15 750	468 687	Fixed: 60.78%	Variable: 39.22%

Notes:

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

Table with notes regarding the performance

Table 3 - Performance (one-year variable remuneration)				
	Description of performance criteria and type of applicable remuneration	Relative weight of performance criteria		a) Measured performance b) Corresponding remuneration (EUR)
Olivier Taelman CEO	Company objectives: operational	55%	a)	49%
			b)	121 275
	Company objectives: strategic/financial	45%	a)	89%
			b)	180 225
	TOTAL			301 500
Loïc Moreau CFO	Company objectives: operational/strategic/financial	50%	a)	67%
			b)	86 726
	Finance objectives	50%	a)	75%
			b)	97 081
	TOTAL			183 807

15.8.3. Share based remuneration

Table 4 - Remuneration in share options												
Name, position	Main conditions of the share option plans						Information regarding the reported financial year					
							Opening balance	During the year				Closing balance
								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 <i>Chairman</i>	ESOP 2021	08 Jun 2022	14 Jun 2023	NA	14 Jun 2023 08 Jun 2027	12,95	25.000	a) 0	a) 25.000	0		
							b) 177.500	b) 177.500	c) 323.750	d) -146.250		
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7,19	0	a) 25.000	a) 0	25.000		
							b) 177.500	b) 177.500	c) 0	d) 0		
Jürgen Hambrecht <i>Non-executive director</i>	ESOP 2021	08 Jun 2022	14 Jun 2023	NA	14 Jun 2023 08 Jun 2027	12,95	25.000	a) 0	a) 25.000	0		
							b) 177.500	b) 177.500	c) 323.750	d) -146.250		
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7,19	0	a) 25.000	a) 0	25.000		
							b) 177.500	b) 177.500	c) 0	d) 0		
Kevin Rakin <i>Non-executive director</i>	ESOP 2021	08 Jun 2022	14 Jun 2023	NA	14 Jun 2023 08 Jun 2027	12,95	25.000	a) 0	a) 25.000	0		
							b) 177.500	b) 177.500	c) 323.750	d) -146.250		
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7,19	0	a) 25.000	a) 0	25.000		
							b) 177.500	b) 177.500	c) 0	d) 0		
Rita Johnson-Mills <i>Non-executive director</i>	ESOP 2021	08 Jun 2022	14 Jun 2023	NA	14 Jun 2023 08 Jun 2027	12,95	25.000	a) 0	a) 25.000	0		
							b) 177.500	b) 177.500	c) 323.750	d) -146.250		
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7,19	0	a) 25.000	a) 0	25.000		
							b) 177.500	b) 177.500	c) 0	d) 0		
Virginia Kirby <i>Non-executive director</i>	ESOP 2021	08 Jun 2022	14 Jun 2023	NA	14 Jun 2023 08 Jun 2027	12,95	25.000	a) 0	a) 25.000	0		
							b) 177.500	b) 177.500	c) 323.750	d) -146.250		
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7,19	0	a) 25.000	a) 0	25.000		
							b) 177.500	b) 177.500	c) 0	d) 0		
Wildman Ventures LLC <i>Non-executive director</i>	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7,19	0	a) 11.398	a) 0	11.398		
							b) 80.926	b) 80.926	c) 0	d) 0		
	ESOP 2022	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7,19	0	a) 13.602	a) 0	13.602		
							b) 96.574	b) 96.574	c) 0	d) 0		
Pierre Gianello <i>Non-executive director</i>	ESOP 2021	08 Jun 2022	14 Jun 2023	NA	14 Jun 2023 08 Jun 2027	12,95	25.000	a) 0	a) 25.000	0		
							b) 177.500	b) 177.500	c) 323.750	d) -146.250		
	ESOP 2021	14 Jun 2023	12 Jun 2024	NA	12 Jun 2024 14 Jun 2028	7,19	0	a) 25.000	a) 0	25.000		
							b) 177.500	b) 177.500	c) 0	d) 0		

Table 4 - Remuneration in share options													
Name, position	Main conditions of the share option plans						Information regarding the reported financial year						
							Opening balance	During the year				Closing balance	
	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 @ date of vesting	d) Surplus value @ date of vesting
Olivier Taelman CEO	ESOP 2021	17 Sep 2021	17 Sep 2024	NA	17 Sep 2024	25,31	8.310	a)	0	a)	0		8.310
					17 Sep 2026		b)		b)	0			
	ESOP 2021	17 Sep 2021	17 Sep 2023	NA	17 Sep 2021	5,42	8.310	a)	0	a)	8.310		0
					24 Mar 2028	(*)	b)		b)	61.162	c)	45.040	d)
	ESOP 2021	24 Mar 2023	24 Mar 2026	NA	24 Mar 2023	5,42	0	a)	25.000	a)	6.250		18.750
					24 Mar 2028		b)	167.000	b)	41.750	c)	33.875	d)
Loïc Moreau CFO	ESOP 2021	21 Feb 2022	21 Feb 2025	NA	21 Feb 2022	5,42	22.500	a)	0	a)	7.500		15.000
					24 Mar 2028	(*)	b)		b)	34.950	c)	40.650	d)
	ESOP 2021	21 Feb 2022	21 Feb 2026	NA	21 Feb 2025	17,76	15.000	a)	0	a)	0		15.000
					21 Feb 2027		b)		b)	0	c)	0	d)
	ESOP 2021	21 Feb 2022	21 Feb 2024	NA	21 Feb 2023	5,42	15.000	a)	0	a)	7.500		7.500
					24 Mar 2028	(**)	b)		b)	34.950	c)	40.650	d)
ESOP 2021	24 Mar 2023	24 Mar 2026	NA	24 Mar 2023	5,42	0	a)	15.284	a)	3.821		11.463	
				24 Mar 2028		b)	102.097	b)	25.524	c)	20.710	d)	4.814

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

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

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

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

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

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

- Form of share options: registered form.
- Transfer of share options: unless the Board of Directors determines otherwise, the share options cannot be sold, assigned, transferred, pledged or otherwise encumbered by the holder of the share options.

- Number of shares to be issued upon exercise of share option:
 - ESOP 2018: each share option can be exercised for 500 new shares, taking into account the share split at a 500:1 ratio that was decided by an extraordinary shareholders' meeting on February 21, 2020.
 - ESOP 2020/ESOP 2021/ESOP 2022: each share option can be exercised for one new share.
- Stock split: in the event of a stock split of the shares, the number of shares to be issued upon the exercise of the share options shall be adjusted accordingly.
- Duration of the share options:
 - Ten years as of their issuance.
 - Contractual expiration period of five years as of the grant, which period shall in no case exceed the ten year period as from issuance.
- Vesting of share options:
 - ESOP 2018/ESOP 2020: unless the Board of Directors determines otherwise: vesting in three tranches: 1/3 of the share options granted vests upon the date of grant, 1/3 vests on the first anniversary date of the relevant share option agreement, 1/3 vests on the second anniversary date of the relevant share option agreement.
 - ESOP 2021/ESOP 2022: unless the Board of Directors determines otherwise: vesting in four tranches: 1/4 of the share options granted vests upon grant, 1/4 vests on the first anniversary of the grant, 1/4 vests on the second anniversary of the grant, 1/4 vests on the third anniversary of the grant.
 - ESOP 2021 granted to directors on June 8, 2022 and on June 14, 2023: vesting in one tranche: all share options granted vest on the first anniversary of the grant.
- Exercise of share options:
 - ESOP 2018/ESOP 2020/ESOP 2021/ESOP 2022: vested share options can be exercised during the following exercise periods: (i) March 1 until June 30; and (ii) September 1 until November 30 of each year during which the share options are valid and exercisable.
- Consequence of termination of relationship between the holder of the share options and the Company: the exercise period and/or vesting period of the share options may vary depending on the circumstances under which the relationship between the holder and the Company is terminated.
- Governing law of the terms and conditions of the share options: laws of Belgium.

15.8.4. Severance payment

During 2023, 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 2023.

15.8.6. Derogations from the remuneration policy

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

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 2023, 2022, 2021 and 2020 only. Going

forward, the remuneration report will each year include information relating to one additional previous year (with a maximum of five years prior to the reported year and with the year 2020 being the earliest year in the comparison).

Yearly remuneration of the directors and the members of executive management

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

(*) The information in this table is derived from the information in this section 15.8 (“Remuneration report”).

(**) The total remuneration for 2020 comprises: board fees (annualized for directors who were only entitled to receive board fees as from September 21, 2020), fee pursuant to consultant agreement between MINV SA and the Company, and salary pursuant to employment agreement between Pierre Gianello and the Company.

The total remuneration for 2021, 2022 and 2023 comprises: board fees paid to directors (excluding, for the avoidance of doubt, reimbursement of out-of-pocket expenses) and salary pursuant to employment agreement between Pierre Gianello and the Company.

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

Yearly performance of the Company

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

Yearly average remuneration of the employees of the Company

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

The average remuneration is calculated as follows:

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

Ratio highest and lowest remuneration

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

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

15.9. Major shareholders

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

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

- (1) As a result of transactions that do not need to be disclosed to Nyxoah or filed with the SEC, the numbers mentioned in this column might not be the actual numbers of shares held by the relevant shareholders at the date of this Annual Report.
- (2) Percentages based on number of shares and denominator at time of event that triggered transparency notification or SEC filing.
- (3) Percentages based on number of shares at time of event that triggered transparency notification or SEC filing but on current denominator.
- (4) Cochlear Investments Pty Ltd is 100% held by Cochlear Limited. Cochlear Limited is not controlled.
- (5) Cooperatieve Gilde Healthcare III Sub-Holding UA and Cooperatieve Gilde Healthcare III Sub-Holding 2 UA hold the shares in Nyxoah. Gilde Healthcare III Management BV is the management company of these two entities and can -in the absence of specific instructions- exercise the voting rights at its discretion. Gilde Healthcare III Management BV is controlled by Gilde Healthcare Holding BV. Gilde Healthcare Holding BV is not controlled.
- (6) Robelga SRL is 100% owned by BMI estate (a partnership (société simple) without legal personality). Robert Taub has 100% usufruct and Robert Taub's children have 100% bare ownership of BMI estate.
- (7) Not controlled.
- (8) Existing shareholders whose shareholding does not exceed 3%.

15.10. Share capital and shares

15.10.1. Number, form and transferability of shares

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

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

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

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

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 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 :

<u>Entity name</u>	<u>Country</u>	<u>Field of activity</u>	<u>Participation</u>
Nyxoah Ltd	Israel	R&D center	100%
Nyxoah GmbH	Germany	Sale 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 116 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 12 ("Description of the principal risks associated with the activities of the Company") and section 14 ("Going concern").

Mont-Saint-Guibert, March 20, 2024

On behalf of the Board of Directors.

Olivier Taelman, CEO