As filed with the Securities and Exchange Commission on June 10, 2021.

Registration Statement No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

NYXOAH SA
(Exact name of Registrant as specified in its charter)

Belgium	**3841**	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

Rue Edouard Belin 12
1435 Mont-Saint-Guibert, Belgium
+32 10 22 23 55
(Address, including zip code, and telephone number, including area code, of Registrant’s principal executive offices)

Corporation Service Company
1090 Vermont Avenue N.W.
Washington D.C. 20005
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Telephone: +1 800 927 9800
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Jonathan L. Kravetz, Esq. **John T. Rudy, Esq.** **Mintz, Levin, Cohn, Ferris, Glovksy & Popeo, P.C.** **One Financial Center** **Boston, MA 02111** **(617) 542 6000**	**Philippe Remels** **NautaDutilh BV/SRL** **Chaussée de La Hulpe 120** **1000 Brussels, Belgium** **+32 2 566 80 00**	**Shayne Kennedy, Esq.** **Latham & Watkins LLP** **650 Town Center Drive** **20th Floor** **Costa Mesa, CA 92626** **(714) 540 1235**

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act.

Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

† The term “new or revised financial accounting standards” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate offering price**(1)	**Amount of registration fee**(2)
Ordinary Shares, no nominal value per share	$ 100,000,000.00	$ 10,910.00

(1) Includes ordinary shares that the underwriters have an option to purchase. See “Underwriting.”

(2) Estimated solely for the purpose of determining the amount of registration fee in accordance with Rule 457(o) under the Securities Act of 1933.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), shall determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated June 10, 2021
Preliminary Prospectus

Nyxoah

Shares

NYXOAH SA

Ordinary Shares

$ per share

Nyxoah SA is offering shares. We anticipate that the initial public offering price will be between $ and $ per share.

This is our initial public offering of our ordinary shares in the United States. We have applied to list our ordinary shares The Nasdaq Global Market under the symbol "NYXH." Our ordinary shares are traded on Euronext Brussels under the symbol "NYXH." On June 9, 2021, the last reported sale price of our ordinary shares on Euronext Brussels was €23.55 per ordinary share, equivalent to a sale price of $28.67 per ordinary share, assuming an exchange rate of €1.00 = $1.2173, the noon buying rate in The City of New York on June 4, 2021 set forth in the H.10 statistical release of the Federal Reserve Board on June 7, 2021.

This investment involves risk. See "Risk Factors" beginning on page 12.

We are an "emerging growth company" as defined under the federal securities laws and, as such, may elect to comply with certain reduced public company reporting requirements in future reports after the completion of this offering. See "Prospectus Summary — Implications of Being an Emerging Growth Company."

	Per Share	Total
Initial public offering price	$	$
Underwriting discount[1]	$	$
Proceeds, before expenses, to Nyxoah SA	$	$

(1) See "Underwriting" beginning on page 179 for additional information regarding underwriting compensation.

Certain of our existing shareholders have indicated an interest in participating in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

The underwriters have a 30-day option to purchase up to additional shares from us at the initial public offering price less the underwriting discount.

Bank Degroof Petercam SA/NV is not a U.S.-registered broker-dealer; therefore, to the extent that it intends to effect any sales of the ordinary shares in the United States, it will do so through Global Alliance Securities, LLC, its affiliated U.S.-registered broker-dealer, in accordance with the applicable U.S. securities laws and regulations, and as permitted by FINRA regulation.

Neither the Securities and Exchange Commission, or SEC, nor any U.S. state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to investors on or about , 2021.

Piper Sandler **Stifel** **Cantor**

Degroof Petercam

The date of this prospectus is , 2021

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ABOUT THIS PROSPECTUS

We are responsible for the information contained in this prospectus and any free-writing prospectus we prepare or authorize. We and the underwriters have not authorized anyone to provide you with different information, and we and the underwriters take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than its date.

For investors outside the United States: neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus or any free writing prospectus must inform themselves about, and observe any restrictions relating to this offering and the distribution of this prospectus and any free writing prospectus outside the United States.

We are a limited liability company (*naamloze vennootschap / société anonyme*) incorporated under the laws of Belgium. Less than a majority of our directors and officers named in this prospectus are citizens or residents of the United States and a significant portion of the assets of the directors and officers named in this prospectus and substantially all of our assets are located outside of the United States. As a result, it may not be possible for you to effect service of process within the United States upon such persons or to enforce against them or against us in U.S. courts judgments predicated upon the civil liability provisions of the federal securities laws of the United States. There is doubt as to the enforceability in Belgium, either in original actions or in actions for enforcement of judgments of U.S. courts, of civil liabilities predicated on the U.S. federal securities laws.

We are incorporated in Belgium, and a majority of our outstanding securities are owned by non-U.S. residents. Under the rules of the U.S. Securities and Exchange Commission, or the SEC, we are currently eligible for treatment as a "foreign private issuer." As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Our financial statements included in this prospectus are presented in Euros and, unless otherwise specified, all monetary amounts are in Euros. All references in this prospectus to "$," "U.S. dollars," and "dollars" means U.S. dollars and all references to "€" and "Euro," mean Euros, unless otherwise noted.

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms "Nyxoah," "the Company," "we," "us" and "our" refer to Nyxoah SA and its wholly owned subsidiaries. In this prospectus, any reference to any provision of any legislation shall include any amendment, modification, reenactment or extension thereof. Words importing the singular shall include the plural and vice versa, and words importing the masculine gender shall include the feminine or neutral gender. All references to "shares" in this prospectus refer to ordinary shares of Nyxoah SA with no nominal value

TRADEMARKS

"Nyxoah," the Nyxoah logo, Genio and other trademarks or service marks of Nyxoah appearing in this prospectus are the property of Nyxoah or its subsidiaries. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus are listed without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their right thereto. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. We do not intend to use or display other companies' trademarks and trade names to imply any relationship with, or endorsement or sponsorship of us by, any other companies.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market opportunity, is based on information from our own management estimates and research, as well as from industry and general publications, research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. The industry publications and third-party studies generally state that the information that they contain has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these publications and third-party studies is reliable, we have not independently verified the market and industry data obtained from these third-party sources. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and uncertainties as the other forward-looking statements in this prospectus. See "Special Note Regarding Forward-Looking Statements." These forecasts and forward-looking information are subject to uncertainty and risk due to a variety of factors, including those described under "Risk Factors." These and other factors could cause results to differ materially from those expressed in our forecasts or estimates or those of independent third parties. While we believe our internal research is reliable and the definition of our market and industry are appropriate, neither such research nor these definitions have been verified by any independent source.

PRESENTATION OF FINANCIAL INFORMATION

This prospectus includes financial information which has been derived from our audited consolidated financial statements as of and for the years ended December 31, 2020 and 2019, our unaudited condensed consolidated interim financial statements for the three months ended March 31, 2021 and 2020, and the related notes, which are collectively referred to as "consolidated financial statements" or "financial statements," and can be found beginning on page F-1 of this prospectus.

We maintain our books and records in Euros and we prepare our audited consolidated financial statements in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. None of the consolidated financial statements in this prospectus were prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. Except with respect to U.S. dollar amounts presented as contractual terms, amounts denominated in U.S. dollars when received or paid and unless otherwise indicated, certain amounts in Euros contained in this prospectus have been translated into U.S. dollars at the rate of $1.00 to €0.85, which was the noon buying rate of the Federal Reserve Bank of New York on March 31, 2021. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars or Euros at that or any other exchange rate as of that or any other rate. We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our ordinary shares. You should read the entire prospectus carefully, including "Risk Factors," "Special Note Regarding Forward-Looking Statements," "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes appearing elsewhere in this prospectus before making an investment decision.

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 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 bilateral hypoglossal nerve stimulation device designed to treat OSA, 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 is the most prevalent sleep disordered breathing condition. It 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. It is estimated that OSA currently affects approximately 936 million people globally between the ages of 30 and 69, of which approximately 425 million people suffer from moderate to severe OSA and require treatment. This chronic disease negatively affects a patient's health and quality of life.

The standard of care first-line therapy for patients with moderate to severe OSA is continuous positive airway pressure, or 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 that make compliance a serious challenge. Various second line therapies such as mandibular oral devices or anatomical surgical procedures also have substantial limitations. In recent years, hypoglossal nerve stimulation 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 to maintain an open airway.

Competitive hypoglossal nerve stimulation systems have proven to provide safe and effective therapy for those suffering from moderate to severe OSA, however there still remain several limitations. The leading hypoglossal nerve stimulation systems consist of multiple implantable components requiring multiple incisions, including an implantable pulse generator with a battery and one or more leads. In addition, existing systems preclude a subset of the OSA patient population diagnosed with complete concentric collapse, or CCC, at the level of the soft palate. These OSA patients are currently contraindicated for hypoglossal nerve stimulation systems. In order to diagnose CCC, a drug induced sleep endoscopy, or DISE, procedure is required. Due to the current contraindication, all OSA patients seeking hypoglossal nerve stimulation therapy are required to undergo a DISE procedure. It is estimated that approximately 30% of moderate to severe OSA patients are affected by CCC and are therefore unable to receive hypoglossal nerve stimulation therapy.

The Genio system is the first neurostimulation system for the treatment of OSA to include a battery-free and leadless neurostimulator capable of delivering bilateral hypoglossal nerve stimulation. The system includes a single implanted component that can be implanted in a minimally invasive procedure requiring only a single incision. 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 our stimulator is external. Unlike competing hypoglossal nerve stimulators, the lack of an implantable battery or additional leads limits the need for complex tunneling and only requires a single incision for implantation. Our 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, our 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.

Our proprietary technology has enabled the CE-Marked system to provide bilateral stimulation to the hypoglossal nerve. Other hypoglossal nerve stimulation systems approved or cleared for treating OSA provide are unilateral and provide hypoglossal nerve stimulation to only one branch 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 has the potential to provide better clinical outcomes. Furthermore, we believe that bilateral stimulation has the potential to address moderate to severe OSA patients with CCC, who are currently contra-indicated for, or unable to be treated with, existing hypoglossal nerve stimulation OSA systems.

We continue to develop a substantial body of clinical data regarding the Genio system. In 2019, we completed our BiLAteral hypoglossal nerve STimulation for treatment of Obstructive Sleep Apnea, or BLAST OSA trial, which was the basis for receiving CE-Mark on the Genio system. Our ongoing BilatEral Hypoglossal Nerve StimulaTion for TreatmEnt of ObstRuctive SLEEP Apnoea clinical trial, or BETTER SLEEP trial, is aimed at evaluating 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 undergo the 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 clinical trial. We are planning to submit the complete trial results to our E.U. Notified Body with the goal of expanding the CE-Marked indication to include CCC. We also are conducting our Dual-sided Hypoglossal neRvE stimulAtion for the treatMent of Obstructive Sleep Apnea clinical trial, or DREAM trial, a pivotal trial designed to support marketing authorization in the United States. We anticipate initial 12-month data for the DREAM trial will be available by the fourth quarter of 2022. Assuming a positive outcome from the DREAM trial, we expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in the second half of 2023.

We are initially targeting markets in Europe, Australia and New Zealand where we have identified a country-specific reimbursement pathway or execution strategy. We began our commercial launch in Germany in July 2020. After obtaining reimbursement approval in Germany through the existing hypoglossal nerve stimulation 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 hypoglossal nerve stimulation and also recently obtained reimbursement under an OSA-specific DRG code in Switzerland from the Federal Statistic Office, or BFS. The reimbursement coverage in both Germany and Switzerland includes the cost of the Genio system, implant procedure, hospital stay and follow-up care. We expect to begin marketing in Switzerland and in Spain in 2021. 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 rely on existing coding and reimbursement. 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, we plan to pursue reimbursement with a strategy that includes (i) making the Genio system commercially available for patients through country specific innovation funding pathways for procedures and products that would not yet be covered by an existing code, (ii) supporting case-by-case funding submission in focus hospitals that can use their budget to fund the therapy, (iii) entering into specific commercial deals with privately funded hospital groups, or (iv) out-of-pocket payment.

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

In addition to our ongoing clinical studies, we are also committed to continuing our research and development efforts related to the Genio system, with an emphasis on improving clinical outcomes, optimizing patient adoption and comfort, increasing access for a greater number of patients, and allowing more physicians to perform the implantation procedure. We also 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.

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***.
- ***Growing body of clinical data and long-term clinical strategy***.
- ***Significant product development and new indication pipeline***.
- ***Platform technology protected by comprehensive and broad intellectual property***.
- ***Strong and experienced team***.

The Genio System Market Opportunity

OSA therapy is a large and growing market. We believe there is a significant population in the United States with moderate to severe OSA who are unable to use or achieve the intended clinical benefit from CPAP and who would be eligible for the Genio system upon approval. Published scientific literature estimates that there are currently approximately 24.5 million individuals with moderate to severe OSA in our initial target markets in Europe, Australia and New Zealand. Based on published scientific literature, we estimate that approximately 2.7 million patients are diagnosed annually in those countries and that approximately 80% of diagnosed patients are prescribed a CPAP device. Published scientific literature reports non-compliance rates to CPAP between 29% and 83%. Based on these data, and for purposes of calculating the total addressable market in Europe, Australia and New Zealand for the Genio system, we estimate that approximately 35% of patients that are prescribed CPAP in those countries are not compliant with the therapy. Additionally, certain patients possesses anatomical characteristics, including higher body-mass-index or increased tongue fat deposition that make them ineligible for hyperglossal nerve stimulation. Taking that into account, we estimate that approximately 70% of those non-compliant patients are eligible for hypoglossal nerve stimulation based on their anatomical characteristics. As a result, we believe the total addressable market in Europe, Australia and New Zealand for the Genio system is at least 520,000 patients, which represents an estimated annual market opportunity of approximately $11 billion based on our current pricing for the Genio system. We also plan to enter the United States market, assuming we obtain marketing authorization in the United States, where published scientific literature estimates 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.

Limitations of Competing Hypoglossal Nerve Stimulation Devices

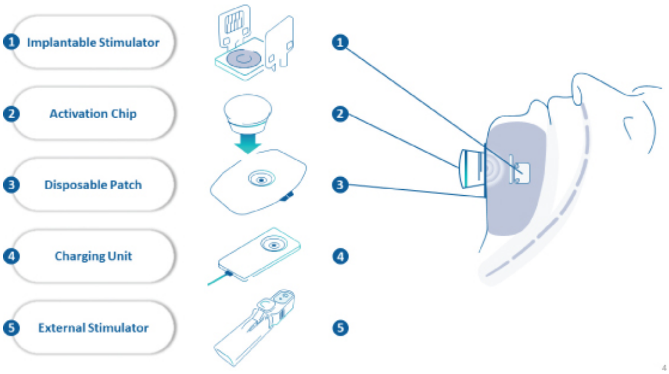
There are several treatment options available to OSA patients, including medical management, involving lifestyle changes such as weight loss, CPAP therapy, mandibular advancement devices, or MADs, surgical interventions, and advanced neurostimulation devices. We are aware of two competing hypoglossal nerve stimulation devices for use in treating patients with OSA. While the benefits of hypoglossal nerve stimulation have been well-recognized, we believe competing hypoglossal nerve stimulation solutions suffer from several limitations, including:

- *Neurostimulator with Internal Battery*
  - In most cases, the internal battery, once depleted, must be replaced in a further surgical procedure. Additional procedures may result in an increased risk of infection at the incision site.
  - The neurostimulator is positioned in a subcutaneous pocket, and the device may be palpable or visible in the chest area.
  - Competing systems have received 1.5T MRI clearance for head/neck and extremity scans only.
- *Multiple Implantable Components Requiring Multiple Surgical Incisions*
  - Competing systems require multiple parts to be implanted including leads and a cuff electrode.
  - Competing systems require multiple surgical incisions and subcutaneous lead tunneling. These multiple steps during implantation, can result in an increased risk of surgical infection.
- *Unilateral Stimulation*
  - Unilateral stimulation delivers stimulation to only one branch of the hypoglossal nerve, which limits options for nonresponding or contraindicated patients, including patients with CCC.

Our Solution

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

The Genio system is the first neurostimulation system for the treatment of OSA to include a battery-free and leadless neurostimulator capable of delivering bilateral hypoglossal nerve stimulation. The system includes a single 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 designed to overcome the limitations of competing neurostimulation devices. The Genio system consists of an implantable stimulator, a detachable external activation chip, a disposable patch, charging unit, and external stimulator used during implantation to test activation and function of the implantable stimulator.



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 from our BLAST OSA trial demonstrated safety and effectiveness data of the Genio system for patients suffering with moderate to severe OSA that was 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 course of the trial.
  - *Compelling clinical data*. Clinical data suggest that the Genio system provides a clinically effective therapy for patients eligible for hypoglossal nerve stimulation treatment. The BLAST OSA trial found a 47.3% reduction in mean individual AHI (p-value<0.0001) and a decrease in mean individual Oxygen Desaturation Index, or ODI, of 43.3% (p-value<0.0001), at six months following implantation, compared to their baseline measurements, for patients using the Genio system.
  - *Convenient therapy leading to strong compliance*. Our device is designed to be convenient for patients to use, once implanted and optimized, requiring no additional programming or therapy titration. The BLAST OSA data reported that 91% of patients used the system more than five nights per week over a period of six months following implantation.
  - *Improved quality of life.* Results from the BLAST OSA trial demonstrated that patients' quality of life significantly improved as assessed using the FOSQ-10 questionnaire, with an increase in mean score by 1.9 units (p-value=0.0157) and a decrease on the Epsworth Sleepiness Scale, or ESS, score, by a mean of 3.3 units (p-value=0.0113). Additionally, the number of sleep partners who reported that their partner did not snore, or snored only softly, increased from 4.2% at baseline to 65%.
- *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 has the potential to provide better clinical outcomes. We also believe that the Genio system's bilateral stimulation has the potential to treat moderate to severe OSA in patients with CCC, and we are currently evaluating this in our BETTER SLEEP clinical trial. These patients are currently contraindicated for hypoglossal neurostimulation 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 systems'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.

Our Strategy

Our mission is to become a global leader in providing innovative and effective 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***.
- ***Promoting awareness of the Genio system among physicians, patients and payors to accelerate market adoption***.
- ***Continuing to enhance the Genio system and expand its indications***.
- ***Pursuing and establishing favorable reimbursement coverage of the Genio system***.
- ***Continuing to build a commercial infrastructure in selected geographies***.

Risks Associated With Our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. These risks include, among others:

- 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.
- Our future financial performance depends on the commercial acceptance of the Genio system in target markets.
- 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.
- We may not receive, or may be delayed in receiving, the necessary marketing authorizations or certifications for our Genio system or any future product candidates, and failure to timely obtain necessary marketing authorizations or certifications for our product candidates would have a material adverse effect on our business.
- Our future financial performance depends on the commercial acceptance of the Genio system in target markets.
- Even if we receive marketing authorizations, clearances or certifications in our target markets to commercialize the Genio system or any product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.
- The ongoing COVID-19 pandemic, and the occurrence of another pandemic, epidemic or other health crisis, could have a negative impact on our product development and manufacturing activities, the recruitment and conduct of our clinical trials and our ability to source required funding, which could delay or prevent us from executing our strategy as planned.

- 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.
- 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 products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.
- 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.
- Our inability to fully protect and exploit our intellectual property and trade secrets may adversely affect our financial performance and prospects.
- The dual listing of our ordinary shares following the U.S. offering may adversely affect the liquidity and value of the ordinary shares.
- We and our independent registered public accounting firm have identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we fail to remediate our material weaknesses, we may not be able to report our financial results accurately or to prevent fraud.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Start-ups Act, or JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- the ability to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly reduced disclosure in management’s discussion and analysis of financial condition and results of operations in this prospectus;
- exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, in the assessment of our internal controls over financial reporting; and
- to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions until such time that we are no longer an emerging growth company. We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer” with at least $700 million of equity securities held by non-affiliates; (iii) the issuance, in any three year period, by our company of more than $1.0 billion in non-convertible debt securities held by non-affiliates; and (iv) the last day of the fiscal year ending after the fifth anniversary of this initial public offering.

We may choose to take advantage of some but not all of these reduced burdens. For example, we have presented only two years of audited financial statements and only two years of related “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus, and intend to take advantage of the exemption from the auditor attestation on the effectiveness of our internal control over financial reporting. Accordingly, the information that we provide shareholders and holders of our ordinary shares may be different than you might obtain from other public companies.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB.

Implications of Being a Foreign Private Issuer

We are also considered a "foreign private issuer" under U.S. securities laws. In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, members of our Board of Directors and our principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of the members of the Board of Directors are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

We have taken advantage of certain reduced reporting and other requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies.

Corporate History and Information

We were incorporated on July 15, 2009 as a company with limited liability (*naamloze vennootschap/société anonyme*) incorporated and operating under the laws of Belgium. We are registered with the legal entities register (*Brabant Wallon*) under enterprise number 0817.149.675. We were publicly listed on Euronext Brussels in September 2020. We have three wholly owned subsidiaries: Nyxoah Ltd, an Israeli limited company incorporated in January 2008 under the name M.L.G. Madaf G. Ltd and our subsidiary since October 2009, Nyxoah Pty Ltd, an Australian limited company incorporated in 2017, and Nyxoah, Inc., a Delaware corporation incorporated in May 2020.

Our headquarters and principal executive offices are located at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium, and our telephone number is +32 10 22 23 55. Our website address is www.nyxoah.com. The information contained on, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase ordinary shares in this offering.

THE OFFERING

Ordinary shares offered by us	ordinary shares.
Underwriters' option to purchase additional ordinary shares in the offering	The underwriters have an option, exercisable within 30 days from the date of this prospectus, to purchase up to additional ordinary shares.
Ordinary shares to be outstanding immediately after the offering	ordinary shares (or ordinary shares if the underwriters exercise in full their option to purchase an additional ordinary shares).
Use of proceeds	We estimate that we will receive net proceeds from the offering of approximately $ million (€ million), based on an assumed offering price of $ per ordinary share, or € per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, (i) to advance the commercialization of the Genio system in our initial target markets in Europe, Australia and New Zealand and for pre-commercialization activities in the United States; (ii) to continue gathering clinical data and to support physician initiated clinical research projects related to OSA patient treatments; (iii) to further finance R&D activities related to the next generation of the Genio system and to continue to build a pipeline of new technologies and explore potential collaboration opportunities in the field of monitoring and diagnostics for OSA; and (iv) the remainder for working capital and general corporate purposes. See "Use of Proceeds" for a more complete description of the intended use of proceeds from the offering.
Risk factors	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the ordinary shares.
Proposed Nasdaq Global Market trading symbol for our ordinary shares	"NYXH."
Euronext Brussels trading symbol for our ordinary shares	"NYXH."

The number of ordinary shares that will be outstanding after this offering is based on 22,107,609 ordinary shares outstanding as of March 31, 2021 and excludes:

- 997,500 ordinary shares issuable upon the exercise of warrants outstanding as of March 31, 2021 pursuant to our warrant plans, at a weighted average exercise price of €9.21 per ordinary share.

Unless otherwise indicated, all information contained in this prospectus does not reflect and does not take into account:

- any issuance of ordinary shares upon the exercise of warrants subsequent to March 31, 2021; and
- any exercise by the underwriters of their option to purchase up to additional ordinary shares in the offering.

Certain of our existing shareholders have indicated an interest in participating in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables summarize our historical consolidated financial data for the periods indicated. We derived the consolidated income statement for the years ended December 31, 2020 and 2019 from our audited consolidated financial statements included elsewhere in this prospectus. Our audited consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB.

We derived the consolidated income statement as of the three months ended March 31, 2020 and 2021, and the consolidated statement of financial position data as of March 31, 2021 from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus, prepared in accordance with International Accounting Standard 34, Interim Financial Reporting, the standard of IFRS applicable to interim financial statements.

Our historical results are not necessarily indicative of the results that may be expected in the future and our results as of March 31, 2021 and for the year ending December 31, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. The following summary consolidated financial data for the periods and as of the dates indicated are qualified by reference to, and should be read in conjunction with, our consolidated financial statements and related notes beginning on page F-1 of this prospectus, as well as the section of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Consolidated Income Statement:

	Years Ended December 31		Three Months Ended March 31	
	2020	2019	2021	2020
(In thousands, except per share data)	€	€	€	€
Revenue	69	—	185	—
Cost of goods sold	(30)	—	(52)	—
Gross Profit	39	—	133	—
General and administrative expenses	(7,522)	(4,226)	(1,818)	(1,178)
Research and development expenses	(473)	(630)	(852)	(7)
Clinical expenses	(1,053)	(848)	(342)	(177)
Manufacturing expenses	(460)	(489)	(901)	(62)
Quality assurance and regulatory expenses	(227)	(227)	(325)	(25)
Patent fees and related	(123)	(267)	(674)	(58)
Therapy development income / (expenses)	(1,864)	(902)	(548)	(352)
Other operating expenses	459	(126)	4	(191)
Operating loss for the period	(11,224)	(7,715)	(5,323)	(2,050)
Financial income	62	71	4	19
Financial expense	(990)	(740)	(325)	(336)
Loss for the period before taxes	(12,152)	(8,384)	(5,644)	(2,367)
Taxes	(93)	(70)	(25)	(13)
Loss for the period	(12,245)	(8,454)	(5,669)	(2,380)
Loss attributable to equity holders	(12,245)	(8,454)	(5,669)	(2,380)
Currency translation differences	(58)	168	(70)	272
Total Comprehensive loss for the period, net of tax	(12,303)	(8,286)	(5,739)	(2,108)
Loss attributable to equity holders	(12,303)	(8,286)	(5,739)	(2,108)
Basic and diluted Loss Per Share	(0.677)	(0.568)	(0.256)	(0.151)

Consolidated Statement of Financial Position:

(In thousands)	As of March 31 Actual 2021	As Adjusted[(1)] 2021
Cash and cash equivalents	€ 86,207	
Total assets	110,650	
Total equity attributable to shareholders	91,503	
Total liabilities	19,147	

(1) As adjusted to give effect to the issuance and sale of ordinary shares in the offering at the assumed initial offering price of € per ordinary share ($ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting commissions and estimated offering expenses payable by us. The as adjusted information presented above is illustrative only and will adjust based on the actual offering price, the actual number of ordinary shares offered by us, and the other terms of the offering determined at pricing. Each €1.00 ($) increase or decrease in the assumed initial offering price of € per ordinary share ($ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease each of as adjusted cash and cash equivalents, total assets and total equity attributable to shareholders by approximately € million ($ million), assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. Each increase or decrease of 1,000,000 in the number of ordinary shares offered by us would increase or decrease each of as adjusted cash and cash equivalents, total assets and total shareholders' equity by approximately € million ($ million), assuming that the initial offering price remains the same, and after deducting estimated underwriting discounts and estimated offering expenses payable by us.

RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including our consolidated financial statements and related notes, before deciding whether to purchase our ordinary shares. If any of the following risks are realized, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the market price of our ordinary shares could decline, and you could lose part or all of your investment. Please also see "Special Note Regarding Forward-Looking Statements."

Risks Related to Our Financial Position

The ongoing COVID-19 pandemic may continue to negatively affect various aspects of our business, including slowing the progress of our clinical trials, delaying or impeding our commercialization activities with respect to the Genio system, disrupting our operations and the operations of third parties with which we conduct business, and impacting our ability to raise additional capital, any or all of which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

As of the date of this prospectus, the COVID-19 pandemic, caused by the novel strain of coronavirus SARS-CoV-2, has caused substantial disruptions of economies and human societies worldwide for over a year. Efforts to contain the spread of the pandemic in our target markets for the Genio system in Europe, in the United States where we will seek to commercialize the Genio system if it ultimately gains marketing authorization, and in many other countries across the globe, have involved imposing widespread restrictions on travel, periodic quarantines and shelter-in-place orders, limitations on the permitted size of group gatherings, shuttering of businesses, implementation of programs for remote schooling, and other crisis-driven measures. Notwithstanding these efforts and remarkable successes achieved in the development and recent distribution of vaccines, vast portions of the populations in most countries have yet to be inoculated, and numerous nations and regions have experienced multiple surges that have sickened millions of people, strained the capacity of healthcare systems, and caused an estimated 2.8 million deaths worldwide. Over the course of the pandemic, government-imposed precautionary measures have been relaxed in certain countries or states as the spread of COVID-19 has decelerated, only to be reinstated in many jurisdictions due to an ensuing resurgence in cases. The concerning emergence of numerous new strains of SARS-CoV-2, which the current vaccines were not specifically designed to immunize against, casts more uncertainty over the future effects of the pandemic.

The duration, geographic scope and costs of the societal and economic disruptions caused by the COVID-19 pandemic cannot be reasonably estimated at this time, and it is not possible to accurately predict the extent of the adverse effects of the pandemic on our business. However, we have experienced certain impacts and may experience others which, if they continue for an extended period of time, could have material adverse effects on our operations and the execution of our business plans. Examples of these include the following:

- We have experienced some delays in the conduct of our current clinical trials, as individuals with moderate to severe obstructive sleep apnea, or OSA, defer seeking treatments, physicians have fewer in-person meetings to recruit and enroll patients, and recruited patients are hindered by restrictions in traveling to and accessing clinical sites. In addition, resources at hospitals have been diverted to dealing with the pandemic, causing delays in scheduling screening evaluations, implant procedures, and follow-up monitoring visits. As a result of the foregoing factors, the expected timeline for data readouts of our clinical trials may be negatively impacted, which would adversely affect our business.
- We rely on independent clinical investigators other third-party service providers to assist us in managing, monitoring and otherwise carrying out our nonclinical studies and clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs.
- We also rely on third party suppliers and contract manufacturers to produce and assemble certain components of the Genio system. Our principal suppliers are Medistri SA, Resonetics, VSI Parylene, Reinhardt Microtech GmbH (Cicor), Lust Hybrid, Meko, S&D Tech SRL. The raw

materials used by our suppliers are purchased in the open market. We could experience supply chain delays or shortages of these system components, which could impact both our ability to meet current timetables for our clinical trials and also hamper our ability to fulfill commercial orders for the system.

- We temporarily closed our executive offices and implemented various governmental safety guidelines, including work-from-home policies for most employees. The effects of government orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.
- We have instituted work-from-home policies for certain of our employees, and this could adversely affect our operations, the productivity of our employees and our ability to conduct and complete our nonclinical studies and clinical trials.
- In our initially targeted European markets, the pandemic could cause delays in pursuing and obtaining governmental and other third-party reimbursement decisions, as the work of these organizations may be slowed due to personnel work-from-home measures and travel and other scheduling constraints.
- The COVID-19 pandemic also presents a number of challenges for our sales and marketing efforts, including, among others, the impact on our marketing and sales team in Europe due to travel limitations and government-mandated work-from-home or shelter-in-place orders, potential decreased product demand due to reduced numbers of in-person meetings with prescribers, and patient visits with physicians, potential delays in scheduling DISE and implant treatments, as well as increased unemployment resulting in lower new prescriptions.
- In addition, the ability of the U.S. Food and Drug Administration, or FDA, and other regulatory authorities or other bodies to engage in routine regulatory and oversight activities, such as the review and authorization or certification of new products and the inspection of manufacturing and clinical trial sites, may be affected by the COVID-19 pandemic. The FDA and other regulatory authorities or other bodies may have slower response times or be under-resourced. If the global health concerns continue to disrupt or prevent regulatory authorities from conducting their regular reviews, inspections, or other regulatory activities, it could significantly impact the timely review and process our marketing applications, clinical trial authorizations, or other regulatory submissions, which could have a material adverse effect on our business.
- The near- and longer-term future impacts of the COVID-19 pandemic on global and national economies, and related impacts on the availability of investment capital in financial markets, continues to be uncertain. Continued economic disruptions could cause a contraction in equity capital and debt markets, making access to financing unavailable on acceptable terms or at all.

The global COVID-19 pandemic continues to evolve rapidly. The ultimate impacts of the COVID-19 pandemic are highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we continue to monitor the COVID-19 situation closely. To the extent the COVID-19 pandemic adversely affects our business, results of operations, cash flows, financial condition and/or prospects, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section. We have included additional discussions of certain impacts and potential impacts of the COVID-19 pandemic in other portions of this “Risk Factor” this section. These are intended to provide examples of such adverse effects and are, by necessity, not comprehensive. The full extent to which the COVID-19 pandemic will impact our business operations, financial condition, results of operations, and cash flows will depend on future developments, including, but not limited to, the ultimate severity, scope and duration of the pandemic before it is brought under control, the pace at which governmental and private travel and other restrictions and concerns about public gatherings will ease, the rate at which historically large increases in unemployment rates will decrease, and the speed with which national economies recover, all of which are highly uncertain.

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. Since commencing commercialization, we have generated only limited revenue from commercial sales of the Genio system. We have incurred operating losses and negative operating cash flows in each period since we were incorporated in 2009, including operating losses of €8.3 million and €12.3 million and negative operating cash flows of €6.0 million and €7.0 million for each of the years ended December 31, 2019 and December 31, 2020, respectively, and operating losses of €2.1 million and €5.3 million and negative operating cash flows of €1.2 million and €4.2 million for each of the three months ended March 31, 2020 and March 31, 2021, respectively. As of March 31, 2021, we had an accumulated deficit of €66.0 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.

Following this offering, 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.

Even if the offering is successful, we may require additional capital in the future, which may not be available to us on commercially favorable terms, or at all.

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. Based on our current operating plan and our existing cash and cash equivalents, together with the anticipated net proceeds from this offering, we expect to be able to fund our operations for . 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. 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 after this offering, the issuance of such securities will result in dilution to our shareholders. The price per share at which we sell additional ordinary shares or securities convertible into or exercisable or exchangeable for ordinary shares in future transactions may be higher or lower than the price per ordinary share paid by investors in this offering.

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. For example, while the overall economic impact caused by the COVID-19 pandemic may be difficult to fully assess, it is currently causing significant disruption to the global financial markets. If these disruptions are sustained or recurrent, they could make it more difficult for us to access capital, which could in the future negatively affect our ability to source required funding and could delay or prevent us from executing our strategy as planned. 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.

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.

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 set forth in Council Directive 90/385/EEC, the Active Implantable Medical Devices Directive, or the AIMD Directive, and in particular to demonstrate that devices are designed and manufactured in such a way that they will not compromise the clinical condition or safety of patients, or the safety and health of users and others (that the potential benefits outweigh potential risks). In addition, medical devices must achieve the performance intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. However, if the Genio system causes or contributes to consumer injuries or other harm or other serious issues arise as to the device’s performance, it may be necessary to conduct further clinical trials to confirm the device can perform safely and effectively.

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

We may not receive, or may be delayed in receiving, the necessary marketing authorizations or certifications for our Genio system or any future product candidates, and failure to timely obtain necessary marketing authorizations or certifications for our product candidates would have a material adverse effect on our business.

In the United States, before we can market a new medical device, or a new use of, or other significant modification to an existing, marketed medical device, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, approval of a premarket approval, or PMA, application or grant of a *de novo* classification request from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is “substantially equivalent” to a legally marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down classified, or a 510(k) exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life sustaining, life supporting or implantable devices. In the *de novo* classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the *de novo* classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

The PMA approval, 510(k) clearance and *de novo* classification processes can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining a PMA or *de novo* classification is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, PMAs and *de novo* classification requests generally require the applicant to have conducted one or more clinical trials. Despite the time, effort and cost expended in seeking a marketing authorization, there is no assurance that the FDA will grant it. Any delay or failure to obtain necessary regulatory marketing authorizations could harm our business. Furthermore, even if we are granted such marketing authorizations, they may include significant limitations on the indicated uses for the device, which may limit the potential commercial market for the device.

To date, we have not obtained authorization from the FDA to market any product candidate in the United States, and we expect to either request a *de novo* classification or submit a PMA application for our Genio system. If the FDA requires us to go through a lengthier, more rigorous examination for our product than we currently expect, our product introduction could be delayed or prevented, which would have a material adverse impact on our business and prospects. Following completion of our DREAM pivotal trial, we expect to engage further with the FDA to discuss the clinical trial results and to determine the most appropriate regulatory pathway to pursue in order to obtain marketing authorization in the United States, which may be either a PMA or a de novo classification request. Even if the FDA determines that a de novo classification request would be acceptable, after reviewing the contents of such a future application, the FDA may nonetheless determine that any special controls we propose to implement do not sufficiently mitigate the risks associated with the device and that the Genio system cannot be reclassified as a Class II device and therefore, must remain in Class III. The FDA will decline a de novo request if it determines that (i) general and special controls are insufficient to provide reasonable assurance of safety and effectiveness of the device; (ii) the data provided in the de novo request are insufficient to determine whether general and special controls can provide a reasonable assurance of safety and effectiveness of the device; or (iii) the probable benefits of the device do not outweigh the probable risks. In such a scenario, the FDA's decision may require us to prepare and submit a PMA for the Genio system, which would then remain a Class III device that could not be legally marketed until FDA reviews and approves the device based on the PMA application. We may not be able to meet the requirements to obtain device reclassification under the de novo pathway or PMA approval, and even if we do obtain marketing authorization under one of those pathways, the FDA may place significant limitations on any such marketing authorization depending on the available safety and effectiveness data for the Genio system for its intended uses.

In order to sell our products in member countries of the European Union, or the EU, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC) and the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC). Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risks) classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive and the Active Implantable Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited or designated by a member state of the EU to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE-Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives and corresponding EU member state laws, we would be unable to continue to affix the CE-Mark to our products, which would prevent us from selling them within the EU.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. Non-compliance with the above requirements would also prevent us from selling our products in these three countries.

Following the end of the “Brexit” Transition Period, from January 1, 2021 onwards, the MHRA will be responsible for the UK medical device market. The new regulations will require medical devices to be registered with the UK Medicines and Healthcare products Regulatory Agency, or MHRA, (but manufacturers will be given a grace period of four to 12 months to comply with the new registration process). Manufacturers based outside the UK will need to appoint a UK Responsible Person to register devices with the MHRA in line with the grace periods. By July 1, 2023, in the UK (England, Scotland, and Wales), all medical devices will require a UKCA (UK Conformity Assessed) mark but CE-Marks issued by EU Notified Bodies will remain valid until this time. However, UKCA marking alone will not be recognized in the EU. The rules for placing medical devices on the Northern Ireland market will differ from those in the UK. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in the UK.

The FDA or foreign regulatory authorities or Notified Bodies can delay, limit or deny marketing authorization or certification of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or Notified Bodies that our products are safe and effective for their intended uses;
- the disagreement of the FDA, foreign regulatory authorities or other foreign (regulatory) body with the design or implementation of our clinical trials or the interpretation of data from non-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our non-clinical studies and clinical trials may be insufficient to support clearance, certification, *de novo* classification or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or foreign regulatory authorities to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

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, our ongoing BETTER SLEEP trial is designed to provide sufficient clinical evidence to enable us to market our Genio system outside the United States to patients suffering from moderate to severe OSA and who also have completed concentric collapse, or CCC. Until the outcomes of that clinical trial are fully available, there can be no assurance that our Genio system will be demonstrated to be safe and effective for the treatment of moderate to severe OSA patients with 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.

Clinical trials involve a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We obtained CE-Mark certification in Europe for the Genio system in March 2019, commenced sales of the Genio system in Germany in July 2020, and are pursuing marketing activities in advance of commencing selling efforts in several other European countries. In the United States, we recently received IDE approval to commence our DREAM trial, which if successfully completed, we anticipate relying upon to support our application for marketing authorization of the Genio system in the U.S. market.

Before obtaining marketing clearance, approval or certification from regulatory authorities or Notified Bodies respectively for the sale of our Genio system, or any additional products we may develop, we expect to conduct clinical trials to demonstrate the safety and efficacy of the device in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing.

It is possible that even if the Genio system has a beneficial effect, that effect may not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect adverse effects caused by our Genio system, or mistakenly believe that our system caused certain adverse effects when that is not in fact the case. Also, the inclusion and exclusion criteria we define may not sufficiently capture a trial subject population that would be most appropriate for treatment with our Genio system.

The outcome of prior clinical trials may not be predictive of the success of later clinical trials. For example, the positive outcome of our BLAST clinical trial, based on which we obtained certification for the Genio system in the EU, does not ensure that our DREAM trial or BETTER SLEEP trials will be successful. Furthermore, interim results of a clinical trial do not necessarily predict final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through non-clinical studies and earlier clinical trials. Many companies in the medical device industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face such setbacks.

The design of a clinical trial can determine whether its results will support marketing authorization or certification of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. We have limited experience in designing clinical trials, and there is no certainty that the design of our ongoing clinical trials will ultimately support marketing authorization or certification. Even if we believe that the results of clinical trials for our product candidates warrant marketing authorization or certification, the FDA or comparable non-U.S. regulatory authorities and Notified Bodies may disagree and may not grant marketing authorization or certification of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Any pivotal or other clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates.

The initiation and completion of clinical trials may be prevented, delayed, or halted for numerous reasons. We may experience delays in our clinical trials for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical trials, including related to the following:

- we may be required to submit additional IDEs to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials, or place restrictions on the conduct of such trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or institutional review boards, or IRBs, or other bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including occurrence of adverse events or other findings that the subjects in our clinical trials are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB or other bodies and/or regulatory authorities for re-examination;

- regulators, IRBs, or other parties or bodies may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators or other bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of any product candidate.

In addition, clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs or other bodies at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under current good manufacturing practice, or cGMP, requirements and other regulations. Furthermore, we rely on clinical trial sites, and we may in the future rely on contract research organizations, or CROs, to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and we may in the future depend on CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the trial to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, conducting clinical trials in various countries may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. service providers, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more trial subject data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line or preliminary data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular registry, trial or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Importantly, interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, the interim, top-line or preliminary results that we report may differ from future results of the same trial, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top-line or preliminary data we previously published.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular non-clinical trial or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our products and product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. For all of the foregoing reasons, interim, top-line and preliminary data should be viewed with caution until the final data are available.

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

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

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

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

- the fact that the Genio system is an implantable device requiring clinical trial subjects to undergo surgery;
- the existence of a competing device with FDA marketing authorization and long-term data supporting its safety and efficacy;
- clinicians’ and patients’ perceptions as to the potential advantages and risks of the Genio system in relation to other available therapies, including any new product candidates that may be approved for the indications we are investigating;
- the severity of the condition, moderate to severe OSA, under investigation and clinicians’ and patients’ perceptions as to the potential advantages and risks of the Genio system in relation to other available therapies, including any new product candidates that may be approved for this indication;
- the size and nature of the patient population;
- the severity of the disease under investigation;
- the eligibility criteria for the trial in question;

- subject compliance with the trial protocol;
- the design of the clinical trial;
- the referral practices of physicians;
- limitations placed on enrollment by regulatory authorities or other bodies;
- the ability to monitor trial subjects adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective subjects;
- the approval of other devices or therapeutics for the target indications;
- efforts to facilitate timely enrollment;
- other clinical trials competing for the same target patients as those of our clinical trials; and
- the necessity for the trial subjects to dedicate their time to multiple visits to the clinic and/or sleep lab for tests, including a sleep test in a lab, forming part of the clinical trial.

In addition, as a result of the COVID-19 pandemic, and related “shelter in place” or “quarantine” orders and other public health guidance measures, we have experienced and may experience in the future disruptions that could materially impact the ability to recruit patients to participate in our trials or otherwise disrupt normal functioning of the healthcare system which could impair our ability to conduct our clinical trials and business in general as planned. Potential causes of these disruptions include but are not limited to:

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

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

Serious adverse events, or SAEs, or undesirable side effects or other unexpected properties of our product candidates may be identified during development that could delay or prevent the product candidate’s marketing authorization or certification.

As is the case with implantable medical devices generally, it is likely that there may be side effects and adverse events associated with the use of our Genio system or any future product candidate. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. SAEs or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, an IRB or regulatory authorities or other bodies to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label or the delay or denial of marketing approval or certification by the FDA, Notified Bodies or comparable non-U.S. regulatory authorities. If any of our product candidates is associated with SAEs or undesirable side effects or has properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many medical devices that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the device.

Additionally, if any of our product candidates, including the Genio system, receives marketing authorization from the FDA, the side effects observed in clinical trials could result in a more restrictive label than we anticipate.

Risks Related to Commercialization and Reimbursement

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

The Genio system is our only commercial product, which we market in certain European countries. The Genio system is CE-Marked since March 2019 for the treatment of OSA. We are working to obtain reimbursement and gain commercial market acceptance of the Genio system in initial target markets in Europe, but to date we have generated only limited revenue from commercial sales of the Genio system in Germany after commencing sales in that country in July 2020. The Genio system may not gain commercial acceptance in target markets. If we are delayed in gaining, or fail to gain and maintain commercial market acceptance of the Genio system in our target markets, because of insufficient price and reimbursement levels from government and third-party payors, competition, or the inability to demonstrate to physicians and other potential customers the benefits and cost-effectiveness of the Genio system relative 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 trial intended to support a U.S. marketing application. Any failure of the Genio system to achieve meaningful market acceptance will harm our business and future prospects.

Even if we receive marketing authorizations, clearances or certifications in our target markets to commercialize the Genio system or any product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.

The commercial success of the Genio system and any other product candidates we develop will depend substantially, both in the United States and abroad, on the extent to which coverage and reimbursement for our products and related procedures will be available from government health administration authorities, private health insurers and other third-party payors such as managed care and similar healthcare management organizations. Thus, our ability to commercialize the Genio system and any product candidates we develop will depend to a significant degree on which government authorities and third-party payors decide to cover our products and at what reimbursement levels. If reimbursement is not available, or is available only to a limited extent, we may not be able to successfully commercialize our products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish and maintain pricing sufficient to realize a meaningful return on our investment.

There is significant uncertainty related to government and other third-party payor coverage and reimbursement of newly approved medical devices. Regulatory approvals and pricing and reimbursement for new device products vary widely from country to country. Some countries require approval of the sale price of a device before it can be marketed. In many countries, the pricing review period begins after marketing authorization or certification is granted. In some non-U.S. markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing authorization or certification for a product in a particular country but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing authorization or certification.

The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products, which could affect our ability to sell our product candidates profitably. These payors may not view the Genio system or any other product candidates, if authorized for marketing, as cost-effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our product candidates, if authorized for marketing, to be sold on a competitive basis. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues. Further, if the prices for our product candidates, if authorized for marketing, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer. Marketing authorization or certification of a product does not guarantee sufficient reimbursement to achieve commercial success.

There may also be delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the indications for which the product is authorized by the FDA or comparable non-U.S. regulatory authorities. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

Obtaining and maintaining coverage and reimbursement can be a time-consuming process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products. Increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We may not be able to provide data sufficient to satisfy governmental and third-party payors that procedures using our products should be covered and reimbursed. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate.

Outside the United States, reimbursement levels vary significantly by country and by region, particularly based on whether the country or region at issue maintains a single-payor system. Annual healthcare budgets generally determine the number of therapeutic devices like the Genio system that will be paid for by the payor in these single-payor system countries and regions. Some countries or regions may require us to gather additional clinical data before granting coverage and reimbursement for our products. We are currently working with payors in the EU to obtain coverage and reimbursement approval in countries and regions where it makes economic sense to do so; however, we may not obtain such coverage, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

We have limited experience marketing and selling our Genio system, and if we are unable to expand, manage and maintain our direct sales and marketing organization, we may not be able to generate revenue growth.

We have only limited experience in marketing and selling our Genio system. To achieve commercial success, we will need to expand our internal sales and marketing organization to commercialize the Genio system in markets that we will target directly. Expanding our sales and marketing team further will entail recruiting additional managerial, operational, financial and other employees, which is expensive and time-consuming and could delay product launches.

For example, if we obtain regulatory authorization to market the Genio system in the United States, we intend to build a direct sales force. We have no experience marketing and selling the Genio system in the United States. To commence commercial launch will require us to hire, develop, grow and retain a U.S.

marketing and sales organization. To do so will require significant investment in recruiting and training as we ramp up to a U.S. commercial launch. There is significant competition for marketing and sales personnel experienced in medical device sales. Once we hired such personnel, we expect to provide them with in-depth training, which can be lengthy, because it will require significant education for new marketing and sales representatives to achieve the level of clinical competency with the Genio system that physicians expect. Upon completion of training, our sales representatives will require lead time in the field to grow their network of accounts and achieve productivity levels we expect them to reach in any individual territory. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, and if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer.

If the commercial launch of the Genio system in the United States or another jurisdiction for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, our sales efforts may be hindered in target markets if we fail to develop complementary products.

We may also decide to target certain markets indirectly via distributors or other arrangements. If we are unable to find suitable distribution partners, lose these distribution partners or if our distribution partners fail to sell our products in sufficient quantities, on commercially viable terms or in a timely manner, the commercialization of the Genio system could be materially harmed, which could prevent us from achieving or maintaining profitability.

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 of 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 commercially available 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 CPAP therapy. If one or more CPAP device manufacturers successfully develop a CPAP 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.

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

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

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, suppliers and other third parties upon whom we rely. Most recently, the global COVID-19 pandemic and government measures taken in response have also had a significant impact on businesses and commerce worldwide, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended across a variety of industries; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In connection with COVID-19, we implemented various governmental safety guidelines, including work-from-home policies for certain employees. The effects of government orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

We depend on a global supply chain to manufacture the components of the Genio system which are sent to our facilities in Israel and Belgium, where final assembly is to be completed. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our ongoing clinical trials have been and may continue to be affected by the COVID-19 pandemic. Clinical site initiation, subject enrollment and activities that require visits to clinical sites, including data monitoring, have been and may continue to be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic. Some trial subjects may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. For example, some clinical trial subjects, including patients in our DREAM clinical trial in the United States may not be able to attend follow-ups and comply with trial protocols. These challenges have and in the future may continue to increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain subjects and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city or state, our clinical trial operations could be adversely impacted. There is also the risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events.

The COVID-19 pandemic has resulted in significant disruption of global financial markets, resulting in economic downturns in many countries that could continue to significantly impact our business and operations and may reduce our ability to access capital, which could in the future negatively affect our access to investment capital. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of the ordinary shares. These and similar, and perhaps more severe, disruptions in our operations could have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

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 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. In addition, if, as a result of COVID-19, our employees are not able to come to work, then this could also have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

We rely, or may rely in the future, on third parties to provide critical advice and conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of clinical trials. 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. 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.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we design our clinical trials and will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other regulatory authorities require us to comply with GCP regulations and international standards relating to the conduct, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control to manage those operations does not relieve us of these responsibilities and requirements. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the marketing authorization or certification process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. We also are required to register ongoing clinical trials and post the results of certain completed clinical trials on certain government-sponsored databases, such as ClinicalTrials.gov in the United States, within specified time frames. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties for any reason, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

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 facility in Tel Aviv. 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.

Risks Related to the Countries in which We Operate

Significant parts of our operations are located in Israel and, therefore, our results may be adversely affected by political, economic and military instability in Israel.

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 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.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our business and operations.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act of 1977, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act (or FCPA); the UK Bribery Act 2010 (the “Bribery Act”); and other anti-corruption laws that apply in countries where we do business. The FCPA, the Bribery Act, and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, a financial or other advantage to government officials or other persons to induce them to improperly perform a relevant function or activity (or reward them for such behavior). U.S. authorities that enforce the FCPA, including the Department of Justice, deem most health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be “foreign officials” under the FCPA. When we interact with foreign health care professionals and researchers in testing and marketing our products abroad, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals such as those needed to initiate clinical trials in foreign jurisdictions. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and the development and maintenance of an adequate system of internal accounting controls for international operations. The SEC is involved with the books and records provisions of the FCPA.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the EU, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations.

If we fail to comply with these laws and regulations, we could be subject to governmental investigations, prosecutions and penalties, including substantial fines and potential imprisonment of the individuals involved. Any such circumstances would carry the risk of substantial damage to our reputation for corporate integrity and would likely have a material adverse effect on our business and future prospects.

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 facility in Tel Aviv is expected to cover the Genio Implantable Stimulator and Genio External Stimulator demand up until the end of 2021. 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 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 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.

Risks Related to Legal and Regulatory Compliance Matters

Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

Our Genio system is regulated as a medical device. We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance, classification and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval trials; and product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces its regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we or our contract manufacturers will be found compliant in connection with any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell the Genio system and any other product candidates, if they obtain marketing authorization, and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

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 prospectus, we have received certification to market the Genio system in the European Union, or EU, member states through CE-Marking and Israeli Medical Devices and Accessories, or AMAR, also through CE-Marking. 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 a process of seeking marketing authorization. We received an IDE approval from the FDA on June 23, 2020, which allows us to proceed with certain clinical testing 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 an IDE, the Genio system may not successfully obtain marketing authorization. In addition, there may be substantial and unexpected delays in the process, for example in the initiation and completion of clinical trial testing and evaluation.

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

Even if we obtain marketing authorization or certification for our product candidates, the terms of such authorizations or certifications and ongoing regulation of our products may limit how we manufacture and market our products. Compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing authorization, certification or approval of a product candidate is received, commercial products and their manufacturers are subject to ongoing review and extensive regulation, including with respect to the manufacture, medical device reporting, import, export, registration, listing of devices and post-market surveillance of the product. For example, medical device manufacturers must submit periodic reports to the FDA after obtaining marketing authorization. These reports include information about failures and certain adverse events associated with the device after its marketing authorization.

Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. Accordingly, assuming we receive marketing authorization or certification for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we are not able to comply with post-market regulatory requirements, we could have any marketing authorizations or certifications we have obtained for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-market regulations may have a negative effect on our operating results and financial condition.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA and other regulatory authorities, which may include, among other things: untitled letters or warning letters; fines, injunctions, consent decrees and civil penalties; recalls, termination of distribution, administrative detention, or seizure of our products; customer notifications or repair, replacement or refunds; operating restrictions or partial suspension or total shutdown of production; delays in or refusal to grant our requests for future clearances, *de novo* classifications, approvals, certifications or other marketing authorizations of new products, new intended uses, or modifications to existing products; withdrawals or suspensions of any granted marketing authorizations or certifications, resulting in prohibitions on sales of our products; or criminal prosecution. Any of these sanctions could have a material adverse effect on our reputation, business, financial condition and results of operations.

In addition, the FDA may change its marketing authorization policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of any product candidate under development or impact our ability to modify any products authorized for market on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain marketing authorizations, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we have obtained.

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 Department of Justice, closely regulate compliance with all requirements governing medical device products, including requirements pertaining to marketing and promotion of devices in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. 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.

Our ability to continue sales of our product in the European Union may be materially impaired if we do not take necessary steps to comply with the certification requirements of the new EU Medical Device Regulation.

On May 25, 2017, the EU Medical Devices Regulation (Regulation 2017/745) entered into force, which repeals and replaces Council Directive 93/42/EEC, or the Medical Devices Directive, and Council Directive 90/385/EEC, or the AIMD Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member state laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation was originally intended to become effective three years after publication, but in April 2020 the transition period was extended by the European Parliament and the Council of the EU by an additional year, until May 26, 2021. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive and the AIMD Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025. Once effective, the new regulations will among other things:

- Strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- Establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- Improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- Set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- Strengthen the rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an effect on the way we design and manufacture product and products candidates and conduct our business in the EU and EEA (also including Norway, Liechtenstein and Iceland). For example, as a result of the transition towards the new regime, Notified Body review times have lengthened, and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. While our products have recently been certified under the AIMD Directive and can remain on the EU market until May 2024 and we are already preparing the implementation of the new requirements of the Medical Devices Regulation, we cannot exclude unexpected regulatory hurdles and possible delays while transitioning towards the new regime.

The EU-UK Trade and Cooperation Agreement, or TCA, came into effect on January 1, 2021. The TCA does not specifically refer to medical devices. However, as a result of Brexit, the EU Medical Devices Regulation will not be implemented in the UK, and previous legislation that mirrored the EU Medical Devices Regulation in the UK law has been revoked. The regulatory regime for medical devices in the UK will continue to be based on the requirements derived from current EU legislation, and the UK may choose to retain regulatory flexibility or align with the EU Medical Devices Regulation going forward. CE-markings will continue to be recognized in the UK, and certificates issued by EU-recognized Notified Bodies will be valid in the UK, until June 30, 2023. For medical devices placed on the UK market after this period, the UK Conformity Assessment, or UKCA, marking will be mandatory. In contrast, UKCA marking and certificates issued by UK Notified Bodies will not be recognized on the EU market. The TCA does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the "rules of origin" criteria will need to be reviewed. Depending on which countries products will be ultimately sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in the UK. These modifications may have an effect on the way we design and manufacture products and we conduct our business in these countries.

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

Under the EU Medical Devices Regulation, 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 new Medical Devices Regulation. Any modification to an existing CE-Marked medical device will also require review and certification under the EU Medical Devices Regulation. Under normal circumstances, medical device manufacturers must undergo on-site audits by Notified Bodies in order to maintain their CE-Mark certifications per the requirements of the EU Medical Devices Directive. As many CE-Mark certifications will become void as part of the transition to the EU Medical Devices Regulation, Notified Bodies also have to start certifying medical devices in accordance with the EU Medical Devices Regulation. As another consequence of the COVID-19 pandemic, Notified Bodies' on-site audits have not been feasible due to quarantine and travel restrictions and most of them have been postponed. Even though some specific measures have been implemented to determine whether remote audits can be conducted or be supplemented with an on-site audit once travel restrictions are lifted, this situation could significantly impact the ability of Notified Bodies to timely review and process our regulatory submissions.

The EU Medical Devices Regulation 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 the May 2021, the effective date of the EU Medical Devices Regulation. In the European Union, not all Notified Bodies have been re-designated so far and the COVID-19 pandemic has significantly slowed down their designation process. Without EU Medical Devices Regulation designation, Notified Bodies may not yet start certifying devices in accordance with the new Regulation.

The CE-Mark obtained in 2019 for our Genio system will remain valid until March 2024, and it must be re-certified under the EU Medical Devices Regulation before then. 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 also require certification under the EU Medical Devices Regulation.

The overall backlogs experienced by the Notified Bodies having already been re-designated (including the Dutch company DEKRA Certification B.V., which issued the CE-Mark and an ISO 13485:2016 certificate to 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 EU Medical Devices Regulation.

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 EU Medical Devices Regulation. If a distributor in the EU fails to meet the EU Medical Devices Regulation requirements, on a timely basis or at all, the marketing and sale of the Genio system by such distributor may be temporarily or permanently prohibited.

Any delay or failure to comply with the EU Medical Devices Regulation could result in the sale of the Genio system 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.

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 prospectus, it is possible that we may be found to be non-compliant with new or existing regulations in the future. In addition, we may be found to be non-compliant as a result of future changes in, or interpretation of, the regulations for quality systems. If we do not achieve compliance or subsequently become non-compliant, 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 non-compliant with quality systems regulations or ISO13485, which could result in enforcement action by regulatory authorities, including, for example a warning letter from the FDA or a requirement to withdraw from the market or suspend distribution, or export or use of products manufactured by one or more of 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 EU Medical Devices Regulation 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.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new marketing authorizations for the device before we may market or distribute the corrected device. Seeking such authorizations may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could also harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

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.

The misuse or off-label use of our product candidates may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Any marketing authorization or certification we may receive for our Genio system or other product candidates will be limited to specified indications for use, and we must also comply with requirements concerning advertising and promotion of the system. Promotional communications with respect to medical devices are subject to a variety of legal and regulatory restrictions and must be consistent with the device's intended use, data from any clinical trials, and established specifications. Thus, we will not be able to promote the Genio system for indications or uses for which they are not authorized. We plan to train our marketing personnel and direct sales force not to promote the Genio system for uses outside of the authorized indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our devices off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our devices off-label, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any other regulatory authority determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or other enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

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.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply to our customers and may impact our reputation. We may not be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future and these efforts may not have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations.

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 prospectus, 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 prospectus, 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.

These healthcare laws and regulations may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute any products for which we obtain marketing approval. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the U.S. federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the U.S. federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. In addition, the government

may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including in some circumstances mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the U.S. federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the U.S. federal transparency requirements under the Physician Payments Sunshine Act require manufacturers of FDA-authorized drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Department of Health and Human Services information related to payments and other transfers of value to physicians, teaching hospitals and physician ownership and investment interests. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to additional healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives; and
- analogous foreign and state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require medical device companies to comply with the device industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring device manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and non-U.S. laws, including the EU General Data Protection Regulation, or GDPR, also govern the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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.

Healthcare policy changes, including legislation or regulations aiming to reform the U.S. healthcare system, could harm our business, financial condition and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our product candidates, if authorized for marketing. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our product candidates, if approved, or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may negatively affect our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- our ability to set a price that we believe is fair for the Genio system;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our product candidates, if approved, which in turn could impact our ability to successfully commercialize our device and could have a material adverse effect on our business, financial condition and results of operations.

We are subject to, or may in the future become subject to, federal, state, and foreign laws and regulations imposing obligations on how we collect, store, use and process information collected from or about patients or their procedures using our products. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such legal requirements could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

The collection and use of personal health data in the European Union and European Economic Area, or EEA, is governed by the GDPR. Since we are located in the European Union, we are subject to the GDPR when we use personal data from anywhere in the world for purposes of our business in the EEA. The territorial reach of the GDPR also includes the activities of businesses located outside of the EEA that relate to the businesses’ provision of goods or services to residents in the EEA, or monitoring the behavior of people in the EEA. We are therefore also subject to the GDPR even where our data processing activities take place outside of the European Union and relate only to our business outside of the European Union to the extent that such activities involve the personal data of individuals located in the European Union and relate to our offer of goods or services to them, or to our monitoring of their behavior. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for “sensitive information” which includes health and genetic information of data subjects and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

The GDPR also regulates the transfer of personal data subject to the GDPR to so-called third countries that have not been found to provide adequate protection to such personal data, including the United States. Recent legal developments in Europe have created complexity and uncertainty regarding such transfers.

For instance, on July 16, 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-U.S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism and potential alternative to the Privacy Shield), it made clear that reliance on such clauses alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, including, in particular, applicable surveillance laws and rights of individuals, and additional measures and/or contractual provisions may need to be put in place; however, whether any particular additional measures would be deemed to be adequate is uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and that the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. Failure to comply with the GDPR could result in penalties for noncompliance (including possible fines of up to the greater of €20 million and 4% of our global annual turnover for the preceding financial year for the most serious violations, as well as the right to compensation for financial or non-financial damages claimed by individuals under Article 82 of the GDPR). If any of these events were to occur, our business and financial results could be significantly disrupted and adversely affected.

In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, leading to additional uncertainties.

In addition to the GDPR, the European Commission has another draft regulation in the approval process that focuses on a person’s right to conduct a private life. The proposed legislation, known as the Regulation on Privacy and Electronic Communications, or ePrivacy Regulation, would replace the current ePrivacy Directive. While the text of the ePrivacy Regulation is still under development, a recent European court decision and regulators’ recent guidance are driving increased attention to cookies and other tracking technologies. Some regulators have started to enforce the strict approach in recent guidance. Compliance with existing and future rules concerning cookies and other tracking technologies could lead to substantial costs, require significant systems changes, limit the effectiveness of our marketing activities, divert the attention of our technology personnel, adversely affect our margins, increase costs and subject us to additional liabilities. Regulation of cookies and similar technologies may lead to broader restrictions on our marketing and personalization activities and may negatively impact our efforts to understand users.

Further, in March 2017, the United Kingdom formally notified the European Council of its intention to leave the European Union pursuant to Article 50 of the Treaty on European Union, or Brexit. The United Kingdom ceased to be a European Union Member State on January 31, 2020, but enacted a Data Protection Act substantially implementing the GDPR, effective in May 2018, which was further amended to align more substantially with the GDPR following Brexit. It is unclear how UK data protection laws or regulations will develop in the medium to longer term and how data transfers to and from the United Kingdom will be regulated. Currently, the data protection laws of the UK and the EU remain closely aligned, which means that the UK also requires additional analysis of local laws and additional measures for transfers of personal data out of the UK to countries (including the U.S.) that have not been deemed by the UK to have adequate data protection laws. While the UK has deemed that the EEA has adequate data protection laws, meaning that we can freely transfer personal data from the U.K. to our business in Belgium or elsewhere in the EEA, the European Commission has not yet deemed the UK to have adequate data protection laws, which could affect our ability to transfer personal data from the EEA to the UK Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on 19 February 2021. If adopted, the decision will enable data transfers from EU member states to the United Kingdom for a four-year period, subject to subsequent extensions. We are required to comply with both the GDPR and the UK GDPR, with each regime having the ability to fine up to the greater of €20 million (in the case of the GDPR) or £17,5 million (in the case of the UK GDPR) and 4% of total annual revenue. We may need to appoint a local representative in the UK, and incur other additional costs and risks as a result of the UK and the EU having separate data protection regimes.

In addition, in the conduct of our business, we may at times process personal data, including health-related personal data. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations. In the EU and the UK, certain guidance issued by the organization representing the national data protection supervisory authorities may conflict with the requirements or guidelines of the entities that oversee clinical trials, creating uncertainty, increased compliance costs and potential delays in the process of gaining approval to conduct our clinical trials.

We also face risks inherent in handling and in protecting the security of personal data, including health-related data. In addition to specific healthcare laws and regulations, the U.S. federal government and various states have adopted or proposed laws, regulations, guidelines, and rules with respect to the collection, distribution, use, and storage of personal information of patients. For example, HIPAA imposes requirements on certain healthcare providers, health plans and healthcare clearinghouses, or Covered Entities, as well as their business associates that perform services for them that involve the use or disclosure of individually identifiable health information, called Protected Health Information, or PHI, under HIPAA, relating to the privacy and security of PHI, including the use of mandatory contractual terms, or Business Association Agreements, in some circumstances, as well as privacy and security standards and breach notification requirements. Failure to comply with the HIPAA privacy and security standards can result in significant civil monetary penalties and, in certain circumstances, criminal penalties. HIPAA also imposes penalties on third parties that wrongfully obtain PHI. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state.

In addition, state privacy and security laws and regulations vary from state to state, constantly evolve, and remain subject to significant change. In some cases, such laws and regulations can impose more restrictive requirements than HIPAA and other U.S. federal laws, thus complicating compliance efforts. By way of example, California and Virginia have enacted significant privacy laws that give residents of those states expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. Failure to comply with these state privacy laws could result in penalties and present unresolved compliance issues. In addition, the enactment of a U.S. federal privacy law is possible. The changing number of U.S. state or federal privacy laws may increase our compliance costs and potential liability. Other states are considering similar bills, which could be enacted in the future. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to patients for misuse of or unauthorized access to personal information.

We are not subject to HIPAA, but our customers, research collaborators and others in the United States with whom we do business are. Accordingly, we must ensure that any business arrangements that we have with Covered Entities are structured to comply with HIPAA and ensure that we have the authority to obtain any PHI that may be disclosed to us. Some countries also are considering or have enacted legislation requiring local storage and processing of data that could increase the cost and complexity of delivering our services. Any actual or perceived failure by us or the third parties with whom we work to comply with privacy or security laws, policies, legal obligations, or industry standards, or any security incident that results in the unauthorized release or transfer of PHI, may result in governmental enforcement actions and investigations by U.S. federal and state regulatory authorities, fines and penalties, claims, litigation, and/or adverse publicity, including by consumer advocacy groups and other private parties, and could cause our customers, their patients and other healthcare professionals to lose trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Any failure, or perceived failure, by us to comply with privacy and data protection laws, rules and regulations could result in proceedings or actions against us by governmental entities or others. These proceedings or actions may subject us to significant penalties and negative publicity, require us to change our business practices, increase our costs and severely disrupt our business.

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. 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.

The secure processing, maintenance and transmission of our confidential business information and other information maintained or processed in our business, including sensitive or confidential patient or employee data, is critical to our operations. Such information includes, among other things, intellectual property and proprietary information, the confidential information of any of our future collaborators and licensees, the personal data of our employees, and personal data from patients using the Genio system, which falls into the specially protected category of health data, for which additional safeguards are required under applicable laws. Unauthorized access to or disclosure of any sensitive or confidential patient, trial participant, or employee data, including whether through breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, or the perception that this has occurred, could result in negative publicity, legal liability and damage to our reputation and could also expose us to sanctions for violations of laws and regulations relating to privacy and data security. Although we have general liability and cybersecurity insurance coverage, our insurance may not cover all claims, continue to be available to us on reasonable terms or be sufficient in amount to cover one or more large claims; additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, prospects, operating results and financial condition.

Despite our security measures, our information technology systems and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. Phishing attempts, social engineering, and other attacks upon our information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. In addition to unauthorized access to or acquisition of personal information, confidential information, or other sensitive information, such attacks could include the deployment of harmful malware and ransomware, and may use a variety of methods, including denial-of-service attacks, social engineering and other means, to attain such unauthorized access or acquisition or otherwise affect service reliability and threaten the confidentiality, integrity and availability of information. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and often are not foreseeable or recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to commercialize our products and conduct clinical trials, which could adversely affect our reputation and delay our commercialization strategy for our Genio system and clinical development of our current and future products.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology or loss of data, including any cyber security incidents, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability which could harm our ability to operate our business effectively and adversely affect our business and reputation.

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology (IT) systems, some of which are in our control and some of which are in the control of third parties. In the ordinary course of our business, we collect and store sensitive data, including personally identifiable information about our employees, intellectual property, and proprietary business information (confidential information). We manage and maintain our applications and data utilizing on-site systems and we also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. These applications and data encompass a wide variety of business-critical information including research and development information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy. Despite the implementation of security measures, our IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, cyber-attacks, computer viruses, ransomware attacks, phishing schemes, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, damage from natural disasters, terrorism, war and telecommunication and electrical failures, or other attempts to harm or access our systems. Moreover, despite network security and back-up measures, some of our servers and those of our business partners are potentially vulnerable to physical or electronic break-ins, including cyber-attacks, computer viruses and similar disruptive problems. These events could lead to the unauthorized access, disclosure and use of confidential information. Breaches resulting in the compromise, disruption, degradation, manipulation, loss, theft, destruction, or unauthorized disclosure or use of confidential information, or the unauthorized access to, disruption of, or interference with our products and services, can occur in a variety of ways, including but not limited to, negligent or wrongful conduct by employees or others with permitted access to our IT systems and information, or wrongful conduct by hackers, competitors, or certain governments. Our third party vendors and business partners face similar risks.

Cyber-attacks come in many forms, including the deployment of harmful malware or ransomware, exploitation of vulnerabilities, phishing and other use of social engineering, and other means to compromise the confidentiality, integrity, and availability of our IT systems and confidential information. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated or remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. There can be no assurance that we will promptly detect or intercept any such disruption or security breach, if at all. If our computer systems are compromised, we could be subject to fines, damages, reputational harm, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business, in addition to possibly requiring substantial expenditures of resources to remedy. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with breach notification laws under GDPR and other legal equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. In addition, the loss of data from clinical trials of the Genio system could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce data, and a cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenues or litigation. Despite precautionary measures to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

Changes in or inadequate funding for, or disruptions caused by global health concerns impacting, the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices to be reviewed and/or authorized by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. Additionally, the FDA and regulatory authorities outside the United States have implemented various restrictions or other policy measures in response to the COVID-19 pandemic.

If a prolonged government shutdown or slowdown occurs or if global health concerns continue to prevent the FDA or other regulatory authorities or bodies from conducting business as usual or conducting inspections or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 the Prospectus, 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.

Patent terms may be inadequate to protect our competitive position with respect to the Genio system and our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive devices. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our owned or licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act, and similar legislation in the European Union and certain other countries. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and nonclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

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.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, and domain names, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future licensors might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our current or future licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;

- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could harm our business, financial condition, results of operations and prospects.

Risks Related to the Offering and these Securities

Investors in the offering will experience immediate and substantial dilution in the book value of their investment.

The initial offering price of the ordinary shares in the offering is substantially higher than the pro forma net tangible book value per ordinary share before giving effect to the offering. Accordingly, if you invest in the ordinary shares in the offering, you will incur immediate substantial dilution of €   per ordinary share ($ per ordinary share), based on an assumed initial offering price of €   per ordinary share ($ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, and our pro forma net tangible book value as of March 31, 2021. In addition, following the offering, investors in the offering will have contributed approximately   % of the total gross consideration paid by shareholders to purchase our ordinary shares, but will only own ordinary shares representing approximately   % of our ordinary shares outstanding after the offering. Furthermore, if the underwriters exercise their option to purchase additional ordinary shares, or if the board authorizes the issue of additional shares, warrants or convertible securities are issued and subsequently exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after the offering, see “Dilution.”

Certain of our existing shareholders have indicated an interest in participating in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

There has been no prior market for the ordinary shares on a U.S. securities exchange and an active and liquid market for the securities may fail to develop, which could harm the market price of the ordinary shares.

Prior to the offering, while our ordinary shares have been traded on Euronext Brussels since September 2020, there has been no public market on a U.S. securities exchange for our ordinary shares.

Although we have applied to list the ordinary shares on the Nasdaq Global Market, an active trading market for the ordinary shares may never develop or be sustained following the offering. The offering price may not be indicative of the market price of the ordinary shares or after the offering. In the absence of an active trading market for the ordinary shares, investors may not be able to sell their ordinary shares at or above the offering price or at the time that they would like to sell.

Following the offering and after the ordinary shares begin trading on the Nasdaq Global Market, our ordinary shares will continue to be admitted to trading on Euronext Brussels. We cannot predict the effect of this dual listing on the value of the ordinary shares. However, the dual listing of the ordinary shares may dilute 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.

The dual listing of our ordinary shares following the U.S. offering may adversely affect the liquidity and value of the ordinary shares.

Following the U.S. offering and after the ordinary shares begin trading on the Nasdaq Global Market, our ordinary shares will continue to be listed on Euronext Brussels. 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.

The trading price of our equity securities may be volatile due to factors beyond our control, and purchasers of the ordinary shares could incur substantial losses.

The market prices of the ordinary shares and shares may be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their ordinary shares or shares at or above the price originally paid for the security. The market price for the ordinary shares may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- the release of new data from our DREAM and other clinical trials;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- currency fluctuations;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- uncertainty caused by and the unprecedented nature of the current COVID-19 pandemic;
- issuances or sales of the ordinary shares by us, our insiders or our other shareholders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for the ordinary shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares or ordinary shares and may otherwise negatively affect the liquidity of the trading market for ordinary shares.

We have broad discretion over the use of the net proceeds from the offering and may use them in ways with which you do not agree and in ways that may not enhance our operating results or the price of the ordinary shares.

Our board of directors and executive management will have broad discretion over the application of the net proceeds that we receive from the offering. We may spend or invest these proceeds in ways with which our shareholders disagree or that do not yield a favorable return, if at all. We intend to use the net proceeds from the offering, together with our existing cash resources as described in "Use of Proceeds." However, our use of these proceeds may differ substantially from our current plans. Failure by our management to apply these funds effectively could harm our business, results of operations, cash flows, financial condition and/or prospects. Pending their use, we may invest the net proceeds from the offering in a manner that does not produce income or that loses value.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ordinary shares and their trading volume could decline.

The trading market for the ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or only limited securities or industry analysts cover our company, the trading price for the ordinary shares could be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities or publishes inaccurate or unfavorable research about our business, the price of ordinary shares would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our securities, demand for ordinary shares could decrease, which could cause the price of the ordinary shares or their trading volume to decline.

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.

In addition, if we choose to pay dividends in the future, exchange rate fluctuations may affect the amount of Euros that we are able to distribute, and the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in euros, if any. Any dividends will generally be subject to Belgian withholding tax. See the section of this prospectus titled "Material Belgian Income Tax Consequences" for a more detailed description of Belgian taxes on dividends. These factors could harm the value of the ordinary shares.

Investors should be aware that the rights provided to our shareholders under Belgian corporate law and our articles of association differ in certain respects from the rights that you would typically enjoy as a shareholder of a U.S. company under applicable U.S. federal and state laws.

We are, and will upon the consummation of the offering be, a Belgian company with limited liability. Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in Belgium. The rights of shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and boards of directors in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board is required by Belgian law to consider the interests of our company, its shareholders, its employees and other stakeholders. It is possible that some of these parties will have interests that are different from, or in addition to, the interests of our shareholders. See "Description of Share Capital and Articles of Association — Articles of Association and Other Share Information."

Future sales, or the perception of future sales, of a substantial number of our ordinary shares could adversely affect the price of the ordinary shares, and actual sales of our equity will dilute shareholders.

Future sales of a substantial number of our ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of the ordinary shares. Following the completion of the offering, based on the number of shares outstanding as of March 31, 2021, we will have   ordinary shares outstanding (assuming no exercise of the underwriters' option to purchase additional ordinary shares). This includes the ordinary shares offered in the U.S. offering, which may be resold in the public market immediately without restriction, unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act, which may be resold only if registered under the Securities Act or in accordance with the requirements of Rule 144 or another applicable exemption from the registration requirements of the Securities Act. See "Ordinary Shares Eligible for Future Sale — Rule 144." Shares held by our directors, executive officers and certain shareholders will be subject to the lock-up agreements described in the "Underwriting" section of this prospectus. If, after the period during which such lock-up agreements restrict sales of the ordinary shares or if Piper Sandler & Co., Stifel, Nicolaus & Company, Inc., and Cantor Fitzgerald & Co. waive the restrictions set forth therein (which may occur at any time), one or more of these shareholders sell substantial amounts of ordinary shares in the public market, or the market perceives that such sales may occur, the market price of the ordinary shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

If we issue ordinary shares in future financings, shareholders may experience dilution and, as a result, our ordinary share price may decline.

We may from time to time issue additional ordinary shares at a discount from the trading price of our ordinary shares. As a result, our shareholders would experience immediate dilution upon the issuance of any of our ordinary shares at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preference shares or shares. If we issue ordinary shares or securities convertible into ordinary shares of our share capital, our shareholders would experience additional dilution and, as a result, our ordinary share price may decline.

It may be difficult for investors outside Belgium to serve process on, or enforce foreign judgments against, us or our directors and senior management.

We are a Belgian public limited liability company. Less than a majority of the members of our board of directors and members of our executive management team are residents of the United States. All or a substantial portion of the assets of such non-resident persons and most of our assets are located outside the United States. As a result, it may not be possible for investors to effect service of process upon such persons or on us or to enforce against them or us a judgment obtained in U.S. courts. Original actions or actions for the enforcement of judgments of U.S. courts relating to the civil liability provisions of the federal or state securities laws of the United States are not directly enforceable in Belgium.

The United States and Belgium do not currently have a multilateral or bilateral treaty providing for reciprocal recognition and enforcement of judgments, other than arbitral awards, in civil and commercial matters. In order for a final judgment for the payment of money rendered by U.S. courts based on civil liability to produce any effect on Belgian soil, it is accordingly required that this judgment be recognized or be declared enforceable by a Belgian court in accordance with Articles 22 to 25 of the 2004 Belgian Code of Private International Law. Recognition or enforcement does not imply a review of the merits of the case and is irrespective of any reciprocity requirement. A U.S. judgment will, however, not be recognized or declared enforceable in Belgium, unless (in addition to compliance with certain technical provisions) the Belgian courts are satisfied of the following:

- the effect of the enforcement judgment is not manifestly incompatible with Belgian public policy;
- the judgment did not violate the rights of the defendant'
- the judgment was not rendered in a matter where the parties transferred rights subject to transfer restrictions with the sole purpose of avoiding the application of the law applicable according to Belgian international private law;
- the judgment is not subject to further recourse under U.S. law;

- the judgment is not incompatible with a judgment rendered in Belgium or with a subsequent judgment rendered abroad that might be recognized in Belgium;
- the claim was not filed outside Belgium after the same claim was filed in Belgium, while the claim filed in Belgium is still pending;
- the Belgian courts did not have exclusive jurisdiction to rule on the matter;
- the U.S. court did not accept its jurisdiction solely on the basis of the presence of the plaintiff or the location of goods not direct linked to the dispute in the United States;
- the judgment did not concern the deposit or validity of intellectual property rights when the deposit or registration of those intellectual property rights was requested, done or should have been done in Belgium pursuant to international treaties;
- the judgment did not relate to the validity, operation, dissolution, or liquidation of a legal entity that has its main seat in Belgium at the time of the petition of the U.S. court;
- if the judgment relates to the opening, progress or closure of insolvency proceedings, it is rendered on the basis of the European Insolvency Regulation (EC Regulation No. 1346/2000 of May 29, 2000) or, if not, that (a) a decision in the principal proceedings is taken by a judge in the state where the most important establishment of the debtor was located or (b) a decision in territorial proceedings was taken by a judge in the state where the debtor had another establishment than its most important establishment;
- the judgment submitted to the Belgian court is authentic under the laws of the state where the judgment was issued; in case of a default judgment, it can be shown that under locally applicable laws the invitation to appear in court was properly served on the defendant; a document can be produced showing that the judgment is, under the rules of the state where it was issued, enforceable and was properly served on the defendant.

In addition to recognition or enforcement, a judgment by a federal or state court in the United States against us may also serve as evidence in a similar action in a Belgian court if it meets the conditions required for the authenticity of judgments according to the law of the state where it was rendered. The findings of a federal or state court in the United States will not, however, be taken into account to the extent they appear incompatible with Belgian public policy.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or members of our board of directors or our executive management any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, the ordinary shares may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an emerging growth company, we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an emerging growth company. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our ordinary shares held by non-affiliates exceeds $700 million as of the end of our second fiscal quarter before that time, in which case we would no longer be an emerging growth company as of the following December 31st (the last day of our fiscal year). We cannot predict if investors will find the ordinary shares less attractive because we may rely on these exemptions. If some investors find the ordinary shares less attractive as a result, there may be a less active trading market for the ordinary shares and the price of the ordinary shares may be more volatile.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we will rely on certain home country corporate governance practices rather than the corporate governance requirements of Nasdaq.

We qualify as a foreign private issuer and have applied to have the ordinary shares listed on Nasdaq. As a result, in accordance with the listing requirements of Nasdaq, we will rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently publish annual and semi-annual reports on our website pursuant to the rules of Euronext Brussels and expect to file such financial reports with the SEC, we will not be required to file periodic reports with the SEC as frequently or as promptly as U.S. public companies. Specifically, we will not be required to file quarterly reports on Form 10-Q or current reports on Form 8-K that a domestic company would be required to file under the Exchange Act. Accordingly, there may be less publicly available information concerning our company than there would be if we were not a foreign private issuer.

In addition, the Listing Rules of the Nasdaq Stock Market require a majority of the directors of a listed U.S. company to be independent, whereas in Belgium, only three directors need to be independent. The Listing Rules of the Nasdaq Stock Market further require that each of the nominating, compensation and audit committees of a listed U.S. company be comprised entirely of independent directors. However, the Belgian Corporate Governance Code recommends only that a majority of the directors on the nomination committee meet the technical requirements for independence under Belgian corporate law. At present, our audit committee is composed of three independent directors out of three members, whereas our nomination and remuneration committees are composed of two independent directors out of three members. Our board of directors has no plan to change the composition of our audit committee and nomination and remuneration committee, and we intend to follow home country practice to the maximum extent possible. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As a foreign private issuer, we are not required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act and related rules and regulations. Following the consummation of the offering, the determination of foreign private issuer status will be made annually on the last business day of our most recently completed second fiscal quarter. Accordingly, we will next make a determination with respect to our foreign private issuer status on December 31, 2021. There is a risk that we will lose our foreign private issuer status in the future.

We would lose our foreign private issuer status if, for instance more than 50% of our ordinary shares are owned by U.S. residents or persons and more than 50% of our assets are located in the United States and we continue to fail to meet additional requirements necessary to maintain our foreign private issuer status. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly greater than the costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP and modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion and modifications would involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers, which could also increase our costs.

U.S. Holders may suffer adverse tax consequences if we are characterized as a passive foreign investment company, or PFIC.

In general, a non-U.S. corporation is a PFIC for U.S. federal income tax purposes for any taxable year in which (i) 50% or more of the average value of its assets (generally determined on a quarterly basis) consists of assets that produce, or are held for the production of, passive income, or (ii) 75% or more of its gross income consists of passive income. For purposes of the above calculations, a non-U.S. corporation that owns, directly or indirectly, at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, investment gains and certain rents and royalties. Cash is generally a passive asset for these purposes. The value goodwill is generally treated as an active asset if it is associated with business activities that produce active income.

If we are a PFIC for any taxable year during which a U.S. holder (as defined below under “Certain Material U.S. Federal Income Tax Considerations to U.S. holders”) holds ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ordinary shares regardless of whether we continue to meet the PFIC test described above, unless the U.S. holder makes a specified election once we cease to be a PFIC. If we are classified as a PFIC for any taxable year during which a U.S. holder holds ordinary shares, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

Based on the current estimates, and expected future composition, of our income and the value of our assets, including goodwill, we do not expect to be a PFIC for our current taxable year. However, our PFIC status for any taxable year is an annual determination that can be made only after the end of that year and will depend on the composition of our income and assets and the value of our assets from time to time. The determination of whether we are a PFIC is fact-intensive and the applicable law is subject to varying interpretation. There can be no assurance that the United States Internal Revenue Service, or IRS, will agree with our conclusion or that the IRS will not successfully challenge our position including our classification of certain income and assets as non-passive or our valuation of our tangible and intangible assets.

A U.S. holder may in certain circumstances mitigate the adverse tax consequences of the PFIC rules by filing an election to treat the PFIC as a QEF, or, if shares of the PFIC are “marketable stock” for purposes of the PFIC rules, by making a mark-to-market election with respect to the shares of the PFIC. However, we do not currently intend to provide the information necessary for U.S. holders to make a QEF election if we were treated as a PFIC for any taxable year and prospective investors should assume that a QEF election will not be available. Furthermore, if a U.S. holder were to make a mark-to-market election with respect to its ordinary shares, the U.S. holder would be required to include annually in its U.S. federal taxable income (taxable at ordinary income rates) an amount reflecting any year end increase in the value of its ordinary shares. For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see the section titled “Certain Material U.S. Federal Income Tax Considerations to U.S. holders.”

The U.S. federal income tax rules relating to PFICs are very complex. Prospective U.S. holders are strongly urged to consult their own tax advisors with respect to the impact of PFIC status on the purchase, ownership and disposition of ordinary shares, the consequences to them of an investment in a PFIC, any elections available with respect to the ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ordinary shares of a PFIC.

If a U.S. Holder is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. holder (as defined below under “Certain Material U.S. Federal Income Tax Considerations to U.S. Holders”) is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our ordinary shares, such U.S. holder may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group, if any. Because our group currently includes at least one U.S. subsidiary, under current law, any of our current non-U.S. subsidiaries and any future newly formed or acquired non-U.S. subsidiaries will be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with controlled foreign corporation reporting obligations may subject a United States shareholder to significant monetary penalties. We cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations applicable under the controlled foreign corporation rules of the Code. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in ordinary shares. See section titled “Certain Material U.S. Federal Income Tax Considerations to U.S. holders” for a more detailed discussion.

We are exposed to changes in foreign currency exchange rates and interest rates.

We incur some of our expenses, and derive certain of our revenues, in currencies other than the Euro. In particular, as we expand our operations and conduct additional clinical trials in the United States, we will incur additional expenses in U.S. dollars. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates.

We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the Euro. Therefore, an unfavorable change in the value of the Euro against the U.S. dollar could have a negative impact on our revenue and earnings growth. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. The ordinary shares being offered in the U.S. offering will trade in U.S. dollars on Nasdaq, while our ordinary shares trade in Euro on Euronext Brussels. Our financial statements are prepared in euro. Therefore, fluctuations in the exchange rate between the Euro and the U.S. dollar will also affect, among other matters, the value of our ordinary shares.

We could also sign contracts denominated in currencies other than the euro, which would increase our exposure to currency risk. In accordance with our business decisions, our exposure to this type of risk could change depending on:

- the currencies in which we receive our revenues;
- the currencies chosen when agreements are signed, such as licensing agreements, or co-marketing or co-development agreements;
- the location of clinical trials; and
- our policy for insurance cover.

At present, we have not put any specific hedging arrangements in place to address these risks. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

Shareholders outside Belgium may be subject to exchange rate risk.

Our ordinary shares are denominated in euros. Accordingly, an investment in the ordinary shares by an investor whose principal currency is not the Euro may expose such investor to foreign currency exchange rate risk. Any depreciation of the Euro against such foreign currency would reduce the value of the investment in the ordinary shares in terms of such foreign currency.

We will incur significant increased costs as a result of operating as a company that is publicly listed on both Nasdaq in the United States and Euronext Brussels in Belgium, and our management will be required to devote substantial time to new compliance initiatives.

As a U.S. public company listed on Nasdaq, we will incur legal, accounting, and other expenses that we did not previously incur. We will be subject to the reporting requirements of the Securities Exchange Act of

1934, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company" and/or a foreign private issuer. The Exchange Act would require that, as a public company, we file annual, semi-annual and current reports with respect to our business, financial condition and result of operations. However, as a foreign private issuer, we are not required to file quarterly and current reports with respect to our business and results. We currently make annual and semiannual reporting with respect to our listing on Euronext Brussels.

Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Further, being a U.S. listed company and a Belgian public company with ordinary shares admitted to trading on Euronext Brussels impacts the disclosure of information and requires compliance with two sets of applicable rules. From time to time, this may result in uncertainty regarding compliance matters and result in higher costs necessitated by legal analysis of dual legal regimes, ongoing revisions to disclosure and adherence to heightened governance practices. As a result of the enhanced disclosure requirements of the U.S. securities laws, business and financial information that we report is broadly disseminated and highly visible to investors, which we believe may increase the likelihood of threatened or actual litigation, including by competitors and other third parties, which could, even if unsuccessful, divert financial resources and the attention of our management from our operations.

As a result of becoming a U.S. public company, we will become subject to additional regulatory compliance requirements, including Section 404, and if we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

Pursuant to Section 404, our management will be required to assess and attest to the effectiveness of our internal control over financial reporting in connection with issuing our consolidated financial statements as of and for the year ending December 31, 2022. Section 404 also requires an attestation report on the effectiveness of internal control over financial reporting be provided by our independent registered public accounting firm beginning with our annual report following the date on which we are no longer an "emerging growth company", which may be up to five fiscal years from the date of the offering.

The cost of complying with Section 404 will significantly increase and management's attention may be diverted from other business concerns, which could adversely affect our results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will further increase expenses. If we fail to comply with the requirements of Section 404 in the required timeframe, we may be subject to sanctions or investigations by regulatory authorities, including the SEC and Nasdaq. Furthermore, if we are unable to attest to the effectiveness of our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, and the market price of our ordinary shares could decline. Failure to implement or maintain effective internal control over financial reporting could also restrict our future access to the capital markets and subject each of us, our directors and our officers to both significant monetary and criminal liability. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expense and a diversion of management's time and attention from revenue generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial position, results and prospects may be adversely affected.

If we fail to implement and maintain effective internal controls over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired.

Following the completion of this offering, we will be subject to reporting obligations under U.S. securities laws and the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act requires that we include a report from management on the effectiveness of our internal control over financial reporting in our second annual report on Form 20-F after we become public. If we fail to remediate the material weakness identified below, our management may conclude that our internal control over financial reporting is not effective. This conclusion could adversely impact the market price of our ordinary shares due to a loss of investor confidence in the reliability of our reporting processes.

In the future, we will be required to perform system and process evaluations and testing of our internal controls over financial reporting, to allow our management and our independent public registered accounting firm to report on the effectiveness of our internal control over financial reporting. In addition, our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense, expend significant management effort and we may need to hire additional accounting and financial staff with the appropriate experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal additional deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. We cannot assure you that there will not be additional material weaknesses or significant deficiencies in our internal control over financial reporting in the future.

If we are unable to conclude that our internal controls are effective or if we have material weaknesses, investors could lose confidence in the accuracy or completeness of our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

For as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We could be an "emerging growth company" for up to five years. At the time when we are no longer an emerging growth company, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur remediation costs. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

In connection with our preparation and the audit of our consolidated financial statements as of and for the years ended December 31, 2020 and 2019, we and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we fail to remediate our material weaknesses, we may not be able to report our financial results accurately or to prevent fraud.

Prior to 2020, we have been a private company with limited accounting personnel and other resources with which to address our internal control over financial reporting. Further, our reporting obligations as a public company will continue to place a significant strain on our management, operational and financial resources and systems for the foreseeable future. Although we are not yet subject to the certification or attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, in connection with the audit of our financial statements as of and for the years ended December 31, 2020 and 2019, we and our independent registered public accounting firm identified material weaknesses as defined by the Public Company Accounting Oversight Board in the United States, or the PCAOB, in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

In connection with the audit of our 2020 and 2019 consolidated financial statements, we and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting related to the fact that we do not have the accounting and financial reporting resources necessary to comply with the obligations of U.S. public reporting company, as well as the necessary expertise to implement and maintain effective internal controls over financial reporting. The identified material weaknesses are primarily related to the (i) lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, and (ii) lack of adequate procedures and controls to ensure that accurate financial statements can be prepared and reviewed on a timely basis for annual reporting purposes.

To address the material weaknesses, we have engaged an external advisor to help prepare the financial statements in accordance with IFRS as well as help us put in place a formal control structure to detect and prevent material misstatements. We intend to continue taking steps to remediate the material weaknesses, including hiring individuals with sufficient technical IFRS knowledge, through formalizing documentation of policies and procedures and implementing additional accounting processes and controls. However, the implementation of these measures may not fully address the material weaknesses in our internal control over financial reporting, and therefore we may not be able to conclude when these material weaknesses will be fully remediated.

If we are unable to successfully remediate our identified material weaknesses, or if we discover additional material weaknesses, we would be required to continue disclosing such material weaknesses in future filings with the SEC, which could adversely impact investor confidence in our company and the market price of our ordinary shares, and could subject us to litigation or regulatory enforcement actions.

The Public Company Accounting Oversight Board, or PCAOB, is currently unable to inspect the audit work and practices of auditors operating in Belgium, including our auditor.

Our auditors, EY Bedrijfsrevisoren BV/Reviseurs d’Entreprises SRL, are registered with the PCAOB. Our auditors, like any other independent registered public accounting firms operating in Belgium, are not yet permitted, because of Belgian regulation impediments, to be subject to inspections by the PCAOB that assess their compliance with U.S. laws and professional standards in connection with the performance of audits of financial statements filed with the SEC. As a result, our investors may not realize the potential benefits of such inspections. Cooperation between the Belgium regulators and the PCAOB is expected in the first half of 2021.

We may be subject to securities litigation, which is expensive and could divert management’s attention.

The market price of the ordinary shares may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

We are a Belgian public limited liability company, and shareholders of our company may have different and in some cases more limited shareholder rights than shareholders of a U.S. listed corporation.

We are, and will upon the consummation of the offering be, a Belgian company with limited liability. Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in Belgium. The rights of shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and boards of directors in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board is required by Belgian law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, the interests of our shareholders. See “Description of Share Capital and Articles of Association — Articles of Association and Other Share Information.”

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 as a result of the offering and taking into account the current shareholding and international network of our current board of directors) 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.

Takeover provisions in the national law of Belgium may make a takeover difficult.

Public takeover bids on our shares and other voting securities, such as warrants or convertible bonds, if any, are subject to the Belgian Act of April 1, 2007 on public takeover bids, as amended and implemented by the Belgian Royal Decree of April 27, 2007, or Royal Decree, and to the supervision by the Belgian Financial Services and Markets Authority, or FSMA. Public takeover bids must be made for all of our voting securities, as well as for all other securities that entitle the holders thereof to the subscription to, the acquisition of or the conversion into voting securities. Prior to making a bid, a bidder must issue and disseminate a prospectus, which must be approved by the FSMA. The bidder must also obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of our company. The Belgian Act of April 1, 2007 provides that a mandatory bid will be required to be launched for all of our outstanding shares and securities giving access to ordinary shares if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting on their account, directly or indirectly holds more than 30% of the voting securities in a company that has 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 Royal Decree. The mere fact of exceeding the relevant threshold through the acquisition of one or more shares will give rise to a mandatory bid, irrespective of whether or not the price paid in the relevant transaction exceeds the current market price.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose important shareholdings and merger control, that may apply to us and which may make an unfriendly tender offer, merger, change in management or other change in control, more difficult. These provisions could discourage potential takeover attempts that third parties may consider and thus deprive the shareholders of the opportunity to sell their shares at a premium (which is typically offered in the framework of a takeover bid).

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, particularly the sections of this prospectus titled “Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements. All statements other than present and historical facts and conditions contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this prospectus, the words “anticipate,” “believe,” “can,” “could,” “estimate,” “expect,” “intend,” “is designed to,” “may,” “might,” “plan,” “potential,” “predict,” “objective,” “should,” or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- timing, progress, completion and results of clinical trials and our research and development programs;
- the timing or likelihood of regulatory filings and approvals;
- our reliance on the success of our Genio system;
- our ability to achieve and maintain adequate levels of coverage or reimbursement for procedures performed with our products and any future products we may seek to commercialize;
- the commercialization of our products;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and technology;
- our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- cost associated with defending intellectual property infringement, product liability and other claims;
- regulatory development in the U.S., Europe and other jurisdictions;
- the rate and degree of market acceptance of our products;
- our expectations about market trends;
- developments relating to our competitors and our industry, including competing products;
- our ability to accurately forecast customer demand and manage our inventory;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance;
- our expected use of proceeds of the offering;
- the future trading price of the ordinary shares and impact of securities analysts’ reports on these prices;
- the impact on our business, financial condition and results of operations from the ongoing and global COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide;
- our plans to remediate our material weaknesses; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

You should refer to the section of this prospectus titled “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this offering.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the Registration Statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

USE OF PROCEEDS

We estimate that we will receive net proceeds from the offering of approximately $ million (€ million), assuming an offering price of $ per ordinary share (€ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and estimated offering expenses payable by us, and assuming no exercise of the underwriters' option to purchase additional ordinary shares. If the underwriters exercise their option in full, we estimate that we will receive net proceeds from the offering of approximately $ million (€ million) after deducting estimated underwriting discounts and estimated offering expenses payable by us.

Each €1.00 ($) increase or decrease in the assumed initial offering price of € per ordinary share ($ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease our net proceeds from the offering by € million ($ million), assuming the number of ordinary shares, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. An increase or decrease of 1,000,000 ordinary shares offered by us would increase or decrease the net proceeds to us by € million ($ million), assuming that the assumed initial offering price remains the same and after deducting estimated underwriting discounts and estimated offering expenses payable by us. The actual net proceeds payable to us will adjust based on the actual number of ordinary shares sold by us, the actual initial offering price and other terms of the offering determined at pricing.

The principal purposes of the offering are to increase our financial flexibility in order to fund product development and R&D activities, build out our commercial capabilities and expand the market for the Genio system. We currently expect to use the net proceeds from the offering, together with our cash and cash equivalents, as follows:

- $ to advance the commercialization of the Genio system in our initial target markets in Europe, Australia and New Zealand and for pre-commercialization activities in the United States;
- $ to continue gathering clinical data and to support physician initiated clinical research projects related to OSA patient treatments;
- $ to further finance R&D activities related to the next generation of the Genio system and to continue to build a pipeline of new technologies and explore potential collaboration opportunities in the field of monitoring and diagnostics for OSA; and
- the remainder for working capital and general corporate purposes.

This expected use of net proceeds from the offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets. However, we have no current plans, commitments or obligations to do so. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the consummation of the offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to commercialize and market the Genio system can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, our plans to develop our in-house product manufacturing capabilities, the status of and results from clinical trials, any collaborations that we may enter into with third parties for the Genio system and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from the offering. See "Risk Factors — Risks Related to the Offering and these Securities — We have broad discretion over the use of the net proceeds from the offering and may use them in ways with which you do not agree and in ways that may not enhance our operating results or the price of the ordinary shares."

As of March 31, 2021, we had cash and cash equivalents of €86.2 million. We believe our cash and cash equivalents, together with the net proceeds of this offering, will be sufficient to fund our operations for .

Pending our use of the net proceeds from the offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our ordinary shares. We do not anticipate paying cash dividends on our equity securities in the foreseeable future and intend to retain all available funds and any future earnings for use in the operation and expansion of our business. All of the ordinary shares offered by this prospectus will have the same dividend rights as all of our other outstanding ordinary shares. In general, distributions of dividends proposed by our board of directors require the approval of our shareholders at a meeting of shareholders with a simple majority vote, although our board of directors may declare interim dividends without shareholder approval, subject to the terms and conditions of the Belgian Code of Companies and Associations, or CCA. See "Description of Share Capital and Articles of Association."

Our ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of our stand-alone statutory accounts prepared in accordance with Belgian GAAP. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of our net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e., summarized, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), and, save in exceptional cases, to be mentioned and justified in the notes to the annual accounts, decreased with the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves (which include, as the case may be, the unamortized part of any revaluation surpluses).

In addition, pursuant to Belgian law and our Articles of Association, we must allocate an amount of 5% of our Belgian GAAP annual net profit to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of our share capital. Our legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing. Accordingly, 5% of our Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, further limiting our ability to pay out dividends to its shareholders.

For information regarding the Belgian withholding tax applicable to dividends and related U.S. reimbursement procedures, see "Material United States Federal Income and Belgian Tax Considerations — Material Belgian Tax Consequences."

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2021 on an actual and on an as adjusted basis to reflect the issuance and sale of ordinary shares in the offering at an assumed initial offering price of € per ordinary share ($ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and estimated offering expenses payable by us.

Our capitalization following the offering will be adjusted based on the actual initial offering price and other terms of the offering determined at pricing. The table should be read in conjunction with the information contained in "Use of Proceeds," "Summary Consolidated Financial Data," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our consolidated financial statements and the related notes included elsewhere in this prospectus.

	As of March 31, 2021	
(in thousands)	**Actual**	**As Adjusted**
Cash and cash equivalents	€ 86,207	
Capital and Reserves		
Capital	3,798	
Share premium	150,986	
Share based payment reserve	2,650	
Currency translation reserve	79	
Retained Earnings	(66,010)	
Total equity	91,503	
Non-current debt		
Secured	2,737	
Unsecured	7,794	
Total non-current debt	10,531	
Current debt		
Secured	475	
Unsecured	8,141	
Total current debt	8,616	
Total debt	19,147	
Total capitalization	110,650	

Each €1.00 ($) increase or decrease in the assumed initial offering price of € per ordinary share ($ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease each of as adjusted cash and cash equivalents, total equity and total capitalization by approximately € million ($ million), assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. Each increase or decrease of 1,000,000 ordinary shares offered by us would increase or decrease each of as adjusted cash and cash equivalents, total equity and total capitalization by approximately € million ($ million), assuming that the assumed offering price remains the same, and after deducting estimated underwriting discounts and estimated offering expenses payable by us.

The number of ordinary shares that will be issued and outstanding after the offering, is based on 22,107,609 ordinary shares outstanding as of March 31, 2021, and excludes:

- 997,500 ordinary shares issuable upon the exercise of warrants outstanding as of March 31, 2021 pursuant to our warrant plans, at a weighted average exercise price of €9.21 per ordinary share.

DILUTION

If you invest in the ordinary shares in this offering, your interest will be immediately diluted to the extent of the difference between the initial public offering price per ordinary share in this offering and our net tangible book value per ordinary share after this offering. Dilution results from the fact that the initial public offering price per ordinary share is substantially in excess of the net book value per ordinary share.

If you invest in the ordinary shares in this global offering, your ownership interest will be diluted to the extent of the difference between the offering price per ordinary share paid by you and the as adjusted net tangible book value per share after the offering. Our net tangible book value as of March 31, 2021 was €74.3 million ($87.2 million), or €3.36 per ordinary share (equivalent to $3.94 per ordinary share). Net tangible book value per share is determined by dividing (i) our total assets less our intangible assets and our total liabilities by (ii) the number of ordinary shares outstanding as of March 31, 2021, or 22,107,609 ordinary shares.

After giving effect to our sale of ordinary shares in the offering, assuming an offering price of € per ordinary share ($ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and estimated offering expenses payable by us, our as adjusted net tangible book value at March 31, 2021 would have been approximately € million ($ million), or € per ordinary share (equivalent to $ per ordinary share). This amount represents an immediate increase in net tangible book value of € per ordinary share ($ per ordinary share) to our existing shareholders and an immediate dilution in net tangible book value of € per ordinary share ($ per or) to new investors.

The following table illustrates this dilution on a per ordinary share basis:

	As of March 31, 2021 Per Ordinary Share	
Assumed initial public offering price		€
Historical net tangible book value per ordinary share	€3.36	
Increase in net tangible book value per ordinary share attributable investors participating in the offering		
As adjusted net tangible book value per ordinary share after the offering		
Dilution in as adjusted net tangible book value per ordinary share to new investors participating in the offering		€

Each €1.00 ($) increase or decrease in the assumed initial offering price of € per ordinary share ($ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease our as adjusted net tangible book value by approximately € million ($ million), or approximately € per ordinary share ($ per ordinary share), and the dilution to new investors participating in this global offering would be approximately € per ordinary share ($ per ordinary share), assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. An increase in the number of ordinary shares offered by us by 1,000,000 would increase the as adjusted net tangible book value by approximately € million ($ million), or € per ordinary share ($ per ordinary share), and the dilution to new investors participating in this global offering would be € per ordinary share ($ per ordinary share), assuming that the initial offering price remains the same, and after deducting estimated underwriting discounts and estimated offering expenses payable by us. Similarly, a decrease in the number of ordinary shares offered by us by 1,000,000 would decrease the as adjusted net tangible book value by approximately € million ($ million), or € per ordinary share ($ per ordinary share), and the dilution to new investors participating in this global offering would be € per ordinary share ($ per ordinary share), assuming that the initial offering price remains the same, and after deducting estimated underwriting discounts and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual offering price, the number of ordinary shares offered by us and other terms of this global offering determined at pricing.

If the underwriters exercise in full their option to purchase additional ordinary shares, the as adjusted net tangible book value after the offering would be € per ordinary share ($ per ordinary share), the increase in the as adjusted net tangible book value to existing shareholders would be € per ordinary share ($ per ordinary share), and the dilution to new investors participating in this global offering would be € per ordinary share ($ per ordinary share).

The following table sets forth consideration paid to us in cash for ordinary shares purchased from us by our existing shareholders (translated into U.S. dollars at an exchange rate of €1.00 for $1.17) and by new investors participating in this global offering based on an assumed offering price of € per ordinary share ($ per ordinary share), which is the midpoint of the price range set forth on the cover page of this prospectus, and before deducting estimated underwriting discounts and estimated offering expenses payable by us.

	Ordinary Shares Purchased		Total Consideration		Average Price Per Ordinary Share
	Number	Percent	Amount (in millions)	Percent	
Existing shareholders	22,107,609	%	$ 168,941,357	%	$ 10.68
Investors participating in this offering					
Total		100%	$	100%	$

If the underwriters exercise in full their option to purchase additional ordinary shares, the percentage of ordinary shares held by existing shareholders would be reduced to % of the total number of ordinary shares outstanding after the offering, and the number of shares held by investors participating in this offering would be increased to % of the total number of ordinary shares outstanding after this offering.

If the underwriters exercise their option to purchase additional ordinary shares in full, the number of ordinary shares held by the existing shareholders after this global offering would be reduced to , or % of the total number of ordinary shares outstanding after the offering, and the number of ordinary shares held by new investors participating in this global offering would increase to , or % of the total number of ordinary shares outstanding after the offering.

The number of ordinary shares that will be outstanding after the offering is based on 22,107,609 ordinary shares outstanding as of March 31, 2021 and excludes:

- 997,500 ordinary shares issuable upon the exercise of warrants outstanding as of March 31, 2021 pursuant to our warrant plans, at a weighted average exercise price of €9.21 per ordinary share.

Certain of our existing shareholders have indicated an interest in participating in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with section entitled "Selected consolidated financial data," our audited financial statements for the years ended December 31, 2019 and 2020, our unaudited condensed interim financial statements for the three months ended March 31, 2020 and 2021, as well as related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and our expectations with respect to liquidity and capital resources, includes forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, those risks and uncertainties described in "Risk factors" and "Special note regarding forward-looking statements" in this prospectus. Our actual results could differ materially from the results described in or implied by these forward-looking statements.

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 therapy for OSA. OSA is the world's most common sleep disordered breathing condition and is associated with increased mortality risk and comorbidities including cardiovascular diseases, depression and stroke. Our innovative technology platform is the first-of-its-kind hypoglossal nerve stimulation device intended to treat OSA through bilateral stimulation, designed to maintain an open airway for a restful night's sleep. We started generating revenue from the Genio system in Europe in July 2020, and we are currently conducting our DREAM trial designed to support marketing approval in the United States. We continue to develop a significant body of clinical evidence to support the strong value proposition of the Genio system and its ability to improve the quality of life of OSA patients.

Our Genio system includes the world's first and only battery-free, leadless and minimally invasive neurostimulator, capable of delivering bilateral hypoglossal nerve stimulation for moderate to severe OSA patients who did not tolerate, have failed or refused conventional CPAP therapy. We developed the Genio system with a patient-centric approach, designed for comfort, safety, compliance and improved 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 hypoglossal nerve stimulators, the lack of an implantable battery or additional leads eliminates the need for complex lead 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. 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.

Since our inception, we have generated minimal revenue. Our ability to generate revenue from product sales and become profitable will depend in our ability to successfully commercialize the Genio system following marketing approval in our initial target markets. Our activities have consisted primarily of developing our Genio system, completing our BLAST OSA trial conducted in France and Australia, commencing our BETTER SLEEP clinical trial being conducted in Australia and New Zealand that is designed to expand our CE-Mark indication to include CCC, beginning our EliSA post-marketing trial in Europe, initiating our DREAM IDE pivotal trial in the United States designed to support FDA marketing authorization, and obtaining European regulatory approval. In June 2021, we announced initial top-line results from the six-month data for the BETTER SLEEP clinical trial. We are planning to submit the complete trial results to our E.U. Notified Body with the goal of expanding the CE-Marked indication to include CCC. We anticipate initial 12-month data for the DREAM trial will be available by the fourth quarter of 2022.

We have identified a country-specific reimbursement pathway and execution strategy for each of our initial target markets in Europe, Australia and New Zealand. We began our commercial launch in Germany in July 2020. After obtaining reimbursement approval in Germany through the existing hypoglossal nerve stimulation 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 hypoglossal nerve stimulation and also recently obtained reimbursement under an OSA-specific DRG code in Switzerland from the Federal Statistic Office, or BFS. The reimbursement coverage in both Germany and Switzerland includes the cost of the Genio system, implant procedure, hospital stay and follow-up care. We expect to begin marketing in Switzerland and in Spain in 2021.

Based on market access activities conducted 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.

Although we plan to commercialize the Genio system in Europe, Australia and New Zealand, bringing the Genio system to the U.S. market is key to our commercial strategy. Assuming a positive outcome from the DREAM trial, we expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in the second half of 2023. We have established a systematic approach to commercializing the Genio system in our target countries which focuses 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 diagnose and treat patients with OSA.

We are actively expanding our current European sales and marketing organization with country-specific sales teams upon receiving country-specific reimbursement, such as in Germany. Our European market development team includes direct sales representatives who focus on prioritizing high volume ENT centers, sleep centers, and building long-standing relationships with key physicians such as sleep doctors, ENT doctors and general practitioners who have strong connectivity to the OSA patient population that may be eligible for our therapy. 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 also 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, targeted key opinion leader, or KOL, development and training, and direct-to-consumer marketing. We plan to build a direct sales and marketing team in the United States as we approach potential FDA marketing authorization of our Genio system.

We rely on third-party suppliers to manufacture all the components of the Genio system to our specifications. Our principal suppliers are Medistri SA, Resonetics, VSI Parylene, Reinhardt Microtech GmbH (Cicor), Lust Hybrid, Meko, and S&D Tech SRL. The raw materials used by our suppliers are purchased in the open market. Outsourcing component manufacturing reduces capital investment and reduces operational expense for us. We manage these suppliers with experienced in-house resources and require them to comply with applicable standards and regulations, as well as use quality assurance processes and technology. We seek to maintain higher levels of inventory to protect ourselves from supply interruptions. We receive all components of the Genio system at our facility in Tel Aviv, Israel where we assemble the final product and package it in our clean room. Product distribution is also done from this facility. We also operate a manufacturing facility in Belgium and plan to use this facility to further scale-up our manufacturing capacity.

To date, our primary sources of capital have been private placements and public offerings of our common stock, debt financing agreements, and revenue from the sale of our products. Since inception, we have raised equity financing of approximately €165.0 million. As of March 31, 2021, we had cash and cash equivalents of €86.2 million, long-term debt of €10.5 million and an accumulated deficit of €66.0 million. We have devoted substantially all of our resources to research and development activities related to our

Genio system, including clinical and regulatory initiatives to obtain marketing approvals and have more recently begun to build our European commercialization infrastructure. During the year ended December 31, 2020, we generated revenue of €69,000 and our net loss was €12.3 million, and during the three months ended March 31, 2021, we generated revenue of €185,000 and our net loss was €5.7 million. Following this offering we expect that our general and administrative, research and development, quality assurance and regulatory, clinical, manufacturing, patent fees and related, therapy development and other expenses will continue to increase as we expand our marketing efforts to increase sales of the Genio system, conduct clinical trials, including our pivotal DREAM trial, seek for additional regulatory approvals and clearances and continue to invest in research and development to create product enhancements and enhance our product offering.

Key Factors and Trends

Obtaining regulatory approval in additional significant markets

We must successfully obtain timely approval or clearances and introduce new markets that gain acceptance with physicians. We are currently approved to market in Europe. And for our sales to grown, we will also need to receive FDA marketing authorization for the Genio system. We recently began the DREAM trial, which is our pivotal trial that we intend to rely on to receive marketing authorization in the United States. We anticipate announcing initial 12-month data from the DREAM trial by the fourth quarter of 2022. Assuming the data is favorable, we intend to apply to the FDA for marketing authorization for the Genio system. Our ability to expand the list of countries in which we are able to market and sell our system will significantly impact our revenue growth and the costs we incur in anticipation of such growth. Seeking for and obtaining regulatory approval for the Genio system in any of these countries is a long, expensive and uncertain process that can be impacted by numerous risks which are outside our control.

Growing and supporting our commercial organization.

We are committed to making additional investments in, and will continue to invest in recruiting, training and retaining experience and specialized sales teams. As of March 31, 2021, our European commercial team consists of seven professionals, who have substantial medical device sales and marketing, training and education as well as clinical experience and are operating from our headquarter in Belgium. Since the Genio system began being reimbursed under a dedicated DRG code in Germany, we have additionally invested in building up a dedicated direct sales and marketing organization of six individuals, led by a country director in Germany. In order to grow our business with existing and new accounts, we will need to continue making significant investments in educating physicians, hospitals and patients in the advantages of the Genio system for the treatment of moderate to severe OSA.

Continuing to invest in developing clinical support.

Publication of clinical results by us can have a significant influence on whether the Genio system is used by physicians. We intend to continue investing in clinical studies on the Genio system. We are initially targeting markets in Europe, Australia and New Zealand where we have identified a country-specific reimbursement pathway or execution strategy. We obtained reimbursement coverage and began marketing in Germany in 2020 and recently obtained reimbursement coverage in Spain and Switzerland, where we expect to begin marketing in 2021.

Increasing physician adoption and acceptance of the Genio System

The growth of our business depends on our ability to gain broader acceptance of the Genio system by continuing to make physicians aware of the benefits of the Genio system in order to generate increased demand and frequency of use and, thus, increase sales to our customers. Our ability to grow our business will also depend on our ability to expand our customer base in existing and new target markets. To date, the Genio system is our only product on the market. The Genio system has not yet received marketing approval in the United States, however. Accordingly, our future financial performance will depend on the successful completion of our planned pivotal trial in the United States.

Securing additional coverage and reimbursement by third-party payors

The level of reimbursement from third-party payors for procedures performed using the Genio system could have a substantial impact on the prices we are able to charge for the Genio system and how widely it is accepted. In many countries, payment for the Genio system will be dependent on obtaining a reimbursement code or codes for the procedure and the Genio system. Obtaining a reimbursement code can be a lengthy process that varies from country to country. While there is general consensus among physicians and payors of the medical necessity to treat OSA and increase the number of hypoglossal nerve stimulation therapy coverage decisions, we continue to develop further clinical evidence demonstrating a long-term meaningful improvement in net health outcomes for patients meeting the specified criteria. We believe that establishing and maintaining reimbursement will be important in achieving broad acceptance of our system by healthcare providers in these markets. For our sales to grow, we will also need to receive FDA marketing authorization for the Genio system. We expect that the outcomes of the ongoing pivotal DREAM trial, if favorable, will support marketing approval and reimbursement in the United States.

Continuing to invest in innovation and growth

We continue to invest in, and innovate with respect to, our existing Genio system to further improve future generations, as well as clinical outcomes, enhance the patient and physician experience and broaden the patient population that can be treated. We are also investing in building our pipeline of new products through our partnership with Vanderbilt University to expand the current neurostimulation options to treat moderate to severe OSA. While developing new products and technologies can be time consuming and costly, we believe that a pipeline of new technologies and next generation products is important for supporting increased adoption of our products. In the short term, we expect these activities to increase our net losses, but in the longer term, we anticipate they will positively impact our business and results of operations.

Due to these and other factors and trends, we expect to experience meaningful variability in our financial performance for the foreseeable future, including, but not limited to: costs, benefits and timing of new product introductions; the availability and cost of components and raw materials; and fluctuations in foreign currency exchange rates. Additionally, we experience quarters in which operating expenses, in particular research and development expenses, fluctuate depending on the stage and timing of product development.

While these factors may present significant opportunities for us, they also pose significant risks and challenges that we must address. See the section titled “Risk Factors” for more information.

Impact of COVID-19 Pandemic

Our business and the business of our development and manufacturing partners and suppliers have been and may in future be affected by pandemics, epidemics, or other health crises, including the ongoing outbreak of COVID-19. The ultimate impact of the COVID-19 outbreak or any similar health pandemic or epidemic is highly uncertain and subject to rapid change. COVID-19-related issues or measures may result in stoppages, interruptions, reductions or breaks in production activities, supply chain and support functions.

The outbreak of COVID-19 and its continued persistence has created an exceptional situation requiring exceptional measures. In response, we implemented governmental safety guidelines, including implementing work-from-home policies for our sales and administrative employees and staggered work times for our lab and manufacturing employees. To date, our Tel Aviv-based manufacturing facility has not experienced a stoppage of production activities and we have not experienced a noticeable delay or decrease in supply of components from our third-party suppliers due to the COVID-19 pandemic. Additionally, our support functions, including our research and development and quality assurance activities, have also continued, albeit at a reduced capacity. We have experienced and are continuing to experience slower than anticipated enrollment in our DREAM trial due to patient screening activities and elective surgeries having been reduced and, in some cases, put on hold in Europe, Australia and the United States. We also foresee challenges in training and proctoring new centers and their surgeons in the United States and Europe. Patients may be less willing to travel to these centers or their travel may be restricted, which could also impact our clinical and commercial activities.

While the ultimate overall economic impact caused by the COVID-19 pandemic may be difficult to assess or predict, it has resulted in significant disruption to the global financial markets. If these disruptions are sustained or recurrent, it may be difficult for us to access capital if and when we need it, which could negatively affect our ability to source required funding and could delay or prevent us from executing our strategy as planned.

Although we are monitoring developments related to the COVID-19 pandemic closely, the impact of COVID-19 on our business is uncertain at this time and will depend on future developments, which cannot be predicted, including new information which may emerge concerning the efficacy or side effects of vaccines and the speed of vaccination activities, the severity of COVID-19 and the actions taken to contain it or address its impact, among other things. Therefore, we do not yet know the full extent of the impact on our business, including our supply chains, our clinical studies and our access to the capital required to execute our business strategy.

Components of Our Results of Operations

Revenue

We currently derive all of our revenue from the sale of our proprietary Genio system, which we have started commercializing in Europe and, more specifically, in Germany. We sell the Genio system to both hospitals and distributors. Revenue from selling the Genio system is recognized at a point in time when control over the Genio system is transferred to the customer, which is in general at delivery at customer site or a predefined location in the country of the customer. The revenue from the Genio system may consist of individual products or a bundle of products in the form of a kit. The revenue is then recognized at an amount that reflects the consideration to which we expect to be entitled in exchange of the Genio system. In determining the transaction price for the sale of the Genio system, we consider the effects of variable consideration. We did not have any contracts with customers subject to IFRS 15 prior to 2020 and thus there is no impact of adopting IFRS 15. As of 2020, contracts with customers are accounted under IFRS 15.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing costs that we incur to obtain the components necessary to manufacture our Genio system. Direct costs from our third-party manufacturers includes costs for raw materials plus the mark-up for the assembly of the components. Cost of goods sold also includes allocated overhead for indirect labor, depreciation and information technology, certain direct costs such as those incurred for shipping our products, and personnel costs, including salary and share-based compensation.

Gross Profit and Gross Margin

We calculate gross profit as revenue less cost of goods sold, and gross margin as gross profit divided by revenue. Our gross margin has and will continue to be affected by a variety of factors, primarily average selling prices, production and ordering volumes, third-party manufacturing costs and cost-reduction strategies. We expect our gross profit to increase in the foreseeable future as our revenue grows. Our gross margin may increase over the long-term to the extent our production volume increases as our fixed manufacturing costs would be spread over a larger number of units.

Operating Expenses

Research and Development Expenses (in aggregate)

Research and development expenses (in aggregate) includes the following components: research and development expenses, clinical expenses, manufacturing expenses, quality assurance and regulatory expenses and patent fees and related expenses.

Research and Development Expenses

Research and development expenses consist primarily of product development, engineering to develop and support our products, testing, consulting services and other costs associated with the next generation of the Genio system. We continue to invest in improving the Genio system to develop next generation products with improved features with respect to patient comfort, therapy efficacy, reliability and patient and market acceptance. These expenses primarily include employee compensation and outsourced development expenses. We expect research and development expenses to increase in the future as we develop the next generation of the Genio system and are investing in building a new product pipeline.

Clinical Expenses

Clinical expenses consist primarily of clinical studies related to the development of our Genio system, consulting services and other costs associated with clinical activities. These expenses include employee compensation, clinical trial management and monitoring, payments to clinical investigators, data management and travel expenses for our various clinical trials. We expect clinical expenses to increase in the future as we continue to enroll additional patients in EliSA and DREAM studies.

Manufacturing Expenses

Manufacturing expenses consist primarily of employee compensation, acquisition costs of the components of the Genio system as well as distribution-related expenses such as logistics and shipping costs or non-commercial units of the Genio system. We expect our manufacturing expenses to increase in the future as we will conduct more clinical studies and continue investing in R&D.

Quality Assurance and Regulatory Expenses

Quality assurance and regulatory expenses consist primarily of quality control, quality assurance and regulatory expenses for activities non-related to the production of commercial units of the Genio system. These expenses include employee compensation, consulting, testing, and travel expenses related to the QA/RA department. We expect our quality assurance and regulatory expenses to increase in the future as we continue increasing our R&D and manufacturing activities.

Patent Fees and Related Expenses

Patent fees and related expenses consist primarily of compensation for personnel, spending related to the protection of company’s intellectual property, prosecution costs and travel expenses. We expect our patent fees and related expenses to increase in the future as we believe our intellectual property portfolio will grow over time.

Selling, General and Administrative (in aggregate)

Selling, general and administrative expenses (in aggregate) includes the following components: general and administrative expenses, therapy development expenses and other operating income/expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for personnel, including salaries, bonuses, benefits, and stock-based compensation, related to our finance, information technology, legal and human resource functions, as well as professional services fees (including legal, audit and tax fees), insurance costs, general corporate expenses and allocated facilities-related expenses. We expect that our general and administrative expenses will increase as we expand our headcount to support our growth and incur additional expenses related to operating as a dual listed public company, including director and officer insurance coverage, legal costs, accounting costs, costs related to exchange listing and costs related to U.S. Securities and Exchange Commission, or SEC, compliance and investor relations.

Therapy Development Expenses

Therapy development expenses consist primarily of compensation for personnel, spending related to direct sale force, market access and reimbursement activities. Other therapy development expenses include training physicians, travel expenses, conferences, market research, advertising and public relations. We expect our therapy development expenses to increase in the future as commercial activities will grow over time.

Other Operating Income/Expenses

Other operating income/expenses consist of the impact of the initial measurement and re-measurement of financial debt and the Australian R&D incentive subsidies receive by our subsidiary in Australia.

Results of Operations

For the Three Months Ended March 31, 2020 and 2021

The following table summarizes our results of operations for the periods presented below:

	Three Months Ended March 31		Year-Over-Year Change	
(in Thousands)	**2021**	**2020**	**Euro Change**	**% Change**
Revenue	€ 185	€ —	€ 185	—
Cost of goods sold	(52)	—	(52)	—
Gross Profit	133	—	133	—
General and administrative expenses	(1,818)	(1,178)	(640)	54.3%
Research and development expenses	(852)	(7)	(845)	*
Clinical expenses	(342)	(177)	(165)	93.2%
Manufacturing expenses	(901)	(62)	(839)	*
Quality assurance and regulatory expenses	(325)	(25)	(300)	*
Patents fees & related expenses	(674)	(58)	(616)	*
Therapy development expenses	(548)	(352)	(196)	55.7%
Other operating income/(expenses)	4	(191)	195	(102.1)%
Operating loss for the period	(5,323)	(2,050)	(3,273)	159.7%
Financial income	4	19	(15)	(78.9)%
Financial expense	(325)	(336)	(11)	(3.3)%
Loss for the period before taxes	(5,644)	(2,367)	(3,277)	138.4%
Taxes	(25)	(13)	(12)	92.3%
Loss for the period	(5,669)	(2,380)	(3,289)	138.2%

* Greater than 1,000%.

Revenue

Revenue was €185,000 for the three months ended March 31, 2021, compared to no revenue for the three months ended March 31, 2020. The increase in revenue was attributable to our commercialization of the Genio system in Europe, which began in July 2020.

Cost of Goods Sold

Cost of goods sold was €52,000 for the three months ended March 31, 2021, compared to no cost for the three months ended March 31, 2020. The increase in cost of goods sold was attributable to the sales of the Genio system in Europe, which began in July 2020.

Research and Development Expenses (in aggregate)

Research and development expenses (in aggregate) increased by €2.8 million from €329,000 for the three months ended March 31, 2020 to €3.1 million for the three months ended March 31, 2021 due to the factors discussed below with respect to each component of research and development expenses (in aggregate).

Research and Development Expenses. Before capitalization of €311,000 for the three months ended March 31, 2020, research and development expenses increased by €0.5 million, or 168%, from €318,000 (or €7,000 after capitalization of €311,000) for the three months ended March 31, 2020 to €0.9 million for the three months ended March 31, 2021, due to an increase in staff and consulting costs to support our R&D activities.

Clinical Expenses. Before capitalization of €1.4 million for the three months ended March 31, 2021 and capitalization of €568,000 for the three months ended March 31, 2020, clinical expenses increased by €1.1 million, or 139%, from €0.7 million (or €177,000 after capitalization of €568,000) for the three months ended March 31, 2020 to €1.8 million for the three months ended March 31, 2021 (or €342,000 after capitalization of €1.4 million). The increase in the expenses was mainly due to an increase in staff and consulting to support the completion of the BETTER SLEEP trial implantations, continuous recruitment for the EliSA trial and the ongoing DREAM IDE trial in the United States.

Manufacturing Expenses. Before capitalization of €215,000 for the three months ended March 31, 2021 and €578,000 for the three months ended March 31, 2020, manufacturing expenses increased by €0.5 million, or 74%, from €0.6 million (or €62,000 after capitalization of €578,000) for the three months ended March 31, 2020 to €1.1 million (or €901,000 after capitalization of €215,000) for the three months ended March 31, 2021. The increase was mainly due to an increase in staff, in the production and engineering team to support capacity and yield improvement, and in purchasing raw materials to support an increase in production.

Quality Assurance and Regulatory Expenses. Before capitalization of €133,000 for the three months ended March 31, 2021 and €263,000 for the three months ended March 31, 2020, quality assurance and regulatory expenses increased by €170,000, or 59%, from €288,000 (or €25,000 after capitalization of €263,000) for the three months ended March 31, 2020 to €458,000 (or €325,000 after capitalization of €133,000) for the three months ended March 31, 2021. The increase was mainly due to an increase in staff and QA & regulatory activities to support the manufacturing scaling-up process.

Patent Fees & Related Expenses. Before capitalization of €56,000 for the three months ended March 31, 2020, patent fees & related expenses increased by €560,000, or 491%, from €114,000 (or €58,000 after capitalization of €56,000) for the three months ended March 31, 2020 to €0.7 million for the three months ended March 31, 2021 due to expenses related to the license agreement with Vanderbilt University.

Selling, General and Administrative Expenses (in aggregate)

Selling, general and administrative expenses (in aggregate) increased by €0.7 million, or 41%, from €1.7 million for the three months ended March 31, 2020 to €2.4 million for the three months ended March 31, 2021 due to the factors discussed below with respect to each component of selling, general and administrative expenses (in aggregate).

General and Administrative Expenses. General and administrative expenses increased by €0.6 million, or 54%, from €1.2 million for the three months ended March 31, 2020 to €1.8 million for the three-months ended March 31, 2021 mainly due to an increase in consulting expenses. The increase in consulting and contractors' fees includes variable compensations for an amount of €253,000 for the three months ended March 31, 2020 and €498,000 for the three-months ended March 31, 2021 related to a cash-settled share based payment transaction.

Therapy Development Expenses. Therapy development expenses increased by €196,000, or 56%, from €352,000 for the three months ended March 31, 2020 to €0.5 million for the three months ended March 31, 2021. The increase in the expenses was mainly due to an increase in staff and consulting to support the launch the commercialization of the Genio system in Europe.

Other Operating Income / (Expenses). We had other operating expenses of €191,000 for the three months ended March 31, 2020 and operating income of €4,000 for the three months ended March 31, 2021. The change in expenses was mainly due to the impact of the initial measurement and re-measurement of the financial debt.

Operating Loss

The increase of operating loss from €2.1 million for the three months ended March 31, 2020 to €5.3 million for the three months ended March 31, 2021, or a change of €3.3 million, was due to increases of activities in all departments. We are currently conducting three clinical trials to continue gathering clinical data and obtain regulatory approvals. In June 2020, we obtained IDE approval to start the DREAM trial in the United States. In line with this strategy, we continue to invest in research and development to improve and develop the next generation of the Genio system and prepare for scaling-up of production capacities.

For the Years Ended December 31, 2019 and 2020

The following table summarizes our results of operations for the periods presented below:

(in Thousands)	For the year ended December 31 2020	2019	Year-Over-Year Change Euro Change	% Change
Revenue	€ 69	€ —	€ 69	—
Cost of goods sold	(30)	—	(30)	—
Gross Profit	**39**	**—**	**39**	**—**
General and administrative expenses	(7,522)	(4,226)	(3,296)	(78.0)%
Research and development expenses	(473)	(630)	157	24.9%
Clinical expenses	(1,053)	(848)	(205)	(24.2)%
Manufacturing expenses	(460)	(489)	29	5.9%
Quality assurance and regulatory expenses	(227)	(227)	—	—
Patents fees & related expenses	(123)	(267)	144	53.9%
Therapy development expenses	(1,864)	(902)	(962)	106.7%
Other operating income/(expenses)	459	(126)	585	464.3%
Operating loss for the period	**(11,224)**	**(7,715)**	**(3,509)**	**(45.5)%**
Financial income	62	71	(9)	(12.7)%
Financial expense	(990)	(740)	(250)	(33.8)%
Loss for the period before taxes	**(12,152)**	**(8,384)**	**(3,768)**	**(44.9)%**
Taxes	(93)	(70)	(23)	(32.9)%
Loss for the period	**(12,245)**	**(8,454)**	**(3,791)**	**(44.8)%**

Revenue

Revenue was €69,000 for the year ended December 31, 2020, compared to zero for the year ended December 31, 2019. The increase in revenue was attributable to our initial commercialization of the Genio system, which began in July 2020.

Cost of Goods Sold

Cost of goods sold was €30,000 for the year ended December 31, 2020, compared to zero for the year ended December 31, 2019. The increase in cost of goods sold was attributable to the initial sales of the Genio system, which began in July 2020.

Research and Development Expenses (in aggregate)

Research and development expenses (in aggregate) decreased by €125,000, or 5.1%, from €2.5 million in 2019 to €2.3 million in 2020 due to the factors discussed below with respect to each component of research and development expenses (in aggregate).

Research and Development Expenses. Research and development expenses decreased by €0.2 million, or 24.9%, from €0.6 million in 2019 to €0.5 million in 2020 due to the increase of development costs of the Genio system of €0.7 million and a decrease of €0.8 million of capitalized costs.

Clinical Expenses. Clinical expenses increased by €205,000, or 24.2%, from €0.9 million for the year ended December 31, 2019 to €1.1 million for the year ended December 31, 2020. The increase in clinical expense was mainly due to an increase of €0.9 million in staff and consulting to support the completion of the BETTER SLEEP trial implantations, for continued recruitment for the EliSA trial and for the launch of the DREAM trial in the United States. The costs related to these three clinical studies increased by €0.5 million and capitalized clinical costs decreased by €1.2 million.

Manufacturing Expenses. Manufacturing expenses decreased by €29,000, or 5.9%, from €489,000 for the year ended December 31, 2019 to €460,000 for the year ended December 31, 2020. The decrease in manufacturing expenses was mainly due to a decrease of capitalized costs of €2.0 million offset by an increase of staff and production costs of €2.0 million as we hired additional staff in the production and engineering team to support capacity and yield improvement and we purchase more raw materials to support increase in the production.

Quality Assurance and Regulatory Expenses. Quality assurance and regulatory expenses remained €227,000 million for each of the years ended December 31, 2019 and 2020. Quality assurance and regulatory expenses are primarily comprised of costs related to staff and quality assurance and regulatory activities to support scaling up our manufacturing process.

Patent Fees & Related Expenses. Patent fees and related expenses decreased by €144,000, or 106.7%, from €267,000 for the year ended December 31, 2019 to €123,000 for the year ended December 31, 2020. The decrease was primarily due to the outsourcing of patent–related activities.

Selling, General and Administrative Expenses (in aggregate)

Selling, general and administrative expenses (in aggregate) increased by €4.3 million, or 83%, from €5.1 million in 2019 to 9.4 million in 2020 due to the factors discussed below with respect to each component of selling, general and administrative expenses (in aggregate).

General and Administrative Expenses. General and administrative expenses increased by €3.3 million, or 78%, from €4.2 million for the year ended December 31, 2019 to €7.5 million for the year ended December 31, 2020. The increase is due to consulting expenses, staff and legal fees to support our growth. The increase in consulting and contractors' fees includes variable compensations for an amount of €2.0 million related to a cash-settled share based payment transaction. The increase of €159,000 in legal fees is due to services and not to any ongoing disputes.

Therapy Development Expenses. Therapy development expenses increased by €1.0 million, or 106.7%, from €0.9 million for the year ended December 31, 2019 to €1.86 million for the year ended December 31, 2020. The increase was primarily due to an increase of €0.7 million in staff and consulting to support the commercialization in Europe.

Other Operating Income / (Expenses). Other operating income increased by €0.6 million, or 464.3%, from an expense of €126,000 for the year ended December 31, 2019 to an income of €456,000 for the year ended December 31, 2020. The increase was primarily due to the increase of €0.6 million in R&D Incentive (Australia) to be received on development expenses incurred by the subsidiary in Australia.

Operating Loss

The increase of operating loss from €7.7 million in 2019 to €11.2 million 2020, or a change of €3.5 million, was due to increases of activities in all departments. We are currently conducting three clinical trials to continue gathering clinical data and obtain regulatory approvals. In June 2020, we obtained IDE approval to start the DREAM trial in the United States. In line with its strategy, we continue to invest in research and development to improve and develop the next generation of the Genio system and prepare for scaling-up of production capacities.

Liquidity and Capital Resources

To date, our primary sources of capital have been private placements and public offerings of our common stock and debt financing agreements. Since inception, we have raised equity financing of approximately €165.0 million. In September 2020, we raised €84.8 million as a result of the initial public offering of new shares on the Euronext. All of our shares were admitted to trading on the regulated market of Euronext Brussels under the symbol "NYXH". As of March 31, 2021, we had cash and cash equivalents of €86.2 million and an accumulated deficit of €66.0 million.

Short-Term and Long-Term Obligations

Grants and Subsidies from the Walloon Region

We have been granted several recoverable cash advances by the Walloon Region since our incorporation in 2009. The recoverable cash advances are dedicated to funding specific research and development programs. The funding covers between 55% to 60% of the budgeted costs of the specified programs and bear interest at one-year Euribor + 100bp. All recoverable cash advances consist of two phases, the “research phase” and the “exploitation phase”.

During the research phase, we receive funds from the Walloon Region based on statements of expenses. At the end of the research phase, we are required to decide within six months whether or not to exploit the results of any given research program. If we decide not to exploit the results of a program, we have to transfer to the Walloon Region all real rights with respect to the results, and the cash advance does not have to be reimbursed. If we decide to exploit the results of a program funded by a recoverable cash advances, the relevant recoverable cash advance becomes refundable during the exploitation phase. The exploitation phase starts once a decision is made and has a maximum duration period determined in the relevant contract or addendum to the relevant contract (until 2037 or 2038).

The repayment of the recoverable cash advances to the Walloon Region consists of two elements:

- fixed repayments paid in annual amounts throughout the duration of the exploitation phase and representing in aggregate 30% of the principal amount; and
- turnover-dependent reimbursements paid as a percentage of sales of the principal amount of the recoverable cash advance depending on the actual outcome of the sales.

Total repayment is, in the aggregate (including the accrued interest), capped at two times the nominal amount.

We have contracted the following recoverable cash advances with the Walloon Region:

(in Thousands)	Contractual Advances	Advances received	Amounts reimbursed
Total	**€ 7,627**	**€ 7,627**	**€519**

In addition to these recoverable cash advances, we have also received several grants from the Walloon Region totaling €1.0 million, related to first requests for patents and territorial extension. The grants partially cover the expenses related to the follow-up actions to be taken after a patent request. In principle, the grants do not have to be reimbursed unless the conditions set out in the contracts related to the exploitation of the patent are not complied with.

Funding Requirements

We use our cash to fund our operations, which primarily include the cost of manufacturing our Genio system, as well operating expenses and related personnel costs. We expect research and development expenses to increase for the foreseeable future as we continue to hire personnel and invest in next-generation innovations of the Genio system and related products. In addition, we expect our general and administrative expenses to increase for the foreseeable future as we hire personnel and expand our infrastructure to both drive and support the anticipated growth in our organization. We will also incur additional expenses as a result of operating as a dual listed public company and also expect to increase the size of our administrative function to support the growth of our business. The timing and amount of our operating expenditures will depend on many factors, including:

- acceptance of our therapy by patients, physicians, government payers, private payers, and the market generally;
- the scope, rate of progress and cost of current or future clinical studies;
- the cost of research and development activities;
- the cost associated with any complications or side effects related to the use of the Genio system;
- 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 and timing of additional regulatory clearances or approvals;
- the cost and timing of establishing additional sales and marketing capabilities;

- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the extent to which we acquires or invests in products, technologies and businesses; and
- the costs of operating as a dual listed public company.

As of March 31, 2021, we had cash and cash equivalents of €86.2 million. Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to meet our capital requirements and fund our operations through . We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Without taking into account the net proceeds we expect to receive from this offering, we believe that our existing cash and cash equivalents will be sufficient to meet our capital requirements and fund our operations for the next twelve months. We may seek to raise any necessary additional capital through public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these or other funding sources. Additional funds may not be available to us on acceptable terms or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, we could be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. If we raise additional funds by issuing equity securities, our shareholders will suffer dilution and the terms of any financing may adversely affect the rights of our shareholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing shareholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Cash Flows

The table below summarizes our cash flows information for the three months ended March 31, 2020 and 2021.

	For the three months ended March 31	
(in Thousands)	**2021**	**2020**
Net cash used in operating activities	€(4,159)	€ (1,197)
Net cash used in investing activities	(1,775)	(1,777)
Net cash used in / generated from financing activities	(104)	24,838
Movement in cash and cash equivalents	**(6,038)**	**21,864**
Effect of exchange rates on cash and cash equivalents	€ (55)	€ 155

Net cash used in operations was €4.2 million for the three months ended March 31, 2021 compared to €1.2 million for the three months ended March 31, 2020. The increase of €3.0 million was primarily due to an increase in a loss for the period of €3.3 million that was mainly attributable to increased general and administrative expenses, research and development expenses, manufacturing expenses and therapy development expenses, which were offset by a positive variation in the working capital of €0.5 million.

Net cash used in investing activities for each of the three months ended March 31, 2021 and the three months ended March 31, 2020 was €1.8 million.

Net cash used in financing activities for the three months ended March 31, 2021 was €104,000 compared to €24.8 million of net cash provided by financing activities during the three months ended March 31, 2020. The decrease was due to a lack of capital increase during the first quarter of 2021.

The table below summarizes our cash flows information for the years ended December 31, 2019 and 2020.

(in Thousands)	For the year ended December 31 2020	2019
Net cash used in operations	€ (7,015)	€ (5,965)
Net cash used in investing activities	(10,693)	(5,795)
Net cash from financing activities	104,176	733
Effects of exchange rate changes	(23)	77
Change in cash and cash equivalents	**€ 86,445**	**€ (10,950)**

Net cash used in operations was €7.0 million for the year ended December 31, 2020 compared to €6.0 million for the year ended December 31, 2019. The increase of cash used in operations of €1.1 million was primarily due to higher losses of €3.8 million that were mainly attributable to increased general and administrative expenses and therapy development expenses, as described in more detail above, and higher interest and tax paid, net by €170,000, which were partially offset by an increase in non-operating cash adjustments of €2.42 million and a positive variation in the working capital of €460,000.

Net cash from investing activities for the year ended December 31, 2020 was €10.7 million compared to €5.8 million for the year ended December 31, 2019. The increase in net cash from investing activities related to higher capitalization of development expenses in 2020.

Net cash from financing activities for the year ended December 31, 2020 was €104.2 million compared to €0.7 million for the year ended December 31, 2019. The increase was primarily due to proceeds from our Euronext IPO that we completed in September 2020 and the proceeds from the February 2020 capital raise.

Contractual Obligations and Commitments

Our principal obligations consist of a lease liability, financial debt (which includes recoverable cash advances and other loan) and trade and other payables. The following table sets out, as of December 31, 2019 and 2020, our contractual obligations and commitments due by period:

	2020				2019		
(in Thousands)	Lease Liability	Financial Debt	Trade & Other Payable	Other Commitments*	Lease Liability	Financial Debt	Trade & Other Payable
Less than 1 year	€ 560	€ 632	€ 5,313	€1,450	353	€ 392	€ 3,658
1 – 5 years	2,186	4,987	—	1,570	709	2,871	547
5+ years	895	4,620	—	—	38	11,470	—
Total	**€ 3,640**	**€10,239**	**€ 5,313**	**€3,020**	**€ 1,100**	**14,733**	**4,205**

* Related to Cochlear Collaboration Agreement

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with the International Financial Reporting Standards as issued by the International Accounting Standards Board. The consolidated financial statements are presented in Euro and all values are rounded to the nearest thousand, except when otherwise indicated.

The preparation of the consolidated financial statements requires the use of certain critical accounting estimates. It also requires management to exercise judgment in the process of applying accounting policies. The areas involving a higher degree of judgment or complexity are areas where assumptions and estimates are significant to the consolidated financial statements.

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

While our critical accounting estimates and assumptions are described in Note 5 to our consolidated financial statements found elsewhere in this prospectus, we believe that the following critical accounting policies and estimates are those most important to the judgments and estimates used in the preparation of our consolidated financial statements.

Recoverable Cash Advances

We benefit from recoverable cash advances granted by the Walloon Region, a governmental Belgian agency. These are, in substance, our financial liabilities towards the Walloon Region. The determination of the amount of the financial liability is subject to a high degree of subjectivity and requires us to make estimates of the future sales we will derive in the future from the products that benefited from the support of the Walloon Region.

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

We estimated the fair value of the liability of the future payment to be made to the Walloon Region based on a forecasted volume of sales. The estimation of the fair value is dependent on the discount rate applied. The fixed part to be reimbursed has been discounted with a discount rate of 5% and the variable part (based on sales forecasts) with a discount rate of 12.5%.

Development expenses capitalized and related impairment testing

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

At December 31, 2019, we capitalized for the first time development costs for the first generation of the Genio System. This amount includes costs related to the development of the Genio System which received CE-Mark approval in March 2019. Therefore, we believe that, from March 2019, development expenditures do meet capitalization criteria. Accordingly, the costs incurred after this date have been recognized as development assets for a total amount of €17.2 million as of March 31, 2021 (March 31, 2020: €7.4 million). In addition, we started capitalizing the development costs for the improved second generation of the Genio System from July 2020 for a total amount of €1.0 million.

The development expenses capitalized have to be tested annually for impairment during the development period, prior to the start of its amortization. We perform the impairment test on the smallest group of assets to which it belongs for which there are separately identifiable cash flows: its cash-generating units. Where the carrying value of an asset exceeds its recoverable amount (i.e. the higher of value in use and fair value less costs to sell), the asset is written down accordingly.

When performing the impairment test, management needs to make significant judgments, estimates and assumptions. We base our impairment calculation on detailed budgets and forecast calculations generally covering a period of five to six years. For longer periods, a long-term growth rate is calculated and applied to future cash flows projected after the terminal year.

Share-Based Payments

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

In addition, we have two cash-settled share-based payment plans in place. Estimating the fair value of those cash-settled share-based payment plans require us to estimate (i) our pre-money valuation of at December 31, 2019 and (ii) to estimate the vesting period considering the most likely date when an Exit event may occur. The assumptions and models used for estimating the fair-value for share-based payment transactions are disclosed in Note 13 to our consolidated financial statements found elsewhere in this prospectus.

Recently Issued Accounting Pronouncements

We applied for the first-time certain standards and amendments, which are effective for annual periods beginning on or before January 1, 2020. The new standards and amendments that apply for the first time in 2020 are not expected to have a material impact on our financial position, results of operations or cash flows and are described in Note 2 to our consolidated financial statements found elsewhere in this prospectus.

Quantitative and Qualitative Disclosures about Financial Risk

Market Risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market prices. Our activities may expose us to changes in foreign currency exchange rates and interest rates. We are not exposed to any equity price risk or commodity price risk as we do not invest in these classes of investments.

Credit Risk

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

Furthermore, we are not exposed to any material credit risk as other receivables are mainly due by the governments in Australia and the Walloon Region and there is no risk associated to this receivable.

Foreign Exchange Risk

We are minimally exposed to currency risk on a limited number of expenses that are denominated in currencies other than the functional currency of our subsidiaries, primarily the U.S. dollar, or USD, Israeli new shekel, or NIS, or Australian dollars, or AUD.

Additionally, earnings variability arises from the translation of monetary assets and liabilities denominated in currencies other than the functional currency of subsidiaries at the rate of exchange at each closing date, the impact of which is reported as a foreign exchange gain or loss in the consolidated statements of comprehensive income. Most foreign exchange transactions were denominated in USD, NIS, or AUD for the subsidiaries that have functional currency in Euro. For the year ended December 31, 2020, if the USD strengthened/weakened by 5% against the Euro with all other variables held constant, net loss for the year then ended would have been €4,000 lower/higher. For the years ended December 31, 2019 and 2020, if the NIS strengthened/weakened by 5% against the Euro with all other variables held constant, net loss for the years then ended would have been €11,000 lower/higher and €12,000 lower/higher, respectively. For the years ended December 31, 2019 and 2020, if the AUD strengthened by 5% against the Euro with all other variables held constant, net loss for the years then ended would have been €39,000 lower and €55,000 lower, respectively. For the years ended December 31, 2019 and 2020, if the AUD weakened by 5% against the Euro with all other variables held constant, net loss for the years then ended would have been €43,000 higher and €61,000 higher, respectively.

We do not generally enter into arrangements to hedge our currency risk exposure.

Internal Control over Financial Reporting

In connection with our preparation and the audit of our consolidated financial statements as of and for the years ended December 31, 2020 and 2019, we and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting. As defined in the standards established by the PCAOB, a “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified during the audit of our consolidated financial statements as of and for the years ended December 31, 2020 and 2019 relate to: (i) lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, and; (ii) lack of adequate procedures and controls to ensure that accurate financial statements can be prepared and reviewed on a timely basis for annual reporting purposes.

We are taking a number of measures to address these material weaknesses, we have engaged an external advisor to help prepare the financial statements in accordance with IFRS. We intend to continue taking steps to remediate the material weaknesses, including hiring individuals with sufficient technical IFRS knowledge, through formalizing documentation of policies and procedures and implementing additional accounting processes and controls. However, the implementation of these measures may not fully address the material weaknesses in our internal control over financial reporting, and therefore we were not able to conclude that these have been fully remediated as of December 31, 2020. The process of designing and implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that is adequate to satisfy our reporting obligations. Our failure to correct these material weaknesses or our failure to discover and address any other control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and make related regulatory filings on a timely basis. As a result, our business, financial condition, results of operation and prospects, as well as the trading price of our ordinary shares, may be materially and adversely affected. See “Risk Factors — Risks Related to the Offering and these Securities — In connection with the audit of our consolidated financial statements as of and for the year ended December 31, 2020 and 2019, we and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we fail to remediate our material weaknesses, we may not be able to report our financial results accurately or to prevent fraud.”

Emerging Growth Company and Foreign Private Issuer Status

Emerging Growth Company Status

As a company with an annual revenue under $1.07 billion, we qualify as an “emerging growth company” as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- the ability to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly reduced disclosure in management’s discussion and analysis of financial condition and results of operations in this prospectus;
- exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, in the assessment of our internal controls over financial reporting; and
- to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions for up to five years or until such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue;

(ii) the date we qualify as a "large accelerated filer" with at least $700 million of equity securities held by non-affiliates; (iii) the issuance, in any three-year period by our company of more than $1.0 billion in non-convertible debt securities held by non-affiliates; and (iv) the last day of the fiscal year ending after the fifth anniversary of this public offering of our ordinary shares.

We may choose to take advantage of some but not all of these reduced burdens. For example, we have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus, and intend to take advantage of the exemption from the auditor attestation on the effectiveness of our internal control over financial reporting. Accordingly, the information that we provide shareholders may be different than you might obtain from other public companies.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

Foreign Private Issuer Status

Upon consummation of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time;
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events; and
- Regulation FD, which regulates selective disclosures of material information by issuers.

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 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 hypoglossal nerve stimulation device designed to treat OSA through bilateral stimulation, by maintaining an open airway for a restful night's sleep. We started generating revenue from the sale of the Genio system in Europe in July 2020, and we are currently conducting our DREAM pivotal trial designed to support marketing authorization in the United States. We are developing a significant body of clinical evidence to further support the strong value proposition of the Genio system and its ability to improve the health and quality of life of OSA patients.

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

Published scientific literature estimates that there are currently approximately 24.5 million individuals with moderate to severe OSA in our initial target markets in Europe, Australia and New Zealand. Based on published scientific literature, we estimate that approximately 2.7 million patients are diagnosed annually in those countries and that approximately 80% of diagnosed patients are prescribed a CPAP device. Published scientific literature reports non-compliance rates to CPAP between 29% and 83%. Based on these data, and for purposes of calculating the total addressable market in Europe, Australia and New Zealand for the Genio system, we estimate that approximately 35% of patients that are prescribed CPAP in those countries are not compliant with the therapy. Additionally, certain patients possesses anatomical characteristics, including higher body-mass-index or increased tongue fat deposition that make them ineligible for hyperglossal nerve stimulation. Taking that into account, we estimate that approximately 70% of those non-compliant patients are eligible for hypoglossal nerve stimulation based on their anatomical characteristics. As a result, we believe the total addressable market in Europe, Australia and New Zealand for the Genio system is at least 520,000 patients which represents an estimated annual market opportunity of approximately $11 billion based on our current pricing for the Genio system. We also plan to enter the United States market, assuming we obtain marketing authorization in the United States, where published scientific literature estimates 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. Hypoglossal nerve stimulation therapies have proven to be a safe and effective treatment for those suffering from moderate to severe OSA. Systems competitive with our Genio system consist of multiple implantable components and incisions, 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. Patients diagnosed with complete concentric collapse at the level of the soft palate, or CCC, are currently contraindicated for hypoglossal nerve stimulation 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. Due to the current contraindication, all patients seeking hypoglossal nerve stimulation OSA therapies are required to undergo a DISE procedure. It is estimated that approximately 30% of moderate to severe OSA patients are affected by CCC and are therefore unable to receive neurostimulation treatment.

Our Genio system includes the first battery-free, leadless and minimally invasive neurostimulator, capable of delivering bilateral hypoglossal nerve stimulation for moderate to severe OSA patients who did not tolerate, have failed or refused conventional CPAP 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 hypoglossal nerve stimulators, 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.

Our proprietary technology is the first to provide bilateral stimulation to the hypoglossal nerve. Other hypoglossal nerve stimulation technologies indicated for treating OSA provide unilateral hypoglossal nerve stimulation to only one branch 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 has the potential to provide better clinical outcomes. Furthermore, we believe that bilateral stimulation has the potential to address moderate to severe OSA patients with CCC, who are currently contradindicated for, or unable to be treated with, existing hypoglossal nerve stimulation OSA therapies.

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 clinical trial. We are planning to submit the complete trial results to our E.U. Notified Body with the goal of expanding the CE-Marked indication to include CCC. We plan to continue to obtain authorization in additional target markets and are currently conducting our Dual-sided Hypoglossal neRvE stimulAtion for the treatMent of Obstructive Sleep Apnea clinical trial, or DREAM trial, a multicenter, prospective, open-label, pivotal Investigational Device Exemption, or IDE, trial designed to support marketing authorization in the United States. We anticipate initial 12-month data for the DREAM trial will be available by the fourth quarter of 2022. Assuming a positive outcome from the DREAM trial, we expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in the second half of 2023.

We are initially targeting markets in Europe, Australia and New Zealand where we have identified a country-specific reimbursement pathway or execution strategy. We began our commercial launch in Germany in July 2020. After obtaining reimbursement approval in Germany through the existing hypoglossal nerve stimulation 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 hypoglossal nerve stimulation and also recently obtained reimbursement under an OSA-specific DRG code in Switzerland from the Federal Statistic Office, or BFS. The reimbursement coverage in both Germany and Switzerland includes the cost of the Genio system, implant procedure, hospital stay and follow-up care. We expect to begin marketing in Switzerland and in Spain in 2021. Based on market access activities conducted by us over the past several years, we have developed tailored reimbursement strategies using assessments of the local requirements of target countries. In countries where there is existing reimbursement coverage in place, we plan to piggyback on existing coding and reimbursement, acting as a fast-follower. In countries where there is no existing reimbursement coverage, we will seek to be the first in that market to obtain reimbursement coverage. In countries without existing reimbursement coverage, the strategy could include (i) making the Genio system commercially available for patients through country specific innovation funding pathways for procedures and products that would not yet be covered by an existing code, (ii) supporting case-by-case funding submission in focus hospitals that can use their budget to fund the therapy, (iii) entering into specific commercial deals with privately funded hospital groups, or (iv) out-of-pocket payment.

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

In addition to our ongoing clinical studies, we are also committed to continuing our research and development efforts related to the Genio system, with an emphasis on improving clinical outcomes, optimizing patient adoption and comfort, increasing access for a greater number of patients, and allowing more physicians to perform the implantation procedure. The primary focus of our research and development efforts in the near-term will be the continued technological advancement of the Genio system. Some of these improvements include features aimed at enhancing a physician’s ability to monitor patient compliance and therapeutic efficacy. In the long term, including through our partnership with Vanderbilt University, we intend to provide new neurostimulation technologies for OSA patients. We continue to enhance our scalable technology platform to allow for quick and streamlined release of new features and functionalities through software, firmware and hardware updates and upgrades and therapy enhancement.

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 hypoglossal nerve stimulation 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 hypoglossal nerve stimulation-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 addition, in June 2021, we announced initial top-line results from the six-month data for the BETTER SLEEP clinical trial. We are planning to submit the complete trial results to our E.U. Notified Body with the goal of expanding the CE-Marked indication to include OSA patients with CCC, which should eliminate the need for a DISE procedure. In December 2020, we implanted the first patient in the DREAM trial, which is designed to support marketing authorization in the United States.

- ***Significant product development and new indication pipeline***. The Genio system is a scalable-technology platform that allows for future external hardware, software and firmware updates to enhance therapeutic capabilities without requiring additional surgical procedures. We continue to invest in improving the Genio system to develop next generation products with features designed to improve patient comfort and compliance, efficacy and patient and market acceptance. Some of these improvements include features aimed at enhancing the physician's ability to monitor patient compliance and therapeutic efficacy, including sensor technology to monitor a patient's sleep position. We are also committed to expanding current treatment options for moderate to severe OSA patients by developing next generation neurostimulation-based technologies. In January 2021, we entered into a licensing agreement with Vanderbilt University pursuant to which we are exploring additional neurostimulation technologies. Under the agreement, we have an exclusive, world-wide 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 May 31, 2021, we had 186 granted or pending patent applications (with 53 issued or allowed U.S. patents), and 46 pending patent applications, eleven of which are U.S. pending patent applications and hold six trademark registrations (with three U.S. trademark registrations). Additionally, we operate a manufacturing facility responsible for silicone overmolding and select assembly of external components, which provides us with enhanced proprietary know-how and control of the supply chain to meet future demand.

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

Our Strategy

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

- ***Obtaining marketing authorization in the United States***. We are conducting clinical trials to further evaluate the efficacy and safety of the Genio system for treating patients with moderate to severe OSA. We are currently conducting the DREAM trial, a pivotal trial designed to support marketing authorization for the Genio system in the United States via either a premarket approval, or PMA, application or a De Novo request. The DREAM trial is a multicenter, prospective, open-label trial designed to enroll 134 patients in approximately 25 centers in the United States and internationally. The trial aims to evaluate the safety and effectiveness of the Genio system to treat patients with moderate to severe OSA who either did not tolerate, failed or refused first-line CPAP therapy. We anticipate initial 12-month data for the DREAM trial will be available by the fourth quarter of 2022. Assuming a positive outcome from the DREAM trial, we expect to apply for marketing authorization in the United States with the aim of being commercially available in the United States in the second half of 2023.

- ***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 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's 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. We are planning to submit the complete trial results to our E.U. Notified Body with the goal of expanding the CE-Marked indication to include OSA patients with CCC in Europe. Currently, these CCC patients are contraindicated for hypoglossal nerve stimulation OSA therapies. In addition, we may look for strategic opportunities, including partnerships or collaborations, to broaden our capabilities and expertise in line with our patient-centric vision.

- ***Pursuing and establishing favorable reimbursement coverage of the Genio system***. While there is general consensus among physicians and payors of the medical necessity to treat OSA and increase the number of hypoglossal nerve stimulation therapy coverage decisions, we continue to develop further clinical evidence intended to demonstrate a long-term meaningful improvement in health outcomes for patients meeting the specified criteria. We are initially targeting markets in Europe, Australia and New Zealand where we have identified a clear reimbursement pathway or execution strategy. In Germany, we have successfully obtained reimbursement under a dedicated DRG code for hypoglossal nerve stimulation, and, in Switzerland, we recently 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.

Market Overview

Overview of Obstructive Sleep Apnea

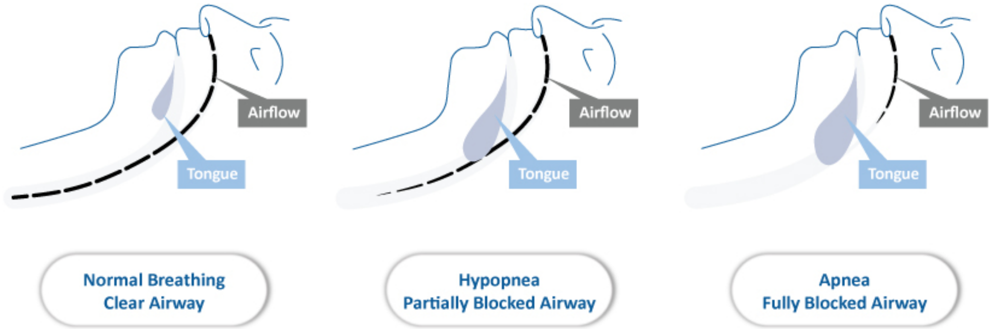
OSA is the most prevalent sleep disordered breathing condition. It is estimated that OSA currently affects approximately 936 million people globally between the ages of 30 and 69, of which approximately 425 million people suffer from moderate to severe OSA and require treatment. Every year, there are over 5.3 million new patients diagnosed with moderate to severe OSA, representing approximately 2.6 million in the United States and 2.7 million in our initial target markets in Europe, Australia and New Zealand.

OSA occurs due to the relaxation of the soft tissue, throat and tongue muscles in a patient’s airway causing 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 to sufficiently oxygenate the blood. During an obstruction, the patient’s oxygen level in the blood, or SpO2, drops, causing an increase of their Oxygen Desaturation Index, or ODI, leading to significant and repeated sleep interruptions. The lack of airflow can last anywhere from ten seconds to more than a minute and, in severe cases, may occur 30 or more times during an hour of sleep. When the airway becomes blocked, the brain detects a stress signal from various biological sources including the chest muscles, lungs and, at times, a drop in blood oxygen content that causes the individual to awaken unconsciously, just enough to tighten the airway muscles and allow normal breathing to resume. A hypopnea is a partially blocked airway; apnea is a fully blocked airway. While regular breathing is restored temporarily, the obstruction typically occurs again, which restarts the apnea cycle. This cycle of obstructions and waking can repeat dozens of times per hour throughout the night, disrupting the rapid eye movement and deep, restorative sleep that are critical to maintaining good health. The overall quality of a patient's sleep, health and quality of life are diminished.

The total number of apneas and hypopneas per hour of sleep is referred to as the Apnea-Hypopnea Index, or AHI. The severity of OSA is based on the following four AHI categories and corresponding events per hour:

Categories	AHI Range
Normal Range	<5 Events Per Hour
Mild OSA	5-14 Events Per Hour
Moderate OSA	15-30 Events Per Hour
Severe OSA	>30 Events Per Hour

The figure below illustrates the physiologic blockage experienced by patients with OSA.



Moderate to severe OSA patients require a dedicated therapy according to published guidelines by sleep doctors' scientific societies such as the American Academy of Sleep Medicine. If left untreated, OSA is associated with increased mortality risk and significant comorbidities, including cardiovascular diseases, depression and stroke.

Symptoms and Diagnosis of OSA

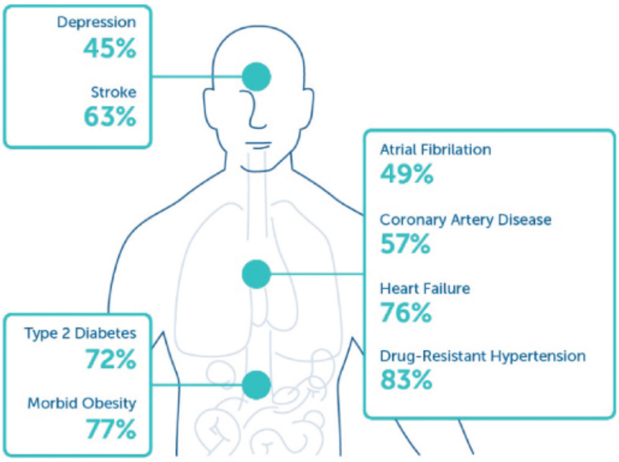
OSA is a serious and chronic sleep breathing disorder that negatively impacts a patient's sleep, health and quality of life. Due to the poor quality and lack of sleep, OSA patients often feel tired and fatigued during the day. They may find it difficult to concentrate and experience emotional stress, including depression. Patients struggling with OSA are typically unaware of their condition as OSA remains significantly underdiagnosed. While sleep apnea has traditionally been perceived as a lifestyle disease, with snoring and tiredness as the main implications, it is now known to be a major underlying risk factor and disease progression accelerator for most cardiovascular diseases and many cognitive and neurodegenerative diseases. Despite the increased availability of diagnostic technology, approximately 80% of people in the United States suffering from sleep apnea are undiagnosed. In recent years, increased awareness of the importance of sleep and the devastating potential consequences of sleep apnea have been on the rise in medical communities, and among patients and patient association groups.

Common first indicators of OSA are a patient's heavy snoring, excessive daytime sleepiness, headaches, depression, memory or concentration problems, nighttime gasping and dry mouth or sore throat. The impact of heavy snoring creates unrest for both the patient and the patient's bed partner and often drives the patient to obtain medical advice and potential diagnosis. Once a physician makes a preliminary diagnosis, the patient may undergo an in-lab sleep trial, or a home sleep apnea test, or HSAT, to obtain a clinically validated diagnosis of OSA. An in-lab sleep trial requires the patient to stay overnight at a sleep center, where nasal air tubes and sensors, electrodes and wires are attached to various parts of the body, including the head, chest and abdomen. The system of monitors and sensors measure the patient's airflow, sleep quality, blood oxygen levels and breathing patterns. More recently, sleep doctors and cardiologists have begun prescribing HSAT in lieu of an in-lab sleep trial to help diagnose OSA. HSATs are low-cost, self-administered portable devices that allow patients to be tested in the comfort of their own homes while, offering greater ease of use. Data is collected, downloaded and interpreted by a board-certified sleep physician. While an in-lab sleep trial is currently considered the standard of care for OSA diagnosis, we expect HSAT acceptance and utilization to continue to increase thereby reducing the percentage of undiagnosed OSA patients.

Comorbidities Associated with OSA

OSA may also be associated with severe medical comorbidities, including coronary artery disease, cardiac arrhythmias such as atrial fibrillation, heart failure, hypertension, obesity, stroke and Type 2 diabetes.

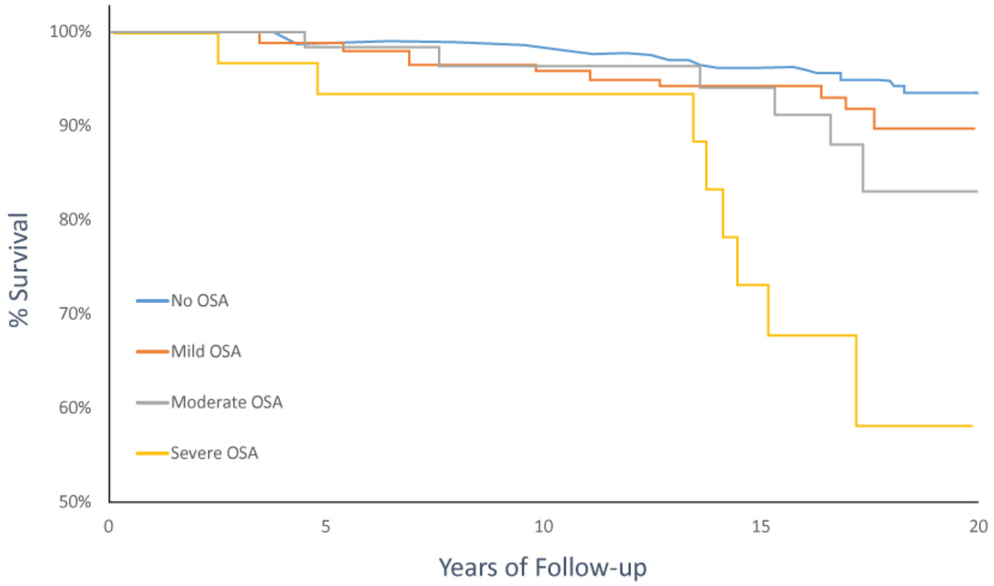
The following graphic summarizes the high prevalence of OSA in key chronic diseases.



Several peer-reviewed, published studies have shown that sleep apnea is a direct contributing factor to the incidence of various forms of cardiovascular disease. Cardiovascular disease is highly prevalent and, often, a severe and potentially fatal medical condition. There is increasing awareness among cardiologists and the general population of the importance of sleep apnea in the causation or promotion of hypertension, coronary artery disease, heart failure, atrial arrhythmias and strokes, and, consequently, a predictor of premature cardiovascular disease.

Published clinical literature, including an 18-year mortality follow-up trial at the University of Wisconsin, has demonstrated strong correlation between OSA and the risk of mortality. Based on the 1,522-person Wisconsin Sleep Cohort sample, participants with untreated moderate and severe OSA experienced a significant impact on mortality with survival rates of approximately 85% and 60%, respectively. Untreated OSA can be deadly, as untreated OSA patients have two times more risk of suffering stroke, two and a half times more risk of heart failure and five times more risk of cardiovascular mortality. Numerous studies have demonstrated the correlation between efficient OSA therapy and the reduction of mortality and comorbidities.

The chart below illustrates the significant impact on mortality and survival rates over time based on severity of OSA.



Economic Costs of Untreated OSA

The socio-economic burden of OSA stems from both direct and indirect health costs. According to a Harvard Medical School trial published in December 2010, the annual economic cost of unmanaged OSA was estimated to be $67 billion to $165 billion based on total direct healthcare costs, incremental healthcare costs from comorbidities, non-medical traffic accident-related costs due to increased fatigue, non-medical workplace accident-related costs, OSA-driven job absenteeism costs and other family-related and other societal costs. This amount is greater than the estimated annual economic cost in the United States of asthma, heart failure, stroke and hypertensive disease, each estimated at $20 to $80 billion annually.

The direct costs associated with OSA include the costs for diagnosis and treatment and associated medical conditions, several of which also result in impaired work productivity and road traffic accidents that give rise to indirect health costs. People with unmanaged OSA are about two to three times more likely to have a traffic accident. OSA is associated with an increase in the rate and severity of motor vehicle accidents, increased healthcare utilization, reduction of work performance and occupational injuries.

Existing Treatments for OSA

There are several treatment options available to OSA patients, including medical management, involving lifestyle changes such as weight loss, CPAP therapy, mandibular advancement devices, or MADs, surgical interventions, and advanced neuromodulation devices.

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 all night. CPAP has demonstrated efficacy in reducing AHI, as well as improving patient sleep quality and daytime sleepiness. Since its introduction in the 1980’s, CPAP therapy has been the first-line therapy for OSA patients of all severities. However, the efficacy of CPAP therapy is directly correlated to the number of hours of use per night and its long-term compliance.

Poor patient compliance and discomfort have been major factors in the efficacy of CPAP treatment. Patients often struggle with sustained regular use of the CPAP device due to mask discomfort, mask leakage, pressure intolerance, skin irritation, nasal congestion, nasal drying, nosebleeds, claustrophobia and lack of intimacy. In addition, the airway pressure can cause severe dryness in the nose and mouth, resulting in the sense of suffocation and nasal congestion. Medicare defines compliance as using a CPAP device at least four hours a night for 70% of nights during any consecutive 30-day period within the first three months of initial usage. CPAP non-compliance is estimated to be between 29% and 83%, and we estimate the CPAP non-compliance rate to be approximately 35%.

Oral Appliances — Mandibular Advancement Devices (MADs)

MADs are similar to orthodontic retainers and are intended to diminish restrictions that occur in the back of the throat by moving the jaw and tongue forward to increase the size of the upper airway and reduce the air resistance that leads to snoring. These devices are utilized nightly by patients. Due to their form factor, MADs have multiple limitations, including tooth and jaw pain, potential tooth displacement and recurrent dental follow-ups. According to published literature, MADs generally provide unpredictable therapy efficacy.

Surgery to Remove or Reposition Patient Tissue or Bone

For patients who have difficulties utilizing or complying with CPAP and MADs, invasive surgical procedures for the nose, throat or mandible, such as uvulopalatopharyngoplasty, or UPPP, and maxillomandibular advancement, or MMA, can be beneficial alternatives. Surgery is suggested to patients with specific anatomical conditions, but this is a highly invasive procedure that irreversibly alters the patient's anatomy, requires extended and painful recovery periods, and has only moderate efficacy. For example, MMA involves enlarging the airway by surgically moving the upper jaw (maxilla) and lower jaw (mandible) forward. The surgical procedure can last up to four or five hours and the patient can only return to work after four to five weeks. Therefore, surgical procedures are often considered as last resort options, due to their invasiveness, cost, the high incidence of side effects and varying responder rates, which are estimated to be between 30% and 60%.

Hypoglossal Nerve Stimulation, a Proven Strategy to Treat OSA

Over the last decade, technologies focused on the stimulation of the hypoglossal nerve have emerged as an alternative treatment option for moderate to severe OSA patients who refused, do not tolerate or are not compliant with conventional CPAP therapy. The hypoglossal nerve controls the tongue and airway muscles. By stimulating the hypoglossal nerve, these therapies trigger the contraction of the tongue muscles and thereby help maintain an open airway during sleep.

Inspire Medical Systems, Inc. is a publicly-traded medical technology company offering FDA-approved unilateral neurostimulation technology. Inspire Medical's STAR trial demonstrated at 12 months an approximately 70% reduction in AHI from a baseline of 29.3 events per hour to 9.0 events per hour at 12 months following initial treatment and a 66% responder rate, defined as the rate of patients that achieved a decrease in AHI of at least 50% and a residual AHI of less than 20 events per hour. Inspire Medical published its pivotal five-year STAR trial in 2018. At five years, the STAR trial reported a 75% responder rate, defined as the rate of patients that achieved a decrease in AHI of at least 50% and a residual AHI of less than 20 events per hour. At five years, median AHI in patients with moderate to severe OSA remained low at 6.2 events per hour.

Many countries, including the Netherlands, Germany and the United States, already recognize the benefits of hypoglossal nerve stimulation as a therapy for moderate to severe OSA and have provided requisite reimbursement for the therapy.

Limitations of Competing Hypoglossal Nerve Stimulation Devices

We are aware of two competing hypoglossal nerve stimulation devices for use in treating patients with OSA. The most widely-used hypoglossal nerve stimulation device is the Inspire system. The Inspire system consists of a remote control and three implantable components: a pressure sensing lead, which detects when the patient is attempting to breathe; a neurostimulator, which houses the electronics and battery power for the device; and a stimulation lead, which delivers electrical stimulation to one branch of the hypoglossal nerve. The other device is similar to the Inspire system, but its implantable pulse generator uses only one lead and contains a rechargeable battery.

While the benefits of hypoglossal nerve stimulation have been well-recognized, we believe competing hypoglossal nerve stimulation solutions suffer from several limitations, including:

- *Neurostimulator with internal battery*
  - Competing neurostimulation systems for the treatment of OSA rely on an implanted neurostimulator that includes an internal battery.
  - In most cases, the internal battery cannot be recharged and, once depleted, the neurostimulator must be replaced in a further surgical procedure. In some cases, the battery can be recharged by the patient, but will eventually become depleted and require surgery to be replaced. Additional procedures may result in an increased risk of infection at the incision site.
  - The neurostimulator has been designed to be large enough to accommodate the additional space necessary for the battery. As a result, the neurostimulator is positioned in a subcutaneous pocket, and the device may be palpable or visible in the chest area.
  - Given the design of the implanted neurostimulator used by competing systems, those systems have received 1.5T MRI clearance for head/neck and extremity scans only.
- *Multiple Implantable Components Requiring Multiple Surgical Incisions*
  - Competing systems require multiple parts to be implanted including leads and a cuff electrode;
  - Competing systems require multiple surgical incisions and subcutaneous lead tunneling including bringing a lead from the pulse generator to the neck and bringing a lead from the pulse generator to the respiratory system, which monitors breathing. These multiple steps during implantation lead to an average implantation procedure of approximately 2 hours, which, combined with additional incisions, can result in an increased risk of surgical infection.
- *Unilateral Stimulation*
  - Unilateral stimulation delivers stimulation to only one branch of the hypoglossal nerve, which limits options for nonresponding or contraindicated patients, including patients with CCC.

The Genio System Market Opportunity

Despite the availability of diagnostics and device-based and surgical treatments, the market for OSA therapy remains highly underpenetrated. OSA is the world’s most common sleep disordered breathing condition, occurring in up to 50% of the population and affecting approximately 936 million people between 30 and 69 years of age globally, of which an estimated 425 million suffer from moderate to severe OSA and require treatment. According to the 2019 Lancet Respiratory Medicine Journal, the estimated prevalence of moderate to severe OSA patients between 30 and 69 years of age in our targeted commercial markets is approximately 63 million people.

The figure below summarizes the prevalence of moderate to severe OSA patients among our targeted initial commercial markets.

ESTIMATED MODERATE TO SEVERE OSA PREVALENCE BY COUNTRY

	Population aged 30 – 69 years	Prevalence of moderate-to-severe OSA in 30 – 69Y old population	Percentage of moderate-to-severe OSA in 30 – 69Y old population
United States			
United States	163,246,772	23,678,109	14.50%
INITIAL TARGET MARKETS			
European Countries			
Germany	43,751,645	14,393,964	32.90%
Spain	26,158,266	4,233,728	16.20%
Netherlands	9,050,266	2,582,583	28.50%
Belgium	5,917,763	931,859	15.7%
Switzerland	4,518,615	1,654,232	36.60%
Australia and New Zealand			
Australia	12,110,362	581,348	4.8%
New Zealand	2,256,063	68,590	3.0%
Total Initial Target Markets			
Total	103,762,980	24,446,304	23.56%

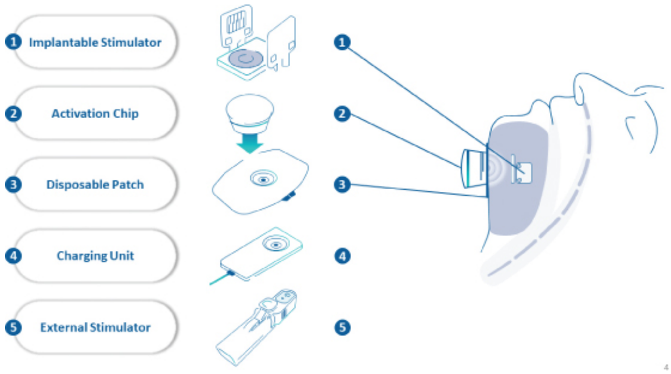
OSA therapy is a large and growing market. We believe there is a significant population in the United States with moderate to severe OSA who are unable to use or achieve the intended clinical benefit from CPAP and who would be eligible for the Genio system upon approval. Published scientific literature estimates that there are currently approximately 24.5 million individuals with moderate to severe OSA in our initial target markets in Europe, Australia and New Zealand. Based on published scientific literature, we estimate that approximately 2.7 million patients are diagnosed annually in those countries and that approximately 80% of diagnosed patients are prescribed a CPAP device. Published scientific literature reports non-compliance rates to CPAP between 29% and 83%. Based on these data, and for purposes of calculating the total addressable market in Europe, Australia and New Zealand for the Genio system, we estimate that approximately 35% of patients that are prescribed CPAP in those countries are not compliant with the therapy. Additionally, certain patients possesses anatomical characteristics, including higher body-mass index or increased tongue fat deposition that make them ineligible for hyperglossal nerve stimulation. Taking that into account, we estimate that approximately 70% of those non-compliant patients are eligible for hypoglossal nerve stimulation based on their anatomical characteristics. As a result, we believe the total addressable market in Europe, Australia and New Zealand for the Genio system is at least 520,000 patients, which represents an estimated annual market opportunity of approximately $11 billion based on our current pricing for the Genio system. We also plan to enter the United States market, assuming we obtain marketing authorization in the United States, where published scientific literature estimates 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.

Our Solution

We developed the Genio system to provide patients suffering from moderate to severe OSA with an alternative hypoglossal nerve stimulation systems 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.

Overview of the Genio system

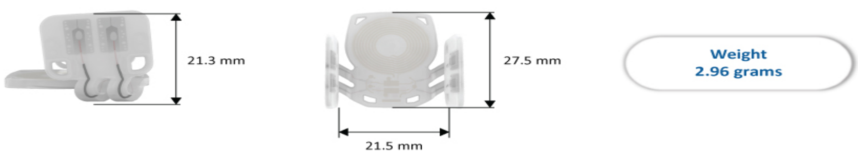
The Genio system is the first neurostimulation system for the treatment of OSA to include a battery-free and leadless neurostimulator capable of delivering bilateral hypoglossal nerve stimulation. The system includes a single implanted component that can be implanted in a minimally invasive procedure requiring only a single incision. We developed the system using a patient-centric approach to offer patients a convenient alternative designed to overcome the limitations of competing neurostimulation devices. The figure below depicts the key components of the Genio system and the relative location of the system.



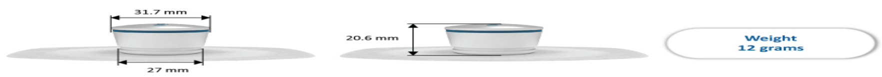
Components of the Genio system

- *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 add 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.

Genio Implantable Stimulator



Genio Activation Chip



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 from our BLAST OSA trial demonstrated safety and effectiveness data of the Genio system for patients suffering with moderate to severe OSA that was 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 course of the trial.
  - *Compelling clinical data*. Clinical data suggest that the Genio system is a clinically effective therapy for patients eligible for hypoglossal nerve stimulation treatment. The BLAST OSA trial found a 47.3% reduction in mean individual AHI (p-value<0.0001) and a decrease in mean individual ODI of 43.3% (p-value<0.0001) at six months following implantation, compared to their baseline measurements, for patients using the Genio system. In statistics, a p-value is a number calculated from a statistical test. It provides the probability that a null hypothesis (*e.g.*, there is no treatment effect) is true for the particular set of observations being tested. The smaller the p-value (typically p-value < 0.05), the stronger the evidence that the null hypothesis should be rejected in favor of an alternative hypothesis (*e.g.*, there is a treatment effect greater than a given threshold). A p-value less than 0.05 is said to be statistically significant. It indicates strong evidence against the null hypothesis, as there is less than a 5% probability that the null hypothesis is correct.
  - *Convenient therapy leading to strong compliance*. Our device is designed to be convenient for patients to use, once implanted and optimized, requiring no additional programming or therapy titration. The BLAST OSA data reported that 91% of patients used the system more than five nights per week over a period of six months following implantation.
  - *Improved quality of life.* Results from the BLAST OSA trial demonstrated that patients' quality of life significantly improved as assessed using the FOSQ-10 questionnaire, with an increase in mean score by 1.9 units (p-value=0.0157) and a decrease on the Epsworth Sleepiness Scale, or ESS, score, by a mean of 3.3 units (p-value=0.0113). Additionally, the number of sleep partners who reported that their partner did not snore, or snored only softly, increased from 4.2% at baseline to 65%.
- *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 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 hypoglossal neurostimulation 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 systems'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.

Treating patients with the Genio system

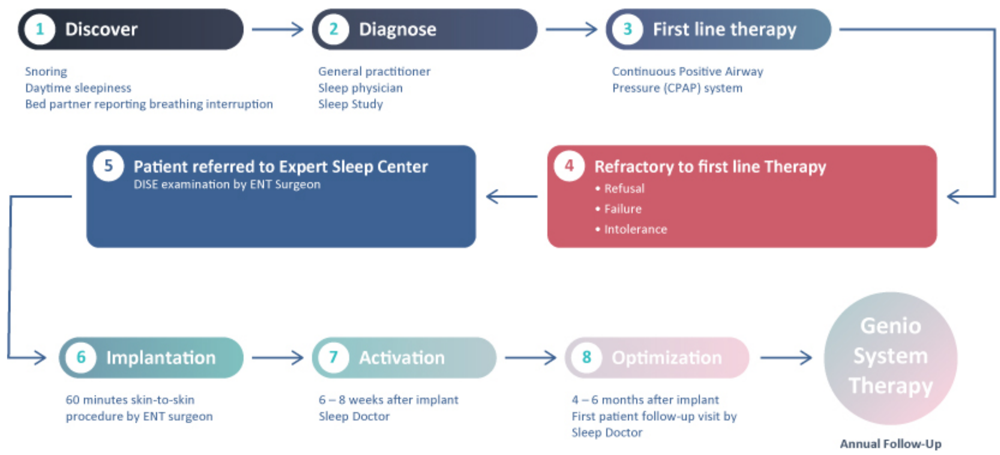
Patient selection

Under CE-Mark approval, the Genio system is indicated for adult patients suffering from moderate to severe OSA with an AHI equal to or exceeding 15, but not exceeding 65. 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: CCC, 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 hypoglossal nerve stimulation. Their physician may refer them to undergo a DISE procedure to confirm they do not exhibit CCC. CCC currently affects approximately 30% of existing OSA patients, for whom existing hypoglossal nerve stimulation OSA therapies are either contraindicated or unavailable.

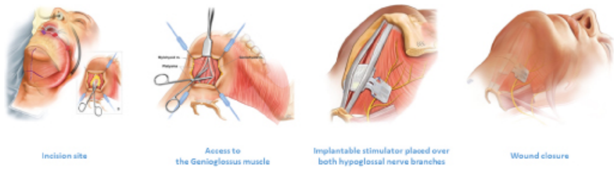
The figure below depicts a common pathway for patients eligible for the Genio system.



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 that exposes the genioglossus muscle and the left and right hypoglossal nerve branches. 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 fixation of 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.

The following figure depicts the Genio system's implantation.

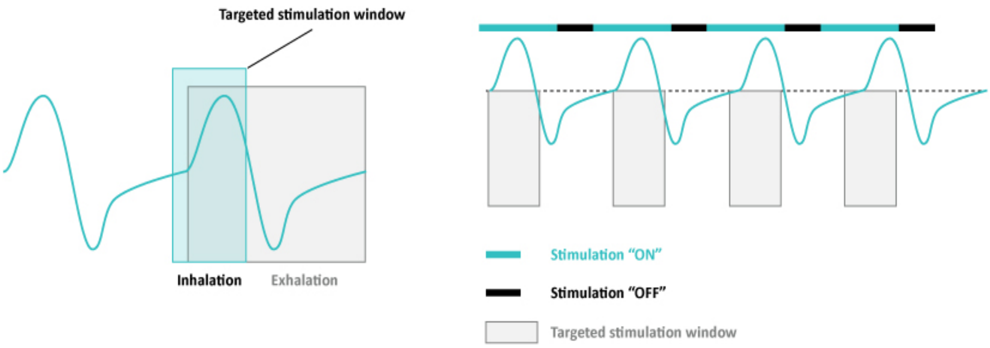


Therapy activation and optimization

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 patient's 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. The goal of physician is to achieve a therapy setting that keeps 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.

Clinical Results and Studies

Clinical Development Pathway

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.

Below is an illustration of our existing marketing authorizations and our anticipated regulatory pathway.

Study	Objective	Enrollment	Detail	Status
BLAST OSA	CE mark approval	27 patients	▪ 2 publications ▪ CE Mark in 2019	COMPLETED & PUBLISHED EUROPEAN RESPIRATORY *journal* Investigative Otolaryngology
ELiSA	Demonstrate long-term safety and efficacy	110 patients	▪ 20 centers in 5 countries ▪ 5-year follow-up	ONGOING
BETTER SLEEP	Expand Genio® therapeutic indications	42 patients	▪ 9 ANZ centers ▪ CCC ~30% OSA patients	ONGOING ▪ *Complete Enrollment Nov. 2020* ▪ *First CCC case study published*
DREAM	FDA approval	134 patients	▪ FDA approved IDE pivotal study in June ▪ Up to 25 US sites	ONGOING ▪ *First patient Nov. 2020* ▪ *First US patient Dec. 2020*

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 are eligible to enroll in the long-term follow-up phase of the trial. The majority of the participants are currently four years post-implantation.

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 ($p\text{-value}<0.0001$). 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.

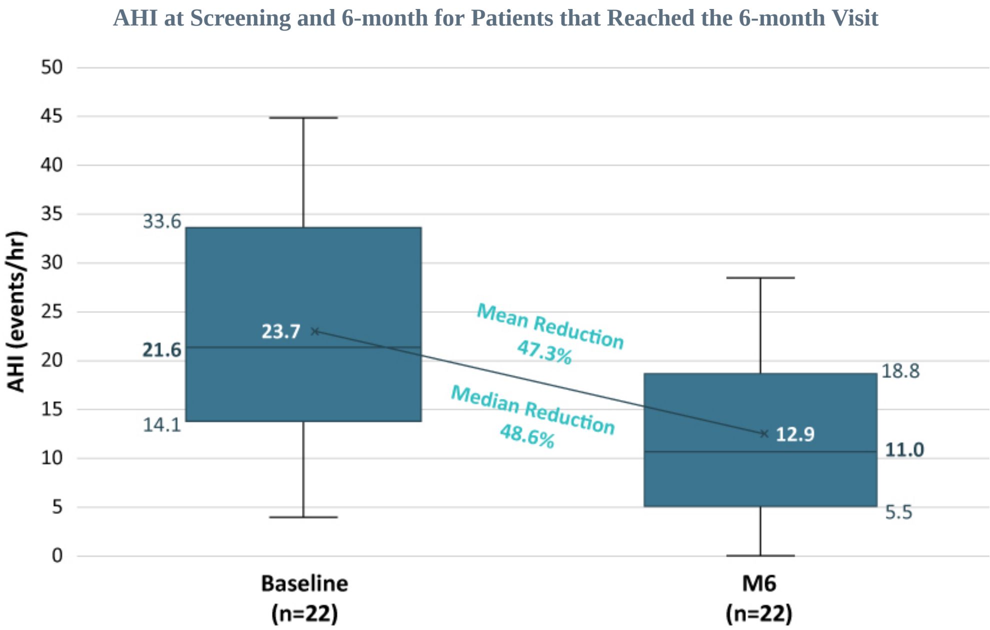
Safety Results

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 ($p\text{-value}<0.0001$).



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% 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.

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 of the soft palate 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 hypoglossal nerve stimulation.

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). The primary safety endpoint was the incidence of device-related SAEs six months post-implantation. The primary performance endpoint was the change in the AHI score from baseline to six months post-implantation measured by counting the number of events (apnea or hypopnea) that occur per hour collected during an overnight sleep study. Patients with moderate to severe AHI scores (15 < AHI < 65) and aged between 21 and 75 years were eligible for enrollment if they failed, refused or did not tolerate PAP treatment. Patients with a body mass index above 32 kg/m^2 were excluded. The trial has been authorized by the Australian and New Zealand regulatory authorities and is being conducted in nine local medical centers.

In June 2021, we announced the following preliminary top-line results from the BETTER SLEEP trial:

- a statistically significant mean reduction in the AHI score from baseline to six months post-implantation in the full-analysis patient population (both CCC and non-CCC patients);
- a statistically significant mean reduction in AHI from baseline to six months post-implantation in the CCC patient subgroup; and
- a statistically significant mean reduction in AHI from baseline to six months post-implantation in the non-CCC patient subgroup.

The results above reflect data from the full analysis patient population (40 patients total, with 17 CCC patients), which excludes two patients who did not complete a six-month visit.

With respect to the primary safety endpoint, preliminary unadjudicated safety data showed four SAEs in three patients during the six-month post-implantation period. Of those, two SAEs in one patient were reported as device related, one SAE in one patient was reported as procedure and device related, and one SAE in one patient was reported as unrelated to procedure or device. Final review and adjudication of SAEs and 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.

While additional data, including responder rates, remains subject to ongoing review and continues to be analyzed, we observed in the per protocol group (35 patients) a 70% responder rate in the non-CCC patient subgroup based on the Sher criteria.

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.

We intend to use the clinical evidence from the subgroup of patients who exhibit CCC to support a potential indication expansion of the Genio system. Specifically, we are planning to submit the complete trial results to our E.U. Notified Body with the goal of expanding the CE-Marked indication to include CCC.

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.

Pivotal DREAM Trial

In June 2020, the FDA approved our IDE application, allowing us to commence our pivotal DREAM trial of the Genio system. Our DREAM trial is a multicenter, prospective, open-label trial during 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 Genio 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 hypoglossal nerve stimulation for the treatment of moderate to severe OSA. The trial will enroll 134 patients who will undergo the implantation procedure with 12-month effectiveness and safety primary endpoints. We have identified 25 centers including up to 18 in the United States, which are enrolling patients and some of which have commenced implantation of the Genio device.

The primary safety endpoint is incidence of device-related SAEs at 12-months post implantation. One of the co-primary effectiveness endpoints is the percentage of responders with at least a 50% reduction in AHI with hypopneas associated with a 4% oxyhemoglobin desaturation and a remaining AHI with hypopneas associated with a 4% oxyhemoglobin desaturation less than 20, together with a 25% reduction of ODI between baseline and 12-month visits. Patients with moderate to severe OSA (AHI score between 15 and 65) and aged between 22 and 75 years are eligible for enrollment if they failed, did not tolerate or refused PAP treatment. Patients with a body mass index above 32 kg/m^2, a CCC observed during a drug induced sleep endoscopy and combined central and mixed AHI above 25 at baseline polysomnography are to be excluded.

We anticipate initial 12-month data will be available by the fourth quarter of 2022. No SAEs have been reported to date.

Sales and Marketing

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. We are initially targeting markets in Europe, Australia and New Zealand where we have identified a clear reimbursement pathway or execution strategy. In Germany, we have successfully obtained reimbursement under a dedicated DRG code for hypoglossal nerve stimulation, 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, with support provided by our corporate team. We expect to begin marketing in Switzerland and in Spain 2021.

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, 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, targeted KOL development and training and direct-to-consumer marketing. 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 hypoglossal nerve stimulation 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.

Research and Development

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

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

Competition

The industry in which we operate is subject to rapid change and is highly sensitive to the introduction of new products and technologies of current or new industry participants. Our primary focus of OSA treatment is as a second line therapy for patients with moderate to severe OSA. If we are not successful in convincing others of the merits of our products or educating them on the use of our products, they may not use our products or use them effectively and we may be unable to increase our sales.

We consider our primary competition to be other device-based neurostimulation therapies designed to treat patients with moderate to severe OSA. Outside the United States, in addition to Inspire, we also are aware of the LivaNova's ImThera device which received CE-Mark approval to market an open-loop neurostimulation device in Europe. In the United States, the Inspire system is the only FDA-approved closed-loop neurostimulation device for moderate to severe OSA. We believe other emerging businesses are in the early stages of developing neurostimulation devices.

We also compete with invasive surgical treatment options such as UPPP, MMA and, to a lesser extent, MADs, which are primarily used in the treatment of mild to moderate OSA. We do not believe we directly compete with CPAP or other types of positive airway pressure devices because CPAP is typically a first line therapy for patients with OSA.

We believe that the primary competitive factors in the OSA treatment market are:

- product safety, reliability and durability;
- company and brand recognition;
- ease of implantation and procedure time;
- quality of clinical data;
- adoption by patients, physicians and sleep centers;
- adequate reimbursement for our device;
- procedure costs to patients;
- product ease of use and patient comfort;
- sales force expansion, experience and access;

- product availability, support and service;
- manufacturing and supply chain;
- technological innovation and product enhancements; and
- intellectual property portfolio.

In addition, our competitors may have greater financial resources or more established distribution networks than we do, or may be acquired by enterprises that have more established distribution networks than we do. Our competitors may also develop and patent processes or products earlier than we can or obtain domestic or international regulatory clearances or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar products. We also compete with our competitors in acquiring technologies and technology licenses complementary to our products or advantageous to our business. We also compete with other medical technology companies to recruit and retain qualified sales, training and other personnel.

Manufacturing and Supply

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

We work with third parties to manufacture and supply the components of the implantable stimulator and external stimulator. The initial assembly of the different electronics components is done by different external suppliers. The final assembly of the external stimulator and the final manufacturing step of the implantable stimulator, the silicone molding, are done internally by our manufacturing team in the clean room at our facility in Tel Aviv, Israel. The capacity of our facility in Tel Aviv is expected to cover our expected product demand for 2021. We are finalizing our plan to establish a manufacturing facility in Liège, Belgium that is expected to provide us with additional capacity for the assembly of implantable stimulators and external stimulators as we progress our commercialization plans.

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

Collaboration and License Agreements

Cochlear Collaboration Agreement

We and Cochlear Limited, or Cochlear, have entered into a collaboration agreement, dated November 2018, under which we and Cochlear agree to collaborate to further develop and progress commercialization of implantable treatments for sleep disordered breathing conditions. Cochlear has significant expertise in the development of implantable devices. The specific contributions and services to be used, applied and provided by both parties are further detailed in a document called "*Statement of Work*" that may be agreed upon by the parties from time to time. The initial Statement of Work was agreed upon by us and Cochlear on November 7, 2018 and is now complete. According to this Statement of Work, Cochlear evaluated various packaging technologies and to support us in the assessment of encapsulation technologies for the implantable stimulator. A new Statement of Work was entered into on June 8, 2020. Under this agreement, Cochlear is working with us in developing and enhancing the next generation implantable stimulator, and we expect to spend approximately €4.3 million on these efforts, of which €1.3 million was paid in June 2020. Upon completion of the remaining milestones, we will have to make milestone payments of €1.4 million, €1.1 million and €0.5 million in June 2021, January 2022 and August 2022, respectively.

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

There are currently no IP licenses granted by Cochlear or by us to the other party.

Man & Science Agreement

We, Man & Science SA, Cephalix SA, Glucobel SA and Surgical Electronics SA, among others, have entered into a multiparty agreement regarding their respective ownership and licensing rights in relation to multiple inventions, including but not limited to inventions generally related to implantable, flexible neurostimulators and inventions for specific medical indications including sleep disordered breathing, head pain, glucose monitoring, hypertension and other indications. This agreement provides that (i) we fully own all rights in relation to the inventions specifically related to the sleep disordered breathing field, which we believe includes sleep disordered breathing conditions such as sleep apnea and snoring, and comorbidities of these conditions and (ii) Man & Science SA is the owner of the generic inventions and granted a fully paid-up, exclusive and worldwide, license with respect to these inventions to several parties, including us in the field of sleep disordered breathing. Pursuant to the terms of the agreement, no party may terminate the licenses.

In June 2016, we, Cephalix SA, Surgical Electronics SA, and Man & Science SA entered into a confirmatory addendum, aiming to confirm that (i) we fully own all rights in relation to the inventions specifically related to the sleep disordered breathing field as further detailed in the agreement, (ii) Man & Science SA granted an exclusive, worldwide, fully paid-up, royalty free and transferable license to us covering certain patents in the sleep disordered breathing field, and (iii) we granted an exclusive, fully paid-up, royalty free, transferable license to use certain of those patents outside the sleep disordered breathing field, namely to Cephalix SA in the head pain field, Surgical Electronics SA in the hypertension field and Man & Science SA outside the head pain field and the hypertension field.

In February 2020, we entered into a clarification of the Confirmatory Addendum, or Clarification, with Man & Science SA. The Clarification confirms that the license granted to us by Man & Science SA under the agreement and the Addendum are irrevocable, transferable, fully paid up, royalty-free and include the right to grant sublicenses in the sleep disordered breathing field, which are retroactive as from the filing date of the oldest of the patents and patent applications and will continue in effect until the last to expire patent, which is expected to occur in 2032 (excluding any potential patent term extension). We have no current or future financial obligation to Man & Science SA pursuant to the agreement. See "Business — Intellectual Property" for more information.

Intellectual Property

Our intellectual property and the rights underlying the same are valuable and important in the medical device and health tech industry in which we operate. Our success depends, in part, on our ability to obtain and maintain intellectual property protection for our product candidates, to defend and enforce our intellectual property rights, to preserve the confidentiality of our know-how and proprietary information, and to operate without infringing upon the proprietary rights of others. We seek to protect our products and product candidates by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We rely heavily on our patent and design portfolio to maintain competitive technological advantage, as well as on our trademarks that support our brand identity.

We have implemented an intellectual property protection policy with the objective of obtaining protection for key aspects of the technology embodied in the Genio system and certain methods of use.

We may, from time to time, file patent applications for inventions that may be of importance to our future business. We may license or acquire rights to patents, patent applications, or other intellectual property owned by third parties, academic partners or commercial companies which are of interest to us. Further, we may decide, from time to time, to license our intellectual property to other parties, for example, in exchange for cash, marketing collaboration, or other valuable consideration to us.

We continuously review our development activities to assess the novelty and patentability of new intellectual property being developed. In addition to patents, we also rely on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements and other contractual provisions and technical measures that help us maintain and develop our competitive position with respect to intellectual property. Despite our efforts to protect our intellectual property rights, third parties might invalidate, engineer around these or challenge our rights in court or patent offices.

Our policy is that our employees and contractors execute a propriety information and inventions assignment agreement, which protects proprietary information and which assigns to us all inventions created by an employee during the term of employment. Where possible and appropriate, agreements with third parties (e.g. consultants and vendors) contain language designed to protect our intellectual property and confidential information, and to assign to us new inventions related to our business.

As of May 31, 2021, we have 186 granted or pending patent applications (both utility and design) comprised of 53 issued or allowed U.S. patents, 10 pending U.S. non-provisional applications, 1 pending U.S. provisional applications, 2 pending international patent applications filed under the Patent Cooperation Treaty, or PCT, and 33 pending patent applications and 87 granted patents in jurisdictions outside the United States, including Australia, Canada, China, Europe, Hong Kong, Israel and Japan. The exclusivity terms of our patents depend upon the laws of the countries in which they are obtained. In the countries in which we currently file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. Current issued patents and patent applications covering our Genio system will expire on dates ranging from 2032 to 2034, if the applications are issued.

In addition to the patent portfolio owned by us, we hold exclusive licenses granting us a fully paid-up, transferrable and sub-licensable, worldwide, irrevocable license and royalty free in the field of sleep disordered breathing in relation to multiple inventions, including but not limited to inventions generally related to implantable flexible neuro-stimulators. Such licenses were granted to us by Man & Science SA (a company held and governed by Robert Taub, TOGETHER Partnership, Jürgen Hambrecht and Noshaq SA). We also hold an exclusive worldwide license from Vanderbilt University, to develop, use, grant sublicense and commercialize products, with a different mechanism of action than the Genio system, in the field of sleep disordered breathing conditions and comorbidities of such conditions. We will also work together with Vanderbilt University to continue prosecution of patent applications made by Vanderbilt. Under the agreement, we paid to Vanderbilt an upfront license issue fee of approximately $650,000. We may be required to make minimum annual royalty payments to Vanderbilt of up to $250,000 in 2024 and 2025, up to $500,000 in 2026 and 2027, and up to $1,000,000 in 2028 and each year thereafter, which are creditable against the earned royalties owed to Vanderbilt for the same calendar year. Additionally, Vanderbilt may be entitled to milestone payments of up to an aggregate of $13,750,000 in connection with patent issuance, clinical studies, regulatory approvals and net sales milestones. We may also be required to pay Vanderbilt a low to mid double digit percentage, not to exceed 40%, of any non-royalty sublicensing revenue we receive. The Vanderbilt Agreement, including the royalty obligations thereunder, will continue on a licensed product-by-licensed product and country-by-country basis until the expiration date of the last-to expire licensed patent in each country. Either we or Vanderbilt may terminate the Vanderbilt Agreement in connection with the other party’s insolvency. Vanderbilt may also terminate the Vanderbilt Agreement in the event we fail to make a payment to Vanderbilt, breach or default our diligence obligations or breach or default on any other material term, and if we fail to make such payment or cure such breach or default within 60 days of written notice from Vanderbilt. We may terminate the agreement by providing 120 days’ advance notice to Vanderbilt.

With respect to trademarks, we use our corporate name, Nyxoah, and associated logo as well as the tagline, in creating awareness of our expertise and in marketing our Genio system technology. We use the trademark Genio to identify our Genio system. We have obtained registration for the Nyxoah name and the Genio trademark in seven jurisdictions around the globe.

Government Regulation

Governmental authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, certification, authorization, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of medical device products. As a medical device manufacturer, our operations are subject to such laws and regulations in the jurisdictions in which we or our research and development partners or affiliates do business.

The processes for obtaining marketing approvals in the United States and in other countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations, as well as policies and rules established by regulatory authorities, require the expenditure of substantial time and financial resources. In addition, the laws and regulations governing our business and interpretations of those laws and regulations and are subject to frequent change, and we must, therefore, devote significant resources to monitoring developments in legislation, enforcement, and regulation in such areas. Our ability to operate profitably will depend in part upon our ability, and that of our research and development partners and affiliates, to operate in compliance with applicable laws and regulations. As the applicable laws and regulations change, we are likely to make conforming modifications in our business processes from time to time. We cannot provide assurance that a review of our business by courts or regulatory authorities will not result in determinations that could adversely affect our operations or that the regulatory environment will not change in a way that restricts our operations.

Regulatory Landscape in the European Union

The European Union, or EU, has adopted specific directives regulating the design, manufacture, clinical investigations, conformity assessment, labeling and adverse event reporting for medical devices. EU directives must be implemented into the national laws of the EU member states and national laws may vary from one member state to another. The EU rules listed below are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet EU requirements.

In the EU, there is currently no premarket government review of medical devices. However, the EU requires that all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Council Directive 93/42/EEC, or the Medical Devices Directive and the Council Directive 90/385/EEC, or the AIMD Directive. AIMDs are defined as medical devices that rely on a source of electrical energy or any source of power other than that generated by the body, which are totally or partially introduced, either surgically or medically, into the human body and intended to remain after the procedure.

An overarching requirement under both the AIMD Directive and the Medical Devices Directive is that any device must be 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. In addition, the device must meet the performance specifications intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in the AIMD Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product, and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a Notified Body. Under this situation, manufacturers of medical devices must make an application to a Notified Body. Alternatively, manufacturers can seek approval from the Notified Body that a representative sample device satisfies the requirements set out in the AIMD

Directive and subsequently ensure and declare that all of its products conform to the standard of the approved sample. Notified Bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A Notified Body would typically audit and examine a product’s technical dossiers and the manufacturers’ quality system (which must, in particular, comply with ISO 13485:2016 related to Medical Devices Quality Management Systems). If satisfied that the AIMD or other medical device conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE-Mark to the device, allowing the device to be legally marketed throughout the EU, indicating that the device conforms to the essential requirements of the applicable directives and may be commercially distributed throughout the EU.

Notified Body certificates of conformity are valid for a fixed duration (which shall not exceed five years). Throughout the term of the certificate, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the Notified Body before it will renew the relevant certificate(s).

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. In order to demonstrate safety and effectiveness for their AIMDs and other medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive and Annex 7 to the AIMD Directive, as well as standards (if any) which may be imposed by national authorities of EU member states in addition to those set out in Annex X to the Medical Devices Directive and Annex 7 to the AIMD Directive. Clinical investigations for medical devices usually require the approval of an ethics committees and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

Once the product has been placed on the market in the EU, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the product. In particular, all manufacturers placing medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, incidents must be reported to the relevant authorities of the EU member states, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

The advertising and promotion of medical devices is subject to some general principles set forth by EU directives. According to the Medical Devices Directive, only devices that are CE-Marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at national level. EU member states laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

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), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

In 2017, European Union regulatory bodies finalized a new Medical Device Regulation, or MDR, which repeals and replaces the existing Medical Devices Directive and AIMD Directive and provided three years for transition and compliance, for a final effective date of May 26, 2020. As a result of the COVID-19 pandemic, however, the European Parliament voted in April 2020 to postpone the implementation of the MDR by one year, until May 26, 2021, assuming no additional delays are needed. The MDR changes several aspects of the existing regulatory framework for medical device marketing in Europe and is expected to result in increased regulatory oversight of all medical devices marketed in the EU, which may, in turn, increase the costs, time and requirements that need to be met in order to place an innovative or high-risk medical device on the European market. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers’ responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union, or EU; and
- strengthen the rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

We obtained the CE-Mark for the Genio system under the AIMD Directive in March 2019. DEKRA Certification B.V., a Notified Body designated for regulatory review of medical devices and their manufacturers under applicable EU regulations, conducted the assessment of the technical dossiers and the manufacturers’ quality system for the Genio system and issued the certificate of conformity for the device. In addition, our manufacturing facility is certified as compliant with ISO 13584:2016.

Although, the MDR will become effective in May 2021, the CE-Mark on the current Genio system design, obtained in March 2019, is valid until March 2024. The recertification process under the MDR requires a demonstration that the performance and the safety of the currently approved medical device has been maintained and that the system meets the new regulatory requirements and standards under the MDR. Further clinical studies will not be required to obtain the recertification for the Genio system under the MDR. We have conducted an in-depth MDR gap analysis and are currently working towards an MDR-compliant Quality Management System.”

In addition, we are registered as a legal manufacturer in Belgium under the AIMD Directive. We also invest significant efforts to maintain compliance with the most updated and harmonized consensus standards, as well as with local and international regulatory requirements.

United Kingdom Regulatory Framework and Operational Impacts Post-Brexit

The United Kingdom left the European Union on January 31, 2020 (commonly referred to as “Brexit”), with a transitional period that expired on December 31, 2020. The United Kingdom and the European Union entered into a trade agreement known as the Trade and Cooperation Agreement, or TCA, which came into effect on January 1, 2021. The TCA does not specifically refer to medical devices. However, as a result of Brexit, the MDR will not be implemented in the UK, and previous legislation that mirrored the MDR in the UK law has been revoked. The regulatory regime for medical devices in the UK will continue to be based on the requirements derived from current EU legislation, and the UK may choose to retain regulatory flexibility or align with the MDR going forward. CE-Markings will continue to be recognized in the UK, and certificates issued by EU recognized Notified Bodies will be valid in the UK, until June 30, 2023. For medical devices placed on the UK market after this period, the UK Conformity

Assessment, or UKCA, marking will be mandatory. In contrast, UKCA marking and certificates issued by UK Notified Bodies will not be recognized on the EU market. The TCA does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the “rules of origin” criteria will need to be reviewed. Depending on which countries products will ultimately be sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in the UK. It remains to be seen how, the UK rules will impact regulatory requirements for our product candidates and our product in the United Kingdom. We are currently evaluating the potential impacts on our business of the new Trade and Cooperation Agreement.

Such outcomes could make it more difficult and expensive for us to do business in Europe, complicate our clinical, manufacturing and regulatory strategies and impair our ability to obtain and maintain regulatory approval for, and, if approved, commercialize, our products and product candidates in Europe.

Regulatory Landscape in the United States

Medical devices are strictly regulated by the Food and Drug Administration, or FDA, in the United States. Under the Federal Food, Drug, and Cosmetic Act, or FDCA, a medical device is defined as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.” This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of a medical product is achieved through chemical action or by being metabolized by the body, the product is usually a drug or biologic. If not, it is generally a medical device.

The Genio system is regulated by FDA as a medical device under the FDCA, as implemented and enforced by the FDA. The FDA regulates the development, testing, manufacturing, labeling, packaging, storage, installation, servicing, advertising, promotion, marketing, distribution, import, export, and market surveillance of our medical devices. The Genio system is not yet approved or cleared for marketing in the United States.

Device Premarket Regulatory Requirements

Before being introduced into the U.S. market, each medical device must obtain marketing authorization or approval from FDA through the premarket notification, or 510(k), process, the *de novo* classification process or the premarket approval, or PMA, process, unless they are determined to be Class I devices or to otherwise qualify for an exemption from one of these available forms of premarket review and authorization by the FDA. Under the FDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device. Class I devices are those for which reasonable assurance of safety and effectiveness can be maintained through adherence to general controls that include compliance with the applicable portions of the FDA’s Quality System Regulation, or QSR, as well as regulations requiring facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. The Class I designation also applies to devices for which there is insufficient information to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but that are not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and that do not present a potential, unreasonable risk of illness of injury.

Class II devices are those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish "special controls." These special controls can include performance standards, post-market surveillance requirements, patient registries and FDA guidance documents describing device-specific special controls. While most Class I devices are exempt from the premarket notification requirement, most Class II devices require a premarket notification prior to commercialization in the United States; however, the FDA has the authority to exempt Class II devices from the premarket notification requirement under certain circumstances. As a result, manufacturers of most Class II devices must submit premarket notifications to the FDA under Section 510(k) of the FDCA (21 U.S.C. § 360(k)) in order to obtain the necessary authorization to market or commercially distribute such devices. To obtain 510(k) clearance, manufacturers must submit to the FDA adequate information demonstrating that the proposed device is "substantially equivalent" to a "predicate device" that is already on the market. A predicate device is a legally marketed device that is not subject to PMA, meaning, (i) a device that was legally marketed prior to May 28, 1976 ("preamendments device") and for which a PMA is not required, (ii) a device that has been reclassified from Class III to Class II or I, or (iii) a device that was found substantially equivalent through the 510(k) process. If the FDA agrees that the device is substantially equivalent to the predicate device identified by the applicant in a premarket notification submission, the agency will grant 510(k) clearance for the new device, permitting the applicant to commercialize the device. Premarket notifications are subject to user fees, unless a specific exemption applies.

After a medical device receives 510(k) clearance, any modification that could significantly affect the device's safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) submission or could require a PMA. The FDA requires each manufacturer to make the determination of whether a device modification requires a new 510(k) or PMA in the first instance, but the FDA may review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA for a particular change, the FDA may retroactively require the manufacturer to submit a 510(k) or PMA application. The FDA may also require the manufacturer to cease its marketing activities for the modified device in the United States and/or recall the device until the appropriate marketing authorization for the modification is obtained.

If there is no adequate predicate to which a manufacturer can compare its proposed device, the proposed device is automatically classified as a Class III device. In such cases, a device manufacturer must then fulfill the more rigorous PMA requirements or can request a risk-based classification determination for its device in accordance with the *de novo* classification process.

Devices that are intended to be life sustaining or life supporting, devices that are implantable, devices that present a potential unreasonable risk of harm or are of substantial importance in preventing impairment of health, and devices that are not substantially equivalent to a predicate device and for which safety and effectiveness cannot be assured solely by the general controls and special controls are placed in Class III. Such devices generally require FDA approval through the PMA process, unless the device is a preamendments device not yet subject to a regulation requiring premarket approval. The PMA process is more demanding than the 510(k) process. For a PMA, the manufacturer must demonstrate through extensive data, including data from preclinical studies and one or more clinical studies, that the device is safe and effective for its proposed indication. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA submission, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review and determine whether the proposed device can be approved for commercialization, although in practice, PMA reviews often takes significantly longer, and it can take up to several years for the FDA to issue a final decision. Before approving a PMA, the FDA generally also performs an on-site inspection of manufacturing facilities for the product to ensure compliance with the QSR.

If an FDA evaluation of a PMA application or manufacturing facility is favorable, the FDA may issue an approval order authorizing commercial marketing of the device, or an "approvable letter," which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been met to the satisfaction of the FDA, the agency will issue a PMA approval order, subject to the conditions of approval and the limitations established in the approval order. If the

FDA's evaluation of a PMA application or manufacturing facility is not favorable, the FDA will deny approval of the PMA or issue a "not approvable letter." The FDA may also determine that additional studies are necessary, in which case the PMA approval may be delayed for several months or years while such additional studies are conducted and data is submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy. PMA approval may also be granted with post-approval requirements such as the need for additional patient follow-up or requirements to conduct additional clinical trials.

New PMA applications or PMA supplements may be required for any modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplements are limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive clinical data or the convening of an advisory panel.

The *de novo* classification process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its device to Class I or Class II, on the basis that the device presents low or moderate risk, as an alternative to following the typical Class III device pathway requiring the submission and approval of a PMA application. Under the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, the FDA is required to classify a device within 120 days following receipt of the *de novo* classification request from an applicant; however, the process may take significantly longer. For example, the most recent FDA user fee goals state that in fiscal year 2021, FDA will attempt to issue a decision within 150 days of receipt on 65% of all *de novo* classification requests received during the year and on 70% of *de novo* requests received during fiscal year 2022. If the manufacturer seeks reclassification into Class II, the classification request must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. If FDA grants the *de novo* request, the device may be legally marketed in the United States. However, the FDA may reject the classification request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) notification or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. *De novo* classification requests are subject to user fees, unless a specific exemption applies.

Device Clinical Studies

Clinical studies are almost always required to support PMAs and are sometimes required to support 510(k) and *de novo* classification submissions. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's good clinical practice, or GCP, regulations, including the investigational device exemption, or IDE, regulations that govern investigational device labeling, prohibit promotion of investigational devices, and specify recordkeeping, reporting and monitoring responsibilities of trial sponsors and trial investigators. If the device presents a "significant risk," as defined by the FDA, the agency requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical studies. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a patient. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA denies the application or notifies us that the investigation is on hold and may not begin until the sponsor provides supplemental information about the investigation that satisfies the agency's concerns. If the FDA determines that there are deficiencies or other concerns with an IDE that require modification of the trial, the FDA may permit a clinical trial to proceed under a conditional approval. In addition, the trial must be approved by, and conducted under the oversight of, an institutional review board, or IRB, for each clinical site. If the device presents a non-significant risk to the patient according to criteria established by FDA as part of the IDE regulations, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate authorization from the FDA, but must still comply with abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

As part of its clinical trial oversight responsibilities, an IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical studies, including details of the protocol and eventually trial results, also must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the ClinicalStudies.gov data registry. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical studies after completion. Disclosure of the results of these studies can be delayed in some cases for up to two years after the date of completion of the trial.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and more frequently if serious adverse events, or SAEs, occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the clinical protocol, cGCP, or other IRB requirements or if the investigational product has been associated with unexpected serious harm to patients.

Post-Marketing Restrictions and Enforcement

After a device is cleared or approved for marketing by the FDA, numerous medical device regulatory requirements continue to apply, such as:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for uncleared or unapproved or "off -label" uses and impose other restrictions on labeling;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post -market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- periodic scheduled or unscheduled inspections by the FDA to assess compliance, which could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products.

The medical device reporting requirements also extend to health care facilities that use medical devices in providing care to patients, or "device user facilities," which include hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities, but not physician offices. A device user facility must report any device-related death to both the FDA and the device manufacturer, or any device-related serious injury to the manufacturer (or, if the manufacturer is unknown, to the FDA) within 10 days of the event. Device user facilities are not required to report device malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur but may voluntarily report such malfunctions through MedWatch, the FDA's Safety Information and Adverse Event Reporting Program.

The FDA also has the authority to require the recall of commercialized medical device products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any distributed devices fail to meet established specifications, are otherwise misbranded or adulterated under the FDCA, or if any other material deficiency is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated.

The failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance, PMA approvals, or other marketing authorization to new products;
- withdrawals of marketing authorizations; or
- in the most serious cases, criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors. Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shutdown of, or restrictions on, manufacturing operations and the recall or seizure of marketed products.

Breakthrough Device Designation

The 21st Century Cures Act, which was signed into law on December 13, 2016, established and directed FDA to implement the Breakthrough Devices Program. Under the program, device manufacturers may voluntarily request breakthrough designation for devices that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions over currently available technology and that meet at least one of the following criteria:

- the device represents breakthrough technology;
- there are no approved or cleared alternatives for the device;
- the device offers significant advantages over existing approved or cleared alternatives; or
- availability of the device is in the best interest of patients.

The goal of the Breakthrough Devices Program is to expedite the development and prioritize the review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. A Breakthrough Device designation offers multiple benefits to the device manufacturer, including prioritized review of the pre-market submission for the device, opportunities to interact directly with FDA's experts throughout the process, and engagement of FDA senior management.

Federal Trade Commission Regulatory Oversight

Our advertising for our products is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission, or FTC, as well as comparable state consumer protection laws. Under the Federal Trade Commission Act ("FTC Act"), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution.

Federal Communications Commission Regulation

The Genio system includes a wireless radio frequency transmitter and receiver and, therefore, is subject to equipment authorization requirements in the United States. The Federal Communications Commission, or FCC, requires advance clearance of all radio frequency devices before they can be imported into, sold or marketed in the United States. These clearances ensure that the proposed products comply with FCC radio frequency emission and power level standards and will not cause interference.

Healthcare Law and Regulation

If the Genio system is approved in the United States, we will have to comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws, false claims laws and price transparency reporting laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. These laws include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent in order to violate it;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Physician Payments Sunshine Act require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Department of Health and Human Services information related to payments and other transfers of value to physicians, teaching

hospitals, and, beginning in 2022 for payments and transfers of value made in the previous year, certain advanced non-physician health care practitioners, as well as physician ownership and investment interests; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers.

Some state laws require medical device companies to comply with the relevant industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring device manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. We also may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Violation of any of the federal and state healthcare laws may result in penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of operations. Our actual or perceived failure to comply with healthcare and data privacy laws could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base and thereby decrease our future revenues.

Coverage and Reimbursement

Sales of the Genio system and any product candidates, if approved, will depend, in part, on the extent to which the procedures using the Genio system and any product candidates are covered by third-party payors, such as government healthcare programs, commercial insurance and managed healthcare organizations. Third-party payors are increasingly limiting coverage and reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, and restrictions on coverage and reimbursement. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical devices and medical services, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net sales and results.

Moreover, the process for determining whether a third-party payor will provide coverage for a product or procedure may be separate from the process for establishing the reimbursement rate that such a payor will pay for the product or procedure. A payor's decision to provide coverage for a product or procedure does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product or procedure does not assure that other payors will also provide coverage. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to ensure profitability.

Healthcare Reform

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the ACA was signed into law and substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year which has been suspended from May 1, 2020 through March 31, 2021, and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny, including increasing legislative and enforcement interest, over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. Individual states in the United States have also become increasingly active in implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Data Privacy and Security

Data privacy and security is governed by both European and national legislation.

At the European Union level, data protection is regulated by Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 (General Data Protection Regulation, “GDPR”) and — specifically with respect to electronic communication — by the Directive 2002/58/EC of the European Parliament and of the Council of July 12, 2002 (Directive on Privacy and Electronic Communications, “e-privacy Directive”)).

Since European Union regulation supersedes congruent national data privacy laws, the GDPR is binding in its entirety and directly applicable in each member state. It was primarily intended to harmonize data protection law in the European Union, to improve data protection enforcement and to strengthen the internal market. Nevertheless, the GDPR contains a number of opening clauses that allow EU member states to create specific national laws relating to individual data processing activities or requirements, such as the protection of employee data. Accordingly, EU member states have enacted national implementation acts which accompany the GDPR.

Under the GDPR, the regulatory requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on a lawful basis. Personal data may only be collected and processed in a manner consistent with those purposes. Personal data must also be adequate, relevant and limited to what is necessary in relation to the purposes for which it is processed. It must be processed in a manner that ensures transparency to the data subject (i.e., an identified or identifiable natural person to whom the personal data relates). The GDPR stipulates strict requirements regarding the processing of special categories of personal data (such as data concerning health, genetic and biometric information), on the duties to prepare documentation and to furnish proof of compliance with the requirements of the GDPR. The rights of data subjects have been strengthened and include, among others, a right to require information about their data being processed, the right to “data portability” as well as the right to restrict certain processing of their data as well as a “right to be forgotten” pursuant to which data subjects may require that their data is to be deleted when there is a problem with the underlying legality of the processing or where they withdraw their consent. The GDPR also provides restrictive requirements as regards automated decision making and profiling activities, which could impact marketing activities based on such processing of data.

Among other requirements, the GDPR regulates the transfer of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. Recent legal developments in Europe have created complexity and uncertainty regarding such transfers. For instance, on July 16, 2020, (so-called Schrems II decision, C-311/18) the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the European Union to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism and alternative to the Privacy Shield), it made clear that reliance on such clauses for personal data transfers from the European Union to so-called third countries (i.e. countries outside the European Economic Area), such as the United States or Russia alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, including, in particular, applicable surveillance laws and rights of individuals, and additional measures and/or contractual provisions may need to be put in place; however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and that the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer.

In addition, the GDPR requires us to implement appropriate technical and organizational measures to ensure a level of security appropriate to the organization’s processing requirements and risk. Accordingly, certain cyber security requirements must be fulfilled to ensure that data is processed and stored safely. Organizations must notify the relevant supervisory authority about data breaches within 72 hours and in some instances, provide notification to data subjects. The GDPR provides for substantial fines of up to 4% of the total worldwide group turnover of the preceding fiscal year or up to €20 million (whichever is higher), considerable civil claims for material and immaterial damages (e.g., for infringements of privacy rights) and a general burden of proof for companies. Individual EU member state implementation laws such as the BDSG also provide criminal sanctions for specific violations.

Privacy regulations, like the GDPR, concerning the use of web analysis are particularly relevant to our online platform. Web analysis technologies (e.g., processing of cookies or tracking records such as through Google Analytics) process personal data in order to enable the operator of a website to personalize its offers and marketing to better match the client’s interests. Most web analysis tools anonymize or pseudonymize collected data, but the use of such tools is nonetheless regulated by data privacy laws. For example, the use of cookies is regulated by the Directive 2002/58/EC on Privacy and Electronic Communications, or the ePrivacy Directive, that provides for an opt-in regime pursuant to which the use of technically non-necessary cookies and comparable tracking technologies requires an informed consent of the enduser of a device.

Currently, the Directive is being reviewed by the European Commission in order to, among other things, ensure consistency with the GDPR. On February 10, 2021 the EU member states agreed on a negotiating mandate regarding the draft proposal for a Regulation on Privacy and Electronic Communications, or the ePrivacy Regulation, which will replace the ePrivacy Directive. The Council and the European Parliament will negotiate the terms of the final text of the ePrivacy Regulation and, as soon as enacted, the ePrivacy Regulation could lead to stricter requirements and could further impact our online platform. The ePrivacy Regulation is expected to be enacted in the course of the year 2021. Furthermore, based on its data strategy, the European Union plans to comprehensively revise the legal framework for the handling of data, for example through the proposed Digital Markets Act and the Digital Services Act

Data Privacy and Security Laws in Belgium

In Belgium, the legislator adopted secondary legislation following the GDPR. Notably, the Act of July 30, 2018 on the Protection of Natural Persons with regard to the Processing of Personal Data, or the Data Protection Act, which addresses various national substantive aspects of the GDPR and introduces several specifications and derogations. The Data Protection Act stipulates 13 years old as the age from which children may provide consent for the use of an information service. This is lower than the age of 16 set by the GDPR. Furthermore, the Data Protection Act imposes additional security measures in relation to sensitive data. An entity processing genetic data, biometric data, data concerning health or data related to criminal convictions and offences must maintain a list of the categories of persons who have access to that data, together with a description of their function related to processing such data. When requested, the list must be disclosed to the competent supervisory authority.

The ePrivacy Directive regulates, among other things, the processing of traffic and location data, unsolicited commercial communications and online targeting of consumers by storing information on the equipment of end-users (e.g. cookies). These requirements have been implemented in Belgium in the Act of June 13, 2005 on Electronic Communications, or the Electronic Communications Act. As regards cookies, Article 129 of the Electronic Communications Act follows the wording of the ePrivacy Directive closely. As a result, Article 129 of the Electronic Communication Act requires prior informed consent and does not allow for the user's consent to be expressed by usage of the appropriate settings of a browser or other application. Furthermore, consumer data may be stored and processed only as long as this is necessary for the provision of services to that consumer.

Data Privacy and Security Laws in the United States

Medical device companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the U.S. Department of Health and Human Services, or HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, or PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Personally identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation.

FCPA and Other Anti-Bribery and Anti-Corruption Laws.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act of 1977, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act (or FCPA); the UK Bribery Act 2010 (the "Bribery Act"); and other anti-corruption laws that apply in countries where we do business. The FCPA, the Bribery Act, and these other laws generally prohibit Nyxoah and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, a financial or other advantage to government officials or other persons to induce them to improperly perform a relevant function or activity (or reward them for such behavior).

In general, the FCPA prohibits offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business for or with, or in order to direct business to, any person. The prohibitions apply not only to payments made to "any foreign official," but also those made to "any foreign political party or official thereof,” to “any candidate for foreign political office” or to any person, while knowing that all or a portion of the payment will be offered, given, or promised to anyone in any of the foregoing categories. “Foreign officials” under the FCPA include officers or employees of a department, agency, or instrumentality of a foreign government. The term “instrumentality” is broad and can include state-owned or state-controlled entities.

Importantly, United States authorities that enforce the FCPA, including the Department of Justice, deem most health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be “foreign officials” under the FCPA. When we interact with foreign health care professionals and researchers in testing and marketing our products abroad, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals such as those needed to initiate clinical studies in foreign jurisdictions.

The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and the development and maintenance of an adequate system of internal accounting controls for international operations. The SEC is involved with the books and records provisions of the FCPA.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the EU, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations.

Employees and Human Capital Resources

As of March 31, 2021, we employed 78.5 full-time equivalents (including employees and consultants), of which 21.2 were based in Belgium, 40.3 were based in Israel, 5 were based in Australia and 12 were based in the United States. None of our employees are represented by labor unions or covered by company specific bargaining agreements.

We believe that one of our key strengths is our employee base, which has extensive know-how across research, manufacturing, quality-control, engineering software programming and marketing and sales. We also believe that developing a diverse, equitable and inclusive culture is critical to continuing to attract and retain the top talent necessary for our long-term success and strategy. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce, including the expansion of individuals with diverse backgrounds in leadership.

Our principles of accountability, honesty, integrity and customer-focused, serve as our cultural pillars. We focus our efforts on creating a collaborative environment where our colleagues feel respected and valued. We provide our employees with competitive compensation, opportunities for equity ownership and a robust employment package, including health care, disability and long-term planning insurance, retirement planning and paid time off. In addition, we regularly interact with our employees to gauge employee satisfaction and identify areas of focus.

Legal Proceedings

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Facilities

We operate out of a leased site in Mont-Saint-Guibert, Belgium, which consists of 570 square meters of office space and is our corporate headquarters and home to our commercial, therapy development and marketing, and clinical activities. The lease for the site in Mont-Saint-Guibert, Belgium expires on September 30, 2025.

We operate out of a leased site in Milmort, Belgium, which consists of 210 square meters of office space and is home to our manufacturing activities. The lease for the site in Milmort, Belgium expires on January 22, 2023 for the manufacturing space and on January 1, 2024 for the office area. The contract may be renewed for three additional years. We can terminate the contract at any time with a notice period of six months.

Nyxoah Ltd operates out of a leased site in Tel Aviv, Israel, which consists of 1,099 square meters of office space and 50 square meters of additional storage space and is home to our research and development and manufacturing activities. The lease for the site in Tel Aviv, Israel expires on September 30, 2022 and may be renewed for two additional years. The landlord may only reject the exercise of the lease extension by us if the landlord plans to pull down the building to construct a new one. The landlord must provide us notice of the decision not to extend the lease 120 days prior to the end of the lease period or prior to the planned demolition, whichever is earlier.

Nyxoah Pty Ltd operates out of a business center in Melbourne, Australia. The services agreement with the business center in Melbourne, Australia expires on August 16, 2021 or can be terminated by either party by giving 30-calendar days prior notice.

MANAGEMENT

Our Board of Directors

The following table sets forth certain information relating to our board of directors as of May 31, 2021.

Name	Age	Position(s)
Robert Taub	74	Non-Executive Director (Chairman of the Board of Directors)
Janke Dittmer, Ph.D.	44	Non-Executive Director
Kevin Rakin	60	Non-Executive Director
Donald Deyo	61	Non-Executive Director
Pierre Gianello, M.D.	64	Non-Executive Director
Jan Janssen	56	Non-Executive Director
Jürgen Hambrecht, Ph.D.	74	Non-Executive Director
Olivier Taelman	50	Executive Director (Chief Executive Officer)

Unless otherwise stated, the address for our directors is Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium. The term of each of our directors ends at the annual meeting of our shareholders held during the year ended December 31, 2024.

The following is the biographical information of the members of our board of 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, a human plasma protein company, from 1983 to 1995. He also founded and managed Omrix Biopharmaceuticals 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 Monsanto, Baxter Travenol Laboratories and the Revlon Health Care Group. Mr. Taub holds an MBA at INSEAD. Currently, Robert is the Chairman of a TSX listed company Aya Gold and Silver.

Janke Dittmer, Ph.D. has served as a non-executive director since June 2016. Dr. Dittmer is a General Partner at Gilde Healthcare, a transatlantic healthcare fund based in Utrecht, the Netherlands and Cambridge, Massachusetts. He has led several investments in medtech, diagnostics and digital health companies. Prior to joining Gilde, he was a Venture General Manager and Head of Business Development & Strategy within Philips' Corporate Venturing unit in Healthcare. He also served as an Engagement Manager at McKinsey. He earned a Ph.D. in Physics from the University of Cambridge and was a post-doc in nanotechnology at the University of California, Berkeley. Dr. Dittmer has informed us that, effective upon and contingent on the closing of the offering, he will resign from his position as a non-executive director.

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. Mr. Rakin also serves as chief executive officer and chairman of the board of HighCape Capital Acquisition Corp. He served as the president of Shire Regenerative Medicine from June 2011 to November 2012. Mr. Rakin was the chairman and chief executive officer of Advanced BioHealing from 2007 until its acquisition by Shire in 2011. Before that, he served as an executive-in-residence at Canaan Partners, a venture capital firm. Until its merger with Clinical Data in 2005, Mr. Rakin was the co-founder, president and chief executive officer of Genaissance Pharmaceuticals, Inc., a pharmacogenomics company. He is currently on the boards of a number of private companies as well as Aziyo Biologics, Inc. (chairman) and Oramed Pharmaceuticals, Inc. Mr. Rakin received an MBA from Columbia University and a B.Com. (Hons) from the University of Cape Town, South Africa.

Donald Deyo has served as a non-executive director since June 2016. Mr. Deyo is the Chairman and CEO of LindaCare NV, or LindaCare, a company that specializes in developing and providing advanced remote digital health solutions for chronic disease. Prior to LindaCare, Mr. Deyo served as CEO and Board

Member for FemPulse Corporation, a company focused on developing bioelectronic medicine (neuromodulation) therapies for women's health concerns, and as CEO and Board Member of Medallion Therapeutic, Inc. Prior to that, he spent 30 years at Medtronic, Inc., or Medtronic, a medical device company, where he served in various executive leadership roles, including Vice President of Research & Development for Neuromodulation, Vice President of Product Development & Technology for Cardiac Rhythm Management and Vice President and General Manager for Medtronic Paceart. He also founded the executive consultancy MedTech Execs, which provides strategic and operational services to medical device and pharmaceutical companies through a global network of experienced executives. Mr. Deyo serves on the Board of Directors for LindaCare NV, where he is Chairman of the Board. He has previously served on the boards of TROD Medical and Sapiens (acquired by Medtronic). Mr. Deyo holds a B.Sc. in Computer Engineering from Iowa State University and an MBA from University of St. Thomas.

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

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

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, a German company, in various responsibilities around the world for almost 45 years, lastly as Chairman of the Supervisory Board from 2014 until 2020. Dr. Hambrecht is Chairman of the Supervisory Board of Trumpf GmbH & Co. KG and a member of the Supervisory Boards of Daimler AG and Daimler Truck AG as well as of Aya Gold & Silver Inc. He earned his doctorate in Chemistry from the University of Tubingen, Germany.

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, a U.S. Med Tech 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 Autonomic, Mr. Taelman was Business Director Neuromodulation at Nevro, 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, 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.

Director Independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have a board of directors comprised of a majority of independent directors, except that our audit committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that, under current listing requirements and rules of Nasdaq and taking into account any applicable committee independence standards, , and are "independent directors." In making such determination, our board of directors considered the relationships that each non-executive director has with us and all other facts and circumstances our board of directors deemed relevant in determining each director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

Under Belgian law, a director will only qualify as an independent director if he or she meets at least the criteria set out in provision 3.5 of the Belgian Code on Corporate Governance, 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 20 September 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 20 September 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 20 September 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.

Role of the Board in Risk Oversight

Our board of directors is responsible for the oversight of our risk management activities and has delegated to the audit committee the responsibility to assist our board in this task. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Powers, Responsibilities and Functioning of the Board of Directors

We have a “one tier” governance structure whereby our board of directors is the ultimate decision making body, with the overall responsibility for the management and control of our company, and is authorized to carry out all actions that are considered necessary or useful to achieve our company’s purpose. Our board of directors has all powers except for those reserved to the general shareholders’ meeting by law or our articles of association. Our board of directors acts as a collegiate body.

Our board of directors has the power to appoint and remove the chief executive officer. The role of the chief executive officer is to implement the mission, strategy and targets set by the board of directors and to assume responsibility our the day-to-day management. The chief executive officer reports directly to the board of directors.

Pursuant to the Belgian CCA, and our articles of association, the board of directors must consist of at least three directors. Our 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 Belgian Code on Corporate Governance, 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 Belgian Code on Corporate Governance. By January 1, 2026, at least one third of the members of the board of directors must be women.

Our directors are elected by our 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 nomination 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 elects a chairperson from among its members on the basis of his or her knowledge, skills, experience and mediation strength. The chairperson is responsible for the leadership and the proper and efficient functioning of the board of directors. As of the date of this prospectus, Mr. Taub is chairperson of the board of directors and Mr. Taelman is the chief executive officer. If the board of directors envisages appointing a former chief executive officer as chairperson, it will carefully consider the positive and negative aspects of such a decision and disclose why such appointment is in our best interest.

The board of directors meets as frequently as our interests require, or at the request of one or more directors. In principle, the board of directors will meet sufficiently regularly. 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.

Committees of our Board of Directors

Our board of directors is assisted by a number of committees in relation to specific matters. The committees advise the board of directors on these matters, but the decision making remains with the board of directors as a whole.

Our 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 Belgian Code on Corporate Governance), (b) the remuneration committee (in accordance with article 7:100 of the Belgian CCA and provisions 4.17 and following of the Belgian Code on Corporate Governance), (c) the nomination committee (in accordance with provisions 4.19 and following of the Belgian Code on Corporate Governance) and (d) the science & technology committee. The terms of reference of these board committees are primarily set out in the Corporate Governance Charter.

Audit Committee

As of the date of this prospectus, our audit committee consists of three directors: Kevin Rakin (Chairman), Donald Deyo and Jürgen Hambrecht.

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 Belgian Code on Corporate Governance. Our board of directors has determined that all three members of our audit committee are independent under Rule 10A-3 of the Exchange Act and the applicable listing standards of Nasdaq and all three members of our audit committee are independent under the applicable rules of the Belgian Code on Corporate Governance.

The members of the audit committee must have a collective competence in our business activities, 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, including qualifying as an “audit committee financial expert” as defined under the Exchange Act. Our board of directors has determined that the members of the audit committee satisfy the competency requirement, and our board of directors has further determined that Kevin Rakin qualifies as an “audit committee financial expert” as defined under the Exchange Act.

The audit committee will be governed by a charter that complies with Nasdaq listing rules and the Belgian Code on Corporate Governance. The role of the audit committee is to:

- inform our 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 our internal control and risk management systems, and our 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. 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 our board of directors on the selection, appointment and remuneration of our statutory auditor in accordance with article 16 §2 of Regulation (EU) No 537/2014.

The audit committee has at least four regularly scheduled meetings each year. The audit committee regularly reports to our board of directors on the exercise of its missions, and at least when the board of directors approves the financial statements and the condensed or short form financial information that will be published. The members of the audit committee have full access to the executive management and to any other employee to whom they may require access in order to carry out their responsibilities.

Without prejudice to the statutory provisions which determine that the statutory auditor must address reports or warnings to our corporate bodies, the statutory auditor must discuss, at the request of the statutory auditor, or at the request of the audit committee or of our board of directors, with the audit committee or with the board of directors, essential issues which are brought to light in the exercise of the statutory audit of the financial statements, which are included in the additional statement to the audit committee, as well as any meaningful shortcomings discovered in our internal financial control system.

Remuneration Committee

As of the date of this prospectus, our remuneration committee consists of three directors: Robert Taub (Chairman), Donald Deyo and Jürgen Hambrecht.

In line with the Belgian CCA and the Belgian Code on Corporate Governance (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 our board of directors or another non-executive director appointed by the committee. Our board of directors has determined that two members of our remuneration committee are independent under the applicable listing standards of Nasdaq and two members of our remuneration committee are independent under the applicable rules of the Belgian Code on Corporate Governance.

Pursuant to the Belgian CCA, the remuneration committee must have the necessary expertise in terms of remuneration policy. Our board of directors has determined that the members of the remuneration committee satisfy this requirement.

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.

Pursuant to the Belgian CCA, the chief executive officer participates in the meetings of the remuneration committee in an advisory capacity each time the remuneration of another member of the executive management is being discussed.

Nomination Committee

As of the date of this prospectus, our nomination committee consists of three directors: Robert Taub (Chairman), Donald Deyo and Jürgen Hambrecht.

In line with the Belgian Code on Corporate Governance (i) the nomination committee consists of a majority of independent directors and (iii) the nomination committee is chaired by the chairperson of our board of directors or another non-executive director appointed by the committee. Our board of directors has determined that two members of our nomination committee are independent under the applicable standards of Nasdaq and two members of our nomination committee are independent under the applicable rules of the Belgian Code on Corporate Governance.

The role of the nomination committee is to:

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

Science & Technology Committee

As of the date of this prospectus, our science & technology committee consists of four directors: Donald Deyo (Chairman), Jan Janssen and Pierre Gianello.

The role of science & technology committee is to assist our board of directors in all matters relating to:

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

Our Executive Management

The following table sets forth certain information relating to our executive management as of February 28, 2021.

Name	Age	Position(s)
Olivier Taelman	50	Chief Executive Officer and Executive Director
Fabian Suarez Gonzalez[(1)]	47	Chief Financial Officer

(1) Acting via ActuaRisk Consulting SRL.

Unless otherwise stated, the address for our executive management is Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

The following is the biographical information of those members of our executive management who do not also serve on our board of directors:

Fabian Suarez Gonzalez, acting via ActuaRisk Consulting SRL, has served as our Chief Financial Officer since 2014. He oversees the finance department and is responsible for infrastructure, IT, human resources and payroll, and other administrative operations. From 2005 to 2014, Mr. Gonzalez held senior roles in several private equity firms, mainly in the renewable energy sector. For five years he was CFO of TTR Energy, an investment vehicle, which managed, in collaboration with Degroof Petercam, several private equity funds. Prior to TTR Energy, he served as a consultant for major financial conglomerates in matters related to risk and asset management. He holds a double MSc. in Physics and Actuarial Sciences and an MBA from Solvay Brussels School of Economics and Management.

Family Relationships

There are no family relationships among any of the members of our executive management or our board of directors.

Corporate Governance Code

We adopted a corporate governance charter that is in line with the Belgian Code on Corporate Governance. The corporate governance charter describes the main aspects of the corporate governance of our company, including our governance structure, the terms of reference of our board of directors and its committees and other important topics. The corporate governance charter must be read together with our articles of association.

The Belgian Code on Corporate Governance is based on a “comply or explain” system: Belgian listed companies are expected to follow the Belgian Code on Corporate Governance, but can deviate from specific provisions and guidelines (though not the principles) provided they disclose the justification for such deviations. We apply the ten corporate governance principles contained in the Belgian Code on Corporate Governance and comply with the corporate governance provisions set forth in the Belgian Code on Corporate Governance, except in relation to the following:

- In deviation of provision 4.14 of the Belgian Code on Corporate Governance, no independent internal audit function has been established. This deviation is explained by our size. Our 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.
- We do not exclude awarding share-based incentives to the non-executive directors. This is contrary to provision 7.6 of the Belgian Code on Corporate Governance that provides that no stock options should be granted to non-executive board members. We believe that this provision of the Belgian Code on Corporate Governance is not appropriate and adapted to take into account the realities of companies in the biotech and life sciences industry that are still in a development phase. Notably, the ability to remunerate non-executive directors with share options allows us to limit the portion of remuneration in cash that we would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. We are of the opinion that granting non-executive directors the opportunity to be remunerated in part in share-based incentives rather than all in cash enables the non-executive directors to link their effective remuneration to our performance and to strengthen the alignment of their interests with the interests of our shareholders. This is in our interest and the interest of our stakeholders. Furthermore, this is customary for directors active in companies in the life sciences industry. In any event, we intend that the portion of the remuneration payable in share options will be limited and shall ensure, in accordance with provision 7.6 of the Belgian Code on Corporate Governance, that non-executive members of our board of directors shall receive part of their remuneration in the form of our shares, it being understood that these shares should be held until at least one year after the non-executive board member leaves the board and at least three years after the moment of award.
- In deviation of provision 7.6 of the Belgian Code on Corporate Governance, the non-executive members of our board of directors do not receive part of their remuneration in the form of shares. This deviation is explained by the fact that the interests of the non-executive members of our board of directors are currently considered to be sufficiently oriented to the creation of long-term value for our company, also considering the fact that some of the non-executive members of our board of directors already hold shares and some of them already hold warrants under our outstanding stock-based incentive plans, the value of which is based on the value of the shares. Therefore, payment in shares is not deemed necessary.
- Pursuant to article 7:91 of the Belgian CCA and provisions 7.6 and 7.11 of the Belgian Code on Corporate Governance, shares should not vest and share options should not be exercisable within three years as of their granting. Our board of directors has been explicitly authorized in our articles of association to deviate from this rule in connection with stock-based incentive plans, compensations, awards and issuances to our employees, directors and service providers and/or our subsidiaries (from time to time). We are of the opinion that this allows for more flexibility when structuring share-based awards. For example, it is customary for share incentive plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.
- In deviation of provision 7.9 of the Belgian Code on Corporate Governance, no minimum threshold of shares to be held by members of our executive management team is set. This deviation is explained by the fact that the interests of the members of the executive management team are currently considered to be sufficiently oriented to the creation of long-term value for our company, also considering the fact that some of them already hold shares and some of them already hold warrants under our outstanding stock-based incentive plans, 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.

What constitutes good corporate governance will evolve with the changing circumstances of a company and with the standards of corporate governance globally, and must be tailored to meet those changing circumstances. Our board of directors intends to update the corporate governance charter as often as required to reflect changes to our corporate governance.

Our articles of association and the corporate governance charter are available on our website (www.nyxoah.com) and can be obtained free of charge at our registered office. Information contained on our website does not constitute part of this prospectus.

Differences between Our Corporate Governance Practices and the Listing Rules of the Nasdaq Stock Market

The listing rules of the Nasdaq Stock Market include certain accommodations in the corporate governance requirements that allow foreign private issuers, to follow “home country” corporate governance practices in lieu of the otherwise applicable corporate governance standards of the Nasdaq Stock Market. The application of such exceptions requires that we disclose each noncompliance with the Nasdaq Stock Market listing rules that we do not follow and describe the Belgian corporate governance practices we do follow in lieu of the relevant Nasdaq Stock Market corporate governance standard.

We intend to continue to follow Belgian corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Stock Market in respect of the following:

- Quorum at Shareholder Meetings. Nasdaq Stock Market Listing Rule 5620(c) requires that for any meeting of shareholders, the quorum must be no less than 33.33% of the outstanding ordinary shares. There is no general quorum requirement under Belgian law for ordinary meetings of shareholders, except in relation to decisions regarding certain matters. See “Description of Share Capital and Articles of Association — Description of the Rights and Benefits Attached to Our Shares — Right to Attend and Vote at Our Meetings of Shareholders — Quorum and Majority Requirements”.
- Compensation Committee. Nasdaq Stock Market Listing Rule 5605(d)(2) requires that compensation of officers must be determined by, or recommended to, the board of directors for determination, either by a majority of the independent directors, or a compensation committee comprised solely of independent directors. Nasdaq Stock Market Listing Rule 5605(e) requires that director nominees be selected, or recommended for selection, either by a majority of the independent directors or a nominations committee comprised solely of independent directors. Under Belgian law, we are not subject to any such requirements. In particular, we are not required by Belgian law to set up any compensation or nominations committees within our board of directors, and are therefore not subject to any Belgian legal requirements as to the composition of such committees either. However, our articles of association provide that our board of directors may form committees from among its members. Our board of directors has set up and appointed a nomination committee and a remuneration committee. Pursuant to article 7:100 of the Belgian CCA, only a majority of the members of the remuneration committee should in principle meet the independence criteria referred to in article 7:87 of the Belgian CCA and set out in provision 3.5 of the Belgian Code on Corporate Governance. Pursuant to provision 4.19 of the Belgian Code on Corporate Governance, only a majority of the members of the remuneration committee must qualify as independent.
- Independent Director Majority. Nasdaq Stock Market Listing Rules 5605(b)(1) and (2) require that a majority of the board of directors must be comprised of independent directors and that independent directors must have regularly scheduled meetings at which only independent directors are present. We are not required under Belgian law to have a majority of independent directors on our board of directors. However, our articles of association provide that our board of directors must be comprised of at least three directors, of which, pursuant to our corporate governance charter and provision 3.4 of the Belgian Code on Corporate Governance, at least three directors must be independent directors under Belgian law. We do not intend to require our independent directors to meet separately from the full board of directors on a regular basis or at all.

Compensation of Our Directors and Executive Management

Our current remuneration practices are designed to attract and retain talented employees; promote continuous improvement in our business and reward performance in order to motivate employees to deliver increased shareholder value through superior business results.

We will prepare a remuneration policy pursuant to Article 7:89/1 CCA and intend to submit this policy to the general shareholders' meeting approving the annual accounts for the year ended December 31, 2020. Upon every material change to the remuneration policy and in any case at least every four years, the remuneration policy will be submitted to the general shareholders' meeting for approval. The shareholders' vote on the remuneration policy is binding. We will only pay remuneration in accordance with the remuneration policy approved by the general shareholders' meeting. If the remuneration policy is not approved, remuneration will be paid in accordance with the most recently approved remuneration policy or, if there is no approved remuneration policy, the existing remuneration practices. Until the approval of the remuneration policy pursuant to Article 7:89/1 CCA, the directors and members of executive management will be remunerated in line with (i) in relation to the directors, the remuneration as determined by the shareholders' meeting as of the closing of our initial public offering on Euronext Brussels in September 2020, and (ii) in relation to the members of executive management, the remuneration of such members of executive management as was in place by the end of 2020.

Compensation of Our Board of Directors

Upon recommendation and proposal of the remuneration committee, our board of directors determines the remuneration of the directors to be proposed to the general shareholders' meeting.

Pursuant to Belgian law, the general shareholders' meeting approves the remuneration of the directors, including *inter alia*, each time as relevant:

(i) in relation to the remuneration of executive and non-executive directors, the exemption from the rule that share based awards can only vest after a period of at least three years as of the grant of the awards (Article 7:91, first subsection of the Belgian CCA);

(ii) in relation to the remuneration of executive directors, the exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years (Article 7:91, second to fourth subsection of the Belgian CCA);

(iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration (independent directors can never receive a variable remuneration) (Article 7:92, fourth and fifth subsection of the Belgian CCA); and

(iv) any provisions of service agreements to be entered into with executive directors providing for severance payments exceeding twelve months' remuneration and if the severance payments exceed eighteen months' remuneration, only with the prior recommendation of the remuneration committee (Article 7:92, first subsection of the Belgian CCA).

Notwithstanding points (i), and (ii) above, pursuant to our articles of association, our board of directors is explicitly authorized to deviate from the provisions of article 7:91 of the Belgian CCA.

In connection with the closing of our initial public offering on Euronext Brussels in September 2020, our shareholders approved the following annual remuneration and compensation of the directors:

	Annual Fixed Fee (€)
Chairman – Non-Executive Director	50,000
Independent Director	25,000
Non-Executive Director	25,000
Additional fee for Audit Committee Member	2,500
Additional fee for Remuneration Committee Member	2,500
Additional fee for Science & Technology Committee Member	2,500

In addition, the chairman of the Audit Committee receives an annual fixed fee of €5,000 and members of the Cochlear project steering committee receive an annual fixed fee of €10,000. We also reimburse reasonable out-of-pocket expenses of directors (including travel and hotel expenses) incurred in performing the mandate of director.

Mr. Taelman, our chief executive officer and a member of our board of directors, does not receive any compensation for his service as a director. Additionally, there are no benefits upon the resignation of a director.

For 2020, the following remuneration or compensation was due to the directors (excluding Olivier Taelman):

	Fees Earned (€)
MINV SA *(Management company of Robert Taub)*	50,000
Robert Taub *(Executive chairman until September 21, 2020; non-executive chairman as of September 21, 2020)*	27,260
Janke Dittmer *(Non-executive director)*	0
Jürgen Hambrecht *(Non-executive director as of September 21, 2020)*	8,384
Kevin Rakin *(Non-executive director)*	8,384
MedTech Execs LLC *(Non-executive director until September 21, 2020) (Management company of Donald Deyo)*	9,025
Donald Deyo *(Non-executive director as of September 21, 2020)*	11,877
Pierre Gianello *(Employee and non-executive director)*	90,958
Jan Janssen *(Non-executive director)*	7,685

The table below provides an overview as of March 31, 2021 of the warrants held by the non-executive directors.

Name	Warrant Awards		
	Number of Ordinary Shares Underlying Warrants	Warrant Exercise Price per Ordinary Share Underlying Warrant (€)	Warrant Expiration Date
Donald Deyo	27,000	5.17	November 3, 2021
Pierre Gianello	6,000	5.17	December 9, 2021
Kevin Rakin	27,000	5.17	November 3, 2021

Compensation of Our Executive Management

The remuneration of the chief executive officer and the other members of our executive management is based on recommendations made by our remuneration committee. The chief executive officer participates in the meetings of the remuneration committee in an advisory capacity each time the remuneration of another member of the executive management is being discussed.

The remuneration is determined by our board of directors, in accordance with the current remuneration practices. After approval by the general shareholders' meeting of a remuneration policy pursuant to Article 7:89/1 CCA, the remuneration will be determined by the board of directors in accordance with the remuneration policy.

As an exception to the foregoing rule, Belgian law provides that the general shareholders' meeting must approve, as relevant:

(i) in relation to the remuneration of members of the executive management and other executives, an exemption from the rule that share-based awards can only vest after a period of at least three years as of the grant of the awards (Article 7:121, last subsection jo. Article 7:91, first subsection of the Belgian CCA);

(ii) in relation to the remuneration of members of the executive management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years (Article 7:121, last subsection jo. Article 7:91, second to fourth subsection of the Belgian CCA); and

(iii) any service agreements to be entered into with members of the executive management and other executives (as the case may be) providing for severance payments exceeding twelve months' remuneration (or, subject to an opinion by the remuneration committee, eighteen months' remuneration) (Article 7:121, last subsection jo. Article 7:92, first subsection of the Belgian CCA).

Notwithstanding points (i) and (ii) above, our board of directors has been explicitly authorized in the Articles of Association to deviate from the provisions of Article 7:91 CCA.

An appropriate proportion of the remuneration package should be structured so as to link rewards to corporate and individual performance, thereby aligning the interest of the executive management with the interests of our shareholders. Our board of directors will determine whether the targets for the variable remuneration of the members of the executive management, as set by our board of directors, are met.

The remuneration of the executive management currently consists of the following main remuneration components:

- **Base remuneration**: annual base salary/fee (fixed);
- **Fringe benefits (employees only)**: includes a company car, laptop, phone and representation allowance;

- **Age and risk provisions (employees only)**: includes a pension plan with a fixed contribution and health insurance;
- **Short-term incentives**: includes a yearly performance bonus or a yearly success fee. If a target is reached, the member receives the full bonus/success fee, but if the target is not reached, they receive no payout; and
- **Long-term incentives**: includes participation in warrant incentive plans.

The short-term and long-term incentives are detailed in the table below:

Short-term incentive plan: yearly performance bonus / yearly success fee

Main provisions	Short description
Performance cycle	One calendar year
Target bonus	NA
Performance criteria and corresponding payout levels	One or more performance criteria (objectives) are determined. For each performance criterion, a target and corresponding payout level are determined: 1. If target is reached: full payout 2. If target is not reached: no payout
Calculation of bonus / success fee	The total bonus / success fee is composed of the sum of the payout levels related to the various performance criteria (if more than one)
Payment modalities	Payment in cash 100% of the bonus / success fee 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	1. Share option plans issued prior to 2020: five years from date of offer of share options 2. Share option plan issued in 2020: ten years from issue of share options
Performance criteria and corresponding offering levels	NA

Short-term incentive plan: yearly performance bonus / yearly success fee

Main provisions	Short description
Calculation of number of offered share options	NA
Vesting	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
Retention	NA

The following table sets forth information regarding compensation paid by us to Olivier Taelman, our chief executive officer, during the year ended December 31, 2020:

	Compensation (€)
Base salary	262,538
Performance bonus	40,000
Pension contributions	19,860
Company car	11,632
Health insurance contributions	1,903

In addition, in April 2020, Mr. Taelman was granted one warrant under our 2013 Share Incentive Plan, 33 warrants under our 2018 Warrants Plan and 320,000 warrants under our 2020 Warrants Plan. There are no benefits upon termination of employment.

We are party to a consulting agreement, dated August 18, 2014, as amended, with ActuaRisk Consulting SRL, or ActuaRisk, a company owned by Fabian Suarez Gonzalez, pursuant to which ActuaRisk, represented by Mr. Suarez, acts as our chief financial officer. For the year ended December 31, 2020, ActuaRisk received fees of €219,333 (excluding VAT) and a success fee of €50,000 (excluding VAT) in connection with the closing of our initial public offering on Euronext Brussels in September 2020.

In addition, as a result of our initial public offering on Euronext Brussels, ActuaRisk is entitled under the terms of the consulting agreement to a one-time payment that will become payable when ActuaRisk invoices such compensation (which was not possible prior to March 18, 2021).

This payment will be calculated as follows:

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

The Exit Value will equal the closing trading price of our shares at the time ActuaRisk invoices us, multiplied by the number of then outstanding shares. If we are acquired through a public takeover offer, the Exit Value will be equal to the value of 100% of our share capital on a fully-diluted basis in the framework of such acquisition. If the Exit results in a sale of less than 100% of the shares, the entitlement to the variable compensation will be calculated in proportion to the percentage of shares sold in the Exit (e.g. if the Exit results from a sale of 60% of the shares, ActuaRisk will be entitled to 60% of the variable compensation that it otherwise would be entitled to). If the sale of shares takes place in different phases, the Exit Value shall be calculated on the basis of the weighted average share price at each different phase of the Exit.

The table below provides an overview as of March 31, 2021 of the warrants held by the members of our executive management.

	Warrant Awards		
Name	Number of Ordinary Shares Underlying Warrants	Warrant Exercise Price (€)	Warrant Expiration Date
Olivier Taelman	500	11.93	December 23, 2024
	133,000	6.52	July 29, 2024
	16,500	11.93	April 7, 2025
	320,000	11.94	February 21, 2030
Fabian Suarez Gonzalez(1)	25,000	5.17	June 13, 2022

(1) Mr. Suarez acts as our chief financial officer via ActuaRisk Consulting SRL. Mr. Suarez holds the warrants personally.

Warrant Plans

We have established a number of warrant plans, under which we have granted warrants to our employees, officers, directors, consultants and advisors.

Each of the warrants issued on May 3, 2013, December 23, 2014, November 3, 2016 and December 12, 2018 gives the holder thereof right to acquire 500 ordinary shares, which accounts for the 500:1 share split which occurred on February 21, 2020. As of March 31, 2021, there were still 895 of such warrants outstanding which entitle the holders thereof to an aggregate of 447,500 of our ordinary shares. Each of the warrants issued on February 21, 2020 gives the holder thereof to subscribe to one of our ordinary shares. As of March 31, 2021, there were still 550,000 of such warrants outstanding which entitle the holders thereof to an aggregate of 550,000 of our ordinary shares. The warrants issued on May 3, 2013 were granted for €1.0 each, and all subsequent warrants were granted for no consideration.

The duration of the warrants issued on May 3, 2013, December 23, 2014, November 3, 2016 and December 12, 2018 is the shorter of ten years from the date of issuance or five years from the date of grant. The duration of the warrants issued on February 21, 2020 is ten years from the date of issuance. With respect to the warrants issued on May 3, 2013 and December 23, 2014, 34% of such warrants granted to and accepted by a beneficiary vest upon the date of the grant, after which the balance of such warrants will vest in equal parts on the anniversary date of the relevant warrant agreement such that 100% of such warrants are vested on the second anniversary of the relevant warrant agreement. With respect to all warrants issued from November 3, 2016 on, one third of such warrants granted to and accepted by a beneficiary vest upon the date of the grant, after which one third of the warrants granted to and accepted by a beneficiary vest on each of the first and second anniversary of the grant date. With respect to all warrants issued from November 3, 2016 on, such warrants immediately vested and became exercisable at least ten business days prior to the closing of our initial public offering on Euronext Brussels in September 2020.

The table below sets forth the details of all warrants granted under the warrant plans in force as of March 31, 2021, including the plan under which the warrants were granted, the offer date, exercise price, expiry date, number of warrants exercised, number of warrants voided and number of warrants outstanding. Aside from the warrants set forth in the below table, there are currently no other stock options, options to purchase securities, or other rights to subscribe for or purchase outstanding securities.

Name of Warrants Plan	Number of Warrants Issued	Number of Warrants lapsed, exercised or no longer available for grant	Number of Warrants outstanding	Issue date	Expiration date	Exercise Price Warrant (€)	Number and type of Shares issuable per ESOP Warrant	Aggregate number and type of Shares issuable upon execise of outstanding Warrants
2013 Share Incentive Plan	640	499	141	05/03/2013 12/23/2014	05/03/2023 12/23/2024	2,585.51(1) 5,966.59(2)	500 Ordinary Shares	70,500 Ordinary Shares
2016 Warrants Plan	1,500	1,065	435	11/03/2016	11/03/2026	2,585.32(1)	500 Ordinary Shares	217,500 Ordinary Shares
2018 Warrants Plan	525	206	319	12/12/2018	12/12/2028	3,259.91(3) 5,966.59(2)	500 Ordinary Shares	159,500 Ordinary Shares s
2020 Warrants Plan	550,000		550,000	02/21/2020	02/21/2030	11.94	1 Ordinary Share	550,000 Ordinary Shares
							Total	**997,500 Ordinary Shares**

(1) This results in a subscription price of €5.17 (rounded) per new share.

(2) Exercise price for one warrant issued under 2013 Share Incentive Plan and 33 warrants issued under 2018 Warrants Plan. This results in a subscription price of €11.93 (rounded) per new share.

(3) This results in a subscription price of €6.52 (rounded) per new share.

PRINCIPAL SHAREHOLDERS

Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares as of May 31, 2021 by:

- each of our directors and executive officers; and
- each person known to us to beneficially own more than 3% of our ordinary shares.

To our knowledge, as of May 31, 2021, 61,000 of our ordinary shares are held of record by two residents of the United States.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including ordinary shares that can be acquired within 60 days of May 31, 2021. Ordinary shares subject to derivative securities currently exercisable or exercisable within 60 days of May 31, 2021 are deemed to be outstanding for computing the percentage ownership of the person holding these securities and the percentage ownership of any group of which the holder is a member, but are not deemed outstanding for computing the percentage of any other person.

The percentage ownership information shown in the table prior to this offering is based upon 22,107,609 ordinary shares outstanding as of May 31, 2021. The percentage ownership information shown in the table after this offering is based on ordinary shares outstanding, assuming the sale of ordinary shares by us in this offering and no exercise of the underwriters' option to purchase additional ordinary shares.

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all ordinary shares shown that they beneficially own, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Act.

Except as otherwise indicated in the table below, addresses of the directors, members of the executive management team and named beneficial owners are in care of Nyxoah SA, Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

		Percentage of Ordinary Shares Beneficially Owned	
Name of beneficial owner	**Number of Ordinary Shares Beneficially Owned**	**Before Offering**	**After Offering**
3% or Greater Shareholders:			
Cochlear Investments Pty Ltd[(1)]	3,947,617	17.86%	
Entities affiliated with Gilde Healthcare[(2)]	3,153,822	14.27%	
Robert Taub[(3)]	2,817,470	12.74%	
TOGETHER Partnership[(4)]	2,503,500	11.32%	
Jürgen Hambrecht[(5)]	1,047,029	4.74%	
Resmed Inc.[(6)]	794,235	3.59%	
BNP Paribas Asset Management SA[(7)]	664,380	3.01%	
Executive Officers and Directors:			
Robert Taub[(3)]	2,817,470	12.74%	
Janke Dittmer	—	—	
Kevin Rakin[(8)]	117,940	*	
Donald Deyo[(9)]	45,000	*	
Pierre Gianello[(10)]	6,000	*	
Jan Janssen	—	—	
Jürgen Hambrecht[(5)]	1,047,029	4.74%	
Olivier Taelman[(11)]	470,000	2.08%	
Fabian Suarez Gonzalez[(12)]	42,883	*	
All current directors and executive management as a group (9 persons)[(13)]	4,546,322	20.52%	

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* Represents beneficial ownership of less than one percent.

(1) Consists of 3,947,617 ordinary shares held by Cochlear Investments Pty Ltd. The principal business address of Cochlear Investments Pty Ltd. is 1 University Avenue, Macquarie University, NSW 2109 (Australia). 100% of the share capital of Cochlear Investments Pty Ltd is owned by Cochlear Limited, a company which is listed on the Australian Securities Exchange and is not a controlled company.

(2) Consists of (i) 1,576,911 ordinary shares held by Coöperatieve Gilde Healthcare III Sub-Holding U.A., or Gilde Sub-Holding, and (ii) 1,576,911 ordinary shares held by Coöperatieve Gilde Healthcare III Sub-Holding 2 U.A., or Gilde Sub-Holding 2. The principal business address of each of Gilde Sub-Holding and Gilde Sub-Holding 2 is Newtonlaan 91, 3584 BP Utrecht, The Netherlands. Gilde Healthcare III Management BV is the management company of Gilde Sub-Holding and Gilde Sub-Holding 2. Gilde Healthcare III Management BV exercises the voting rights attached to our ordinary shares at its discretion. Gilde Healthcare III Management BV is controlled by Gilde Healthcare Holding BV. Gilde Healthcare Holding BV is not a controlled entity.

(3) Consists of (i) 2,121,470 ordinary shares held by Robert Taub, a member of our board of directors, and (ii) 696,000 ordinary shares held by MINV SA, a company controlled by Mr. Taub.

(4) Consists of 2,503,500 ordinary shares held by TOGETHER Partnership. The principal business address of TOGETHER Partnership is Uitbreidingsstraat 10-16, 2600 Antwerp, Belgium. TOGETHER Partnership is not a controlled entity.

(5) Consists of 1,047,029 ordinary shares held by Dr. Hambrecht.

(6) Consists of 794,235 ordinary shares held by Resmed Inc. The principal business address of Resmed Inc. is 9001 Spectrum Center Boulevard., San Diego, CA 92123. Resmed Inc. is a public company that is listed on the New York Stock Exchange and is not a controlled company.

(7) The shares are held by BNP Paribas Asset Management France SAS and BNP Paribas Asset Management UK Ltd, which are both controlled by BNP Paribas Asset Management SA, which in turn is controlled by BNP Paribas SA, which benefits from the exemption to aggregate its holdings with those of its subsidiaries that are investment companies in accordance with art. 21 paragraph 2 of the Royal Decree of February 14, 2008 regarding the disclosure of major holdings. BNP Paribas Asset Management France SAS and BNP Paribas Asset Management UK Ltd are investment companies that exercise voting rights in a discretionary way.

(8) Consists of (i) 45,470 ordinary shares held by Mr. Rakin, (ii) 45,470 ordinary shares held by Kevin L. Rakin Irrevocable Trust and (iii) 27,000 ordinary shares issuable upon the exercise of warrants held by Mr. Rakin that are immediately exercisable or exercisable within 60 days of May 31, 2021.

(9) Consists of (i) 18,000 ordinary shares held by Mr. Deyo and (ii) 27,000 ordinary shares issuable upon the exercise of warrants held by Mr. Deyo that are immediately exercisable or exercisable within 60 days of May 31, 2021.

(10) Consists of 6,000 ordinary shares issuable upon the exercise of warrants held by Mr. Gianello that are immediately exercisable or exercisable within 60 days of May 31, 2021.

(11) Consists of 470,000 ordinary shares issuable upon the exercise of warrants held by Mr. Taelman that are immediately exercisable or exercisable within 60 days of May 31, 2021.

(12) Consists of (i) 17,883 ordinary shares held by Mr. Suarez and (ii) 25,000 ordinary shares issuable upon the exercise of warrants held by Mr. Suarez that are immediately exercisable or exercisable within 60 days of May 31, 2021.

(13) Consists of (i) 3,991,322 ordinary shares and (ii) 555,000 ordinary shares issuable upon the exercise of warrants that are immediately exercisable or exercisable within 60 days of May 31, 2021.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Cochlear Collaboration Agreement

We are party to a collaboration agreement, dated November 7, 2018 with Cochlear Ltd., or Cochlear, a holder of more than 3% of our ordinary shares, pursuant to which we and Cochlear agreed to collaborate to further develop and progress commercialization of implantable treatments for sleep disordered breathing conditions. Under the agreement, we and Cochlear agreed to collaborate on the development and commercialization of implantable treatments for sleep disordered breathing conditions. The specific contributions and services to be provided by us and Cochlear for each project is set forth in a statement of work.

The term of the Cochlear Agreement ends on the date of completion of the last statement of work. We or Cochlear may terminate the Cochlear Agreement by giving at least 30 days' prior written notice to the other if we or Cochlear conclude, on reasonable grounds and after consultation with the project steering committee, that there is no reasonable prospect of achieving the objectives of the project. We or Cochlear may also terminate the Cochlear Agreement with immediate effect by written notice in connection with a material breach of the Cochlear Agreement, the subscription agreement or the shareholders' agreement that remains uncured 30 days after written notice of the breach, in connection with the other party's insolvency and if the other party ceases to carry on its business. We or Cochlear may also terminate the Cochlear Agreement upon 30 days' notice following a change of control of the other party.

Under the first statement of work, entered into in November 2018, Cochlear evaluated three packaging technologies and supported us in the assessment of our encapsulation technologies. Under the second statement of work, entered into in June 2020, Cochlear is bringing a ceramic pouch concept through design verification and prototype manufacturing. See "Business — Collaborations and License Agreements — Cochlear Collaboration Agreement" for more information. Jan Janssen, a member of our board of directors, is the Chief Technology Officer of Cochlear.

Man & Science Agreement

We, Man & Science SA (a company held and controlled by Robert Taub, TOGETHER Partnership and Jürgen Hambrecht and Noshaq SA), Cephalix SA, Glucobel SA and Surgical Electronics SA, among others, have entered into a multiparty agreement regarding their respective ownership and licensing rights in relation to multiple inventions, including but not limited to inventions generally related to implantable, flexible neurostimulators and inventions for specific medical indications including sleep disordered breathing, head pain, glucose monitoring, hypertension and other indications. This agreement provides that (i) we fully own all rights in relation to the inventions specifically related to the sleep disordered breathing field, which we believe includes sleep disordered breathing conditions such as sleep apnea and snoring, and comorbidities of these conditions and (ii) Man & Science SA is the owner of the generic inventions and granted a fully paid-up, exclusive and worldwide, license with respect to these inventions to several parties, including us in the field of sleep disordered breathing. Pursuant to the terms of the agreement, no party may terminate the licenses.

In June 2016, we, Cephalix SA, Surgical Electronics SA, and Man & Science SA entered into a confirmatory addendum, aiming to confirm that (i) we fully own all rights in relation to the inventions specifically related to the sleep disordered breathing field as further detailed in the agreement, (ii) Man & Science SA granted an exclusive, worldwide, fully paid-up, royalty free and transferable license to us covering certain patents in the sleep disordered breathing field, and (iii) we granted an exclusive, fully paid-up, royalty free, transferable license to use certain of those patents outside the sleep disordered breathing field, namely to Cephalix SA in the head pain field, Surgical Electronics SA in the hypertension field and Man & Science SA outside the head pain field and the hypertension field.

In February 2020, we entered into a clarification of the Confirmatory Addendum, or Clarification, with Man & Science SA. The Clarification confirms that the license granted to us by Man & Science SA under the agreement and the Addendum are irrevocable, transferable, fully paid up, royalty-free and include the right to grant sublicenses in the sleep disordered breathing field, which are retroactive as from the filing date of the oldest of the patents and patent applications and will continue in effect until the last to expire patent, which is expected to occur in 2032 (excluding any potential patent term extension). We have no current or future financial obligation to Man & Science SA pursuant to the agreement. See "Business — Intellectual Property" for more information.

Employment Agreement with Olivier Taelman

We are party to an employment agreement, dated June 30, 2019, as amended, with Olivier Taelman, our chief executive officer. Pursuant to the terms of his employment agreement, as from 2021, Mr. Taelman receives a base salary of €300,000 and is eligible to receive an annual cash bonus of up to 60% of his base salary based on performance criteria established by our remuneration committee and board of directors. The employment agreement has an indefinite term and can be terminated by either us or Mr. Taelman at any time subject to prior notice in accordance with Belgian law. We can immediately terminate the employment agreement in case of serious cause. For more information see "Management — Compensation of Our Directors and Executive Management — Compensation of Executive Management."

Consulting Arrangements

ActuaRisk Consulting SRL Consulting Agreement

We are party to a consulting agreement, dated August 18, 2014, as amended, with ActuaRisk, a company owned by Fabian Suarez Gonzalez, pursuant to which ActuaRisk, represented by Mr. Suarez, acts as our chief financial officer. Pursuant to the terms of the consulting agreement, ActuaRisk receives an annual fee of €230,000. In addition, pursuant to the terms of the consulting agreement, ActuaRisk received a success fee of €50,000 upon the closing of our initial public offering on Euronext Brussels in September 2020. For more information see "Management — Compensation of Our Directors and Executive Management — Compensation of Executive Management."

MINV Consulting Agreements

We were previously party to a consulting agreement, dated September 26, 2019, with MINV SA, a company under the control of Robert Taub, the chairman of our board of directors and a holder of more than 5% of our ordinary shares, pursuant to which MINV SA provided various consultancy services, including (i) to support our executive management in business development activities and (ii) to assist our executive management during investor meetings in connection with our initial public offering on Euronext Brussels. We paid MINV SA a total fee of €100,000 for services in connection with an initial public offering process and business development activities rendered over a period from mid-2019 through mid-2020. This consultant agreement expired under its terms in March 2020, except for certain provisions related to confidentiality and intellectual property rights.

Similarly, on June 9, 2021, we entered into another consulting agreement with MINV SA, pursuant to which MINV SA will provide various consultancy services, including (i) to support our executive management in business development activities and (ii) to assist our executive management during investor meetings in connection with our initial public offering on Nasdaq. We will pay MINV SA a total fee of €120,000 for said services to be rendered over a period from the effective date of the agreement for a duration of 12 months.

Participation in Offering

Certain of our existing shareholders have indicated an interest in participating in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

Shareholders' Agreement

We were previously party to a shareholders' agreement, dated February 21, 2020, with then-existing holders of our ordinary shares. The shareholders' agreement contained, among other items, terms regarding our business and governance, as well as preemption rights and transfer restrictions in favor of the shareholders with respect to our ordinary shares. The shareholders' agreement was terminated effective upon the closing of our initial public offering on Euronext Brussels in September 2020.

Warrants to Our Board Directors and Executive Management

We have granted warrants to certain members of our board of directors and executive management. For more information regarding the warrants granted to our board of directors and executive Management, see "Management — Compensation of Our Directors and Executive Management."

Policies and Procedures for Related Person Transactions

Prior to the closing of this offering, we expect to adopt a related person transaction policy setting forth the policies and procedures for the identification, review and approval or ratification of related person transactions.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

Description of Share Capital

The following description of our share capital summarizes certain provisions of our articles of association and the Belgian CCA. Because this description is a summary, it may not contain all information important to you. Accordingly, this description is qualified entirely by references to our articles of association. Copies of our articles of association will be publicly available as an exhibit to the registration statement of which this prospectus forms a part.

The following description includes comparisons of certain provisions of our articles of association and the Belgian CCA applicable to us and the Delaware General Corporation Law, or the DGCL, the law under which many publicly listed companies in the United States are incorporated. Because such statements are summaries, they do not address all aspects of Belgian law that may be relevant to us and our shareholders or all aspects of Delaware law which may differ from Belgian law, and they are not intended to be a complete discussion of the respective rights.

Share Capital

Share Capital and Shares

Our share capital is represented by ordinary shares without nominal value. Our share capital is fully paid-up. Our shares are not separated into classes.

The number of shares issued is expressed in units.

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

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

- the conversion of all preferred shares into ordinary shares. As a result of this conversion, our capital stock constituted 29,758 ordinary shares,
- the cancellation of the outstanding Series B Anti-Dilution Warrants and Series B2 Anti-Dilution Warrants, and
- a reverse ordinary share split at a ratio of 500:1.

As of March 31, 2021, our share capital amounts to € 3,797,765.64 million, represented by 22,107,609 fully authorized and subscribed and paid-up shares without nominal value. This number does not include outstanding warrants issued by us and granted to certain of our directors, employees and non-employees nor any other capital increases after March 31, 2021. Neither we nor any of our subsidiaries holds any of our own shares.

Other Outstanding Securities

In addition to the shares already outstanding, we have granted warrants, which upon exercise will lead to an increase in the number of our outstanding shares. A total of 895 warrants (where each warrant entitles the holder to subscribe for 500 new shares (in respect of the 2013 ESOP Warrants, 2016 ESOP Warrants and 2018 ESOP Warrants)) and a total of 550,000 warrants (where each warrant entitles the holder to subscribe to one new share (in respect of the 2020 ESOP Warrants)) were outstanding and granted as of March 31, 2021. For further information, see “Management — Warrant Plans.”

History of Securities Issuances

All shares issued have been fully paid.

The changes to our actual share capital since January 1, 2016 is summarized as follows:

Date	Transaction	Increase (reduction) of share capital (€)	Number of shares issued	Class of shares issued	Issue price per Share / Par value per Share (€, rounded)	Resulting share capital (€)	Existing shares
6/29/2016	Capital Increase(1)	719,224.50	7,032	Preferred B shares	2,585.32 / 102.28	2,004,255.29	Total: 19,336 7,637 common shares 4,061 preferred A shares 7,638 preferred B shares
10/05/2018	Capital Increase(2)	159,014.44	1,534	Preferred B2 shares	3,259.91 / 103.66	2,163,269.73	Total: 20,870 7,637 common shares 4,061 preferred A shares 7,638 preferred B shares 1,534 preferred B2 shares
11/07/2018	Capital Increase	318,028.88	3,068	Preferred B2 shares	3,259.91 / 103.66	2,481,296.61	Total: 23,980 7,637 common shares 4,061 preferred A shares 7,638 preferred B shares 4,602 preferred B2 shares
2/21/2020	Share Consolidation (as described below)	NA	NA	NA	NA	2,481,296.61	29,758 common shares
2/21/2020	Capital Increase (as further described below)	435,372	4,200	common shares	5,966.59 / 103.66	2,916,670.61	33,958 common shares
2/21/2020	Share Split with a ratio of 500:1 (as described below)	NA	NA	common shares	NA	2,916,670.61	16,979,000 common shares
9/07/2020	Exercise of ESOP Warrants	7,645.10	44,500	common shares	5.17 / 0.1718	2,924,315.71	17,023,500 common shares
9/21/2020	Capital increase	755,981.68	4,400,359	common shares	17 / 0.1718	3,680,297.39	21,423,859 common shares
9/29/2020	Capital increase	111,712.95	650,250	common shares	17 / 0.1718	3,792,010.34	22,074,109 common shares
10/28/2020	Exercise of ESOP Warrants	4,037.30	23,500	common shares	5.17 / 0.1718	3,796,047.64	22,097,609 common shares
2/22/2021	Exercise of ESOP Warrants	1,718.00	10,000	common shares	5.17 / 0.1718	3,797,765.64	22,107,609 common shares

(1) A new category of registered preferred shares (Preferred B Shares) was created and 688 ordinary shares were converted to 606 Preferred B Shares.

(2) A new category of registered preferred shares (Preferred B2 Shares) was created.

The total number of shares issued and outstanding as of March 31, 2021 totals 22,107,609. All shares are ordinary shares.

Articles of Association and Other Share Information

Corporate Profile

Our legal and commercial name is Nyxoah SA. We are a limited liability company incorporated in the form of a naamloze vennootschap / société anonyme under Belgian law. We are registered with the Register of Legal Entities (RPM Brabant Wallon) under the enterprise number 0817.149.675. Our principal executive and registered offices are located at rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium and our telephone number is +32 10 22 23 55. Our agent for service of process in the United States is Corporation Service Company.

We were incorporated in Belgium on July 15, 2009 for an unlimited duration. Our fiscal year ends December 31.

Corporate Purpose

Our corporate purpose as set forth in Article 3 of our articles of association is as follows:

"*The purpose of our company is, both in Belgium and abroad, in its own name and for its own account, the research and development, the manufacturing and the sale of medical devices.*

For this purpose, our company may, in any manner, collaborate and participate, or take an interest in other companies, directly or indirectly.

Our company may guarantee to secure its own obligations or those of third parties by, among other things, granting a mortgage or pledge over its assets, including its own business assets.

Our company may generally carry out all commercial, industrial, financial, movable or real estate transactions which directly or indirectly relate to its purpose or which could facilitate the realization thereof."

Choice of Forum/Governing Law

Our articles of association provide that the courts of the jurisdiction of the registered office of our company are the exclusive forum for all disputes relating to corporate matters and the implementation of these articles of association between our company, our shareholders, holders of bonds, holders of warrants, or holders of other securities or certificates issued by or with the cooperation of our company, our directors, statutory auditors, or liquidators, unless otherwise determined by applicable law. Any person or entity purchasing or otherwise acquiring any interest in our share capital shall be deemed to have notice of and to have consented to the choice of forum provisions of our articles of association. This exclusive forum provision may limit a shareholder's ability to bring a claim in a judicial forum of its choosing, which may discourage lawsuits against us and our directors. This exclusive forum provision is mainly intended to apply to claims arising under Belgian law, but will also apply to claims brought under other applicable laws provided that such other laws do not provide for exclusive jurisdiction for non-Belgian courts. The exclusive forum provision in our articles of association will not relieve us from our duties to comply with U.S. federal securities laws and the rules and regulations thereunder, and shareholders will not be deemed to have waived our compliance with these laws, rules and regulations. Therefore the provision in our articles of association providing for exclusive jurisdiction of Belgian courts would not apply to claims brought pursuant to the Securities Act or the Exchange Act or any other claim for which U.S. federal courts would have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, both U.S. state and federal courts have jurisdiction to entertain such claims. We note that investors cannot waive compliance with U.S. federal securities laws and the rules and regulations thereunder.

As a company incorporated in Belgium, we believe that the choice of the courts of the jurisdiction of the registered office of our company as our exclusive forum for resolving all shareholder complaints, unless otherwise determined by applicable law, allows us to more efficiently and affordably respond to such actions, and provides consistency in the application of Belgian law to such actions.

Board of Directors

Belgian law does not specifically regulate the ability of directors to borrow money from us.

Directors are expected to arrange their personal and business affairs so as to avoid conflicts of interest with our 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 minutes of the relevant board meeting must be communicated to the statutory auditor. The relevant sections of the minutes of the meeting of our board of directors that sets forth the statements of the conflicted director, the nature of the transaction, the financial impact of the matter on us and the justification of the decision of our board of directors must be published in our annual report. The statutory auditors’ report on the annual accounts must contain a description of the financial impact on us of each of the decisions of our board of directors where director conflicts arise.

The Corporate Governance Charter contains the procedure for transactions between our company and the directors which are not covered by the legal provisions on conflicts of interest.

In case of non-compliance with the foregoing, we may request the annulment of the decision or the transaction which has taken place in breach of these provisions if the counterparty to the decision or the transaction was, or should have been, aware of such breach.

There are no outstanding loans granted by our company to any of the members of the board of directors and members of the executive management, nor are there any guarantees provided by our company for the benefit of any of the members of the board of directors and members of the executive management.

None of the members of the board of directors and members of the executive management has a family relationship with any other of the members of the board of directors and members of the executive management.

The DGCL generally permits transactions involving a Delaware corporation and an interested director of that corporation if (i) the material facts as to the director’s relationship or interest and as to the transaction are disclosed and a majority of disinterested directors consent, (ii) the material facts are disclosed as to the director’s relationship or interest and a majority of shares entitled to vote thereon consent or (iii) the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the shareholders.

We rely on a provision in the Listing Rules of the Nasdaq Stock Market that allows us to follow Belgian corporate law with respect to certain aspects of corporate governance. This allows us to continue following certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on the Nasdaq Global Market. In particular, the Listing Rules of the Nasdaq Stock Market require a majority of the directors of a listed U.S. company to be independent, whereas in Belgium, only three directors need to be independent. The Listing Rules of the Nasdaq Stock Market further require that each of the nominating, compensation and audit committees of a listed U.S. company be comprised entirely of independent directors. However, the Belgian Corporate Governance Code recommends only that a majority of the directors on the nomination committee meet the technical requirements for independence under Belgian corporate law. At present, our audit committee is composed of three independent directors out of three members. Our nomination and remuneration committees are composed of two independent directors out of three members. Our board of directors has no plan to change the composition of our audit committee and nomination and remuneration committee.

Form and Transferability of Our Shares

All of our shares belong to the same class of securities and are in registered form or in dematerialized form. All of our outstanding shares are fully paid-up and freely transferable, subject to any contractual restrictions.

Belgian company law and our articles of association entitle shareholders to request, in writing and at their expense, the conversion of their dematerialized shares into registered shares and vice versa. Any costs incurred as a result of the conversion of shares into another form will be borne by the shareholder. For shareholders who opt for registered shares, the shares will be recorded in our shareholder register.

Currency

Our share capital, which is represented by our outstanding ordinary shares, is denominated in euros.

Changes to Our Share Capital

In principle, changes to our share capital are decided by our shareholders. Our shareholders may at any time at a meeting of shareholders decide to increase or decrease our share capital. Any such resolution of shareholders must satisfy the quorum and majority requirements that apply to an amendment of the articles of association, as described below in "— Description of the Rights and Benefits Attached to Our Shares — Right to Attend and Vote at Our Meeting of Shareholders — Quorum and Majority Requirements". No shareholder is liable to make any further contribution to our share capital other than with respect to shares held by such shareholder that would not be fully paid-up.

Share Capital Increases by Our Board of Directors

Subject to the quorum and majority requirements described below in "— Description of the Rights and Benefits Attached to Our Shares — Right to Attend and Vote at Our Meeting of Shareholders — Quorum and Majority Requirements", our meeting of shareholders may authorize our board of directors, within certain limits, to increase our share capital without any further approval of our shareholders. A capital increase that is authorized in this manner is referred to as authorized capital. This authorization can only be granted for a renewable period of a maximum of five years as from the date of the publication of the authorization in the Annexes to the Belgian Official Gazette (Belgisch Staatsblad/Moniteur Belge) and may not exceed the amount of the registered share capital at the time of the authorization. On September 7, 2020, our meeting of shareholders granted this authorization in respect of the authorized capital.

Without prejudice to more restrictive rules set forth by law, our board of directors was authorized to increase the registered capital of our company in one or more transactions with a maximum amount that cannot exceed €3.680.297,39 (excluding issuance premiums, if any).

Normally, the authorization of the board of directors to increase our share capital through contributions in kind or in cash with cancellation or limitation of the preferential right of the existing shareholders is suspended if we are notified by the Belgian Financial Services and Markets Authority, or the FSMA, of a public takeover bid on the financial instruments of our company. The shareholders' meeting can, however, authorize the board of directors to increase the share capital by issuing further shares. On September 7, 2020, the extraordinary shareholders' meeting decided to authorize the board of directors to increase our share capital, including with limitation or cancellation of the shareholders' preferential subscription rights, in one or more times and including the authorization to make use of such authorized capital in the framework of a public tender offer.

Preferential Subscription Rights

In the event of a capital increase for cash with the issue of new shares, or in the event we issue convertible bonds or subscription rights, the existing shareholders have a preferential right to subscribe, pro rata, to the new shares, convertible bonds or subscription rights. These preferential subscription rights are transferable during the subscription period.

Our shareholders may, at a meeting of shareholders, decide to limit or cancel these preferential subscription rights, subject to special reporting requirements. Such decision by the shareholders needs to satisfy the same quorum and majority requirements as the decision to increase our share capital.

The shareholders may also decide to authorize our board of directors to limit or cancel the preferential subscription right within the framework of the authorized capital, subject to the terms and conditions set forth in the Belgian CCA.

Generally, unless expressly authorized in advance by the general shareholders' meeting, the authorization of our board of directors to increase our share capital through contributions in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to us by the FSMA of a public takeover bid on our financial instruments. Our general shareholders' meeting did not grant such express authorization to our board of directors. See also "— Share Capital Increases by Our Board of Directors" above.

Under the DGCL, shareholders of a Delaware corporation have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the corporation's certificate of incorporation.

Purchases and Sales of Our Own Shares

We 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 BelgianCCA. 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 us 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 we purchases the shares to offer them to our 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 authorized to dispose of our own shares to one or more specific persons other than our employees or our 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 our shares 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.

Our general shareholders' meeting did not grant such authorization to the board of directors.

As of the date of this prospectus, our company does not hold any own shares.

Under the DGCL, a Delaware corporation may purchase or redeem its own shares, unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation.

Description of the Rights and Benefits Attached to Our Shares

Right to Attend and Vote at Our Meetings of Shareholders

Annual Meeting of Shareholders.

Our annual general shareholders' meeting is held at the registered office of our company or at the place determined in the notice convening the general shareholders' meeting. The meeting is held every year on the second Wednesday of the month of June, at 2:00 p.m. CET. If this day is a public holiday, even if it is only a public holiday in one of the communities of Belgium, the meeting will be held on the next business day. At our annual general shareholders' meeting, the board of directors submits to the shareholders the audited non-consolidated and consolidated annual financial statements and the reports of the board of directors and of the statutory auditor with respect thereto.

The general shareholders' meeting then decides on the approval of the statutory annual financial statements, the proposed allocation of our company's profit or loss, the release from liability of the directors and the statutory auditor, the advisory vote on the remuneration report included in the annual report of the board of directors and, when applicable, the (re-)appointment or dismissal of the statutory auditor and/or of all or certain directors. In addition, as relevant, the general shareholders' meeting must also decide on the approval of the remuneration of the directors and statutory auditor for the exercise of their mandate, and on the approval of provisions of service agreements to be entered into with executive directors, members of the executive management and other executives providing (as the case may be) for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration committee, eighteen months' remuneration).

Special and Extraordinary Meetings of Shareholders

Our board of directors or the statutory auditor (or the liquidators, if appropriate) may, whenever the interest of our company so requires, convene a special or extraordinary general shareholders' meeting. Pursuant to article 7:126 of the Belgian CCA, such general shareholders' meeting must also be convened every time one or more shareholders holding, alone or together, at least 10% of our company's share capital so request. Shareholders that do not hold at least 10% of our company's share capital do not have the right to have the general shareholders' meeting convened.

Under the DGCL, special meetings of the shareholders of a Delaware corporation may be called by such person or persons as may be authorized by the certificate of incorporation or by the bylaws of the corporation, or if not so designated, as determined by the board of directors. Shareholders generally do not have the right to call meetings of shareholders, unless that right is granted in the certificate of incorporation or the bylaws.

Notices Convening Meetings of Shareholders and Agenda

The notice convening the general shareholders' meeting must state the place, date and hour of the meeting and must include an agenda indicating the items to be discussed. The notice needs to contain a description of the formalities that shareholders must fulfil in order to be admitted to the general shareholders' meeting and exercise their voting right, information on the manner in which shareholders can put additional items on the agenda and table draft resolutions, information on the manner in which shareholders can ask questions during the general shareholders' meeting, information on the procedure to participate to the general shareholders' meeting by means of a proxy or to vote by means of a remote vote, and, as applicable, the registration date for the general shareholders' meeting. The notice must also mention where shareholders can obtain a copy of the documentation that will be submitted to the general shareholders' meeting, the agenda with the proposed resolutions or, if no resolutions are proposed, a commentary by the board of directors, updates of the agenda if shareholders have put additional items or draft resolutions on the agenda, the forms to vote by proxy or by means of a remote vote, and the address of the webpage on which the documentation and information relating to the general shareholders' meeting will be made available. This documentation and information, together with the notice and the total number of outstanding voting rights, must also be made available on our company's website at the same time as the publication of the notice convening the meeting, for a period of five years after the relevant general shareholders' meeting.

The notice convening the general shareholders' meeting has to be published at least 30 calendar days prior to the general shareholders' meeting in the Belgian Official Gazette (Belgisch Staatsblad/Moniteur Belge), in a newspaper that is published nation-wide in Belgium and in media that can be reasonably relied upon for the dissemination of information within the EEA in a manner ensuring fast access to such information on a non-discriminatory basis. A publication in a nationwide newspaper is not needed for annual general shareholders' meetings taking place on the date, hour and place indicated in the articles of association of our company if the agenda is limited to the treatment of the financial statements, the annual report of the board of directors, the remuneration report and the report of the statutory auditor, the discharge from liability of the directors and statutory auditor, and the remuneration of directors. See also "— Annual Meeting of Shareholders" above. In addition to this publication, the notice has to be distributed at least 30 calendar days prior to the meeting via the website of our company (www.nyxoah.com). The term of 30 calendar days prior to the general shareholders' meeting for the publication and distribution of the convening notice can be reduced to 17 calendar days for a second meeting if, as the case may be, the applicable quorum for the meeting is not reached at the first meeting, the date of the second meeting was mentioned in the notice for the first meeting and no new item is put on the agenda of the second meeting. See also further below under "— Quorum and Majority Requirements".

At the same time as its publication, the convening notice must also be sent to the holders of registered shares, holders of registered bonds, holders of registered warrants, holders of registered certificates issued with the co-operation of our company (if any), and, as the case may be, to the directors and statutory auditor of our company.

Under the DGCL, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the shareholders of a Delaware corporation must be given to each shareholder entitled to vote at the meeting not less than ten nor more than sixty days before the date of the meeting and shall specify the place, date, hour and, in the case of a special meeting, the purpose of the meeting.

Admission to Meetings

All holders of shares, warrants, profit-sharing certificates, non-voting shares, bonds, subscription rights or other securities issued by our company, as the case may be, and all holders of certificates issued with the co-operation of our company (if any) can attend the general shareholders' meetings insofar as the law or the articles of association entitles them to do so and, as the case may be, gives them the right to participate in voting.

In order to be able to attend a general shareholders' meeting, a holder of securities issued by our company must satisfy two criteria: being registered as holder of securities on the registration date for the meeting, and notify our company:

- Firstly, the right to attend general shareholders' meetings applies only to persons who are registered as owning securities on the fourteenth calendar day prior to the general shareholders' meeting at midnight (CET) via registration, in the applicable register book for the securities concerned (for registered securities) or in the accounts of a certified account holder or relevant settlement institution for the securities concerned (for dematerialized securities or securities in book-entry form).
- Secondly, in order to be admitted to the general shareholders' meeting, securities holders must notify our company at the latest on the sixth calendar day prior to the general shareholders' meeting whether they intend to attend the meeting and indicate the number of shares in respect of which they intend to do so. For the holders of dematerialized securities or securities in book-entry form, the notice should include a certificate confirming the number of securities that have been registered in their name on the record date. The certificate can be obtained by the holder of the dematerialized securities or securities in book-entry form with the certified account holder or the applicable settlement institution for the securities concerned.

The formalities for the registration of securities holders, and the notification of our company must be further described in the notice convening the general shareholders' meeting.

Each shareholder has the right to attend a general shareholders' meeting and to vote at the general shareholders' meeting in person or through a proxy holder, who need not be a shareholder. A shareholder may designate, for a given meeting, only one person as proxy holder, except in circumstances where Belgian law allows the designation of multiple proxy holders. The appointment of a proxy holder may take place in paper form or electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law), through a form which shall be made available by our company. The signed original paper or electronic form must be received by our company at the latest on the sixth calendar day preceding the meeting. The appointment of a proxy holder must be made in accordance with the applicable rules of Belgian law, including in relation to conflicts of interest and the keeping of a register.

The notice convening the meeting may allow shareholders to vote remotely in relation to the general shareholders' meeting, by sending a paper form or, if specifically allowed in the notice convening the meeting, by sending a form electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law). These forms shall be made available by our company. The original signed paper form must be received by our company at the latest on the sixth calendar day preceding the date of the meeting. Voting through the signed electronic form may occur until the last calendar day before the meeting.

Our company may also organize a remote vote in relation to the general shareholders' meeting through other electronic communication methods, such as, among others, through one or several websites. Our company shall specify the practical terms of any such remote vote in the convening notice.

Holders of securities who wish to be represented by proxy or vote remotely must, in any case comply with the formalities to attend the meeting. Holders of shares without voting rights, profit-sharing certificates without voting rights, convertible bonds, warrants or certificates issued with the cooperation of our company may attend the general shareholders' meeting, but only with an advisory vote.

Votes

Each shareholder is entitled to one vote per share.

Voting rights can be mainly suspended in relation to shares:

- which are not fully paid up, notwithstanding the request thereto of the board of directors;
- to which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 3%, 5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of our company on the date of the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified us and the FSMA at least 20 calendar days prior to the date of the general shareholders' meeting in accordance with the applicable rules on disclosure of major shareholdings; and
- of which the voting right was suspended by a competent court or the FSMA.

Quorum and Majority Requirements

In general, there is no attendance quorum requirement for a general shareholders' meeting and decisions are generally passed with a simple majority of the votes of the shares present or represented. However, capital increases (other than those decided by the board of directors pursuant to the authorized capital), decisions with respect to our company's dissolution, mergers, demergers and certain other reorganizations of our company, amendments to the articles of association (other than an amendment of the corporate purpose), and certain other matters referred to in the Belgian CCA do not only require the presence or representation of at least 50% of the share capital of our company but also 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 our 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 our 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.

Under the DGCL, the certificate of incorporation or bylaws of a Delaware corporation may specify the number of shares required to constitute a quorum but in no event shall a quorum consist of less than one-third of shares entitled to vote at a meeting. In the absence of such specifications, a majority of shares entitled to vote shall constitute a quorum.

Right to Ask Questions at our Meetings of Shareholders

Within the limits of article 7:139 of the Belgian CCA, holders of securities have a right to ask questions to the directors in connection with the report of the board of directors or the items on the agenda of such general shareholders' meeting. Holders of securities can also ask questions to the statutory auditor in connection with its report. Such questions can be submitted in writing prior to the meeting or can be asked at the meeting. The statutory auditor will immediately communicate any written questions to the board of directors. Written questions must be received by our company no later than the sixth calendar day prior to the meeting. Written and oral questions will be answered during the meeting concerned in accordance with applicable law. In addition, in order for written questions to be considered, the shareholders who submitted the written questions concerned must comply with the formalities to attend the meeting.

Dividends

All shares participate in the same manner in our profits, if any. Pursuant to the Belgian CCA, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of our company's board of directors. The shareholders shall lose their right to receive the dividends five years after the payment date of these dividends pursuant to Article 2277 of the Belgian Civil Code. From that date onwards, our company shall no longer be required to pay such dividends. The articles of association also authorize the board of directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

Our ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of our stand-alone statutory accounts prepared in accordance with Belgian GAAP. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of our net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e., summarized, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), and, save in exceptional cases, to be mentioned and justified in the notes to the annual accounts, decreased with the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves (which include, as the case may be, the unamortized part of any revaluation surpluses).

In addition, pursuant to Belgian law and our Articles of Association, we must allocate an amount of 5% of our Belgian GAAP annual net profit to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of our share capital. Our legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing. Accordingly, 5% of our Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, further limiting our ability to pay out dividends to its shareholders. Furthermore, additional financial restrictions and other limitations may be contained in future credit agreements.

The right to payment of dividends expires five years after the board of directors declared the dividend payable.

Under the DGCL, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for either or both of the fiscal year in which the dividend is declared and the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). Dividends may be paid in the form of shares, property or cash.

Appointment of Directors

Pursuant to the Belgian CCA and the articles of association, the board of directors must consist of at least three directors. Our 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

Belgian Code on Corporate Governance, 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 Belgian Code on Corporate Governance. By 1 January 2026, at least one third of the members of the board of directors must be of the opposite gender.

Liquidation Rights

Our company can only be voluntarily dissolved by a shareholders' resolution passed with a majority of at least 75% of the votes cast at an extraordinary meeting of shareholders where at least 50% of the share capital is present or represented. In the event 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 meeting of shareholders can validly deliberate and decide regardless of the number of shares present or represented.

Under the DGCL, unless the board of directors approves the proposal to dissolve, dissolution of a Delaware corporation must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. The DGCL allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.

In the event of the dissolution and liquidation of our company, the assets remaining after payment of all debts and liquidation expenses will be distributed to the holders of our shares, each receiving a sum on a pro rata basis.

Pursuant to article 7:228 of the Belgian CCA, if, as a result of losses incurred, the ratio of our company's net assets (determined in accordance with Belgian legal and accounting rules for non-consolidated financial statements) to share capital is less than 50%, the board of directors must convene an extraordinary general shareholders' meeting within two months as of the date upon which the board of directors discovered or should have discovered this undercapitalization. At this general shareholders' meeting the board of directors needs to propose either the dissolution of our company or the continuation of our company, in which case the board of directors must propose measures to redress our company's financial situation. The board of directors must justify its proposals in a special report to the shareholders. Shareholders representing at least 75% of the votes validly cast at this meeting have the right to dissolve our company, provided that at least 50% of our company's share capital is present or represented at the meeting.

If, as a result of losses incurred, the ratio of our company's net assets to share capital is less than 25%, the same procedure must be followed, it being understood, however, that in that event shareholders representing 25% of the votes validly cast at the meeting (whereby abstentions are not included in the numerator nor in the denominator) can decide to dissolve our company.

Pursuant to article 7:229 of the Belgian CCA, if the amount of our company's net assets has dropped below €61,500, any interested party is entitled to request the competent court to dissolve our company. The court can order the dissolution of our company or grant a grace period within which our company is to remedy the situation.

If our company is dissolved for any reason, the liquidation must be carried out by one or more liquidators appointed by the general shareholders' meeting and whose appointment has been ratified by the enterprise court. Any balance remaining after discharging all debts, liabilities and liquidation costs must first be applied to reimburse, in cash or in kind, the paid-up capital of the shares not yet reimbursed. Any remaining balance shall be equally distributed amongst all the shareholders.

Belgian Legislation

Disclosure of Significant Shareholdings

Pursuant to the Belgian Act of 2 May 2007 on the disclosure of significant shareholdings in issuers whose securities are admitted to trading on a regulated market and containing various provisions, as amended from time to time, a notification to our company and to the FSMA is required by all natural persons and legal entities (i.e. legal person, enterprise without legal personality, or trust), in the following circumstances:

- an acquisition or disposal of voting securities, voting rights or financial instruments that are treated as voting securities;
- the reaching of a threshold by persons or legal entities acting in concert;
- the conclusion, modification or termination of an agreement to act in concert;
- the downward reaching of the lowest threshold;
- the passive reaching of a threshold;
- the holding of voting securities in our company upon first admission thereof to trading on a regulated market;
- where a previous notification concerning the financial instruments treated as equivalent to voting securities is updated;
- the acquisition or disposal of the control of an entity that holds voting securities in our company; and
- where our company introduces additional notification thresholds in the articles of association,

in each case where the percentage of voting rights attached to the securities held by such persons reaches, exceeds or falls below the legal threshold, set at 5% of the total voting rights, and 10%, 15%, 20% and so on in increments of 5% or, as the case may be, the additional thresholds provided in the articles of association. Our company has provided for an additional threshold of 3% in the articles of association that will enter into force subject to, and with effect as from, the closing of the Offering.

The notification must be made promptly and at the latest within four trading days following the moment on which the person who is subject to the notification obligation received knowledge or could be deemed to have received knowledge of the acquisition or disposal of the voting rights triggering the reaching of the threshold. Where our company receives a notification of information regarding the reaching of a threshold, it has to publish such information within three trading days following receipt of the notification. The person who has failed to make such notification 20 days before the general shareholders' meeting may not vote at the general meeting for 25% or more than 25% of the total voting rights at the date of the general shareholders' meeting.

The forms on which such notifications must be made, as well as further explanations, can be found on the website of the FSMA (www.fsma.be). Violation of the disclosure requirements may result in the suspension of voting rights, a court order to sell the securities to a third party and/or criminal liability. The FSMA may also impose administrative sanctions. Our company is required to publicly disclose any notifications received regarding increases or decreases in a shareholder's ownership of our company's securities, and must mention these notifications in the notes to its financial statements. A list as well as a copy of such notifications will be accessible on our company's website.

In accordance with U.S. federal securities laws, holders of our ordinary shares will be required to comply with disclosure requirements relating to their ownership of our securities. Any person that, after acquiring beneficial ownership of our ordinary shares, is the beneficial owners of more than 5% of our outstanding ordinary shares must file with the SEC a Schedule 13D or Schedule 13G, as applicable, disclosing the information required by such schedules, including the number of our ordinary shares that such person has acquired (whether alone or jointly with one or more other persons). In addition, if any material change occurs in the facts set forth in the report filed on Schedule 13D (including a more than 1% increase or decrease in the percentage of the total shares beneficially owned), the beneficial owner must promptly file an amendment disclosing such change.

Disclosure of Net Short Positions

Pursuant to the Regulation (EU) No. 236/2012 of the European Parliament and the Council on short selling and certain aspects of credit default swaps, any person that acquires or disposes of a net short position relating to our issued share capital, whether by a transaction in shares, or by a transaction creating or relating to any financial instrument where the effect or one of the effects of the transaction is to confer a financial advantage on the person entering into that transaction in the event of a decrease in the price of such shares is required to notify the FSMA if, as a result of which acquisition or disposal his net short position reaches, exceeds or falls below 0.2% of our issued share capital and each 0.1% above that. If the net short position reaches 0.5%, and also at every 0.1% above that, the FSMA will disclose the net short position to the public.

Public Takeover Bids

Public takeover bids for the shares and other securities giving access to voting rights (such as war-rants or convertible bonds, if any) are subject to supervision by the FSMA. Any public takeover bid must be extended to all of our 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.

Belgium has implemented the Thirteenth Company Law Directive (European Directive 2004/25/EC of 21 April 2004) by the Belgian Act of 1 April 2007 on public takeover bids, as amended (the "Belgian Takeover Act") and the Belgian Royal Decree of 27 April 2007 on public takeover bids, as amended (the "Belgian Takeover Decree"). 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 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 our 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 our 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 (see "— Disclosure of Significant Shareholding" above) and merger control, that may apply towards our 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 share-holders 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 our 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 our company by the FSMA of a public takeover bid on the securities of our company. The general shareholders' meeting can, however, under certain conditions, expressly authorize the board of directors to increase the capital of our 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 general shareholders' meeting expressly authorized the board of directors to increase our company's capital as a protective mechanism against potential public takeover bids.

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

Squeeze-Out

Pursuant to article 7:82 of the Belgian CCA or the regulations promulgated thereunder, a person or legal entity, or different persons or legal entities acting alone or in concert, who own, together with our company, at least 95% of the securities with voting rights in a listed company are entitled to acquire the totality of the securities with voting rights in that company following a squeeze-out offer. The securities that are not voluntarily tendered in response to such an offer are deemed to be automatically transferred to the bidder at the end of the procedure. At the end of the squeeze-out procedure, our company is no longer deemed a listed company. The consideration for the securities must be in cash and must represent the fair value (verified by an independent expert) as to safeguard the interests of the transferring shareholders.

A squeeze-out offer is also possible upon completion of a public takeover bid, provided that the bidder holds at least 95% of the voting capital and 95% of the voting securities of the public company. In such a case, the bidder may require that all remaining shareholders sell their securities to the bidder at the Offering Price of the takeover bid, provided that, in case of a voluntary takeover offer, the bidder has also acquired 90% of the voting capital to which the offer relates. The shares that are not voluntarily tendered in response to any such offer are deemed to be automatically transferred to the bidder at the end of the procedure.

The DGCL provides for shareholders appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the shareholder's shares, in connection with certain mergers and consolidations.

Limitations on the Right to Own Securities

Neither Belgian law nor our articles of association impose any general limitation on the right of non-residents or foreign persons to hold our securities or exercise voting rights on our securities other than those limitations that would generally apply to all shareholders.

Exchange Controls and Limitations Affecting Shareholders

There are no Belgian exchange control regulations that impose limitations on our ability to make, or the amount of, cash payments to residents of the United States.

We are in principle under an obligation to report to the National Bank of Belgium certain cross-border payments, transfers of funds, investments and other transactions in accordance with applicable balance-of-payments statistical reporting obligations. Where a cross-border transaction is carried out by a Belgian credit institution on our behalf, the credit institution will in certain circumstances be responsible for the reporting obligations.

Securities Exercisable for Ordinary Shares

Equity Incentives

See the section of this prospectus titled "Management — Warrant Plans" for a description of securities granted by our board of directors to our directors, members of the executive management team, employees and other service providers.

Listing

We intend to apply to list the ordinary shares on the Nasdaq Global Market under the symbol "NYXH". Our ordinary shares are currently listed on Euronext Brussels under the symbol "NYXH."

Transfer Agent and Registrar

Upon the closing of the offering, the transfer agent and registrar for the ordinary shares will be Computershare Trust Company, N.A.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to the offering, although our ordinary shares are admitted to trading on Euronext Brussels since 2020, there has been no public market on a U.S. national securities exchange for our ordinary shares and we cannot assure you that a significant public market in the United States for the ordinary shares will be established or sustained after this offering.

Some of our ordinary shares are subject to contractual and legal restrictions on resale as described below. There may be sales of substantial amounts of the ordinary shares in the public market after such restrictions lapse, which could adversely affect prevailing market prices and could impair our future ability to raise equity capital.

Based on the number of ordinary shares outstanding on March 31, 2021, upon the closing of the offering, ordinary shares will be outstanding, or ordinary shares if the underwriters exercise in full their options to purchase an additional ordinary shares in the offering. The ordinary shares sold in the offering will be freely tradable without restriction or further registration under the Securities Act, except for any ordinary shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, sales of which would be subject to Rule 144 resale restrictions described below, other than the holding period requirement.

The ordinary shares held by existing shareholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the United States on the Nasdaq Global Market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 or Rule 701 promulgated under the Securities Act.

Rule 144

Rule 144 provides an exemption from the registration requirements of the Securities Act for restricted securities and securities held by certain affiliates of an issuer being sold in the United States, to U.S. persons or through U.S. securities markets. In general, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, a person (or persons whose securities are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the three months preceding a sale, and who have beneficially owned restricted securities for at least six months, and any of our affiliates who owns either restricted or unrestricted securities, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-Affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 without complying with the manner of sale, volume limitation or notice provisions of Rule 144 if:

- the restricted securities have been held for at least six months, including the holding period of any prior owner other than one of our affiliates;
- we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of restricted securities without complying with any of the requirements of Rule 144, including the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting.

Affiliates

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above.

Once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our affiliates who have beneficially owned the securities proposed to be sold for at least six months and comply with the manner of sale and notice provisions of Rule 144 would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of ordinary shares then outstanding, which will equal approximately ordinary shares immediately after the consummation of this offering based on the number of ordinary shares outstanding as of March 31, 2021; or
- the average weekly trading volume of the ordinary shares on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Such sales under Rule 144 by our affiliates or persons selling ordinary shares on behalf of our affiliates are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and in the section of this prospectus titled “Underwriting” and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus delivery requirements of the Securities Act.

Lock-up Agreements

Each of our directors and executive officers and certain shareholders have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ordinary shares or such securities convertible or exercisable ordinary shares for a period of 90 days after the date of this prospectus, without the prior written consent of Piper Sandler & Co., Stifel, Nicolaus & Company Inc., and Cantor Fitzgerald & Co. See “Underwriting.”

In September 2020, subject to certain exceptions, all of our existing shareholders at the time of our initial public offering on Euronext Brussels entered into a lock-up arrangement with the underwriters. Holders of shares or other securities representing more than 2% of our shares on a fully diluted basis (excluding the new shares that were issued pursuant to the initial public offering) entered into a lock-up arrangement with the underwriters with respect to certain of their shares and other securities issued by us for a period of twelve months after the listing date, September 18, 2020, and holders of shares or other securities representing 2% or less of our shares on a fully diluted basis (excluding the new shares that were issued pursuant to the initial public offering) entered into a lock-up arrangement with the underwriters with respect to certain of their shares and other securities issued by us for a period of six months after the listing date.

MATERIAL UNITED STATES FEDERAL INCOME AND BELGIAN TAX CONSIDERATIONS

Certain Material U.S. Federal Income Tax Considerations to U.S. Holders

The following is a summary of certain material U.S. federal income tax considerations relating to ownership and disposition of ordinary shares by a U.S. holder (as defined below) that is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code; existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder, administrative and judicial interpretations thereof; and the income tax treaty between Belgium and the United States in each case as of and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the U.S. Internal Revenue Service, or the IRS, will not take a contrary or different position concerning the tax consequences of ownership and disposition of the ordinary shares or that such a position would not be sustained. Holders should consult their own tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning, and disposing of the ordinary shares in their particular circumstances.

This summary addresses only the U.S. federal income tax considerations for U.S. holders of our ordinary shares and that will hold such ordinary shares as capital assets for U.S. federal income tax purposes. This summary does not address all U.S. federal income tax matters that may be relevant to a particular U.S. holder. This summary does not address all tax considerations that may be applicable to a holder of ordinary shares that may be subject to special tax rules including, without limitation, the following:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax-exempt entities or organizations, including an “individual retirement account” or “Roth IRA” as defined in Section 408 or 408A of the Code (as defined below), respectively;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold the ordinary shares as part of a “hedging,” “integrated” or “conversion” transaction or as a position in a “straddle” for U.S. federal income tax purposes;
- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities (including S Corporations), or persons that will hold the ordinary shares through such an entity;
- persons that received our ordinary shares as compensation for the performance of services;
- certain former citizens or long-term residents of the United States;
- holders that own directly, indirectly, or through attribution 10% or more of the voting power or value of our ordinary shares; and
- holders that have a “functional currency” for U.S. federal income tax purposes other than the U.S. dollar.

Further, this summary does not address the U.S. federal estate, gift, or alternative minimum tax considerations, or any U.S. state, local, or non-U.S. tax considerations of the ownership and disposition of the ordinary shares.

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds ordinary shares, the U.S. federal income tax consequences relating to an investment in our ordinary shares will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax considerations of owning and disposing of our ordinary shares in its particular circumstances.

For the purposes of this summary, a “U.S. holder” is a beneficial owner of ordinary shares that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;

- a corporation, or other entity that is treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust or has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a “passive foreign investment company,” or a PFIC.

Persons considering an investment in our ordinary shares should consult their own tax advisors as to the particular tax consequences applicable to them relating to ownership and disposition of our ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Distributions. Although we do not currently plan to pay dividends, and subject to the discussion under “— Passive Foreign Investment Company Considerations” below, the gross amount of any distribution (before reduction for any amounts withheld in respect of Belgian withholding tax) actually or constructively received by a U.S. holder with respect to ordinary shares will be taxable to the U.S. holder as a dividend to the extent of the U.S. holder’s pro rata share of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder’s adjusted tax basis in the ordinary shares. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as either long-term or short-term capital gain depending upon whether the U.S. holder has held the ordinary shares for more than one year as of the time such distribution is received. However, since we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Non-corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below) if we are a “qualified foreign corporation” and certain other requirements (discussed below) are met. A non-U.S. corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on ordinary shares which are readily tradable on an established securities market in the United States. The ordinary shares are listed on the Nasdaq Global Select Market, or Nasdaq, which is an established securities market in the United States, and we expect the ordinary shares to be readily tradable on Nasdaq. However, there can be no assurance that the ordinary shares will be considered readily tradable on an established securities market in the United States in later years. We are incorporated under the laws of Belgium, and we believe that we qualify as a resident of Belgium for purposes of, and are eligible for the benefits of, The Convention between the Government of the United States of America and the Government of the Kingdom of Belgium for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, signed on November 27, 2006, or the U.S.-Belgium Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-Belgium Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Therefore, subject to the discussion under “— Passive Foreign Investment Company Considerations” below, such dividends will generally be “qualified dividend income” in the hands of individual U.S. holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. The dividends will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

A U.S. holder generally may claim the amount of any Belgian withholding tax as either a deduction from gross income or a credit against U.S. federal income tax liability. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Generally, the credit cannot exceed the same proportion of a U.S. holder's U.S. federal income tax liability which such U.S. holder's "foreign source" taxable income bears to such U.S. holder's worldwide taxable income. In applying this limitation, a U.S. holder's various items of income and deduction must be classified, under complex rules, as either "foreign source" or "U.S. source." In addition, this limitation is calculated separately with respect to specific categories of income. The amount of a distribution with respect to the ordinary shares that is treated as a "dividend" may be lower for U.S. federal income tax purposes than it is for Belgian income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. holder. Furthermore, Belgian income taxes that are withheld in excess of the rate applicable under the U.S.-Belgium Tax Treaty or that are refundable under Belgian law will not be eligible for credit against a U.S. holder's federal income tax liability. Each U.S. holder should consult its own tax advisors regarding the foreign tax credit rules.

In general, the amount of a distribution paid to a U.S. holder in a foreign currency will be the dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the U.S. holder receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in a foreign currency are converted into U.S. dollars on the day they are received, a U.S. holder should not be required to recognize foreign currency gain or loss in respect of the dividend.

Sale, Exchange or Other Taxable Disposition of the Ordinary Shares. A U.S. holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale, exchange or other taxable disposition of ordinary shares in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or exchange and the U.S. holder's tax basis for those ordinary shares. Subject to the discussion under "— Passive Foreign Investment Company Considerations" below, this gain or loss will generally be a capital gain or loss. The adjusted tax basis in the ordinary shares generally will be equal to the cost of such ordinary shares. Capital gain from the sale, exchange or other taxable disposition of ordinary shares of a non-corporate U.S. holder is generally eligible for a preferential rate of taxation applicable to capital gains, if the non-corporate U.S. holder's holding period determined at the time of such sale, exchange or other taxable disposition for such ordinary shares exceeds one year (i.e., such gain is a long-term taxable gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of the ordinary shares that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer that does not make such an election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. holder realizes will be U.S. source ordinary income or loss.

Net Investment Income Tax. Certain U.S. holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ordinary shares. Each U.S. holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Net Investment Income tax to its income and gains in respect of its investment in the ordinary shares.

Passive Foreign Investment Company Considerations. If we are a PFIC for any taxable year, a U.S. holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A corporation organized outside the United States generally will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of its subsidiaries, either: (i) at least 75% of its gross income is “passive income” or (ii) at least 50% of the average quarterly value of its total gross assets, for which purpose, assuming we are treated as a publicly traded company pursuant to Section 1297(e)(3) of the Code, the total value of our assets may be determined in part by reference to the market value of its ordinary shares, which is subject to change) is attributable to assets that produce “passive income” or are held for the production of “passive income.”

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of cash, including the funds raised in offerings of the ordinary shares. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation’s income for purposes of the PFIC tests. If we are classified as a PFIC for any year with respect to which a U.S. holder owns ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns ordinary shares, regardless of whether we continue to meet the tests described above.

Whether we are a PFIC for any taxable year will depend on the composition of our income and the projected composition and estimated fair market values of our assets in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC for any taxable year. The market value of our assets is generally determined in large part by reference to the market price of the ordinary shares, which is likely to fluctuate. Based on the foregoing, with respect to our 2021 taxable year, we do not anticipate that we will be a PFIC based upon the expected value of our assets, including any goodwill, and the expected composition of our income and assets, however, as previously mentioned, we cannot provide any assurances regarding our PFIC status for the current or future taxable years. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for the current or any future taxable year.

If we are a PFIC for any taxable year, then unless you make one of the elections described below, a special tax regime will apply to both (a) any “excess distribution” by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for the ordinary shares) and (b) any gain realized on the sale or other disposition of the ordinary shares. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. holder’s regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under “— Distributions.”

If we are a PFIC for any year during which a U.S. holder holds our ordinary shares, we must generally continue to be treated as a PFIC by that U.S. holder for all succeeding years during which the U.S. holder holds our ordinary shares, unless we cease to meet the requirements for PFIC status and the U.S. holder makes a “deemed sale” election with respect to our ordinary shares. If such election is made, the U.S. holder will be deemed to have sold our ordinary shares it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences applicable to sales of PFIC shares described above. After the deemed sale election, the U.S. holder’s ordinary shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

Certain elections exist that would result in an alternative treatment (such as mark-to-market treatment) of the ordinary shares. If a U.S. holder makes the mark-to-market election, the U.S. holder generally will recognize as ordinary income any excess of the fair market value of the ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. holder makes the election, the U.S. holder's tax basis in the ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The mark-to-market election is available only if we are a PFIC and our ordinary shares are "regularly traded" on a "qualified exchange." Our ordinary shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of our ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement as disregarded). Nasdaq is a qualified exchange for this purpose and, consequently, if our ordinary shares are regularly traded, the mark-to-market election will be available to a U.S. holder. However, even if a U.S. holder validly makes a mark-to-market election with respect to our ordinary shares, the U.S. holder may continue to be subject to PFIC rules (described above) with respect to its indirect interest in any of our investments that are lower-tier PFICs (as defined below). In addition, it is possible that a mark-to-market election in our ordinary shares may result in a U.S. holder being taxed on the earnings and profits of a lower-tier PFIC that will result in a double counting of the same income.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a U.S. holder were able to make a valid "qualified electing fund," or QEF, election. However, we do not currently intend to provide the information necessary for U.S. holders to make a QEF election if we were treated as a PFIC for any taxable year and prospective investors should assume that a QEF election will not be available. U.S. holders should consult their tax advisors to determine whether any of these above elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. holders in respect of any of our subsidiaries that also may be determined to be PFICs ("lower-tier PFICs").

If a U.S. holder owns ordinary shares during any taxable year in which we are a PFIC, the U.S. holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company and any lower-tier PFICs, generally with the U.S. holder's federal income tax return for that year. If our company were a PFIC for a given taxable year, then you should consult your tax advisor concerning your annual filing requirements.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisers with respect to ownership and disposition of our ordinary shares, the consequences to them of an investment in a PFIC, any elections available with respect to our ordinary shares and the IRS information reporting obligations with respect to ownership and disposition of the ordinary shares.

Backup Withholding and Information Reporting. U.S. holders generally will be subject to information reporting requirements with respect to dividends on ordinary shares and on the proceeds from the sale, exchange or disposition of ordinary shares that are paid within the United States or through U.S.-related financial intermediaries, unless the U.S. holder is an "exempt recipient." In addition, U.S. holders may be subject to backup withholding on such payments, unless the U.S. holder provides a correct taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting. Certain U.S. holders who are individuals and certain entities controlled by individuals may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ordinary shares.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

Material Belgian Tax Consequences

The following are the material Belgian federal income tax consequences of the acquisition, ownership and disposal of shares by an investor, but does not address all tax consequences of the ownership and disposal of shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. The following does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, shares as a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions.

A Belgian resident is (i) an individual subject to Belgian personal income tax (i.e. an individual who has his domicile in Belgium or has the seat of his estate in Belgium, or a person assimilated to a Belgian resident), (ii) a company subject to Belgian corporate income tax, i.e. a company that has its principal establishment, administrative seat or effective place of management in Belgium (and that is not excluded from the scope of the Belgian corporate income tax) (A company having its registered seat in Belgium shall be presumed, unless the contrary is proved, to have its principal establishment, administrative seat or effective place of management in Belgium), (iii) an Organization for Financing Pensions, or an OFP, subject to Belgian corporate income tax (i.e., a Belgian pension fund incorporated under the form of an OFP), or (iv) a legal entity subject to the Belgian tax on legal entities (i.e. a legal entity other than a company subject to the corporate income tax that has its principal establishment, administrative seat or effective place of management in Belgium). A Belgian non-resident is a person that is not a Belgian resident.

Investors are encouraged to consult their own advisers as to the tax consequences of the acquisition, ownership and disposal of the shares.

Belgian taxation of dividends on Shares

For Belgian income tax purposes, the gross amount of all distributions made by the company to its shareholders is generally taxed as a dividend distribution, except for the repayment of capital carried out in accordance with the Belgian Code on Companies and Associations to the extent that such repayment is imputed to the "fiscal" capital. The fiscal capital includes, in principle, the actual paid-up statutory capital and, subject to certain conditions, the paid issue premiums and the amounts subscribed to at the time of the issue of profit sharing certificates. Note that Article 18 of the Belgian Income Tax Code 1992 ("ITC") was amended by the law of 25 December 2017. As a consequence, for any decision of capital reduction taken as from 1 January 2018 in accordance with the Belgian Code on Companies and Associations, the amount of the capital reduction will be deemed to be derived proportionally (a) from our fiscal capital, on the one hand and (b) on the other hand, from the total of (i) certain taxed reserves incorporated in our capital, (ii) certain taxed reserves not incorporated into our capital and (iii) certain untaxed reserves incorporated into our capital (it being understood that the imputation of the capital reduction on these different categories of reserves will be made in that order of priority). The part of the capital reduction that is deemed to be derived from the abovementioned taxed and untaxed reserves will be treated as a dividend distribution from a tax perspective and be subject to Belgian withholding tax, if applicable. The part of the capital reduction that is deemed to derive from the abovementioned untaxed reserves may additionally give rise to a corporate income tax charge at the level of the company.

In general, a Belgian withholding tax of (currently) 30% is levied on dividends. In the case of a redemption of shares, the redemption price (after deduction of the part of the paid-up fiscal capital represented by the shares redeemed) will be treated as dividend that is subject to a Belgian withholding tax of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if such redemption is carried out on a stock exchange and meets certain conditions. In the event of our liquidation, a withholding tax of 30% will be levied on any distributed amount exceeding the paid-up fiscal capital, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Belgian tax law provides for certain exemptions from Belgian withholding tax on Belgian source dividends. If there is no exemption applicable under Belgian domestic tax law, the Belgian withholding tax can potentially be reduced or exempted for investors who are non-residents pursuant to the treaties regarding the avoidance of double taxation concluded between the Kingdom of Belgium and the state of residence of the non-resident shareholder (see below).

Belgian income tax

Belgian resident individuals

Belgian resident individuals who hold ordinary shares offered hereby as a private investment do not have to declare the dividend income in their personal income tax return since the 30% Belgian withholding tax fully discharges their personal income tax liability. If the dividend income would be declared in the personal income tax return, it will be taxed at 30% or, if lower, at the progressive personal income tax rates applicable to the taxpayer's overall declared income. The first EUR 800 (amount applicable for income year 2021) of reported ordinary dividend income will be exempt from tax, subject to certain conditions. For the avoidance of doubt, all reported dividends (hence, not only dividends distributed on the shares) are taken into account to assess whether said maximum amount is reached.

If the dividends are declared in the personal income tax return, the Belgian withholding tax paid can be credited against the final personal income tax liability of the investor and may also be refunded to the extent that it exceeds the final personal income tax liability, provided that the dividend distribution does not result in a reduction in value of, or capital loss on, the shares. This condition is not applicable if the Belgian individual can demonstrate that he has had full ownership of the shares during an uninterrupted period of 12 months prior to the attribution of the dividends.

Belgian resident individuals who acquire and hold the shares for professional purposes must always declare the dividend income in their personal income tax return and will be taxable at the individual's personal income tax rate increased with local surcharges. Withholding tax withheld at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, subject to two conditions: (i) the taxpayer must own the shares in full legal ownership on the day the beneficiary of the dividend is identified, and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the shares. The latter condition is not applicable if the individual can demonstrate that he has held the full legal ownership of the shares for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

Belgian resident companies

For Belgian resident companies, the dividend withholding tax does not fully discharge the corporate income tax liability. For such companies, the gross dividend income (including the Belgian withholding tax and excluding the foreign withholding tax, if any) must be declared in the corporate income tax return and will be added to their taxable income, which is, in principle, taxed at the ordinary corporate income tax rate of 25% (as of assessment year 2021 for financial years starting on or after 1 January 2020). In certain circumstances and subject to certain conditions, a reduced corporate income tax rate of 20% (as of assessment year 2021 for financial years starting on or after 1 January 2020) applies to small companies and Medium Sized Enterprises (as defined by Article 1:24, §1 to §6 of the Belgian Code on Companies and Associations) on the first EUR 100,000 of taxable profits.

Belgian resident companies can generally deduct up to 100% of the gross dividend received from the taxable income ("dividend received deduction"), provided that at the time of a dividend payment or attribution: (1) the Belgian resident company holds shares representing at least 10% of the share capital of the company or a participation in the company with an acquisition value of at least EUR 2,500,000; (2) the shares have been held or will be held in full legal ownership for an uninterrupted period of at least one year; and (3) the conditions relating to the taxation of the underlying distributed income, as described in article 203 of the ITC are met (together the "Conditions for the application of the dividend received deduction regime").

For qualifying investment companies, certain of the aforementioned conditions with respect to the dividend received deduction do not apply. The Conditions for the application of the dividend received deduction regime depend on a factual analysis and for this reason the availability of this regime should be verified upon each dividend distribution.

The Belgian withholding tax may, in principle, be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due, subject to the two following conditions: (i) the taxpayer must own the shares in full legal ownership on the day the beneficiary of the dividend is identified and (ii) the dividend distribution may not give rise to a reduction in the value of, or a capital loss on, the shares. The latter condition is not applicable if the company proves that it held the shares in full legal ownership during an uninterrupted period of 12 months prior to the attribution of the dividends or if, during that period, the shares never belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the Shares in a Belgian establishment.

No Belgian withholding tax will be due on dividends paid by us to a resident company provided the resident company owns, at the time of the distribution of the dividend, at least 10% of our share capital for an uninterrupted period of at least one year and, provided further, that the resident company provides us or our paying agent with a certificate as to its status as a resident company and as to the fact that it has owned a 10% shareholding for an uninterrupted period of one year. For those companies owning a share participation of at least 10% in our share capital for less than one year, we will levy the withholding tax but will not transfer it to the Belgian Treasury provided that the Belgian resident company certifies its qualifying status, the date from which it has held such minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The Belgian resident company must also inform us or our paying agent if the one-year period has expired or if its shareholding will drop below 10% of our share capital before the end of the one-year holding period. As soon as the investor owns the share participation of at least 10% in our capital for one year, it will receive the amount of this temporarily levied withholding tax.

Please note that the above described dividend received deduction and withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements ("rechtshandeling of geheel van rechtshandelingen"/"acte juridique ou un ensemble d'actes juridiques") for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine ("kunstmatig"/"non authentique") and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the EU Parent-Subsidiary Directive of 30 November 2011 (2011/96/EU) ("Parent-Subsidiary Directive") in another EU Member State. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Belgian resident organisations for financing pensions

For Belgian pension funds incorporated under the form of an Organization for Financing Pensions ("organismen voor de financiering van pensioenen"/"organismes de financement de pensions") within the meaning of article 8 of the Belgian Act of 27 October 2006, the dividend income is generally tax exempt. Subject to certain limitations, any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due.

Belgian (or foreign) OFPs not holding the Shares — which give rise to dividends — for an uninterrupted period of 60 days in full ownership amounts to a rebuttable presumption that the arrangement or series of arrangements ("rechtshandeling of geheel van rechtshandelingen"/"acte juridique ou un ensemble d'actes juridiques") which are connected to the dividend distributions, are not genuine ("kunstmatig"/"non authentique"). The withholding tax exemption will in such case not apply and/or any Belgian dividend withholding tax levied at source on the dividends will in such case not be credited against the corporate income tax, unless counterproof is provided by the OFP that the arrangement or series of arrangements are genuine.

Other Belgian resident legal entities subject to Belgian legal entities tax

Belgian resident legal entities will be subject to the Belgian withholding tax on the dividends distributed by us. Under the current Belgian tax rules, Belgian withholding tax will represent the final tax liability and the dividends should, therefore, not be included in the tax returns of the legal entities.

Non-resident individuals and companies

For non-resident individuals and companies, the dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds the shares in connection with a business conducted in Belgium through a fixed base in Belgium or a Belgian permanent establishment.

If the shares are acquired by a non-resident in connection with a business in Belgium, the investor must report any dividends received, which will be taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Belgian withholding tax levied at source may be credited against non-resident individual or corporate income tax and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (1) the taxpayer must own the shares in full legal ownership on the day the beneficiary of the dividend is identified and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the shares. The latter condition is not applicable if (a) the non-resident individual or the non-resident company can demonstrate that the shares were held in full legal ownership for an uninterrupted period of 12 months prior to the payment or attribution of the dividends or (b) with regard to non-resident companies only, if, during the relevant period, the shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the shares in a Belgian establishment.

Non-resident companies whose Shares are invested in a Belgian PE may deduct 100% of the gross dividends received from their taxable income if, at the date the dividends are paid or attributed, the Conditions for the application of the dividend received deduction regime are met (see supra). Application of the dividend received deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Belgian dividend withholding tax relief for non-residents

Dividends distributed to non-resident individuals who do not use the Shares in the exercise of a professional activity, may be eligible for the tax exemption with respect to ordinary dividends in an amount of up to EUR 800 (amount applicable for income year 2021) per year. For the avoidance of doubt, all dividends paid or attributed to such non-resident individual (and hence not only dividends paid or attributed on the Shares) are taken into account to assess whether said maximum amount is reached. Consequently, if Belgian withholding tax has been levied on dividends paid or attributed to the Shares, such non-resident individual may request in its Belgian non-resident income tax return that any Belgian withholding tax levied on up to such an amount be credited and, as the case may be, reimbursed. However, if no Belgian non-resident income tax return has to be filed by the non-resident individual, any Belgian withholding tax levied on up to such an amount could in principle be reclaimed by filing a request thereto addressed to the tax official (“Adviseur-generaal Centrum Buitenland”/”Conseiller-général du Centre Étranger”) appointed by the Royal Decree of 28 April 2019. Such a request has to be made at the latest on 31 December of the calendar year following the calendar year in which the relevant dividend(s) have been received, together with an affidavit confirming the non-resident individual status and certain other formalities determined in the Royal Decree.

Belgian tax law provides for certain exemptions from withholding tax on Belgian source dividends distributed to non-resident investors. Under Belgian tax law, withholding tax is not due on dividends paid to a foreign pension fund which satisfies the following conditions: (i) it is a non-resident saver within the meaning of Article 227, 3° of the Belgian Income Tax Code which implies that it has separate legal personality and has its tax residence outside of Belgium; (ii) whose corporate purpose consists solely in managing and investing funds collected in order to pay legal or complementary pensions; (iii) whose activity is limited to the investment of funds collected in the exercise of its corporate purpose, without any profit making aim; (iv) which is exempt from income tax in its country of residence; and (v) provided that it is not contractually obliged to redistribute the dividends to any ultimate beneficiary of such dividends for whom it would manage the Shares, nor obliged to pay a manufactured dividend with respect to the Shares under a securities borrowing transaction. The exemption will only apply if the foreign pension fund provides a certificate confirming that it is the full legal owner or usufruct holder of the Shares and that the above conditions are satisfied. The pension fund must then forward that certificate to us or our paying agent.

Dividends distributed to non-resident qualifying parent companies established in a Member State of the EU or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause, will, under certain conditions, be exempt from Belgian withholding tax provided that the Shares held by the non-resident company, upon payment or attribution of the dividends, amount to at least 10% of our share capital and such minimum participation is held or will be held during an uninterrupted period of at least one year. A non-resident company qualifies as a parent company provided that (i) for companies established in a Member State of the EU, it has a legal form as listed in the annex to the EU Parent-Subsidiary Directive, as amended from time to time, or, for companies established in a country with which Belgium has concluded a qualifying double tax treaty, it has a legal form similar to the ones listed in such annex; (ii) it is considered to be a tax resident according to the tax laws of the country where it is established and the double tax treaties concluded between such country and third countries; and (iii) it is subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime. In order to benefit from this exemption, the non-resident company must provide us or our paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions.

If the non-resident company holds a minimum participation for less than one year at the time the dividends are attributed to the Shares, we must levy the withholding tax but does not need to transfer it to the Belgian Treasury provided that the non-resident company provides us or our paying agent with a certificate confirming, in addition to its qualifying status, the date as of which it has held the minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The non-resident company must also inform us or our paying agent when the one-year period has expired or if its shareholding drops below 10% of our share capital before the end of the oneyear holding period. Upon satisfying the one-year holding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the non-resident company.

Please note that the above withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements (“rechtshandeling of geheel van rechtshandelingen”/”acte juridique ou un ensemble d’actes juridiques”) for which the tax Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine (“kunstmatig”/”non authentique”) and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the Parent-Subsidiary Directive in another EU Member State. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Dividends distributed by a Belgian company to non-resident companies on a share participation of less than 10% will under certain conditions be subject to an exemption from withholding tax, provided that the non- resident companies (i) are either established in another Member State of the EEA or in a country with which Belgium has concluded a double tax treaty, where that treaty, or any other treaty concluded between Belgium and that jurisdiction, includes a qualifying exchange of information clause; (ii) have a legal form as listed in Annex I, Part A to the Parent-Subsidiary Directive as amended from time to time, or a legal form similar to the legal forms listed in the aforementioned annex and which is governed by the laws of another Member State of the EEA or a similar legal form in a country with which Belgium has concluded a double tax treaty; (iii) hold a share participation in the Belgian dividend distributing company, upon payment or attribution of the dividends, of less than 10% of our share capital but with an acquisition value of at least €2.5 million; (iv) hold or will hold the Shares which give rise to the dividends in full legal ownership during an uninterrupted period of at least one year; and (v) are subject to the corporate income tax or a tax regime similar to the corporate income tax without benefiting from a tax regime which deviates from the ordinary regime. The exemption from withholding tax is only applied to the extent that the Belgian withholding tax, which would be applicable absent the exemption, could not be credited nor reimbursed at the level of the qualifying, dividend receiving, company. The non-resident company must provide us or our paying agent with a certificate confirming, in addition to its full name, legal form, address and fiscal identification number (if applicable), its qualifying status and the fact that it meets the required conditions mentioned under (i) to (v) above, and indicating to which extent the withholding tax, which would be applicable absent the exemption, is in principle creditable or reimbursable on the basis of the law as applicable on December 31 of the year preceding the year during which the dividend is paid or attributed.

If there is no exemption applicable under Belgian domestic tax law, the Belgian dividend withholding tax can potentially be reduced or exempted for investors who are non-residents pursuant to the treaties regarding the avoidance of double taxation concluded between the Kingdom of Belgium and the state of residence of the non-resident shareholder. Belgium has concluded tax treaties with more than 95 countries, reducing the dividend withholding tax rate to 15%, 10%, 5% or 0% for residents of those countries, depending on conditions, among others, related to the size of the shareholding and certain identification formalities.

Belgium and the United States have concluded a double tax treaty concerning the avoidance of double taxation (the “U.S. — Belgium Treaty”). The U.S. — Belgium Treaty reduces the applicability of Belgian withholding tax to 15%, 5% or 0% for U.S. taxpayers, provided that the U.S. taxpayer meets the limitation of benefits conditions imposed by the U.S. — Belgium Treaty. The Belgian withholding tax is generally reduced to 15% under the U.S. — Belgium Treaty. The 5% withholding tax applies in case where the U.S. shareholder (beneficial owner) is a company which owns directly at least 10% of our shares. A 0% Belgian withholding tax applies when the shareholder is a company (beneficial owner) which has owned directly at least 10% of our shares during at least 12 months, or is, subject to certain conditions, a U.S. pension fund. The U.S. shareholders are encouraged to consult their own tax advisers to determine whether they can invoke the benefits and meet the limitation of benefits conditions as imposed by the U.S. — Belgium Treaty.

Prospective holders are encouraged to consult their own tax advisers to determine whether they qualify for an exemption or a reduction of the withholding tax rate upon payment of dividends and, if so, the procedural requirements for obtaining such an exemption or a reduction upon the payment of dividends or making claims for reimbursement.

Capital gains and losses on Shares

Belgian resident individuals

Belgian resident individuals acquiring the shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the shares and capital losses are not tax deductible. However, capital gains realized by a private individual are taxable at 33% (plus local surcharges) if the capital gain is deemed to be realized outside the scope of the normal management of the individual’s private estate. Capital losses incurred in such transactions are generally not tax deductible.

Capital gains realized by Belgian resident individuals on the disposal of the shares for consideration, outside the exercise of a professional activity, to a non-resident company (or a body constituted in a similar legal form), to a foreign state (or one of its political subdivisions or local authorities) or to a non-resident legal entity, each time established outside the EEA, are in principle taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned directly or indirectly, alone or with his/her spouse or with certain relatives, a substantial shareholding in us (i.e., a shareholding of more than 25% in us). Capital losses are, however, not tax deductible in such event.

Capital gains realised by Belgian resident individuals upon redemption of the Shares or upon our liquidation will generally be taxable as a dividend. See “— Belgian taxation of dividends on Shares — Belgian income tax — Belgian resident individuals.”

Belgian resident individuals who hold shares for professional purposes are taxed at the ordinary progressive income tax rates increased by the applicable local surcharges on any capital gains realized upon the disposal of the shares, except for the Shares held for more than five years, which are taxable at a separate rate of 10% (capital gains realised in the framework of the cessation of activities under certain circumstances) or 16.5% (other), plus local surcharges. Capital losses on the Shares incurred by Belgian resident individuals who hold the Shares for professional purposes are in principle tax deductible.

Belgian resident companies

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of the shares provided that the Conditions for the application of the dividend received deduction regime are met. If one or more of the Conditions for the application of the dividend received deduction regime are not met, any capital gain realised would be taxable at the standard corporate income tax rate of 25% (as of assessment year 2021 for financial years starting on or after January 1, 2020), unless the reduced corporate income tax rate of 20% for small companies and Medium Sized Enterprises applies (see supra).

Capital losses on the Shares incurred by Belgian resident companies are as a general rule not tax deductible.

However, shares held in the trading portfolios of Belgian qualifying credit institutions, investment enterprises and management companies of collective investment undertakings are subject to a different regime. In general, the capital gains on such shares are taxable at the corporate income tax rate of 25% and capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

Capital gains realised by Belgian resident companies upon redemption of the Shares or upon our liquidation will, in principle, be subject to the same taxation regime as dividends.

Belgian resident organisations for financing pensions

Belgian pension funds incorporated under the form of an OFP are, in principle, not subject to Belgian capital gains taxation on the disposal of the shares, and capital losses are not tax deductible.

Capital gains realized by Belgian OFPs upon the redemption of ordinary shares or upon the our liquidation will in principle be taxed as dividends.

Other Belgian resident legal entities subject to Belgian legal entities tax

Capital gains realised upon disposal of the Shares by Belgian resident legal entities are in principle not subject to Belgian income tax and capital losses are not tax deductible.

Capital gains realised upon disposal of (part of) a substantial participation in a Belgian company (i.e. a participation representing more than 25% of our share capital at any time during the last five years prior to the disposal) may, however, under certain circumstances be subject to income tax in Belgium at a rate of 16.5%.

Capital gains realised by Belgian resident legal entities upon redemption of the Shares or upon our liquidation will, in principle, be subject to the same taxation regime as dividends.

Non-resident individuals, non-resident companies or non-resident entities

Non-resident individuals, companies or entities are, in principle, not subject to Belgian income tax on capital gains realised upon disposal of the Shares, unless the Shares are held as part of a business conducted in Belgium through a fixed base in Belgium or a Belgian PE. In such a case, the same principles apply as described with regard to Belgian individuals (holding the Shares for professional purposes), Belgian companies, Belgian resident organisations for financing pensions or other Belgian resident legal entities subject to Belgian legal entities tax.

Non-resident individuals who do not use the Shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the Shares to Belgium, might be subject to tax in Belgium if the capital gains are obtained or received in Belgium and arise from transactions which are to be considered speculative or beyond the normal management of one’s private estate or in case of disposal of a substantial participation in a Belgian company as mentioned in the tax treatment of the disposal of the shares by Belgian individuals (see supra). Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax adviser.

Capital gains realised by non-resident individuals or non-resident companies upon redemption of the Shares or upon our liquidation will, in principle, be subject to the same taxation regime as dividends.

Belgian Tax on Stock Exchange Transactions

A tax on stock exchange transactions (*Taxe sur les opérations de bourse / Taks op de beursverrichtingen*) at the rate of 0.35% (subject to a maximum amount of EUR 1,600 per party and per transaction) will in principle be levied upon the sale and purchase and any other acquisition or transfer for consideration of the Shares on the secondary market if (i) it is entered into or carried out in Belgium through a professional intermediary, or (ii) deemed to be entered into or carried out in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence (gewone verblijfplaats/residence habituelle) in Belgium, or legal entities for the account of their seat or establishment in Belgium (both, a "Belgian Investor"). A separate tax is due from each of the seller and the purchaser, both collected by the professional intermediary. No tax on stock exchange transactions will be due on the issuance of the Shares (primary market transaction).

However, if the order is directly or indirectly made to a professional intermediary established outside of Belgium by a Belgian Investor, the tax on stock exchange transactions will in principle be due by this Belgian Investor (who will be responsible for the filing of a stock exchange tax return and for the timely payment of the amount of stock exchange tax due), unless that Belgian Investor can demonstrate that the tax on stock exchange transactions due has already been paid by the professional intermediary established outside of Belgium. In such a case, the foreign professional intermediary also has to provide each client (which gives such intermediary an order) with a qualifying order statement ("bordereau"/"borderel"), at the latest on the business day after the day the transaction concerned was realised. The qualifying order statements must be numbered in series and a duplicate must be retained by the professional intermediary. The duplicate can be replaced by a qualifying day-to-day listing, numbered in series. Alternatively, professional intermediaries established outside of Belgium could appoint a stock exchange tax representative in Belgium, subject to certain conditions and formalities ("Stock Exchange Tax Representative"). Such Stock Exchange Tax Representative will then be liable towards the Belgian Treasury for the tax on stock exchange transactions due on behalf of clients that fall within one of the aforementioned categories (provided that these clients do not qualify as exempt persons for stock exchange tax purposes — see below) and for complying with the reporting obligations and the obligations relating to the order statement (bordereau/borderel) in that respect. If such a Stock Exchange Tax Representative would have paid the tax on stock exchange transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the tax on stock exchange transactions.

Moreover, a tax on repurchase transactions (*taks op de reportverrichtingen/taxe sur les reports* (tax on a sale combined with a forward purchase) at the rate of 0.085 per cent (subject to a maximum of EUR 1,600 per party and per transaction) will be due from each party to any such transaction entered into or settled in Belgium in which a stockbroker acts for either party.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in article 2, 9° and 10° of the Belgian Law of 2 August 2002 on the supervision of the financial sector and financial services; (ii) insurance companies described in article 2, §1 of the Belgian Law of 9 July 1975 on the supervision of insurance companies; (iii) pension institutions referred to in article 2,1° of the Belgian Law of 27 October 2006 concerning the supervision of pension institutions; (iv) undertakings for collective investment; (v) regulated real estate companies; and (vi) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

As stated below, the tax on stock exchange transactions and the tax on repurchase transactions should be abolished once the FTT enters into force. The proposal is still subject to negotiation between the participating Member States and therefore may be changed at any time.

Other Income Tax Considerations

In addition to the income tax consequences discussed above, we may be subject to tax in one or more other jurisdictions where we conduct activities. The amount of any such tax imposed upon our operations may be material.

New annual tax on securities accounts

On 17 February 2021, the new annual tax on securities accounts ("solidarity contribution") has been adopted by the Belgian Parliament (publication in the Belgian State Gazette on 25 February 2021).

The tax is levied at a rate of 0.15% on the average value of taxable financial instruments held on securities accounts during a reference period of twelve consecutive months (in principle) starting on 1 October and ending on 30 September of the subsequent year. The tax targets securities accounts held by resident individuals, companies and legal entities, irrespective as to whether these accounts are held with a financial intermediary which is established or located in Belgium or abroad. The tax also applies to securities accounts held by non-resident individuals, companies and legal entities with a financial intermediary established or located in Belgium. The financial instruments envisaged include not only shares, bonds and notes, but also derivatives. When applicable, the amount of the tax would be limited to 10% of the difference between the taxable base and the threshold of EUR 1 million. Each securities account would be assessed separately. When multiple holders hold a securities account, each holder shall be jointly and severally liable for the payment of the tax and each holder may fulfill the declaration requirements for all holders.

There are various exemptions, such as securities accounts held by specific types of regulated entities for their own account.

A financial intermediary is defined as (i) the National Bank of Belgium, the European Central Bank and foreign central banks performing similar functions, (ii) a central securities depository included in article 198/1, §6, 12° of the Belgian Income Tax Code, (iii) a credit institution or a stockbroking firm as defined by Article 1, §3 of the Law of 25 April 2014 on the status and supervision of credit institutions and investment companies and (vi) the investment companies as defined by Article 3, §1 of the Law of 25 October 2016 on access to the activity of investment services and on the legal status and supervision of portfolio management and investment advice companies, which are, pursuant to national law, admitted to hold financial instruments for the account of customers.

An anti-abuse provision is also included to counter certain actions to avoid the tax, such as moving the taxable financial instruments to multiple security accounts to avoid exceeding the EUR 1 million threshold, converting taxable financial instruments into non-taxable nominative securities, or transferring to foreign securities accounts, among others. The anti-abuse provisions apply retroactively as from 30 October 2020.

Investors are advised to consult their tax advisors about the consequences of the tax on securities accounts on their own tax situation.

Common Reporting Standard

Following recent international developments, the exchange of information is governed by the Common Reporting Standard ("CRS"). More than 100 jurisdictions have signed the multilateral competent authority agreement ("MCAA"). The MCAA is a multilateral framework agreement to automatically exchange financial and personal information, with the subsequent bilateral exchanges coming into effect between those signatories that file the subsequent notifications.

More than 45 jurisdictions, including Belgium, have committed to a specific and ambitious timetable leading to the first automatic information exchanges in 2017, relating to income year 2016 ("early adopters"). More than 50 jurisdictions have committed to exchange information as from 2018.

Under CRS, financial institutions resident in a CRS country are required to report, according to a due diligence standard, financial information with respect to reportable accounts, which includes interest, dividends, account balance or value, income from certain insurance products, sales proceeds from financial assets and other income generated with respect to assets held in the account or payments made with respect to the account. Reportable accounts include accounts held by individuals and entities (which includes trusts and foundations) with fiscal residence in another CRS country. The standard includes a requirement to look through passive entities to report on the relevant controlling persons.

On 9 December 2014, EU Member States adopted Directive 2014/107/EU on administrative cooperation in direct taxation ("DAC2"), which provides for mandatory automatic exchange of financial information as foreseen in CRS. DAC2 amends the previous Directive on administrative cooperation in direct taxation, Directive 2011/16/EU.

The mandatory automatic exchange of financial information by EU Member States as foreseen in DAC2 started as of 30 September 2017 (as of 30 September 2018 for Austria).

The Belgian government has implemented said Directive 2014/107/EU, respectively the Common Reporting Standard, per the Law of 16 December 2015 regarding the exchange of information on financial accounts by Belgian financial institutions and by the Belgian tax administration, in the context of an automatic exchange of information on an international level and for tax purposes.

As a result of the Law of 16 December 2015, the mandatory automatic exchange of information applies in Belgium (i) as of income year 2016 (first information exchange in 2017) towards the EU Member States, (ii) as of income year 2014 (first information exchange in 2016) towards the US and (iii), with respect to any other non-EU States that have signed the MCAA, as of the respective date as determined by the Royal Decree of 14 June 2017. The Royal Decree provides that (i) for a first list of 18 countries, the mandatory exchange of information applies as of income year 2016 (first information exchange in 2017) and (ii) for a second list of 44 countries, the mandatory automatic exchange of information applies as of income year 2017 (first information exchange in 2018), (iii) as from 2019 (for the 2018 financial year) for another single jurisdiction and (iv) as from 2020 (for the 2019 financial year) for a third list of 6 jurisdictions.

Investors who are in any doubt as to their position should consult their professional advisers

The proposed financial transactions tax (“FTT”)

On 14 February 2013, the European Commission published a proposal (the “Commission’s Proposal”) for a Directive for a common financial transaction tax (“FTT”), to be levied on transactions in financial instruments by financial institutions if at least one of the parties to the transaction is located in the ‘FTT-zone’ as defined in the Commission’s Proposal. It was approved by the European Parliament in July 2013. Originally, the adopted Commission’s Proposal foresaw the financial transaction tax for 11 “Participating Member States” (Belgium, Germany, Estonia, Greece, Spain, France, Italy, Austria, Portugal, Slovenia and Slovakia). However, on 16 March 2016 Estonia formally withdrew from the group of states willing to introduce the FTT. The actual implementation date of the FTT would depend on the future approval of the European Council and consultation of other EU institutions, and the subsequent transposition into local law.

If the financial transaction tax is introduced, under current published proposals financial institutions and certain other parties would be required to pay tax on transactions in financial instruments with parties (including, with respect to the EU-wide proposal, its affiliates) located in the FTT-zone. The proposed FTT has very broad scope and could, if introduced in its current form, apply to certain dealings in the Shares in certain circumstances. It is a tax on derivatives transactions (such as hedging activities) as well as on securities transactions, i.e. it applies to trading in instruments such as shares and bonds. The initial issue of instruments such as shares and bonds is exempt from financial transaction tax in the current Commission’s Proposal. This means that the issuance and subscription of the Shares should not become subject to financial transaction tax. Under current proposals the FTT could apply in certain circumstances to persons both within and outside of the participating Member States. Generally, it would apply to certain dealings in the Shares where at least one party is a financial institution, and at least one party is established in a participating Member State. A financial institution may be, or be deemed to be, “established” in a participating Member State in a broad range of circumstances, including (a) by transacting with a person established in a participating Member State or (b) where the financial instrument which is subject to the dealings is issued in a participating Member State.

In 2019, Finance Ministers of the Member States participating in the enhanced cooperation indicated that they were discussing a new FTT proposal based on the French model of the tax and the possible mutualisation of the tax as a contribution to the EU budget.

According to the latest draft of this new FTT proposal (submitted by the German government), the FTT would be levied at a rate of at least 0.2 per cent. of the consideration for the acquisition of ownership of shares (including ordinary and any preference shares) admitted to trading on a trading venue or a similar third country venue, or of other securities equivalent to such shares ("Financial Instruments") or similar transactions (e.g. an acquisition of Financial Instruments by means of an exchange of Financial Instruments or by means of a physical settlement of a derivative). The FTT would be payable to the Participating Member State in whose territory the issuer of a Financial Instrument has established its registered office. According to the latest draft of the new FTT proposal, the FTT would not apply to straight notes. Like the Commission's Proposal, the latest draft of the new FTT proposal also stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax).

As a consequence, Belgium should abolish the tax on stock exchange transactions and the tax on repurchase transactions once the FTT enters into force. However, the FTT Commission's Proposal remains subject to negotiation between the participating Member States. Further, its legality is at present uncertain. It may therefore be altered prior to any implementation, the timing of which remains unclear. Additional EU Member States may decide to participate. Prospective Noteholders are advised to seek their own professional advice in relation to the FTT.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement among us and Piper Sandler & Co., Stifel, Nicolaus & Company, Inc., and Cantor Fitzgerald & Co., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, at the initial public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of ordinary shares listed opposite its name below.

Underwriter	Number of Shares
Piper Sandler & Co.	
Stifel, Nicolaus & Company, Inc.	
Cantor Fitzgerald & Co.	
Bank Degroof Petercam SA/NV	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the ordinary shares if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the ordinary shares as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the ordinary shares, that you will be able to sell any of the ordinary shares held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the ordinary shares subject to their acceptance of the ordinary shares from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Bank Degroof Petercam SA/NV is not a U.S.-registered broker-dealer; therefore, to the extent that it intends to effect any sales of the ordinary shares in the United States, it will do so through Global Alliance Securities, LLC, its affiliated U. S.-registered broker-dealer, in accordance with the applicable U.S. securities laws and regulations, and as permitted by FINRA regulation.

The address for Piper Sandler & Co. is 800 Nicollet Mall, Suite #1000, Minneapolis, MN 55402. The address for Stifel, Nicolaus & Company, Inc. is 787 7th Ave, 11th Floor, New York, NY 10019. The address for Cantor Fitzgerald & Co. is 499 Park Avenue, 6th Floor, New York, NY 10022. The address for Bank Degroof Petercam SA/NV is Nijverheidsstraat 44, 1040 Brussels, Belgium.

Certain of our existing shareholders have indicated an interest in participating in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

Option to Purchase Additional Shares

We have granted the underwriters an option to buy up to additional ordinary shares from us to cover over-allotments, if any. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional ordinary shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

Discounts, Commissions and Expenses

The underwriters have advised us that they propose to offer the ordinary shares to the public at the initial public offering price set forth on the cover of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per ordinary share. After the offering, the initial public offering price and concession may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover of this prospectus.

The underwriting fee is equal to the public offering price per share less the amount paid by the underwriters to us per share. The following table shows the per share and total underwriting discount to be paid by the underwriters in connection with this offering, assuming either no exercise or full exercise of the option to purchase additional shares:

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discounts and commissions	$	$	$
Proceeds, before expenses, to us	$	$	$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $ million. We have agreed to reimburse the underwriters for expenses of up to $ relating to the clearance of this offering with the Financial Industry Regulatory Authority.

Indemnification of Underwriters

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

Determination of Offering Price

Prior to this offering, there has not been a public market for our ordinary shares in the United States. Consequently, the initial public offering price for our ordinary shares in this offering will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the ordinary shares will trade in the public market subsequent to the offering or that an active trading market for our ordinary shares will develop and continue after the offering.

Listing

Our ordinary shares are traded on Euronext Brussels under the symbol “NYXH.” We have applied to have our ordinary shares listed on The Nasdaq Global Market under the symbol “NYXH.”

No Sales of Similar Securities

We have agreed that we will not (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, or file with or confidentially submit to, the Securities and Exchange Commission a registration statement under the Securities Act, relating to any options or warrants to purchase our ordinary shares or any securities that are convertible into or exercisable or exchangeable for, or that represent the right to receive, our ordinary shares or any such substantially similar securities, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing or (B) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our ordinary shares or any such other securities, whether any such transaction described in clause (A) or (B) above is to be settled by delivery of our ordinary shares or such other securities, in cash or otherwise, in each case without the prior written consent of Piper

Sandler & Co., Stifel, Nicolaus & Company, Inc., and Cantor Fitzgerald & Co. for a period of 90 days after the date of this prospectus (other than the ordinary shares to be sold in this offering), subject to certain exceptions.

Our directors and executive officers and shareholders affiliated with our directors and executive officers have agreed, subject to certain exceptions, that, without the prior written consent of Piper Sandler & Co., Stifel, Nicolaus & Company, Inc., and Cantor Fitzgerald & Co. on behalf of the underwriters, they will not, or publicly disclose an intention to, during the period ending 180 days after the date of this prospectus (the "restricted period"):

- offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, any ordinary shares or any securities convertible into, exercisable or exchangeable for or that represent the right to receive ordinary shares whether now owned or hereafter acquired;
- enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of ordinary shares or any such other securities;
- make any demand for or exercise any right with respect to, the registration of any ordinary shares or any security convertible into or exercisable or exchangeable for ordinary shares; or
- publicly disclose the intention to do any of the foregoing.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the Underwriters and the lock-up parties do not apply, subject to various conditions and limitations, to certain transactions, including:

- transfers as a bona fide gift or gifts;
- transfers to any trust for the direct or indirect benefit of the lock-up party or such party's immediate family;
- if the lock-up party is a corporation, partnership, limited liability company, trust or other business entity, (A) transfers to a corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act) of the lock-up party or (B) distributions to limited partners, limited liability company members or stockholders of the lock-up party;
- if the lock-up party is a trust, transfers to the beneficiary of such trust;
- transfers by testate succession or intestate succession;
- transfers pursuant to the underwriting agreement;
- the exercise of share options or warrants granted pursuant to our equity incentive plans
- stock options, restricted stock units or other equity awards granted pursuant to the equity incentive plans, or the exercise of any warrant to purchase shares of common stock or any security convertible into or exercisable or exchangeable for common stock; or
- the establishment of a trading plan pursuant to Rule 10b5-1 of the Exchange Act.

Piper Sandler & Co., Stifel, Nicolaus & Company, Inc., and Cantor Fitzgerald & Co., in their sole discretion, may release the securities subject to the lock-up agreements described above in whole or in part at any time.

Price Stabilization, Short Positions and Penalty Bids

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the ordinary shares at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional ordinary shares in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional ordinary shares or purchasing ordinary shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional ordinary shares. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our ordinary shares in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of ordinary shares on behalf of the underwriters for the purpose of fixing or maintaining the price of the ordinary shares. A syndicate covering transaction is the bid for or the purchase of ordinary shares on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our ordinary shares or preventing or retarding a decline in the market price of our ordinary shares. As a result, the price of our ordinary shares may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the ordinary shares originally sold by such syndicate member are purchased in a syndicate covering transaction and, therefore, have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our ordinary shares. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of ordinary shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

Selling Restrictions

General

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

European Economic Area and United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each, a “Relevant State”), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a “qualified investor” within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an “offer to the public” in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the “Order”) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000. Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Germany

Each person who is in possession of this prospectus is aware of the fact that no German securities prospectus (*wertpapierprospekt*) within the meaning of the German Securities Prospectus Act (*Wertpapier-prospektgesetz*, or the Act) of the Federal Republic of Germany has been or will be published with respect to our ordinary shares. In particular, each underwriter has represented that it has not engaged and has agreed that it will not engage in a public offering in the Federal Republic of Germany within the meaning of the Act with respect to any of our ordinary shares otherwise than in accordance with the Act and all other applicable legal and regulatory requirements

Hong Kong

The ordinary shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to the ordinary shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase ordinary shares under the Israeli Securities Law, 5728 — 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728-1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the "Addressed Investors"); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 — 1968, subject to certain conditions (the "Qualified Investors"). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 — 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our ordinary shares to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in the First Addendum to the Israeli Securities Law, 5728 — 1968. In particular, we may request, as a condition to be offered ordinary shares, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 — 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 — 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 — 1968 and the regulations promulgated thereunder in connection with the offer to be issued ordinary shares; (iv) that the ordinary shares that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 — 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 — 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

Singapore

Singapore SFA Product Classification — In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of shares, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products). Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

(a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA;

(b) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA and in accordance with the conditions specified in Section 275 of the SFA; or

(c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities or

(c) securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

    (i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 276(4)(i)(B) of the SFA;

    (ii) where no consideration is or will be given for the transfer;

    (iii) where the transfer is by operation of law;

(iv) as specified in Section 276(7) of the SFA; or

(v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Switzerland

The ordinary shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the “SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the ordinary shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the ordinary shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of the ordinary shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of the ordinary shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (“CISA”). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of the ordinary shares.

United Arab Emirates

This offering has not been approved or licensed by the Central Bank of the United Arab Emirates (the “UAE”), Securities and Commodities Authority of the UAE and/or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai Financial Services Authority (“DFSA”), a regulatory authority of the Dubai International Financial Centre (“DIFC”). The offering does not constitute a public offer of securities in the UAE, DIFC and/or any other free zone in accordance with the Commercial Companies Law, Federal Law No 8 of 1984 (as amended), DFSA Offered Securities Rules and Nasdaq Dubai Listing Rules, accordingly, or otherwise. The ordinary shares may not be offered to the public in the UAE and/or any of the free zones.

The ordinary shares may be offered and issued only to a limited number of investors in the UAE or any of its free zones who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned.

France

This prospectus (including any amendment, supplement or replacement thereto) is not being distributed in the context of a public offering in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (*Code monétaire et financier*).

This prospectus has not been and will not be submitted to the French *Autorité des marchés financiers* (the “AMF”) for approval in France and accordingly may not and will not be distributed to the public in France.

Pursuant to Article 211-3 of the AMF General Regulation, French residents are hereby informed that:

1. the transaction does not require a prospectus to be submitted for approval to the AMF;
2. persons or entities referred to in Point 2°, Section II of Article L.411-2 of the Monetary and Financial Code may take part in the transaction solely for their own account, as provided in Articles D. 411-1, D. 734-1, D. 744-1, D. 754-1 and D. 764-1 of the Monetary and Financial Code; and

3. the financial instruments thus acquired cannot be distributed directly or indirectly to the public otherwise than in accordance with Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the Monetary and Financial Code.

This prospectus is not to be further distributed or reproduced (in whole or in part) in France by the recipients of this prospectus. This prospectus has been distributed on the understanding that such recipients will only participate in the issue or sale of our ordinary shares for their own account and undertake not to transfer, directly or indirectly, our ordinary shares to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 and L. 411-2 of the French Monetary and Financial Code.

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia: You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

EXPENSES OF THIS OFFERING

The following table sets forth the costs and expenses, other than underwriting discounts, payable in connection with the sale of ordinary shares in the offering. All amounts are estimated except the SEC registration fee, the Nasdaq initial listing fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee. Except as otherwise noted, all the expenses below will be paid by us.

Expense	Amount
SEC registration fee	$ 10,910.00
Nasdaq initial listing fee	150,000.00
FINRA filing fee	15,500.00
Printing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous costs	*
Total	*

* To be completed by amendment.

LEGAL MATTERS

The validity of the ordinary shares and certain other legal matters of Belgian law will be passed upon for us by NautaDutilh BV/SRL. Certain matters of U.S. federal law will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. Legal counsel to the underwriters in connection with this offering is Latham & Watkins, LLP.

EXPERTS

The consolidated financial statements of Nyxoah SA at December 31, 2020 and 2019, and for each of the two years in the period ended December 31, 2020, appearing in this Prospectus and Registration Statement have been audited by EY Reviseurs d'Entreprises / EY Bedrijfsrevisoren SRL/BV, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

ENFORCEMENT OF LIABILITIES

We are a corporation organized under the laws of Belgium. The majority of our directors are citizens and residents of countries other than the United States, and the majority of our assets are located outside of the United States. Accordingly, it may be difficult for investors:

- to obtain jurisdiction over us or our non-U.S. resident officers and directors in U.S. courts in actions predicated on the civil liability provisions of the U.S. federal securities laws;
- to enforce judgments obtained in such actions against us or our non-U.S. resident officers and directors;
- to bring an original action in a Belgian court to enforce liabilities based upon the U.S. federal securities laws against us or our non-U.S. resident officers or directors; and
- to enforce against us or our directors in non-U.S. courts, including Belgian courts, judgments of U.S. courts predicated upon the civil liability provisions of the U.S. federal securities laws.

The United States currently does not have a treaty with Belgium providing for the reciprocal recognition and enforcement of judgments, other than arbitral awards, in civil and commercial matters. Consequently, a final judgment rendered by any federal or state court in the United States, whether or not predicated solely upon U.S. federal or state securities laws, would not automatically be enforceable in Belgium. Actions for the recognition and enforcement of judgments of U.S. courts are regulated by Articles 22 to 25 of the 2004 Belgian Code of Private International Law. Recognition or enforcement does not imply a review of the merits of the case and is irrespective of any reciprocity requirement. A U.S. judgment will, however, not be recognized or declared enforceable in Belgium, unless (in addition to compliance with certain technical provisions) the Belgian courts are satisfied of the following:

- The effect of the recognition or enforcement of judgment is not manifestly incompatible with (Belgian) public order.
- The judgment did not violate the rights of the defendant.
- The judgment was not rendered in a matter where the parties did not freely dispose of their rights, with the sole purpose of avoiding the application of the law applicable according to Belgian international law.
- The judgment is not subject to further recourse under U.S. law.
- The judgment is not incompatible with a judgment rendered in Belgium or with a prior judgment rendered abroad that might be recognized in Belgium.
- The claim was not filed outside Belgium after a claim was filed in Belgium, if the claim filed in Belgium relates to the same parties and the same subject and is still pending.
- The Belgian courts did not have exclusive jurisdiction to rule on the matter.

- The U.S. court did not accept its jurisdiction solely on the basis of either the presence of the plaintiff or the location of goods not direct linked to the dispute in the United States in the United States.
- The judgment did not concern the deposit or validity of intellectual property rights when the deposit or registration of those intellectual property rights was requested, done or should have been done in Belgium pursuant to international treaties.
- The judgment did not relate to the validity, operation, dissolution, or liquidation of a legal entity that has its main seat in Belgium at the time of the petition of the U.S. court.
- If the judgment relates to the opening, progress or closure of insolvency proceedings, it is rendered on the basis of the European Insolvency Regulation (EC Regulation No. 1346/2000 of May 29, 2000) or, if not, that (a) a decision in the principal proceedings is taken by a judge in the state where the most important establishment of the debtor was located or (b) a decision in territorial proceedings was taken by a judge in the state where the debtor had another establishment than its most important establishment.
- The judgment submitted to the Belgian court is authentic under the laws of the state where the judgment was issued; in case of a default judgment, it can be shown that under locally applicable laws the invitation to appear in court was properly served on the defendant; a document can be produced showing that the judgment is, under the rules of the state where it was issued, enforceable and was properly served on the defendant.

In addition, with regard to the enforcement by legal proceedings of any claim (including the exequatur of foreign court decisions in Belgium), a registration tax of 3% (to be calculated on the total amount that a debtor is ordered to pay) is due, if the sum of money that the debtor is ordered to pay by a Belgian court judgment, or by a foreign court judgment that is either (i) automatically enforceable and registered in Belgium or (ii) rendered enforceable by a Belgian court, exceeds €12,500. The debtor is liable for the payment of the registration tax.

A stamp duty is payable for each original copy of an enforcement judgment rendered by a Belgian court, with a maximum of €1,450.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement, including relevant exhibits, with the SEC on Form F-1 under the Securities Act with respect to the underlying ordinary shares to be sold in the offering. This prospectus, which constitutes a part of the registration statement on Form F-1, does not contain all of the information contained in the registration statement. You should read our registration statements and their exhibits and schedules for further information with respect to us and the ordinary shares. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we file any of these documents as an exhibit to the registration statement, we refer you to the copy of the document that has been filed for a complete description of its terms. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Immediately upon the effectiveness of the registration statement on Form F-1 of which this prospectus forms a part, we will become subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we will be required to file reports, including annual reports on Form 20-F, and other information with the SEC. All information filed with the SEC can be obtained over the internet at the SEC’s website at www.sec.gov.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we intend to furnish the depositary with our annual reports, which will include a review of operations and annual audited consolidated combined financial statements prepared in conformity with IFRS, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders.

As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. We are, however, still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5 of the Exchange Act. Since many of the disclosure obligations required of us as a foreign private issuer are different than those required by U.S. domestic reporting companies, our shareholders, potential shareholders and the investing public in general should not expect to receive information about us in the same amount and at the same time as information is received from, or provided by, U.S. domestic reporting companies.

We maintain a corporate website at www.nyxoah.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and our website address is included in this prospectus as an inactive textual reference only.

NYXOAH SA

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of

Nyxoah SA

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Nyxoah SA ("the Company") as of December 31, 2020 and 2019, the related consolidated statements of loss and other comprehensive loss, changes in equity and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with the International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EY Réviseurs d'Entreprises / EY Bedrijfsrevisoren SRL/BV

We have served as the Groups' auditors since 2016.

Diegem, Belgium

April 16, 2021

NYXOAH SA

CONSOLIDATED BALANCE SHEETS
(in thousands)

	As of December 31	
	2020	2019
ASSETS		
Non-current assets		
Property, plant and equipment	€ 713	€ 322
Intangible assets	15,853	5,734
Right of use assets	3,283	1,066
Deferred tax asset	32	21
Other long-term receivables	91	78
	€ 19,972	**€ 7,221**
Current assets		
Inventory	55	—
Other receivables	1,644	2,108
Other current assets	109	11
Cash and cash equivalents	92,300	5,855
	€ 94,108	**€ 7,974**
Total assets	**€ 114,080**	**€ 15,195**
EQUITY AND LIABILITIES		
Capital and reserves		
Common shares	3,796	1,122
Preferred shares	—	1,359
Share premium	150,936	47,668
Share based payment reserve	2,650	420
Currency translation reserve	149	207
Retained Earnings	(60,341)	(48,415)
Total equity attributable to shareholders	**€ 97,190**	**€ 2,361**
LIABILITIES		
Non-current liabilities		
Financial debt	7,607	7,146
Lease liability	2,844	735
Pension Liability	37	30
Other payables	—	547
	€ 10,488	**€ 8,458**
Current liabilities		
Financial debt	616	378
Lease liability	473	340
Trade payables	1,190	1,385
Other payables	4,123	2,273
	€ 6,402	**€ 4,376**
Total liabilities	**€ 16,890**	**€ 12,834**
Total equity and liabilities	**€ 114,080**	**€ 15,195**

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

NYXOAH SA

CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	For the year ended December 31	
	2020	**2019**
Revenue	€ 69	€ —
Cost of goods sold	(30)	—
Gross Profit	**€ 39**	**€ —**
General and administrative expenses	(7,522)	(4,226)
Research and development expenses	(473)	(630)
Clinical expenses	(1,053)	(848)
Manufacturing expenses	(460)	(489)
Quality assurance and regulatory expenses	(227)	(227)
Patents Fees & Related	(123)	(267)
Therapy Development expenses	(1,864)	(902)
Other operating income/ (expenses)	459	(126)
Operating loss for the period	**€ (11,224)**	**€ (7,715)**
Financial income	62	71
Financial expense	(990)	(740)
Loss for the period before taxes	**€ (12,152)**	**€ (8,384)**
Income Taxes	(93)	(70)
Loss for the period	**€ (12,245)**	**€ (8,454)**
Other comprehensive loss		
Items that may be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	(58)	168
Total comprehensive loss for the year, net of tax	**€ (12,303)**	**€ (8,286)**
Loss attributable to equity holders	**€ (12,303)**	**€ (8,286)**
Basic Loss Per Share	€ (0.677)	€ (0.568)
Diluted Loss Per Share	€ (0.677)	€ (0.568)

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

NYXOAH SA

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(in thousands, except share and per share data)

	Attributable to owners of the parent						
	Common Shares	**Preferred Shares**	**Share premium**	**Share based payment reserve**	**Currency translation reserve**	**Retained earnings**	**Total**
Balance at January 1, 2019	**€ 1,122**	**€ 1,359**	**€ 47,668**	**€ 80**	**€ 39**	**€(39,967)**	**€ 10,301**
Loss for the year	—	—	—	—	—	(8,454)	(8,454)
Other comprehensive income for the year	—	—	—	—	168	—	168
Total comprehensive income/(loss) for the year	—	—	—	—	**€ 168**	**€ (8,454)**	**€ (8,286)**
Equity-settled share-based payments	—	—	—	340	—	6	346
Balance at December 31, 2019	**€ 1,122**	**€ 1,359**	**€ 47,668**	**€ 420**	**€ 207**	**€(48,415)**	**€ 2,361**
Balance at January 1, 2020	**€ 1,122**	**€ 1,359**	**€ 47,668**	**€ 420**	**€ 207**	**€(48,415)**	**€ 2,361**
Loss for the year	—	—	—	—	—	(12,245)	(12,245)
Other comprehensive loss for the year					(58)		(58)
Total comprehensive loss for the year	**—**	**—**	**—**	**—**	**€ (58)**	**€(12,245)**	**€ (12,303)**
Equity-settled share-based payments	**—**	**—**	**—**	**2,230**	**—**	**319**	**2,549**
Conversion of preferred shares to common shares	1,359	(1,359)	—	—	—	—	**—**
Issuance of shares for cash	1,304	—	108,857	—	—	—	110,161
Conversion convertible loan	11	—	989	—	—	—	1,000
Transaction cost	—	—	(6,578)	—	—	—	(6,578)
Total transactions with owners of the company recognized directly in equity	**€ 2,674**	**(1,359)**	**€103,268**	**€ 2,230**	**—**	**€ 319**	**€107,132**
Balance at December 31, 2020	**€ 3,796**	**—**	**€150,936**	**€ 2,650**	**€ 149**	**€(60,341)**	**€ 97,190**

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

NYXOAH SA

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the year ended December 31	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss before tax for the year	**€ (12,152)**	**€ (8,384)**
Adjustments for:		
Finance income	(62)	(71)
Finance expenses	990	740
Depreciation and impairment of property, plant and equipment and right-of-use assets	620	433
Share-based payment transaction expense	2,549	346
Pension-related expenses	7	30
Other non-cash items	(134)	70
Cash generated before changes in working capital	**€ (8,182)**	**€ (6,836)**
Changes in working capital:		
Increase in Inventory	(55)	—
Decrease/(Increase) in other receivables	365	(1,385)
Increase in Trade and other payables	1,109	2,342
Cash generated from changes in operations	**€ (6,763)**	**€ (5,879)**
Interests received	3	8
Interests paid	(151)	(33)
Income tax paid	(104)	(61)
Net cash used in operating activities	**€ (7,015)**	**€ (5,965)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(562)	(51)
Capitalization of intangible assets	(10,118)	(5,734)
Increase of long-term deposits	(13)	(10)
Net cash used in investing activities	**€ (10,693)**	**€ (5,795)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of principal portion of lease liabilities	(479)	(341)
Repayment of other loan	(63)	(82)
Recoverable cash advance received	190	1,196
Repayment of recoverable cash advance	(55)	(40)
Proceeds from convertible loan	1,000	—
Proceeds from issuance of shares, net of transaction costs	103,583	—
Net cash generated from financing activities	**€ 104,176**	**€ 733**
Movement in cash and cash equivalents	**€ 86,468**	**€ (11,027)**
Effect of exchange rates on cash and cash equivalents	(23)	77
Cash and cash equivalents at January 1	**€ 5,855**	**€ 16,805**
Cash and cash equivalents at December 31	**€ 92,300**	**€ 5,855**

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

NYXOAH SA

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. General Information

Nyxoah SA (the "Company") is a public listed company with limited liability (naamloze vennootschap/société anonyme) incorporated and operating under the laws of Belgium and is domiciled in Belgium. The Company is registered with the legal entities register (Brabant Walloon) under enterprise number 0817.149.675. The Company's registered office is in Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

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

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

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

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

These Consolidated Financial Statements have been authorized for issue on April 8, 2021 by the Board of Directors of the Company.

2. Significant accounting policies

Basis of Preparation and Going Concern

Basis of preparation

These Consolidated Financial Statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

The Consolidated Financial Statements are presented in Euro (€) and all values are rounded to the nearest thousand, except when otherwise indicated.

The preparation of the Consolidated Financial Statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company's accounting policies. The areas involving a higher degree of judgment or complexity, are areas where assumptions and estimates are significant to the Consolidated Financial Statements. They are disclosed in note 5.

NYXOAH SA

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

Going concern principle

The Consolidated Financial Statements have been prepared on a going concern basis. Please refer to note 5.1 for the detailed explanation of the going concern.

New and amended standards and interpretations applicable.

Effective for the annual periods beginning on or before January 1, 2020

The Company applied for the first-time certain standards and amendments, which are effective for annual periods beginning on or before January 1, 2020. The following new standards and amendments that apply for the first time in 2020, do not have a material impact on the Consolidated Financial Statements of the Company:

— Amendments to IAS 1 and IAS 8 Definition of Material

— Amendments to IFRS 3 Business Combinations: Definition of a Business

— Amendments to IFRS 9, IAS 39 and IFRS 7 Interest Rate Benchmark Reform — Phase 1

— Amendments to references to the Conceptual Framework in IFRS standards

Effective for the annual period beginning after January 1, 2020

Certain new accounting standards and interpretations have been published that are not mandatory for December 31, 2020 reporting periods and have not been early adopted by the Company. These standards are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

(a) Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current (applicable for annual periods beginning on or after January 1, 2023, but not yet endorsed in the EU)

(b) Amendments to IAS 16 Property, Plant and Equipment: Proceeds before Intended Use (applicable for annual periods beginning on or after January 1, 2022, but not yet endorsed in the EU)

(c) Amendments to IAS 37 Provisions, Contingent Liabilities and Contingent Assets: Onerous Contracts — Cost of Fulfilling a Contract (applicable for annual periods beginning on or after January 1, 2022, but not yet endorsed in the EU)

(d) Amendments to IFRS 3 Business Combinations: Reference to the Conceptual Framework (applicable for annual periods beginning on or after January 1, 2022, but not yet endorsed in the EU)

(e) Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform — Phase 2 (applicable for annual periods beginning on or after January 1, 2021, but not yet endorsed in the EU)

(f) Annual Improvements to IFRS Standards 2018-2020 (applicable for annual periods beginning on or after January 1, 2022, but not yet endorsed in the EU)

Basis of Consolidation

The Consolidated Financial Statements comprise the financial statements of the Company and its subsidiaries as at December 31, 2020 and 2019.

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

NYXOAH SA

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

Subsidiaries are fully consolidated from the date on which control is transferred to the Company. They are deconsolidated from the date control ceases.

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

Foreign Currency Translations

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

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

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

Intangible Assets

Patents

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

Research and Development Costs

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

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

The Company started recognizing the development expenditure as an asset since March 2019 triggered by obtaining CE-Mark for the first generation of the Genio system. As from July 2020, the Company started recognizing the development expenditure as an asset for the improved second generation of the

NYXOAH SA

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

Genio system. The asset is carried at cost less any accumulated amortization and accumulated impairment losses. Development costs include employee compensation and outsourced development expenses. Amortization of the asset begins when development is complete and the asset is available for use. During the period of development, the asset is tested for impairment annually. Amortization for the first generation of the Genio system will start and be recognized in R&D and Clinical departments during 2021. Since we started generating revenue in late 2020, the amortization for 2020 would have been immaterial. See note 8.

Property, Plant and Equipment

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

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

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

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

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

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

Impairment of Intangible Assets and Property, Plant and Equipment

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

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

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

Financial assets and liabilities

Financial assets and financial liabilities are recognized when the Company becomes a party to the contractual provisions of the instruments.

NYXOAH SA

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

Financial assets and financial liabilities are initially measured at fair value. Transactions costs that are directly attributable to the acquisition or issue of financial assets and liabilities are added or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition.

The Company does not use any financial instruments for trading or hedging purposes.

Financial Assets

Financial assets include mainly other long-term receivables, trade receivables, other receivables and cash and cash equivalents, and are measured at amortized cost using the effective interest method, less impairment allowance. Interest income is recognized by applying the effective interest rate, except for short-term receivables when the effect of discounting is immaterial.

Derecognition

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

Impairment of Financial Assets

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

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

Financial Liabilities

The financial liabilities include financial debt, trade payables and other payables. Those financial liabilities are measured at amortized cost using the effective interest rate method. Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortization is included as financial cost in the consolidated income statement. When the estimated contractual cash flows are modified, the entity recalculates the gross carrying amount of the financial liability as the present value of the modified cash flows discounted at the original effective interest rate. The difference between the recalculated carrying amount and the initial carrying amount is included in other operating income & expense in the consolidated income statement.

Derecognition

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

Fair value measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by

NYXOAH SA

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

the Company. The fair value of an asset or liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that the market participants act in their economic best interest.

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

Level 1: quoted (unadjusted) market prices in active markets for identical assets or liabilities;

Level 2: valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable; and

Level 3: valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

Cash and Cash Equivalents

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

Equity Instruments

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

Convertible Loan

The Company has issued a convertible loan on 26 June 2020 for a total amount of €1.0 million.

The Company identified two components included in the convertible loan agreement: a host loan and an embedded derivative failing the equity classification. The Company has applied the simplification method called the “fair value option”.

Under this approach, a contract that contains one or more embedded derivatives that would normally be required to be accounted for separately can instead be accounted for jointly with its host instrument at fair value through income statement. Until conversion and at each reporting date, the Company revaluates the fair value of the convertible loan. Upon subsequent evaluation, the element of gains or losses attributable to changes in credit risk should be recognized in other comprehensive income with the remainder recognized in profit or loss. The estimation of the fair value of the convertible loan on initial or subsequent recognition is dependent on the discount rate and maturity date. The fair value measurement of the convertible loan is classified as level 3. The Company used a discount rate of 5% for the initial recognition of the convertible loan. Given the potential equity transaction, the Company estimated the maturity of the convertible loan to be 3 months as of June 30, 2020.

Income Taxes

Income taxes include current income tax and deferred income tax.

Current Income Tax

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

Deferred Income Tax

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

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

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

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

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

Employee Benefits

Short-Term Employee Benefits

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

Post-Employment Benefits

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

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

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

estimated duration of the post-employment benefits obligations. The actuarial calculations of post-employment obligations are performed by independent actuaries.

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

Share-Based Compensation

Equity-settled share-based compensation

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

Each warrant gives the beneficiaries the right to subscribe to one or several common shares of the Company. The warrants are granted for free and their exercise price is determined by the Board of Directors of the Company. The only vesting condition of the warrants is that the holder still be an employee at the vesting date. In general, the vesting schedule is as follows: 1/3 at the grant date, 1/3 at the first anniversary of the grant date and 1/3 at the second anniversary.

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

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

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

Cash-settled share-based payment transaction

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

Provisions

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

Leases

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

Right-of-use assets:

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of-use assets are subject to impairment, but no impairment has been identified in fiscal year 2019 and 2020.

Lease liabilities:

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

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

Short-term leases and leases of low-value assets:

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value (i.e., below €5,000). Lease payments on short-term leases and leases of low-value assets are recognized as expense on a straight-line basis over the lease term. See note 31.

Revenue

The Company has started commercializing the Genio system in Europe. The Company sells The Genio system to hospitals and distributors. Revenue from selling the Genio system is recognized at a point in time when control over The Genio system is transferred to the customer, which is in general at delivery at customer site or a predefined location in the country of the customer. The revenue from the Genio system may consist of individual products or a bundle of products in the form of a kit. The revenue is then recognized at an amount that reflects the consideration to which the Company expects to be entitled in exchange of the Genio system. In determining the transaction price for the sale of the Genio system, the Company considers the effects of variable consideration.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

We did not have any contracts with customers subject to IFRS 15 prior to 2020 and, thus, there is no impact of adopting IFRS 15. As of 2020, contracts with customers are accounted under IFRS 15.

Variable consideration including volume rebates

Some contracts for the sale of the Genio system could include a variable amount. The Company estimates the amount of the consideration to which it will be entitled in exchange for transferring the goods to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognition will not occur when the underlying uncertainty is subsequently resolved.

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

The contracts with customers do not have right of returns.

Warranty obligations

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

Recoverable cash advances and other government grants

Government grants are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. When the grant relates to an asset, it is recognized as income in equal amounts over the expected useful life of the related asset.

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

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

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

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

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

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

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

The Company also has received research and development incentives in Australia in relation to certain development activities and clinical trials. The Company recognizes the research and development incentives as another receivable and other operating income when it is reasonably certain that all conditions (which are limited and only protective in nature such as having an entity in Australia, conducting R&D activities in Australia) are satisfied and the incentive will be received, which is when the development activities and clinical trials are being performed. See note 10 and 24.

Segment Reporting

Based on the organizational structure, as well as the nature of financial information available and reviewed by the Company’s chief operating decision makers to assess performance and make decisions about resource allocations, the Company has concluded that its total operations represent one reportable segment. The chief operating decision maker is the CEO.

3. Capital Management

The Company’s objectives when managing capital are to maintain sufficient liquidity to meet its working capital requirements and fund capital investment in order to safeguard its ability to continue operating as a going concern. The capital structure of the Company consists of equity attributable to the shareholders, such as share capital, share premium, reserves and retained earnings, and of borrowings. The capital of Nyxoah SA amounts to €3.8 million at December 31, 2020 (2019: €2.5 million). Total cash and cash equivalents amount to €92.3 million at December 31, 2020 (2019: €5.9 million). The current cash situation and the anticipated cash generation are the most important parameters in assessing the capital structure. The Company’s policy is to maintain a strong capital base in order to maintain investor confidence in its capacity to support the future development of its operations.

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

4. Management of Financial Risks

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

Market Risk

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

Credit risk

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

Furthermore, the Company is not exposed to any material credit risk as other receivables are mainly due by the governments in Australia and the Walloon Region and there is limited risk associated to this receivable.

Foreign Exchange Risk

The Company is minimally exposed to currency risk on a limited number of expenses that are denominated in currencies other than the functional currency of the company's subsidiaries: NIS, AUD, and USD.

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

	2020 rates		2019 rates	
Currency	**Closing**	**Average**	**Closing**	**Average**
NIS	3.92758	3.92330	3.87700	3.99220
AUD	1.58636	1.65548	1.60102	1.61057
USD	1.22239	1.15189	—	—

Based on the Company's foreign currency exposures noted above, varying the above foreign exchange rates to reflect positive and negative changes of 5% of the NIS, AUD and USD would have the following impact:

	Change in foreign exchange rate	Effect on loss (before tax)			Effect on pretax equity		
		NIS	**USD**	**AUD**	**NIS**	**USD**	**AUD**
2020	5%	12	-4	55	83	-7	208
	-5%	-12	4	-61	-91	8	-230
2019	5%	11	—	39	71	—	127
	-5%	-11	—	-43	-77	—	-141

The Company does not generally enter into arrangements to hedge its currency risk exposure.

Liquidity Risk

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

4. Management of Financial Risks (continued)

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

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

	2020				2019		
(in EUR 000)	**Lease Liability**	**Financial Debt**	**Trade & Other Payable**	**Other Commitments***	**Lease Liability**	**Financial Debt**	**Trade & Other Payable**
Less than 1 year	560	632	5,313	€1,450	353	392	3,658
1-5 years	2,185	4,987	—	1,570	709	2,871	547
5+ years	895	4,620	—	—	38	11,470	—
TOTAL	3,640	10,239	5,313	**€3,020**	1,100	14,733	4,205

* Related to Cochlear Collaboration Agreement

Fair Value

The carrying amount of cash and cash equivalents, trade receivables, other receivables and other current assets approximate their value due to their short-term character. Derivatives financial instruments, such as foreign exchange forward contracts, are also measured at fair value. However, none of the contracts were on-going at year end.

The carrying value of current liabilities approximates their fair value due to the short-term character of these instruments.

The fair value of non-current liabilities (financial debt and other non-current liabilities) is evaluated based on their interest rates and maturity date. These instruments have fixed interest rates and their fair value measurements are subject to changes in interest rates. The fair value measurement is classified as level 3. Please refer to note 2.10 for information on the valuation of non-current liabilities.

	Carrying value		Fair value	
(in EUR 000)	**2020**	**2019**	**2020**	**2019**
Financial Assets				
Other long-term receivables (level 3)	91	78	91	78
Trade and other receivables (level 3)	1,644	2,107	1,644	2,107
Other current assets (level 3)	109	11	109	11
Cash and cash equivalents (level 1)	92,300	5,855	92,300	5,855
Financial liabilities				
Financial debt (level 3)	313	376	250	321
Lease liability (level 3)	3,317	1,075	3,317	1,075
Recoverable cash advances (level 3)	7,910	7,148	7,910	7,148
Trade and other payables (level 3)	5,313	4,205	5,313	4,205

5. Critical Accounting Estimates and Assumptions

When preparing the Consolidated Financial Statements, judgments, estimates and assumptions are made that affect the carrying amount of certain assets, liabilities and expenses. These include the going concern assessment, the share-based payment transactions, the accounting for research and development expenses, the recoverable cash advances and deferred taxes. These judgments, estimates and assumptions have been

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Critical Accounting Estimates and Assumptions (continued)

reviewed for each year and are reviewed on a regular basis, taking into consideration past experience and other factors deemed relevant under the then prevailing economic conditions. Changes in such conditions might accordingly result in different estimates in the Company's future Consolidated Financial Statements.

Critical Judgments

Going Concern

As at December 31, 2020, the Company had cash and cash equivalents of €92.3 million. Based on cash flow forecasts for the years 2021 and 2022, which include significant expenses and cash outflows in relation to -among others- the ongoing clinical trials, the continuation of research and development projects, and the scaling-up of the Company's manufacturing facilities, the Company believes that this cash position will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of this Annual Report.

In view of the above, and notwithstanding a loss brought forward of €60.3 million as of December 31, 2020, the Board of Directors has decided, after due consideration, that the application of the valuation rules in the assumption of a "going concern" is justified. ***Critical Accounting Estimates and Assumptions***

Recoverable Cash Advances

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

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

Management estimates the fair value of the liability of the future payment to be made to the Walloon Region based on a forecasted volume of sales. The estimation of the fair value is dependent on the discount rate applied. The fixed part to be reimbursed has been discounted with a discount rate of 5% and the variable part (based on sales forecasts) with a discount rate of 12.5%. Refer also to note 14

Development Expenses capitalized and related impairment testing

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

At December 31, 2019, for the first time the Company capitalized amount of development costs for the first generation of the Genio System. This amount includes costs related to the development of the Genio System which received CE-Mark approval in March 2019 and related improvements. Therefore, the Company is of the opinion that, from March 2019, development expenditures do meet capitalization criteria. The Company uses an estimate for certain research and development expenses related to the Genio System and related improvements to determine the amount to be capitalized or recorded as an expense. Accordingly, the costs incurred for the first generation of the Genio System have been recognized as development assets for a total amount of €14.2 million as of December 31, 2020 (2019: €5.3 million). In addition, the Company started capitalizing the development costs for the improved second generation of the Genio System as from July 2020 for a total amount of €1.0 million. See Note 8

The development expenses capitalized have to be tested annually for impairment during the development period, prior to the start of its amortization. The Company performs the impairment test on the smallest

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Critical Accounting Estimates and Assumptions (continued)

group of assets to which it belongs for which there are separately identifiable cash flows: its cash-generating units ("CGU's"). Where the carrying value of an asset exceeds its recoverable amount (i.e. the higher of value in use and fair value less costs to sell), the asset is written down accordingly. The Company is a one product line company and the capitalized development expenses are only related to this product (Genio System).

When performing the impairment test, management needs to make significant judgments, estimates and assumptions. The Company bases its impairment calculation on detailed budgets and forecast calculations generally covering a period of five to six years. For longer periods, a long-term growth rate is calculated and applied to future cash flows projected after the terminal year. See note 8

Share-Based Payments

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

In addition, the Company has two cash-settled share-based payment plans in place. Estimating the fair value of those cash-settled share-based payment plans require the Company to estimate (i) the pre-money valuation of the Company at December 31, 2019 and (ii) to estimate the vesting period considering the most likely date when an Exit event may occur. The assumptions and models used for estimating the fair-value for share-based payment transactions are disclosed in note 13.

6. Subsidiaries

For all years ended as at December 31, 2020 and 2019 respectively, the Company owns 100% of the shares of Nyxoah Ltd, an Israeli company located in Tel-Aviv that was incorporated in 2009 and has a share capital of NIS 1.00.

The Company also owns 100% of the shares of Nyxoah Pty Ltd, an Australian company located in Collingwood that was incorporated in 2017 and has a share capital of AUD 100.

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

7. Property Plant and Equipment

(in EUR 000)	Furniture and office equipment	Leasehold improvements	Laboratory equipment	Total
Gross value				
Opening Gross value	439	190	133	**762**
Additions	48	—	3	51
Gross value at 31/12/2019	**487**	**190**	**136**	**813**
Additions	178	358	26	562
Gross value at 31/12/2020	**665**	**548**	**162**	**1,375**
Depreciation				
Opening accumulated depreciation	(283)	(72)	(37)	(392)
Depreciation charge	(64)	(24)	(12)	(100)
Depreciation at 31/12/2019	**(347)**	**(96)**	**(49)**	(492)
Depreciation charge	(83)	(74)	(12)	(169)
Depreciation at 31/12/2020	**(430)**	**(170)**	**(61)**	**(661)**
Opening Exchange differences	(3)	2	2	1
Exchange differences	(1)	—	—	(1)
Exchange differences at 31/12/2020	**(4)**	**2**	**2**	**—**
Net book value at 31/12/2019	**137**	**96**	**89**	**322**
Net book value at 31/12/2020	231	380	103	**713**

In 2020 and 2019 additions were mainly related to leasehold improvements, IT and office equipment.

The yearly depreciation charge amounts to €169,000 in 2020 and €100,000 in 2019.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

8. Intangible assets

(in EUR 000)	Development Cost	Patents and licenses	Total
Cost			
Opening Gross value	—	—	—
Additions	5,311	335	5,646
Gross value at 31/12/2019	**5,311**	**335**	**5,646**
Additions	9,874	256	10,130
Gross value at 31/12/2020	**15,185**	**591**	**15,776**
Amortization			
Opening amortization	—	—	—
Amortization	—	—	—
Amortization at 31/12/2019	—	—	—
Amortization	—	—	—
Amortization at 31/12/2020	—	—	—
Opening Exchange differences	88	—	88
Exchange differences	(11)	—	(11)
Exchange differences at 31/12/2020	**77**	—	**77**
Net book value at 31/12/2019	**5,399**	**335**	**5,734**
Net book value at 31/12/2020	**15,262**	**591**	**15,853**

There is only one development project: the Genio system. The Company has capitalized a total of €14.2 million as at December 31, 2020 (2019: €5.3 million) related to the first generation of the Genio system. During 2020, the Company launched the commercialization of Genio system in Europe. As at December 31, 2020, the Company was still in the early stage of the commercialization and production in that region. The Company will start amortizing the first-generation Genio system as from January 1, 2021.

The Company continues to incur development expenditures as from July 2020 with regard to the improved second-generation Genio system for a total amount of €1.0 million as at December 31, 2020.

In accordance with the accounting principle, the intangible assets have to be tested annually for impairment during the development period, prior to the start of its amortization. The Genio system is currently the unique product line developed by the Company and the Company determined that it has only one cash generating unit for which a value in use analysis has been performed. The discount rate and a long-term growth rate applied over the expected term that the asset will generate economic benefits, used are respectively 13% and 7.5%. The discount has been determined by reference to the analyst reports covering the Company which are publicly available.

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

9. Right-of-use assets and lease liabilities

The Company has lease contracts for buildings and vehicles used in its operations. Leases of building generally have lease terms between four and nine years, while motor vehicles generally have lease terms of five years. The Company’s obligations under its leases are secured by the lessor’s title to the leased assets.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. Right-of-use assets and lease liabilities (continued)

Generally, the Company is restricted from assigning and subleasing the leased assets and some contracts require the Company to maintain certain financial ratios.

The Company also has certain leases of office equipment with low value. The Company applies the "short-term lease" and "lease of low-value assets" recognition exemptions for these leases.

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

(in EUR 000)	Building	Motor vehicles	Total
Gross value			
As of January 1, 2019	1,131	192	1,323
Addition	—	—	—
Gross value at 31/12/2019	**1,131**	**192**	**1,323**
Addition	3,194	233	3,427
Disposal	(1,207)	(23)	(1,230)
Gross value at 31/12/2020	**3,117**	**402**	**3,519**
Depreciation			
As of January 1, 2019	—	—	—
Depreciation of the year	(281)	(52)	(333)
Depreciation at 31/12/2019	**(281)**	**(52)**	**(333)**
Depreciation of the year	(383)	(68)	(451)
Disposal	470	11	481
Depreciation at 31/12/2020	**(194)**	**(109)**	**(303)**
Opening exchange difference	76	—	76
Exchange difference	(9)	—	(9)
Exchange difference at 31/12/2020	**67**	**—**	**67**
Net carrying value at 31/12/2019	**926**	**140**	**1,066**
Net carrying value at 31/12/2020	**2,990**	**293**	**3,283**

The disposal in buildings for 2020 relate to the termination of the office leases in Israel and Belgium which were replaced by new office leases with significant different terms and conditions. The initial lease contract was terminated resulting in the disposal. The loss on disposal recognized amounts to €6,000. The new offices leases explain the addition of €3.24 million in buildings during 2020.

The carrying amounts of lease liabilities and the movements during the period is as follows:

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. Right-of-use assets and lease liabilities (continued)

(in EUR 000)	
As at January 1, 2019 – Adoption of IFRS 16	**1,323**
Addition	—
Accretion of interest	17
Payments	(341)
Exchange difference	76
Net carrying value at 31/12/2019	**1,075**
Addition	3,427
Disposal	(743)
Accretion of interest	47
Payments	(479)
Exchange difference	(10)
Net carrying value at 31/12/2020	**3,317**
Non-Current	735
Current	340
Net carrying value at 31/12/2019	**1,075**
Non-Current	2,844
Current	473
Net carrying value at 31/12/2020	**3,317**

The maturity analysis of lease liabilities is disclosed in note 4, the table hereunder details the amounts recognized in profit or loss:

(in EUR 000)	31/12/2020	31/12/2019
Depreciation expense of right-of-use assets	451	333
Interest charge on lease liabilities	47	17
Rent expenses (note 0)	89	115

10. Other receivables

(in EUR 000)	2020	2019
Recoverable cash advance receivable	—	1,100
R&D Incentive receivable (Australia)	951	495
VAT receivable	607	153
Current tax receivable	(3)	30
Other	89	330
Total Other receivables	**1,644**	**2,108**

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

The recoverable cash advance of 2019 was related to the Walloon Region who confirmed a final payment of €1.1 million in connection with the convention 7388.

Current tax receivable relates to excess prepayment of corporate income tax in Israel.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. Cash and Cash Equivalents

(in EUR 000)	2020	2019
Short term deposit	28	28
Three months term deposit	6	363
Current accounts	92,266	5,463
Petty Cash	—	1
Total Cash and cash equivalents	**92,300**	**5,855**

12. Capital, Share Premium, Reserves

Capital and share premium

The number of shares and the par value in the paragraph below take into account resolutions adopted by the shareholders' meeting of February 21, 2020. All existing preferred shares were converted into common shares, and then a share split of 500:1 was approved by the shareholders' meeting. The tables and comments below reflect the number of shares after the share split of 500:1 as of January 1, 2019.

As of December 31, 2019, the share capital of the Company amounts to €2.5 million, represented by 14,879,000 shares, and the share premium amounts to €47.7 million. As at December 31, 2019, there were four categories of shares, including 3 types of preferred shares (Preferred "A" shares, preferred "B" shares and preferred "B2" shares). Preferred shares had specific rights which can be summarized as follows: Holders of preferred shares can propose the appointment of a board director, have a liquidation preference and anti-dilution protection. In addition, preferred B and B2 shares have specific rights to preferred dividends. In connection with the capital increase of February 21, 2020, the shareholders' meeting of the Company has decided to convert all preferred shares in common shares and to cancel all anti-dilutive warrants granted to holders of preferred shares.

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

Evolution of the share capital and share premium over the last two years is as follows:

(Number of shares[(1)] except otherwise stated)	Common Shares	Preferred Shares	Total of Shares	Par value (EUR)	Share Capital	Share Premium
January 1, 2019 (adjusted for share split in 2020)	6,728,500	8,150,000	14,879,000	0.17	2,481	47,668
December 31, 2019 (adjusted for share split in 2020)	6,728,500	8,150,000	14,879,000	0.17	2,481	47,668
February 21, 2020 – Conversion of preferred shares to common shares	8,150,000	(8,150,000)	—	—	—	—
February 21, 2020 – Capital increase	2,100,000	—	2,100,000	0.21	436	24,624
September 7, 2020 – Exercise warrants	44,500	—	44,500	0.17	8	222
September 21, 2020 – IPO	4,335,000	—	4,335,000	0.17	745	72,950
September 21, 2020 – Convertible loan	65,359	—	65,359	0.17	11	989
September 29, 2020 – Exercise warrants	650,250	—	650,250	0.17	112	10,943
October 28, 2020 – Exercise warrants	23,500	—	23,500	0.17	4	117
December 31, 2020 (adjusted for share split in 2020)	22,097,609	—	22,097,609	0.17	3,796	157,514

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

12. Capital, Share Premium, Reserves (continued)

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

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

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

On September 7, 2020, pursuant to the exercise of warrants, the aggregate capital of the Company increased with €230,110.39 (including share premium) in exchange for 44,500 new shares in the Company.

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

The Initial Public Offering (IPO) on Euronext Brussels (Belgium) resulted in an aggregate capital increase in the Company of €73.7 million (including share premium) in exchange for 4,335,000 new shares in the Company at the price of EUR 17 per share. The conversion of a convertible loan of €1.0 million in shares resulted (triggered by the IPO) in an aggregate capital increase in the Company of €1.0 million (including share premium) in exchange for 65,359 new shares in the Company. The convertible loan was entered into between the Company and Noshaq SA ("Noshaq") on June 26, 2020 for an amount of €1.0 million. The convertible loan had a non-compounding interest rate of 2.50% per annum. The trigger events for a mandatory conversion were (i) an initial public offering, (ii) qualifying financing and (iii) a trade sale. If no mandatory conversion has taken place on or prior to the second anniversary of date of the loan, we will be able to opt for an optional conversion to force Noshaq to convert the entire outstanding Principal Amount at nominal value into new shares. The convertible loan was accounted for prior to conversion at fair value with changed in fair value through the profit or loss. Change in fair value of this conversion feature between the issue date and the conversion date is immaterial.

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

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

On October 28, 2020, pursuant to the exercise of warrants, the aggregate capital of the Company increased with €121,510.04 (including share premium) in exchange for 23,500 new shares in the Company.

Reserves

The reserves included the share-based payment reserve (see note 13), the currency translation reserve and the retained earnings. Retained earnings is comprised primarily of accumulated losses.

13. Share-Based Compensation

As of December 31, 2020, the Company has four outstanding equity-settled share-based incentive plans, including (i) the 2013 warrants plan (the 2013 Plan), (ii) the 2016 warrants plan (the 2016 Plan), (iii) the

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation (continued)

2018 warrants plan (the 2018 Plan), and (iv) the 2020 warrants plan (the 2020 plan). The Company had an extraordinary shareholders' meeting on February 21, 2020, where it was decided to achieve a share split in a ratio of 500:1. Per Warrant issued before February 21, 2020, 500 common shares will be issuable. For presentation purposes the tables and comments below reflect the number of shares the warrants give right to across all plans.

Pursuant to a decision of the February 21, 2020 extraordinary shareholders' meeting, the AD Warrants were cancelled.

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

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

Number of shares (after share split) warrants give right to across all plans	2020	2019
Outstanding at January 1	1,143,500	1,012,000
Granted	567,000	246,000
Forfeited/Cancelled	(635,000)	(114,500)
Exercised	(68,000)	0
Outstanding at December 31	1,007,500	1,143,500
Exercisable at December 31	1,007,500	968,503

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

Description of the equity-settled share-based incentive plans

(a) 2013 Plan

On 3 May 2013, the shareholders' meeting of the Company approved the issuance of 340 warrants, giving each the right to subscribe to one common share of the Company before share split (500 shares after the share split). These warrants are valid until May 3, 2023. In addition, on December 23, 2014, the shareholders' meeting of the Company issued 300 additional warrants under the 2013 Plan. The Shareholders' Meeting granted a special proxy to the Board of Directors of the Company in order to (i) identify the beneficiaries, (ii) offer the issued warrants to workers of the Company, and (iii) determine the exercise price of the concerned warrants.

The exercise price of each warrant is €2,585.51 before share split for warrants granted before April 2020. Taking into consideration the share split, this would result in an exercise price of EUR 5.17 per share. The exercise price of each warrant is €5,966.59 before share split for warrants granted in April 2020. Taking into consideration the share split, this would result in an exercise price of €11.94 per share. The key features of the warrants granted under the 2013 Plan are as follows (i) each warrant could be exercised for one share before share split (500 shares after the share split), (ii) the warrants are granted for free, (iii) the warrants have a term of five years since the grant date, (iv) the only vesting condition is that the holder is still an employee of the Company at the vesting date, and (v) the warrants vest accordingly: 34% at the grant date, 33% at the first anniversary of the grant date, 33% at the second anniversary. As a result of the IPO, all warrants that had not yet vested before, vested on September 7, 2020, i.e. ten business days prior to the closing of the IPO on September 21, 2020.

In April 2020, 1 warrant was granted under the 2013 Plan with an exercise price of €5,966.59 (€11.94 per share after the share split).

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

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13. Share-Based Compensation (continued)

Number of shares (after share split) warrants give right to for Plan 2013	2020	2019
Outstanding at January 1	208,000	269,500
Granted	500	0
Forfeited/Cancelled	(83,500)	(61,500)
Exercised	(44,500)	0
Outstanding at December 31	80,500	208,000
Exercisable at December 31	80,500	208,000

With respect to the warrants exercised in 2020, a total of 89 warrants representing 44,500 shares after share split were exercised. Since the 2013 warrant plan prescribes that each warrant gives right to 500 shares and our table above presents the impact on the number of shares, the actual remaining number of warrants as per December 31, 2020 equals 161 representing 80,500 shares.

(b) 2016 Plan

On 3 November 2016, the shareholders' meeting of the Company approved the issuance of 1.500 warrants, giving each the right to subscribe to one common share of the Company before share split (500 shares after the share split). Under this plan, up to 1.500 warrants can be issued. By consequence, the Company can issue up to 1.500 common shares before share split (750,000 shares after the share split) if all warrants are exercised.

The total amount of warrant owners cannot exceed 150 individuals. Unless the Board of Directors determines otherwise, the 2016 ESOP Warrants are not transferable inter vivos once they have been granted to a holder of the 2016 ESOP Warrants, and may not be pledged or encumbered with any security, pledge or right in rem in any other way, either voluntarily, by operation of law or otherwise. The exercise price of each warrant cannot be less than €2,585.32. Taking into consideration the share split, this would result in an exercise price of €5.17 per share. The key features of the warrants granted under the 2016 Plan are as follows (i) each warrant could be exercised for one share before share split (500 shares after the share split), (ii) the warrants are granted for free, (iii) the warrants have a term of maximum ten years since the grant date, (iv) the only vesting condition is the holder is still an employee of the Company at the vesting date, and (v) the warrants vest accordingly: 34% at the grant date, 33% at the first anniversary of the grant date, 33% at the second anniversary. Accordingly, the fair value of the plan is expensed over the vesting period. All 1,500 warrants were granted throughout the years 2016, 2017 and 2018. As a result of the IPO, all warrants that had not yet vested before, vested on September 7, 2020, i.e. ten business days prior to the closing of the IPO on September 21, 2020.

The status of the 2016 warrant plan at December 31, is as follows:

Number of shares (after share split) warrants give right to for Plan 2016	2020	2019
Outstanding at January 1	742,500	742,500
Granted	0	0
Forfeited/Cancelled	(501,500)	0
Exercised	(23,500)	0
Outstanding at December 31	217,500	742,500
Exercisable at December 31	217,500	695,500

With respect to the warrants exercised in 2020, a total of 47 warrants representing 23,500 shares were exercised. Since the 2016 warrant plan prescribes that each warrant gives right to 500 shares and our table above presents the impact on the number of shares, the actual remaining number of warrants as per December 31, 2020 equals 435 representing 217,500 shares.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation (continued)

(c) 2018 Plan

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

The total amount of warrant owners cannot exceed 150 individuals. Unless the Board of Directors determines otherwise, the 2018 ESOP Warrants are not transferable inter vivos once they have been granted to a holder of the 2018 ESOP Warrants, and may not be pledged or encumbered with any security, pledge or right in rem in any other way, either voluntarily, by operation of law or otherwise. The exercise price of each warrant cannot be less than €3,259.91. Taking into consideration the share split, this would result in an exercise price of €6.52 per share. The key features of the warrants granted under the 2018 Plan are as follows (i) each warrant could be exercised for one share before share split (500 shares after the share split), (ii) the warrants are granted for free, (iii) the warrants have a term of maximum ten years since the grant date, (iv) the only vesting condition is the holder is still an employee of the Company at the vesting date, and (v) the warrants vest accordingly: 34% at the grant date, 33% at the first anniversary of the grant date, 33% at the second anniversary. Accordingly, the fair value of the plan is expensed over the vesting period. As a result of the IPO, all warrants that had not yet vested before, vested on September 7, 2020, i.e. ten business days prior to the closing of the IPO on September 21, 2020.

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

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

Number of shares (after share split) warrants give right to for Plan 2018	2020	2019
Outstanding at January 1	193,000	0
Granted	16,500	246,000
Forfeited/Cancelled	(50,000)	(53,000)
Exercised	0	0
Outstanding at December 31	159,500	193,000
Exercisable at December 31	159,500	65,000

No warrants were exercised in 2020. Since the 2018 warrant plan prescribes that each warrant gives right to 500 shares and our table above presents the impact on the number of shares, the actual remaining number of warrants as per December 31, 2020 equals 319 representing 159,500 shares.

(d) 2020 Plan

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

The total number of warrant beneficiaries cannot exceed 150 individuals. Unless the Board of Directors determines otherwise, the 2020 ESOP Warrants are not transferable inter vivos once they have been granted to a holder of the 2020 ESOP Warrants, and may not be pledged or encumbered with any security, pledge or right in rem in any other way, either voluntarily, by operation of law or otherwise. The key features of the warrants granted under the 2020 Plan are as follows (i) each warrant could be exercised for one share, (ii) the warrants are granted for free, (iii) the warrants have a term of maximum ten years since the grant date, (iv) the only vesting condition is the holder is still an employee of the Company at the

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation (continued)

vesting date, and (v) the warrants vest accordingly: 34% at the grant date, 33% at the first anniversary of the grant date, 33% at the second anniversary. Accordingly, the fair value of the plan is expensed over the vesting period. As a result of the IPO, all warrants that had not yet vested before, vested on September 7, 2020, i.e. ten business days prior to the closing of the IPO on September 21, 2020.

The exercise price of each warrant amounts to €11.94.

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

Number of shares warrants give right to for Plan 2020	2020
Outstanding at January 1	0
Granted	550,000
Forfeited/Cancelled	0
Exercised	0
Outstanding at December 31	550,000
Exercisable at December 31	550,000

No warrants were exercised in 2020.

Accounting for Equity-settled Share-Based Payment

The fair value of the plan is expensed over the vesting period. The share-based compensation expense for all vested warrants recognized in the income statement was €2.5 million for the year ended December 31, 2020, €346,000 for the year ended December 31, 2019, €28,000 for the year ended December 31, 2018.

The table below details the number of exercisable (vested) warrants and their weighted average exercised price. For presentation purposes the table reflect the number of shares the warrants give right to across all plans.

Total	2020	2019	2018
Exercisable Warrants at December 31	550,915	1,940	1,807
Shares representing the Exercisable Warrants at December 31	1,007,500	1,143,500	1,012,000
Weighted average exercise price per share	9.17	5.26	5.17

Fair value

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

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

The following table provides the input to the Black-Scholes model for warrants granted in 2018, 2019 and 2020 related to the 2013 warrant plan, the 2016 warrant plan, the 2018 warrant plan and the 2020 warrant plan. The table and notes uses as a basis, the number of shares the warrants give right to across all plans.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation (continued)

	Plan 2016 (grant 2018)	Plan 2018 (grant 2019)	Plan 2013 (grant 2020)	Plan 2018 (grant 2020)	Plan 2020 (grant 2020)
Return Dividend	0%	0%	0%	0%	0%
Expected volatility	66.92%	56.32%	56.32%	56.32%	56.32%
Risk-free interest rate	0.35%	-0.20%	-0.20%	-0.20%	-0.20%
Expected life	3	3	3	3	3
Exercise price	5.17	6.52	11.94	11.94	11.94
Stock price	1.09	10.24	10.20	10.20	10.20
Fair value	0.10	5.30	3.31	3.31	3.31

The weighted average fair value of warrants granted during the year was €3.31 in 2020, €5.30 in 2019 and €0.10 in 2018.

The weighted average remaining contractual life for the share options outstanding as at December 31, was 3.4 in 2020, 2.5 in 2019 and 2.99 in 2018.

Cash-settled share-based payment transactions

The Company has signed a service agreement with ActuaRisk Consulting SRL in 2014 and amended afterwards for an indefinite period which includes a variable compensation for the services delivered under the service agreement. The variable compensation will become payable upon an “Exit of the Company” (“Exit”), unless ActuaRisk Consulting SRL becomes a bad leaver as defined in the service agreement prior to the Exit. The variable compensation can be invoiced by ActuaRisk Consulting SRL, as from the 6th month following an Exit at an amount equal to the closing trading of the Shares of the company at the time of invoice multiplied by the number of the then outstanding shares adjusted with then outstanding warrants and multiplied by a variable % between 0% and 0.5% depending on the exit value. The exercise period has no maturity. The vesting period is variable and starts at the signing date of the service agreement and the expected date of an Exit. The vesting term was estimated at December 31, 2019 at 82 months. The IPO completed on September 21, 2020 qualifies as an Exit under the service agreement and as such the rights are vested at December 31, 2020.

The Company has signed a service agreement with Mr. Kezirian in 2015 and amended afterwards for an indefinite period which include a variable compensation for the services delivered under the service agreement. The variable compensation will be 0,5% of 100% of the shares on a fully diluted basis, less any expenses, costs and fees incurred by the shareholders or the Company in the framework of the Exit. The variable compensation will vest fully within 5 years anniversary of the service agreement, i.e. November 25, 2020 or a vesting period of 60 months. The variable compensation becomes payable upon an “Exit of the Company” (“Exit”), unless Mr. Kezirian becomes a bad leaver as defined in the service agreement prior to the Exit. The IPO completed on September 21, 2020 qualifies as an Exit under the service agreement.

Both arrangements qualify as a cash-settled share-based payment transaction. The liability for the cash-settled share-based payment arrangements amount to €1.8 million at December 31, 2020 (€1.4 million in 2019) with an expense recognized in general and administrative expense of €2.0 million (2019: €1.2 million). The total intrinsic value of the fully vested liability at December 31, 2020 is €1.8 million. The arrangement with Mr. Kezirian has been exercised on September 21, 2020 following the IPO with a total payment of €1.5 million in September 2020. The arrangement with ActuaRisk Consulting SRL has vested in full on September 21, 2020 and will be exercisable as from the 6th month following the IPO. At December 31, 2019, none of the arrangements were exercisable.

14. Financial Debt

Financial debt consists of recoverable cash advances and other loan. Related amounts can be summarized as follows:

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

14. Financial Debt (continued)

(in EUR 000)	2020	2019
Recoverable cash advances – Non-current	7,419	6,874
Recoverable cash advances – Current	491	274
Total Recoverable cash advances	**7,910**	**7,148**
Other loan – Non-current	188	272
Other loan – Current	125	104
Total Other loan	**313**	**376**
Non-current	7,607	7,146
Current	616	378
Total Financial debt	**8,223**	**7,524**

Financial debt related to recoverable cash advances

Recoverable cash advances received

As at December 31, 2020, the details of recoverable cash advances received can be summarized as follows:

(in EUR 000)	Contractual Advances	Advances received	Amounts reimbursed
Sleep apnea device (6472)	1,600	1,600	420
First Articles (6839)	2,160	2,160	84
Clinical Trial (6840)	2,400	2,400	—
Activation chip improvements (7388)	1,467	1,467	15
Total	**7,627**	**7,627**	**519**

- The Convention 6472 “Sleep apnea device” for a total amount of €1.6 million was signed in 2011. The total amount of the advance has been received before January 1, 2015. The turnover dependent reimbursement is based on 0.224% of the sales achieved by June 2037. The Company has notified his intention to exploit the results of this project before 2015. As a result, cumulated fixed reimbursements amount to €420,000 (excluding interests) out of which €40,000 in 2020 and €40,000 in 2019.
- The Convention 6839 “First Articles” for a total amount of €2.2 million was signed on December 5, 2012. At January 1, 2015, the advance received amounted to €1.9 million. The outstanding amount of €226,000 has been received in 2018. The turnover dependent reimbursement is based on 0.3% of the sales achieved by June 2037. The Company notified to the Region its decision about the exploitation of the results during 2017, therefore fixed reimbursement started in 2018 (€84,000 excluding interests). The Region has informed the Company that the fixed reimbursement related to 2019 and 2020 will be due in 2021. At the end of 2020, the total reimbursement (excluding interests), amounted to €84,000.
- The Convention 6840 “Clinical Trial” for a total amount of €2.4 million was signed on December 6, 2012. At December 31, 2020, the advance received amounted to €2.4 million (2019: €2.2 million) after an amount of €190,000 was received as part of the advance in 2020. The turnover dependent reimbursement is based on 0.336% of the sales achieved by December 2038. The Company has notified to the Region its decision about the exploitation of the results in the course of 2018.
- The Convention 7388 “Implant for Obstructive Sleep Apnea, “Activation Chip Improvements” for a total amount of €1.5 million was signed in December 2015. During 2016, an amount of

14. Financial Debt (continued)

€367,000 was received as part of this advance. Since 2019, the Company received the remaining balance of €1.1 million. The turnover dependent reimbursement is based on 0.45% of the sales achieved to December 2038. In 2019, the Company has notified to the Region its decision about the exploitation of the results. In 2020, a total of €15,000 was reimbursed (excluding interests).

Evolution of the financial debt in the financial statements

The determination of the amount to be reimbursed to the Walloon Region under the signed agreements is subject to a degree of uncertainty as it depends on the amount of the future sales that the Company will generate or not in the future. To determine the fair value of those advances, management of the Company has considered the possible outcomes of the program currently benefiting from the support of the Walloon Region. Management has considered that the probability to have to reimburse the 30% non-revocable repayment has a probability of 100% to occur. The reimbursement of the variable part, the fair value of which is determined on the basis of the sales forecasts largely depends on external factors such as CE-Marking, social security programs, post-market studies and expected timing and level of sales.

The Management performed an initial recognition of the financial debt for the variable part using a discount rate of 12.5%.

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

(in EUR 000)	2020	2019
Recoverable cash advances received	7,627	7,437
Amounts to be reimbursed (2 times)	15,254	14,874
Amounts reimbursed at year-end (interests included)	(582)	(517)
Total Recoverable cash advances (undiscounted)	**14,672**	**14,357**

Based on expected timing of sales and after discounting, the financial debt related to the recoverable cash advances is as follows:

(in EUR 000)	2020	2019
Contract 6472	1,421	1,296
Contract 6839	2,214	2,115
Contract 6840	2,592	2,232
Contract 7388	1,683	1,505
Total Recoverable cash advances	**7,910**	**7,148**
Non-current	7,419	6,874
Current	491	274
Total Recoverable cash advances	**7,910**	**7,148**

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

14. Financial Debt (continued)

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

(in EUR 000)	2020	2019
As of January 1	7,148	5,357
Advances received	190	1,196
Advances reimbursed (excluding interests)	(55)	(40)
Initial measurement and re-measurement	(145)	60
Discounting impact	772	575
As of December 31	**7,910**	**7,148**

The discounting impact is included and presented in the financial expenses and amounted to €0.8 million (2019: €0.6 million). The initial measurement and re-measurement are included in other operating income/expenses and amounted to (€145,000) (2019: €60,000).

A sensitivity analysis of the carrying amount of recoverable cash advances has been done to assess the impact of a change in assumptions. Nyxoah tested reasonable sensitivity to changes in revenue projections of +/- 25% and in the discount rates of +/- 25%. The table hereunder details the sensitivity results:

Fair Value of Liabilities as of end of 2020 (in EUR 000)	Variation of revenue projections		
Variation of discount rates*	-25%	0%	25%
-25%	8,787	9,099	9,281
0%	7,567	7,910	8,114
+25%	6,566	6,922	7,138

* A change of -25% in the discount rates implies that the discount rate used for the fixed part of the recoverable cash advances is 3.8% instead of 5% while the one used for the variable part is 9.4% instead of 12.5%.

An increase of 25% of revenue projections implies, if discount rates does not change, an increase of the expected liability as repayment of the liability is accelerated.

An increase of 25% of the discount rate decreases the expected liability if revenue projections remain unchanged.

Other Financial Liabilities

The Company has contracted a loan of €500,000 on 29 June 2016 with a maturity of 8 years, repayable as from 30 June 2018 and bearing interest of 1.284% p.a. The loan has a carrying amount of €313,000 at December 31, 2020 and €376,000 at December 31, 2019. The payments have been postponed for 3 months due to COVID-19 so the maturity date of the loan has been extended until June 30, 2024.

15. Trade Payables

(in EUR 0000029	2020	2019
Payables	815	1,174
Invoices to be received	375	211
Total Trade payables	**1,190**	**1,385**

The increase of the trade payables between 2020 and 2019 is mainly due to increase in general activities. The Company normally settles its trade payable in 30 days.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

16. Current and Non-current Other Payables

(in EUR 000)	2020	2019
Total other non-current payables	**—**	**547**
Holiday pay accrual	376	243
Salary	382	381
Accrued expenses	1,244	687
Other	2,121	962
Total Other current payables	**4,123**	**2,273**

The increase of the accrued expenses in 2020, compared to 2019, is mainly due to hospital services for the clinical trials in Australia. The category other current and non-current payables include a variable compensation for an amount of €1.8 million at December 31, 2020 (2019: €1.3 million of which €0.5 million non-current and €0.8 million current) of a cash-settled share-based payment transaction. See note 13.

17. Revenue and costs of goods sold

For the first time since its inception, the company started generating revenue as of July 2020. The revenue for the amount of €69,000 is generated under the existing HGNS NUB coding in Germany. Revenue is recognized at a point in time upon satisfaction of the performance obligation, being the moment control over the Genio system is transferred to the customer.

(in EUR 000)	2020
Purchases of goods and services	85
Inventory movement	(55)
Cost of goods sold	**30**

18. General and Administrative expenses

General and administrative expenses consist primarily of payroll and personnel-related costs, and spending related to finance, information technology and human resource functions. Other general and administrative expenses include travel expenses, professional services fees, audit fees, insurance costs and general corporate expenses, including facilities-related expenses.

(in EUR 000)	2020	2019
Staff costs	3,015	1,327
Consulting and contractors’ fees	2,883	1,733
Legal fees	201	42
Rent	89	115
Facilities	116	67
Depreciation and amortization expense	599	415
ICT	234	151
Travel	134	186
Other expenses	251	190
Total General and Administrative expenses	**7,522**	**4,226**

General and administrative expenses increased by 78% from €4.2 million in 2019 to €7.5 million in 2020. The increase is due to consulting expenses, staff and legal fees to support the Company growth. The increase in consulting and contractors’ fees includes variable compensations for an amount of €2.0 million in 2020 and €1.2 million in 2019 related to a cash-settled share based payment transaction.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

18. General and Administrative expenses (continued)

See note 13. The increase of €159,000 in legal fees is due to services and not to any ongoing disputes.

19. Research and Development expenses

Research and development expenses consist primarily of product development, engineering to develop and support our products, testing, consulting services and other costs associated with the next generation of the Genio system. These expenses primarily include employee compensation and outsourced development expenses.

(in EUR 000)	2020	2019
Staff costs	1,304	1,252
Consulting and contractors' fees	—	11
Outsourced developments	1,717	1,054
Depreciation and amortization expense	20	16
Travel	4	33
Other	21	9
Capitalized costs	(2,593)	(1,745)
Total Research and development expenses	**473**	**630**

Before capitalization of €2.6 million in 2020, Research and development expenses increased by 29% from €2.4 million in 2019 to €3.1 million in 2020 due mainly to the further development of the Genio system.

20. Clinical expenses

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

(in EUR 000)	2020	2019
Staff costs	1,531	921
Consulting and contractors' fees	748	474
Clinical activities	1,731	1,190
Travel	51	182
Other	255	114
Capitalized costs	(3,263)	(2,033)
Total Clinical expenses	**1,053**	848

Before capitalization of €3.3 million in 2020, clinical expenses increased by 50% from €2.9 million in 2019 to €4.3 million in 2020. The increase in the expenses was mainly due to an increase in staff and consulting to support the completion of the BETTER SLEEP trial implantations, continuous recruitment for Elisa study and the launch of the new Dream IDE study in the US.

21. Manufacturing expenses

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

21. Manufacturing expenses (continued)

(in EUR 000)	2020	2019
Staff costs	1,211	613
Consulting and contractors' fees	—	—
Manufacturing	2,427	1,071
Travel	25	41
Other	139	87
Capitalized costs	(3,342)	(1,323)
Total Manufacturing expenses	**460**	**489**

Before capitalization of €3.3 million in 2020, manufacturing expenses increased by 110% from €1.8 million in 2019 to €3.8 million in 2020. The increase in the expenses was mainly due to an increase in staff, in production and engineering team to support capacity and yield improvement, and also due to purchasing raw materials to support increase in the production.

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

(in EUR 000)	2020	2019
Implantable stimulator	1,660	686
Activation chip	228	67
Disposable patch	102	113
External stimulator	69	37
Other	368	168
Capitalized costs	(2,254)	(800)
Total	173	**271**

22. Quality Assurance and Regulatory expenses

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

(in EUR 000)	2020	2019
Staff costs	641	353
Consulting and contractors' fees	291	400
QA & regulatory	542	148
Travel	—	27
Capitalized costs	(1,247)	(701)
Total Quality Assurance and Regulatory expenses	**227**	**227**

Before capitalization of €1.2 million in 2020, Quality assurance and regulatory expenses increased by 59% from €0.9 million in 2019 to €1.5 million in 2020. The increase in the expenses was mainly due to an increase in staff and QA & regulatory activities to support manufacturing scaling up process.

23. Patents and Therapy Development expenses

Patents fees & related expenses

Patents fees and relate expenses consist primarily of compensation for personnel, spending related to the protection of company's intellectual property, prosecution costs and travel expenses. Up to 2019, patents

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

23. Patents and Therapy Development expenses (continued)

fees and related expenses were not capitalized following an accounting policy similar to the one applied to development expenses.

Before capitalization of €256,000 in 2020 (2019: €335,000), patents fees and related expenses amounted to €379,000 in 2020 (2019: €0.6 million).

Therapy development expenses

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

Therapy development expenses increased by 107% from €0.9 million in 2019 to €1.9 million in 2020. The increase in the expenses was mainly due to an increase in staff and consulting, to support the launch the commercialization in Europe.

24. Other Operating Income / (Expenses)

(in EUR 000)	2020	2019
Recoverable cash advances		
— Initial measurement and re-measurement	147	(61)
R&D Incentives (Australia)	1,000	425
Capitalization of R&D Incentive	(573)	(493)
Other income/(expenses)	(115)	3
Total Other Operating Income/(Expenses)	**459**	**(126)**

The impact of the recoverable cash advances is further detailed in note 14. It includes the impact of the initial measurement and re-measurement of the financial debt.

The R&D Incentive (Australia) relates to incentive to be received on development expenses incurred by the subsidiary in Australia. The 2020 R&D incentive of €0.6 million (2019: €493,000) has been deducted from the clinical expenses capitalized.

25. Employee Benefits

(in EUR 000)	2020	2019
Salaries	4,577	3,625
Social charges	562	518
Fringe benefits	104	153
Defined contribution plan	249	258
Holiday pay	273	99
Share-based payment (see note 13)	2,548	346
Other	138	127
Total employee benefits	**8,451**	**5,126**
General and administrative expenses	3,015	1,327
Research & Development costs	1,304	1,252
Clinical expenses	1,531	921
Operation & Manufacturing expenses	1,211	613
QA expenses	641	353
Other expenses (therapy development, patents, etc.)	749	660
Total employee benefits	**8,451**	**5,126**

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

25. Employee Benefits (continued)

As at December 31, 2020, the Nyxoah Group employed 71.9 (2019: 42.5) full-time equivalents, including white-collar employees and consultants. The following table presents a breakdown of the Company's full-time equivalents as at December 31, 2020 and 2019:

	As at December 31,	
	2020	2019
General & Administration	9	5.8
IP & Trademark	—	1.0
Research & Development	10.8	10.6
Clinical & Regulatory Affairs	23.2	8.2
Quality Assurance & Regulatory	7.9	5.9
Operations	15	9.0
Therapy Development (including the sales team)	6	2.0
Total	71.9	42.5

As of December 31, 2020, the Company had 20.2 full-time equivalents located in Belgium (2019: "10.2"), 36.7 full-time equivalents located in Israel (2019:"28.3") 5 full-time equivalents located in Australia (2019: "4"), and 10 full-time equivalents located in USA.

26. Pension Schemes

Defined contribution plan:

The Company offers Defined Contribution Plan funded through group insurances to its employees of the Israel entity. The total expense recognized in the consolidated income statement for contributions under this plan amount to €171,000 (2019: €148,000).

Defined benefit plan:

The Company offers a pension plan with a minimum return guaranteed by law to its employees of the Belgian entity. The contributions to this plan amount to minimum 7.0% of the salary, partly paid by the employer and partly by the employees. As explained hereafter, this pension plan qualifies as Defined Benefit Plan under IFRS. As a result, a provision of €37,000 (2019: €30,000) has been recorded for the net benefit obligation in 2020. The impact on the OCI was not material.

As a consequence of the law of 18 December 2015, minimum returns guaranteed by the employers are as follows:

A. For the contributions paid as from January 1, 2016, a new variable return based on OLO rates comprised between 1.75% and 3.75%. The rate is currently set to 1.75%.

B. For the contributions paid until end December 2015, the previously applicable legal returns of 3.75% on employee contributions and 3.25% on employer contributions continue to apply until retirement date of the participants.

The insurance companies managing these plans for the Company also guarantee a minimum return on the reserves as well as on future contributions for some portions of the plan. They have evolved as follows: 4.75% until 1998, 3.25% from 1999 till 2012 and between 0.50% and 2.25% since 2013. They are currently set between 0.50% and 1.50%. The assets of the plan are entirely managed by external insurance companies "qualifying third party" which do not have any link with the Company.

The weighted average duration until the pension age for the Belgian plan is 20 years at December 31, 2020. In view of the minimum legal returns guaranteed, this pension Plan qualifies as Defined Benefit Plan under IFRS. Indeed, it induces a financial risk for the Company during periods of declining market

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

26. Pension Schemes (continued)

interest rates when the returns guaranteed by the insurance companies are lower than the minimum legal returns, which is currently the case. In this case, the intervention of the insurance company is limited, and the Company shall fund the balance between the return delivered by the insurance company and the legal return.

A complete actuarial calculation has been performed for this plan by external actuaries based on the “Projected Unit Credit Method without future contribution” according to the IAS 19.115 as follows:

(a) Projection of the minimum return guaranteed by the law till the retirement date and discounting of this amount with the discount rate used for the valuation (rate of high-quality corporate bonds);

(b) The discounted net obligation is the maximum between this discounted projection and the projection of the accrued reserves discounted at the discount rate used for the valuation (rate of high-quality corporate bonds).

The net defined benefit obligation was established at €37,000 as of December 31, 2020 (2019: €30,000).

(in EUR 000)	2020	2019
Net defined benefit liability at the beginning of the year	**30**	**13**
Defined benefit cost included in profit or loss	93	90
Total remeasurement included in OCI	—	—
Employer contributions	(77)	(73)
Transfer reserves (terminated participants)	(9)	—
Net defined benefit liability at the end of the year	**37**	**30**

The gross defined benefit liability is as follows:

(in EUR 000)	2020	2019
Gross defined benefit liability at the beginning of the year	**209**	**118**
Current service cost	90	90
Interest cost	1	2
Taxes on contributions	(8)	(1)
Transfer reserves (terminated participants)	(60)	—
Actuarial loss due to change in financial assumptions	16	—
Gross defined benefit liability at the end of the year	**248**	**209**

The fair value of the plan assets is as follows:

(in EUR 000)	2020	2019
Fair value plan assets at the beginning of the year	**179**	**106**
Interest income	2	1
Employer contributions	77	73
Taxes on contributions	(8)	(1)
Transfer reserves (terminated participants)	(55)	—
Actuarial gain on fair value of the plan assets	16	—
Fair value plan assets at the end of the year	**211**	**179**

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

26. Pension Schemes (continued)

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

	2020	2019
Active members	14	8
Inactive members	—	—
Average age	43	48

All plan assets are invested in an insurance contract with guaranteed interest rate (branch 21 product).

The defined benefit calculation has been performed based on the below assumptions:

	2020	2019
Discount rate	0.1%	0.6%
Inflation rate	2%	2%
Salary increase (in excess of inflation)	0%	0%
Withdrawal rate based on age (between)	1.5% and 8.50%	1.5% and 8.50%

The discount rate was derived from the EIOPA term structure on each valuation date, considering the weighted average duration of liabilities. The inflation rate is based on the long-term objective of the European Central Bank. Retirement age assumption is in line with current legal requirements. The withdrawal rate and the salary increase rate reflect the expectations of the company on a long-term basis. The impact on the OCI is immaterial.

A sensitivity with reasonable possible changes on the discount rate will impact the net defined benefit liability as follows (positive = increase net defined benefit liability / negative = decrease of net defined benefit liability):

(in EUR 000)	2020
Increase of 0,25% in the discount rate	(2)
Decrease of 0,25% in the discount rate	2

The expected employer contributions for the year 2021 amounts to €100,000.

27. Financial Income

(in EUR 000)	2020	2019
Interests	3	8
Exchange differences	59	63
Total Financial income	**62**	**71**

28. Financial Expense

(in EUR 000)	2020	2019
Recoverable cash advances, Discounting	772	575
Interest and bank charges	151	33
Interest on lease liabilities	47	17
Exchange differences	20	115
Total Financial expense	**990**	**740**

The discounting impact of the recoverable cash advances is further detailed in note 14 above.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

29. Taxes

The major components of income tax expense for the years ended December 31, 2020 and 2019 are as follows:

(in EUR 000)	2020	2019
Current tax	(104)	(61)
Deferred tax Income/(Expense)	11	(9)
Total Income Tax Expenses	(93)	(70)

Current tax mainly relates to income tax paid by the subsidiary in Israel. The deferred tax also relates to the subsidiary in Israel where some payroll accruals are temporary differences in the determination of the taxable income. These temporary differences generate deferred tax income/(expense) of €11,000 in 2020 and €(9,000) in 2019, and deferred tax assets of €32,000 (2019: €21,000).

The income tax expenses can be reconciled to the Company's Belgian statutory income tax rate of 25% (29.58% in 2019) as follows:

(in EUR 000)	2020	2019
Pre-Tax Book Income /(loss)	(12,152)	(8,384)
Company Statutory Income Tax Rate	25.00%	29.58%
Income Tax at Company Statutory Tax Rate:	3,038	2,480
Unrecognized DTA on tax losses and temporary differences	(2,681)	(2,132)
Nondeductible expenses	(488)	(426)
Foreign Tax Rate Differential	58	38
Other temporary differences	(20)	(30)
Income Tax at Company Effective Tax Rate	(93)	(70)
Company Effective Income Tax Rate	(0.77)%	(0.83)%

As mentioned above, the subsidiary in Israel is paying income taxes and recognized deferred tax on some temporary differences. The applicable tax rate being 16%, amounts are reconciled as described in the above table.

The Belgian entity and the Australian entity both have historical losses that can be carried forward to future taxable income. The Belgian entity has tax losses for €56.3 million as at December 31, 2020 (2019: €44.1 million) but also has recoverable temporary differences (€6.0 million on valuation of recoverable cash advances (2019: €5.4 million) and €0.7 million taxed reserves (2019: €2.0 million). The Australian entity has tax losses for 0.8 million as at December 31 2020 (2019: €0.5 million). Due to the fact that these entities are not expected to generate significant profits in the near future, no deferred tax assets on tax losses carried forward and temporary differences have been recognized at this stage.

30. Earnings Per Share (EPS)

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

EPS has been presented in the income statement taking into account resolutions adopted by the shareholders' meeting of February 21, 2020. All existing preferred shares were converted into common

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

30. Earnings Per Share (EPS) (continued)

shares, and then a share split of 500:1 was approved by the shareholders' meeting. Applying this split to the existing shares as of December 31, 2019 provides the following information:

	2020	2019
As at December 31, after conversion and share split		
Outstanding common shares at year-end	22,097,609	6,728,500
Weighted average number of common shares outstanding	18,097,988	6,728,500
Number of Shares resulting of the exercise of outstanding warrants	1,007,500	1,143,500

Basic and Diluted EPS, based on weighted average number of shares outstanding after conversion and share split are as follows:

	2020	2019
Loss of year attributable to common holders (in EUR)	(12,245,000)	(3,823,000)
Loss of year attributable to preferred holders (in EUR)	0	(4,631,000)
Loss of year attributable to equity holders (in EUR)	(12,245,000)	(8,454,000)
Weighted average number of common shares outstanding (in units)	18,097,988	6,728,500
Basic earnings per share in EUR (EUR/unit)	**(0.677)**	**(0.568)**
Diluted earnings per share in EUR (EUR/unit)	**(0.677)**	**(0.568)**

31. Commitments

Capital Commitments

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

Lease expenses

The lease expense recognized in the income statement mainly relate to municipality taxes, electricity charges and low-value leases:

(in EUR 000)	2020	2019
Expense	89	115
Total	**89**	**115**

Other commitments

The Company has granted in October 2020 an amount of €500,000 towards an institute under the Company's Sponsored Grant Program. The institute will have to perform over a total period of two years certain clinical and research activities and training and education activities. The future payment commitments amount to €400,000 at December 31, 2020 which will be paid quarterly in instalments over the remaining period if the institute performs its activities.

32. Related Party Transactions

Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

32. Related Party Transactions (continued)

Remuneration of Key Management

The remuneration of the senior management consists of the remuneration of the CEO of the Company:

(in EUR 000)	2020	2019
Short-term remuneration & compensation	337	612
Share based payment	1,576	231
Total	**1,913**	**843**

In the period between 2017 and November 2019, Mr. Enrique Vega served as the Company's CEO. As of November 2019, Mr. Olivier Taelman was appointed as CEO of the Company. The total compensation for Mr. Enrique Vega in 2019 was €0.6 million.

In 2020 and 2019, ActuaRisk Consulting, a company owned by a member of executive management, invoiced Nyxoah SA for an amount of €309,000 and €234,000, respectively, for consulting services. Of the €309,000 invoiced in 2020, €39,600 related to fees due in relation to 2019. The Company also recognized a share-based payment expense of €1.8 million in 2020 (2019: €0.5 million) in relation to the variable remuneration rights which vested at the time of the IPO. See note 13.3.

In 2020, a loan of €8,800 was granted by Nyxoah SA to Olivier Taelman in connection with the payment of taxes due following the acceptance of warrants. No other loans or other guarantees have been given to a member of the executive management team.

Transactions with Non-Executive Directors and Shareholders

	12/31/2020			12/31/2019	
(in EUR 000)	R&D Collaboration	Consulting services	Board remuneration	Consulting services	Board remuneration
Cochlear	1,300	—	—	839	—
Noshaq	—	10	—	—	—
MINV SA	—	50	—	79	—
Man & Science S.A	—	44	—	6	—
Christopher Smith	—	—	—	9	11
Medtech Execs LLC	—	—	9	—	31
Robert Taub	—	—	28	—	—
Kevin Rakin	—	—	8	—	—
Donald Deyo	—	—	12	—	—
Pierre Gianello	—	—	8	—	—
Jan Janssen	—	—	8	—	—
Jurgen Hambrecht	—	—	9	—	—
Total	**1,300**	**104**	**90**	**935**	**42**

33. Events after the Balance-Sheet Date

After closing of the financial year, Nyxoah signed an exclusive license agreement with Vanderbilt University (Nashville, TN, USA). This agreement allows Nyxoah to develop new neurostimulation technologies for the treatment of sleep disordered breathing conditions based on inventions and patents owned by Vanderbilt University, which will potentially expand Nyxoah's future pipeline.

On February 22, 2021, the Company issued 10,000 shares pursuant to an exercise of subscription rights. Consequently, on the date of this Annual Report, the Company's registered capital amounts to €3,797,765.64, represented by 22,107,609 shares.

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS AS OF MARCH 31, 2021 AND FOR THE THREE MONTH PERIODS ENDED MARCH 31, 2021 AND 2020

NYXOAH SA

INTERIM CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	As of March 31 2021	As of December 31 2020
ASSETS		
Non-current assets		
Property, plant and equipment	€ 852	€ 713
Intangible assets	17,247	15,853
Right of use assets	3,158	3,283
Deferred tax asset	41	32
Other long-term receivables	91	91
	€ 21,389	**€ 19,972**
Current assets		
Inventory	106	55
Trade Receivables	185	
Other receivables	1,699	1,644
Other current assets	1,064	109
Cash and cash equivalents	86,207	92,300
	€ 89,261	**€ 94,108**
Total assets	**€ 110,650**	**€ 114,080**
EQUITY AND LIABILITIES		
Capital and reserves		
Common shares	3,798	3,796
Share premium	150,986	150,936
Share-based payment reserve	2,650	2,650
Currency translation reserve	79	149
Retained earnings	(66,010)	(60,341)
Total equity attributable to shareholders	**€ 91,503**	**€ 97,190**
LIABILITIES		
Non-current liabilities		
Financial debt	7,757	7,607
Lease liability	2,737	2,844
Pension Liability	37	37
	€ 10,531	**€ 10,488**
Current liabilities		
Financial debt	658	616
Lease liability	475	473
Trade payables	2,802	1,190
Other payables	4,681	4,123
	€ 8,616	**€ 6,402**
Total liabilities	**€ 19,147**	**€ 16,890**
Total equity and liabilities	**€ 110,650**	**€ 114,080**

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

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS AS OF MARCH 31, 2021 AND FOR THE THREE MONTH PERIODS ENDED MARCH 31, 2021 AND 2020

NYXOAH SA

INTERIM CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share data)

	For the three months ended March 31	
	2021	2020
Revenue	€ 185	€ —
Cost of goods sold	(52)	—
Gross Profit	**€ 133**	**€ —**
General and administrative expenses	(1,818)	(1,178)
Research and development expenses	(852)	(7)
Clinical expenses	(342)	(177)
Manufacturing expenses	(901)	(62)
Quality assurance and regulatory expenses	(325)	(25)
Patents fees & related	(674)	(58)
Therapy development expenses	(548)	(352)
Other operating income / (expenses)	4	(191)
Operating loss for the period	**€(5,323)**	**€(2,050)**
Financial income	4	19
Financial expense	(325)	(336)
Loss for the period before taxes	**€(5,644)**	**€(2,367)**
Income taxes	(25)	(13)
Loss for the period	**€(5,669)**	**€(2,380)**
Other comprehensive loss		
Items that may be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	(70)	272
Total comprehensive loss for the year, net of tax	**€(5,739)**	**€(2,108)**
Loss attributable to equity holders	**€(5,739)**	**€(2,108)**
Basic Loss Per Share	€(0.256)	€(0.151)
Diluted Loss Per Share	€(0.256)	€(0.151)

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

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS AS OF MARCH 31, 2021 AND FOR THE THREE MONTH PERIODS ENDED MARCH 31, 2021 AND 2020

NYXOAH SA

INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(unaudited)
(in thousands)

	Attributable to owners of the parent						
As of and for the three months ended March 31, 2021	**Common Shares**	**Preferred Shares**	**Share premium**	**Share based payment reserve**	**Currency translation reserve**	**Retained earnings**	**Total**
Balance at January 1, 2021	**€ 3,796**	**—**	**€150,936**	**€ 2,650**	**€ 149**	**€(60,341)**	**€ 97,190**
Loss for the period	—	—	—	—	—	(5,669)	(5,669)
Other comprehensive loss for the period	—	—	—	—	(70)	—	(70)
Total comprehensive loss for the period	**—**	**—**	**—**	**—**	**€ (70)**	**€ (5,669)**	**€ (5,739)**
Issuance of shares for cash	2	—	50	—	—	—	52
Total transactions with owners of the Company recognized directly in equity	**€ 2**	**—**	**€ 50**	**—**	**—**	**—**	**€ 52**
Balance at March 31, 2021	**€ 3,798**	**—**	**€150,986**	**€ 2,650**	**€ 79**	**€(66,010)**	**€ 91,503**

As of and for the three months ended March 31, 2020	**Common Shares**	**Preferred Shares**	**Share premium**	**Share based payment reserve**	**Currency translation reserve**	**Retained earnings**	**Total**
Balance at January 1, 2020	**€ 1,122**	**€ 1,359**	**€ 47,668**	**€ 420**	**€ 207**	**€(48,415)**	**€ 2,361**
Loss for the period						(2,380)	(2,380)
Other comprehensive income for the period	—	—	—	—	272	—	272
Total comprehensive income/(loss) for the period	**—**	**—**	**—**	**—**	**€ 272**	**€ (2,380)**	**€ (2,108)**
Equity-settled share-based payments	—	—	—	147	—	50	197
Issuance of shares for cash	436	—	24,624	—	—	—	25,060
Transaction cost	—	—	(96)	—	—	—	(96)
Conversion of preferred shares to common shares	1,359	(1,359)	—	—	—	—	—
Total transactions with owners of the Company recognized directly in equity	**€ 1,795**	**(1,359)**	**€ 24,528**	**€ 147**	**—**	**€ 50**	**€25,161**
Balance at March 31, 2020	**€ 2,917**	**—**	**€ 72,196**	**€ 567**	**€ 479**	**€(50,745)**	**€25,414**

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

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS AS OF MARCH 31, 2021 AND FOR THE THREE MONTH PERIODS ENDED MARCH 31, 2021 AND 2020

NYXOAH SA

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	For the three months ended March 31	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss before tax for the period	**€ (5,644)**	**€ (2,367)**
Adjustments for:		
Finance income	(4)	(19)
Finance expenses	325	336
Depreciation and impairment of property, plant and equipment and right-of-use assets	375	128
Share-based payment transaction expense	—	197
Other non-cash items	3	111
Cash used before changes in working capital	**€ (4,945)**	**€ (1,614)**
Changes in working capital:		
Increase in inventory	(51)	—
Increase in trade receivables	(185)	—
Decrease/(increase) in other receivables	(1,010)	402
Increase in trade and other payables	2,170	35
Cash used for changes in operations	**€ (4,021)**	**€ (1,177)**
Interests received	1	2
Interests paid	(105)	(5)
Income tax paid	(34)	(17)
Net cash used in operating activities	**€ (4,159)**	**€ (1,197)**
CASH FLOWS USED IN INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(169)	(84)
Capitalization of intangible assets	(1,606)	(1,694)
Increase of long-term deposits	—	1
Net cash used in investing activities	**€ (1,775)**	**€ (1,777)**
CASH FLOWS USED IN / GENERATED FROM FINANCING ACTIVITIES		
Payment of principal portion of lease liabilities	(135)	(105)
Repayment of other loan	(21)	(21)
Proceeds from issuance of shares, net of transaction costs	52	24,964
Net cash used in/generated from financing activities	**€ (104)**	**€ 24,838**
Movement in cash and cash equivalents	**€ (6,038)**	**€ 21,864**
Effect of exchange rates on cash and cash equivalents	(55)	155
Cash and cash equivalents at January 1	**€92,300**	**€ 5,855**
Cash and cash equivalents at March 31	**€86,207**	**€ 27,874**

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

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

1. General information

Nyxoah SA (the "Company") is a public listed company with limited liability (naamloze vennootschap/société anonyme) incorporated and operating under the laws of Belgium and is domiciled in Belgium. The Company is registered with the legal entities register (Brabant Walloon) under enterprise number 0817.149.675. The Company's registered office is in Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

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

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

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

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

The interim condensed consolidated financial statements of Nyxoah SA and its subsidiaries (collectively, the Group) as of March 31, 2021 and for the three-month periods ended March 31, 2021 and 2020 have been authorized for issue on May 21, 2021 by the Board of Directors of the Company.

2. Significant accounting policies

Basis of Preparation of the interim condensed consolidated financial statements

The Company's interim condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 — Interim Financial Reporting ("IFRS"), as issued by the International Accounting Standards Board (IASB). They do not include all the information required for complete annual financial statements and should be read in conjunction with the Company's last annual consolidated financial statements as at and for the year ended December 31, 2020.

Except for the application of standards, interpretations and amendments being mandatory as of January 1, 2021, the accounting policies used for the preparation of the interim condensed consolidated financial statements are consistent with those used for the preparation of the Company's annual consolidated financial statements as of and for the year ended December 31, 2020.

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

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

The preparation of the interim condensed consolidated financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company's accounting policies. The areas involving a higher degree of judgment or complexity, are areas where assumptions and estimates are significant to the consolidated financial statements. The critical accounting estimates used in the preparation of the interim consolidated financial statements are consistent with those followed in the preparation of the Company's annual consolidated financial statements as of and for the year ended December 31, 2020.

An entity shall determine the net defined benefit liability (asset) with sufficient regularity that the amounts recognized in the financial statements do not differ materially from the amounts that would be determined at the end of the reporting period. The current pension obligation results from defined benefit liability does not materially differ on a quarterly basis therefore the Company has determined to recognize the net defined benefit liability on annual basis being at the end of the reporting period.

Going concern principle

The Unaudited Interim Condensed Consolidated Financial Statements have been prepared on a going concern basis. As at March 31, 2021, the Company had cash and cash equivalents of €86.2 million. Based on cash flow forecasts for the years 2021 and 2022, which include significant expenses and cash outflows in relation to - among others - the ongoing clinical trials, the continuation of research and development projects, and the scaling-up of the Company's manufacturing facilities, the Company believes that this cash position will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of this Interim Report.

New and amended standards and interpretations applicable.

Effective for the annual periods beginning on January 1, 2021

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

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

— Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform — Phase 2 (applicable for annual periods beginning on or after January 1, 2021, but not yet endorsed in the EU).

Significant events and transactions of the interim period:

The Company generated its first commercial sales in July 2020. In the three-month period ended March 31, 2021, the Company generated revenue in Germany. See note 17.

In the three-month period ended March 31, 2021, the Company entered into an exclusive license agreement with Vanderbilt University. This agreement allows the Company to develop new neurostimulation technologies for the treatment of sleep disordered breathing conditions based on inventions and patents owned by Vanderbilt University, which will potentially expand the Company's future pipeline. Under the agreement, the Company paid to Vanderbilt an upfront license issue fee of approximately $650,000. The Company may be required to make minimum annual royalty payments to Vanderbilt of up to $250,000 in 2024 and 2025, up to $500,000 in 2026 and 2027, and up to $1,000,000 in 2028 and each year thereafter, which are creditable against the earned royalties owed to Vanderbilt for the same calendar year. Additionally, Vanderbilt may be entitled to milestone payments of up to an aggregate of $13,750,000 in connection with patent issuance, clinical studies, regulatory approvals and net sales milestones. The Company may also be required to pay Vanderbilt a low to mid double digit

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

2. Significant accounting policies (continued)

percentage, not to exceed 40%, of any non-royalty sublicensing revenue that the Company receives. The Vanderbilt Agreement, including the royalty obligations thereunder, will continue on a licensed product-by-licensed product and country-by-country basis until the expiration date of the last-to-expire licensed patent in each country. Either the Company or Vanderbilt may terminate the Vanderbilt Agreement in connection with the other party's insolvency. Vanderbilt may also terminate the Vanderbilt Agreement in the event the Company fails to make a payment to Vanderbilt, breach or default the Company's diligence obligations or breach or default on any other material term, and if the Company fails to make such payment or cure such breach or default within 60 days of written notice from Vanderbilt. The Company may terminate the agreement by providing 120 days' advance notice to Vanderbilt. During the three-month period ended March 31, 2021, the upfront license issue fee and past patenting costs relating to this agreement were expensed as incurred. See note 17.

3. Critical accounting estimates and assumptions

The preparation of interim financial statements in accordance with IFRS requires management to make judgments, estimates and assumptions that may significantly affect the reported amounts of revenues, expenses, assets and liabilities, and the disclosure of contingent liabilities, at the end of the reporting period.

Refer to the disclosure note 5 from the Group's 2020 year-end consolidated financial statements for further details about the main critical accounting estimates and assumptions.

4. Segment Reporting

Based on the organizational structure, as well as the nature of financial information available and reviewed by the Company's chief operating decision makers to assess performance and make decisions about resource allocations, the Company has concluded that its total operations represent one reportable segment. The chief operating decision maker is the CEO.

5. Fair Value

The carrying amount of cash and cash equivalents, trade receivables, other receivables and other current assets approximate their value due to their short-term character. Derivatives financial instruments, such as foreign exchange forward contracts, are also measured at fair value. However, none of the contracts were on-going at year end.

The carrying value of current liabilities approximates their fair value due to the short-term character of these instruments.

The fair value of non-current liabilities (financial debt and other non-current liabilities) is evaluated based on their interest rates and maturity date. These instruments have fixed interest rates and their fair value measurements are subject to changes in interest rates. The fair value measurement is classified as level 3.

	Carrying value		Fair value	
(in EUR 000)	**As at March 31, 2021**	**As at December 31, 2020**	**As at March 31, 2021**	**As at December 31, 2020**
Financial Assets				
Other long-term receivables (level 3)	91	91	91	91
Trade and other receivables (level 3)	1,884	1,644	1,884	1,644
Other current assets (level 3)	1,064	109	1,064	109
Cash and cash equivalents (level 1)	86,207	92,300	86,207	92,300

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NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

5. Fair Value (continued)

(in EUR 000)	Carrying value		Fair value	
	As at March 31, 2021	As at December 31, 2020	As at March 31, 2021	As at December 31, 2020
Financial liabilities				
Financial debt (level 3)	292	313	268	250
Recoverable cash advances (level 3)	8,123	7,910	8,123	7,910
Trade and other payables (level 3)	7,484	5,313	7,484	5,313

6. Subsidiaries

For all periods that are mentioned in this report, the Company owns 100% of the shares of Nyxoah LTD, an Israeli company located in Tel-Aviv that was incorporated in 2009 and has a share capital of NIS 1.00.

The Company also owns 100% of the shares of Nyxoah PTY LTD, an Australian company located in Collingwood that was incorporated in 2017 and has a share capital of AUD 100.

In May 2020, the Company incorporated Nyxoah Inc, an American company located in Delaware with a share capital of 100 USD. The Company owns 100% of the shares of Nyxoah, Inc.

7. Property, Plant and Equipment

For the three-month period ended March 31, 2021 and 2020, acquisitions were mainly related to furniture and office equipment, and leasehold improvements and amounted to €169,000 (2020: €84,000).

The depreciation charge amounts to €32,000 in 2021 and €27,000 in 2020 for the three-month period ended March 31.

8. Intangible assets

There is only one development project: The Genio® system. Refer to note 1.

(in EUR 000)	Development Cost	Patents and licenses	Total
Cost			
Opening Gross value at 01/01/2020	5,311	335	5,646
Additions	1,653	56	1,709
Gross value at 03/31/2020	**6,964**	**391**	**7,355**
Opening Gross value at 01/01/2021	15,185	591	15,776
Additions	1,598	—	1,598
Gross value at 03/31/2021	**16,783**	**591**	**17,374**
Amortization			
Opening amortization at 01/01/2020	—	—	—
Amortization	—	—	—
Amortization at 03/31/2020	—	—	—
Opening amortization at 01/01/2021	—	—	—
Amortization	(211)	—	(211)
Amortization at 03/31/2021	**(211)**	**—**	**(211)**

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

8. Intangible assets (continued)

(in EUR 000)	Development Cost	Patents and licenses	Total
Opening Exchange differences at 01/01/2020	88	—	88
Exchange differences	(15)	—	(15)
Exchange differences at 03/31/2020	**73**	—	**73**
Opening Exchange differences at 01/01/2021	**77**	—	**77**
Exchange differences	7	—	7
Exchange differences at 03/31/2021	**84**	—	**84**
Net book value at 03/31/2020	**6,037**	**391**	**7,428**
Net book value at 03/31/2021	**16,656**	**591**	**17,247**

The Company has started amortizing the first-generation Genio system as of January 1, 2021. The amortization amounted to €211,000 for the three-month period ended March 31, 2021 and is included in Research and development expenses (€181,000) and in Clinical expenses (€30,000).

The Company continues to incur in 2021 development expenses with regard to the improved second-generation Genio System and clinical trials to obtain additional regulatory approvals in certain countries or to be able to sell the Genio System in certain countries. The total capitalized development expenses amounted to €1.6 million and €1.7 million for the three-month period ended March 31, 2021, and 2020, respectively.

9. Right of use assets and lease liabilities

For the three-month period ended March 31, 2021, the Company did not enter into new lease agreements. For the preceding period of three months ended March 31, 2020, the impact of new leases was €432,000. The repayments of lease liabilities amounted to €135,000 (2020: €105,000). The depreciations on the right of use assets amounted to €132,000 and €101,000 for the three-month period ended March 31, 2021, and 2020, respectively.

10. Trade and Other receivables

(in EUR 000)	As of March 31, 2021	As of December 31, 2020
R&D incentive receivable (Australia)	1,222	951
VAT receivable	398	607
Current tax receivable	28	(3)
Other	51	89
Total other receivables	**1,699**	**1,644**

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

The increase of €185,000 in trade receivables in the three month period ended March 31, 2021 are due to generated revenue by the Company in Germany.

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

11. Other current assets

(in EUR 000)	As of March 31, 2021	As of December 31, 2020
Prepaid transaction costs	915	—
Other prepaid	149	109
Total other current assets	**1,064**	**109**

Prepaid transaction costs were incurred in anticipation of a potential issuance of equity instruments relating to the proposed public offering of its ordinary shares in the United States. The Company is deferring those costs and will subsequently reclassify them as a deduction from the equity when the equity instruments are issued or will recognize themin the income statement if the issuance of equity is aborted.

12. Cash and cash equivalents

(in EUR 000)	As of March 31, 2021	As of December 31, 2020
Short term deposit	28	28
Three months term deposit	6	6
Current accounts	86,173	92,266
Total cash and cash equivalents	**86,207**	92,300

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

13. Capital, Share Premium, Reserves

Evolution of the share capital and share premium over the three-month period ended March 31, 2021, and 2020:

(Number of shares [1] except otherwise stated)	Common Shares	Preferred Shares	Total of Shares	Par value (EUR)	Share Capital	Share Premium
January 1, 2020 (adjusted for share split in 2020)	**6,728,500**	**8,150,000**	**14,879,000**	**0.17**	**2,481**	**47,668**
February 21, 2020 – Conversion of preferred shares to common shares	8,150,000	(8,150,000)	—	—	—	—
February 21, 2020 – Capital increase	2,100,000	—	2,100,000	0.21	436	24,624
March 31, 2020 (adjusted for share split in 2020)	**16,979,000**	**—**	**22,097,609**	**0.17**	**3,796**	**157,514**
September 7, 2020 – Exercise warrants	44,500		44,500	0,17	8	222
September 21, 2020 – IPO	4,335,000	—	4,335,000	0.17	745	72,950
September 21, 2020 – Convertible loan	65,359	—	65,359	0.17	11	989
September 29, 2020 – Exercise warrants	650,250	—	650,250	0.17	112	10,943
October 28, 2020 – Exercise warrants	23,500	—	23,500	0.17	4	117
December 31, 2020 (adjusted for share split in 2020)	**22,097,609**	**—**	**22,097,609**	**0.17**	**3,796**	**157,514**
February 22, 2021 – Capital increase	10,000	—	10,000	0.17	2	50
March 31, 2021 (adjusted for share split in 2020)	**22,107,609**	**—**	**22,107,609**	**0.17**	**3,798**	**157,564**

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

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

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

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

On September 7, 2020, pursuant to the exercise of warrants, the aggregate capital of the Company increased with €230,110.39 (including share premium) in exchange for 44,500 new shares in the Company.

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NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

13. Capital, Share Premium, Reserves (continued)

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

The Initial Public Offering (IPO) resulted in an aggregate capital increase in the Company of €73.7 million (including share premium) in exchange for 4,335,000 new shares in the Company at the price of EUR 17 per share. The conversion of a convertible loan of €1.0 million in shares resulted (triggered by the IPO) in an aggregate capital increase in the Company of €1.0 million (including share premium) in exchange for 65,359 new shares in the Company. The convertible loan was entered into between the Company and Noshaq SA ("Noshaq") on June 26, 2020 for an amount of €1.0 million. The convertible loan had a non-compounding interest rate of 2.50% per annum. The trigger events for a mandatory conversion were (i) an initial public offering, (ii) qualifying financing and (iii) a trade sale. If no mandatory conversion has taken place on or prior to the second anniversary of date of the loan, the Company will be able to opt for an optional conversion to force Noshaq to convert the entire outstanding Principal Amount at nominal value into new shares. The convertible loan was accounted for prior to conversion at fair value with changed in fair value through the profit or loss. Change in fair value of this conversion feature between the issue date and the conversion date is immaterial.

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

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

On October 28, 2020, pursuant to the exercise of warrants, the aggregate capital of the Company increased with €121,510.04 (including share premium) in exchange for 23,500 new shares in the Company.

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

14. Share-Based compensation

Equity-settled share-based payment transactions

As of March 31, 2020, the Company had four outstanding equity-settled share-based incentive plans, including (i) the 2013 warrants plan (the 2013 Plan), (ii) the 2016 warrants plan (the 2016 Plan), (iii) the 2018 warrants plan (the 2018 Plan), and (iv) the 2020 warrants plan (the 2020 plan). The Company had an extraordinary shareholders' meeting on February 21, 2020, where it was decided to achieve a share split in a ratio of 500:1. Per Warrant issued before February 21, 2020, 500 common shares will be issuable.

The Company has recognised €0 and €197,000 share-based payment expense for the three-month period ended March 31, 2021, and 2020, respectively. All equity-settled share-based payment transactions have fully vested and are fully exercisable as from September 7, 2020, i.e., ten business days prior to the IPO on September 21, 2020.

Cash-settled share-based payment transactions

The Company has signed service agreements with ActuaRisk Consulting SRL in 2014 and with Mr. Kezirian in 2015. Both arrangements qualify as a cash-settled share-based payment transaction.

The liability for the cash-settled share-based payment arrangements amount to €2.3 million at March 31, 2021 and €1.8 million at December 31, 2020, with an expense recognized in general and administrative

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NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

14. Share-Based compensation (continued)

expense of €498,000 and €253,000 in the three-month period ended March 31, 2021, and 2020, respectively. The total intrinsic value of the fully vested liability at December 31, 2020 was €1.8 million.

The arrangement with Mr. Kezirian has been exercised on September 21, 2020 following the IPO with a total payment of €1.5 million in September 2020. The arrangement with ActuaRisk Consulting SRL has vested in full on September 21, 2020 and exercisable as from March 21, March 2021.

15. Financial Debt

Financial debt consists of recoverable cash advances and other loan. Related amounts can be summarized as follows:

(in EUR 000)	As of March 31, 2021	As of December 31, 2020
Recoverable cash advances — Non-current	7,590	7,149
Recoverable cash advances — Current	533	491
Total recoverable cash advances	**8,123**	**7,910**
Other loan – Non-current	167	188
Other loan – Current	125	125
Total Other loan	**292**	**313**
Non-current	7,757	7,607
Current	658	616
Total Financial debt	**8,415**	**8,223**

Financial debt related to recoverable cash advances

Recoverable cash advances received

As at March 31, 2021 and as at December 31, 2020, the details of recoverable cash advances received can be summarized as follows:

(in EUR 000)	Contractual Advances	Advances received	Amounts reimbursed
Sleep apnea device (6472)	1,600	1,600	420
First articles (6839)	2,160	2,160	84
Clinical trial (6840)	2,400	2,400	—
Activation chip improvements (7388)	1,467	1,467	15
Total	**7,627**	**7,627**	**519**

During the three months ended March 31, 2021 and 2020, the Company did not receive or pay any new amounts.

(in EUR 000)	As of March 31, 2021	As of December 31, 2020
Contract 6472	1,464	1,421
Contract 6839	2,272	2,214
Contract 6840	2,659	2,592
Contract 7388	1,728	1,683
Total recoverable cash advances	**8,123**	**7,910**
Non-current	7,590	7,419
Current	533	491
Total recoverable cash advances	**8,123**	**7,910**

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NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

15. Financial Debt (continued)

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

(in EUR 000)	2021	2020
As of January 1	7,910	7,148
Initial measurement and re-measurement	(8)	100
Discounting impact	220	193
As of March 31, 2021	**8,123**	**7,442**

16. Other payables

(in EUR 000)	As of March 31, 2021	As of December 31, 2020
Holiday pay accrual	486	376
Salary	355	382
Accrued expenses	1,070	1,244
Other	2,769	2,121
Total other payables	4,680	4,123

For the three-month periods ended March 31, 2021 and 2020, the increase of other payables is mainly due to the increase of liability related to a variable compensation (€2.3 million at March 31, 2021 and €1.8 million at December 31, 2020) of a cash-settled share-based payment transaction.

17. Results of operation

Revenue and cost of goods sold

In the three-month period ended March 31, 2021, the Company generated revenue for the amount of €185,000 (2020: €0). Revenue is recognized at a point in time upon satisfaction of the performance obligation, being the moment control over the Genio system is transferred to the customer, which is in general at delivery at customer site or a predefined location in the country of the customer. The revenue from the Genio system may consist of individual products or a bundle of products in the form of a kit. The revenue is then recognized at an amount that reflects the consideration to which the Company expects to be entitled in exchange of the Genio system. In determining the transaction price for the sale of the Genio system, the Company considers the effects of variable consideration. All sales were generated in Germany.

Cost of goods sold for the three-month periods ended March 31, 2021 and 2020:

(in EUR 000)	2021	2020
Purchases of goods and services	103	—
Inventory movement	(51)	—
Total cost of goods sold	**52**	**—**

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

17. Results of operation (continued)

Operating expenses

The table below details the operating expenses for the three-month periods ended March 31, 2021 and 2020:

(in EUR 000)	Total Cost	Capitalized	Operating expense for the period
General and administrative expenses	1,818	—	1,818
Research and development expenses	852	—	852
Clinical expenses	1,779	(1,437)	342
Manufacturing expenses	1,116	(215)	901
Quality assurance and regulatory expenses	458	(133)	325
Patents fees & related expenses	674	—	674
Therapy development expenses	548	—	548
Other operating expenses/(income)	(191)	187	(4)
For the three months ended March 31, 2021	**7,054**	**(1,598)**	**5,456**

(in EUR 000)	Total Cost	Capitalized	Operating expense for the period
General and administrative expenses	1,178	—	1,178
Research and development expenses	318	(311)	7
Clinical expenses	745	(568)	177
Manufacturing expenses	640	(578)	62
Quality assurance and regulatory expenses	288	(263)	25
Patents fees & related	114	(56)	58
Therapy development expenses	352	—	352
Other operating expenses/(income)	124	67	191
For the three months ended March 31, 2020	**3,759**	**(1,709)**	**2,050**

General and Administrative expenses

(in EUR 000)	For the three-month period ended March 31, 2021	For the three-month period ended March 31, 2020
Staff costs	366	426
Consulting and contractors' fees	936	431
Legal fees	53	22
Rent	61	36
Facilities	24	21
Depreciation and amortization expense	161	124
ICT	112	26
Travel	25	56
Other expenses	80	36
Total general and administrative expenses	1,818	1,178

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

17. Results of operation (continued)

General and administrative expenses increased by €641,000, or 54%, from €1.2 million for the three months ended March 31, 2020 to €1.8 million for the three months ended March 31, 2021 mainly due to an increase in consulting expenses. The increase in consulting and contractors' fees includes variable compensations for an amount of €253,000 for the three months ended March 31, 2020 and €498,000 for the three months ended March 31, 2021 related to a cash-settled share-based payment transaction.

Research and Development expenses

(in EUR 000)	For the three-month period ended March 31, 2021	For the three-month period ended March 31, 2020
Staff costs	414	273
Outsourced developments	238	39
Depreciation and amortization expense	184	3
Travel	—	3
Other	16	—
Capitalized costs	—	(311)
Total research and development expenses	852	7

Research and development expenses increased by €0.5 million, or 168%, from €318,000 for the three months ended March 31, 2020 to €0.9 million for the three months ended March 31, 2021, due to an increase in staff and consulting costs to support R&D activities.

Before capitalization of €1.4 million for the three months ended March 31, 2021, clinical expenses increased by €1.1 million or, 139%, from €0.7 million for the three months ended March 31, 2020 to €1.8 million for the three months ended March 31, 2021. The increase in the expenses was mainly due to an increase for staff and consulting to support the completion of the BETTER SLEEP trial implantations, continuous recruitment for EliSA trial and the ongoing DREAM IDE trial in the United States.

Manufacturing expenses

(in EUR 000)	For the three-month period ended March 31, 2021	For the three-month period ended March 31, 2020
Staff costs	313	179
Consulting and contractors' fees	—	—
Manufacturing	793	404
Travel	—	23
Other	10	34
Capitalized costs	(215)	(578)
Total manufacturing expenses	901	62

Before capitalization of €215,000 for the three months ended March 31, 2021, manufacturing expenses increased by €0.5 million, or 74%, from €0.6 million for the three months ended March 31, 2020 to €1.1 million in the three-month period ended March 31, 2021. The increase in the expenses was mainly due to an increase in staff, in production and engineering team to support capacity and yield improvement, and also due to purchasing raw materials to support increase in the production.

Before capitalization of €133,000 for the three months ended March 31, 2021, Quality assurance and regulatory expenses increased by €170,000, or 59%, from €288,000 for the three months ended March 31,

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

17. Results of operation (continued)

2020 to €458,000 for the three months ended March 31, 2021. The increase in the expenses was mainly due to an increase in staff and QA & regulatory activities to support manufacturing scaling up process.

Patent fees and related expenses increased by €446,000, or 491%, from €114,000 for the three months ended March 31, 2020 to €0.7 million for the three months ended March 31, 2021 due to expenses related to the in-licensing agreement with Vanderbilt University.

Therapy development expenses increased by €196,000, or 56%, from €352,000 for the three months ended March 31, 2020 to €548,000 for the three months ended March 31, 2021. The increase in the expenses was mainly due to an increase in staff and consulting, to support the launch the commercialization in Europe.

The Company had other operating expenses of €191,000 for the three months ended March 31, 2020 and €4,000 income for the three months ended March 31, 2021, the evolution being mainly due to the impact of the initial measurement and re-measurement of the financial debt. The impact of the recoverable cash advances is further detailed in note 15.

18. Earnings Per Share (EPS)

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

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

	2021	2020
As at March 31, after conversion and share split		
Outstanding common shares at year-end	22,107,609	16,979,000
Weighted average number of common shares outstanding	22,101,766	15,789,000
Number of Shares resulting of the exercise of outstanding warrants	997,500	1,007,500

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

	2021	2020
Loss of year attributable to equity holders (in EUR)	(5,669,000)	(2,380,000)
Weighted average number of common shares outstanding (in units)	22,101,766	15,789,000
Basic earnings per share in EUR (EUR/unit)	**(0.256)**	**(0.151)**
Diluted earnings per share in EUR (EUR/unit)	**(0.256)**	**(0.151)**

19. Other commitments

The Company has granted in October 2020 an amount of €500,000 towards an institute under the Company's Sponsored Grant Program. The institute will have to perform over a total period of two years certain clinical and research activities and training and education activities. The future payment commitments amount to €400,000 at December 31, 2020 which will be paid quarterly in instalments over the remaining period if the institute performs its activities. During the three-month period ended March 31, 2021, the Company recognized €79,000 in Therapy Development expenses.

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

20. Related Party Transactions

Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes.

Remuneration of Key Management

The remuneration of the senior management consists of the remuneration of the CEO of the Company for the three months period ended March 31:

(in EUR 000)	2021	2020
Short-term remuneration & compensation	69	61
Share based payment	—	—
Total	**69**	**61**

During the three-month period ended March 31, 2021 and 2020, ActuaRisk Consulting, a company owned by a member of executive management, invoiced the Company SA for an amount of €89,100 and €57,500, respectively, for consulting services. Of the €89,100 invoiced in the first three months of 2020, €39,600 correspond to a variable compensation. The Company also recognized a share-based payment expense of €253,000 and €498,000 for the three-month period ended March 31, 2020 and 2021, respectively, related to a cash-settled share-based payment transaction.

No loans or other guarantees have been given to a member of the executive management team.

Transactions with Non-Executive Directors and Shareholders

	As of March 31, 2021			As of March 31, 2020	
(in EUR 000)	R&D Collaboration	Consulting services	Board remuneration	Consulting services	Board remuneration
Cochlear	—	—	—	—	—
Noshaq	—	—	—	—	—
MINV SA	—	—	—	—	—
Man & Science S.A	—	—	—	—	—
Medtech Execs LLC	—	—	—	—	3
Donald Deyo	—	—	11	—	—
Robert Taub	—	—	13	—	—
Kevin Rakin	—	—	8	—	—
Pierre Gianello	—	—	7	—	—
Jan Janssen	—	—	7	—	—
Jurgen Hambrecht	—	—	8	—	—
Total	—	—	54	—	3

The Company and Cochlear Limited, or Cochlear, have entered into a collaboration agreement, dated November 2018, under which they agreed to collaborate to further develop and progress commercialization of implantable treatments for sleep disordered breathing conditions. A new Statement of Work was entered into on June 8, 2020. Under this agreement, Cochlear is working with the Company in developing and enhancing the next generation implantable stimulator. This collaboration agreement did not lead to any financial impact for the three-month periods ended March 31, 2021 and 2020, compared to €1.3 million as at December 31, 2020.

NYXOAH SA

NOTES TO THE UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

21. Events after the Balance-Sheet Date

After closing of the financial quarter, the Company has confidentially submitted on April 16, 2021 a draft Registration Statement on Form F-1 to the Securities and Exchange Commission (the “SEC”) relating to the proposed public offering of its ordinary shares in the United States. The number of ordinary shares to be offered and the price for the proposed offering have not yet been determined. The public offering is expected to take place after the SEC completes its review process, subject to market and other conditions.

Shares

NYXOAH SA

Ordinary Shares

PROSPECTUS

Through and including , 2021, (the 25th day after the date of this prospectus), all dealers effecting transactions in the ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Piper Sandler **Stifel** **Cantor**

Degroof Petercam

, 2021

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 6. Indemnification of Directors and Officers.

Under Belgian law, the directors of a company may be liable for damages to our company in case of improper performance of their duties. Our directors may be liable to our company and to third parties for infringement of our articles of association or Belgian company law. Under certain circumstances, directors may be criminally liable. We maintain liability insurance for the benefit of our directors and members of our executive management team.

We maintain liability insurance for our directors and officers, including insurance against liability under the Securities Act of 1933, as amended, and we intend to enter into agreements with our directors and executive officers to provide contractual indemnification. With certain exceptions and subject to limitations on indemnification under Belgian law, these agreements will provide for indemnification for damages and expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity.

These agreements may discourage shareholders from bringing a lawsuit against our directors and executive officers for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and executive officers, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these insurance agreements.

Certain of our non-employee directors may, through their relationships with their employers or partnerships, be insured and/or indemnified against certain liabilities in their capacity as members of our board of directors.

In the underwriting agreement, the form of which is filed as Exhibit 1.1 to this registration statement, the underwriters will agree to indemnify, under certain conditions, us, the members of our board of directors and persons who control our company within the meaning of the Securities Act against certain liabilities, but only to the extent that such liabilities are caused by information relating to the underwriters furnished to us in writing expressly for use in this registration statement and certain other disclosure documents.

Item 7. Recent Sales of Unregistered Securities.

From January 1, 2018 through the date of the filing of this registration statement, we have issued the securities in the following transactions that were not registered under the Securities Act:

Issuances of Share Capital

On October 5, 2018, we issued and sold to investors in a private placement an aggregate 1,534 Preferred B2 shares for an aggregate consideration of €5.0 million.

On November 7, 2018, we issued and sold to investors in a private placement an aggregate 3,068 Preferred B2 shares for an aggregate consideration of €10.0 million.

On February 21, 2020, we issued and sold to investors in a private placement an aggregate 4,200 common shares for an aggregate consideration of €25.1 million.

On September 7, 2020, we issued 44,500 common shares pursuant to an exercise of subscription rights for an aggregate consideration of €230,065.

On September 21, 2020, we issued and sold in a public offering an aggregate 4,335,000 common shares for an aggregate consideration of €73.7 million.

On September 28, 2020, we issued and sold following the exercise of an over-allotment option in connection with a public offering an aggregate 650,250 common shares for an aggregate consideration of €11.1 million.

On October 28, 2020, we issued 23,500 common shares for an aggregate consideration of €121,495.

On February 22, 2021, we issued 10,000 common shares pursuant to an exercise of subscription rights for an aggregate consideration of €51,700.

Issuances under Our Warrant Plans

On December 12, 2018, we issued 525 warrants to purchase ordinary shares under the 2018 Warrants Plan, of which 319 warrants remain outstanding for an aggregate of 159,500 ordinary shares upon exercise of the outstanding warrants.

On February 21, 2021, we issued 550,000 warrants to purchase ordinary shares under the 2020 Warrants Plan, of which 550,000 warrants remain outstanding for an aggregate of 550,500 ordinary shares upon exercise of the outstanding warrants.

The offers, sales and issuances of the securities described in the preceding paragraphs were exempt from registration either: (a) under Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and sophisticated investors and did not involve any public offering within the meaning of Section 4(a)(2); (b) in reliance on Rule 144A promulgated under the Securities Act in that offers, sales and issuances were made only to "qualified institutional buyers" (as such term is defined in Rule 144A(a)(1); (c) under Rule 701 promulgated under the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation; or (d) under Regulation S promulgated under the Securities Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States.

Item 8. Exhibits and Financial Statement Schedules

(a) Exhibits

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated herein by reference.

(b) Financial Statement Schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or has been included in the consolidated financial statements and notes thereto.

Item 9. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant under the foregoing provisions or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1) or (4) or 497(h) under the Securities Act will be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

Exhibits number	Description of exhibit
1.1*	Form of Underwriting Agreement
3.1	Articles of Association of Nyxoah SA (English Translation)
4.1	Articles of Association of Nyxoah SA (English Translation) (included in Exhibit 3.1)
5.1*	Opinion of NautaDutilh BV/SRL
8.1*	Tax Opinion of NautaDutilh BV/SRL
10.1#	Cochlear Collaboration Agreement, dated November 2018, by and between the registrant and Cochlear Limited
10.2#	Man & Science SA License Agreement, by and between the registrant and Cephalix SA, Glucobel SA, Surgical Electronics SA and Man & Science SA, among others, as amended by the Confirmatory Addendum to the Multiparty Agreement, dated as of June 23, 2016, by and between the registrant and Cephalix SA, Surgical Electronics SA and Man & Science SA and as further amended by the Clarification of the Confirmatory Addendum to the Multiparty Agreement, dated as of February 10, 2020, by and between the registrant and Man & Science SA.
10.3#	Unprotected Lease Contract, dated as of August 20, 2020, by and between Nyxoah Ltd. and Block 7093 Parcel 162 Ltd. (English Translation)
10.4	Form of 2013 Share Incentive Plan (English Translation)
10.5	Form of 2016 Warrants Plan (English Translation)
10.6	Form of 2018 Warrants Plan (English Translation)
10.7	Form of 2020 Warrants Plan (English Translation)
21.1	List of Subsidiaries of the registrant
23.1	Consent of EY Réviseurs d’Entreprises / EY Bedrijfsrevisoren SRL/BV, independent registered public accounting firm
23.2*	Consent of NautaDutilh BV/SRL (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page to this registration statement)

* To be filed by amendment.

\# Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets (“[***]”) because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Mont-Saint-Guibert, Belgium, on June 10, 2021.

NYXOAH SA

By: /s/ Olivier Taelman

Name: Olivier Taelman
Title: Chief Executive Officer

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Olivier Taelman and Fabian Suarez Gonzalez, and each of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this Registration Statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this Registration Statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his or her substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Olivier Taelman Olivier Taelman	Chief Executive Officer and Executive Director (*Principal Executive Officer*)	June 10, 2021
/s/ Fabian Suarez Gonzalez Fabian Suarez Gonzalez, acting via ActuaRisk Consulting SRL	Chief Financial Officer (*Principal Financial and Accounting Officer*)	June 10, 2021
/s/ Robert Taub Robert Taub	Chairman of the Board of Directors	June 10, 2021
/s/ Janke Dittmer Janke Dittmer	Director	June 10, 2021
/s/ Kevin Rakin Kevin Rakin	Director	June 10, 2021
/s/ Donald Deyo Donald Deyo	Director	June 10, 2021

Signature	Title	Date
/s/ Pierre Gianello Pierre Gianello	Director	June 10, 2021
/s/ Jan Janssen Jan Janssen	Director	June 10, 2021
/s/ Jürgen Hambrecht Jürgen Hambrecht	Director	June 10, 2021

SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF THE REGISTRANT

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Nyxoah SA, has signed this registration statement on Form F-1 on June 10, 2021.

NYXOAH, INC.

By: /s/ Olivier Taelman

Name: Olivier Taelman
Title: Chief Executive Officer, President and Secretary

NYXOAH SA
Rue Edouard Belin 12
B-1435 Mont-Saint-Guibert
Register of legal entities of Walloon Brabant
VAT: BE 0817.149.675

TITLE I. LEGAL FORM, NAME, REGISTERED OFFICE, OBJECT AND DURATION

Article 1 LEGAL FORM - NAME

The company has the legal form of a public limited liability company (*naamloze vennootschap/société anonyme*).

The name of the company is "**Nyxoah**". This name shall always be preceded or followed by the words "société anonyme" or the abbreviation "SA" in French.

Article 2 REGISTERED OFFICE, E-MAIL ADDRESS AND WEBSITE

The registered office of the company is located in the Walloon Region.

The board of directors may transfer the company's registered office, provided the transfer does not result in a change to the language of the articles pursuant to the applicable linguistic rules. Such decision does not require an amendment to the articles of association, unless the company's registered office is transferred to another Region. In this case, the board of directors has the power to amend the articles.

If, due to a transfer of the company's registered office, the language of the articles of association must be changed, only the general shareholders' meeting has the power to take the decision, in accordance with the rules applicable to amendment of the articles of association.

The company may establish, by a simple decision of the board of directors, management offices, subsidiaries or branches in Belgium or abroad.

The company's website is the following: www.nyxoah.com

For purposes of communication as referred to in article 2:31 of the Code of Companies and Associations, the company can be contacted on the following e-mail address: corporate@nyxoah.com.

The board of directors may modify the e-mail address and the website of the company in accordance with the provisions of the Code of Companies and Associations.

Article 3 PURPOSE

The purpose of the company is, both in Belgium and abroad, in its own name and for its own account, the research and development, the manufacturing and the sale of medical devices.

For this purpose, the company may, in any manner, collaborate and participate, or take an interest in other companies, directly or indirectly.

The company may guarantee to secure its own obligations or those of third parties by, among other things, granting a mortgage or pledge over its assets, including its own business assets.

The company may generally carry out all commercial, industrial, financial, movable or real estate transactions which directly or indirectly relate to its purpose or which could facilitate the realisation thereof.

Article 4 TERM

The company is established for an unlimited duration.

TITLE II. CAPITAL – SHARES

Article 5 CAPITAL

The capital amounts to three million seven hundred ninety-seven thousand seven hundred sixty-five euro sixty-four cent (EUR 3,797,765.64).

It is represented by twenty-two million one hundred seven thousand six hundred nine (22,107,609) shares, without nominal value, each representing an equal part of the company's capital.

Article 6 NATURE OF THE SHARES - EXERCISE OF RIGHTS ATTACHED TO SHARES

The shares shall be in registered or dematerialized form, at the discretion of their owner or holder (hereinafter, both the "**Holder**") and within the limits set by applicable law. The Holder may at any time, at its expense, request the conversion of registered shares into a dematerialized form and vice versa.

The register of all registered shares can be held in electronic form. The board of directors can decide to entrust a third party with keeping and the administration of the electronic register.

The shares are indivisible vis-à-vis the company. If a share belongs to different persons, if the rights attached to a share are divided over different persons, or if different persons hold rights in rem to the same shares, the board of directors may suspend the exercise of the rights attached thereto until one single person has been designated as shareholder vis-à-vis the company and notification thereof has been given to the company. All convocations, notifications and other announcements by the company to the different persons entitled to one share are made validly and exclusively to the designated common representative.

The rights attached to shares that are pledged or subject to usufruct shall be exercised by the owner-pledgor and the person having the usufruct, respectively, unless agreed otherwise in an agreement signed by all relevant parties and notified to the company.

Article 7 AUTHORISED CAPITAL

The board of directors is authorised to increase the capital of the company on one or several occasions in accordance with the Code of Companies and Associations by a maximum aggregate amount of three million six hundred eighty thouand two hundred ninety-seven euro thirty-nine cent (EUR 3,680,297.39).

This authorisation is valid for a period of five years as from the date of publication in the Annexes to the Belgian State Gazette of an extract of the minutes of the extraordinary shareholders' meeting of the company held on 7 September 2020.

Every capital increase decided upon by the board of directors in the context of authorised capital shall be effected in accordance with the modalities to be determined by the board of directors, and may amongst others be achieved (i) by contributions in cash or in kind, or a combination of both, (ii) by capitalisation of reserves, whether available or unavailable for distribution, and capitalisation of issue premiums, (iii) with or without the issuance of new shares (at, above or below the par value and with or without issue premium), with or without voting rights, that will have the rights as will be determined by the board of directors, or (iv) with issuance of convertible bonds or warrants, bonds with warrants or other securities.

The board of directors is authorized, when exercising its powers within the framework of the authorized capital, to restrict or cancel, in the interest of the company, the preferential subscription rights of each shareholder, and - as far as needed and applicable - of each holder of subscription rights issued by the Company. This restriction or cancellation of the preferential subscription rights can also be done in favor of members of the personnel of the company or of its subsidiaries, or in favor of one or more persons other than members of the personnel of the company or of its subsidiaries.

In the event of a capital increase decided by the board of directors within the framework of the authorised capital, any issue premiums shall be booked on one or more separate reserve accounts "issue premiums.

The board of directors is also expressly authorised to increase the company's capital after having been notified by the FSMA that the company is the subject of a public takeover bid. This authorisation is valid with respect to the public takeover offers of which the FSMA has notified the company no later than three years following 7 September 2020.

The board of directors is also authorized, with the right of substitution, to amend the company's articles of association after each capital increase that has occurred within the framework of the authorised capital, in order to align them with the new situation of the capital and the shares.

Article 8 CALLS FOR PAYMENT

The board of directors independently decides on calls for payment on shares which have not been entirely liberated.

Each payment called is accounted to all of the shares of which the shareholder is the owner.

The board of directors can authorise shareholders to pre-pay uncalled capital on their shares. In this case, the board of directors will fix the terms pursuant to which these prepayments will be permitted. The prepayments will qualify as advances.

Any shareholder who is in default of payments called, automatically has to pay the company interest at the statutory rate increased by two percent, as from the date such payment call was originally due and the voting rights attached to the relevant shares shall be suspended automatically for as long as the relevant payments have not been made.

The board of directors can, if such failure is not remedied within one month of a notice of default (or such other period as the board of directors may decide), cause such shares to be sold on the stock exchange, with or without the assistance of an intermediary, without prejudice to the right to claim from such shareholder any amount that remains outstanding plus such damages and interests as may apply.

Article 9 CAPITAL REDUCTION

The capital of the company can be reduced in accordance with the applicable legal provisions.

Article 10 ACQUISITION, PLEDGE AND DISPOSAL OF OWN SHARES

The company may acquire, pledge and dispose of its own shares in accordance with the applicable legal provisions.

Article 11 OTHER SECURITIES

The company is authorised to issue all securities not prohibited by or pursuant to the law. These securities may be in registered form or dematerialised.

Article 12 DISCLOSURE OF MAJOR SHAREHOLDINGS

Without prejudice to the applicable legal provisions relating to the disclosure of significant shareholdings, every natural person or legal entity that acquires, directly or indirectly, securities of the company granting voting rights, whether they represent the company's capital or not, must notify the board of directors of the company and the FSMA of the number and percentage of existing voting rights he or she holds, whether directly or indirectly, or whether alone or in concert with one or several other persons, as a result of the acquisition, if the voting rights attached to the securities granting voting rights reach or exceed 3%, 5%, 10%, 15%, 20%, or any further multiple of 5% of the total outstanding voting rights. Without prejudice to the applicable legal provisions relating to the disclosure of significant shareholdings, the same notification is required when, as a result of the transfer of securities, the number of voting rights drops below one of the aforementioned thresholds.

TITRE III. MANAGEMENT AND AUDIT

Article 13 COMPOSITION OF THE BOARD OF DIRECTORS

The company is managed by a board of directors composed of at least three members, natural or legal entities, who need not be a shareholder.

Directors are appointed by the general shareholders' meeting. The duration of their mandate may not exceed four years. Directors whose mandate came to an end may be reappointed.

In the event of one or more vacancies, the remaining directors, at a board meeting, shall be empowered to provisionally fill the vacancies, until the next general shareholders' meeting. The first general shareholders' meeting that follows shall decide whether to confirm the appointment of the co-opted director(s).

The general shareholders' meeting may remove a director from office at any time, with immediate effect and without cause.

When a legal entity is appointed as director of the company, such legal entity must appoint a permanent representative in accordance with the applicable legal provisions.

Article 14 CHAIRPERSON OF THE BOARD OF DIRECTORS

The board of directors elects a chairperson from among its members. The chairperson of the board of directors may elect a vice-chairperson. If no chairperson has been appointed or if he or she is absent or hindered, the meeting shall be chaired by the vice-chairperson, if appointed and not absent or hindered, or otherwise by the oldest director.

Article 15 REMUNERATION

The general shareholders' meeting can decide whether or not the mandate of the directors is remunerated by awarding a fixed and/or variable remuneration.

The amount thereof is determined by the general shareholders' meeting and will be borne by the general expenses of the company. The general shareholders' meeting can determine the aggregate amount of the remuneration allocated to the directors, who shall then divide this amount among themselves.

Unless the general shareholders' meeting decides otherwise, the mandate of a director is deemed not to be remunerated.

The board of directors is authorised to award an extraordinary remuneration to directors who are charged with special functions or assignments. This extraordinary remuneration shall be booked as company expense.

The restrictions provided for in Article 7:91 of the Code of Companies and Associations shall not apply to the Company in respect of any persons falling within the scope of these provisions (whether directly, pursuant to Article 7:121 of the Code of Companies and Associations, or otherwise).

Article 16 MEETINGS

The board of directors shall meet as frequently as the interest of the company requires. The board of directors shall meet when convened by the chairperson or, in case he or she is absent or hindered, a vice-chairperson, if any, or, in the absence the latter, by a director appointed by the other directors. A board meeting must be called upon the request of two or more directors.

Unless all directors agree otherwise, convening notices must be given at least four (4) calendar days before the board meeting, except in case of emergency. In case of emergency, the convening notice must be given with not less than two (2) business days' notice, and the reasons for the emergency should be specified in the notice.

Convening notices are valid if delivered by ordinary letter, e-mail or any other means of communication specified in Article 2281 of the Belgian Civil Code. Board meetings are held at the registered office or at the place indicated in the convening notice. Each director can instruct, by means of an ordinary letter, e-mail or any other means of communication or medium bearing his or her signature (including an electronic signature), another director to represent him or her it at a specified board meeting and to vote in his or her place. In that case, the instructing director shall be deemed present. A director can represent multiple members of the board of directors and can, in addition to his or her own vote, cast as many votes for which he or she has a proxy from other directors.

Board meetings can be held by using any telecommunication means permitting a joint discussion, such as telephone conferencing or video conferencing. Directors taking part in a meeting held by telephone conferencing or video conference shall be deemed present at the meeting.

At least half of the directors need to be present or represented to have a quorum. If the quorum is not reached, each director shall be entitled to convene a second meeting that may validly deliberate and decide on the items that were on the agenda of the first meeting regardless of the number of directors present or represented, provided that at least two (2) directors are present. The convening notice for such second board meeting needs to be sent at least seven (7) calendar days prior to the date of the second meeting, unless in case of emergency the reasons of which should then be specified in the convening notice.

The board of directors can only validly deliberate on items that are not mentioned on the agenda, if all directors are present or represented at the board meeting and unanimously consent to do so. This consent is assumed to have been given if no objection is recorded in the minutes.

Board resolutions can also be adopted by unanimous written consent of all directors. This written procedure cannot be used to establish the annual financial statements or to use the authorised capital. Unless specified otherwise, the resolutions adopted by unanimous written consent shall be deemed to have been taken at the seat of the company on the date that they are signed by the last director.

Article 17 DELIBERATIONS AND RESOLUTIONS

Unless otherwise provided in these articles of association, the board resolutions shall be adopted by a simple majority of the votes cast by the directors present or represented at the board meeting, and in case of abstentions, by a simple majority of the votes of the other directors present or represented at the board meeting.

Each director has one (1) vote, but can, in addition to his or her own vote, cast as many votes for which he or she has a proxy from other directors.

In case votes are tied, the person chairing the board meeting shall have a casting vote.

Article 18 CONFLICTS OF INTEREST

In the event that a director has a direct or indirect interest of a proprietary nature that is opposed to that of a transaction on which the board of directors is called upon to pronounce or a decision that the board of directors is called upon to take, the rules and formalities provided by law shall apply. In such case, the conflicted director(s) shall be disregarded for the collation of the quorum and the votes. In case all directors or all but one director have such conflict of interest, the relevant decision or transaction should be submitted to the general meeting of shareholders. In case of approval by the general meeting of shareholders', the decision or transaction can be implemented by the board of directors.

Article 19 POWERS OF THE BOARD OF DIRECTORS – DAILY MANAGEMENT

The board of directors is empowered with the most extensive powers to perform all acts necessary or useful to achieve the company's purpose, with the exception of those reserved by law or the articles of association to the general shareholders' meeting.

The board of directors is authorised to delegate the day-to-day management of the company and the representation as far as such management is concerned to one or more persons, directors or not. In case these persons are directors, they are called "managing directors". In case the daily management of the company is delegated to more than one person, these persons will form a collegial organ.

Unless the board of directors decides otherwise, the mandate of a person in charge with daily management is deemed not to be remunerated. The restrictions provided for in Article 7:121 juncto 7:91 of the Code of Companies and Associations shall not apply to persons entrusted with daily management, nor to any other leading persons the company in respect of any persons, for all persons falling within the scope of these as meant in Article 3:6 §3 the Code of Companies and Associations.

The board of directors can delegate a part of its powers to one or more persons who need not to be directors. It will determine their powers and remuneration. It can dismiss them and, if necessary, replace them.

The persons in charge of the daily management can give special proxies to any agent within the limits of their own powers.

The board of directors can draw up internal rules.

Article 20 COMMITTEES OF THE BOARD OF DIRECTORS

The board of directors shall have the power and, to the extent required by applicable law, the obligation to establish, one or more advisory committees in its midst and under its responsibility, such as (but not limited to) an audit committee, a nomination committee and a remuneration committee (which can be combined with the nomination committee).

The board of directors determines the composition and the missions of these committees and may draw up their terms of reference.

Article 21 MINUTES

The board resolutions are recorded in minutes, which are kept at the registered office of the company, and are signed by the director that chaired the meeting and the directors that wish to do so..

Copies or extracts of the minutes, to be produced in court or elsewhere, are signed by the chairperson of the board of directors, by two directors, or as the case may be, by any person(s) to whom daily management powers have been delegated, or by a special proxy holder.

Article 22 REPRESENTATION OF THE COMPANY

Notwithstanding the general powers of representation of the board of directors as a collegial body, the company shall be validly represented, for all deeds and acts, including those involving a public or ministerial official as well as before a court, as claimant or defendant:

- by two directors, acting jointly;
- within the scope of the daily management, by any person to whom such daily management has been delegated, and should the daily management by exercised by a collegial organ, by two of its members;
- by any other person acting within the mandate granted to such person by the board of directors or a person in charge of the daily management.

Third parties cannot demand a prior decision of the board of directors as proof of the special powers of representation of these persons.

Article 23 AUDIT

The financial position, the annual financial statements and the compliance of the transactions to be reflected in the annual financial statements, pursuant to the law and the articles of association shall be audited by one or more statutory auditors. The statutory auditors are appointed among the members of the Institute of Certified Auditors (*Institut des Réviseurs d'Entreprises*/*Instituut der Bedrijfsrevisoren*). The statutory auditors are appointed and remunerated in accordance with the relevant legal provisions.

The general meeting shall determine the number of auditors and fix their emoluments. In case more than one auditor has been appointed, they will act as a collegial body. They may divide their audit duties between them.

The appointment of retiring auditors which have not been re-appointed shall terminate after the closing of the annual shareholders' meeting.

TITLE IV. GENERAL SHAREHOLDERS' MEETING

Article 24 MEETING

The annual shareholders' meeting is held on the second Wednesday of the month of June, at 2:00 p.m. CET. Should this day be a public holiday, even if it is only a public holiday in one of the communities of Belgium, the meeting shall take place on the next working day at the same time, not including Saturday or Sunday.

The annual, special and extraordinary general shareholders' meetings are held at the place and time indicated in the convening notices. They can be held at a different place in Belgium than at the registered office of the company.

One or more shareholders holding at least ten (10) % of the company's capital may, in accordance with the Code of Companies and Associations, request that a general shareholders' meeting be held in order to submit one or more proposals. Notices shall be sent within the time limits and in accordance with the provisions of the Code of Companies and Associations.

One or more shareholders holding at least three (3) % of the company's capital may, in accordance with the Code of Companies and Associations, request the inclusion of items on the agenda of any general shareholders' meeting and submit proposals for resolutions on the items included or to be included on the agenda.

Article 25 CONVENING NOTICES

General shareholders' meetings shall be convened in accordance with the relevant legal provisions. The convening notice shall contain the agenda for the meeting, as well as the information required by applicable law.

The convening notices drafted by the board of directors can be validly signed in its name by a person to whom the daily management of the company has been delegated.

The persons participating in or represented at a general shareholders' meeting are considered to have been validly convened. They can also, before or after the general shareholders' meeting that they did not attend, waive the convening notice, or any irregularity in the convening notice, in writing.

The convening notices are assumed to be given on the day they are sent out.

Article 26 ADMISSION TO THE GENERAL SHAREHOLDERS' MEETING

The right to participate in a general shareholders' meeting and to vote is only granted based on an accounting registration of the shares on the name of the shareholder, on the fourteenth (14th) day before the general shareholders' meeting, at midnight (CET), either by their registration in the register of registered shares of the company, or by their registration on the accounts of a recognized account holder or of a clearing institution, irrespective of the number of shares the shareholder possesses at the day of the general shareholders' meeting.

The day and time referred to in the first paragraph of this article form the record date.

The shareholder notifies the company, or the person appointed by the company for this purpose, ultimately on the sixth (6th) day before the date of the general shareholders' meeting, that he wants to participate in the general shareholders’ meeting. The recognized account holder or the clearing institution provides the shareholder with a certificate evidencing the number of dematerialized shares registered in the shareholder’s name on his accounts on the record date, for which the shareholder has indicated his desire to participate in the general shareholders’ meeting.

In a register designated by the board of directors, the name and address or registered office of each shareholder who has notified the company of its intention to participate in the general shareholders’ meeting are noted, as well as the number of shares he or she possessed on the record date and for which he or she has indicated to be participating in the general shareholders’ meeting, and the description of the documents demonstrating that he or she was in possession of the shares on said record date.

The holders of profit sharing certificates (*parts bénéficiaires/winstbewijzen*), non-voting shares, bonds, warrants or other securities issued by the company, as well as the holders of certificates issued with the collaboration of the company and representing securities issued by the company (if any such exist), may attend the general shareholders’ meeting with advisory vote insofar permitted by law. They may only participate in the vote in the cases determined by law. They are in any event subject to the same formalities as those imposed on the shareholders with respect to notice of attendance and admission, and the form and submission of proxies.

Article 27 REPRESENTATION

Each shareholder who is entitled to participate in the general shareholders' meeting, can be represented at said general shareholders' meeting by a proxy holder who has been granted a written proxy. Such proxies must be granted in accordance with the applicable law and/or as set out (in accordance with the applicable law) in the convening notice, as the case may be.

The holders of a proxy must comply with the relevant legal provisions concerning proxies for general shareholders' meetings, as relevant. In particular, the proxy must be signed by the shareholder and be sent to the company's e-mail address or the e-mail address specifically indicated in the notice of the meeting, at the latest six (6) days before the general shareholders' meeting.

The board of directors can establish a template for the proxies and make them available to the security holders.

Article 28 BUREAU

Each general shareholders' meeting shall be chaired by the chairperson of the board of directors, or, in case he or she is absent or hindered, a vice-chairperson of the board of directors, if any, or, in the absence of the latter, a director appointed by the board of directors or its chairperson, or in the absence of such appointment, by another director present or another person appointed by the directors present.

Unless otherwise decided by the shareholders present and represented at the general shareholders' meeting, the chairperson will appoint a secretary, who does not need to be a shareholder or a proxyholder of a shareholder.

In the event the number of participants in the general shareholders' meeting so requires, the chairperson of the general shareholders' meeting will appoint one or more tellers from among the shareholders or their proxy holders.

The chairperson of the general shareholders' meeting, the secretary and the tellers, if any, together make up the bureau of the general shareholders' meeting.

The chairperson can assemble the bureau prior to the general shareholders' meeting and, as such, the assembled bureau can proceed with the verification of the proxies granted to the participants of the general shareholders' meeting prior to the opening of the meeting.

Article 29 NUMBER OF VOTES

Each share carries one vote, without prejudice to the cases in which the voting rights are suspended pursuant to these articles of association, the Code of Companies and Associations or any other applicable legislation.

Article 30 REMOTE VOTING BEFORE THE GENERAL MEETING

When provided for in the convocation notice to the general meeting, shareholders shall be authorised to vote remotely, by correspondence or via the company's website, using a form prepared and provided by the company. This form must indicate the date and place of the general shareholders' meeting, the shareholder’s name, domicile or registered office, the number of votes which the shareholder wishes to cast at the general shareholders' meeting, the type of shares held and the items on the agenda for the meeting (including proposed resolutions) and include a space allowing the shareholder to vote for or against each resolution or to abstain as well as the deadline by which the voting form must reach the company. It shall expressly stipulate that the form must be signed and reach the company no later than the sixth (6^{th}) day prior to the general shareholders' meeting. Digital votes via the company's website can be cast up to the day prior to the general meeting.

Article 31 DELIBERATIONS

The general shareholders’ meeting cannot deliberate on items that are not mentioned in the agenda, unless all shareholders are present or represented at the meeting and they unanimously decide to deliberate on these items.

Except when otherwise provided for by legal provisions or by the articles of association, the resolutions are taken by simple majority of the votes cast, irrespective of the number of shares represented at the general shareholders' meeting, except in the cases the law prescribes an attendance quorum. Blank and invalid votes are not taken into account to determine the votes cast.

The articles of association may only be amended by a majority of at least three quarters of the votes cast or, for amendments to the purpose of the company, four fifths of the votes cast, excluding abstentions.

The votes cast during the general shareholders' meeting are taken by raising hands or by calling off names, unless the general shareholders' shareholders' meeting decides otherwise by simple majority of the votes cast.

An attendance list indicating the names of the shareholders and the number of shares held by each shall be signed by each shareholder or his or her proxyholder before entering the general shareholders' meeting.

Article 32 ADJOURNMENTS

Without prejudice to the right to adjourn pursuant to the applicable legal provisions, the board of directors has the right to adjourn the deliberations of each annual general meeting by five (5) weeks, even during the meeting itself.

Article 33 MINUTES

The minutes of the general shareholders' meeting shall be signed by the members of the bureau and by those shareholders who ask to do so.

The minutes of the general shareholders' meeting shall mention for each resolution the number of shares for which votes have been cast validly, the percentage of the capital represented by these shares, the total number of votes validly cast, and the number of votes cast in favour of against each resolution, as well as the number of abstentions, if any. The company shall publish this information on its website within fifteen (15) calendar days after the general shareholders' meeting.

Copies or extracts from the **minutes are** signed by two directors, acting jointly, or by a managing director.

Article 34 REMOTE PARTICIPATION

If so provided in the convening notice for the general shareholders' meeting, each holder of shares, convertible bonds, warrants or certificates issued with the collaboration of the company can participate remotely to the general shareholders' meeting via electronic means of communication made available by the company, unless applicable law does not permit it.

As far as compliance with quorum and majority requirements is concerned, those who participate in this way to the general shareholders' meeting are considered to be present at the place where the meeting is held.

The aforementioned electronic means of communication must enable the company to verify the capacity and identity of the holder of the securities. The modalities to verify the capacity and identity of the person wishing to participate remotely are determined by the board of directors.

The holder of securities that wants to make use of this should at least be able to follow the deliberations directly, simultaneously and continuously during the general shareholders' meeting and shareholders need to be able cast their vote on each item on which the meeting needs to express itself.

TITLE V. ACCOUNTING YEAR – DISTRIBUTIONS OF PROFITS – (INTERIM) DIVIDENDS

Article 35 ACCOUNTING YEAR

The financial year starts on the first (1) of January and ends on the thirty-first (31) of December each year.

At the end of each financial year the board of directors draws up an inventory as well as the annual accounts.

To the extent required by law, the directors also draw up an annual report in which they account for their management. This report contains a comment on the annual accounts in which a true overview is given of the operations and of the position of the company, as well as the information prescribed by the Code of Companies and Associations.

Article 36 DISTRIBUTION OF PROFITS

The net profits of the financial year are distributed in accordance with the applicable legal provisions.

Five (5) percent of the company's net profit is deducted each year to form a legal reserve. Once this legal reserve amounts to one tenth ($1/10^{th}$) of the capital, such deduction is no longer required.

The general shareholders' meeting allocates the balance of the net profit by a simple majority of the votes upon the proposal of the board of directors.

Article 37 INTERIM DIVIDEND

The board of directors can, at its own responsibility, declare the payment of interim dividends, in the cases and within the time limits provided by law.

Article 38 DIVIDENDS

The dividends will be paid at the times and places as determined by the board of directors. All dividends not claimed within five years are time-barred and remain acquired by the company. They will be allocated to the legal reserve.

TITLE VI. DISSOLUTION AND LIQUIDATION

Article 39 APPOINTMENT AND POWERS OF LIQUIDATORS

If the company is wound up, for any reason and at any time whatsoever, liquidation shall be carried out by a liquidator or liquidators appointed by the general shareholders' meeting.

If it appears from the report summarising the company's assets and liabilities prepared in accordance with the Code of Companies and Associations that all creditors cannot be satisfied in full, the appointment of the liquidator(s) in the articles of association or by the general shareholders' meeting must be submitted to the president of the business court, unless it appears from this summary that the company only has debts to its shareholders and all shareholders who are creditors of the company confirm in writing their agreement with the appointment.

In the absence of the appointment of a liquidator or liquidators, the members of the board of directors shall be considered, by operation of law, as liquidators with regard to third parties, without however possessing the powers which the law and the articles of association grant to the liquidator appointed in the articles, by law or by the court, with respect to liquidation transactions.

The general shareholders' meeting shall determine the liquidators' fees, where appropriate.

The company's liquidation shall be concluded in accordance with the provisions of the Code of Companies and Associations.

Article 40 ALLOCATION OF THE LIQUIDATION PROCEEDS

Following settlement of all debts, charges and costs of the liquidation, the net assets are first used to pay back, in cash or in kind, the fully paid-up and not yet paid back amount of the shares.

The balance, as the case may be, is divided in equal parts among all shares.

If the net proceeds are not sufficient to pay back all shares, the liquidators will first pay back these shares that are paid-up to a higher extent until they are at a level equal to the shares that are paid-up to a lesser extent, or they call for an additional paying-up of capital for the latter shares.

TITLE VII. GENERAL PROVISIONS

Article 41 ELECTION OF DOMICILE

Any holder of registered securities domiciled abroad shall be required to elect domicile in Belgium for all matters relating to the execution of these articles of association. In the absence of such an election of domicile, he or she is deemed to have elected domicile at the registered office of the company, where all notifications, notices and summonses and convocations can be validly served upon them.

Holders of registered shares must notify the company of any change of domicile. In the absence of such a notification, all communications, convocations or notifications will be validly made at their last known address.

The directors, the persons in charge of the daily management, the auditors and the liquidators, domiciled abroad, shall be deemed, throughout their term of office, to have elected domicile at the registered office of the company at which all judicial acts are validly sent to them.

Each director, person in charge of the daily management, auditor or liquidator may elect domicile at
the registered office of the company for all matters relating to the exercise of their mandate. This election of domicile is enforceable against third parties in accordance with the legal provisions.

Article 42 CHOICE OF FORUM

All disputes relating to corporate matters and the implementation of these articles of association between the company, its shareholders, holders of bonds, holders of warrants, or holders of other securities or certificates issued by or with the cooperation of the company, its directors, statutory auditors, or liquidators, shall be subject to the exclusive jurisdiction of the courts of the jurisdiction of the registered office of the company, unless otherwise determined by the applicable law.

Article 43 COMMON LAW

Any provisions of these articles of association that are contrary to any other applicable legislation shall be considered null and void. The invalidity of an article or part of an article in these articles of association shall have no effect on the validity of the remaining provisions (or parts thereof).

Article 44 APPLICABLE LAW

For all matters that are not expressly regulated in these articles of association, or for the legal provisions from which would not be deviated validly in these articles of association, the provisions of the Code of Companies and Associations and the other provisions of Belgian law apply.

Hear now. And always Cochlear®

CONFIDENTIAL TREATMENT REQUESTED - REDACTED COPY

COLLABORATION AGREEMENT

CONTRACT DETAILS

1.	**COCHLEAR**	Name of Contracting Party ABN Address Contact Phone Contact Person Copy of legal notices to be addressed to:	**Cochlear Limited ("Cochlear")** **96 002 618 073** **1 University Avenue, Macquarie University NSW 2109, Australia** **[***]** **[***]** **[***]**
2.	**NYXOAH**	Name of Contracting Party Registration number in Crossroads Bank for Enterprises (Banque Carrefour des Enterprises) Address Contact Phone Contact Person	**Nyxoah SA ("Nyxoah")** **0817.149.675** **Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium** **[***]** **[***]**
3.	**COMMENCEMENT DATE**		7 November 2018
4.	**PROJECT**		Collaboration between Cochlear and Nyxoah for the purposes of, among other potential areas of collaboration between them, furthering development and progressing commercialisation of implantable treatments for sleep disordered breathing, as further detailed in the Initial Statements of Work attached as Schedule 1.

Important Note: By signing below the parties agree to the terms set out above and in the attached document entitled "Collaboration Terms and Conditions".

SIGNED AS AN AGREEMENT:

Authorised Representative for Cochlear Limited			
Name	[***]		
Position	[***]		
Signature	[***]	**Date**	6 November 2018
Authorised Representative for Nyxoah SA			
Name	[***]		
Position	[***]		
Signature	[***]	**Date**	7 November 2018

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

COLLABORATION AGREEMENT TERMS AND CONDITIONS

Important Note: This document must be read in conjunction with the Contract Details (as defined below)

RECITALS

(A) Cochlear (as defined in item 1 of the Contract Details) and its Affiliates carry on the business of research, development, manufacturing and sale of hearing prostheses, speech processors and other medical apparatuses and implants, including relevant parts, accessories, associated equipment and software, and of improving hearing health generally.

(B) Nyxoah (as defined in item 2 of the Contract Details) and its Affiliates carry on the business of research, development, manufacturing and sale of apparatuses and implants, including relevant parts, accessories, associated equipment and software for sleep disordered breathing, and for improving sleep disordered breathing generally.

(C) The Parties wish to enter into a collaborative project initially as described in the Initial Statements of Work. The Parties agree to conduct the Project on the terms of this Agreement and all agreed Statements of Work.

IT IS AGREED THAT:

1 DEFINITIONS

1.1 In this Agreement:

Affiliate with respect to either Party, a firm, corporation or other entity which directly or indirectly owns or Controls said Party, or is owned or Controlled by said Party, or is under common ownership or Control with said Party.

Agreement means this agreement, including the Contract Details and Schedules.

Authorisation means

(a) an authorisation, approval, consent, declaration, exemption, notarisation or waiver, however it is described; and

(b) in relation to anything that could be prohibited or restricted by law if a Government Agency acts in any way within a specified period, the expiry of that period without that action being taken,

including any relating to human research, animal research, or hazardous substances, and including any renewal or amendment.

Background IP means, in relation to a Party, all Intellectual Property owned by or licenced to that Party before the Commencement Date or acquired or developed by that Party after the Commencement Date (other than Project IP).

Belgian VAT Code means the Belgian "*Wetboek van de belasting over de toegevoegde waarde / Code de la taxe sur la valeur ajoutée*" as amended from time to time.

Business Day means any day (other than a Saturday or a Sunday) on which commercial banks are open for business in each of Brussels, Belgium, Tel Aviv, Israel and Sydney, Australia.

C-2-C SCC means the SCC adopted by the European Commission in its Decision C(2004)915, enabling transfers of personal data from a Controller located in the EEA to another Controller located outside the EEA.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

C-2-P SCC means the SCC adopted by the European Commission in its Decision C(2010)593, enabling transfers of personal data from a Controller located in the EEA to a Processor located outside the EEA.

Change of Control means any change of Control of the Person concerned, including:

(a) the loss of the exclusive Control;

(b) the loss of one or more of the (three) criteria used in the definition of Control; or

(c) in case of common Control, the loss of common Control or the modification of the parties of the common Control, including the replacement of any Person holding the common Control.

Cochlear Field means [***].

Commencement Date means the date specified in item 3 of the Contract Details or, if no date is so specified, the date this Agreement is executed by the last of the parties to execute it.

Commercialise or **Commercialisation** means, in relation to Project IP:

(a) to use the Project IP to provide a service for which a financial gain or benefit is received;

(b) to use the Project IP to create a product which is, or is to be, marketed, offered for sale, sold, hired, leased, distributed, made available to others or otherwise used for financial gain or benefit;

(c) to incorporate the Project IP into a product which is, or is to be, marketed, offered for sale, sold, hired, leased, distributed or made available to others for financial gain or benefit;

(d) to grant others rights to use the Project IP for a financial gain or benefit.

Confidential Information means in respect of a Party, all information in any form or media:

(a) relating to that Party's Party Data, Party Materials, Project IP or Background IP; or

(b) other information (including Personal Information) given by, or acquired from, that Party or its Personnel, directly or indirectly, whether before, on or after the date of this Agreement, including information relating to, but not limited to strategic, business, market insights, commercial, financial, clinical, scientific or technical information, software, demonstration programs, routines, algorithms, computer systems, techniques, documentation, designs, devices, hardware, procedures, formulas, inventions, improvements, concepts, mock-ups, images, records, files, memoranda, reports, drawings, plans, price lists, vendor and customer lists, and/or other commercial or scientific information**,**

but does not include information that the Recipient can establish, to the reasonable satisfaction of the Discloser, is Excluded Information.

Contract Details means all of the details set out on page 1 of this Agreement.

Contributions in relation to a Party, means the cash or in-kind contributions to the Project as set out in a Statement of Work.

Control means and any derivation thereof, means with respect to any Person, any other Person, who has, directly or indirectly:

(a) the majority of the outstanding voting interests in the Person concerned;

(b) the power, by contract or otherwise, to exercise, legally or factually, a determining influence on the appointment or dismissal of the majority of the directors, trustees, general partners or other governing body as applicable, in the Person, or

(c) the power, by contract or otherwise, to exercise, legally or factually, a determining influence on the orientation of the Person's management.

Controller shall have the meaning given to it in the GDPR.

EEA means European Economic Area, i.e. the Member States of the European Union plus Iceland, Norway and Liechtenstein.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

EU Data Protection Legislation means any applicable law of the European Union (including the GDPR) or any of its Member States protecting Personal Data.

Excluded Information means information that:

(a) is or has become generally known or available to the public or is or has become known or available to one or more other Persons who are under no obligation to maintain its confidentiality, unless such knowledge or availability is due to any breach of any obligation of confidentiality; or

(b) was in the possession of a Party at the time the other Party first disclosed the relevant information to the first Party, other than as a result of any breach of any obligation of confidentiality to the other Party by any Person; or

(c) is or was independently developed by a Party without relying on, referring to, or incorporating any of the Confidential Information of the other Party.

Discloser means:

(a) in respect of Confidential Information, the Party which discloses that Confidential Information to the other Party; and

(b) in respect of Project Confidential Information, either Party.

Disclosure Requirement means any order of or from any Government Agency, court or other tribunal having power or jurisdiction over the relevant Person and requiring the disclosure of any Confidential Information or Project Confidential Information, or any other requirement to disclose Confidential Information or Project Confidential Information under any law or regulation applicable to the relevant Person (including the listing rules of any relevant securities or commodities exchange).

Encumbrance means a licence, option, mortgage, charge, pledge, lien, legal or equitable interest, right of evaluation or refusal, undertaking as to confidentiality, hypothecation or title retention arrangement, or an easement, restrictive covenant, caveat or similar restriction over property, or an agreement to create any of them or to allow any of them to exist.

End Date means the date of completion of the last Statement of Work under this Agreement.

Fees mean compensation payable to a Party in respect of Contributions or Services provided by the other Party under a Statement of Work (for the avoidance of doubt, excluding royalties and/or technology access fees).

GDPR means European Regulation No 2016/679 dated 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC

Generic Field means [***].

Government Agency means:

(a) a government or government department or other body (including any administrative body);

(b) a governmental, semi–governmental or judicial person including a statutory corporation (including a securities or commodities exchange); or

(c) a Person (whether autonomous or not) who is charged with the administration of a law.

GST, **GST Law** and other terms used in clause 14 have the meanings used in the *A New Tax System (Goods and Services Tax) Act 1999* (Australia), except that **GST Law** includes any applicable rulings issued by the Commissioner of Taxation (Australia).

Hearing Conditions means [***].

Improvements means any modification, improvement or enhancement to, or development of Background IP created in the course of the Project, but shall not include any modification, improvement, enhancement or development that is patentable in its own right or which is based on Know How or Confidential Information of the Party not owning the relevant Background IP.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

Initial Statements of Work means the Statements of Work attached at Schedule 1, as they may be amended in accordance with this Agreement.

Intellectual Property means any and all existing and future rights throughout the world conferred by statute, common law, equity or any corresponding law in or in relation to copyright, trademarks, designs, patents (including Patent Rights), databases, circuit layouts, plant varieties, business and domain names, inventions, trade secrets, Know How and Confidential Information and other results of intellectual activity in the industrial, commercial, scientific, literary or artistic fields whether or not registrable, registered or patentable. These rights include all rights in all applications to register these rights all renewals and extensions of these rights and all rights in the nature of these rights, excluding Moral Rights.

Know How means scientific, technical and other information which is not in the public domain including discoveries, concepts, data, formulae and algorithms, ideas, specifications, procedures for experiments and tests and results of experiments, experimentation and testing, results of research and development and information in laboratory records, case reports, data analyses and summaries.

Licenced Background IP means a Party's Background IP that has been explicitly designated in an agreed Statement of Work as being subject to the licences contemplated in clauses 6.1(b) to 6.1(d) and for which associated licensing terms, including technology access fees and/or royalties (if any), have been agreed in the Statement of Work.

Loss means any damage, loss, cost, expense, claim, obligation or liability (including lost profits, fines, charges, compensation and penalties) effectively incurred, borne or made by the relevant legal entity or individual, to be calculated in accordance with the provisions of the Belgian Civil Code (including articles 1149, 1150 and 1151 of the Belgian Civil Code) and including, for the avoidance of doubt, any reasonable lawyers' fees and expenses.

Milestones means any significant event, stage or waypoint in relation to the conduct of the Project as set out in any Statement of Work.

Moral Rights means a right of integrity of authorship, a right of attribution of authorship, a right not to have authorship falsely attributed, an initial divulgation right and/or a right of a similar non-pecuniary nature which is conferred by Title 5 of Book XI of the Code of Economic Law, and which exists or comes to exist anywhere in the world, in relation to a copyright work or other copyright subject matter.

Nyxoah Field means methods, apparatuses, software and systems directed to:

(a) [***]; and

(b) [***].

Parties means the parties to this Agreement and Party means any of them.

Party Data means all data and information (including Confidential Information) relating to a Party and its Affiliates and its and their operations, facilities, Personnel, assets, products, sales and transactions in whatever form whether entered into, stored in, generated by or processed as part of the Project, and includes any:

(a) database in which such data or information is stored; and

(b) documentation or records related to such data or information.

Party Materials means any software, technical documentation, research records or other material or information (whether in written or electronic form) supplied by a Party or any of its Personnel in connection with the Project.

Patent Rights means rights with respect to existing and future patent applications (including all divisional, continuation, and continuations-in-part, patents of addition, utility models or like patent applications claiming or sharing priority therefrom), any and all issued and unexpired patents arising from any of such applications, any and all issued and unexpired reissues, re-examinations, renewals, extensions, restorations, and supplemental protection certificates, including the right to apply for registration of any of the foregoing rights.

Person includes any natural person, firm, corporation, partnership, association, joint venture, government department or agency, or any other person or persons (incorporated or unincorporated).

Personal Information has the meaning attributed to that term in the Privacy Legislation and includes all information which constitutes "personal data" under the GDPR.

Personnel means, in relation to a Party, any director, officer, employee, agent, contractor, sub-contractor, or other representative of that Party or of any of its Affiliates.

Premises means any building, premises or location occupied by a Party or any of its Affiliates and from or at which the relevant entity carries on its business(es) or conducts its activities.

Privacy Legislation means the *Privacy Act 1988* (Australia), as applicable, the EU Data Protection Legislation, as applicable, and/or any other applicable data privacy legislation in any jurisdiction from time to time which applies to the Parties.

Processor shall have the meaning given to it in the GDPR.

Project means the project represented by all agreed Statements of Work.

Project Confidential Information means information regarding the substance and status of work undertaken in the Project, including Reports, Records and other work papers, but does not include:

(a) information that a Party can establish, to the reasonable satisfaction of the other Party, is Excluded Information; or

(b) the outcomes and final results of the Statement of Work (except for details of the Statement of Work to be kept confidential in accordance with clause 9.5(d)).

Project IP means all Intellectual Property created or developed by the Parties in or in relation to the conduct of the Project, but does not include Background IP or Improvements.

Project Leaders has the meaning given in clause 3.1.

Project Steering Committee means an oversight committee in respect of the Project, initially comprising the Personnel of the Parties nominated in this Agreement.

Recipient means:

(a) in respect of Confidential Information, the Party which acquires that Confidential Information from the other Party or the other Party's Personnel; and

(b) in respect of Project Confidential Information, each Party.

Records has the meaning given in clause 5.1.

Reports means all reports in relation to the Project provided in accordance with this Agreement and any agreed Statement of Work.

Representatives means all Personnel of a Party involved in the Services under this Agreement.

Representative Data means Personal Information relating to Representatives.

Services means the services to be provided by Nyxoah and Cochlear and each of their Affiliates, in each case as set out in a Statement of Work.

Shareholders' Agreement means the shareholders' agreement relating to Nyxoah, dated 5 October 2018, entered into between the shareholders of Nyxoah (including Cochlear Investments Pty Ltd) in the presence of Nyxoah.

Standard Contractual Clauses or **SCC** means a template personal information transfer agreement pre-approved by the European Commission enabling transfers between legal entities located in the EEA and legal entities located outside in compliance with the EU Data Protection Legislation.

Subscription Agreement means the subscription agreement relating to a Series B2 Preferred Share investment in Nyxoah, dated 20 September 2018, entered into between Nyxoah, Cochlear Investments Pty Ltd and the shareholders of Nyxoah.

Surviving Provisions means clauses 1, 4.7, 4.8, 5, 6,7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20 and 21 of this Agreement.

Statement of Work means the Initial Statements of Work and any other statement of work that may be agreed by the Parties from time to time in accordance with this Agreement.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

Tax means any tax, levy, impost, charge, rate or tariff (including any Value Added Tax) which is levied, imposed, demanded or collected under any legislation or by any government Person including any associated interest, charge, penalty, fine or other amount.

Term has the meaning given to it in clause 15.1.

Value Added Tax means GST or any other form of sales or value added tax in an applicable jurisdiction.

2 CONDUCT OF THE PROJECT

2.1 The Parties will conduct the Project in accordance with this Agreement and all agreed Statements of Work.

2.2 Each Statement of Work will be agreed and executed by the Parties and will set out the Parties' respective Contributions and Services to be used, applied and provided under the Statement of Work, including in respect of the agreed phase and Milestone specified in the Statement of Work, as well as a detailed breakdown of the overall costs and expenses to be incurred under the Statement of Work. Each Statement of Work will also set out:

(a) the Fees payable by each Party for the Contributions and Services of the other Party as agreed in the Statement of Work (which may be charged on a per hourly basis or subject to a fee cap or other fixed priced mechanism as agreed in the relevant Statement of Work);

(b) the Licenced Background IP (if any) to be licenced under clauses 6.1(b) to 6.1(d) in connection with the Statement of Work, and the terms and amount of royalties and/or technology access fees payable (if any) in respect of that Licenced Background IP as agreed in accordance with clause 2.5; and

(c) any other agreed parameters for the work to be performed under the Statement of Work, which may include timelines, service levels, deliverables and designation of relevant Party Personnel.

2.3 Subject to other arrangements which may be specified in a Statement of Work, the Parties will invoice Fees on a monthly basis, with payment due within 30 days of the invoice date and overdue Fees will accrue simple interest daily at a rate of 5% per annum.

2.4 Where under a Statement of Work the provision of any Services, Contributions or access to Background IP is conditional upon achievement of any Milestone, the relevant Party will only be required to provide the Service, Contribution or access to Background IP upon achievement of the relevant Milestone (unless otherwise agreed by the Parties in writing).

2.5 Any new Statement of Work may include, and either Party may request that any existing Statement of Work may be amended or supplemented from time to time in accordance with clause 4.2(c) to add, Licenced Background IP to the Statement of Work. Where a Party requests that Licenced Background IP (which may, for the avoidance of doubt, include any relevant Intellectual Property, also beyond Patent Rights) be added to an existing Statement of Work:

(a) the Parties will:

(i) first discuss in good faith whether the proposed Licenced Background IP should be added to the Statement of Work; and

(ii) if the Parties agree that the proposed Licenced Background IP should be added to the Statement of Work, negotiate the terms and amount of any royalties and/or technology access fees (if any) payable in respect of the proposed Licenced Background IP in good faith with regard to a fair and reasonable assessment (assuming arm's length negotiations) of the value of the proposed Licenced Background IP;

(b) either Party may elect to pause work on the Statement of Work for a period not to exceed 30 days to facilitate the discussions and negotiations contemplated in clause 2.5(a); and

(c) where the Parties have been unable to agree whether to include the proposed Licenced Background IP in the Statement of Work, or the terms and amount of royalties and/or technology access fees to be paid (if any) in respect of the proposed Licenced Background IP, after the period referred to in clause 2.5(b), the Party to whom the proposed Licenced Background IP was proposed to be licenced may elect to terminate further work under the relevant Statement of Work.

2.6 Subject to clause 6.9, each Party must:

(a) use good faith and diligent efforts to discharge its obligations under each Statement of Work in a timely manner and within the budget parameters set in the relevant Statement of Work;

(b) discharge its obligations under each Statement of Work using due care and skill, and in accordance with all applicable laws, regulations and research and development practice standards and codes;

(c) use good faith and diligent efforts to obtain and maintain for the Term all Authorisations which are required in order to carry out its obligations under each Statement of Work, and notify the other Party in writing promptly if any such Authorisation is cancelled, withdrawn or suspended;

(d) apply the appropriate equipment, facilities and Personnel reasonably necessary to carry out its obligations under each Statement of Work;

(e) comply with all laws, regulations and terms of use, and the requirements of any Government Agency or Authorisation, applicable to its provision of Contributions and Services under each Statement of Work; and

(f) discuss in good faith arrangements and funding to address any delays or cost overruns in respect of any agreed Statement of Work, having regard to the Parties' respective obligations under the Statement of Work and the reasons for the relevant delay or cost overrun. Without prejudice to the prior sentence, the Parties acknowledge that this clause 2.6(f) does not mean that a Party shall be obliged to accept delays or cost overruns.

2.7 Subject to clause 6.9, the Parties must and must procure that their respective Personnel:

(a) use good faith and diligent efforts to conduct the Project efficiently and expeditiously in accordance with each Statement of Work;

(b) not knowingly infringe the Intellectual Property of any Person in carrying out the Project; and

(c) comply with the terms and conditions of this Agreement as if each of their respective Personnel was a party to this Agreement.

2.8 Each Party represents and warrants to the other Party that:

(a) subject to the acquisition of any equipment or consumables referred to in an agreed Statement of Work, it has the facilities and resources to carry out its obligations under each agreed Statement of Work; and

(b) it has no reason to believe that any of the timeframes specified in an agreed Statement of Work are unlikely to be met.

2.9 At either Party's request, the Parties must meet to discuss and review the conduct of work under each existing Statement of Work.

2.10 Each Party’s obligation to provide Contributions or Services in respect of the Project will be subject to the following limitations:

(a) each of the Parties acknowledges that, subject at all times to a Party’s compliance with its obligations as set out in the relevant Statement of Work, in performing the Services and providing Contributions, each Party will be entitled to make all decisions regarding the manner of its performance of its obligations under a Statement of Work, including the internal allocation of its resources including Personnel; it being understood, however, that each Party will have the right to object to the allocation of Personnel made by the other Party following a reasonable assessment of the Personnel credentials and/or their suitability for the Project and the other Party shall take any such objection(s) into account without prejudice to clause 17;

(b) in no event will a Party be required to provide Services or Contributions where in the Party's reasonable opinion, doing so would violate any law or regulation applicable to it or any of its Affiliates, or any contractual rights or terms of use that apply to any of them; provided, however, that where a Party is excused from providing Services or Contributions under this clause 2.10, it will consider in good faith a reasonable proposal from the other Party as to how the relevant Services or Contributions might be provided in compliance with the relevant law, regulation, contractual rights or terms of use and the Parties will in good faith agree any associated incremental costs.

2.11 Except as provided in clause 6.9 and unless explicitly agreed otherwise between the Parties, to the extent of any inconsistency between the terms and conditions of this Agreement and the contents of a Statement of Work, the contents of this Agreement will prevail.

3 PROJECT LEADERS

3.1 Work under each agreed Statement of Work is to be coordinated by two project leaders, one appointed by Nyxoah and one appointed by Cochlear (the **Project Leaders**), under the guidance and supervision of the Project Steering Committee on any issues for which the Project Steering Committee deems this useful.

3.2 If a Project Leader ceases to be employed by a Party, or is otherwise unable to continue in his or her role for any reason, the Party that appointed that Project Leader may nominate a replacement with suitable experience and qualifications and reasonably acceptable to the other Party. If the other Party reasonably and in good faith objects to a nominated replacement, the nominating Party will be entitled to nominate an alternative replacement. If the Parties are unable to agree a replacement Project Leader within 40 Business Days, either party may commence the dispute resolution procedure in clause 18.

3.3 The Project Leaders are to meet and discuss progress of work under the relevant Statement of Work as often as is necessary for the proper conduct of such work, and in any event at least monthly (or more frequently if agreed in the Statement of Work).

3.4 The Project Leaders will discuss and agree:

(a) overall management of work under the relevant Statement of Work, including coordination and management of designated resources;

(b) changes to the work plan under any Statement of Work (within any parameters set in the Statement of Work), including deployment of resources or allocation of roles or responsibilities; and

(c) design decisions and changes (within any parameters set in the relevant Statement of Work).

3.5 All decisions of the Project Leaders, including in respect of any decision under clauses 3.4(b) or 3.4(c) will be by mutual consent (consensus).

3.6 The Project Leaders must jointly prepare and issue to the Project Steering Committee:

(a) on a monthly basis, a written or electronic summary report updating the progress of the Project, and summarising work under each open Statement of Work since the previous report; and

(b) on a quarterly basis for discussion at the meeting of the Project Steering Committee to be held under clause 4.3(a), a summary of Project IP reported under clause 6.7 for each open Statement of Work and a summary of Background IP of either Party that has been identified as potentially necessary to the work contemplated under each open Statement of Work (it being understood that this summary will be based on the actual knowledge of the Project Leaders at the time of preparing the summary).

3.7 Within 90 Business Days of completion of a Statement of Work, the Project Leaders must jointly prepare and issue to the Project Steering Committee a final written report in respect of the Statement of Work, including:

(a) whether all development goals set out in the relevant Statement of Work were achieved, and if not, the reasons why not;

(b) a review of the Parties' respective issued patent portfolios for the purpose of identifying the Parties' respective patents (if any) that apply to the results of the Statement of Work; and

(c) details of the Statement of Work that they propose to be kept confidential in accordance with clause 9.5(d).

3.8 Within 30 Business Days of the End Date or earlier termination of this Agreement for any reason, the Project Leaders must jointly prepare and issue to the Project Steering Committee a final written report, including:

(a) whether all development goals set out in all open Statements of Work were achieved, and if not, the reasons why not; and

(b) any recommendations for further work.

4 PROJECT STEERING COMMITTEE AND PERSONNEL

4.1 Each Party must appoint two members of its Personnel to the Project Steering Committee for the Project (which for Nyxoah must include at least one member of Nyxoah's executive team). The initial members of the Project Steering Committee will be:

For Nyxoah	[***] [***]
For Cochlear	[***] [***]

Each Party is entitled to replace either or both of its members of the Project Steering Committee at any time on written notice to the other Party.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

4.2 Each Party must ensure that its members of the Project Steering Committee oversee the Project on behalf of that Party, including:

(a) monitoring and managing the overall relationship between the Parties;

(b) consulting with each of the Parties on the strategic direction of the collaboration between the Parties and on potential future work packages and Statements of Work;

(c) approving any amendment or supplementation of any Statement of Work, including any changes with respect to the work plan, scope, costs, timing or other operational parameters under the Statement of Work;

(d) ensuring that budget and resources for the Project are allocated in accordance with this Agreement and each Statement of Work;

(e) monitoring the progress of the Project with a view to meeting the timeframes (including any Milestones and Project phases) specified in each Statement of Work;

(f) determining which details of a Statement of Work are to be kept confidential in accordance with clauses 9.5(d) and 9.5(f); and

(g) liaising with the other Party's Project Steering Committee members in the management of the Project from time to time, including in respect of escalation of key issues from the Project Leaders.

4.3 Each Party will ensure that its Project Steering Committee members comply with the following requirements for proceedings of the Project Steering Committee:

(a) the Project Steering Committee will meet no less frequently than quarterly during the Term;

(b) quorum for any meeting of the Project Steering Committee will require attendance by at least one Project Steering Committee member nominated by each Party including the member of Nyxoah’s executive team on the Project Steering Committee;

(c) without prejudice to clause 4.4, decisions of the Project Steering Committee will require an affirmative vote of at least one Project Steering Committee member nominated by each Party; and

(d) at its first meeting, the Project Steering Committee will adopt policies and procedures for future meetings (including for agenda setting and conduct of the meetings).

4.4 Each Party acknowledges that members of the Project Steering Committee will act as representatives of their nominating Party and will be permitted to represent their nominating Party’s interests and to share all information obtained as members of the Project Steering Committee with their nominating Party.

4.5 Each Party must notify the other Party prior to or immediately upon the occurrence of any change in the circumstances, role, or status of any of the first Party’s Project Steering Committee members. Each Party must use its best endeavours to replace as soon as is reasonably practicable a Project Steering Committee member who resigns or ceases or suspends for 30 consecutive days his or her participation in the Project with a person of equivalent skills and experience.

4.6 Each Party must ensure that before commencing any work on the Project or having access to any Confidential Information of the other Party, the first Party's Personnel have contractually:

(a) assigned and agreed to assign to the first Party their entire interest in any Project IP they may develop or acquire, and waive their Moral Rights in such Project IP to the extent permitted by law; and

(b) undertaken to keep the other Party's Confidential Information and the Project Confidential Information confidential on substantially the same terms as the first Party's obligations under this Agreement.

4.7 Each Party is solely responsible for:

(a) all remuneration and entitlements;

(b) work care levies, workers' compensation, group tax, payroll tax, superannuation or pension fund guarantee charges and other imposts or levies imposed by law;

(c) any expenses and allowances;

(d) any payment on termination of employment; and

(e) any payment on termination of the Project,

payable to, or in relation to, that Party's Personnel.

4.8 Each Party is solely responsible for checking and approving all references and background checks for that Party's Personnel in accordance with its customary practices.

5 REPORTING AND RECORDS

5.1 Each Party must procure that its Personnel engaged on the Project prepare Reports to the Project Steering Committee in the form and at the times specified by the Project Steering Committee. These Reports will be provided directly to Nyxoah and Cochlear as well.

5.2 Each Party must, and must ensure that its Personnel:

(a) maintain organised and legible records, in sufficient detail and in good scientific manner, which are complete and accurate and which fully and properly reflect all work done and results achieved in the performance of the Project ("**Records**"); and

(b) keep and maintain the Records for the Term and three (3) years after the Term, or such longer period as the other Party reasonably requests or as required by law.

5.3 Each Party must keep and maintain during the Term and for three (3) years thereafter, or such longer period as the other Party reasonably requests or as required by law, separate financial accounts, prepared in accordance with applicable laws and (unless inconsistent with those laws) applicable accounting standards to record all payments made to it by the other Party, and all expenditure(s) incurred by it in carrying out the Project.

5.4 Either Party may during the Term and for three (3) years thereafter with reasonable notice to the other Party and during normal business hours, visit the other Party's or its Affiliates' premises to audit the other Party's and its Affiliates' records, procedures and systems as is required under the auditing Party's quality management system. This right of audit may only be exercised to the extent reasonably required to comply with the auditing Party's quality management system, and in any event not more than twice in any given 12 month period. In conducting the audit, the auditing Party must take reasonable steps to minimise its distraction to the audited Party's (or its Affiliates') operations.

5.5 Each Party must provide to the other Party, within 14 days of a written request by the other Party, a copy of any Records or financial accounts in respect of the Project required to be kept by it under this clause 5.

6 INTELLECTUAL PROPERTY

6.1 The following arrangements apply in respect of each Party's Background IP:

(a) each Party acknowledges that the other Party retains ownership of the other Party's Background IP;

(b) for the duration of the Term:

i. Cochlear hereby grants to Nyxoah a [***] licence to the Cochlear Licenced Background IP specifically identified in each agreed Statement of Work for use in the Nyxoah Field (except as explicitly agreed otherwise in the relevant Statement of Work), but only for the purpose of carrying out the Project, and in the Cochlear Field but only to the extent required for carrying out the Project; and

ii. Nyxoah hereby grants to Cochlear a [***] licence to the Nyxoah Licenced Background IP specifically identified in each agreed Statement of Work for use in the Cochlear Field (except as explicitly agreed otherwise in the relevant Statement of Work), but only for the purpose of carrying out the Project, and in the Nyxoah Field, but only to the extent required for carrying out the Project; and

(c) for the duration of the Term, each Statement of Work will specify any royalties and/or technology access fees (agreed in accordance with clauses 2.2 or 2.5) to be payable in respect of the licences granted under clause 6.1(b) (if any); and

(d) effective as of the expiration or earlier termination of the Term:

i. the licences granted under clauses 6.1(b) will terminate;

ii. other than where Cochlear has terminated this Agreement under clause 15.3(a) (or where a licence in respect of the relevant Cochlear Licenced Background IP has already been agreed by the Parties for the period following expiration or earlier termination of the Term), Cochlear will grant to Nyxoah a [***] licence to the specific Cochlear Licenced Background IP licenced under clause 6.1(b)i for use in the Nyxoah Field (except as explicitly agreed otherwise in the relevant Statement of Work) on terms (which may include an obligation for Nyxoah to pay to Cochlear royalties and/or technology access fees) agreed in good faith with regard to a fair and reasonable assessment (assuming arm's length negotiations) of the value of the relevant Cochlear Licenced Background IP; and

iii. other than where Nyxoah has terminated this Agreement under clause 15.3(a) (or where a licence in respect of the relevant Nyxoah Licenced Background IP has already been agreed by the Parties for the period following expiration or earlier termination of the Term), Nyxoah will grant to Cochlear a [***] licence to the specific Nyxoah Licenced Background IP licenced under clause 6.1(b)ii for use in the Cochlear Field (except as explicitly agreed otherwise in the relevant Statement of Work) on terms (which may include an obligation for Cochlear to pay to Nyxoah royalties and/or technology access fees) agreed in good faith with regard to a fair and reasonable assessment (assuming arm's length negotiations) of the value of the relevant Nyxoah Licenced Background IP.

6.2 The following arrangements apply in respect of Improvements:

(a) [***];

(b) [***]; and

(c) [***].

6.3 The following arrangements apply in respect of Project IP in which Patent Rights subsist:

(a) [***];

(b) [***];

(c) [***];

(d) for the duration of the Term:

(i) Cochlear hereby grants to Nyxoah a [***] licence, exclusive (including as to Cochlear) in the Nyxoah Field and non-exclusive in any other field except for the Cochlear Field (in which no licence is granted), to the Project IP vesting in Cochlear under clause 6.3(a);

(ii) Nyxoah hereby grants to Cochlear:

6.3.b.ii.1 a [***] licence to the Project IP vesting in Nyxoah under clauses 6.3(b) and 6.3(c) for the sole purpose of carrying out the Project; and

6.3.b.ii.2 a [***] licence, exclusive (including as to Nyxoah) in the Cochlear Field and non-exclusive in any other field except for the Nyxoah Field (in which no licence is granted), to the Project IP vesting in Nyxoah under clauses 6.3(b) and 6.3(c), [***]; and

(e) effective as of the expiration or earlier termination of the Term:

(i) the Party holding title to the Project IP in which Patent Rights subsist pursuant to this clause 6.3 will be free to exploit any such Intellectual Property for any purpose (including, subject to the limitations in clauses 6.3(e)(ii) and6.3(e)(iii), sub-licensing and Commercialisation) without notice, consent or accounting to the other Party;

(ii) other than where Cochlear has terminated this Agreement under clause 15.3(a), Cochlear will grant to Nyxoah a [***] licence in all fields except for the Cochlear Field (in which no licence is granted) to the specific Project IP licenced under clause 6.3(d)(i). Cochlear agrees that:

6.3.c.ii.1 [***]; and

6.3.c.ii.2 [***]; and

(iii) other than where Nyxoah has terminated this Agreement under clause 15.3(a), Nyxoah will grant to Cochlear a [***] licence in all fields except for the Nyxoah Field (in which no licence is granted) to the specific Project IP licenced under clause 6.3(d)(ii). Nyxoah agrees that:

6.3.c.iii.1 [***]; and

6.3.c.iii.2 [***].

6.4 Title to all Intellectual Property subsisting in Project IP in which no Patent Rights subsist vests in [***].

6.5 Patent Rights in Project IP will be presumed not to exist unless otherwise determined by agreement of the Parties (acting reasonably and in good faith).

6.6 Each Party acknowledges and agrees that, during the Term, the licences granted under clauses 6.1(b), and the licence granted to Cochlear under clause 6.3.d.ii.1, will be sub-licensable by the other Party:

(a) to any Affiliate of the other Party that is involved in the Project; and

(b) with the prior written consent (not to be unreasonably withheld or delayed) of the Party granting the licence, to third parties supplying services in connection with the Project,

(c) in either case only to the extent necessary to undertake the Project in accordance with this Agreement and each agreed Statement of Work.

6.7 If at any time either Party considers that any Project IP it develops is patentable or suitable for any other form of registration, it must promptly communicate that fact to the other Party. Promptly following such notification, the Intellectual Property representatives of each of the Parties shall discuss in good faith the registration procedure (including the scope of the patent disclosure and the patent filing strategy). The owner of the relevant Project IP shall be responsible for the maintenance and prosecution costs.

6.8 Each Party shall promptly execute and deliver to the other Party any instrument or other document which the other party may reasonably request in order to give effect to this clause 6, give the other Party all information and assistance reasonably requested by the other Party (at the other Party’s expense) for the purpose of any application for registration or protection of any the other Party’s rights under this clause 6 and shall promptly execute and deliver any document required in connection with any such application.

6.9 Each Party acknowledges and agrees that the provisions of this clause 6 are subject to any Intellectual Property arrangements specifically agreed between the Parties in a Statement of Work, and will be superseded by any such arrangements in case of any inconsistency.

6.10 Each Party represents and warrants to the other Party that:

(a) it owns or controls its Licenced Background IP;

(b) it has full right, power and authority to grant the licenses and other rights to the other Party referred to in this clause 6; and

(c) there is no Encumbrance on any Project IP or any of its Licenced Background IP in any manner which is inconsistent with the rights granted to the other Party in this Agreement.

6.11 Each Party acknowledges that where a licence granted under this clause 6 is said to be granted on an exclusive basis, the related Intellectual Property may be subject to non-exclusive licences granted to third parties prior to the date of this Agreement. Where such pre-existing licences are listed on an agreed Statement of Work, they will be deemed to be agreed exceptions from the requirement to grant the licence under this clause 6 on an exclusive basis.

7 PUBLICATIONS

7.1 A Party (the **Publishing Party**) wishing to submit for publication, publish, present or otherwise make available to any third party any information referring or relating to the Project, including in any announcement, release, advertising, referral or publicity material (including in any electronic media (a **Proposed Publication**), must give written notice to the other Party (the **Reviewing Party**) together with the Proposed Publication at least 60 days prior to the proposed date of the presentation or publication (the **Approval Period**), unless mutually agreed in writing otherwise.

7.2 During the Approval Period, the Reviewing Party may notify the Publishing Party of any of the following steps it considers should be taken to protect any of the Reviewing Party's Intellectual Property before the Proposed Publication is published or presented:

(a) amending the Proposed Publication to remove any Confidential Information or Project Confidential Information of the Reviewing Party; or

(b) delaying publication to allow the Reviewing Party to seek appropriate protection or registration of any of its Intellectual Property for a period not exceeding 120 days.

7.3 If the Reviewing Party notifies the Publishing Party under clause 7.2 of any steps the Reviewing Party considers should be taken before publication:

(a) the Publishing Party must not submit for publication, publish, present or otherwise make available to any third party the Proposed Publication until all such steps are taken to the Reviewing Party's reasonable satisfaction; and

(b) the Reviewing Party must use reasonable endeavours to take such steps, but the Reviewing Party is not required to take any steps, or to approve any publication which the Reviewing Party considers is contrary to its commercial interests.

7.4 If the Reviewing Party does not notify the Publishing Party under clause 7.2 during the Approval Period, the Proposed Publication is taken to have been approved by the Reviewing Party.

7.5 Nothing in this clause 7 is intended to limit or delay a permitted use or disclosure of Confidential Information or Project Confidential Information under clauses 9.2 and 9.3.

7.6 If requested by a Party, any publication by the other Party must acknowledge the role of the first Party in the Project.

8 NON-SOLICITATION

8.1 During the Term, neither Party may solicit the services of or offer any employment or engagement to any Personnel of the other Party (or its subsidiaries) without first obtaining the approval of an authorised officer of the other Party. The publication of publicly circulated and non-targeted advertisements for employment or the hiring of a person who responds to such an advertisement of his or her own volition will not be deemed to be a breach of this clause.

8.2 If any Party becomes aware of any infringement of the provisions of this clause 8 by the other Party, that Party shall give a notice to the other Party enjoining it to cease any such infringement within fifteen days. In case of failure to comply with this injunction, the other Party shall pay damages ("*dommages et intérêts*" / "*schadevergoeding*") in a lump sum amount of EUR [***], to be increased with EUR [***] for each day that such infringement continues after the fifteenth day after the notice, without prejudice to the Party's right to claim additional damages if it can establish that it has incurred a prejudice exceeding the above amounts.

8.3 In case any provisions of this clause 8 would ever be held to exceed the limitations imposed by applicable law, they shall not be nullified but the Parties shall be deemed to have agreed to such provisions which are conform with the maximum permitted by applicable law, and any provision of this clause 8 exceeding such limitations shall automatically be amended accordingly.

9 CONFIDENTIALITY AND ANNOUNCEMENTS

9.1 A Recipient must only use Confidential Information and Project Confidential Information disclosed to it for the purposes of or under this Agreement (including undertaking the Project in accordance with this Agreement and the Statements of Work). A Recipient must not disclose or knowingly permit to be disclosed to any Person (except for any Personnel who need to know the Confidential Information and Project Confidential Information for the purposes of this Agreement or the Project) any Project Confidential Information or Confidential Information which is disclosed to it, without the prior written consent of the Discloser. The Parties hereby agree that any breach of this clause 9 would constitute irreparable harm and that the non-breaching Party shall be entitled to seek specific performance or injunctive relief to enforce this clause 9. The provisions of this clause 9 shall survive the expiration or other termination of this Agreement for a period of [***] years (other than with respect to clearly identified trade secrets of either party, for which this clause 9 shall survive the expiration or other termination of this Agreement indefinitely). Notwithstanding the foregoing provisions of this clause 9.1, a Party is entitled to disclose information required to be disclosed in the context of procuring Project IP rights including patents (whether registrable, registered or patentable), design rights, circuit layouts, copyrights and trademarks under this Clause 9 provided;

(a) that the application for the intellectual property right listed in 9.1. has been presented and reviewed by the Project Steering Committee prior to filing or any other disclosure of such application; and

(b) that the disclosed information does not include or refer to any Background IP of the other Party.

9.2 Clause 9.1 does not apply to the extent a Recipient reasonably believes that use or disclosure of any Confidential Information or Project Confidential Information is necessary to lessen or prevent a risk to the life, health or safety of any individual, or to public health or safety.

9.3 Subject to clause 9.4, clause 9.1 does not apply to the extent that any Confidential Information or Project Confidential Information is required to be disclosed pursuant to a Disclosure Requirement.

9.4 If the Recipient receives or becomes subject to a Disclosure Requirement it must, where permitted to do so by the relevant Disclosure Requirement:

(a) notify the Discloser promptly in writing of the existence and nature of the Disclosure Requirement together with reasonable details of the Confidential Information or Project Confidential Information required to be disclosed pursuant to the Disclosure Requirement; and

(b) seek the consent of the Discloser prior to making any disclosure of Confidential Information or Project Confidential Information required to be disclosed pursuant to the Disclosure Requirement and must cooperate fully, at the Discloser’s sole cost and expense, with all lawful efforts that the Discloser may wish to make in order to oppose or limit the extent of the disclosure of Confidential Information or Project Confidential Information in connection with the Disclosure Requirement.

9.5 Notwithstanding clause 9.1 each Party shall be allowed to disclose:

(a) the existence and terms of this Agreement;

(b) the existence and terms of all agreed Statements of Work;

(c) the results and costing of finalized Statements of Work;

(d) other details of all finalized Statements of Work, other than those that the Project Steering Committee has decided to designate as confidential (acting reasonably);

(e) the general status, intermediate results, timing and costing to-date of open Statements of Work; and

(f) other details of the open Statements of Work, other than those that the Project Steering Committee has decided to designate as confidential (acting reasonably),

in the framework of a due diligence or similar exercise to Persons considering to provide financing to, making an investment in or acquiring securities in the Party and who have entered into confidentiality undertakings with the Party that provide for confidentiality obligations in respect of the information disclosed that are substantially similar to clauses 9.1 to 9.4 and clause 9.6. A Party that discloses to such a potential financier, investor or acquirer under this clause 9.5 will be liable to the other Party for any disclosure by such potential financier, investor or acquirer that would, if done by the disclosing Party, be a breach of this clause 9 (for that purpose disregarding this clause 9.5), unless such potential financier, investor or acquirer has entered into similar confidentiality undertakings directly with the disclosing Party or any of its Affiliates.

9.6 Each Party must use commercially reasonable efforts to ensure that it has in place appropriate technical and organizational measures to protect against unauthorised or unlawful processing of the other Party's Confidential Information and Project Confidential Information and against accidental loss or destruction of, or damage, to the other Party's Confidential Information and Project Confidential Information.

9.7 Other than:

(a) as required by a Disclosure Requirement;

(b) release of the agreed form of press release attached to this Agreement as Schedule 5 shortly following execution of this Agreement; and

(c) as may be otherwise agreed in in advance by the Parties (each acting reasonably),

(which shall form exceptions to clause 9.1) each Party agrees that it will not:

(d) disclose the terms of this Agreement or the details of the collaboration between Cochlear and Nyxoah, including any Project Confidential Information; or

(e) in any way use or include the other Party's corporate or trade name or any of the other Party's trademarks (or any corporate or trade name or trademark of an Affiliate of the other Party),

in any announcement, release, advertising, referral or publicity material (including in any electronic media); provided, however that each Party may repeat in subsequent releases or communications the content of the press release attached to this Agreement as Schedule 5, without the prior written consent of the other Party.

10 PRIVACY

10.1 Processing of Personal Information and Role of the Parties

Any processing of Personal Information under this Agreement constitutes a processing of Personal Information under the Privacy Legislation.

In the framework of the Agreement, Cochlear and Nyxoah will process:

(a) Personal Information relating to each other's Representatives, both acting as a Controller pursuant to clause 10.2; and

(b) Personal Information provided by the other Party, on behalf and upon instruction of that other Party pursuant to clause 10.3, the Party issuing the instructions acting as the Controller and the Party processing the Personal Information on that basis acting as Processor.

Each Party must do all things requested in writing by the other Party (acting reasonably) to enable each Party to comply with all requirements of the Privacy Legislation, including without limitation the conclusion of the necessary data processing or transfer agreements (such as C-2-C SCC or C-2-P SCC) and the negotiation in good faith of any amendments to this Agreement or such data processing or transfer agreements, in the case that the circumstances of the data processing activities described in a Statement of Work change during the term of this Agreement.

10.2 Processing of Personal Information by the Parties as Controller

Each Party shall comply as Controller with the applicable requirements of Privacy Legislation in relation to its processing of Representative Data. In this regard, the Parties conclude the C-2-C SCC which are attached as Schedule 3 and form an integral part of this Agreement.

The Parties agree that they will immediately notify the other Party of any actual unauthorised or unlawful access to or processing, loss, destruction or disclosure of that other party's Personal Information, it being understood that they will likewise notify each other if such event involves Personal Information of a third party but is reasonably relevant for the activities under a Statement of Work.

10.3 Processing of Personal Information by a Party acting as Processor on behalf of the other Party acting as Controller

Under this Agreement, each Party may interchangeably act as Controller or Processor under 10.1(b) above, each Party's qualification depending on the nature of its involvement in each individual Statement of Work. The specific role of each Party as either Controller or Processor for each Project shall be described in the Statement of Work for the relevant Project.

When the Party acting as Processor in the performance of a specific Statement of Work is established within the EEA (i.e. a transfer from a EEA based Controller to a EEA based Processor or a transfer from a non-EEA based Controller to a EEA based Processor), the Parties agree that the provisions set out in Schedule 4 shall apply to the processing of Personal Information under such Statement of Work.

When the Party acting as Processor in the performance of a specific Statement of Work is established outside the EEA (i.e. transfer from a EEA based Controller to a non-EEA based Processor), the Parties agree to conclude C-2-P SCC, where applicable, for the data transfers under such Statement of Work.

11 WARRANTIES, INDEMNITY AND INSURANCE

11.1 Each Party warrants that:

(a) it has the power and authority to enter into and perform its obligations under this Agreement and that the execution of this Agreement by it has been duly and validly authorised by all necessary corporate action;

(b) it has obtained all necessary consents and approvals required for it to lawfully enter into this Agreement;

(c) its obligations under this Agreement are valid and binding and enforceable against it in accordance with their terms, subject to applicable bankruptcy and insolvency laws, principles of equity and concepts of materiality, reasonableness, good faith and fair dealing; and

(d) it has sufficient expertise and know-how to enable it to perform its obligations under this Agreement.

11.2 The Parties must effect and maintain during the period of the Project and for seven years thereafter all insurances that a reasonable and prudent person who is engaged in activities of a similar nature to the Project would effect and maintain including:

(a) public liability insurance for not less than EUR [***] per claim and EUR [***] in the aggregate;

(b) clinical trials insurance; and

(c) professional indemnity insurance (including for medical negligence) for not less than EUR [***] per claim and EUR [***] in the aggregate,

and upon request by the other Party, a Party must provide the other Party with evidence of the terms and currency of such insurances.

11.3 Subject to the limitations set out in clause 11.4, each Party agrees and undertakes to indemnify and hold harmless the other Party (the "**Indemnified Party**") for, from and against any Loss incurred by the Indemnified Party (and its successors and assigns) arising from any breach by such Party of its warranties or its other obligations under this Agreement.

11.4 The aggregate liability of each Party under this Agreement and all Statements of Work (in each case other than directly caused by that Party's wilful misconduct) arising out of all acts, omission and events whenever occurring will not under any circumstances:

(a) in respect of a breach of the Party's warranties in clause 6.10, and/or the Party's breach of its obligations to provide a licence in accordance with clause 6, exceed [***];

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

(b) in respect of all other claims under this Agreement and all Statements of Work (other than a breach of a Party's obligations under clause 9), exceed [***];

(c) provided that in no event will a Party's aggregate liability under clauses 11.4(a) and 11.4(b) exceed the lesser of (i) [***]; and (ii) [***]; and

(d) in respect of any Losses suffered by a Party in connection with all claims by third parties that the Party's use of the other Party's Background IP in connection with the Project or as Licenced Background IP, infringes any right of the third party, exceed [***].

12 WORK HEALTH AND SAFETY

12.1 At all times when a Party or any of its Personnel enter into or upon any of the other Party's Premises in connection with this Agreement or the Project, the Party/Personnel must comply with and must procure that its Personnel comply with:

(a) all of the other Party's applicable work health and safety policies, procedures and programs; and

(b) any and all directions on health and safety from any designated officer of the other Party.

13 WITHHOLDING TAX

13.1 Any payment under this Agreement is made without deduction or withholding for Taxes except to the extent required by any applicable law. Any Tax required to be withheld under any applicable law on amounts payable to the Payee Party under this Agreement shall promptly be paid by the Paying Party on behalf of the Payee Party to the appropriate governmental authority, and the Paying Party will furnish the Payee Party with proof of payment of such Tax as soon as practicable. Any such Tax required to be withheld will be an expense of and borne by the Payee Party, and for the avoidance of doubt, the Payee Party will indemnify and hold the Paying Party (and its Affiliates) harmless from and against any Loss incurred, suffered or sustained by the Paying Partee (or an Affiliate of the Paying Partee) with respect to any Tax required to be withheld.

13.2 The Parties shall cooperate with respect to all documentation required by the relevant taxation authorities or reasonably requested by the Paying Party to secure a refund of Taxes withheld or a reduction in the rate of applicable Taxes withheld.

14 VALUE ADDED TAX

14.1 Notwithstanding any other provision in this Agreement, if any Party to this Agreement is or becomes liable to pay Value Added Tax in connection with any supplies made pursuant to this Agreement (**Affected Supplies**):

(a) the Party liable to pay the Value Added Tax may add to the price of all Affected Supplies the amount of Value Added Tax for which said Party is or becomes liable in respect of those Affected Supplies, as calculated by said Party in accordance with the GST Law, the Belgian VAT Code or other applicable law;

(b) if required by the applicable legislation, the Party providing consideration for the Affected Supplies (**Receiver**) will pay the amounts or provide any other consideration required to be provided under other provisions of this Agreement for the Affected Supplies (**Agreement Price**) plus the calculated amount in respect of the Value Added Tax;

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

(c) the additional amount in respect of Value Added Tax (if any) will be payable at the same time or times as the Agreement Price is required to be provided to the relevant Party under the other provisions of this Agreement; and

(d) the Party supplying the Affected Supplies will issue a tax invoice which enables the Receiver, if permitted by the GST Law, the Belgian VAT Code or such other applicable law, to claim a credit or refund of Value Added Tax.

14.2 If, for any reason, Value Added Tax liability in respect of a particular taxable supply is varied from the additional amount paid by the Receiver in respect of Value Added Tax under paragraph 14.1, then:

(a) the Party supplying the Affected Supplies must repay to the Receiver the amount of any excess paid by the Receiver to that Party in respect of Value Added Tax above the Value Added Tax liability for the relevant taxable supply (as varied); or

(b) the Receiver must pay to the Party supplying the Affected Supplies the amount of any shortfall between the amount paid by the Receiver to that Party in respect of Value Added Tax and the Value Added Tax liability for the taxable supply (as varied),

as the case may be.

14.3 If, as a result of the abolition of or reduction in the rate of any tax, duty, excise or other Government Agency impost where such abolition or reduction is associated with the introduction of the Value Added Tax (other than income tax), the Party supplying Affected Supplies realises a reduction in the cost of that Party performing its obligations under this Agreement, that Party will reduce the amounts payable by the Receiver under this Agreement in order to pass on the benefits of those cost reductions to the Receiver.

14.4 A reference in this clause 14 to a Party being liable for Value Added Tax includes a reference to the representative member of any GST group or other relevant Value Added Tax group to which that Party may belong.

15 DURATION, BREACH AND TERMINATION

15.1 This Agreement commences on the Commencement Date and continues in full force until the earlier of the End Date and the date on which this Agreement is terminated in accordance with this clause 15 (**Term**).

15.2 Either Party may terminate this Agreement at any time by giving at least 30 days’ prior written notice to the other Party if that Party concludes on reasonable grounds, and after consultation with the Project Steering Committee, that there is no reasonable prospect of the objectives of the Project being achieved.

15.3 Either Party may terminate this Agreement with immediate effect by notice in writing to the other Party if the other Party:

(a) commits any material breach of this Agreement (which includes a failure to pay amounts owing under this Agreement when due and payable) the Subscription Agreement (other than a breach of any representation given in such agreement) or the Shareholders’ Agreement and, in the case of a breach capable of being remedied, has failed to remedy the breach within thirty (30) days after receiving a notice requiring it to do so;

(b) is or becomes insolvent or bankrupt or enters into or becomes subject to any form of insolvency or bankruptcy administration or proceedings anywhere in the world; or

(c) ceases or threatens to cease to carry on its business(es) (or any material part of its business or business(es)) in the usual course, or if any resolution is proposed or passed for the winding up and liquidation of the Party.

15.4 Either Party may terminate this Agreement with immediate effect on 30 days' notice following a Change of Control of the other Party.

15.5 Termination or expiry of this Agreement will not prejudice any accrued rights or liabilities of a Party or excuse any Party from a breach of this Agreement occurring prior to termination or expiry.

15.6 Any clause of this Agreement which by its nature is intended to survive the termination or expiry of this Agreement will survive and will continue to apply after termination or expiry. Without prejudice to the generality of this clause 15.6, the Surviving Provisions will survive any termination or expiry of this Agreement.

16 CONSEQUENCES OF TERMINATION

16.1 Except as set out in clause 16.2, upon termination or expiry of the Agreement, each Party must, at no additional cost to the other Party:

(a) immediately cease using and within 14 days return to the other Party (or at the request or with the consent of the other Party, destroy) any physical materials which contain, refer to or embody the Confidential Information of the other Party or the Project Confidential Information, and any hardware, equipment, or property of the other Party in the possession, custody or power of that Party or of any Person to whom that Party has given access; and

(b) erase or destroy in another way all electronic and other intangible records containing, recording or referring to Confidential Information of the other Party in the possession, custody or power of that Party or of any Person to whom that Party has given access, except that:

(i) one copy of the Confidential Information and Project Confidential Information may be retained by the Party's internal or external lawyers;

(ii) copies of the Confidential Information and Project Confidential Information may be retained on a confidential basis if they are:

A. electronically archived and not readily accessible; or

B. contained in board papers or other internal senior management reports; and

(iii) each Party is entitled to keep Confidential Information and Project Confidential Information held in the files and records it compiles in connection with this Agreement;

provided, however, that in each case the Confidential Information and Project Confidential Information is maintained in accordance with this Agreement for so long as it is retained under this clause 16.1.

16.2 Clause 16.1 shall not apply to any Confidential Information or Project Confidential Information contained in whole or in part in any documents, records or other materials, whether in written, electronic or other intangible form, prepared for purposes of completing work under any agreed Statements of Work, provided, however, that the all such documents are maintained as Confidential information in accordance with this Agreement for so long as it is retained under this clause 16.2.

16.3 In the event of early termination of this Agreement, the Parties agree that they will each cooperate in good faith in reaching decisions concerning the completion of work in progress under outstanding Statements of Work.

17 RELATIONSHIP OF THE PARTIES

17.1 Each of the Parties is an independent contractor and nothing contained in this Agreement shall be construed to (i) give either Party the power to direct and control the day-to-day activities of the other Party, (ii) assume between the Parties a relationship as employer and employee, principal and agent, joint ventures, co-owners or as members of a joint undertaking. Neither Party shall have the right to bind the other Party to any agreement with a third party or to incur any obligation or liability on behalf of the other Party, except as provided herein.

17.2 Nothing in this Agreement creates or constitutes or should be deemed to create or constitute any relationship between the Parties or between a Party and the other Party's Personnel of partnership, joint venture, agency, employment or any other relationship by which one Party may become liable for the acts or omissions of the other Party.

17.3 Nothing in this Agreement permits a Party or its Personnel to act as agent for the other Party or its Personnel or in any way to bind or commit the other Party or its Personnel to any obligation. Neither Party may represent that it has the authority to do so or allow itself to be perceived as having the authority to do so.

17.4 Nothing in this Agreement gives a Party authority to negotiate agreements on behalf of the other Party, to conclude agreements in the name of the other Party or to bind the other Party in any way. Each Party shall be solely and exclusively authorized to negotiate and enter into such agreements on its behalf.

17.5 Nothing in this Agreement permits a Party to hold itself out or permit any person to hold itself out as being authorized to bind the other Party in any way, nor act or reasonably create the impression that it is authorized to bind the other Party in any way.

17.6 Each Party represents and warrants to the other Party that it will make no representations to any third parties regarding the other Party, unless specifically authorized in writing by the other Party.

17.7 Nothing in this Agreement permits a Party to incur or purport to incur any commitment or obligation on behalf of the other Party.

18 DISPUTE RESOLUTION

18.1 In the event of any dispute or difference arising between the Parties in connection with this Agreement (**Dispute**) the Parties must, for a period of 30 Business Days before either Party institutes any legal proceedings, in good faith attempt to resolve the Dispute by negotiations between nominated representatives of the Parties, each having the power and authority to resolve the Dispute on behalf of the Party they represent.

18.2 Notwithstanding the existence of a Dispute, each of Cochlear and Nyxoah will continue to perform their respective obligations under this Agreement.

18.3 Clause 18.1 does not apply to any legal proceedings instituted by a Party for the purpose of applying for any urgent interlocutory or injunctive relief.

19 COMMUNICATIONS

19.1 Any notices or communications under or relating to this Agreement must be given or made to the contact person for the relevant Party using the contact details set out in the Contract Details, or such other contact details as notified by the relevant Party for the purposes of this clause 19 from time to time.

19.2 A notice or other communication under this Agreement is only effective if it is in writing, signed and either left at the addressee's address or sent to the addressee by mail or email. If it is delivered, it is taken to have been received when it has been left at the addressee's address. If it is sent by mail, it is taken to have been received five Business Days after it is posted. If it is sent by email, it is taken to have been received when the addressee actually receives it in full and in legible form.

20 SUBCONTRACTING

20.1 A Party must not subcontract all or any part of its obligations under this Agreement without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed, unless otherwise permitted in an agreed Statement of Work, in which case no consent shall be required. Where a Party subcontracts any of its obligations under this Agreement, it will be liable for all acts and omissions of its subcontractors as if they were its own acts and omissions.

21 GENERAL

21.1 This Agreement constitutes the entire agreement of the Parties with respect to the subject matter of this Agreement.

21.2 Neither Party has relied upon any oral or written representation made to it or to its Personnel by the other Party, other than those specifically and expressly set out in this Agreement. Each Party has made its own independent investigations into all matters it deemed relevant before executing and delivering this Agreement.

21.3 A waiver by a Party of any default under this Agreement by the other Party will be of no effect unless the waiver is in writing and signed by the Party giving it. The waiver of any default will not be deemed a waiver of any other default or of any continuing or subsequent default.

21.4 A reference in this Agreement to any clause of this Agreement includes all sub-clauses of that clause.

21.5 A reference to “includes” or “including” is not a form of limitation.

21.6 A reference to any legislation includes that legislation as amended, modified, re-enacted or replaced from time to time and any rules, regulations or statutory instruments issued or proclaimed pursuant to it.

21.7 If an act must be done on a specified day which is not a Business Day, the act must be done instead on the next Business Day.

21.8 This Agreement may only be amended by an instrument in writing signed by all of the Parties.

21.9 Except as expressly permitted by this Agreement, neither Party may assign or transfer this Agreement or any rights or obligations under this Agreement to any Person, without the prior written consent of the other Party (not to be unreasonably withheld).

21.10 Each Party agrees and acknowledges that if it defaults under any provision of this Agreement including in relation to:

(a) the protection or registration of any Project IP; or

(b) the unauthorised use or disclosure of Confidential Information or Project Confidential Information,

the other Party may not have an adequate remedy at law and may apply for immediate injunctive relief.

21.11 If any provision of this Agreement (in whole or part) is held or found to be void, invalid or otherwise unenforceable, that provision (or the relevant part of it) will be severed from this Agreement. The invalidity of any provision in whole or part does not affect the validity of the remaining provisions of this Agreement.

21.12 This Agreement terminates and supersedes all previous agreements between or among the Parties in relation to its subject matter.

21.13 This Agreement may be executed in any number of counterparts and all counterparts taken together constitute one instrument, but this Agreement is of no force or effect until the signed counterparts are exchanged.

21.14 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by and must be construed in accordance with the laws of Belgium.

21.15 The courts of Brussels, Belgium shall have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement (including a dispute relating to non-contractual obligations arising out of or in connection with this Agreement).

SCHEDULE 1

[***]

Company Confidential

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

SCHEDULE 2

[***]

SCHEDULE 3

[***]

SCHEDULE 4

[***]

SCHEDULE 5

[***]

CONFIDENTIAL TREATMENT REQUESTED - REDACTED COPY

MULTIPARTY AGREEMENT
AMONG
[***], NYXOAH, CEPHALIX, GLUCOBEL, SURGICAL ELECTRONICS, MAN & SCIENCE

In this agreement (the "**Agreement**") **Dr. [***]** ("**[***]**"), an individual residing at [***], **Nyxoah SA** ("**Nyxoah**"), a corporation of Belgium whose post office address is 2 Rue Fond Cattelain, B-1435 Mont-St-Guibert, Belgium, company number 0817.149.675; **Man & Science SA** ("**Man & Science**"), a corporation of Belgium whose post office address is 2 Rue Fond Cattelain, B-1435 Mont-St-Guibert, Belgium, company number 0837.403.572; **Cephalix SA** ("**Cephalix**"), a corporation of Belgium whose post office address is 2 Rue Fond Cattelain, B-1435 Mont-St-Guibert, Belgium, company number 0837.403.770 ; **Glucobel SA** ("**Glucobel**"), a corporation of Belgium whose post office address is 2 Rue Fond Cattelain, B-1435 Mont-St-Guibert, Belgium, company number 0840.135.410; and **Surgical Electronics SA** ("**Surgical Electronics**"), a corporation of Belgium whose post office address is 2 Rue Fond Cattelain, B-1435 Mont-St-Guibert, Belgium, company number 0837.403.671 (collectively, the "**Parties**"), agree as follows:

<u>Background</u>

1. [***] is an inventor named on the patents and patent applications listed in Appendix A. All patents and patent applications listed in Appendix A and all future patents and patent applications that may claim priority on any patent or patent applications listed in Appendix A, including all continuation, continuation-in-part, divisional, and national phase applications and patents directly or indirectly issuing therefrom (collectively the "**Patent Documents**") are subject to this Agreement.

2. The **Patent Documents** disclose multiple inventions, including but not limited to inventions generally related to implantable flexible neuro-stimulators ("**Generic Inventions**") and inventions for specific medical indications including sleep disordered breathing, head pain, glucose monitoring, hypertension and other indications (each specific medical indication invention referred to collectively herein as the "**Specific Medical Indication Inventions**"; a **Specific Medical Indication Invention** is one that can be used in treating only one Specific Medical Indication, while a Generic Invention may be used in treating more than one Specific Medical Indication).

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

3. Nyxoah, Cephalix, Glucobel, and Surgical Electronics (collectively, the “**Neuro-Stimulation Companies**”) are each respectively focused on developing solutions associated with a single medical indication as follows: Nyxoah is solely focused on implantable flexible neuro-stimulators for treatment of sleep disordered breathing (“**Sleep Disordered Breathing Field**”); Cephalix is solely focused on implantable flexible neuro-stimulators for the treatment of head pain (“**Head Pain Field**”); Glucobel is solely focused on implantable flexible glucose monitoring (“**Glucose Monitoring Field**”); and Surgical Electronics is solely focused on implantable flexible neuro-stimulators for the treatment of hypertension (“**Hypertension Field**”). Each of the foregoing fields with their associate company is referred to herein as the company’s specific “field of endeavor”. Other specific fields of endeavor are contemplated. For purposes of this Agreement, an issued patent or pending patent application with claims only directed to one specific field of endeavor is referred to herein as a “**Specific Patent**” and a patent or pending patent application with claims directed to either a **Generic Invention** or to two or more specific fields of endeavor is referred to herein as a “**Shared Patent**.”

4. By agreements dated January 4, 2013, March 4, 2013, May 24, 2013, and January 23, 2014 (collectively the “**[***] Conveyances**”), [***] assigned to Nyxoah the **Specific Medical Indication Inventions** in the Sleep Disordered Breathing Field (Specific Patents for Sleep Disordered Breathing are listed in Appendix B). Prior to this Agreement, Adi Mashiach had retained all rights to other **Specific Medical Indication Inventions** and **Generic Inventions**. The **Specific Medical Indication Inventions** related to head pain are listed in Exhibit C, related to glucose monitoring are listed in Exhibit D, and related to hypertension are listed in Exhibit E. The **Generic Inventions** are listed in Exhibit F.

5. By an agreement dated August 30, 2011, Nyxoah assigned all world-wide patent rights in U.S. Patent Application SN 12/581,907 to Man & Science (the “**Prior Nyxoah Conveyance**”).

6. By separate agreements, [***], [***], and [***], co-inventors of some of the **Patent Documents**, each assigned to Nyxoah all of their respective world-wide patent rights in the **Patent Documents** (collectively the “**European Inventor Conveyances**”).

7. By separate agreements, [***], a co-inventor of some of the **Patent Documents**, assigned to Nyxoah all of his rights in **Specific Medical Indication Inventions** and associated **Specific Patents** related to sleep disordered breathing and assigned all other rights in the **Patent Documents** (collectively “**[***] Conveyances**”).

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

8. By a separate agreement dated July 5, 2013, [***], who is not named as an inventor on any of the **Patent Documents**, and Biotronic Sciences, assigned to Nyxoah whatever worldwide rights [***] or Biotronic Sciences may have had in the **Patent Documents** (collectively, the "**[***] Conveyance**").

9. [***] has an ownership interest in Man & Science, which is designated as a holding company for **Generic Inventions** and **Shared Patents** and desires, through this Agreement, to assign all **Generic Inventions** and **Shared Patents** to Man & Science.

<u>Conveyance of Rights Associated With the Patent Documents</u>

10. To the extent not already conveyed to Nyxoah as described in Paragraph 4, [***] hereby assigns, transfers and sets over all of his remaining rights in and to the **Patent Documents** to Man & Science. The intention of this paragraph is that no rights in the Patent Documents remain with [***].

11. To the extent Nyxoah, at the date of this Agreement, owns, by invention, assignment or otherwise, rights in any **Generic Inventions** or **Shared Patent**, in any **Specific Medical Indication Inventions** other than for the Sleep Disordered Breathing Field, or in any **Specific Patent** directed to fields other than the **Sleep Disordered Breathing Field**, Nyxoah hereby assigns, transfers and sets over all such rights in and to Man & Science. Rights transferred by this paragraph include but are not limited to rights obtained by Nyxoah from all assignments and agreements executed prior to the date of this Agreement, including but not limited to the **[***] Conveyances**, the **Prior Nyxoah Conveyance**, the **[***] Conveyances**, the **European Inventor Conveyances**, and **the [***] Conveyance**. The intention of this paragraph is that no rights in the **Patent Documents** other than those related to Sleep Disordered Breathing Field remain in Nyxoah.

12. To the extent Cephalix, Glucobel and Surgical Electronics had any rights or claim of rights in the **Patent Documents** outside of their specific fields of endeavor ("**Preexisting Unrelated Rights**"), Cephalix, Glucobel and Surgical Electronics, each individually, hereby sells, assigns, transfers and sets over in and to Man & Science all **Preexisting Unrelated Rights**.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

13. The operation of the forgoing Paragraphs results in the following division of rights: Inventions specifically related to the Sleep Disordered Breathing Field as listed in Appendix B are, through this Agreement and preexisting agreements, owned fully by Nyxoah; inventions related to the Head Pain Field as listed in Appendix C are, through this Agreement and preexisting agreements, owned fully by Cephalix; inventions related to the Glucose Monitoring Field as listed in Appendix D are, through this Agreement and preexisting agreements, owned fully by Glucobel; inventions related to the Hypertension Field as listed in Appendix E are, through this Agreement and preexisting agreements, owned fully by Surgical Electronics; and **Generic Inventions** as listed in Appendix F are, through this Agreement and preexisting agreements, owned fully by Man & Science, with field of use licenses granted to each Man & Science Licensee in each licensee's specific medical field as set out in Paragraph 3. In the attached Appendices B-F, for pending patent applications, "inventions" as referred to in this paragraph, are defined by the subject matter of the listed patent claims (or in the case of a listed issued patent, by the subject matter of all the issued claims in the patent). To the extent that some of the listed application claims are subject to a restriction requirement or are otherwise not currently under examination, the Party owning the listed subject matter has the right to file continuing patent application(s) claiming such subject matter. The rights or claims held by Man & Science in the Patent Documents following the assignments and conveyances by the various parties prior to or under this Agreement are herein referred to as the "**Man & Science Portfolio**".

14. Man & Science hereby grants to Nyxoah a fully-paid up, world-wide, exclusive license under the **Man & Science Portfolio** to make, use, sell, offer for sale, and/or import all products and methods solely in the **Sleep Disordered Breathing Field**. The conveyances in this paragraph do not provide Nyxoah any rights outside of the **Sleep Disordered Breathing Field**.

15. Man & Science hereby grants to Cephalix a fully-paid up, world-wide, exclusive license under the **Man & Science Portfolio** to make, use, sell, offer for sale, and/or import all products and methods solely in the **Head Pain Field**. The conveyances in this paragraph do not provide Cephalix any rights outside of the **Head Pain Field**.

16. Man & Science hereby grants to Glucobel a fully-paid up, world-wide, exclusive license under the **Man & Science Portfolio** to make, use, sell, offer for sale, and/or import all products and methods solely in the **Glucose Monitoring Field**. The conveyances in this paragraph do not provide Glucobel any rights outside of the **Glucose Monitoring Field**.

17. Man & Science hereby grants to Surgical Electronics a fully-paid up, world-wide, exclusive license under the **Man & Science Portfolio** to make, use, sell, offer for sale, and/or import all products and methods solely in the **Hypertension Field**. The conveyances in this paragraph do not provide Surgical Electronics any rights outside of the **Hypertension Field**.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

18. Other than the rights conveyed in Paragraphs 14, 15, 16 and 17 above, the **Neuro-Stimulation Companies** neither obtain or retain any other rights in the **Man & Science Portfolio**, and Man & Science has the unencumbered right to grant licenses under the **Man & Science Portfolio** to companies other than the **Neuro-Stimulation Companies** in fields other than the **Sleep Disordered Breathing Field**, **Head Pain Field**, **Glucose Monitoring Field**, and **Hypertension Field** without permission of, accounting to or any remuneration to any **Neuro-Stimulation Company**. All present and future licensees of Man & Science under the **Man & Science Portfolio**, including the **Neuro-Stimulation Companies**, are herein collectively referred to as "**Man & Science Licensees**".

19. So long as a Man & Science Licensee does not violate the exclusive patent rights of any other **Man & Science Licensee**, nothing in this Agreement prevents any **Man & Science Licensee** from operating outside is specific field of endeavor as contemplated in Paragraph 3.

<u>Future Obligations to Perfect and Enforce IP Rights</u>

20. The Parties hereto covenant and agree that, as far as commercially reasonable, they will (either individually or through their employees) communicate with the other Parties hereto, their successors and assigns, any facts known to them respecting the **Patent Documents** and will testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver any and all papers that may be necessary or desirable to perfect the title to the **Patent Documents** in the appropriate party, as set forth in this Agreement, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid the parties hereto and their successors and assigns, to obtain and enforce proper patent protection in the **Generic Inventions** and their **Specific Medical Indication Inventions** in the United States and any country world-wide, it being understood that any expense incident to the application of this Paragraph shall be borne by the party for whom the papers are executed, its successors and assigns.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

21. Man & Science agrees that if any **Man & Science Licensee** identifies an infringer in the Man & Science Licensee's field of endeavor that the Licensee wishes to stop through patent enforcement, Man & Science will work with the Licensee in good faith to determine an appropriate mechanism for resolving the dispute. Appropriate mechanisms may involve a negotiated resolution, the Licensee asserting its own patent on a **Specific Medical Indication Invention** and/or Man & Science asserting a one of its patents for a **Generic Invention**. In weighing the appropriate mechanism, Man & Science may take into account the impact that assertion of a **Generic Invention** may have on the rights of other **Man & Science Licensees**. If good faith discussions result in a joint decision to assert a patent on a **Generic Invention**, Man & Science will join in the suit to the extent required by law, and the Licensee will bear all litigation costs. Any damages collected as the result of such suit will be split according to an arrangement to be decided in advance by Man & Science and the Licensee based on the particular circumstances.

22. The non-numbered headings in this Agreement are for reference purposes only and are not to be used in interpreting this agreement.

23. Each Party covenants and agrees that it has the full right to convey the interests conveyed herein, and has not executed and will not execute any agreement in conflict with this Agreement.

24. This Agreement is subject to and will be construed under the laws of the State of New York, U.S.A.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

IN TESTIMONY WHEREOF, we have hereunto set my hand.

Name: Dr. [***]
Address: [***]

[***]

Signature
By:
Date:

Company: Nyxoah SA

Address: 2 Rue Fond Cattelain

B-1435

Mont-St-Gilbert

Belgium

By: *Signature*
Title:
Date:

Company: Glucobel

Address:

By: *Signature*
Title:
Date:

Company: Surgical Electronics

Address:

By: *Signature*
Title:
Date:

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

Company: Man & Science

Address:

By: *Signature*

Title:

Date:

Appendix A: The Patent Documents [***]

Appendix B: Sleep Disordered Breathing Inventions [***]

Appendix C: Head Pain Inventions [***]

Appendix D: Glucose Monitoring Inventions [***]

Appendix E: Hypertension Inventions [***]

Appendix F: Generic Inventions [***]

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

CONFIRMATORY ADDENDUM TO THE MULTIPARTY AGREEMENT

This addendum ("**Addendum**") is entered into on 23 June 2016

between:

(1) **Nyxoah SA**, a company organized and existing under Belgian law, with registered office at Rue du Fond Cattelain 2, B-1435 Mont-St-Guibert, Belgium, registered with the Belgian Crossroads Bank for Enterprises under number 0817.149.675,

validly represented by Robert Taub, Administrateur-Délégué,

hereinafter referred to as "**Nyxoah**";

(2) **Cephalix SA**, a company organized and existing under Belgian law, with registered office at Rue Fond Cattelain 2, B-1435 Mont-St-Guibert, Belgium, registered with the Belgian Crossroads Bank for Enterprises under number 0837.403.770,

validly represented by Robert Taub, Administrateur-Délégué,

hereinafter referred to as "**Cephalix**";

(3) **Surgical Electronics SA**, a company organized and existing under Belgian law, with registered office at Rue du Fond Cattelain 2, B-1435 Mont-St-Guibert, Belgium, registered with the Belgian Crossroads Bank for Enterprises under number 0837.403.671,

validly represented by Robert Taub, Administrateur-Délégué,

hereinafter referred to as "**Surgical Electronics**".

and

(4) **Man & Science SA**, a company organized and existing under Belgian law, with registered office at Rue du Fond Cattelain 2, B-1435 Mont-St-Guibert, Belgium, registered with the Belgian Crossroads Bank for Enterprises under number 0837.403.572,

validly represented by Robert Taub, Administrateur-Délégué,

hereinafter referred to as "**Man & Science**".

The parties mentioned above are hereinafter also referred to collectively as the "**Parties**" and individually as a "**Party**".

Whereas:

(A) Parties have executed a multiparty agreement ("MPA", a copy of which is attached as <u>Schedule 5</u> to this Addendum), regarding their respective ownership and licensing rights in relation to implantable flexible neuro-stimulators;

(B) Parties would like to clarify and confirm in this Addendum their common intent and understanding as set out in the MPA.

It is agreed as follows:

1 Definitions

All definitions in the MPA will be applicable to this Addendum and are taken over by reference.

2 Specific Patents in the Sleep Disordered Breathing Field owned by Nyxoah

2.1 Notwithstanding anything to the contrary in the MPA, Parties confirm that the patent rights listed in Schedule 1 to this Addendum constitute Specific Patents in the Sleep Disordered Breathing Field, all title and interest of which have been duly transferred to and are exclusively owned by Nyxoah.

2.2 Nyxoah grants an exclusive, worldwide, fully paid-up, royalty-free, transferable license to use the patents listed in Schedule 4 outside the Sleep Disordered Breathing Field:

2.2.1 to Cephalix, in the Head Pain Field;

2.2.2 to Surgical Electronics in the Hypertension Field; and

2.2.3 to Man & Science, outside the Head Pain and Hypertension Fields.

3 Shared Patents owned by Man & Science

Notwithstanding anything to the contrary in the MPA, Parties confirm that the patent rights in Schedule 2 to this Addendum constitute Shared Patents, all title and interest of which have been duly transferred to and are exclusively owned by Man & Science.

4 Exclusive license granted to Nyxoah for use of the Shared Patents in the Sleep Disordered Breathing Field

Without prejudice to Clause 14 of the MPA, Man & Science confirms to have granted to Nyxoah an exclusive, worldwide, fully paid-up, royalty-free, transferable license to use the Shared Patents listed in Schedule 2 within the Sleep Disordered Breathing Field.

5 Patents including claims owned by Nyxoah and Man & Science Parties agree that:

5.1 any claims part of the Shared Patents listed in Schedule 3 to this Addendum relating specifically to the Sleep Disordered Breathing Field will be the subject of a divisional patent application with the aim of those specific claims becoming included in a new Specific Patent in the Sleep Disordered Breathing Field, it being understood that all title and interest to these patents have been duly transferred to and are exclusively owned to Nyxoah;

5.2 any claims part of the Shared Patents listed in Schedule 3 to this Addendum not relating specifically to the Sleep Disordered Breathing Field will remain included in a Shared Patent, it being understood that all title and interest to these patents have been duly transferred to and are exclusively owned to Man & Science.

5.3 Schedule 1 and Schedule 2 to this Addendum will be updated systematically to reflect any of these divisional patent applications being filed and subsequent patent registrations being obtained.

6 Initial conveyances

The Parties acknowledge that Schedule 6 includes a documented overview of the initial conveyances set out in sections 4, 5, 6, 7 and 8 of the MPA.

7 Change of control

Any possible change of the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of either Party to any third party, whether through the ownership of voting securities, by contract or otherwise (through a sale, a contribution, a donation or any other transaction, including the sale or contribution of a division ("*branche d'activité*" / "*bedrijfstak*") or of a business as a whole ("*universalité*" / "*algemeenheid*"), a merger or a split) shall not affect the rights and obligations of Parties under the MPA.

8 Assignment

The provisions of the MPA (including this Addendum) shall inure to the benefit of and shall be binding upon Parties and their respective heirs, successors and assigns. In case a particular Party intends to assign any of its rights and obligations under the MPA (including this Addendum), that assigning Party undertakes to transfer all obligations under the MPA (including this Addendum) to such respective heir, successor and/or assign.

9 Severability

9.1 If any provision of the MPA (including this Addendum) is held to be illegal, invalid or unenforceable, in whole or in part, under any applicable law, then such provision or part of it shall be deemed not to form part of the MPA, and the legality, validity or enforceability of the remainder of the MPA shall not be affected.

9.2 In such case, each Party shall use its best efforts to immediately negotiate in good faith a valid replacement provision that is as close as possible to the original intention of Parties and has the same or as similar as possible economic effect.

10 Miscellaneous provisions

10.1 This Addendum confirms and clarifies the terms of the MPA. In case of conflict between the terms of the MPA and this Addendum, the terms of this Addendum will prevail.

10.2 The Schedules to this Addendum form an integral part hereof and any reference to this Addendum includes the Schedules and vice versa.

10.3 This Addendum, and any non-contractual obligations arising out of or in connection with it, shall be governed by and construed in accordance with Belgian law. Any dispute or difference arising out of or under or in connection with this Addendum, and any non-contractual obligations arising out of or in connection with it, shall be finally settled before the courts of Brussels (Belgium).

Executed in as many originals as there are Parties to this Addendum in Mont-Saint-Guibert, each Party acknowledging receipt of its own original.

Nyxoah SA

Signature	*Signature*
Name: Robert Taub	Name: [***]
Function: Administrateur	Function: Administrateur

Cephalix SA

Signature	*Signature*
Name: Robert Taub	Name: [***]
Function: Administrateur	Function: Administrateur

Surgical Electronics SA

Signature	*Signature*
Name: Robert Taub	Name: [***]
Function: Administrateur	Function: Administrateur

Man & Science SA

Signature	*Signature*
Name: Robert Taub	Name: [***]
Function: Administrateur	Function: Administrateur

Schedules: 6

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

Schedule 1
Specific Patents in the Sleep Disordered Breathing Field Owned by Nyxoah
[***]

Schedule 2
Shared Patents Owned by Man & Science
[***]

Schedule 3
Shared Patents including claims relating to the Sleep Disordered Breathing Field
[***]

Schedule 4
License rights granted by Nyxoah outside Sleep Disordered Breathing Field
[***]

Schedule 5
MPA
[***]

Schedule 6
Initial Conveyances
[***]

CLARIFICATION OF THE CONFIRMATORY ADDENDUM
TO THE MULTIPARTY AGREEMENT

This Clarification of the Confirmatory Addendum to the Multiparty Agreement ("Clarification") is agreed upon and executed on 10 February 2020

between

1. **Man & Science SA**, a company organized and existing under Belgian law, with registered office at Avenue Blücher 63, B-1180 Brussels, Belgium, registered with the Belgian Crossroads Bank for Enterprises under number 0837.403.770, validly represented by Robert Taub, Administrateur-Délégué, here inafter referred to as "**Man & Science**"

and

2. **Nyxoah SA**, a company organized and existing under Belgian law, with registered office at Rue du Edouard Belin 12, B-1435 Mont-St-Guibert, Belgium, registered with the Belgian Crossroads Bank for Enterprises under number 0817.149.675, validly represented by Olivier Taelman, Chief Executive Officer, hereinafter referred to as "**Nyxoah**".

The parties mentioned above are hereinafter also referred to collectively as the "Parties" and individually as a "**Party**".

Whereas:

(a) The Parties have, together with other parties, executed a multiparty agreement ("**MPA**", a copy of which is attached as Schedule 1 to this Clarification), regarding their respective ownership and licensing rights in relation to implantable flexible neuro-stimulators;

(b) The Parties have, together with certain other parties to the MPA, executed a Confirmatory Addendum to the MPA ("**CAMPA**", a copy of which is attached a Schedule 2 to this Clarification) to clarify and confirm their common intent and understanding as set out in the MPA;

(c) The Parties find it useful to confirm and clarify their common intent and understanding of the license granted by Man & Science to Nyxoah under Article 14 MPA and Article 4 CAMPA (collectively, the "**Licenses**").

It is agreed as follows:

1. All definitions in the MPA and CAMPA will be applicable to this Clarification and are taken over by reference.

2. The Parties confirm, for the avoidance of any doubt, that the Licenses granted to Nyxoah under the Shared Patents and the Man & Science Portfolio in the Sleep Disordered Breathing Field, as defined in the MPA and CAMPA, including the right to make, use, sell, offer for sale and/or import products and methods in the Sleep Disordered Breathing Field, are irrevocable, transferable, fully paid up, royalty-free, and include the right to grant sublicenses in the Sleep Disordered Breathing Field. The Licenses are effective retroactively as from the filing/priority date of the oldest of the Shared Patents or the patents in the Man & Science Portfolio and will continue in effect until the last to expire of the Shared Patents or the patents in the Man & Science Portfolio.

3. No party may terminate the Licenses. In the event of a breach of the MPA, the CAMPA or this Clarification by a Party, (i) the other Party shall have the right to seek its available remedies at law or in equity, but (ii) no party may terminate the Licenses granted under the MPA or the CAMPA as such Licenses are clarified by this Clarification. Even if the MPA or the CMPA or this Clarification were terminated *per impossibile*, the Licenses are irrevocable and will survive the termination of the MPA, the CMPA and this Clarification for the entire duration of the Licenses as specified above.

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

4. This Clarification, and any non-contractual obligations arising out of or in connection with it, shall be governed by and construed in accordance with Belgian law. Any dispute or difference arising out of, or under, or in connection with, this Clarification, and any non-contractual obligations arising out of, or in connection with, it, shall be finally settled before the courts of Brussels (Belgium).

Executed in two originals in Mont-Saint-Guibert on 10 February 2020, each Party acknowledging receipt of its original.

For Man & Science	For Nyxoah
Signature	*Signature*
Name: [***] Function: Administrateur-Délégué	Name: Oliver Taelman Function: CEO

Schedule 1 - MPA

[***]

Schedule 2 - CAMPA

[***]

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

Unprotected Lease Contract

Made and signed in Tel Aviv on August _20_, 2020.

Between: **Block 7093 Parcel 162 Ltd.**
P.C. 510583156
of 3 Menorat Hamaor Street, Tel Aviv 67448
Telephone: 03-6955185 Fax.: 03-6955183
Email: krz1905@012.net.il
(the "**Landlord**")
of the first part

and: **Nyxoah Ltd.**
P.C. 514082726
(the "**Tenant**")
of the second part

Whereas the Landlord is the holder (owner of the property) and the owner of the exclusive rights of ownership in the Building, as defined in this agreement, which includes the Leased Premises, as defined in this agreement; and

Whereas the Tenant wishes to lease the Leased Premises from the Landlord in an unprotected lease in accordance with the attached plans; and

Whereas the parties wish to regulate their legal and other relations, in this contract below:

Therefore, the parties stipulated, declared and agreed as follows:

1. Preamble and annexes

1.1 The preamble of this contract and the annexes hereto constitute an integral part hereof.

1.2 The annexes to the agreement that are attached hereto constitute an integral part of the agreement and the terms and conditions hereof.

1.3 The headings of the sections of the agreement are for the sake of orientation and convenience only, are not part of the agreement, and shall not be used for purposes of the interpretation hereof.

2. Definitions

In this agreement, the following terms shall bear the meaning stated alongside them.

[Initials] *[Initials]*

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

The "Building"	The commercial building located at **126 Yigal Alon Street** in Tel Aviv which is known as part of Parcel 533 (previously 162) in Block 7093 which includes the Leased Premises as defined below, and which is comprised of commercial spaces and office spaces. An updated land registration extract is attached to this agreement and marked **Annex A**.
The "Leased Premises"	Offices in the Building which are located on level two (2) at 126 Yigal Alon Street as specified in Section 4 below and as marked in the drawing attached to this agreement as **Annex B**. *[For the]* avoidance of doubt, it is clarified that the Leased Premises are within the area of the office spaces.
The "Addition"	An area of **245 sqm** on the second floor in the Building which is adjacent to the original space of Nyxoah Ltd. which shall be added to its area starting from the taking effect of this lease agreement.
The "Management Company"	The Landlord itself or a company owned thereby and/or authorized thereby and/or on behalf thereof and/or in its stead and/or therefor, which operates for the management of the Building.
The "Architect"	The architect who will be selected by the Tenant for designing interior adjustments in the Leased Premises.
"Floor Plan"	The Architect's plan as specified in Annex 1 to Annex C.

3. Non-applicability of the tenant protection laws to the lease

3.1 The Tenant hereby declares and confirms that the lease pursuant to this contract is an unprotected lease according to the Tenant Protection Law (Consolidated Version), 5732-1972 and/or other tenant protection laws including the various amendments thereto.

3.2 The Tenant hereby declares that it was not required to pay and did not pay any amount whatsoever to the Landlord as key money for the right to lease the Leased Premises and that other than the Rent as provided in this contract below, the Tenant did not give the Landlord any amount of money or money equivalent as key money, firm or benefit of any kind for the right to lease the Leased Premises as aforesaid and that upon vacation of the Leased Premises the Tenant shall not be entitled to claim from the Landlord any amount whatsoever and/or benefit whatsoever as key money and/or by virtue of the Tenant Protection Law, Consolidated Version, 5732-1972 and/or as an outcome of this contract.

[Initials] *[Initials]*

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

4. <u>The lease and the Leased Premises</u>

4.1 The Landlord declares that it owns all of the rights in the Leased Premises and it is the exclusive holder thereof.

4.2 The Landlord declares that the Leased Premises and the Building were built pursuant to the law by virtue of a lawful building permit and that no work and/or act in the Leased Premises which requires a lawful building permit was performed unlawfully. That a Form 4 and a certificate of completion were issued with respect to the Leased Premises and that the permitted use thereof by virtue of the zoning plan and the building permit is *inter alia* for the purpose of offices and/or the hi-tech industry and that the Building and Leased Premises contain no defect, flaw and non-conformity, either patent or latent, and that all the systems of the Building and the Leased Premises are functioning and in good working order including the communication, electricity, air conditioning and lighting systems in the Leased Premises.

The Landlord declares that there is no impediment to its engagement in this agreement with the Tenant and that it did not confer any right on any third party with respect to the Leased Premises and that there is no (lawful and/or planning and/or other) impediment to the management of a business in accordance with the purpose of the lease as provided in this agreement in the Leased Premises.

4.3 The Landlord hereby leases to the Tenant, and the Tenant hereby leases from the Landlord, the Leased Premises that are marked in the drawing in bright yellow, which are on the second floor in the Building at 126 Yigal Alon Street, Tel Aviv.

4.4 The gross area of the Leased Premises is approx. **1099 sqm** on the second floor. The Tenant declares that it has seen the Leased Premises and subject to the performance of the Landlord's works in the area of the "Addition" as specified in **<u>Annex D</u>** which is attached to this agreement and other than a latent non-conformity and/or flaw and/or malfunction and/or defect, accepts them in their condition as is.

4.5 It is clarified that the Tenant is given the exclusive right of use in the Leased Premises area and that the same does not derogate from and/or prejudice the right of the Tenant and/or its guests and/or its visitors and/or any other on its behalf to use the common areas in the Building and the right of way therein.

4.6 Until the date of handing over of possession of the Leased Premises, the Landlord shall perform, at its expense, adjustment works in the area of the "Addition" to the Leased Premises, which include what is specified in **<u>Annex D</u>** which is attached to this agreement (above and below, the "**Landlord's Works**").

[Initials] *[Initials]*

Certain identified information has been omitted from this exhibit because it is not material and would likely cause competitive harm to the registrant if publicly disclosed. [***] indicates that information has been omitted.

5. <u>The term of the lease</u>

5.1 The original term of the lease according to this contract shall commence on **August 23, 2020** and the date of expiration of the original lease is after the lapse of **36** months on **August 22, 2023** (the "**Original Term of the Lease**").

5.2 The Tenant is given the option to extend the Original Term of the Lease by two option periods of two years each with regard to the Leased Premises (the "**Option Periods**"). The Tenant shall give notice of its intention to exercise the Option Periods up to 90 days before the date of commencement of the option period. The rent for the first option period shall increase by **10%** over and above the rent in the Original Term of the Lease. The Tenant has a first option to extend the term of the lease by two more years until August 22, 2025 and a second option period to extend the term of the lease by two more years until **August 22, 2027**. The amount of the rent for the second option period shall be determined in a meeting between the parties up to **90** days before the date of renewal of the option according to the accepted standard of prices at such time. A condition to the exercise of the option shall be that the Tenant shall have fulfilled all of the material terms and conditions of this contract during the Original Term of the Lease in a full and timely manner.

5.3 **The provisions of Section 5.2 of this agreement notwithstanding, the Landlord reserves the right to refuse the exercise of the options by the Tenant solely if it is required to remove all of the tenants of the Building for the purpose of demolishing it and constructing a new building in its stead, provided that the same shall not prejudice the first term of the lease and/or on reasonable grounds which shall be specified in writing, and a written notice as aforesaid regarding the need to vacate shall be delivered to the Tenant at least 6 months in advance before the vacation date.**

5.4 It is agreed that the Tenant shall bear any and all payments that apply thereto pursuant to this contract for the term of the lease, whether or not it shall have actually held and/or used the Leased Premises, provided that there is no impediment to making reasonable use of the Leased Premises in accordance with the purpose of the lease.

5.5 The parties' undertaking under this section is a material undertaking whose breach shall constitute a fundamental breach of the contract.

[Initials] *[Initials]*

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6. <u>The Rent</u>

6.1. For the area of the Leased Premises, **in the first year of the Original Term of the Lease** the Tenant shall pay monthly rent to the Landlord in the amount of ILS [***] (which include the rent in the amount of ILS [***] and the management fees in the amount of ILS [***]) for each sqm gross and in total, the Tenant shall pay the Landlord for the entire area of the Leased Premises, rent and managements fees in the total amount of ILS [***] before VAT, for each month of rent, excluding parking spaces (the "**Rent**"). The Rent shall be linked to the ratio between the consumer price index which is known on the date of signing of the original lease agreement that was signed on **September 21, 2016** and the index which is known on the date of issuance of every quarterly Rent bill during the first lease year that will expire on **August 14, 2021** which is **99.2**.

6.2. The Rent (including the management fees) as aforesaid shall be paid by the Tenant to the Landlord together with lawful VAT. The aforesaid VAT shall be paid by the Tenant to the Landlord in a postdated check no later than on the date of payment of the VAT to the tax authorities pursuant to the law.

6.3. The Rent **starting from the second year of the Original Term of the Lease** shall be ILS [***] per sqm which include rent in the amount of ILS [***] per sqm and management fees in the amount of ILS [***] per sqm and shall be linked to the ratio between the consumer price index which will be known on such date (the "**New Base Index**") and the index which is known on the date of issuance of each quarterly bill for payment (the "**New Index**"). The base index that will be known on this date is the **July 2021** index which will be published on **August 15, 2021** and it shall be ____.

6.4. If on the date of issuance of the invoice for payment it transpires that the New Index as defined above is higher than the base index, the Tenant shall pay the Landlord Rent that is increased by the rate at which the New Index shall have risen versus the base index. If the index decreases below the base index, the invoice shall be calculated according to the base index. The Rent shall be paid to the Landlord once every three months in advance at the beginning of each calendar year quarter, in other words, on January 1, April 1, July 1 and October 1 (the "**Quarter**").

The parties' undertaking under this section is a material undertaking whose breach shall constitute a fundamental breach of this contract.

[Initials] *[Initials]*

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7. <u>The purpose of the lease</u>

7.1. The Leased Premises are hereby leased to the Tenant for the purpose of management of its business which includes development of medical devices.

The Tenant has available thereto the right to sublet **part** of the area of the Leased Premises to any other subtenant, including companies that are directly or indirectly connected to the Tenant, provided that the Landlord shall not object to the identity of the subtenant, except on reasonable grounds.

7.2. The Landlord hereby declares and confirms that the purpose of the use conforms with the building permits and the zoning plan which applies to the land and that the use specified above does not constitute use which deviates from a plan or permit.

7.3. The parties agreed and stipulated that the Tenant shall not be entitled to use the Leased Premises for any purpose other than the above-specified purpose without the Landlord's consent thereto in advance and in writing. Use for one of the items of the purpose or part thereof shall not constitute a different purpose. The Landlord and/or others on its behalf may enter the Leased Premises at any reasonable time and with advance coordination with the Landlord, in order to examine the condition of the Leased Premises and ensure the Tenant's fulfillment of the terms and conditions of this contract.

7.4. The Landlord undertakes to sign any document and/or application that will be required for obtaining a business license and/or other permit that is required to launch the transaction for the purpose of the lease, to the extent that will be necessary.

7.5. The Tenant's undertaking and the Landlord's representations pursuant to this section are a material undertaking whose breach shall constitute a fundamental breach of the contract.

8. <u>Liability, maintenance</u>

8.1. The Tenant undertakes, in the entire term of the lease, to maintain the Leased Premises including any and all equipment therein, in good condition and working order, to repair at its expense within a reasonable time any defect, malfunction and damage that will be caused to the Leased Premises as a result of a negligent act or omission by the Tenant and/or another on its behalf and/or any of its employees, customers, visitors or suppliers and/or persons authorized thereby to enter the Leased Premises and/or deriving from inappropriate use by the Tenant for which it is liable pursuant to the law, and other than any malfunction or damage deriving from reasonable wear and tear caused due to proper use of the Leased Premises and/or malfunction or damage deriving from a negligent or malicious act or omission by the Landlord and/or another on its behalf and/or its employees and/or if pursuant to the law, the Landlord and/or another on its behalf are liable for the damage and/or malfunction as aforesaid, the Landlord shall be liable for the repair thereof. The Tenant undertakes to notify the Landlord within a reasonable time of any material damage, malfunction or defect that will occur in the Leased Premises as aforesaid. It is agreed that the Tenant's undertaking as provided in this main section applies and shall apply solely to current and standard maintenance of the Leased Premises and the equipment therein and does not apply to latent non-conformities and/or defects in the Leased Premises and/or the systems thereof.

[Initials] *[Initials]*

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8.2. The Landlord shall repair, immediately upon the first demand and in such manner as will not harm the Tenant's reasonable use of the Leased Premises, any malfunction and/or defect and/or damage in the Leased Premises and Building, including the equipment, facilities and other appliances and/or the facilities with which the Leased Premises and Building were equipped as aforesaid, which are owned by the Landlord, and/or equipment and/or facilities which serve the Leased Premises and are installed outside the Leased Premises. If the Landlord or Management Company do not make the necessary repairs as aforesaid within a reasonable time, the Tenant shall be entitled but not obligated to perform any and all repairs and any and all acts as it will deem fit in order to repair the damage and/or bring the Leased Premises to an appropriate standard and quality as aforesaid and/or restore the prior condition, at the Landlord's expense. If the damage and/or malfunction are caused as provided in Section 8.1 above as a result of negligence and/or maliciously by the Tenant and any other on its behalf as specified in Section 8.1 above, they shall be repaired by, and at the expense of the Tenant.

8.3. Because the Building in which the Leased Premises are located is maintained by a Management Company, the management fees for the activity of which will be paid by the Tenant in the context of the Rent, the parties agree and declare that the Management Company is required to maintain and arrange for the cleanliness of the common areas and to repair any and all flaws and/or defects and/or damage and/or malfunctions in the Building and all of its systems, equipment, infrastructures and facilities, immediately when any flaw and/or defect and/or malfunction is discovered and in such manner as will not harm and/or derogate from the Tenant's right to use the Leased Premises and the Building. In accordance with the aforesaid, the Tenant shall not have any arguments, demands or claims against the Landlord, directly and/or indirectly, with respect to the Building's systems and/or infrastructures unless the Management Company does not fulfill its undertakings in this regard as aforesaid. If the Management Company does not fulfill its undertakings as aforesaid, the Landlord undertakes to arrange for the repairs and good working order of the Leased Premises and the systems in the Building at its expense, and to offset the costs against the management fees that will be transferred to the Management Company.

[Initials] *[Initials]*

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8.4. The Landlord undertakes that the management services to be provided by the Management Company will be performed in a current manner and at a standard that will be no less than the accepted standard in projects of this kind which will enable use of the Leased Premises for the purpose for which they were leased.

8.5. The parties' undertakings under this section are material undertakings whose breach shall constitute a fundamental breach of the contract.

9. <u>Insurance</u>

9.1. The Tenant shall take out, at its expense, insurance of the entire content of the Leased Premises, at the real value thereof, covering the Tenant's entire activity. The Tenant shall take out, at its expense, an insurance policy against liabilities vis-à-vis third parties, with a liability cap of [***] per occurrence and in the aggregate. In the aforesaid insurance, the Tenant shall add the Landlord as an insured due to the liability thereof as the owner of the Leased Premises and/or due to its vicarious liability for the Tenant's acts and/or omissions.

9.2. The Tenant shall take out, at its expense, an employers' liability insurance policy for the entire term of the lease, in the amount of ILS [***] per occurrence and up to ILS [***]in the aggregate. In the aforesaid insurance, the Tenant shall add the Landlord as an insured due to the liability thereof as the owner of the Leased Premises and/or due to its vicarious liability for the Tenant's acts and/or omissions. The above-included policy shall include a clause on cancellation or non-renewal of the insurance by an advance notice of 30 (thirty) days before the date of expiration of the insurance period.

9.3. The Landlord shall take out, at its expense, an insurance of the Leased Premises' building, including the attachments thereto at the real value thereof, that shall include extended fire insurance, break-in and attempted break-in damage.

9.4. The Tenant and the Landlord hereby waive the right of subrogation vis-à-vis one another and/or vis-à-vis any others on behalf thereof and/or acting in their stead, other than if any of the aforementioned shall have maliciously caused damage.

9.5. The parties shall present a copy of the aforesaid insurance policies upon demand.

[Initials] *[Initials]*

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9.6. The mere taking out of the aforesaid insurances shall not exempt the parties and/or release them in any way and manner from their liability under this contract or any law.

9.7. If the Tenant does not maintain the insurances that apply thereto as aforesaid, the Landlord may maintain the aforesaid insurances in its stead, and the Tenant shall bear the insurance payments and pay the Landlord upon its first demand.

10. <u>Transfer of rights</u>

10.1. The Landlord shall be entitled to transfer its rights in the Leased Premises to any third party, provided that it does so while protecting all of the Tenant's rights pursuant to the terms and conditions of this contract. The Landlord may continue construction of additional floors in the aforesaid property, provided that the same does not prevent the buyer's reasonable use of the property and passage therefrom and thereto. The Landlord shall act insofar as possible to reduce interference, including construction of the frame at nighttime, advance coordination of acts that are related to the Tenant's activity, etc.

10.2. Without derogating from the provisions of Section 7.1 above, the Tenant shall have the right to assign all or part of its rights in relation to this agreement, in each of the cases specified below: (a) Transfer or assignment and/or permission of use of rights as aforesaid to a subsidiary and/or an affiliate and/or a sister company of the Tenant; (b) In case of a merger and/or acquisition and/or other transaction which the Tenant will perform, as a result of which the means of control of the Tenant will pass to a third party, and provided that the tenant to which the agreement shall have been assigned as aforesaid will fulfill all the terms and conditions of this agreement. In any case of assignment of rights as aforesaid, the following provisions shall apply: (1) The Tenant shall inform the Landlord of the assignment in advance; (2) The company to which the rights will be assigned undertakes to sign an annex to this agreement whereby it assumes all of the undertakings in this agreement. The Landlord is afforded the opportunity to reasonably object to the assignment of the rights.

10.3. Even if this agreement provides otherwise, the parties agree that the Tenant may terminate the term of the lease early, if the Tenant offers the Landlord an alternate tenant which will come in its stead and sign a lease agreement with the Landlord. The Landlord shall not unreasonably withhold its consent to the transfer of the rights to the alternate tenant as provided in this section.

[Initials] *[Initials]*

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11. Changes to the Leased Premises

11.1. Without derogating from, and in addition to the aforesaid, the Tenant may perform slight adjustments to the Leased Premises, limited to 10% of all of the plasterboards and at an identical standard, such as changes to the interior partitions and the works related thereto, without requiring the Landlord's approval for such works. The Tenant shall not touch walls made of blocks. It is clarified that the Tenant is obligated to inform the Landlord in advance of any and all material changes, repairs or additions that will be made in the Leased Premises, including changes that do not require its consent. Insofar as the Tenant exceeds the permitted renovations by more than 10% it shall restore the prior condition upon expiration of the lease if it is so required by the Landlord until the expiration of the term of the lease.

12. Various payments

During the term of the lease, in addition to the Rent, the Tenant shall also make the following payments against a tax invoice that will be issued by the Landlord:

Electricity – subject to Section 14 of this contract.

Water – according to a reading from the floor meter and division according to the area ratio.

Municipal tax – shall be paid directly by the Tenant to the City.

13. Payment dates and arrears

Any and all payments that apply to any one of the parties pursuant to the terms and conditions of this contract and any law shall be made on the scheduled date.

Any and all payments that apply to the Tenant pursuant to the terms and conditions of this contract and any law that were not made within 14 days from the scheduled date, shall bear prime interest plus 2% (2 percent) per annum from the payment date until the date of the actual payment.

14. Electricity supply

14.1. The Tenant declares that it is aware that the Landlord is the exclusive holder of the rights vis-à-vis the Israel Electric Corporation (IEC) with respect to receipt and supply of electricity to the Leased Premises and the surroundings thereof, subject to Section 14. The Tenant hereby absolutely and irrevocably waives its right to engage with the IEC with respect to the electricity supply to the Leased Premises, all subject to the Landlord's undertaking to immediately handle any problem and/or malfunction and/or damage in connection with the electricity in the Leased Premises.

[Initials] *[Initials]*

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14.2. The electricity to the Leased Premises shall be supplied by bulk to and from the Building by the Landlord to the Leased Premises, all as the Landlord determines with the IEC. The Tenant shall bear the payments of the electricity consumption according to a detailed invoice that will be sent thereto by the Landlord each and every month, which will be based on a TAOZ meter reading and subject to the IEC's tariffs for non-bulk consumers, as the same will be determined by the IEC from time to time, including graded tariffs, if any, and any and all other rights that are due from the IEC. The payment shall be made to the Landlord within **20** days from the demand date. A separate meter shall be installed in the building for the Leased Premises. In floors where the same meter is shared by several companies, the bill shall be divided between the companies according to the area ratio, so long as the nature of the work and the working hours of the companies are similar.

14.3. In the event of a change to the electricity system in the Leased Premises, including an increase in the electricity supply, the Tenant shall be required to notify the Landlord in advance and in writing. The Landlord shall have the right to reasonably object thereto.

16. Vacation of the Leased Premises

16.1. In any case that the Tenant is required to vacate the Leased Premises subject to the terms and conditions of this contract and/or any law and for any reason whatsoever, the Tenant shall return the Leased Premises to the Landlord, free and clear of any person and mobile object, other than the Landlord's property which includes all the fixtures that are connected to the floor and walls, in proper condition, including all the additions installed therein, and other than reasonable wear and tear as a result of proper use thereof.

16.2. If the Tenant does not vacate the Leased Premises in a timely manner according to the terms and conditions of this contract, either at the end of the Original Term of the Lease and/or the option period, if exercised, or due to the lawful termination of the contract for whatever reason, the Tenant shall pay liquidated damages to the Landlord in an amount that will be equal to [***]**%** ([***] percent) of Rent per day for every day of delay in the vacation of the Leased Premises as specified above, plus lawful VAT. If there is no replacement tenant, the Tenant may be up to **30** days late in vacating the Leased Premises without payment of the [***]**%**. This period shall be deemed as a lease period for all intents and purposes, including Rent and municipal tax payments.

16.3. One month before the vacation of the Leased Premises and up to one week thereafter, the damage in the Leased Premises, if any, will be assessed by the Landlord and the Tenant, together, and the cost of the damage will be estimated. The Tenant undertakes to restore the prior condition, subject to reasonable wear and tear as a result of proper use of the Leased Premises.

16.4. The Tenant's undertaking under this section is a material undertaking whose breach shall constitute a fundamental breach of the contract.

[Initials] *[Initials]*

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17. <u>Collateral</u>

17.1. As collateral for the fulfillment of all of the Tenant's undertakings under this agreement, the Tenant undertakes to make a supplemental payment to the Landlord, at the time of signing of this agreement, to reach the amount of ILS [***](which is equal to Rent plus management fees for four months of lease) **against which the payments towards collateral that shall have already been made until the signing of this agreement shall be offset.** The aforesaid amount shall be used against the last four months of the Tenant's lease of the Leased Premises, however, if malfunctions and/or damage are found in the Leased Premises, this amount shall be used for repairing the Leased Premises and restoring their good working order.

17.2. A condition to the enforcement of the collateral by the Landlord is if the Tenant breaches one or more of its material and fundamental undertakings pursuant to this agreement. Forfeiture as aforesaid shall only be performed subject to and provided that the Tenant shall have been given a 30-day prior written notice by registered mail with confirmation of delivery, and provided that the Tenant shall not have remedied this fundamental breach within 21 days from the date of actual receipt of the aforesaid notice.

[Initials] *[Initials]*

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18. Arbitration

The parties hereby agree to refer all the disputes between them to a single arbitrator who will be chosen by them. In the absence of consent between them regarding the arbitrator's identity, the arbitrator shall be chosen by the Head of the Bar Association. The arbitrator shall be bound by the substantive law but not by procedural laws. This section constitutes a valid arbitration contract between the parties without requiring another document.

19. General

19.1. Any and all changes to the terms and conditions of this contract shall not be valid in any way unless made in writing and signed by both parties.

19.2. The provisions of this contract above and below notwithstanding, and without derogating from the generality of the aforesaid, the parties reserve the right to any and all remedies to which they will be entitled due to the breach of this contract pursuant to any law.

19.3. Each party shall bear the fee of its attorney.

19.4. Other than a notice as provided in Section 17.2 above, any notice dispatched by one party to the other party shall be deemed received by the addressee after 72 hours from the time of dispatch thereof by post in Israel according to the addresses as specified at the top of this contract.

19.5. The parties agree that, starting from the date of signing of this agreement, this agreement supersedes, for all intents and purposes, any lease agreement and/or addendum signed between the parties and/or between the Tenant and the Landlord with respect to the Leased Premises, and the Leased Premises shall only be governed by the provisions of this agreement.

In witness whereof the parties have hereunto set their hands:

Signature	*Signature & Stamp*
Nyxoah Ltd.	**Block 7093 Parcel 162 Ltd.**

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Exhibit 10.4

NYXOAH S.A.

2013 SHARE INCENTIVE PLAN

1. Purpose

The purpose of this 2013 Share Incentive Plan (the “Plan”) of Nyxoah S.A., a Belgian corporation (the “Company”), is to advance the interests of the Company’s shareholders by enhancing the Company’s ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing such persons with equity ownership opportunities and performance-based incentives and thereby better aligning the interests of such persons with those of the Company’s shareholders. Except where the context otherwise requires, the term “Company” shall include any of the Company’s present or future Subsidiary Corporations. “Subsidiary Corporation” means any corporation (other than the employer corporation) in an unbroken chain of corporations beginning with the employer corporation if, at the time of the offering and/or granting of the warrant, each of the corporations other than the last corporation in the unbroken chain owns shares possessing 50 percent or more of the total combined voting power of all classes of shares in one of the other corporations in such chain. (When appearing in this Plan, the terms “offer” and “grant” are to be interpreted according to the laws and/or tax regulations of the appropriate jurisdiction that govern such transactions.)

2. Eligibility

All of the Company’s employees, officers, directors, consultants and advisors (and any individuals who have accepted an offer for employment or to provide professional services to the Company) are eligible to be offered and/or granted warrants, restricted stock awards, or other stock-based awards (each, an “Award”) under the Plan. Each person who has been offered and/or granted an Award under the Plan shall be deemed a “Participant”.

3. Administration, Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board of Directors of the Company (the “Board”). The Board shall have authority to offer and/or grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board’s sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award. No director or person acting pursuant to the authority delegated by the Board shall be liable for any action or determination relating to or under the Plan made in good faith.

(b) Delegation to Executive Officers. To the extent permitted by applicable law, the Board may delegate to one or more executive officers of the Company the power to make Awards and exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the maximum number of shares subject to Awards and the maximum number of shares for any one Participant to be made by such executive officers.

(c) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a “Committee”). All references in the Plan to the “Board” shall mean the Board or a Committee of the Board or the executive officer referred to in Section 3(b) to the extent that the Board’s powers or authority under the Plan have been delegated to such Committee or executive officer.

4. Shares Available for Awards

(a) Number of Shares. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 340 ordinary shares of the Company (the "Ordinary Shares"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part or results in any Ordinary Shares not being issued, the unused Ordinary Shares covered by such Award shall again be available for the offer and/or grant of Awards under the Plan. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

5. Warrants

(a) General. The Board may offer and/or grant warrants to purchase Ordinary Shares (each, a "Warrant") and determine the number of Ordinary Shares to be covered by each Warrant, the exercise price of each Warrant and the conditions and limitations applicable to the exercise of each Warrant.

(b) Exercise Price. The Board shall establish the exercise price at the time each Warrant is offered and/or granted and specify it in the applicable warrant agreement.

(c) Duration of Warrants. Each Warrant shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable warrant agreement.

(d) Exercise of Warrant. Warrants may be exercised by delivery to the Company of a written notice of exercise signed by the proper person or by any other form of notice (including electronic notice) approved by the Board together with payment in full as specified in Section 5(e) for the number of shares for which the Warrant is exercised.

(e) Payment Upon Exercise. Ordinary Shares purchased upon the exercise of an Warrant granted under the Plan shall be paid for as follows:

(1) in cash, bank transfer or by check, payable to the order of the Company;

(2) except as the Board may, in its sole discretion, otherwise provide in a warrant agreement, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price;

(3) when the Ordinary Shares are registered under the Securities Act of 1933 (USA), as amended and/or any other applicable law under any other jurisdiction (the "Securities Act"), by delivery of the Ordinary Shares owned by the Participant valued at their fair market value as determined by (or in a manner approved by) the Board in good faith ("Fair Market Value"), provided (i) such method of payment is then permitted under applicable law and (ii) such Ordinary Shares were owned by the Participant at least six months prior to such delivery;

(4) to the extent permitted by the Board, in its sole discretion by (i) delivery of a promissory note of the Participant to the Company on terms determined by the Board, or (ii) payment of such other lawful consideration as the Board may determine; or

(5) by any combination of the above permitted forms of payment.

6. Restricted Stock

(a) Offers / Grants. The Board may offer and/or grant Awards entitling recipients to acquire Ordinary Shares, subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award (each, a "Restricted Stock Award").

(b) Terms and Conditions. The Board shall determine the terms and conditions of any such Restricted Stock Award, including the conditions for repurchase (or forfeiture) and the issue price, if any. Any stock certificates issued in respect of a Restricted Stock Award shall be registered in the name of the Participant and, unless otherwise determined by the Board, deposited by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death (the "Designated Beneficiary"). In the absence of an effective designation by a Participant, Designated Beneficiary shall mean the Participant's estate.

7. Other Stock-Based Awards

The Board shall have the right to offer and/or grant other Awards based upon the Ordinary Shares having such terms and conditions as the Board may determine, including the offer and/or grant of shares based upon certain conditions, the offer and/or grant of securities convertible into Ordinary Shares and the offer and/or grant of stock appreciation rights.

8. Adjustments for Changes in Ordinary Shares and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any distribution to holders of Ordinary Shares other than a normal cash dividend, (i) the number and class of securities available under this Plan, (ii) the number and class of securities and exercise price per share subject to each outstanding Warrant, (iii) the repurchase price per share subject to each outstanding Restricted Stock Award, and (iv) the terms of each other outstanding Award shall be appropriately adjusted by the Company (or substituted Awards may be made, if applicable) to the extent the Board shall determine, in good faith, that such an adjustment (or substitution) is necessary and appropriate. If this Section 8(a) applies and Section 8(c) also applies to any event, Section 8(c) shall be applicable to such event, and this Section 8(a) shall not be applicable.

(b) Liquidation or Dissolution. In the event of a proposed liquidation or dissolution of the Company, the Board shall upon written notice to the Participants provide that all then unexercised Warrants will (i) become exercisable in full as of a specified time at least 10 business days prior to the effective date of such liquidation or dissolution and (ii) terminate effective upon such liquidation or dissolution, except to the extent exercised before such effective date. The Board may specify the effect of a liquidation or dissolution on any Restricted Stock Award or other Award granted under the Plan at the time of the grant of such Award.

(c) Acquisition and Change in Control Events

(1) Definitions

(a) An "Acquisition Event" shall mean:

(i) any merger or consolidation of the Company with or into another entity as a result of which the Ordinary Shares are converted into or exchanged for the right to receive cash, securities or other property; or

(ii) any exchange of shares of the Company for cash, securities or other property pursuant to a statutory share exchange transaction.

(b) A "Change in Control Event" shall mean:

(i) the acquisition by an individual, entity or group (including but not limited to in the event that two or more persons act as partnership, limited partnership, syndicate or other group for the purpose of acquiring, holding or disposing of securities) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns 50% or more of either (x) the then-outstanding ordinary shares of the Company (the "Outstanding Company Ordinary Shares") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control Event: (A) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for ordinary shares or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (B) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (C) any acquisition by any corporation pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (iii) of this definition; or

(ii) the consummation of a merger, consolidation, reorganization, recapitalization or statutory share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Ordinary Shares and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding ordinary shares and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries), (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Ordinary Shares and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding the Acquiring Corporation or any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation beneficially owns, directly or indirectly, 50% or more of the then-outstanding ordinary shares or common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination).

(c) “Good Reason” shall mean any significant diminution in the Participant’s title, authority, or responsibilities from and after such Acquisition Event or Change in Control Event, as the case may be, or any reduction in the annual cash compensation payable to the Participant from and after such Acquisition Event or Change in Control Event, as the case may be, or the relocation of the place of business at which the Participant is principally located to a location that is greater than 50 miles from the current site.

(d) “Cause” shall mean any (i) willful failure by the Participant, which failure is not cured within 30 days of written notice to the Participant from the Company, to perform his or her material responsibilities to the Company or (ii) willful misconduct by the Participant which affects the business reputation of the Company. The Participant shall be considered to have been discharged for “Cause” if the Company determined, within 30 days after the Participant’s resignation, that discharge for Cause was warranted.

(2) <u>Effect on Warrants</u>

(a) <u>Acquisition Event</u>. Upon the occurrence of an Acquisition Event (regardless of whether such event also constitutes a Change in Control Event), or the execution by the Company of any agreement with respect to an Acquisition Event (regardless of whether such event will result in a Change in Control Event), the Board shall provide that all outstanding Warrants shall be assumed, or equivalent warrants shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof); provided that if such Acquisition Event also constitutes a Change in Control Event, except to the extent specifically provided to the contrary in the instrument evidencing any Warrant or any other agreement between a Participant and the Company, (A) one-half of the number of shares subject to the Warrant which were not already vested shall be exercisable upon the occurrence of such Acquisition Event and, subject to (B) below, the remaining one-half of such number of shares shall continue to become vested in accordance with the original vesting schedule set forth in such warrant, with one-half of the number of shares that would otherwise have first become vested becoming so vested on each subsequent vesting date in accordance with the original schedule and (B) such assumed or substituted warrants shall become immediately exercisable in full if, on or prior to the first anniversary of the date of the consummation of the Acquisition Event, the Participant’s employment with the Company or the acquiring or succeeding corporation is terminated for Good Reason by the Participant or is terminated without Cause by the Company or the acquiring or succeeding corporation. For purposes hereof, a Warrant shall be considered to be assumed if, following consummation of the Acquisition Event, the Warrant confers the right to purchase, for each Ordinary Share subject to the Warrant immediately prior to the consummation of the Acquisition Event, the consideration (whether cash, securities or other property) received as a result of the Acquisition Event by holders of Ordinary Shares for each Ordinary Share immediately prior to the consummation of the Acquisition Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Ordinary Shares); provided, however, that if the consideration received as a result of the Acquisition Event is not solely ordinary shares or common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of Warrants to consist solely of ordinary shares or common stock of the acquiring or succeeding corporation (or an affiliate thereof) equivalent in fair market value to the per share consideration received by holders of outstanding Ordinary Shares as a result of the Acquisition Event.

Notwithstanding the foregoing, if the acquiring or succeeding corporation (or an affiliate thereof) does not agree to assume, or substitute for, such Warrants, then the Board shall, upon written notice to the Participants, provide that all then unexercised Warrants will become exercisable in full as of a specified time prior to the Acquisition Event and will terminate immediately prior to the consummation of such Acquisition Event, except to the extent exercised by the Participants before the consummation of such Acquisition Event; provided, however, in the event of an Acquisition Event under the terms of which holders of Ordinary Shares will receive upon consummation thereof a cash payment for each Ordinary Share surrendered pursuant to such Acquisition Event (the "Acquisition Price"), then the Board may instead provide that all outstanding Warrants shall terminate upon consummation of such Acquisition Event and that each Participant shall receive, in exchange therefor, a cash payment equal to the amount (if any) by which (A) the Acquisition Price multiplied by the number of Ordinary Shares subject to such outstanding Warrants (whether or not then exercisable), exceeds (B) the aggregate exercise price of such Warrants.

(b) Change in Control Event that is not an Acquisition Event. Upon the occurrence of a Change in Control Event that does not also constitute an Acquisition Event, except to the extent specifically provided to the contrary in the instrument evidencing any Warrant or any other agreement between a Participant and the Company, the vesting schedule of such Warrant shall be accelerated in part so that one-half of the number of shares that would otherwise have first become vested on any date after the date of the Change in Control Event shall immediately become exercisable. The remaining one-half of such number of shares shall continue to become vested in accordance with the original vesting schedule set forth in such Warrant, with one-half of the number of shares that would otherwise have first become vested becoming so vested on each subsequent vesting date in accordance with the original schedule; provided, however, that each such Warrant shall be immediately exercisable in full if, on or prior to the first anniversary of the date of the consummation of the Change in Control Event, the Participant's employment with the Company or the acquiring or succeeding corporation is terminated for Good Reason by the Participant or is terminated without Cause by the Company or the acquiring or succeeding corporation.

(3) Effect on Restricted Stock Awards

(a) Acquisition Event that is not a Change in Control Event. Upon the occurrence of an Acquisition Event that is not a Change in Control Event, the repurchase and other rights of the Company under each outstanding Restricted Stock Award shall inure to the benefit of the Company's successor and shall apply to the cash, securities or other property which the Ordinary Shares were converted into or exchanged for pursuant to such Acquisition Event in the same manner and to the same extent as they applied to the Ordinary Shares subject to such Restricted Stock Award.

(b) Change in Control Event. Upon the occurrence of a Change in Control Event (regardless of whether such event also constitutes an Acquisition Event), except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock Award or any other agreement between a Participant and the Company, the vesting schedule of all Restricted Stock Awards shall be accelerated in part so that one-half of the number of shares that would otherwise have first become free from conditions or restrictions on any date after the date of the Change in Control Event shall immediately become free from conditions or restrictions. Subject to the following sentence, the remaining one-half of such number of shares shall continue to become free from conditions or restrictions in accordance with the original schedule set forth in such Restricted Stock Award, with one-half of the number of shares that would otherwise have first become free from conditions or restrictions becoming free from conditions or restrictions on each subsequent vesting date in accordance with the original schedule. In addition, each such Restricted Stock Award shall immediately become free from all conditions or restrictions if, on or prior to the first anniversary of the date of the consummation of the Change in Control Event, the Participant's employment with the Company or the acquiring or succeeding corporation is terminated for Good Reason by the Participant or is terminated without Cause by the Company or the acquiring or succeeding corporation.

(4) Effect on Other Awards

(a) Acquisition Event that is not a Change in Control Event. The Board shall specify the effect of an Acquisition Event that is not a Change in Control Event on any other Award granted under the Plan at the time of the grant of such Award.

(b) Change in Control Event. Upon the occurrence of a Change in Control Event (regardless of whether such event also constitutes an Acquisition Event), except to the extent specifically provided to the contrary in the instrument evidencing any other Award or any other agreement between a Participant and the Company, the vesting schedule of all other Awards shall be accelerated in part so that one-half of the number of shares that would otherwise have first become exercisable, realizable, vested or free from conditions or restrictions on any date after the date of the Change in Control Event shall immediately become exercisable, realizable, vested or free from conditions or restrictions. Subject to the following sentence, the remaining one-half of such number of shares shall continue to become exercisable, realizable, vested or free from conditions or restrictions in accordance with the original schedule set forth in such Award, with one-half of the number of shares that would otherwise have first become exercisable, realizable, vested or free from conditions or restrictions becoming so exercisable, realizable, vested or free from conditions or restrictions on each subsequent vesting date in accordance with the original schedule. In addition, each such Award shall immediately become fully exercisable, realizable, vested or free from conditions or restrictions if, on or prior to the first anniversary of the date of the consummation of the Change in Control Event, the Participant's employment with the Company or the acquiring or succeeding corporation is terminated for Good Reason by the Participant or is terminated without Cause by the Company or the acquiring or succeeding corporation.

(5) Limitations. Notwithstanding the foregoing provisions of this Section 8c if the Change in Control Event is intended to be accounted for as a "pooling of interests" for financial accounting purposes, and if the acceleration to be effected by the foregoing provisions of this Section 8(c) would preclude accounting for the Change in Control Event as a "pooling of interests" for financial accounting purposes, then no such acceleration shall occur upon the Change in Control Event.

(6) Notwithstanding anything stipulated above, the Board may adopt, on a case by case basis of respective Participants, such provisions derogating from the provisions of the effect of an Acquisition Event and/or Change in Control Event on Awards as stipulated above, and which such amended and/or derogated provisions shall be deemed to override and be superior to the provisions contained herein, all to be specifically implemented in the respective Award and/or the related agreement with the Participant.

9. General Provisions Applicable to Awards

(a) Transferability of Awards. Except as the Board may otherwise determine or provide in an Award, Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) Documentation. Each Award shall be evidenced by a written instrument in such form as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, retirement, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award.

(e) Withholding. Each Participant shall pay to the Company, or make provision satisfactory to the Board for payment of, any taxes and/or social security contributions required by law to be withheld in connection with Awards to such Participant no later than the date of the event creating the tax and/or social security liability. Except as the Board may otherwise provide in an Award, when the Ordinary Shares are registered under the Securities Act, Participants may, to the extent then permitted under applicable law, satisfy such tax and/or social security obligations in whole or in part by delivery of Ordinary Shares, including shares retained from the Award creating the tax and/or social security obligation, valued at their Fair Market Value. The Company may, to the extent permitted by law, deduct any such tax and/or social security obligations from any payment of any kind otherwise due to a Participant.

(f) Amendment of Award. The Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, provided that the Participant's consent to such action shall be required unless the Board determines that the action, taking into account any related action, would not materially and adversely affect the Participant.

(g) Conditions on Delivery of Shares. The Company will not be obligated to deliver any Ordinary Shares pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) Acceleration. The Board may at any time provide that any Warrants shall become immediately exercisable in full or in part, that any Restricted Stock Awards shall be free of restrictions in full or in part or that any other Awards may become exercisable in full or in part or free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

10. Provisions relating to Israeli Employees and/or Directors and/or Office Holders

Notwithstanding anything stipulated in the Plan, the following conditions shall be superior to any provision of the Plan in relation to employees and/or directors and/or office holders ("**Nosei Misra**" - as such term is defined in the Israeli Companies Law) of the Company and/or its affiliate residing and exercising their employment in Israel and who has been deemed to be a Participant (hereinafter the "**Israeli Participant**").

(a) Warrants granted under the Plan to an Israeli Participant may contain such terms as will allow the Warrants and the Ordinary Shares purchased pursuant to the Plan to be recognized (hereinafter "**Eligible Warrants**") pursuant to Section 102 of the Israel Income Tax Ordinance (New Version), as amended (the "**Ordinance**") and to comply with the Ordinance and its regulations and the Income Tax Rules (Tax Benefits in Share Issuances to Employees) 5363¬2003 (the "**Rules**").

(b) Eligible Warrants, Warrants and/or Ordinary Shares, as the case may be, shall be held in escrow for the benefit of such Israeli Participant by an escrow agent approved by the Israeli Tax Authority (the "**ITA**") for such purpose (the "**Escrow Agent**").

(c) Application of section 102 of the Ordinance:

(i) Warrants and/or Ordinary Shares, as the case may be, granted to Israeli Participants who are deemed to be a "**Controlling Shareholder**", as such term is defined in Section 32(i) of the Ordinance, shall be subject to Section 3(i) of the Ordinance, as shall apply from time to time. The Board shall have the absolute discretion to decide whether Warrants and/or Ordinary Shares granted pursuant to Section 3(i) of the Ordinance shall be held with the Escrow Agent.

(ii) The Escrow Agent and each Israeli Participant in the Plan shall comply with the Ordinance and Rules and with the escrow agreement entered into between the Company and the Escrow Agent.

(iii) Without derogating from the aforementioned, the Board shall have the authority to determine the specific procedures and conditions of the trusteeship with the Escrow Agent in a separate agreement between the Company and the Escrow Agent.

(iv) The Eligible Warrants, Warrants and/or Ordinary Shares, as the case may be, and any underlying rights (including bonus shares and dividends), shall be issued to and held by the Escrow Agent for the benefit of the Israeli Participant in accordance with the provisions of Section 102 of the Ordinance (under the tax route chosen by the Company) and the provisions of the Rules at least for the period required by the Ordinance and the Rules, or such other period as may be required by the ITA. All rights accruing out of and/or resulting from the Eligible Warrants, Warrants and/or Ordinary Shares, as the case may, including, but not limited to bonus shares, shall be vested with the Escrow Agent until the end of the holding period prescribed by the Ordinance and/or the Rules.

(v) After the required holding period and subject to any further period included in this Plan, or the warrant agreement with the Israeli Participant, the Escrow Agent may release the Eligible Warrants, Warrants and/or Ordinary Shares, as the case may be to the Israeli Participant only after the receipt by the Escrow Agent of an acknowledgment from the ITA that the Israeli Participant has paid or will pay any applicable tax due pursuant to the Ordinance and Rules.

(vi) The validity of any order given to the Escrow Agent by the Israeli Participant shall be subject to the approval of the Company. The Company shall render its decision regarding whether to approve orders given by any Israeli Participant to the Escrow Agent within a reasonable period of time. The Company shall not be required to approve any order which is incomplete, is not in accordance with the provisions of this Plan and the relevant warrant agreement or which the Company believes should not be executed for any reasonable reason. The Company shall notify the Israeli Participant of the reason for not approving his order. Approval by the Company of any order given to the Escrow Agent by an Israeli Participant shall not constitute proof of the Company’s recognition of any right of such Escrow Agent.

(vii) Israeli Participants shall pay the Exercise Price upon exercise of any Eligible Warrants, Warrants and/or Ordinary Shares, as the case may be in cash or its equivalent or, subject to prior approval by ITA, any other method specified in the Plan.

(viii) In the event a stock dividend and/or bonus shares is declared on the Eligible Warrants, Warrants and/or Ordinary Shares, as the case may be according to section 8(a) of the Plan, such dividend shares shall be subject to the provisions of this Plan and the holding period for such dividend shares shall be measured from the commencement of the holding period for the Eligible Warrants, Warrants and/or Ordinary Shares, as the case may be, from which the dividend was declared.

(ix) According to today’s laws, the exemption under Section 102 of the Ordinance shall be forfeited and the Israeli Participant shall be required to pay any applicable tax promptly at such time as (i) the Company or the Israeli Participant fail to comply with one or more of the conditions for the exemption as required by the Ordinance, Rules or ITA; or (ii) the ITA withdraws or cancels the exemption for the Plan or for the particular Israeli Participant. Notwithstanding the loss of an exemption, the Escrow Agent shall continue to hold the Eligible Warrants, Warrants and/or Ordinary Shares, as the case may be (to the extent the Warrant remains exercisable following termination of employment) for the remainder of the applicable holding period under Section 102 of the Ordinance.

(x) Notwithstanding the aforesaid, an Israeli Participant shall not be entitled to the issuance or exercise the Eligible Warrants, Warrants and/or Ordinary Shares, including, but not limited to declared dividends and/or bonus shares, as the case may be, prior to the end of the holding period by the Escrow Agent, in accordance with the tax route elected by the Company.

(d) All tax, duties and levies liabilities regarding the issue and/or exercise and/or the transfer, waiver, or expiration and/or the disposal of the Eligible Warrants, Warrants and/or Ordinary Shares, including, but not limited to declared dividends and/or bonus shares, as the case may be, shall be borne by the Israeli Participant and in the event of death of such Israeli Participant, by their heirs, all in accordance with the tax route elected by the Company.

Neither the Company nor any Subsidiary Corporation nor the Escrow Agent shall be required to bear the aforementioned taxes, duties and/or levies liabilities, directly or indirectly, nor shall they be required to gross up such taxes, duties and/or levies liabilities in the Israeli Participant's salaries or remuneration. The applicable taxes, duties and/or levies liabilities shall be deducted from the proceeds of disposal of the Eligible Warrants, Warrants and/or Ordinary Shares or shall be paid to the Escrow Agent or to the Company, as the case may be, by the Israeli Participant. The Company is also entitled to withhold taxes, duties and/or levies liabilities in accordance with relevant law, rules and regulations.

Without derogating from the above, the Eligible Warrants, Warrants and/or Ordinary Shares which are granted to Israeli Participants shall be subject to the provisions of Section 102 of the Ordinance, as shall apply from time to time, and the Rules promulgated thereunder. The Board shall have the absolute discretion to choose between any available tax routes to the Israeli Participant under Section 102 of the Ordinance, subject to the provisions of the Ordinance.

The Israeli Participant shall agree and undertake to indemnify the Escrow Agent and the Company and its Subsidiary Corporations and hold each of them harmless against and from any taxes, duties and/or levies liability, including interest and/or fines of any type and/or linkage differentials in respect of such taxes, duties and/or levies liability and/or withheld tax and penalties thereon, which may be incurred as a result of the granting or exercise of an Eligible Warrant or the issuance of Ordinary Shares pursuant to such Warrants.

The Company's or the Escrow Agent's obligation to deliver Ordinary Shares upon the exercise of an Award or to sell or transfer Ordinary Shares is subject to payment (or provision of payment satisfactory to the Board) by the Israeli Participant of all taxes, duties and/or levies liability due under any applicable law.

The ramifications of any future modification of any applicable law regarding the taxation of Eligible Warrants, Warrants and/or Ordinary Shares granted to Israeli Participants shall apply to the Israeli Participants accordingly and such Israeli Participants shall bear the full cost thereof, unless such modified laws expressly provide otherwise. For the avoidance of doubt, should the applicability of such taxing arrangements to this Plan or to securities issued in the framework thereof be conditioned on an application by the Company or by the Escrow Agent that same shall apply, the Company shall be entitled to decide, at its absolute discretion, whether to apply such taxing arrangements and to instruct the Escrow Agent to act accordingly.

11. Miscellaneous

(a) No Right To Employment or Other Status. No person shall have any claim or right to be offered and/or granted an Award, and the offer and/or grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Shareholder. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a shareholder with respect to any Ordinary Shares to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding the foregoing, in the event the Company effects a split of the Ordinary Shares by means of a stock dividend and the exercise price of and the number of shares subject to such Warrant are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then a Participant who exercises a Warrant between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the Ordinary Shares acquired upon such Warrant exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be offered and/or granted under the Plan after the completion of ten years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's shareholders, but Awards previously offered and/or granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time.

(e) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the Belgium, without regard to any applicable conflicts of law. Any dispute arising out of or in connection with the Plan and any related Award, including any question regarding its existence, validity or termination, shall be settled by the Courts of Brussels (Belgium).

(f) Tax Consequences. Any tax consequences arising from the offer, grant or exercise of any warrant, from the payment for shares covered thereby or from any other event or act, hereunder, shall be borne solely by Participant. The Company shall withhold taxes according to the requirements of the applicable laws, rules, and regulations, including the withholding of taxes and social security contributions at source. Furthermore, the Participant shall indemnify the Company and hold it harmless against and from any and all liability for any such tax or social security contribution as well as any related interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any payment made to the Participant.

The Company shall not be required to release any shares certificate to any Participant or record an entry on its share register indicating ownership of shares by a Participant until all required payments have been fully made.

Exhibit 10.5

NYXOAH SA

Rue du Fond Cattelain 2

1435 Mont-Saint-Guibert

Register of Legal Entities Nivelles

VAT: BE 0817.149.675

(the “**Company**”)

2016 WARRANTS PLAN

1 Definitions

For the purposes of this Plan, the following terms shall have the following meaning:

“**Articles of Association**” means the articles of association of the Company.

“**Beneficiary**” means a person duly designated by the Holder, be it his spouse or his legal heirs, to exercise the rights of the Holder under this Plan after the decease of the Holder. Designation, revocation and re-designation of a Beneficiary shall be done in writing. In the absence of any valid designation, the heirs of the Holder will, in accordance with the applicable laws of inheritance, be deemed to be the Beneficiary. In case there are several heirs, all heirs acting jointly, or a person designated by all heirs acting jointly, will be deemed to be the Beneficiary.

“**Board of Directors**” means the board of directors of the Company.

“**Change of Control**” (*Changement de contrôle*) has the meaning set out in the Articles of Association

“**Common Share**” means a common share (“*Action Ordinaire*”) in the Company.

“**Company**” means NYXOAH SA, a company limited by shares subject to Belgian law (“*société anonyme*”), with registered office at Rue du Fond Cattelain 2, 1435 Mont-Saint-Guibert, Belgium and registered with the Register of Legal Entities (Nivelles) under number 0817.149.675.

“**Control**” (*Contrôle*) has the meaning set out in the Articles of Association.

“**Controlling Shareholder**” has the meaning as set out in Clause 7.

“**Deemed Liquidation Event**” means (i) sale, lease transfer, exclusive license or other disposition of all or substantially all of the Company’s assets (including for the avoidance of doubt the material intellectual property rights of the Company and its Subsidiaries (if any)) or Shares, in a single transaction or series of related transactions, (ii) transaction or series of transactions resulting in a Change of Control over the shareholding of the Company (meaning a transaction as a result of which a third party acquires the exclusive Control over the company), or (iii) merger, reverse merger or consolidation (with or into another entity) in which outstanding Shares of the Company or Subsidiary are exchanged for securities or other consideration issued, or caused to be issued, by the acquiring company or its Subsidiary and in which the shareholders of the Company immediately prior to the transaction do not own a majority of the shares of the surviving entity.

"**Eligible Warrants**" has the meaning as set out in Clause 7.

"**End of Mandate**" means the effective date of the termination, for whatsoever reason, of (i) the employment contract between the concerned Holder and any Group Company, (ii) the director's mandate exercised by the concerned Holder with any Group Company, or (iii) the services or other collaboration agreement between the concerned Holder and any Group Company. Such termination will not imply the "End of Mandate", however, if the termination of the relationship with the concerned Group Company is accompanied by the simultaneous entering into of an employment agreement with another Group Company, by the simultaneous appointment as a director of another Group Company, or by the simultaneous entering into of a services agreement with another Group Company.

"**Escrow Agent**" has the meaning as set out in Clause 7.

"**Exercise Period**" means any of the periods during which, in accordance with Clause 6.2 of this Plan, the Holder can exercise Warrants granted to him/her so as to obtain Common Shares.

"**Final Exercise Date**" means the last date of the last Exercise Period.

"**Group Companies**" means the Company and its Subsidiaries from time to time.

"**Holder**" means a physical person or a legal entity to whom the Company has granted Warrants and who/that has completely or partially accepted these Warrants.

"**IPO**" means an initial public offering of the Company's Shares.

"**Israeli Participant**" has the meaning as set out in Clause 7.

"**ITA**" has the meaning as set out in Clause 7.

"**Liquidation Event**" means a liquidation, dissolution, winding up or bankruptcy of the Company.

"**Ordinance**" has the meaning as set out in Clause 7.

"**Plan**" means this 2016 Warrants Plan regarding warrants issued by the Company.

"**Rules**" has the meaning as set out in Clause 7.

"**Series A Preferred Shares**" ("*Actions Préférentielles de Catégorie A*") has the meaning set out in the Articles of Association.

"**Series B Preferred Shares**" ("*Actions Préférentielles de Catégorie B*") has the meaning set out in the Articles of Association.

"**Share**" means any share in the Company irrespective of the series it belongs to (on the date of this Plan, either Common Shares, Series A Preferred Shares or Series B Preferred Shares).

"**Subsidiary**" has the meaning as set out in Article 6 of the Companies Code.

"**Warrant**" means a subscription right regarding a newly to be issued Common Share, issued and granted on the basis of this Plan.

2 Object and purpose of the Plan

Each Warrant shall entitle its Holder to subscribe for one (1) Common Share upon exercise of the Warrant, under the terms and conditions set out in this Plan.

In the framework of this Plan no more than one thousand five hundred (1,500) Warrants can be issued. Consequently, the Company can issue up to one thousand five hundred (1,500) Common Shares as a result of the exercise of the Warrants.

The purpose of this Plan is to advance the interests of the Company and its shareholders by enhancing the Group Companies' ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company or any other Group Company by providing such persons with equity ownership opportunities and performance-based incentives and thereby better aligning the interests of such persons with those of the Company and its shareholders.

3 Granting and acceptance of the Warrants

The Warrants can be granted by the Board of Directors to employees, officers, directors (subject to the approval by the shareholders' meeting regarding any Warrants granted to directors of the Company), consultants and advisors of any Group Company and any persons who have accepted an offer for employment or to provide professional services to a Group Company.

Warrants will primarily be granted to employees of the Group Companies. The Board of Directors will make sure that the number of Holders to whom Warrants will be granted but who are not an employee of a Group Company only will make up a minority of the total number of Holders.

The total number of Holders shall, in any event, be lower than 150.

Each Holder has the possibility to accept or to refuse the individual grant of Warrants by the Board of Directors. The acceptance of Warrants needs to be done in writing by checking the option acceptance, mentioning the number of accepted Warrants, on the answer form prepared for these purposes The answer form must be completed and signed by the Holder and be delivered to the Company within 60 days after the date of the grant, or prior to any earlier date stated therein. If the Holder does not accept in writing the offer of Warrants prior to the ultimate date stated in the answer form, he/she is deemed to have refused the offer of Warrants.

Notwithstanding the foregoing, the offering and acceptance of Warrants may also be included in a specific warrant agreement, or inserted in another agreement signed by the Company and the Holder.

Warrants that have been granted but that are refused by the Holder or that are not timely accepted in writing, shall become automatically null and void and cannot be offered again.

4 Terms and conditions of the Warrants

4.1 Warrant price

The Warrants shall be granted by the Company free of charge.

4.2 Vesting

4.2.1 When granting the Warrants, the Board of Directors may freely decide if, when and to which extent the attributed Warrants will effectively vest for the Holders.

4.2.2 Except as explicitly provided otherwise in this Plan and unless the Board of Directors decides otherwise at the time of the relevant grant of the Warrants and subject to the End of Mandate (i) one third of the Warrants granted to and accepted by a Holder (whereby fractions of Warrants shall be rounded down) shall be deemed definitively vested on the date of the granting of the Warrants, (ii) one third of the Warrants granted to and accepted by a Holder (whereby fractions of Warrants shall be rounded down) shall be deemed definitively vested on the first anniversary of the date of the relevant grant of the relevant Warrants, and (iii) the remainder of the Warrants granted to and accepted by a Holder shall be deemed definitively vested on the second anniversary of the date of the relevant grant of the relevant Warrants.

4.2.3 The Board of Directors (subject to the approval by the shareholders' meeting regarding any Warrants granted to directors of the Company) can also decide to modify the vesting conditions after the granting of Warrants, provided that the rights of the Holder may not be restricted without the latter's consent. Prior to the End of Mandate, the Board of Directors will, for example, in mutual agreement with the Holder, be able to allow that all or a part of the Warrants that have not yet definitively vested at the End of Mandate, are definitively vested.

4.3 Exercise price

The exercising price of each Warrant is equal to the market value of one Common Share at the time of granting of the Warrants as determined by the Board of Directors and confirmed by the Company's auditor ("*commissaire*") or, if the Company has not appointed an auditor, an ad hoc auditor ("*réviseur d'entreprise*") or external accountant ("*expert-comptable externe*") designated by the Board of Directors, provided that the exercise price of one (1) Warrant cannot be lower than two thousand five hundred eighty-five euro and thirty-two eurocent (EUR 2,585.32).

Upon exercise, the portion of the exercise price up to the par value of the existing Shares (being EUR 2,004,255.29 / 19,336) needs to be recorded as capital. The portion of the exercise price exceeding the par value of the existing Shares needs to be recorded on a separate account unavailable for distribution called "Issuance premiums".

4.4 Duration of the Warrants

4.4.1 The Warrants have a duration of ten (10) years as from the date of the extraordinary shareholders' meeting of the Company deciding on the issuance of the Warrants, unless the Board of Directors decides otherwise at the time of the relevant grant of the Warrants.

4.4.2 Any Warrant shall immediately become automatically null and void if not exercised in accordance with the modalities provided for in this Plan (i) within ten (10) years after the date of the issuance of the Warrant, (ii) prior to a bankruptcy of the Company, (iii) in case of a Liquidation Event other than bankruptcy, prior to the effective date of such Liquidation Event, or (iv) in case of a Deemed Liquidation Event, prior to the completion of such Deemed Liquidation Event, unless the Board of Directors decides otherwise at the time of the relevant grant of the Warrants.

4.5 Nature

The Warrants are and will remain registered. They will be recorded in the register of warrant holders, which will be kept by the Company at the registered office, mentioning the identity of each Holder and the number of Warrants held by such Holder.

4.6 Adjustments

4.6.1 Modification of the Company's capital structure

Contrary to Article 501 of the Companies Code and without prejudice to the exceptions provided for by law, the Company shall retain the right to take decisions and close transactions that could have an influence on its capital, the distribution of profit or the liquidation bonuses, or that could possibly have another influence on the Holders' rights, except if such decisions or transactions only are aimed at diminishing the Holders' benefits.

In case the rights of the Holder are affected by such decision or transaction, the Holder will not be entitled to a modification of the exercise price or the exercise conditions, nor to any other form of financial or other compensation. The Board of Directors may, at its own discretion, make amendments to the number of Common Shares to which one Warrant relates and/or to the exercise price, however. As soon as reasonably possible, the Company will inform the Holder of any such amendment by way of a written notification.

4.6.2 Reorganizations of Shares

In the event that the Company shall (i) sub-divide its Shares into a larger number of Shares, (ii) combine its Shares into a smaller number of Shares, (iii) increase or decrease the number of Shares by a reclassification of Shares (without an increase or decrease of the Company's share capital), then the number of Shares to be issued upon exercise of the Warrant after the occurrence of one of such events shall be adjusted (if and to the extent required) so that, after giving effect to such adjustment, the Holder of the Warrant shall be entitled to receive the number of Common Shares upon exercise of the Warrant that such Holder would have owned or have been entitled to receive had this Warrant been exercised immediately prior to the occurrence of the event concerned An adjustment made pursuant to this Clause 4 6,2 shall become effective immediately after the effective date of the event concerned. The Company shall inform the Holders of such adjustment by means of a notice as soon as practicable after the effective date of the event concerned.

4.6.3 Mergers de-mergers

In the event that there shall be (i) a merger ("*fusion*") of the Company with or into another person or entity whereby the Company is not the surviving entity, or (ii) a de-merger ("*scission*") of the Company. whereby in both (i) and (ii) the Shares of the Company are exchanged into shares, other securities, cash or other property of one or more other persons, then the Common Shares to be issued upon exercise of the Warrant after the occurrence of one of such events shall be adjusted (if and to the extent required) so that, after giving effect to such adjustment, the Holder of the Warrant shall upon exercise of the Warrant be entitled to receive the number of shares, other securities, cash or other property of the successor or acquiring persons that such Holder would have owned or have been entitled to receive had this Warrant been exercised immediately prior to the occurrence of the event concerned. An adjustment made pursuant to this Clause 4.6.3 shall become effective immediately after the effective date of the event concerned. The Company shall inform the Holders of such adjustment by means of a notice as soon as practicable after the effective date of the event concerned.

5 End of Mandate - Transfer of the Warrants - Adjustments

5.1 End of Mandate

5.1.1 Unless the Board of Directors decides otherwise upon granting of the Warrants, at the End of Mandate of a Holder:

(i) all Warrants that have been granted to such Holder but have not yet vested in accordance with this Plan, shall become automatically null and void, unless, prior to the End of Mandate, it is expressly agreed otherwise in writing between the Company and the Holder in accordance with Clause 4.2.3 of this Plan; and

(ii) all Warrants that have been granted to such Holder and have vested in accordance with this Plan, shall remain with such Holder for a period of 3 months after the End of Mandate and all Warrants that are not exercised prior to the expiry of such 3 months' period shall become automatically null and void.

5.1.2 Notwithstanding Clause 5.1.1 of this Plan if the agreement or other relationship between the Holder and a Group Company is terminated for "cause", all unexercised Warrants (even those already vested) that have been granted to such Holder shall become automatically null and void at the End of Mandate of such Holder. For the purposes of this Clause 5.1.2_ "cause" means wilful misconduct by the Holder or wilful failure by the Holder to perform his/her responsibilities to the Group Company (including. without limitation, breach by the Holder of any provision of any employment, consulting, advisory, non-disclosure, non-competition or other similar agreement between the Holder and the Group Company) as determined by the Company which determination shall be conclusive. The Holder shall be considered to have been discharged for "cause" if the Company determines, within 30 days after the Holder's resignation, that discharge for cause was warranted.

5.2 Member of the group

Unless the Board of Directors decides otherwise, all Warrants that have not yet vested in accordance with Clause 4.2 of this Plan shall become automatically null and void in case the company (other than the Company), of which the Holder is an employee, officer, director, consultant or advisor, is no longer Controlled by the Company.

5.3 Disability

5.3.1 If a Holder becomes fully disabled prior to the Final Exercise Date, all Warrants of the disabled Holder that have vested already in accordance with Clause 4.2 of this Plan prior to the date on which he/she became fully disabled shall immediately become exercisable until the first anniversary of the date on which the relevant Holder became fully disabled. All such Warrants that have not been exercised (or could not yet be exercised) in accordance with the modalities defined in this Plan prior to the first anniversary of the date on which the relevant Holder became fully disabled shall become automatically null and void.

5.3.2 All Warrants that have not yet vested in accordance with Clause 4.2 of this Plan prior to the date on which the relevant Holder became fully disabled shall become automatically null and void.

5.4 Decease

5.4.1 If a Holder deceases, all Warrants of the deceased Holder that have vested already in accordance with Clause 4.2 of this Plan at the time of his/her decease, are transferred to the Beneficiaries of the Warrant Holder, and they shall immediately become exercisable until the first anniversary of the decease of the relevant Holder. All such Warrants that have not been exercised (or could not yet be exercised) in accordance with the modalities defined in this Plan prior to the first anniversary of the decease of the relevant Holder shall become automatically null and void.

5.4.2 All Warrants that have not yet vested in accordance with Clause 4.2 of this Plan at the time of the decease of the Holder shall become automatically null and void_

5.5 Transferability

5.5.1 Unless the Board of Directors decides otherwise, the Warrants are not transferable *inter vivos* once they have been granted to a Holder, and may not be pledged or encumbered with any security, pledge or other right in rem in any other way, either voluntarily, by operation of law or otherwise.

5.5.2 Warrants that have been pledged or encumbered in violation of the preceding, shall become automatically null and void.

6 **Exercise of the Warrants**

6.1 General

6.1.1 The Warrants can only be exercised by the Holder if they have effectively vested pursuant to Clause 4.2 of this Plan and in accordance with any additional exercise restrictions decided by the Board of Directors upon the respective grant of the Warrants. The Warrants that consequently become exercisable must be exercised in accordance with the exercise modalities provided for in this Plan.

6.1.2 In case the Warrants, that are not yet exercisable in accordance with the terms and conditions of the Plan. become prematurely exercisable in accordance with Article 501 of the Companies Code and are effectively exercised in accordance with such Article, the Common Shares that are issued as a result of such exercise will not be transferable until the moment that the Warrants would have been exercisable pursuant to the terms and conditions of the Plan. unless express approval is obtained from the Company and without prejudice to any other applicable share transfer restrictions (including, but not limited to, those set out in the Articles of Association).

6.1.3 In case Warrants that are effectively vested would not be exercised on the last day of the last Exercise Period during the duration of the Warrants as set out in Clause 4.4 of this Plan, such Warrants shall become automatically null and void.

6.2 Warrant Exercise Period

6.2.1 Without prejudice to Clause 6.1.1 of this Plan,

(i) Warrants may be exercised during the following periods:

- from 1 to 31 March; and

- from 1 to 30 September,

of each year during which they are valid and exercisable; and

(ii) in the event of the End of Mandate of a Holder, such Holder can exercise his/her Warrants during a period of 3 months following the End of Mandate.

Within the legal boundaries, the Board of Directors can decide to amend the Exercise Periods, however, without being able to shorten them.

The exercise of the Warrants at the exercise price is unconditional.

6.2.2 Liquidation Event, Deemed Liquidation Event or IPO

Notwithstanding Clauses 4.2, 6.1.1 and 6.2.1 of this Plan, and unless the Board of Directors decides otherwise at the time of the relevant grant of the Warrants, the Warrants will immediately vest and be exercisable during at least ten (10) business days (i) prior to the effective date of a Liquidation Event other than bankruptcy, (ii) prior to the completion of a Deemed Liquidation Event, and (iii) in the event of a IPO, prior to the admission of all or part of the Shares to an official listing of a stock exchange in a member state of the European Union, in the United States of America or in any regulated market declared equivalent to these markets by Royal Decree, it being understood that such vesting and exercise of the Warrants shall be conditional upon the effectiveness of such Liquidation Event, Deemed Liquidation Event or IPO_ As the case may be, the provisions in the Articles of Association regarding pre-emption, tag-along and drag along rights shall apply.

6.3 Exercise restriction

The Board of Directors may impose additional restrictions and conditions to the exercisability of the Warrants at the time the Board of Directors grants them.

6.4 Exercise modalities

In order to exercise a Warrant, at the latest on the Final Exercise Date, the Company needs to receive a written notice of exercise of the Warrants. The notification shall take place by registered mail, against receipt confirmation, or by personal delivery to the Board of Directors or the secretary of the Company at the registered office of the Company. The notice shall be signed by the Holder (or, if applicable, his/her Beneficiaries) and must explicitly state the number of Warrants being exercised and the number of Common Shares consequently being subscribed to. If the Warrants are exercised by one or more Beneficiaries, the notice of exercise needs to be accompanied by an appropriate proof of the right of this person or these persons to exercise the Warrants.

The full payment of the exercise price of the exercised Warrants needs to be paid in cash and deposited by wire transfer on a blocked account of the Company of which the bank account number is communicated by the Board of Directors. This payment shall take place within ten (10) business days after having received the aforementioned communication of the bank account number from the Board of Directors, or within ten (10) business days after the date of the notice of exercise in the event that the bank account number concerned has already previously been communicated by the Board of Directors.

6.5 Issuance of Common Shares

6.5.1 The Company will only be obliged to issue Common Shares as a result of the exercise of Warrants if such Common Shares are fully paid up and the other conditions set out in this Plan have been fulfilled.

6.5.2 Warrants exercised by any Holder will give right to Common Shares only.

6.5.3 The Common Shares will be issued as soon as reasonably possible, taking into account administrative formalities, after the end of the Exercise Period during which the concerned Warrant was validly exercised. To this effect, the Board of Directors will acknowledge before a notary public that the capital was increased in accordance with Article 591 of the Companies Code.

6.5.4 The Common Shares that are issued as a result of this exercise of Warrants shall be delivered in registered form and will be fully profit sharing as from the beginning of the financial year during which the Common Shares are issued and the following financial years.

6.5.5 After the issuance of the Common Shares, which are subscribed for through the exercise of Warrants, one or more directors of the Company will, as attorney-in-fact, register the Common Shares in the name of the subscriber in the Company’s share register.

6.6 Rights as shareholders

The Holder or, as the case may be, the Holder’s Beneficiary does not have any rights and privileges of a shareholder regarding the Common Shares, object of this Plan, until the date these Common Shares are effectively issued by the Company to the Holder or, as the case may be, the Holder’s Beneficiary, Once the Common Shares have been issued by the Company to the Holder. the latter enjoys, in his capacity as shareholder, the same rights as the other shareholders of the same series in the Company, and such Common Shares shall be subject to the provisions of the Articles of Association (including but not limited to the share transfer restrictions).

7 Provisions regarding Israeli Holders

7.1 Notwithstanding anything stipulated in the Plan, the following conditions shall take precedence over any provision of the Plan in relation to Holders who are employees, officers, directors, consultants and/or advisors ("**Nosei Misra**" - as such term is defined in the Israeli Companies Law) of a Group Company residing and exercising their employment, mandate or function in Israel (hereinafter the "**Israeli Participant**").

7.2 Warrants granted under the Plan to an Israeli Participant may contain such terms as will allow the Warrants and the Common Shares acquired pursuant to the exercise of such Warrants to be recognized (hereinafter "**Eligible Warrants**") pursuant to Section 102 of the Israel Income Tax Ordinance (New Version), as amended (the "**Ordinance**") and to comply with the Ordinance and its regulations and the Income Tax Rules (Tax Benefits in Share Issuances to Employees) 5363-2003 (the "**Rules**")

7.3 Eligible Warrants, Warrants and/or Common Shares, as the case may be, shall be held in escrow for the benefit of such Israeli Participant by an escrow agent approved by the Israeli Tax Authority (the "**ITA**") for such purpose (the "**Escrow Agent**").

7.4 Application of section 102 of the Ordinance:

7.4.1 Warrants and/or Common Shares, as the case may be, granted to Israeli Participants who are deemed to be a "**Controlling Shareholder**", as such term is defined in Section 32(i) of the Ordinance, shall be subject to Section 3(i) of the Ordinance, as shall apply from time to time. The Board of Directors shall have the absolute discretion to decide whether Warrants and/or Common Shares granted pursuant to Section 3(i) of the Ordinance shall be held with the Escrow Agent.

7.4.2 The Escrow Agent and each Israeli Participant in the Plan shall comply with the Ordinance and Rules and with the escrow agreement entered into between the Company and the Escrow Agent.

7.4.3 Without derogating from the aforementioned, the Board of Directors shall have the authority to determine the specific procedures and conditions of the trusteeship with the Escrow Agent in a separate agreement between the Company and the Escrow Agent.

7.4.4 The Eligible Warrants, Warrants and/or Common Shares, as the case may be, and any underlying rights (including bonus shares and dividends), shall be issued to and held by the Escrow Agent for the benefit of the Israeli Participant in accordance with the provisions of Section 102 of the Ordinance (under the tax route chosen by the Company) and the provisions of the Rules at least for the period required by the Ordinance and the Rules, or such other period as may be required by the ITA. All rights accruing out of and/or resulting from the Eligible Warrants, Warrants and/or Common Shares, as the case may, including, but not limited to bonus shares shall be vested with the Escrow Agent until the end of the holding period prescribed by the Ordinance and/or the Rules.

7.4.5 After the required holding period and subject to any further period included in this Plan. or the warrant agreement with the Israeli Participant, the Escrow Agent may release the Eligible Warrants, Warrants and/or Common Shares, as the case may be to the Israeli Participant only after the receipt by the Escrow Agent of an acknowledgment from the 1TA that the Israeli Participant has paid or will pay any applicable tax due pursuant to the Ordinance and Rules.

7.4.6 The validity of any order given to the Escrow Agent by the Israeli Participant shall be subject to the approval of the Company. The Company shall render its decision regarding whether to approve orders given by any Israeli Participant to the Escrow Agent within a reasonable period of time. The Company shall not be required to approve any order which is incomplete, is not in accordance with the provisions of this Plan and the relevant warrant agreement or which the Company believes should not be executed for any reasonable reason. The Company shall notify the Israeli Participant of the reason for not approving his order. Approval by the Company of any order given to the Escrow Agent by an Israeli Participant shall not constitute proof of the Company's recognition of any right of such Escrow Agent.

7.4.7 In the event a stock dividend and/or bonus shares is declared on the Eligible Warrants, Warrants and/or Common Shares, such dividend shares shall be subject to the provisions of this Plan and the holding period for such dividend shares shall be measured from the commencement of the holding period for the Eligible Warrants, Warrants and/or Common Shares, as the case may be, from which the dividend was declared.

7.4.8 According to today's laws, the exemption under Section 102 of the Ordinance shall be forfeited and the Israeli Participant shall be required to pay any applicable tax promptly at such time as (i) the Company or the Israeli Participant fail to comply with one or more of the conditions for the exemption as required by the Ordinance, Rules or ITA; or (ii) the ITA withdraws or cancels the exemption for the Plan or for the particular Israeli Participant. Notwithstanding the loss of an exemption, the Escrow Agent shall continue to hold the Eligible Warrants, Warrants and/or Common Shares, as the case may be (to the extent the Warrant remains exercisable following termination of employment) for the remainder of the applicable holding period under Section 102 of the Ordinance.

7.4.9 Notwithstanding the aforesaid, an Israeli Participant shall not be entitled to the issuance or exercise the Eligible Warrants, Warrants and/or Common Shares, including, but not limited to declared dividends and/or bonus shares, as the case may be, prior to the end of the holding period by the Escrow Agent, in accordance with the tax route elected by the Company.

7.5 All tax, duties and levies liabilities regarding the issue and/or exercise and/or the transfer, waiver, or expiration and/or the disposal of the Eligible Warrants, Warrants and/or Common Shares, including, but not limited to declared dividends and/or bonus shares, as the case may be, shall be borne by the Israeli Participant and in the event of death of such Israeli Participant, by his/her Beneficiaries, all in accordance with the tax route elected by the Company.

7.6 Neither the Company nor any of its Subsidiaries nor the Escrow Agent shall be required to bear the aforementioned taxes, duties and/or levies liabilities_ directly or indirectly, nor shall they be required to gross up such taxes, duties and/or levies liabilities in the Israeli Participant's salaries or remuneration. The applicable taxes, duties and/or levies liabilities shall be deducted from the proceeds of disposal of the Eligible Warrants, Warrants and/or Common Shares or shall be paid to the Escrow Agent or to the Company, as the case may be, by the Israeli Participant. The Company is also entitled to withhold taxes, duties and/or levies liabilities in accordance with relevant law, rules and regulations.

7.7 Without derogating from the above, the Eligible Warrants, Warrants and/or Common Shares which are granted to Israeli Participants shall be subject to the provisions of Section 102 of the Ordinance, as shall apply from time to time, and the Rules promulgated thereunder. The Board of Directors shall have the absolute discretion to choose between any available tax routes to the Israeli Participant under Section 102 of the Ordinance, subject to the provisions of the Ordinance.

7.8 The Israeli Participant shall agree and undertake to indemnify the Escrow Agent and the Company and its Subsidiaries and hold each of them harmless against and from any taxes, duties and/or levies liability, including interest and/or fines of any type and/or linkage differentials in respect of such taxes, duties and/or levies liability and/or withheld tax and penalties thereon, which may be incurred as a result of the granting or exercise of an Eligible Warrant or the issuance of Common Shares pursuant to such Warrants.

7.9 The Company's or the Escrow Agent's obligation to deliver Common Shares upon the exercise of Warrants is subject to payment (or provision of payment satisfactory to the Board of Directors) by the Israeli Participant of all taxes, duties and/or levies liability due under any applicable law.

7.10 The ramifications of any future modification of any applicable law regarding the taxation of Eligible Warrants, Warrants and/or Common Shares granted to Israeli Participants shall apply to the Israeli Participants accordingly and such Israeli Participants shall bear the full cost thereof, unless such modified laws expressly provide otherwise. For the avoidance of doubt, should the applicability of such taxing arrangements to this Plan or to securities issued in the framework thereof be conditioned on an application by the Company or by the Escrow Agent that same shall apply, the Company shall be entitled to decide, at its absolute discretion, whether to apply such taxing arrangements and to instruct the Escrow Agent to act accordingly.

7.11 During the required holding period, the Israeli Participant shall not release from trust or sell, assign, transfer or give as collateral, the Common Shares issuable upon the exercise or (if applicable) vesting of a 102 trustee award and/or any securities issued or distributed with respect thereto, until the expiration of the required holding period. Notwithstanding the above, if any such sale, release or other action occurs during the required holding period it may result in adverse tax consequences to the Israeli Participant under Section 102 of the Ordinance and the Rules, which shall apply to and shall be borne solely by such Israeli Participant.

8 Miscellaneous

8.1 Amendments, suspension and termination of this Plan

The terms and conditions set out in this Plan may entirely or partially be amended_ modified, suspended or terminated by the shareholders' meeting at any time, except with regard to the Exercise Period which, as stated in Clause 6,2 1 of this Plan, can be modified by the Board of Directors, The amendment. suspension or termination of this Plan may not modify or limit the rights and obligations under a granted Warrant without the consent of the concerned Holder. No warrant can be granted when this Plan is suspended or after the termination of this Plan.

8.2 National legislation

Notwithstanding any provision of the Plan, the Board of Directors may modify or extend the provisions of the Plan and the conditions of the Warrants to the extent that it considers this to be necessary or preferable to take into account, to limit the disadvantageous consequences of, or to be in compliance with foreign legislation, including, but not limited to, tax and financial legislation applicable to the Holder. to the extent that the terms and conditions of the Warrants granted to such Holder are not more advantageous than the terms and conditions of the Warrants granted to the other Holders.

8.3 Costs and taxes

The costs regarding the capital increase shall be incurred by the Company. Seal rights stock exchange taxes and other similar rights and taxes imposed as a result of the exercise of the Warrants and the delivery of new Shares are borne by the Holders. Any other possible taxes or rights due as a result of the grant of Warrants will also be borne by the Holders,

The costs regarding the issuance of the Warrants and the capital increase relating to the issuance and exercise of the Warrants are borne by the Company.

Holders (or, if applicable, his/her Beneficiaries) will have to bear any taxes (including but not limited to income taxes, capital gains taxes and stock exchange taxes) and employee or self-employed social security contributions due in connection with (a) the grant, exercise, and or transfer of the Warrants and (b) the delivery and ownership of the new Common Shares, in accordance with applicable tax and social security legislation.

The Company or a Subsidiary shall, upon granting of the Warrants pursuant to this Plan, levy any withholding tax provided for in the relevant applicable tax and/or social security laws, as provided for therein.

8.4 Employment conditions

No provision of this Plan can be construed as creating an obligation of employment (either by way of an employment agreement, an appointment as director or a services agreement) between a Group Company and a Holder or an obligation for the Board of Directors to offer Warrants. Upon termination of the employment, the Holder shall in no event be entitled to demand damages within the framework of this Plan. The foregoing also applies, but is not limited to, the application of the tax legislation.

8.5 Nullity of a provision

The nullity or unenforceability of any provision of this Plan does not in any way affect the validity or enforceability of the remaining provisions of this Plan. In this case, the invalid or unenforceable provision will be replaced by an equivalent valid and enforceable provision having a similar economic effect for the parties concerned.

8.6 Applicable law

This Plan and any non-contractual obligations arising out of or in connection with it shall be governed by and construed in accordance with Belgian law.

8.7 Competent courts

The courts of Brussels (Belgium) have exclusive jurisdiction to settle any dispute arising out of or in connection with this Plan (including a dispute relating to non-contractual obligations arising out of or in connection with this Plan).

8.8 Notices

Any notice to the Holders (and. if applicable, his/her Beneficiaries) shall be validly made to the address mentioned in the register of warrant holders.

Any notice to the Company, shall be validly made to the attention of the Board of Directors or the secretary of the Company at the address of the registered office of the Company.

Address modifications must be notified immediately by the Holders (and, if applicable, his/her Beneficiaries) to the Company in accordance with this provision.

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Adopted by the Board of Directors on 16 September 2016, subject to approval by the shareholders' meeting.

On behalf of the Board of Directors:

Robert Taub	**Jürgen Hambrecht**
Common Director	A Director

Exhibit 10.6

NYXOAH SA

Rue Edouard Belin 12

1435 Mont-Saint-Guibert

Register of Legal Brabant wallon

VAT: BE 0817.149.675

(the "**Company**")

2018 WARRANTS PLAN

1 Definitions

For the purposes of this Plan, the following terms shall have the following meaning:

"**Articles of Association**" means the articles of association of the Company.

"**Beneficiary**" means a person duly designated by the Holder, be it his spouse or his legal heirs, to exercise the rights of the Holder under this Plan after the decease of the Holder. Designation, revocation and re-designation of a Beneficiary shall be done in writing. In the absence of any valid designation, the heirs of the Holder will, in accordance with the applicable laws of inheritance, be deemed to be the Beneficiary. In case there are several heirs, all heirs acting jointly, or a person designated by all heirs acting jointly, will be deemed to be the Beneficiary.

"**Board of Directors**" means the board of directors of the Company.

"**Change of Control**" (*Changement de Contrôle*) has the meaning set out in the Articles of Association

"**Common Share**" means a common share ("*Action Ordinaire*") in the Company.

"**Company**" means NYXOAH SA, a company limited by shares subject to Belgian law ("*société anonyme*"), with registered office at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium and registered with the Register of Legal Entities (Brabant wallon) under number 0817.149.675.

"**Control**" (*Contrôle*) has the meaning set out in the Articles of Association.

"**Controller**" has the meaning as set out in Clause 8.1.

"**Controlling Shareholder**" has the meaning as set out in Clause 7.

"**Deemed Liquidation Event**" means (i) sale, lease transfer, exclusive license or other disposition of all or substantially all of the Company's assets (including for the avoidance of doubt the material intellectual property rights of the Company and its Subsidiaries (if any)) or Shares, in a single transaction or series of related transactions, (ii) transaction or series of transactions resulting in a Change of Control over the shareholding of the Company (meaning a transaction as a result of which a third party acquires the exclusive Control over the company), or (iii) merger, reverse merger or consolidation (with or into another entity) in which outstanding Shares of the Company or Subsidiary are exchanged for securities or other consideration issued, or caused to be issued, by the acquiring company or its Subsidiary and in which the shareholders of the Company immediately prior to the transaction do not own a majority of the shares of the surviving entity.

“**Eligible Warrants**” has the meaning as set out in Clause 7.

“**End of Mandate**” means the effective date of the termination, for whatsoever reason, of (i) the employment contract between the concerned Holder and any Group Company, (ii) the director’s mandate exercised by the concerned Holder with any Group Company, or (iii) the services or other collaboration agreement between the concerned Holder and any Group Company. Such termination will not imply the “End of Mandate”, however, if the termination of the relationship with the concerned Group Company is accompanied by the simultaneous entering into of an employment agreement with another Group Company, by the simultaneous appointment as a director of another Group Company, or by the simultaneous entering into of a services agreement with another Group Company.

“**Exercise Period**” means any of the periods during which, in accordance with Clause 6.2 of this Plan, the Holder can exercise Warrants granted to him/her so as to obtain Common Shares.

“**Final Exercise Date**” means the last date of the last Exercise Period.

“**Group Companies**” means the Company and its Subsidiaries from time to time.

“**Holder**” means a physical person or a legal entity to whom the Company has granted Warrants and who/that has completely or partially accepted these Warrants.

“**IPO**” means an initial public offering of the Company’s Shares.

“**Israeli Participant**” has the meaning as set out in Clause 7.

“**ITA**” has the meaning as set out in Clause 7.

“**Liquidation Event**” means a liquidation, dissolution, winding up or bankruptcy of the Company.

“**Ordinance**” has the meaning as set out in Clause 7.

“**Personal Data**” has the meaning as set out in Clause 8.2.

“**Plan**” means this 2016 Warrants Plan regarding warrants issued by the Company.

“**Processor**” has the meaning as set out in Clause 8.4.

“**Rules**” has the meaning as set out in Clause 7.

“**Series A Preferred Shares**” (“*Actions Préférentielles de Catégorie A*”) has the meaning set out in the Articles of Association.

“**Series B Preferred Shares**” (“*Actions Préférentielles de Catégorie B*”) has the meaning set out in the Articles of Association.

“**Series B2 Preferred Shares**” (“*Actions Préférentielles de Catégorie B2*”) has the meaning set out in the Articles of Association.

“**Share**” means any share in the Company irrespective of the series it belongs to (on the date of this Plan, either Common Shares, Series A Preferred Shares or Series B2 Preferred Shares).

“**Subsidiary**” has the meaning as set out in Article 6 of the Companies Code.

“**Warrant**” means a subscription right regarding a newly to be issued Common Share, issued and granted on the basis of this Plan.

“**Trustee**” has the meaning as set out in Clause 7.

2 Object and purpose of the Plan

Each Warrant shall entitle its Holder to subscribe for one (1) Common Share upon exercise of the Warrant, under the terms and conditions set out in this Plan.

In the framework of this Plan no more than five hundred twenty-five (525) Warrants can be issued. Consequently, the Company can issue up to five hundred twenty-five (525) Common Shares as a result of the exercise of the Warrants.

The purpose of this Plan is to advance the interests of the Company and its shareholders by enhancing the Group Companies’ ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company or any other Group Company by providing such persons with equity ownership opportunities and performance-based incentives and thereby better aligning the interests of such persons with those of the Company and its shareholders.

3 Granting and acceptance of the Warrants

The Warrants can be granted to employees, officers, directors, consultants and advisors of any Group Company and any persons who have accepted an offer for employment or to provide professional services to a Group Company. The Warrants are granted by the Board of Directors, except for grants of Warrants to directors of the Company which must be approved by the shareholders' meeting.

Warrants will primarily be granted to employees of the Group Companies. The Board of Directors will make sure that the number of Warrants granted to Holders who are not an employee of a Group Company only will make up a minority of the total number of Warrants.

The total number of Holders shall, in any event, be lower than 150.

Each Holder has the possibility to accept or to refuse the individual grant of Warrants by the Board of Directors. The acceptance of Warrants needs to be done in writing by checking the option acceptance, mentioning the number of accepted Warrants, on the answer form prepared for these purposes. The answer form must be completed and signed by the Holder and be delivered to the Company within 60 days after the date of the grant, or prior to any earlier date stated therein. If the Holder does not accept in writing the offer of Warrants prior to the ultimate date stated in the answer form, he/she is deemed to have refused the offer of Warrants.

Notwithstanding the foregoing, the offering and acceptance of Warrants may also be included in a specific warrant agreement, or inserted in another agreement signed by the Company and the Holder.

Warrants that have been granted but that are refused by the Holder or that are not timely accepted in writing, shall become automatically null and void and cannot be offered again.

4 Terms and conditions of the Warrants

4.1 Warrant price

The Warrants shall be granted by the Company free of charge.

4.2 Vesting

4.2.1 When granting the Warrants, the Board of Directors may freely decide if, when and to which extent the attributed Warrants will effectively vest for the Holders.

4.2.2 Except as explicitly provided otherwise in this Plan and unless the Board of Directors (or the shareholders' meeting of the Company for grants of Warrants to directors of the Company) decides otherwise at the time of the relevant grant of the Warrants and subject to the End of Mandate (i) one third of the Warrants granted to and accepted by a Holder (whereby fractions of Warrants shall be rounded down) shall be deemed definitively vested on the date of the granting of the Warrants, (ii) one third of the Warrants granted to and accepted by a Holder (whereby fractions of Warrants shall be rounded down) shall be deemed definitively vested on the first anniversary of the date of the relevant grant of the relevant Warrants, and (iii) the remainder of the Warrants granted to and accepted by a Holder shall be deemed definitively vested on the second anniversary of the date of the relevant grant of the relevant Warrants.

4.2.3 The Board of Directors (subject to the approval by the shareholders' meeting of the Company regarding any Warrants granted to directors of the Company) can also decide to modify the vesting conditions after the granting of Warrants, provided that the rights of the Holder may not be restricted without the latter's consent. Prior to the End of Mandate, the Board of Directors will, for example, in mutual agreement with the Holder, be able to allow that all or a part of the Warrants that have not yet definitively vested at the End of Mandate, are definitively vested.

4.3 Exercise price

The exercising price of each Warrant shall be equal to the market value of one Common Share at the time of granting of the Warrants as determined by the Board of Directors and confirmed by the Company's auditor ("*commissaire*") or, if the Company has not appointed an auditor, an ad hoc auditor ("*réviseur d'entreprise*") or external accountant ("*expert-comptable externe*") designated by the Board of Directors, provided that the exercise price of one (1) Warrant cannot be lower than the highest of three thousand two hundred fifty-nine euro and ninety-one eurocent (EUR 3,259.91) and the book value of the existing Shares as it appears in the most recently approved annual accounts of the Company.

Upon exercise, the portion of the exercise price up to the par value of the existing Shares needs to be recorded as capital. The portion of the exercise price exceeding the par value of the existing Shares needs to be recorded on a separate account unavailable for distribution called "Issuance premiums".

4.4 Duration of the Warrants

4.4.1 The Warrants have a duration of ten (10) years as from the date of the extraordinary shareholders' meeting of the Company deciding on the issuance of the Warrants.

4.4.2 Any Warrant shall immediately become automatically null and void if not exercised in accordance with the modalities provided for in this Plan (i) within ten (10) years after the date of the issuance of the Warrant, (ii) prior to a bankruptcy of the Company, (iii) in case of a Liquidation Event other than bankruptcy, prior to the effective date of such Liquidation Event, or (iv) in case of a Deemed Liquidation Event, prior to the completion of such Deemed Liquidation Event, unless the Board of Directors (or the shareholders' meeting of the Company for grants of Warrants to directors of the Company) decides otherwise at the time of the relevant grant of the Warrants.

4.5 Nature

The Warrants are and will remain registered. They will be recorded in the register of warrant holders, which will be kept by the Company at the registered office, mentioning the identity of each Holder and the number of Warrants held by such Holder.

4.6 Adjustments

4.6.1 Modification of the Company's capital structure

Contrary to Article 501 of the Companies Code and without prejudice to the exceptions provided for by law, the Company shall retain the right to take decisions and close transactions that could have an influence on its capital, the distribution of profit or the liquidation bonuses, or that could possibly have another influence on the Holders' rights, except if such decisions or transactions only are aimed at diminishing the Holders' benefits.

In case the rights of the Holder are affected by such decision or transaction, the Holder will not be entitled to a modification of the exercise price or the exercise conditions, nor to any other form of financial or other compensation. The Board of Directors may, at its own discretion, make amendments to the number of Common Shares to which one Warrant relates and/or to the exercise price, however. As soon as reasonably possible, the Company will inform the Holder of any such amendment by way of a written notification.

4.6.2 Reorganizations of Shares

In the event that the Company shall (i) sub-divide its Shares into a larger number of Shares, (ii) combine its Shares into a smaller number of Shares, (iii) increase or decrease the number of Shares by a reclassification of Shares (without an increase or decrease of the Company's share capital), then the number of Shares to be issued upon exercise of the Warrant after the occurrence of one of such events shall be adjusted (if and to the extent required) so that, after giving effect to such adjustment, the Holder of the Warrant shall be entitled to receive the number of Common Shares upon exercise of the Warrant that such Holder would have owned or have been entitled to receive had this Warrant been exercised immediately prior to the occurrence of the event concerned, An adjustment made pursuant to this Clause 4,6.2 shall become effective immediately after the effective date of the event concerned. The Company shall inform the Holders of such adjustment by means of a notice as soon as practicable after the effective date of the event concerned.

4.6.3 Mergers, de-mergers

In the event that there shall be (i) a merger ("*fusion*") of the Company with or into another person or entity whereby the Company is not the surviving entity, or (ii) a de-merger ("*scission*") of the Company, whereby in both (i) and (ii) the Shares of the Company are exchanged into shares, other securities, cash or other property of one or more other persons, then the Common Shares to be issued upon exercise of the Warrant after the occurrence of one of such events shall be adjusted (if and to the extent required) so that, after giving effect to such adjustment, the Holder of the Warrant shall upon exercise of the Warrant be entitled to receive the number of shares, other securities, cash or other property of the successor or acquiring persons that such Holder would have owned or have been entitled to receive had this Warrant been exercised immediately prior to the occurrence of the event concerned. An adjustment made pursuant to this Clause 4.6.3 shall become effective immediately after the effective date of the event concerned. The Company shall inform the Holders of such adjustment by means of a notice as soon as practicable after the effective date of the event concerned.

5 End of Mandate - Transfer of the Warrants - Adjustments

5.1 End of Mandate

5.1.1 Unless the Board of Directors (or the shareholders' meeting of the Company for grants of Warrants to directors of the Company) decides otherwise upon granting of the Warrants, at the End of Mandate of a Holder:

(i) all Warrants that have been granted to such Holder but have not yet vested in accordance with this Plan, shall become automatically null and void, unless, prior to the End of Mandate, it is expressly agreed otherwise in writing between the Company and the Holder in accordance with Clause 4.2.3 of this Plan; and

(ii) all Warrants that have been granted to such Holder and have vested in accordance with this Plan, shall remain with such Holder for a period of 3 months after the End of Mandate and all Warrants that are not exercised prior to the expiry of such 3 months' period shall become automatically null and void.

5.1.2 Notwithstanding Clause 5.1.1 of this Plan, if the agreement or other relationship between the Holder and a Group Company is terminated for "cause", all unexercised Warrants (even those already vested) that have been granted to such Holder shall become automatically null and void at the End of Mandate of such Holder. For the purposes of this Clause 5.1.2, "cause" means wilful misconduct by the Holder or wilful failure by the Holder to perform his/her responsibilities to the Group Company (including, without limitation, breach by the Holder of any provision of any employment, consulting, advisory, non-disclosure, non-competition or other similar agreement between the Holder and the Group Company) as determined by the Company, which determination shall be conclusive. The Holder shall be considered to have been discharged for "cause" if the Company determines, within 30 days after the Holder's resignation, that discharge for cause was warranted.

5.2 Member of the group

Unless the Board of Directors decides otherwise, all Warrants that have not yet vested in accordance with Clause 4.2 of this Plan shall become automatically null and void in case the company (other than the Company), of which the Holder is an employee, officer, director, consultant or advisor, is no longer Controlled by the Company.

5.3 Disability

5.3.1 If a Holder becomes fully disabled prior to the Final Exercise Date, all Warrants of the disabled Holder that have vested already in accordance with Clause 4.2 of this Plan prior to the date on which he/she became fully disabled shall immediately become exercisable until the first anniversary of the date on which the relevant Holder became fully disabled. All such Warrants that have not been exercised (or could not yet be exercised) in accordance with the modalities defined in this Plan prior to the first anniversary of the date on which the relevant Holder became fully disabled shall become automatically null and void.

5.3.2 All Warrants that have not yet vested in accordance with Clause 4.2 of this Plan prior to the date on which the relevant Holder became fully disabled shall become automatically null and void.

5.4 Decease

5.4.1 If a Holder deceases, all Warrants of the deceased Holder that have vested already in accordance with Clause 4.2 of this Plan at the time of his/her decease, are transferred to the Beneficiaries of the Warrant Holder, and they shall immediately become exercisable until the first anniversary of the decease of the relevant Holder. All such Warrants that have not been exercised (or could not yet be exercised) in accordance with the modalities defined in this Plan prior to the first anniversary of the decease of the relevant Holder shall become automatically null and void.

5.4.2 All Warrants that have not yet vested in accordance with Clause 4.2 of this Plan at the time of the decease of the Holder shall become automatically null and void.

5.5 Transferability

5.5.1 Unless the Board of Directors decides otherwise, the Warrants are not transferable *inter vivos* once they have been granted to a Holder, and may not be pledged or encumbered with any security, pledge or other right in rem in any other way, either voluntarily, by operation of law or otherwise.

5.5.2 Warrants that have been pledged or encumbered in violation of the preceding, shall become automatically null and void.

6 Exercise of the Warrants

6.1 General

6.1.1 The Warrants can only be exercised by the Holder if they have effectively vested pursuant to Clause 4.2 of this Plan and in accordance with any additional exercise restrictions decided by the Board of Directors upon the respective grant of the Warrants. The Warrants that consequently become exercisable must be exercised in accordance with the exercise modalities provided for in this Plan.

6.1.2 In case the Warrants, that are not yet exercisable in accordance with the terms and conditions of the Plan, become prematurely exercisable in accordance with Article 501 of the Companies Code and are effectively exercised in accordance with such Article, the Common Shares that are issued as a result of such exercise will not be transferable until the moment that the Warrants would have been exercisable pursuant to the terms and conditions of the Plan, unless express approval is obtained from the Company and without prejudice to any other applicable share transfer restrictions (including, but not limited to, those set out in the Articles of Association).

6.1.3 In case Warrants that are effectively vested would not be exercised on the last day of the last Exercise Period during the duration of the Warrants as set out in Clause 4.4 of this Plan, such Warrants shall become automatically null and void.

6.2 Warrant Exercise Period

6.2.1 Without prejudice to Clause 6.1.1 of this Plan,

(i) Warrants may be exercised during the following periods:

- from 1 to 31 March; and
- from 1 to 30 September,

of each year during which they are valid and exercisable; and

(ii) in the event of the End of Mandate of a Holder, such Holder can exercise his/her Warrants during a period of 3 months immediately following the End of Mandate.

Within the legal boundaries, the Board of Directors can decide to amend the Exercise Periods, however, without being able to shorten them.

The exercise of the Warrants at the exercise price is unconditional.

6.2.2 Liquidation Event, Deemed Liquidation Event or IPO

Notwithstanding Clauses 4.2, 6.1.1 and 6.2.1 of this Plan, and unless the Board of Directors (or the shareholders' meeting of the Company for grants of Warrants to directors of the Company) decides otherwise at the time of the relevant grant of the Warrants, the Warrants will immediately vest and be exercisable during at least ten (10) business days (i) prior to the effective date of a Liquidation Event other than bankruptcy, (ii) prior to the completion of a Deemed Liquidation Event, and (iii) in the event of a IPO, prior to the admission of all or part of the Shares to an official listing of a stock exchange in a member state of the European Union, in the United States of America or in any regulated market declared equivalent to these markets by Royal Decree, it being understood that such vesting and exercise of the Warrants shall be conditional upon the effectiveness of such Liquidation Event, Deemed Liquidation Event or IPO. As the case may be, the provisions in the Articles of Association regarding pre-emption, tag-along and drag along rights shall apply.

6.3 Exercise restriction

The Board of Directors (or the shareholders' meeting of the Company for grants of Warrants to directors of the Company) may impose additional restrictions and conditions to the exercisability of the Warrants at the time of grant of the Warrants.

6.4 Exercise modalities

In order to exercise a Warrant, at the latest on the Final Exercise Date, the Company needs to receive a written notice of exercise of the Warrants. The notification shall take place by registered mail, against receipt confirmation, or by personal delivery to the Board of Directors or the secretary of the Company at the registered office of the Company. The notice shall be signed by the Holder (or, if applicable, his/her Beneficiaries) and must explicitly state the number of Warrants being exercised and the number of Common Shares consequently being subscribed to. If the Warrants are exercised by one or more Beneficiaries, the notice of exercise needs to be accompanied by an appropriate proof of the right of this person or these persons to exercise the Warrants.

The full amount of the exercise price of the exercised Warrants needs to be paid in cash and deposited by wire transfer on a blocked account of the Company of which the bank account number is communicated by the Board of Directors. This payment shall take place within ten (10) business days after having received the aforementioned communication of the bank account number from the Board of Directors, or within ten (10) business days after the date of the notice of exercise in the event that the bank account number concerned has already previously been communicated by the Board of Directors.

6.5 Issuance of Common Shares

6.5.1 The Company will only be obliged to issue Common Shares as a result of the exercise of Warrants if such Common Shares are fully paid up and the other conditions set out in this Plan have been fulfilled.

6.5.2 Warrants exercised by any Holder will give right to Common Shares only.

6.5.3 The Common Shares will be issued as soon as reasonably possible, taking into account administrative formalities, after the end of the Exercise Period during which the concerned Warrant was validly exercised. To this effect, the Board of Directors or one of the directors will acknowledge before a notary public that the capital was increased in accordance with Article 591 of the Companies Code.

6.5.4 The Common Shares that are issued as a result of this exercise of Warrants shall be delivered in registered form and will be fully profit sharing as from the beginning of the financial year during which the Common Shares are issued and the following financial years.

6.5.5 After the issuance of the Common Shares, which are subscribed for through the exercise of Warrants, one or more directors of the Company will, as attorney-in-fact, register the Common Shares in the name of the subscriber in the Company's share register.

6.6 Rights as shareholders

The Holder or, as the case may be, the Holder's Beneficiary does not have any rights and privileges of a shareholder regarding the Common Shares, object of this Plan, until the date these Common Shares are effectively issued by the Company to the Holder or, as the case may be, the Holder's Beneficiary. Once the Common Shares have been issued by the Company to the Holder, the latter enjoys, in his capacity as shareholder, the same rights as the other shareholders of the same series in the Company, and such Common Shares shall be subject to the provisions of the Articles of Association (including but not limited to the share transfer restrictions).

7 **Provisions regarding Israeli Holders**

7.1 Notwithstanding anything stipulated in the Plan, the following conditions shall take precedence over any provision of the Plan in relation to Holders who are employees, officers, directors, consultants and/or advisors ("**Nosei Misra**" - as such term is defined in the Israeli Companies Law) of a Group Company residing and exercising their employment, mandate or function in Israel (hereinafter the "**Israeli Participant**").

7.2 Warrants granted under the Plan to an Israeli Participant may contain such terms as will allow the Warrants and the Common Shares acquired pursuant to the exercise of such Warrants to be recognized (hereinafter "**Eligible Warrants**") pursuant to Section 102 of the Israel Income Tax Ordinance (New Version), as amended (the "**Ordinance**") and to comply with the Ordinance and its regulations and the Income Tax Rules (Tax Benefits in Share Issuances to Employees) 5363-2003 (the "**Rules**").

7.3 Eligible Warrants, Warrants and/or Common Shares, as the case may be, shall be held in escrow for the benefit of such Israeli Participant by an Israeli Trustee appointed by the Company to hold in trust, the Eligible Warrants, Warrants and/or the (underlying) Common Shares issued upon exercise of such Warrants, on behalf of Israeli Participant(s) (the "**Trustee**").

7.4 Application of section 102 of the Ordinance:

7.4.1 Warrants and/or Common Shares, as the case may be, granted to Israeli Participants who are deemed to be a "**Controlling Shareholder**", as such term is defined in Section 32(i) of the Ordinance, or any Israeli resident serving as a consultant of the Company or an Israeli resident affiliate of the Company, and is not entitled to receive stock options under Section 102 of the Ordinance, shall be subject to Section 3(i) of the Ordinance, as shall apply from time to time. The Board of Directors shall have the absolute discretion to decide whether Warrants and/or Common Shares granted pursuant to Section 3(i) of the Ordinance shall be held with the Trustee.

7.4.2 Warrants and/or Common Shares, as the case may be, may be granted under Section 102 of the Ordinance to an Israeli tax resident who is an employee or a director of the Company or an Israeli affiliate of the Company, on behalf of whom a stock option is granted under Section 102 of the Ordinance.

7.4.3 The Trustee and each Israeli Participant in the Plan shall comply with the Ordinance and Rules and with the trust agreement entered into between the Company and the Trustee.

7.4.4 Without derogating from the aforementioned, the Board of Directors shall have the authority to determine the specific procedures and conditions of the trusteeship with the Trustee in a separate agreement between the Company and the Trustee.

7.4.5 The Eligible Warrants, Warrants and/or Common Shares, as the case may be, and any underlying rights, shall be issued to and held by the Trustee for the benefit of the Israeli Participant in accordance with the provisions of Section 102 of the Ordinance (under the tax route chosen by the Company) and the provisions of the Rules at least for the period required by the Ordinance and the Rules, or such other period as may be required by the Israeli Tax Authority ("**ITA**"). All rights accruing out of and/or resulting from the Eligible Warrants, Warrants and/or Common Shares, as the case may, including, but not limited to bonus shares, shall be vested with the Trustee until the end of the holding period, if and to the extent prescribed by the Ordinance and/or the Rules.

7.4.6 After the required holding period and subject to any further period included in this Plan, or the warrant agreement with the Israeli Participant, the Trustee may release the Eligible Warrants, Warrants and/or Common Shares, as the case may be to the Israeli Participant only after the receipt by the Trustee of an acknowledgment from the ITA that the Israeli Participant has paid or will pay any applicable tax due pursuant to the Ordinance and Rules.

7.4.7 The validity of any order given to the Trustee by the Israeli Participant shall be subject to the approval of the Company. The Company shall render its decision regarding whether to approve orders given by any Israeli Participant to the Trustee within a reasonable period of time. The Company shall not be required to approve any order which is incomplete, is not in accordance with the provisions of this Plan and the relevant warrant agreement or which the Company believes should not be executed for any reasonable reason. The Company shall notify the Israeli Participant of the reason for not approving his order. Approval by the Company of any order given to the Trustee by an Israeli Participant shall not constitute proof of the Company's recognition of any right of such Trustee.

7.4.8 In the event a stock dividend and/or bonus shares is declared on the Eligible Warrants, Warrants and/or Common Shares, such dividend shares shall be subject to the provisions of this Plan and the holding period for such dividend shares shall be measured from the commencement of the holding period for the Eligible Warrants, Warrants and/or Common Shares, as the case may be, from which the dividend was declared.

7.4.9 According to today's laws, the exemption under Section 102 of the Ordinance shall be forfeited and the Israeli Participant shall be required to pay any applicable tax promptly at such time as (i) the Company or the Israeli Participant fail to comply with one or more of the conditions for the exemption as required by the Ordinance, Rules or ITA; or (ii) the ITA withdraws or cancels the exemption for the Plan or for the particular Israeli Participant_ Notwithstanding the loss of an exemption, the Trustee shall continue to hold the Eligible Warrants, Warrants and/or Common Shares, as the case may be (to the extent the Warrant remains exercisable following termination of employment) for the remainder of the applicable holding period under Section 102 of the Ordinance.

7.4.10 Notwithstanding the aforesaid, an Israeli Participant shall not be entitled to the issuance or exercise the Eligible Warrants, Warrants and/or Common Shares, including, but not limited to declared dividends and/or bonus shares, as the case may be, prior to the end of the holding period by the Trustee, in accordance with the tax route elected by the Company,

7.5 All tax, duties and levies liabilities regarding the issue and/or exercise and/or the transfer, waiver, or expiration and/or the disposal of the Eligible Warrants, Warrants and/or Common Shares, including, but not limited to declared dividends and/or bonus shares, as the case may be, shall be borne by the Israeli Participant and in the event of death of such Israeli Participant, by his/her Beneficiaries, all in accordance with the tax route elected by the Company.

7.6 Neither the Company nor any of its Subsidiaries nor the Trustee shall be required to bear the aforementioned taxes, duties and/or levies liabilities, directly or indirectly, nor shall they be required to gross up such taxes, duties and/or levies liabilities in the Israeli Participant's salaries or remuneration. The applicable taxes, duties and/or levies liabilities shall be deducted from the proceeds of disposal of the Eligible Warrants, Warrants and/or Common Shares or shall be paid to the Trustee or to the Company, as the case may be, by the Israeli Participant. The Company is also entitled to withhold taxes, duties and/or levies liabilities in accordance with relevant law, rules and regulations.

7.7 Without derogating from the above, the Eligible Warrants, Warrants and/or Common Shares which are granted to Israeli Participants shall be subject to the provisions of Section 102 of the Ordinance, as shall apply from time to time, and the Rules promulgated thereunder. The Board of Directors shall have the absolute discretion to choose between any available tax routes to the Israeli Participant under Section 102 of the Ordinance, subject to the provisions of the Ordinance.

7.8 The Israeli Participant shall agree and undertake to indemnify the Trustee and the Company and its Subsidiaries and hold each of them harmless against and from any taxes, duties and/or levies liability, including interest and/or fines of any type and/or linkage differentials in respect of such taxes, duties and/or levies liability and/or withheld tax and penalties thereon, which may be incurred as a result of the granting or exercise of an Eligible Warrant or the issuance of Common Shares pursuant to such Warrants.

7.9 The Company's obligation to deliver Common Shares upon the exercise of Warrants is subject to payment (or provision of payment satisfactory to the Board of Directors) by the Israeli Participant of all taxes, duties and/or levies liability due under any applicable law.

7.10 The ramifications of any future modification of any applicable law regarding the taxation of Eligible Warrants, Warrants and/or Common Shares granted to Israeli Participants shall apply to the Israeli Participants accordingly and such Israeli Participants shall bear the full cost thereof, unless such modified laws expressly provide otherwise. For the avoidance of doubt, should the applicability of such taxing arrangements to this Plan or to securities issued in the framework thereof be conditioned on an application by the Company or by the Trustee that same shall apply, the Company shall be entitled to decide, at its absolute discretion, whether to apply such taxing arrangements and to instruct the Trustee to act accordingly.

7.11 During the required holding period, the Israeli Participant shall not release from trust or sell, assign, transfer or give as collateral, the Common Shares issuable upon the exercise or (if applicable) vesting of a 102 trustee award and/or any securities issued or distributed with respect thereto, until the expiration of the required holding period. Notwithstanding the above, if any such sale, release or other action occurs during the required holding period it may result in adverse tax consequences to the Israeli Participant under Section 102 of the Ordinance and the Rules, which shall apply to and shall be borne solely by such Israeli Participant.

8 Privacy and processing of Personal Data

To enable the proper set-up and management of the Plan and the (electronic) register of Warrant holders and the (electronic) share register of the Company, information about each Holder will need to be collected and used. For Holders who are natural persons, this Clause 8 sets out the obligations of the Company and the rights of each of the Holders regarding this collection and use, and provides the legally required information in this respect.

8.1 Identity of the person responsible for Holders' Personal Data.

The Company is the so-called "Controller", i.e. the person responsible for the collection and use of Personal Data as is necessary for the setting-up, implementation, administration and management of the Plan, the (electronic) register of Warrant holders and the (electronic) share register of the Company.

8.2 Nature of the Personal Data

The following items of information relating to each of the Holders will be collected and used:

(i) identification data (e.g. name, contact details);

(ii) electronic identification data;

(iii) personal characteristics (e.g. date of birth, gender, nationality);

(iv) employer's or contractor's identity;

(v) preferred language;

(vi) financial data (e.g. bank account); and

(vii) details of all Warrants, underlying Shares and all other entitlement awarded, cancelled, purchased, vested, unvested or outstanding,

together the "Personal Data".

8.3 Why and how Personal Data is collected and used

The Personal Data collected by way of the Company's HR systems, any Warrant agreement or acceptance form will be used exclusively for the purposes of the setting-up, implementation, administration and management of the Plan and the maintenance of the (electronic) register of Warrant holders and (electronic) share register of the Company.

8.4 Other persons having access to the Personal Data and purpose thereof

The Controller can transfer the Personal Data to the following categories of recipients:

(i) any service provider designated by the Controller to collect or use Personal Data on behalf of the Controller in accordance with this Clause 8 for the purposes of implementing, administrating and managing the Plan and, if applicable, the (electronic) register of Warrant holders and (electronic) share register of the Company (the "**Processors**"); and

(ii) regulatory authorities for complying with legal obligations in connection with the Plan.

Such recipients may be located in jurisdictions outside the European Economic Area that offer an adequate level of personal data protection, in particular Israel. For the avoidance of doubt, Israel has been recognised by the European Commission as a country located outside the European Economic Area that does offer an adequate level of personal data protection.

8.5 Legal basis allowing the Company to collect and use Personal Data

With respect to the setting-up, implementation, administration and management of the Plan and the (electronic) register of Warrant holders and (electronic) share register of the Company, the collection, processing and use of the Personal Data is necessary to perform Company's contractual obligations towards the Holders. If the Personal Data of a Holder cannot be collected, processed or used, this Holder cannot participate in the Plan.

8.6 Rights of the Holders

The Holders can exercise their right to request access to and rectification or erasure of their Personal Data or restriction of processing concerning the Holders or to object to processing as well as the right to data portability by sending a written and signed request to the Company's registered office at Rue Edouard Belin 12, 1453 Mont-Saint-Guibert, Belgium, for the attention of Ms. Maya Shmailov or by email to maya.shmailov@nyxoah.com.

Finally, if Holders are not satisfied with how the Company processes their Personal Data, they can contact the Company's Data Protection Officer at Rue Edouard Belin 12, 1453 Mont-Saint-Guibert, Belgium, for the attention of Ms. Maya Shmailov or by email to maya.sh ma ilov@nyxoa h .com.

Holders also always have the right to make a complaint to the competent data protection authority in the EU Member State of their habitual residence, their place of work or of an alleged infringement of the applicable data protection rules.

8.7 Storage period of the Personal Data

Personal Data will be stored for a period of ten (10) years following the later of (i) the termination of the Plan or (ii) the end of a Holder's participation in the Plan.

9 **Miscellaneous**

9.1 Amendments, suspension and termination of this Plan

The terms and conditions set out in this Plan may entirely or partially be amended, modified, suspended or terminated by the shareholders' meeting at any time, except with regard to the Exercise Period which, as stated in Clause 6.21 of this Plan, can be modified by the Board of Directors. The amendment, suspension or termination of this Plan may not modify or limit the rights and obligations under a granted Warrant without the consent of the concerned Holder. No warrant can be granted when this Plan is suspended or after the termination of this Plan.

9.2 National legislation

Notwithstanding any provision of the Plan, the Board of Directors may modify or extend the provisions of the Plan and the conditions of the Warrants to the extent that it considers this to be necessary or preferable to take into account, to limit the disadvantageous consequences of, or to be in compliance with foreign legislation, including, but not limited to, tax and financial legislation applicable to the Holder, to the extent that the terms and conditions of the Warrants granted to such Holder are not more advantageous than the terms and conditions of the Warrants granted to the other Holders.

9.3 Costs and taxes

The costs regarding the capital increase shall be incurred by the Company. Seal rights, stock exchange taxes and other similar rights and taxes imposed as a result of the exercise of the Warrants and the delivery of new Shares are borne by the Holders. Any other possible taxes or rights due as a result of the grant of Warrants will also be borne by the Holders.

The costs regarding the issuance of the Warrants and the capital increase relating to the issuance and exercise of the Warrants are borne by the Company.

Holders (or, if applicable, his/her Beneficiaries) will have to bear any taxes (including but not limited to income taxes, capital gains taxes and stock exchange taxes) and employee or self-employed social security contributions due in connection with (a) the grant, exercise, and or transfer of the Warrants and (b) the delivery and ownership of the new Common Shares, in accordance with applicable tax and social security legislation.

The Company or a Subsidiary shall, upon granting of the Warrants pursuant to this Plan, levy any withholding tax provided for in the relevant applicable tax and/or social security laws, as provided for therein.

9.4 Employment conditions

No provision of this Plan can be construed as creating an obligation of employment (either by way of an employment agreement, an appointment as director or a services agreement) between a Group Company and a Holder or an obligation for the Board of Directors to offer Warrants. Upon termination of the employment, the Holder shall in no event be entitled to demand damages within the framework of this Plan. The foregoing also applies, but is not limited to, the application of the tax legislation.

9.5 Nullity of a provision

The nullity or unenforceability of any provision of this Plan does not in any way affect the validity or enforceability of the remaining provisions of this Plan. In this case, the invalid or unenforceable provision will be replaced by an equivalent valid and enforceable provision having a similar economic effect for the parties concerned,

9.6 Applicable law

This Plan and any non-contractual obligations arising out of or in connection with it shall be governed by and construed in accordance with Belgian law.

9.7 Competent courts

The courts of Brussels (Belgium) have exclusive jurisdiction to settle any dispute arising out of or in connection with this Plan (including a dispute relating to non-contractual obligations arising out of or in connection with this Plan).

9.8 Notices

Any notice to the Holders (and, if applicable, his/her Beneficiaries) shall be validly made to the address mentioned in the register of warrant holders.

Any notice to the Company, shall be validly made to the attention of the Board of Directors or the secretary of the Company at the address of the registered office of the Company.

Address modifications must be notified immediately by the Holders (and, if applicable, his/her Beneficiaries) to the Company in accordance with this provision.

* *

Adopted by the Board of Directors on 16 September 2016, subject to approval by the shareholders' meeting.

On behalf of the Board of Directors:

Robert Taub	**Janke Dittmer**
Common Director and Chairman	B Director and Vice-Chairman

Exhibit 10.7

NYXOAH SA

Rue Edouard Belin 12

1435 Mont-Saint-Guibert

Register of Legal Brabant wallon

VAT: BE 0817.149.675

(the **"Company"**)

2020 WARRANTS PLAN

1 Definitions

For the purposes of this Plan, the following terms shall have the following meaning:

"Articles of Association" means the articles of association of the Company.

"Beneficiary" means a person duly designated by the Holder, be it his spouse or his legal heirs, to exercise the rights of the Holder under this Plan after the decease of the Holder. Designation, revocation and re-designation of a Beneficiary shall be done in writing. In the absence of any valid designation, the heirs of the Holder will, in accordance with the applicable laws of inheritance, be deemed to be the Beneficiary. In case there are several heirs, all heirs acting jointly, or a person designated by all heirs acting jointly, will be deemed to be the Beneficiary.

"Board of Directors" means the board of directors of the Company.

"Change of Control" means any change of Control of the Person concerned, including (i) the loss of the exclusive Control, (ii) the loss of one or more of the (three) criteria used in the definition of Control, (iii) in case of common Control, the loss of common Control or the modification of the Shareholders of the common Control, including the replacement of any Person holding the common Control, (iv) in case of succession of a Person being a natural person, the change of Control from such Person to the heirs thereof, (v) in case of nomination of a guardian, provisional administrator or similar act on a Person, being a natural person, the change of Control from such Person to the guardian or administrator thereof; provided, however, that a Change of Control does not include a change of Control resulting from a person acquiring securities which are quoted on an internationally recognised stock exchange..

"Company" means NYXOAH SA, a company limited by shares subject to Belgian law ("*société anonyme*"), with registered office at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium and registered with the Register of Legal Entities (Brabant wallon) under number 0817.149.675.

“**Control**” and any derivation thereof, means with respect to any Person, any other Person, who has, directly or indirectly, (i) the majority of the outstanding voting interests in the Person concerned, (ii) the power, by contract or otherwise, to exercise, legally or factually, a determining influence on the appointment or dismissal of the majority of the directors, trustees, general partners or other governing body as applicable, in the Person, or (iii) the power, by contract or otherwise, to exercise, legally or factually, a determining influence on the orientation of the Person’s management.

“**Controller**” has the meaning as set out in Clause 8.1.

“**Controlling Shareholder**” has the meaning as set out in Clause 7.

“**Deemed Liquidation Event**” means (i) sale, lease transfer, exclusive license or other disposition of all or substantially all of the Company’s assets (including for the avoidance of doubt the material intellectual property rights of the Company and its Subsidiaries (if any)) or Shares, in a single transaction or series of related transactions, (ii) transaction or series of transactions resulting in a Change of Control over the shareholding of the Company (meaning a transaction as a result of which a third party acquires the exclusive Control over the company), or (iii) merger, reverse merger or consolidation (with or into another entity) in which outstanding Shares of the Company or Subsidiary are exchanged for securities or other consideration issued, or caused to be issued, by the acquiring company or its Subsidiary and in which the shareholders of the Company immediately prior to the transaction do not own a majority of the shares of the surviving entity.

“**Eligible Warrants**” has the meaning as set out in Clause 7.

“**End of Mandate**” means the effective date of the termination, for whatsoever reason, of (i) the employment contract between the concerned Holder and any Group Company, (ii) the director’s mandate exercised by the concerned Holder with any Group Company, or (ii) the services or other collaboration agreement between the concerned Holder and any Group Company. Such termination will not imply the “End of Mandate”, however, if the termination of the relationship with the concerned Group Company is accompanied by the simultaneous entering into of an employment agreement with another Group Company, by the simultaneous appointment as a director of another Group Company, or by the simultaneous entering into of a services agreement with another Group Company.

“**Exercise Period**” means any of the periods during which, in accordance with Clause 6.2 of this Plan, the Holder can exercise Warrants granted to him/her so as to obtain Shares.

“**Final Exercise Date**” means the last date of the last Exercise Period.

“**Group Companies**” means the Company and its Subsidiaries from time to time.

“**Holder**” means a physical person or a legal entity to whom the Company has granted Warrants and who/that has completely or partially accepted these Warrants.

“**IPO**” means an initial public offering of the Company’s Shares.

"Israeli Participant" has the meaning as set out in Clause 7.

"ITA" has the meaning as set out in Clause 7.

"Liquidation Event" means a liquidation, dissolution, winding up or bankruptcy of the Company.

"Ordinance" has the meaning as set out in Clause 7.

"Person" means any natural person, corporation, general partnership, limited partnership, limited liability company, proprietorship, investment fund, other business organisation, trust, union or association.

"Personal Data" has the meaning as set out in Clause 8.2.

"Plan" means this 2020 Warrants Plan regarding warrants issued by the Company.

"Processor" has the meaning as set out in Clause 8.4.

"Rules" has the meaning as set out in Clause 7. "Share" means any common share in the Company.

"Subsidiary" has the meaning as set out in Article 1:15 of the Code of Companies and Associations.

"Trustee" has the meaning as set out in Clause 7.

"Warrant" means a subscription right regarding a newly to be issued Share, issued and granted on the basis of this Plan.

2 Object and purpose of the Plan

Each Warrant shall entitle its Holder to subscribe for one (1) Share upon exercise of the Warrant, under the terms and conditions set out in this Plan.

In the framework of this Plan no more than five hundred fifty thousand (550,000) Warrants can be issued. Consequently, the Company can issue up to five hundred fifty thousand (550,000) Shares as a result of the exercise of the Warrants.

The purpose of this Plan is to advance the interests of the Company and its shareholders by enhancing the Group Companies' ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company or any other Group Company by providing such persons with equity ownership opportunities and performance-based incentives and thereby better aligning the interests of such persons with those of the Company and its shareholders.

3 Granting and acceptance of the Warrants

The Warrants can be granted to employees, officers, directors, consultants and advisors of any Group Company and any persons who have accepted an offer for employment or to provide professional services to a Group Company. The Warrants are granted by the Board of Directors, except for grants of Warrants to directors of the Company which must be approved by the shareholders' meeting.

The total number of Holders shall, in any event, be lower than one hundred fifty (150).

Each Holder has the possibility to accept or to refuse the individual grant of Warrants by the Board of Directors. The acceptance of Warrants needs to be done in writing by checking the option acceptance, mentioning the number of accepted Warrants, on the answer form prepared for these purposes. The answer form must be completed and signed by the Holder and be delivered to the Company within sixty (60) days after the date of the grant, or prior to any earlier date stated therein. If the Holder does not accept in writing the offer of Warrants prior to the ultimate date stated in the answer form, he/she is deemed to have refused the offer of Warrants.

Notwithstanding the foregoing, the offering and acceptance of Warrants may also be included in a specific warrant agreement, or inserted in another agreement signed by the Company and the Holder.

Warrants that have been granted but that are refused by the Holder or that are not timely accepted in writing, shall become automatically null and void and cannot be offered again.

4 Terms and conditions of the Warrants

4.1 Warrant price

The Warrants shall be granted by the Company free of charge.

4.2 Vesting

4.2.1 When granting the Warrants, the Board of Directors may freely decide if, when and to which extent the attributed Warrants will effectively vest for the Holders.

4.2.2 Except as explicitly provided otherwise in this Plan and unless the Board of Directors (or the shareholders' meeting of the Company for grants of Warrants to directors of the Company) decides otherwise at the time of the relevant grant of the Warrants and subject to the End of Mandate (i) one third of the Warrants granted to and accepted by a Holder (whereby fractions of Warrants shall be rounded down) shall be deemed definitively vested on the date of the granting of the Warrants, (ii) one third of the Warrants granted to and accepted by a Holder (whereby fractions of Warrants shall be rounded down) shall be deemed definitively vested on the first anniversary of the date of the relevant grant of the relevant Warrants, and (iii) the remainder of the Warrants granted to and accepted by a Holder shall be deemed definitively vested on the second anniversary of the date of the relevant grant of the relevant Warrants.

4.2.3 The Board of Directors (subject to the approval by the shareholders' meeting of the Company regarding any Warrants granted to directors of the Company) can also decide to modify the vesting conditions after the granting of Warrants, provided that the rights of the Holder may not be restricted without the latter's consent. Prior to the End of Mandate, the Board of Directors will, for example, in mutual agreement with the Holder, be able to allow that all or a part of the Warrants that have not yet definitively vested at the End of Mandate, are definitively vested.

4.3 Exercise price

4.3.1 Warrants granted prior to an IPO

The exercise price of each Warrant granted prior to an IPO shall be equal to the market value of one Share at the time of granting of the Warrants as determined by the Board of Directors and confirmed by the Company's auditor ("commissaire") or, if the Company has not appointed an auditor, an ad hoc auditor ("réviseur d'entreprise") or an external accountant ("expert-comptable externe") designated by the Board of Directors, provided that the exercise price of one (1) Warrant cannot be lower than the book value of the existing Shares as it appears in the most recently approved annual accounts of the Company.

4.3.2 Warrants granted after an IPO

Unless the Board of Directors at the time of the grant of the Warrant determines a higher exercise price, the exercise price of a Warrant granted after an IPO will be equal to the lowest of the following prices:

(i) the last closing price of the Company's Share ,on the stock exchange where the Company's shares are (first) listed, prior to the date on which the Warrant is offered; or

(ii) the average closing price of the Company's Share, on the stock exchange where the Company's shares are (first) listed, over the thirty (30) day period preceding the date on which the Warrant is offered.

4.3.3 The exercise price may never be below the par value of the existing Shares at the date on which the Warrants were issued.

4.3.4 Upon exercise, the portion of the exercise price up to the par value of the existing Shares needs to be recorded as capital. The portion of the exercise price exceeding the par value of the existing Shares needs to be recorded on a separate account unavailable for distribution called "Issuance premiums".

4.4 Duration of the Warrants

4.4.1 The Warrants have a duration of ten (10) years as from the date of the extraordinary shareholders' meeting of the Company deciding on the issuance of the Warrants.

4.4.2 Any Warrant shall immediately become automatically null and void if not exercised in accordance with the modalities provided for in this Plan (i) within ten (10) years after the date of the issuance of the Warrant, (ii) prior to a bankruptcy of the Company, (iii) in case of a Liquidation Event other than bankruptcy, prior to the effective date of such Liquidation Event, or (iv) in case of a Deemed Liquidation Event, prior to the completion of such Deemed Liquidation Event, unless the Board of Directors (or the shareholders' meeting of the Company for grants of Warrants to directors of the Company) decides otherwise at the time of the relevant grant of the Warrants.

4.5 Nature

The Warrants are and will remain registered. They will be recorded in the register of warrant holders, which will be kept by the Company at the registered office, mentioning the identity of each Holder and the number of Warrants held by such Holder.

4.6 Adjustments

4.6.1 Modification of the Company's capital structure Contrary to Article 7:71 of the Code of Companies and Associations and without prejudice to the exceptions provided for by law, the Company shall retain the right to take decisions and close transactions that could have an influence on its capital, the distribution of profit or the liquidation bonuses, or that could possibly have another influence on the Holders' rights, except if such decisions or transactions only are aimed at diminishing the Holders' benefits.

In case the rights of the Holder are affected by such decision or transaction, the Holder will not be entitled to a modification of the exercise price or the exercise conditions, nor to any other form of financial or other compensation. The Board of Directors may, at its own discretion, make amendments to the number of Shares to which one Warrant relates and/or to the exercise price, however. As soon as reasonably possible, the Company will inform the Holder of any such amendment by way of a written notification.

4.6.2 Reorganizations of Shares

In the event that the Company shall (i) sub-divide its Shares into a larger number of Shares, (ii) combine its Shares into a smaller number of Shares, (iii) increase or decrease the number of Shares by a reclassification of Shares (without an increase or decrease of the Company's share capital), then the number of Shares to be issued upon exercise of the Warrant after the occurrence of one of such events shall be adjusted (if and to the extent required) so that, after giving effect to such adjustment, the Holder of the Warrant shall be entitled to receive the number of Shares upon exercise of the Warrant that such Holder would have owned or have been entitled to receive had this Warrant been exercised immediately prior to the occurrence of the event concerned. An adjustment made pursuant to this Clause 4.6.2 shall become effective immediately after the effective date of the event concerned. The Company shall inform the Holders of such adjustment by means of a notice as soon as practicable after the effective date of the event concerned.

4.6.3 Mergers, de-mergers

In the event that there shall be (i) a merger ("*fusion*") of the Company with or into another person or entity whereby the Company is not the surviving entity, or (ii) a de-merger ("*scission*") of the Company, whereby in both (i) and (ii) the Shares of the Company are exchanged into shares, other securities, cash or other property of one or more other persons, then the Shares to be issued upon exercise of the Warrant after the occurrence of one of such events shall be adjusted (if and to the extent required) so that, after giving effect to such adjustment, the Holder of the Warrant shall upon exercise of the Warrant be entitled to receive the number of shares, other securities, cash or other property of the successor or acquiring persons that such Holder would have owned or have been entitled to receive had this Warrant been exercised immediately prior to the occurrence of the event concerned. An adjustment made pursuant to this Clause 4.6.3 shall become effective immediately after the effective date of the event concerned. The Company shall inform the Holders of such adjustment by means of a notice as soon as practicable after the effective date of the event concerned.

5 End of Mandate - Transfer of the Warrants - Adjustments

5.1 End of Mandate

5.1.1 Unless the Board of Directors (or the shareholders' meeting of the Company for grants of Warrants to directors of the Company) decides otherwise upon granting of the Warrants, at the End of Mandate of a Holder:

(i) all Warrants that have been granted to such Holder but have not yet vested in accordance with this Plan, shall become automatically null and void, unless, prior to the End of Mandate, it is expressly agreed otherwise in writing between the Company and the Holder in accordance with Clause 4.2.3 of this Plan; and

(ii) all Warrants that have been granted to such Holder and have vested in accordance with this Plan, shall remain with such Holder for a period of 3 months after the End of Mandate and all Warrants that are not exercised prior to the expiry of such 3 months' period shall become automatically null and void.

5.1.2 Notwithstanding Clause 5.1.1 of this Plan, if the agreement or other relationship between the Holder and a Group Company is terminated for "cause", all unexercised Warrants (even those already vested) that have been granted to such Holder shall become automatically null and void at the End of Mandate of such Holder. For the purposes of this Clause 5.1.2, "cause" means wilful misconduct by the Holder or wilful failure by the Holder to perform his/her responsibilities to the Group Company (including, without limitation, breach by the Holder of any provision of any employment, consulting, advisory, non-disclosure, non-competition or other similar agreement between the Holder and the Group Company) as determined by the Company, which determination shall be conclusive. The Holder shall be considered to have been discharged for "cause" if the Company determines, within 30 days after the Holder's resignation, that discharge for cause was warranted.

5.2 Member of the group

Unless the Board of Directors decides otherwise, all Warrants that have not yet vested in accordance with Clause 4.2 of this Plan shall become automatically null and void in case the company (other than the Company), of which the Holder is an employee, officer, director, consultant or advisor, is no longer Controlled by the Company.

5.3 Disability

5.3.1 If a Holder becomes fully disabled prior to the Final Exercise Date, all Warrants of the disabled Holder that have vested already in accordance with Clause 4.2 of this Plan prior to the date on which he/she became fully disabled shall immediately become exercisable until the first anniversary of the date on which the relevant Holder became fully disabled. All such Warrants that have not been exercised (or could not yet be exercised) in accordance with the modalities defined in this Plan prior to the first anniversary of the date on which the relevant Holder became fully disabled shall become automatically null and void.

5.3.2 All Warrants that have not yet vested in accordance with Clause 4.2 of this Plan prior to the date on which the relevant Holder became fully disabled shall become automatically null and void.

5.4 Decease

5.4.1 If a Holder deceases, all Warrants of the deceased Holder that have vested already in accordance with Clause 4.2 of this Plan at the time of his/her decease, are transferred to the Beneficiaries of the Warrant Holder, and they shall immediately become exercisable until the first anniversary of the decease of the relevant Holder. All such Warrants that have not been exercised (or could not yet be exercised) in accordance with the modalities defined in this Plan prior to the first anniversary of the decease of the relevant Holder shall become automatically null and void.

5.4.2 All Warrants that have not yet vested in accordance with Clause 4.2 of this Plan at the time of the decease of the Holder shall become automatically null and void.

5.5 Transferability

5.5.1 Unless the Board of Directors decides otherwise, the Warrants are not transferable *inter vivos* once they have been granted to a Holder, and may not be pledged or encumbered with any security, pledge or other right in rem in any other way, either voluntarily, by operation of law or otherwise.

5.5.2 Warrants that have been pledged or encumbered in violation of the preceding, shall become automatically null and void.

6 Exercise of the Warrants

6.1 General

6.1.1 The Warrants can only be exercised by the Holder if they have effectively vested pursuant to Clause 4.2 of this Plan and in accordance with any additional exercise restrictions decided by the Board of Directors upon the respective grant of the Warrants. The Warrants that consequently become exercisable must be exercised in accordance with the exercise modalities provided for in this Plan.

6.1.2 In case the Warrants, that are not yet exercisable in accordance with the terms and conditions of the Plan, become prematurely exercisable in accordance with Article 7:71 of the Code of Companies and Associations and are effectively exercised in accordance with such Article, the Shares that are issued as a result of such exercise will not be transferable until the moment that the Warrants would have been exercisable pursuant to the terms and conditions of the Plan, unless express approval is obtained from the Company and without prejudice to any other applicable share transfer restrictions (including, but not limited to, those set out in the Articles of Association).

6.1.3 In case Warrants that are effectively vested would not be exercised on the last day of the last Exercise Period during the duration of the Warrants as set out in Clause 4.4 of this Plan, such Warrants shall become automatically null and void.

6.2 Warrant Exercise Period

6.2.1 Without prejudice to Clause 6.1.1 of this Plan,

(i) Warrants may be exercised during the following periods:

- from 1 to 31 March; and
- from 1 to 30 September,

of each year during which they are valid and exercisable; and

(ii) in the event of the End of Mandate of a Holder, such Holder can exercise his/her Warrants during a period of 3 months immediately following the End of Mandate.

Within the legal boundaries, the Board of Directors can decide to amend the Exercise Periods, however, without being able to shorten them. For example, in order to avoid insider trading following an IPO, the Board of Directors can decide to introduce closed periods, during which the Warrants cannot be exercised. If such closed periods would fall within the aforementioned Exercise Periods, the Board of Directors can determine one or more additional Exercise Periods as compensation and communicate the new Exercise Periods in writing to the Warrant Holders.

Following an IPO, Warrants cannot be exercised and/or the Shares cannot be traded in the event that the Warrant Holder has inside information. In accordance with article 7, paragraph 1, a) of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse, “inside information” means information of a precise nature, which has not been made public, relating, directly or indirectly, to the Company or to one or more financial instruments issued by the Company, and which, if it were made public, would be likely to have a significant effect on the prices of those financial instruments or on the price of related derivative financial instruments.

Holders whose exercise rights are limited as a consequence of the conditions of this Plan or of any “Dealing Code” of the Company, are never entitled to any indemnification or compensation from the Company.

The exercise of the Warrants at the exercise price is unconditional.

6.2.2 Liquidation Event, Deemed Liquidation Event or IPO

Notwithstanding Clauses 4.2, 6.1.1 and 6.2.1 of this Plan, and unless the Board of Directors (or the shareholders’ meeting of the Company for grants of Warrants to directors of the Company) decides otherwise at the time of the relevant grant of the Warrants, the Warrants will immediately vest and be exercisable during at least ten (10) business days (i) prior to the effective date of a Liquidation Event other than bankruptcy, (ii) prior to the completion of a Deemed Liquidation Event, and (iii) in the event of a IPO, prior to the admission of all or part of the Shares to an official listing of a stock exchange in a member state of the European Union, in the United States of America or in any regulated market declared equivalent to these markets by Royal Decree, it being understood that such vesting and exercise of the Warrants shall be conditional upon the effectiveness of such Liquidation Event, Deemed Liquidation Event or IPO. As the case may be, the provisions in the Articles of Association regarding pre-emption, tag-along and drag along rights shall apply.

6.3 Exercise restriction

The Board of Directors (or the shareholders' meeting of the Company for grants of Warrants to directors of the Company) may impose additional restrictions and conditions to the exercisability of the Warrants at the time of grant of the Warrants.

6.4 Exercise modalities

In order to exercise a Warrant, at the latest on the Final Exercise Date, the Company needs to receive a written notice of exercise of the Warrants. The notification shall take place by registered mail, against receipt confirmation, or by personal delivery to the Board of Directors or the secretary of the Company at the registered office of the Company. The notice shall be signed by the Holder (or, if applicable, his/her Beneficiaries) and must explicitly state the number of Warrants being exercised and the number of Shares consequently being subscribed to. If the Warrants are exercised by one or more Beneficiaries, the notice of exercise needs to be accompanied by an appropriate proof of the right of this person or these persons to exercise the Warrants.

The full amount of the exercise price of the exercised Warrants needs to be paid in cash and deposited by wire transfer on a blocked account of the Company of which the bank account number is communicated by the Board of Directors. This payment shall take place within ten (10) business days after having received the aforementioned communication of the bank account number from the Board of Directors, or within ten (10) business days after the date of the notice of exercise in the event that the bank account number concerned has already previously been communicated by the Board of Directors.

6.5 Issuance of Shares

6.5.1 The Company will only be obliged to issue Shares as a result of the exercise of Warrants if such Shares are fully paid up and the other conditions set out in this Plan have been fulfilled.

6.5.2 The Shares will be issued as soon as reasonably possible, taking into account administrative formalities, after the end of the Exercise Period during which the concerned Warrant was validly exercised. To this effect, the Board of Directors or one of the directors will acknowledge before a notary public that the capital was increased in accordance with Article 7:187 of the Code of Companies and Associations.

6.5.3 The Shares that are issued as a result of the exercise of the Warrants will be common shares in the Company and will be fully profit sharing as from the beginning of the business year during which the Shares are issued and the following financial years.

6.5.4 The Shares that are issued as a result of this exercise of Warrants shall be delivered in registered form and will be fully profit sharing as from the beginning of the financial year during which the Shares are issued and the following financial years.

6.5.5 At the option of the Company, and to the extent legally and practically possible, the Shares shall be delivered as registered shares, or in dematerialised form. In case the Holder (or, as the case may be, the Holder's Beneficiary) explicitly indicates in his/her/its notice of exercise the form in which he/she/it wants to see the Shares delivered, the Company will deliver the Shares in the form requested to the extent legally and practically possible and to the extent that this would be in accordance with the Articles of Association. The Company will inform the concerned Holder (or, as the case may be, the Holder's Beneficiary) of the form of delivery in due time.

6.5.6 After the issuance of the Shares in registered form, which are subscribed for through the exercise of Warrants, one or more directors of the Company will, as attorney-in-fact, register the Shares in the name of the subscriber in the Company's share register.

6.6 Rights as shareholders

The Holder or, as the case may be, the Holder's Beneficiary does not have any rights and privileges of a shareholder regarding the Shares, object of this Plan, until the date these Shares are effectively issued by the Company to the Holder or, as the case may be, the Holder's Beneficiary. Once the Shares have been issued by the Company to the Holder, the latter enjoys, in his capacity as shareholder, the same rights as the other shareholders in the Company, and such Shares shall be subject to the provisions of the Articles of Association (including but not limited to the share transfer restrictions).

7 Provisions regarding Israeli Holders

7.1 Notwithstanding anything stipulated in the Plan, the following conditions shall take precedence over any provision of the Plan in relation to Holders who are employees, officers, directors, consultants and/or advisors ("**Nosei Misra**" - as such term is defined in the Israeli Companies Law) of a Group Company residing and exercising their employment, mandate or function in Israel (hereinafter the "**Israeli Participant**").

7.2 Warrants granted under the Plan to an Israeli Participant may contain such terms as will allow the Warrants and the Shares acquired pursuant to the exercise of such Warrants to be recognized (hereinafter "**Eligible Warrants**") pursuant to Section 102 of the Israel Income Tax Ordinance (New Version), as amended (the "**Ordinance**") and to comply with the Ordinance and its regulations and the Income Tax Rules (Tax Benefits in Share Issuances to Employees) 5363-2003 (the "**Rules**").

7.3 Eligible Warrants, Warrants and/or Shares, as the case may be, shall be held in escrow for the benefit of such Israeli Participant by an Israeli Trustee appointed by the Company to hold in trust, the Eligible Warrants, Warrants and/or the (underlying) Shares issued upon exercise of such Warrants, on behalf of Israeli Participant(s) (the "**Trustee**").

7.4 Application of section 102 of the Ordinance:

7.4.1 Warrants and/or Shares, as the case may be, granted to Israeli Participants who are deemed to be a "**Controlling Shareholder**", as such term is defined in Section 32(i) of the Ordinance, or any Israeli resident serving as a consultant of the Company or an Israeli resident affiliate of the Company, and is not entitled to receive stock options under Section 102 of the Ordinance, shall be subject to Section 3(i) of the Ordinance, as shall apply from time to time. The Board of Directors shall have the absolute discretion to decide whether Warrants and/or Shares granted pursuant to Section 3(i) of the Ordinance shall be held with the Trustee.

7.4.2 Warrants and/or Shares, as the case may be, may be granted under Section 102 of the Ordinance to an Israeli tax resident who is an employee or a director of the Company or an Israeli affiliate of the Company, on behalf of whom a stock option is granted under Section 102 of the Ordinance.

7.4.3 The Trustee and each Israeli Participant in the Plan shall comply with the Ordinance and Rules and with the trust agreement entered into between the Company and the Trustee.

7.4.4 Without derogating from the aforementioned, the Board of Directors shall have the authority to determine the specific procedures and conditions of the trusteeship with the Trustee in a separate agreement between the Company and the Trustee.

7.4.5 The Eligible Warrants, Warrants and/or Shares, as the case may be, and any underlying rights, shall be issued to and held by the Trustee for the benefit of the Israeli Participant in accordance with the provisions of Section 102 of the Ordinance (under the tax route chosen by the Company) and the provisions of the Rules at least for the period required by the Ordinance and the Rules, or such other period as may be required by the Israeli Tax Authority ("**ITA**"). All rights accruing out of and/or resulting from the Eligible Warrants, Warrants and/or Shares, as the case may, including, but not limited to bonus shares, shall be vested with the Trustee until the end of the holding period, if and to the extent prescribed by the Ordinance and/or the Rules.

7.4.6 After the required holding period and subject to any further period included in this Plan, or the warrant agreement with the Israeli Participant, the Trustee may release the Eligible Warrants, Warrants and/or Shares, as the case may be to the Israeli Participant only after the receipt by the Trustee of an acknowledgment from the ITA that the Israeli Participant has paid or will pay any applicable tax due pursuant to the Ordinance and Rules.

7.4.7 The validity of any order given to the Trustee by the Israeli Participant shall be subject to the approval of the Company. The Company shall render its decision regarding whether to approve orders given by any Israeli Participant to the Trustee within a reasonable period of time. The Company shall not be required to approve any order which is incomplete, is not in accordance with the provisions of this Plan and the relevant warrant agreement or which the Company believes should not be executed for any reasonable reason. The Company shall notify the Israeli Participant of the reason for not approving his order. Approval by the Company of any order given to the Trustee by an Israeli Participant shall not constitute proof of the Company's recognition of any right of such Trustee.

7.4.8 In the event a stock dividend and/or bonus shares is declared on the Eligible Warrants, Warrants and/or Shares, such dividend shares shall be subject to the provisions of this Plan and the holding period for such dividend shares shall be measured from the commencement of the holding period for the Eligible Warrants, Warrants and/or Shares, as the case may be, from which the dividend was declared.

7.4.9 According to today's laws, the exemption under Section 102 of the Ordinance shall be forfeited and the Israeli Participant shall be required to pay any applicable tax promptly at such time as (i) the Company or the Israeli Participant fail to comply with one or more of the conditions for the exemption as required by the Ordinance, Rules or ITA; or (ii) the ITA withdraws or cancels the exemption for the Plan or for the particular Israeli Participant. Notwithstanding the loss of an exemption, the Trustee shall continue to hold the Eligible Warrants, Warrants and/or Shares, as the case may be (to the extent the Warrant remains exercisable following termination of employment) for the remainder of the applicable holding period under Section 102 of the Ordinance.

7.4.10 Notwithstanding the aforesaid, an Israeli Participant shall not be entitled to the issuance or exercise the Eligible Warrants, Warrants and/or Shares, including, but not limited to declared dividends and/or bonus shares, as the case may be, prior to the end of the holding period by the Trustee, in accordance with the tax route elected by the Company.

7.5 All tax, duties and levies liabilities regarding the issue and/or exercise and/or the transfer, waiver, or expiration and/or the disposal of the Eligible Warrants, Warrants and/or Shares, including, but not limited to declared dividends and/or bonus shares, as the case may be, shall be borne by the Israeli Participant and in the event of death of such Israeli Participant, by his/her Beneficiaries, all in accordance with the tax route elected by the Company.

7.6 Neither the Company nor any of its Subsidiaries nor the Trustee shall be required to bear the aforementioned taxes, duties and/or levies liabilities, directly or indirectly, nor shall they be required to gross up such taxes, duties and/or levies liabilities in the Israeli Participant's salaries or remuneration. The applicable taxes, duties and/or levies liabilities shall be deducted from the proceeds of disposal of the Eligible Warrants, Warrants and/or Shares or shall be paid to the Trustee or to the Company, as the case may be, by the Israeli Participant. The Company is also entitled to withhold taxes, duties and/or levies liabilities in accordance with relevant law, rules and regulations.

7.7 Without derogating from the above, the Eligible Warrants, Warrants and/or Shares which are granted to Israeli Participants shall be subject to the provisions of Section 102 of the Ordinance, as shall apply from time to time, and the Rules promulgated thereunder. The Board of Directors shall have the absolute discretion to choose between any available tax routes to the Israeli Participant under Section 102 of the Ordinance, subject to the provisions of the Ordinance.

7.8 The Israeli Participant shall agree and undertake to indemnify the Trustee and the Company and its Subsidiaries and hold each of them harmless against and from any taxes, duties and/or levies liability, including interest and/or fines of any type and/or linkage differentials in respect of such taxes, duties and/or levies liability and/or withheld tax and penalties thereon, which may be incurred as a result of the granting or exercise of an Eligible Warrant or the issuance of Shares pursuant to such Warrants.

7.9 The Company's obligation to deliver Shares upon the exercise of Warrants is subject to payment (or provision of payment satisfactory to the Board of Directors) by the Israeli Participant of all taxes, duties and/or levies liability due under any applicable law.

7.10 The ramifications of any future modification of any applicable law regarding the taxation of Eligible Warrants, Warrants and/or Shares granted to Israeli Participants shall apply to the Israeli Participants accordingly and such Israeli Participants shall bear the full cost thereof, unless such modified laws expressly provide otherwise. For the avoidance of doubt, should the applicability of such taxing arrangements to this Plan or to securities issued in the framework thereof be conditioned on an application by the Company or by the Trustee that same shall apply, the Company shall be entitled to decide, at its absolute discretion, whether to apply such taxing arrangements and to instruct the Trustee to act accordingly.

7.11 During the required holding period, the Israeli Participant shall not release from trust or sell, assign, transfer or give as collateral, the Shares issuable upon the exercise or (if applicable) vesting of a 102 trustee award and/or any securities issued or distributed with respect thereto, until the expiration of the required holding period. Notwithstanding the above, if any such sale, release or other action occurs during the required holding period it may result in adverse tax consequences to the Israeli Participant under Section 102 of the Ordinance and the Rules, which shall apply to and shall be borne solely by such Israeli Participant.

8 Privacy and processing of Personal Data

To enable the proper set-up and management of the Plan and the (electronic) register of warrant holders and the (electronic) share register of the Company, information about each Holder will need to be collected and used. For Holders who are natural persons, this Clause 8 sets out the obligations of the Company and the rights of each of the Holders regarding this collection and use, and provides the legally required information in this respect.

8.1 Identity of the person responsible for Holders' Personal Data.

The Company is the so-called "**Controller**", i.e. the person responsible for the collection and use of Personal Data as is necessary for the setting-up, implementation, administration and management of the Plan, the (electronic) register of Warrant Holders and the (electronic) share register of the Company.

8.2 Nature of the Personal Data

The following items of information relating to each of the Holders will be collected and used:

(i) identification data (e.g. name, contact details);

(ii) electronic identification data;

(iii) personal characteristics (e.g. date of birth, gender, nationality);

(iv) employer's or contractor's identity;

(v) preferred language;

(vi) financial data (e.g. bank account); and

(vii) details of all Warrants, underlying Shares and all other entitlement awarded, cancelled, purchased, vested, unvested or outstanding, together the "**Personal Data**".

8.3 Why and how Personal Data is collected and used The Personal Data collected by way of the Company's HR systems, any Warrant agreement or acceptance form will be used exclusively for the purposes of the setting-up, implementation, administration and management of the Plan and the maintenance of the (electronic) register of Warrant holders and (electronic) share register of the Company.

8.4 Other persons having access to the Personal Data and purpose thereof

The Controller can transfer the Personal Data to the following categories of recipients:

(i) any service provider designated by the Controller to collect or use Personal Data on behalf of the Controller in accordance with this Clause 8 for the purposes of implementing, administrating and managing the Plan and, if applicable, the (electronic) register of Warrant Holders and (electronic) share register of the Company (the "**Processors**"); and

(ii) regulatory authorities for complying with legal obligations in connection with the Plan.

Such recipients may be located in jurisdictions outside the European Economic Area that offer an adequate level of personal data protection, in particular Israel. For the avoidance of doubt, Israel has been recognised by the European Commission as a country located outside the European Economic Area that does offer an adequate level of personal data protection.

8.5 Legal basis allowing the Company to collect and use Personal Data

With respect to the setting-up, implementation, administration and management of the Plan and the (electronic) register of Warrant Holders and (electronic) share register of the Company, the collection, processing and use of the Personal Data is necessary to perform Company's contractual obligations towards the Holders. If the Personal Data of a Holder cannot be collected, processed or used, this Holder cannot participate in the Plan.

8.6 Rights of the Holders

The Holders can exercise their right to request access to and rectification or erasure of their Personal Data or restriction of processing concerning the Holders or to object to processing as well as the right to data portability by sending a written and signed request to the Company's registered office at Rue Edouard Belin 12, 1453 Mont-Saint-Guibert, Belgium, for the attention of Ms. Maya Shmailov or by email to maya.shmailov@nyxoah.com.

Finally, if Holders are not satisfied with how the Company processes their Personal Data, they can contact the Company's Data Protection Officer at Rue Edouard Belin 12, 1453 Mont-Saint-Guibert, Belgium, for the attention of Ms. Maya Shmailov or by email to maya.shmailov@nyxoah.com.

Holders also always have the right to make a complaint to the competent data protection authority in the EU Member State of their habitual residence, their place of work or of an alleged infringement of the applicable data protection rules.

8.7 Storage period of the Personal Data

Personal Data will be stored for a period of ten (10) years following the later of (i) the termination of the Plan or (ii) the end of a Holder's participation in the Plan.

9 Miscellaneous

9.1 Amendments, suspension and termination of this Plan

The terms and conditions set out in this Plan may entirely or partially be amended, modified, suspended or terminated by the shareholders' meeting at any time, except with regard to the Exercise Period which, as stated in Clause 6.2.1 of this Plan, can be modified by the Board of Directors. The amendment, suspension or termination of this Plan may not modify or limit the rights and obligations under a granted Warrant without the consent of the concerned Holder. No warrant can be granted when this Plan is suspended or after the termination of this Plan.

9.2 National legislation

Notwithstanding any provision of the Plan, the Board of Directors may modify or extend the provisions of the Plan and the conditions of the Warrants to the extent that it considers this to be necessary or preferable to take into account, to limit the disadvantageous consequences of, or to be in compliance with foreign legislation, including, but not limited to, tax and financial legislation applicable to the Holder, to the extent that the terms and conditions of the Warrants granted to such Holder are not more advantageous than the terms and conditions of the Warrants granted to the other Holders.

9.3 Costs and taxes

The costs regarding the capital increase shall be incurred by the Company. Seal rights, stock exchange taxes and other similar rights and taxes imposed as a result of the exercise of the Warrants and the delivery of new Shares are borne by the Holders. Any other possible taxes or rights due as a result of the grant of Warrants will also be borne by the Holders.

The costs regarding the issuance of the Warrants and the capital increase relating to the issuance and exercise of the Warrants are borne by the Company.

Holders (or, if applicable, his/her Beneficiaries) will have to bear any taxes (including but not limited to income taxes, capital gains taxes and stock exchange taxes) and employee or self-employed social security contributions due in connection with (a) the grant, exercise, and or transfer of the Warrants and (b) the delivery and ownership of the new Shares, in accordance with applicable tax and social security legislation.

The Company or a Subsidiary shall, upon granting of the Warrants pursuant to this Plan, levy any withholding tax provided for in the relevant applicable tax and/or social security laws, as provided for therein.

9.4 Investment risk

An investment in Warrants or Shares involves substantial risks.

Before making an investment decision with respect to the acceptance and/or exercise of the Warrants; the Beneficiary / Holder should consider the risks and uncertainties with which the Company is or might be confronted (including but not limited to those mentioned in the annual reports of the Company) and read the annual accounts and annual reports of the Company. Past performances of the Company give no guarantees for the future.

It cannot be excluded that the market value of a Share during the entire duration of the Warrants will be lower than the applicable exercise price of a Warrant. The taxes and social security contributions that may be due in connection with the granting of the Warrants cannot be recovered, even if the Warrants expire without having been exercised. It can also not be excluded that the value of the Shares after exercise of Warrants will decrease and that the Holder loses all or part of his investment in Shares.

9.5 Employment conditions

No provision of this Plan can be construed as creating an obligation of employment (either by way of an employment agreement, an appointment as director or a services agreement) between a Group Company and a Holder or an obligation for the Board of Directors to offer Warrants. Upon termination of the employment, the Holder shall in no event be entitled to demand damages within the framework of this Plan. The foregoing also applies, but is not limited to, the application of the tax legislation.

9.6 Nullity of a provision

The nullity or unenforceability of any provision of this Plan does not in any way affect the validity or enforceability of the remaining provisions of this Plan. In this case, the invalid or unenforceable provision will be replaced by an equivalent valid and enforceable provision having a similar economic effect for the parties concerned.

9.7 Applicable law

This Plan and any non-contractual obligations arising out of or in connection with it shall be governed by and construed in accordance with Belgian law.

9.8 Competent courts

The courts of Brussels (Belgium) have exclusive jurisdiction to settle any dispute arising out of or in connection with this Plan (including a dispute relating to non-contractual obligations arising out of or in connection with this Plan).

9.9 Notices

Any notice to the Holders (and, if applicable, his/her Beneficiaries) shall be validly made to the address mentioned in the register of warrant holders.

Any notice to the Company, shall be validly made to the attention of the Board of Directors or the secretary of the Company at the address of the registered office of the Company.

Address modifications must be notified immediately by the Holders (and, if applicable, his/her Beneficiaries) to the Company in accordance with this provision.

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Adopted by the Board of Directors on 14 February 2020, subject to approval by the shareholders' meeting.

On behalf of the Board of Directors:

Robert Taub	**Janke Dittmer**
Common Director and Chairman	B Director and Vice-Chairman

Exhibit 21.1

Nyxoah SA Subsidiaries

Name of Subsidiary	Jurisdiction of Incorporation or Organization
Nyxoah Inc.	Delaware
Nyxoah Ltd	Israel
Nyxoah Pty Ltd	Australia

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated April 16, 2021, in the Registration Statement (Form F-1) and related Prospectus of Nyxoah SA for the registration of its common stock.

/s/ EY Réviseurs d’Entreprises / EY Bedrijfsrevisoren SRL/BV

Diegem, Belgium

June 10, 2021