



Nyxoaah SA  
Rue Edouard Belin, 12, 1435 Mont-Saint-Guibert, Belgium

**Offering of up to 3,871,000 ordinary Shares**

**Price Range: € 14.00 to € 17.00 per Offered Share**

**Listing of all Shares on Euronext Brussels**

This prospectus (the "**Prospectus**") relates to the initial offering (the "**Offering**") by Nyxoaah SA (the "**Company**"), a limited liability company organized under the laws of Belgium, of up to 3,871,000 new shares, with no nominal value, of the Company (the "**Shares**"). The Shares being offered by the Company during the Offering are herein referred to as the "**Offered Shares**".

The Offering consists of (i) an initial public offering to retail and institutional investors in Belgium (the "**Belgian Offering**"); (ii) a placement in the United States to persons that are reasonably believed to be qualified institutional buyers ("**QIBs**") (as defined in Rule 144A ("**Rule 144A**") under the U.S. Securities Act of 1933, as amended (the "**U.S. Securities Act**"); and (iii) a placement to certain qualified and/or institutional investors outside Belgium and the United States (those qualified and/or institutional investors together with the QIBs are collectively being referred to as the "**Institutional Investors**"). The Offering outside the United States will be made in compliance with Regulation S ("**Regulation S**") under the U.S. Securities Act. Prospective purchasers are hereby notified that sellers of the Shares may be relying on the exemption from the provisions of Section 5 of the U.S. Securities Act provided by Rule 144A.

The aggregate number of new shares offered in the Offering may be increased by up to 15% of the aggregate number of new shares initially offered to a number of 4,451,650 new shares (the "**Increase Option**"). Any decision to exercise the Increase Option will be communicated, at the latest, on the date of the announcement of the Offering Price (as defined below).

Belfius Bank NV/SA, acting as stabilization manager (the "**Stabilization Manager**"), acting on behalf of the Underwriters (as defined herein), is expected to be granted a warrant to purchase additional new Shares in a number equal to up to 15% of the number of Shares subscribed for in the Offering (i.e., including the new Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) at the Offering Price to cover over-allotments or short positions, if any, in connection with the Offering (the "**Over-allotment Option**"). The Over-allotment Option will be exercisable for a period of 30 days following Listing Date (as defined herein). The Stabilization Manager, acting on behalf of the Underwriters, may engage in transactions that stabilize, maintain or otherwise affect the price of the Shares during a period of 30 calendar days following the Listing Date (as defined below). These activities may support the market price of the Shares at a higher level than that which might otherwise prevail.

There is no minimum amount for the Offering. Certain existing shareholders of the Company, and other investors (the "**Participating Investors**") have irrevocably committed to subscribe for an aggregate amount of € 23,064,000 in the Offering at the Offering Price (as defined below), subject to the closing of the Offering (the "**Subscription Commitments**"). In the event of over-subscription of the Offering, in principle the Subscription Commitments of the Participating Investors in cash for an amount of approximately € 9,768,000 can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering, whereas the Subscription Commitments for the remaining amount shall not be reduced but be allocated entirely. However, the Company will allocate to Participating Investors that are existing shareholders a number of Offered Shares for an aggregate amount of at least € 15,000,000. As there is no minimum amount of the Offering, if not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from the Subscription Commitments.

**An investment in the Offered Shares involves substantial risks and uncertainties. Prospective investors should read the entire document, and, in particular, should read Part 0 (Risk Factors) for a discussion of certain factors that should be considered in connection with an investment in the Offered Shares, including the risks that (i) even though the Company has obtained regulatory approval (CE-mark) in Europe for the Genio® system based on first positive clinical trial results, this does not imply that clinical efficacy has been demonstrated and there is no guarantee that ongoing and future clinical trials intended to support further marketing authorisations (such as in the US) will be successful and that the Genio® system will perform as intended, (ii) the Company's future financial performance will depend on the results of ongoing and future clinical studies and the commercial acceptance (including reimbursement) of the Genio® system (the Company's only commercial-stage product at the date of this Prospectus), (iii) the Company has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability, (iv) the Company will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit the Company's access to additional capital. Not taking into account any proceeds of the Offering, the Company does not have sufficient working capital to meet its working capital needs for a period of at least 12 months from the date of the Prospectus. All of these factors should be considered before investing in the Offered Shares. Prospective investors must be able to bear the economic risk of an investment in the Shares and should be able to sustain a partial or total loss of their investment.**

The price per Offered Share (the "**Offering Price**") will be determined during the Offering Period (as defined below) through a book-building process in which only qualified and/or institutional investors may participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time. See "*The Offering - Offering Price*" for further information. The Offering Price, the number of Offered Shares sold in the Offering and the allocation of Offered Shares to retail investors is expected to be made public in the Belgian financial press on or about 23 September 2020 and in any event no later than the first business day after the end of the Offering Period. The Offering Price will be a single price in Euros, exclusive of the Belgian tax on stock exchange transactions, and of costs, if any, charged by financial intermediaries for the submission of applications. The Offering Price is expected to be between € 14.00 and € 17.00 per Offered Share (the "**Price Range**"). The Offering Price may be set within the Price Range or below the lower end of the Price Range but will not exceed the higher end of the Price Range. A supplement to the Prospectus shall be published should the Offering Price be set below the lower end of the Price Range. If a supplement to the Prospectus is published, investors will have the right to withdraw their orders made prior to the publication of the supplement.

The offering period will begin on 9 September 2020 and is expected to end no later than 4:00 pm (CET) on 22 September 2020 (the "**Offering Period**"), subject to early closing, provided that the Offering Period will in any event be open for at least six business days from the availability of this Prospectus. However, in accordance with the possibility provided for in Article 3, §2 of the Royal Decree of 17 May 2007 on primary market practices (the "**Royal Decree on Primary Market Practices**"), the subscription period for the retail offering is expected to end no later than 4:00 pm (CET) on 21 September 2020, the day before the end of the institutional bookbuilding period, due to the timing and logistical constraints associated with the centralization of the subscriptions placed by retail investors with the Joint Bookrunners and with other financial institutions. Any early closing of the Offering Period will be announced in the Belgian financial press by means of a press release, and the dates for pricing, allocation, publication of the Offering Price and results of the Offering, "if-and-when-issued-and/or-delivered" trading and closing of the Offering will in such case be adjusted accordingly. A supplement to the Prospectus shall be published in case of an early closing of the Offering Period without placement of the total number of Offered Shares.

Prior to the Offering, there has been no public market for the Shares. An application has been made to list all of the Company's existing Shares as well as newly issued Offered Shares on the regulated market of Euronext Brussels under the symbol "NYXH". Trading of the Shares on Euronext Brussels is expected to commence, on an "if-and-when-issued and/or delivered" basis, on or about 24 September 2020 (the "**Listing Date**"), provided that this may be accelerated in case of early closing.

Delivery of the Offered Shares is expected to take place in dematerialized (book-entry) form against payment therefore in immediately available funds on or around 25 September 2020 (the "**Closing Date**"), provided that this may be accelerated in case of early closing, to investors' securities accounts via Euroclear Belgium, the Belgian central securities depository. By way of exception to the foregoing, the Offered Shares that will be issued to Participating Investors pursuant to the Pre-commitments (unless the Participating Investor has an existing client relationship and securities account with Bank Degroof Petercam NV/SA or Belfius Bank NV/SA and has opted to have such Offered Shares delivered in dematerialized (book-entry) form and credited on such securities account), will be delivered in registered form on or about their issuance. See "*The Offering - Form of the Offered Shares and*".

This document constitutes an offer and listing prospectus for purposes of Article 3 of Regulation 2017/1129 of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market (the "**Prospectus Regulation**"). The English language version of this Prospectus was approved by the Belgian Financial Services and Market Authority (the "**FSMA**") on 8 September 2020.

**This Prospectus will be valid until 8 September 2021. The obligation to supplement this Prospectus in the event of significant new factors, material mistakes or material inaccuracies does not apply when this Prospectus is no longer valid.**

The Shares have not been and will not be registered under the U.S. Securities Act or the applicable securities laws of any state or other jurisdiction of the United States and may not be offered, sold, pledged or transferred within the United States, except pursuant to an applicable exemption from the registration requirements of the U.S. Securities Act. The Shares are being offered outside the United States in reliance on Regulation S under the Securities Act. For a description of certain restrictions on transfer of the Shares, see "*Notice to prospective investors in the United States*".

*Joint Global Coordinators & Joint Bookrunners*

Bank Degroof Petercam NV/SA

Belfius Bank NV/SA



Prospectus dated 8 September 2020

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## 1. SUMMARY

### A. Introduction and warnings

#### 1. Introduction

Name and international securities identification code	Nyxoah ordinary share, with ISIN code BE0974358906.
Identity and contact details of the issuer	Nyxoah SA - enterprise number: 0817.149.675 - registered office: Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium - Legal Entity Identifier ("LEI"): 5493002O1ESKZ18OXR80 – telephone number: +32 10 22 23 55.
Competent authority	Financial Services and Markets Authority ("FSMA"), rue du Congrès 12-14, 1000 Brussels, Belgium.
Date of prospectus approval	The FSMA approved the English version of this Prospectus (including the Summary) in accordance with Article 20 of the Prospectus Regulation on 8 September 2020.

Unless otherwise stated in this Summary, the capitalized terms used in this Summary shall have the meaning as defined in the Prospectus.

#### 2. Warnings

This Summary should be read as an introduction to the Prospectus. Any decision to invest in the Offered Shares should be based on a consideration of the Prospectus as a whole by the investor and not just the Summary. An investor could lose all or part of the invested capital. Where a claim relating to the information contained in, or incorporated by reference into, the Prospectus is brought before a court, the plaintiff investor might, under national law of the Member States of the European Economic Area, have to bear the costs of translating the Prospectus and any documents incorporated by reference in it before the legal proceedings can be initiated. Civil liability attaches only to those persons who have tabled the Summary, including any translation thereof, but only where the Summary is misleading, inaccurate or inconsistent, when read together with the other parts of the Prospectus, or where it does not provide, when read together with the other parts of the Prospectus, key information in order to aid investors when considering whether to invest in the Offered Shares.

### B. Key Information on the Company

#### 1. Who is the issuer of the Offered Shares?

**Identification.** The Company is a public 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 Wallon) under enterprise number 0817.149.675. The Company's registered office is located at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium. The Company's LEI is 5493002O1ESKZ18OXR80.

**Principal activities.** The Company is a health-technology company focused on the development and commercialization of solutions and services to treat sleep disordered breathing conditions. At the date of this Prospectus, the main activities (i.e. research and development and manufacturing) are located in Israel. The Company's innovative solution platform is based on the Genio® system, a CE-Mark validated, user-centered, next generation neurostimulation therapy for obstructive sleep apnea ("OSA"), the world's most common sleep disordered breathing condition that is associated with increased mortality risk and comorbidities including cardiovascular diseases, depression and strokes. Globally about 425 million people between 30 and 69 years of age suffer from moderate-to-severe OSA. Taking into account, amongst others, a CPAP non-compliance rate of 35%, the yearly pool of patients newly eligible for hypoglossal nerve stimulation is estimated at approximately 500,000 patients in the United States and 600,000 patients in Europe and Australia/New Zealand. The product is intended to be used as a second-line therapy to treat moderate-to-severe OSA patients who have failed conventional therapy, including Continuous Positive Airway Pressure ("CPAP"), which, despite its proven efficacy, has been associated with many limitations, making compliance a serious challenge. In addition, other second-line treatments, such as oral devices, are more suitable to treat mild to moderate OSA or are highly invasive.

Compared to other hypoglossal nerve stimulation technologies for the treatment of OSA (such as the CE-marked and FDA-approved Inspire and the CE-marked ImThera devices), the Genio® system is the world's first and only battery-free, minimally invasive and leadless neurostimulator implant and is capable of delivering bilateral hypoglossal nerve stimulation to keep the upper airway open. The Genio® system is a 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 left and right branches of the hypoglossal nerve.

**Major shareholders.** Certain existing shareholders of the Company and other investors (the "**Participating Investors**") have irrevocably committed to subscribe for an aggregate amount of € 23,064,000 in the Offering at the Offering Price, subject to the closing of the Offering (the "**Subscription Commitments**"). Noshaq SA granted a convertible loan in the principal amount of €1 million to the Company (the "**Noshaq Convertible Loan**") and has committed to convert in full the outstanding principal amount under such loan into new Shares in the Company at a subscription price per new Share equal to the Offering Price minus 10%. The following table presents (i) an overview of the shareholders owning 3% or more of the Company's Shares (on an undiluted basis) prior to the closing of the Offering, and (ii) an overview of the existing shareholders and Participating Investors expected to own 3% or more of the Company's Shares (on an undiluted basis) immediately after the closing of the Offering assuming (a) an Offering Price at the mid-point of the Price Range, (b) conversion in full of the outstanding principal amount under the Noshaq Convertible Loan

into new Shares at a subscription price per new Share equal to the Offering Price minus 10%, (c) placement of the maximum number of Offered Shares in the Offering (and including the exercise in full of the Increase Option and the Over-allotment Option), and (d) an allocation of new Shares to the Participating Investors for the full amount of their Subscription Commitments but excluding any new Shares otherwise subscribed in the Offering:

Shareholder or Participating Investor	Prior to closing of the Offering		Immediately after closing of the Offering	
	Number of Shares	Shares %	Number of Shares	Shares % (rounded)
Cochlear Investments Pty Ltd	3,653,500	21.46	3,976,080	17.90
TOGETHER Partnership	2,366,500	13.90	2,540,693	11.44
Robert Taub + MINV SA	2,641,000	15.51	2,834,548	12.76
Coöperatieve Gilde Healthcare III Sub-Holding U.A. and Coöperatieve Gilde Healthcare III Sub-Holding 2 U.A.	3,095,000	18.18	3,288,548	14.80
Jürgen Hambrecht	973,500	5.72	1,054,145	4.75
ResMed Inc.	755,000	4.44	798,032	3.59

It is the Company's current belief that, as at the Closing Date, the Company will not be controlled in the sense of Article 1:14 Belgian CCA.

**Key directors.** As of closing of the Offering the Company's Board of Directors shall consist of eight members: (i) Robert Taub, (ii) Janke Dittmer, (iii) Kevin Rakin, (iv) Donald Deyo, (v) Pierre Gianello, (vi) Jan Janssen, (vii) Jürgen Hambrecht and (viii) Olivier Taelman.

**Statutory auditor.** The Company's statutory auditor is EY Réviseurs d'Entreprises SRL, with registered office at De Kleetlaan 2, 1831 Diegem, Belgium, represented by Carlo-Sébastien D'Addario, auditor.

## 2. What is the key financial information regarding the Company?

### *Selected financial information.*

The financial data set forth below as 30 June 2020 and 2019 and as at 31 December 2019, 2018 and 2017 and for the six-months periods and years then ended have been extracted without material adjustment from the the unaudited half-yearly financial statements ended 30 June 2020 and 2019 and the audited consolidated financial statements of the Issuer as of and for the years ended 31 December 2019, 2018 and 2017. The annual financial statements have been prepared in accordance with International Financial Reporting Standards, as adopted by the European Union.

<i>(in € 000)</i>	Period ending at 30 June		Period ending at 31 December		
	2020	2019	2019	2018	2017
Total revenue	0	0	0	0	0
Operating loss for the period	3,605	3,189	6,516	8,450	10,143
Loss for the period before taxes	3,939	3,548	7,185	9,038	10,334
Loss attributable to equity holders	3,963	3,566	7,255	9,079	10,371
Total assets	38,167	16,344	15,195	17,979	11,145
Net financial debt (LT debt + ST debt – Cash)	(14,831)	(4,016)	2,774	(10,990)	(4,841)
Total equity attributable to shareholders	25,411	6,954	3,713	10,454	4,527
Cash at beginning of period	5,855	16,805	16,805	10,105	17,446
Cash Flow from Financing Activities	25,735	(200)	733	15,002	1,113
Cash Flow from investing Activities	(3,655)	(2,079)	(5,795)	(75)	(91)
Cash Flow from Operation Activities	(4,024)	(3,015)	(5,965)	(8,139)	(8,287)
Cash at end of period	23,880	11,518	5,855	16,805	10,105

**Other financial information.** No *pro forma* financial information is provided in the Prospectus. There are no qualifications to the audit report on the historical financial information.

### 3. What are the key risks that are specific to the Company?

The following is a selection of key risks that, alone or in combination with other events or circumstances, could have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

#### a) *Risks relating to clinical development*

**Risks relating to the performance of the Genio® system.** Even though the Company has obtained regulatory approval, i.e. the CE-Mark (which is to be re-approved before May 2024) in Europe for the Genio® system based on first positive BLAST OSA clinical trial results (in which all study safety and performance endpoints were met with statistically significant p-values but based on a limited sample size obtained with an observational study without control group), this does not imply that clinical efficacy has been demonstrated and there is the possibility that ongoing and future clinical trials intended to support further marketing authorisations (or maintenance of existing ones) will not be successful and that the Genio® system will not perform as intended. For a CE mark, devices only need to demonstrate that they perform or will probably perform as designed and that the potential benefits outweigh potential risks. Future clinical evidence could be needed with respect to whether the Genio® system's results can also be considered as sufficient for the sleep community, which will be evaluated by the FDA. The performance of the Genio® system in commercial use may be different from the performance observed during the clinical studies for a number of reasons, including without limitation less control of the Company on the selection of patients suitable for use of the products, use by physicians with different experience and training, and failure to adhere to a follow-up regimen in the absence of clinical study enrolment and oversight. Furthermore, issues with product performance may subsequently be identified once a product is on the market, which could lead to the recall, modification, exchange, destruction or retrofitting of the device.

**Risks relating to attracting patients to perform clinical studies and COVID-19.** The Company may not be able to initiate or, continue and/or complete in a timely manner clinical studies if it is unable to locate and enroll a sufficient number of eligible patients within the planned recruitment period to participate in these studies as required by the applicable regulatory authorities in the United States, Europe and any other applicable jurisdictions. The occurrence of a pandemic or other public health crisis, such as COVID-19, may impact the ability to recruit patients and otherwise disrupt normal functioning of the healthcare system which could impair the ability to conduct clinical studies as planned. In addition, some patients may not be able to comply with clinical study protocols if quarantines or other measures impede patient movement or interrupt healthcare services. Any difficulties in enrolling a sufficient number of patients for any of its clinical studies could result in significant delays and could require the Company to abandon one or more clinical studies altogether. If study centers and Centers of Excellence are restricted in performing elective surgeries and/or following up with their study patients, this may lead to missing information and may potentially impact clinical trial data quality and integrity. Enrolment delays in the Company's clinical studies may result in increased development costs that may exceed the resources available to the Company and in delays to commercially launch the Genio® system in target markets, if approved.

**Risks relating to hesitation to change and concern by physicians.** The success of the Genio® system will require acceptance and adoption by physicians. Physicians will likely only adopt the Genio® system if they determine that the system is an attractive treatment solution, and that third party payers, such as government programs and private health insurance plans, provide appropriate reimbursement for its use. Even if the safety and efficacy of the Genio® system is established, physicians may be hesitant to change their medical treatment practices or accept and adopt the Genio® system. Economic, social, psychological, cultural and other concerns may also limit general acceptance and adoption.

#### b) *Risks relating to commercialization and reimbursement*

**Risks relating to commercial acceptance.** At the date of this Prospectus, the Genio® system is the only product on the market by the Company. The Genio® system received a CE-Mark in March 2019 for the treatment of OSA. The CE-Mark cannot be construed as evidence of (statistically significant) efficacy or safety of the Genio® system. The Company is working to gain commercial market acceptance of the Genio® system in target markets and has generated only limited revenue from commercial sales. The Company sold the first commercial units in July 2020. The Genio® system might not gain commercial acceptance in target markets. If the Company fails to gain and maintain commercial market acceptance in its target markets, 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.

**Risks relating to third-party payments.** The existence of coverage and adequate reimbursement for the Company's products by government and/or private payers will be critical for market adoption of the Genio® system. Physicians and hospitals are unlikely to use the Genio® system at all or to a great extent, if they do not receive adequate reimbursement for the procedures utilizing the product, and potential patients may be unable or unwilling to pay for the Genio® system themselves. The price that the Company may receive for, and the marketability of, the Genio® system for which the Company receives regulatory approval may suffer significantly if the government and/or third-party payers fail to provide adequate coverage and reimbursement or if further governmental cost containment or other health reform initiatives are adopted or implemented resulting in the Company possibly failing to achieve or maintain reimbursement levels sufficient to support a commercial infrastructure or realize an appropriate return on its investment in product development. At this stage of development and penetration of hypoglossal nerve stimulation therapy in the OSA field, there are no large clinical studies available (yet) to confirm the long-term cost effectiveness of hypoglossal nerve stimulation. Although there is a general consensus about the medical necessity to treat OSA and notwithstanding the increasing number of hypoglossal nerve stimulation therapy coverage decisions, the Company is currently in discussions and negotiations to secure reimbursement coverage and might be at risk of currently not having sufficient evidence (yet) to determine that the Genio® therapy results demonstrate a meaningful improvement in net health outcomes for patients meeting the specified criteria. If so, further evidence might be necessary, while in the meantime the Company will make the Genio® system available through country-specific innovation funding pathways.

**Risks relating to the expansion of the sales, marketing and distribution capabilities.** The Company will need on the one hand to

expand its internal sales and marketing organization to commercialize the Genio® system in markets that the Company will target directly, which may entail risks as set out above. On the other hand, the Company may decide to target certain other markets indirectly via distributors or other arrangements. If the Company is unable to find suitable distribution partners, loses these distribution partners or if the Company's distribution partners fail to sell its products in sufficient quantities, on commercially viable terms and in a timely manner, the commercialization of the Genio® system could be materially harmed, which could prevent the Company from achieving or maintaining profitability. Another factor that may inhibit the Company's efforts to commercialize the Genio® system in target markets is the lack of complementary products to be offered by sales personnel, which may put the Company at a competitive disadvantage relative to companies with more products.

**Risks relating to COVID-19.** The occurrence of a pandemic, epidemic or other health crisis, including the recent outbreak of COVID-19, could have a negative impact on the Company's product development and manufacturing activities, the recruitment and conduct of its clinical studies and its ability to source required funding, which could delay or prevent it from executing its strategy as planned. Due to the high degree of unpredictability of COVID-19, the Company foresees challenges in training and proctoring new centers and their surgeons in the United States and Europe. Patients being less willing to travel to these centers or their travelling being restricted, could become an issue and potentially impact the Company's clinical and commercial activities.

*c) Risks relating to the markets and countries in which the Company operates*

**Risks relating to competition.** The market for sleep disordered breathing and OSA solutions is increasingly competitive. The commercial availability of any approved competing product could potentially inhibit recruitment and enrolment in the Company's clinical studies. The Company may successfully conclude its clinical studies and obtain final regulatory approval, and nevertheless may fail to compete against competitors or alternative treatments that may be available or developed for the relevant indication.

*d) Risks relating to the Company's financial situation*

**Risks relating to capital and expenditure needs and further financing.** The Company believes that the net proceeds from this Offering, together with its existing cash, cash equivalents, short-term investments and revenue will be sufficient to meet its capital requirements and fund its operations for at least 12 months. However, the Company has based these estimates on assumptions that may prove to be incorrect, and the Company could spend its available financial resources much faster than currently expected. Any additional equity or debt financing that the Company raises may contain terms that are not favorable to the Company or its shareholders. If the Company raises additional funds by selling additional Shares or other securities convertible into or exercisable or exchangeable for Shares after this Offering, the issuance of such securities will result in dilution to the Company's shareholders.

**Risks relating to profitability.** The Company has incurred operating losses and negative operating cash flows in each period since it was incorporated in 2009. As of 31 December 2019, the Company had a loss brought forward of € 47.1 million. The Company intends to fund amongst others the continued development of its technology and the Genio® product line and to expand manufacturing capabilities. The Company plans to conduct additional clinical studies and as a result, management expects that clinical affairs expenses will increase significantly over the next several years. These expenses, together with anticipated commercial/sales, R&D and general and administrative expenses, will likely result in the Company incurring further losses for at least the next few years. The Company may not achieve profitability, which could impair its ability to sustain operations or obtain any required additional funding.

*e) Legal and regulatory risks*

**Risks relating to seeking and obtaining regulatory approval for active implantable medical devices.** The regulations to which the Company is subject to are complex and have become more stringent over time. The Company may be adversely affected by potential changes in government policy or legislation applicable to implantable medical devices. At the date of this Prospectus, the Company has only received regulatory approval for the EEA Member States (through CE-Marking) for its Genio® system. In the United States, the Company is in the early stages of a long process of seeking marketing approval, where it received an investigational device exemption ("IDE") from the FDA but has not yet formally confirmed the appropriate regulatory pathway to pursue to receive marketing authorization. Even though the Genio® system has received an IDE, it may not successfully obtain marketing authorization. In addition, even if marketing authorization is granted by the FDA, it may be withdrawn. Since the Genio® system is a wireless medical device, additional complications may arise with respect to obtaining marketing authorization in the United States.

## **C. Key Information on the Offered Shares**

### **1. What are the main features of the Offered Shares?**

**Type, class and ISIN.** All Offered Shares shall be of the same class as the existing ordinary Shares, without nominal value and will be fully paid-up upon delivery. The Shares are expected to be listed under the symbol "NYXH" with ISIN code BE0974358906. The issuance will be in euros. On the date of the Prospectus, the Company's share capital is represented by 17,023,500 fully paid-up ordinary Shares.

**Rights attached to the Offered Shares.** Each shareholder of the Company is entitled to one vote per Share. As of the closing of the Offering, all of the Shares, including the Offered Shares, will entitle the holder thereof to an equal right to participate in dividends declared after the Closing Date, in respect of the financial year ending 31 December 2020 and future years. All of the Shares will participate equally in the Company's profits (if any). 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. 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. In principle, changes to the share capital are decided by the shareholders and the general shareholders' meeting may at any time decide to increase or reduce the share capital of

the Company. In the event of a capital increase for cash with the issue of new Shares, or in the event of an issue of convertible bonds or subscription rights, the existing shareholders in principle have a preferential right to subscribe, *pro rata*, to the new Shares, convertible bonds or subscription rights. If the Company is dissolved for any reason 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.

**Ranking.** All Shares represent an equal share of the share capital and shall all rank junior to all debt (instruments) of the Company.

**Restrictions on the free transferability.** Subject to the general restrictions for the Offering and the distribution of the Prospectus, and the specific standstill and lock-up restrictions to which the Company and certain securities holders are committed in the context of this transaction, there are no restrictions on the free transferability of the Shares (including the Offered Shares) other than those applicable by law.

**Dividend policy.** The Company has not declared or paid dividends on its Shares in the past. In the future the Company's Board of Directors expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future.

## 2. Where will the Offered Shares be traded?

An application has been made for the listing and admission to trading on the regulated market of Euronext Brussels of all Shares, including the Offered Shares. The Shares are expected to be listed under the symbol "NYXH" with ISIN code BE0974358906. Trading is expected to commence on or about 24 September 2020 (unless in case of early closing or extension of the Offering Period) and will start at the latest on the Closing Date, when the Offered Shares are delivered to investors.

## 3. Key risks that are specific to the Offered Shares

The following is a summary of selected key risks that relate to the Offered Shares and the Offering as such:

**Risks relating to the absence of a minimum amount.** The Company has the right to proceed with a capital increase in a reduced amount, corresponding to a number of Offered Shares that is lower than the maximum number of Offered Shares in the Offering. If not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from Subscription Commitments. As a result, only a number of Shares that is lower than the maximum number of Offered Shares in the Offering could be available for trading on the market, which could limit the liquidity of the Shares. Furthermore, the Company's financial means in view of the uses of proceeds would in such case also be reduced. If this were to be the case, the Company may have to reduce its level of investments or look for further external funding.

**Risks relating to the absence of a prior public market for the Shares.** Prior to the Offering, there has been no public trading market for the Shares. An active trading market may not develop or, if developed, may not be sustained or be sufficiently liquid following the closing of the Offering, in which case the liquidity and trading price of the Shares could be adversely affected. Furthermore, the Offering Price is not necessarily indicative of the prices at which the Shares will subsequently trade on the stock exchange. In addition, the market price of the Shares may prove to be highly volatile and may fluctuate significantly in response to a number of factors, many of which are beyond the Company's control. The market price of the Shares may be adversely affected by most of the preceding or other factors regardless of the Company's actual results of operations and financial condition. The degree of liquidity of the Shares may negatively impact the price at which an investor can dispose of the Shares where the investor is seeking to achieve a sale within a short timeframe.

## D. Key Information on the Offering

### 1. Under which conditions and timetable can I invest in the Offered Shares?

**General.** The Offering consists of: (i) an initial public offering to retail and institutional investors in Belgium; (ii) a placement in the United States to persons that are reasonably believed to be QIBs as defined in Rule 144A under the U.S. Securities Act, and (iii) a placement to certain qualified and/or institutional investors in the rest of the world outside the United States and Belgium (those qualified and/or institutional investors together with the QIBs are collectively being referred to as the "**Institutional Investors**"). The Offering outside the U.S. will be made in compliance with Regulation S under the U.S. Securities Act. Private placements may take place in member states of the EEA pursuant to an exemption under the Prospectus Regulation. The Offering is an offering of up to 3,871,000 new Shares in the Company. Such number may be increased by up to 15% to a number of 4,451,650 new shares if the Increase Option is exercised. The actual number of new Shares issued by the Company in the Offering will only be determined after the Offering Period and will be published in the financial press, by means of a press release, simultaneously with the publication of the Offering Price and the allocation of Shares to Retail Investors. An application has been made for the listing and admission to trading on the regulated market of Euronext Brussels of all Shares, including the Offered Shares.

**Stabilization Manager.** The Stabilization Manager, acting on behalf of the Underwriters, is expected to be granted by the Company the Over-allotment Option, in the form of a warrant, which entitles the Stabilization Manager, acting on behalf of the Underwriters, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the new Shares subscribed for in the Offering (i.e., including the new Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) at the Offering Price to cover over-allotments or short positions, if any, in connection with the Offering.

**Offering Period.** The Offering Period will begin on 9 September 2020 and is expected to close no later than 4:00 p.m. (CET) on 22 September 2020, subject to the possibility of an early closing or extension, provided that the Offering Period will in any event be open for at least six business days. However, the Company expects the subscription period for the retail offering to end at 4:00 p.m. (CET) on 21 September 2020 (i.e. the day before the end of the institutional bookbuilding period).

**Minimum amount.** There is no minimum amount for the Offering.

**Right to withdraw.** The Company reserves the right to withdraw the Offering or to reduce the maximum number of Offered Shares at any time prior to the allocation of the Offered Shares. Any withdrawal of the Offering will be published in the financial press, by means of a press release. To the extent required, a supplement to the Prospectus will be published. In the event of a withdrawal of the Offering, all orders received will automatically be cancelled and withdrawn, and investors will not have any claim to the delivery of the Offered Shares or any compensation. A reduction in the number of Offered Shares prior to expiry of the Offering Period will be published in the financial press, by means of a press release, and in a supplement to the Prospectus. In the event of a publication of a supplement to the Prospectus, investors will have the right to withdraw their orders made prior to the publication of the supplement. Investors withdrawing their order will not have any claim to the delivery of the Offered Shares or any compensation.

**Offering Price.** The Offering Price will be a single price in euro and will be determined within the Price Range (€ 14.00 to € 17.00 per Offered Share) on the basis of a book-building process in which only Institutional Investors can participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time. Costs, if any, charged by financial intermediaries for the submission of applications, will apply to all investors, whether Retail Investors or Institutional Investors. The Price Range has been determined by the Company in agreement with the Underwriters. The Company reserves the right to increase or decrease the lower limit of the Price Range or to decrease the upper limit of the Price Range. If the Price Range is narrowed through an increase of the lower limit and/or a decrease of the upper limit, or if the Price Range is narrowed to a single price, the change will be published in the financial press and by means of a press release. Any other change to the Price Range will also be published in the financial press and by means of a press release, through electronic information services, as well as in a supplement to the Prospectus. Investors who have submitted subscription orders will not be notified individually by the Company. Although the Company has no obligation to notify the investors, the financial intermediaries are required to contact the investor individually. The Offering Price for investors shall not, however, exceed the higher end of the Price Range. In the event of a publication of a supplement to the Prospectus, investors will have the right to withdraw their orders made prior to the publication of the supplement). Retail Investors in Belgium can only acquire the Offered Shares at the Offering Price and are legally bound to acquire the number of Offered Shares indicated in their subscription order at the Offering Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void or (ii) in the event of the publication of a supplement to the Prospectus, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement.

**Allocation and results.** The number of Offered Shares allotted to investors will be determined at the end of the Offering Period by the Company in agreement with the Underwriters on the basis of the respective demand of both Retail Investors and Institutional Investors and on the quantitative, and, for Institutional Investors only, the qualitative analysis of the order book, in accordance with Belgian regulations relating to allocation to Retail Investors and Institutional Investors as set forth below. In accordance with Belgian regulations, a minimum of 10% of the Offered Shares shall be allocated to Retail Investors, subject to sufficient retail demand. In case of over-subscription of the Offered Shares reserved for Retail Investors, the allocation to Retail Investors will be made on the basis of objective and quantitative allocation criteria, whereby all Retail Investors will be treated equally.

The results of the Offering, the allocation for Retail Investors, the Offering Price, and the allocation criteria (in case of over-subscription) will be announced by the Company on or about 23 September 2020 and in any event no later than the first business day after the end of the Offering Period. In the event of the over-allotment of Offered Shares, the Underwriters will use reasonable efforts to deliver the newly issued Shares to individual persons residing in Belgium and to investors subject to Belgian income tax on legal entities (*rechtspersonenbelasting/impôt des personnes morales*), in this order of priority.

**Expected timetable.** Certain key dates in connection with the Offering are summarized in the following table. These are all anticipated dates, which are subject to any unforeseen circumstances and to an early closing of the Offering Period.

Date	Event
9 September 2020, 9 a.m. CET	Expected start of the Offering Period
21 September 2020, 4:00 p.m. CET	Expected end of the Offering Period for retail investors
22 September 2020, 4:00 p.m. CET	Expected end of the Offering Period for institutional investors <sup>1</sup>
23 September 2020	Expected publication of the Offering Price and results of the Offering and communication of allocations
24 September 2020	Expected Listing Date (listing and start of "if-and-when-issued-and/or-delivered" trading)
25 September 2020	Expected Closing Date (payment, settlement and delivery of the Offered Shares)

<sup>1</sup> In the event of an early closing or extension of the Offering Period, these dates will be amended and published in the same manner as the announcement of the start of the Offering Period. If the Offering Period is extended by more than five business days, this will also be published in a supplement to the Prospectus.

Date	Event
24 October 2020	Expected last possible exercise date of the Over-allotment Option <sup>2</sup>

**Dilution.** An existing Shareholder who holds 1% of the Company's share capital prior to the issue and who does not subscribe to the Offering will hold 0.77% of the Company's share capital after the issue of the Offered Shares, assuming full placement of the Offered Shares (including the exercise in full of the Increase Option and the Over-allotment Option).

**Estimated expenses.** The aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the Offering estimated at approximately € 5.4 million are paid by the Company.

## 2. Why is this Prospectus being produced?

**Estimated net proceeds.** Assuming that the Offering Price is at the midpoint of the Price Range and taking into account the expenses of the Offering, the Company estimates to receive net proceeds of (i) approximately € 55.5 million in case of a placement of the maximum number of new Shares in the Offering but excluding the exercise of the Increase Option and the Over-allotment Option, (ii) approximately € 64.1 million in case of a placement of the maximum number of Offered Shares in the Offering, including the exercise in full of the Increase Option but excluding the Over-allotment Option, and (iii) approximately € 73.9 million in case of a placement of the maximum number of Offered Shares in the Offering, including the exercise in full of the Increase Option and the Over-allotment Option.

**Reasons of the Offering and use of proceeds.** The principal purpose of the Offering is to obtain additional capital to support the execution of the Company strategy. In particular, the Company intends to use the net proceeds of the Offering as follows: (i) €27.5 million to conduct clinical trials in the United States, in Europe and in Australia, (ii) €14.5 million to fund product development and research and development activities, in particular regarding the future generation of the Company's products, (iii) a portion to fund the marketing strategy and commercialization efforts and (iv) the remainder for working capital and general corporate purposes.

**Underwriting agreement.** The Underwriters (i.e. Bank Degroof Petercam SA/NV and Belfius Bank SA/NV) are expected (but have no obligation) to enter into an underwriting agreement, upon the determination of the Offering Price, which is expected to take place on or about 23 September 2020. The entering into the Underwriting Agreement may depend on various factors including, but not limited to, market conditions and the results of the book-building process. The Underwriters shall have no obligation to underwrite any of the Underwritten Shares prior to the execution of the Underwriting Agreement (and then only in accordance with the terms and subject to the conditions set forth therein).

**Material conflicts of interests.** The Joint Global Coordinators might have conflicts of interests, which could have an adverse effect on the interests of the shareholders. Potential investors should be aware that the Company is involved in a general business relationship or/and in specific transactions with the Joint Global Coordinators and that they might have conflicts of interests which could have an adverse effect to the interests of the Shareholders. As of the date of this Prospectus, the Joint Global Coordinators have granted no credit facilities to the Company. However, it is possible that following the date of this Prospectus, the Joint Global Coordinators will grant certain credit facilities to the Company as part of their commercial banking activities, and such credit facilities may be for a significant amount.

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<sup>2</sup> To enable the Stabilization Manager, acting on behalf of the Underwriters, to cover over-allotments or short positions, if any, resulting from the over-allotment, if any (for further information, see section 15.4 (*Over-allotment Option and price*)).

## 2. RISK FACTORS

*This Part sets out risk factors, divided broadly into nine categories depending on their nature, that the Company believes may affect the value of an investment in the Offered Shares or may be material for the purpose of assessing the market risks associated with the Offered Shares. Although the risk factors are not necessarily all ranked in order of their materiality, in each category the risk factors which in the assessment of the Company are the most material, taking into account the negative impact on the Company and the probability of its occurrence, are mentioned first. Prospective investors should note that the risks summarized in the Summary are the risks that the Company believes to be the most essential for a prospective investor when assessing or considering an investment in the Offered Shares. However, as the risks that the Company faces relate to events and depend on circumstances that may or may not occur in the future, prospective investors should consider not only the information on the key risks summarized in the Summary but also, among other things, the risks and uncertainties described below.*

*If any of those risks occur, the value of the Offered Shares may decline and investors could lose all or part of their investment. Prospective investors should also read the detailed information set out elsewhere in this Prospectus (including any documents incorporated by reference herein) and should reach their own views prior to making any investment decision with respect to the Offered Shares. Furthermore, before making an investment decision with respect to any Offered Shares, prospective investors should consult their own stockbroker, bank manager, lawyer, auditor or other financial, legal and tax advisers and carefully review the risks associated with an investment in the Offered Shares and consider such an investment decision in light of the prospective investor's own circumstances.*

### 2.1 Risks relating to clinical development

***Even though the Company has obtained regulatory approval (CE-Mark) in Europe for the Genio® system based on first positive clinical trial results, this does not imply that clinical efficacy has been demonstrated and there is the possibility that ongoing and future clinical trials intended to support further marketing authorisations (or maintenance of existing ones) will not be successful, that the Genio® system will not perform as intended and that the sleep community will not accept the trial results as sufficient.***

Even though the Company has obtained regulatory approval, i.e. the CE-Mark (which is to be re-approved before May 2024), in Europe for the Genio® system based on first positive BLAST OSA clinical trial results (in which all study safety and performance endpoints were met with statistically significant p-values but based on a limited sample size obtained with an observational study without control group) as described in Part 8 – (Business), section 8.6.5b (*Completed studies*), there is the possibility that ongoing and future clinical trials intended to support further marketing authorisations (or maintenance of existing ones) will not be successful and that the Genio® system will not perform as intended. Future clinical evidence on efficacy could be needed with larger sample size, control group and long-term follow-up for final conclusion as to whether the Genio® system's results can also be considered as sufficient for the sleep community, which will be evaluated by the FDA. For a CE Mark, devices only need to demonstrate that they perform or will probably perform as designed and that the potential benefits outweigh potential risks.

The Company's clinical results are not necessarily predictive of the final results of its ongoing or future clinical trials, and successful results from the clinical trials thus far may not be replicated in later and larger

clinical trials for example due to different patient populations and demographics, social, cultural or psychological factors which might be location specific. If the results of the ongoing or future clinical trials are inconclusive with respect to the efficacy of the Genio® system or if the Company does not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with the Genio® system or if it takes more time to recruit the necessary number of patients for a trial, it may be prevented and/or delayed in obtaining further marketing approvals. Alternatively, even if the Company obtains regulatory approval, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. The Company may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy.

In particular, even if regulatory approval has been obtained in Europe, there is no guarantee for success in the US pivotal trial. For example, Apnex Medical Inc. obtained a CE-Mark in 2011 for its hypoglossal nerve stimulation device to treat OSA, based on initial clinical results, but shut down in 2013 after negative clinical results that failed to meet the primary endpoints in its pivotal study for FDA approval.

The performance of the Genio® system in commercial use may be different from the performance observed during the clinical studies for a number of reasons, including without limitation less control of the Company on the selection of patients suitable for use of the products, use by physicians with different experience and training, and failure to adhere to a follow-up regimen in the absence of clinical study enrolment and oversight. Furthermore, issues with product performance may subsequently be identified once a product is on the market, which could lead to the recall, modification, exchange, destruction or retrofitting of the device.

***Attracting patients to perform clinical studies and meeting clinical study objectives can be more costly and time-consuming than expected and could be adversely impacted by the occurrence of a pandemic, epidemic or other health crisis, including the recent outbreak of COVID-19.***

Due to the high degree of unpredictability of COVID-19, the Company foresees challenges in training and proctoring new centers and their surgeons in the United States and Europe. Patients being less willing to travel to these centers or their travelling being restricted, could become an issue and potentially impact the Company's clinical and commercial activities.

Clinical study patients may be sourced from the Investigator's own practice clinic or hospital or may be referred by another physician. Potential clinical study patients must sign an informed consent before undergoing certain clinical tests used to determine whether the patient meets the enrolment criteria for the clinical study (patient inclusion or exclusion). Once a patient is enrolled in the clinical study, the patient must comply with the study requirements and undergo periodic time-consuming tests, including a sleep test in a sleep lab. Not all patients will be eligible for the therapy. Moreover, some of the eligible patients may not comply with the requirements of the study, thereby leading to poor or unusable data, or may withdraw from the study, which may compromise the results of the clinical study.

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

and any other applicable jurisdictions.

Despite an increased awareness regarding the Nyxoah technology since the publication of the BLAST OSA data in the European Respiratory Journal in October 2019, patient enrolment may be affected by other factors including the following: (i) the fact that the Genio® system is an implantable device requiring clinical study patients to undergo surgery, (ii) the severity of the disease under investigation, (iii) the patient eligibility criteria for the study in question, (iv) the perceived risks and benefits of the Genio® system for the indication under study, (v) the referral practices of physicians, (vi) the ability to monitor patients adequately during and after treatment, (vii) the proximity and availability of clinical study sites for prospective patients, (viii) the approval of other devices or therapeutics for the target indications, (ix) other clinical studies for the same target patients as those of the Company and (x) the necessity for the patients 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 study.

As a result of the COVID-19 pandemic, or similar pandemics, and related "shelter in place" or "quarantine" orders and other public health guidance measures, the Company has experienced and may experience in the future disruptions that could materially impact the ability to recruit patients or otherwise disrupt normal functioning of the healthcare system which could impair the ability of the Company to conduct its clinical studies and business in general as planned. Potential disruptions include but are not limited to:

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

Any difficulties in enrolling a sufficient number of patients for any of the Company's clinical studies, any patient withdrawing from the clinical studies or not complying with the study protocols could result in significant delays and could require the Company to abandon one or more clinical studies altogether. If study centers and Centers of Excellence are restricted in performing elective surgeries and/or following up with their study patients, this may lead to missing information and may potentially impact clinical trial data quality and integrity. Enrolment delays and other issues with the Company's clinical studies may result in increased research and development costs that may exceed the resources available to the Company and in delays to commercially launch the Genio® system in target markets, if approved.

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

Performing clinical studies requires the engagement of many different and diverse hospitals, clinics and clinicians. In particular, the Company must engage a physician at each clinical study center to maintain overall responsibility for conduct of the clinical study (the "**Investigator**"). Each Investigator may have additional physicians working under his or her direction to conduct a study. The Company may not be able to attract sufficiently qualified Investigators or enough Investigators to conduct clinical studies within an adequate timeframe. As described in Part 8 – (Business), section 8.3.1b (*Education and training*), at the date of this Prospectus, the Company has only trained 16 surgeons in Europe and 9 in Australia.

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

Even if the safety and efficacy of the Genio® system is established, physicians may be hesitant to change their medical treatment practices or accept and adopt the Genio® system, including for the following reasons:

- general conservatism about the adoption of new treatment practices;
- personal history of adverse events and severe 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.

Economic, social, psychological and other concerns may also limit general acceptance and adoption of the Genio® system. Lack of acceptance and adoption of the Genio® system by a sufficient number of relevant physicians would substantially increase the duration of trials and their costs.

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

Developing (new) products is expensive and time-consuming and could divert management's attention away from the Company's core business. The Company continues to invest in improving the Genio® system to

develop next generation products with improved features with respect to patient comfort, therapy efficacy and reliability. The success of any new product offering or product enhancements to the Company's technology will depend on several factors, including the Company's ability to do the following:

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

If the Company is not successful in expanding indications (such as for instance treating complete concentric collapse patients) and developing and commercializing new products and product enhancements, its ability to increase its revenue in the future may be impaired. See Part 8 – (Business), section 8.6.7 (Research *and development*) and section 8.12 (*Material contracts*) for more information on the Company's research and development projects and collaborative research and development agreements.

## **2.2 Risks relating to commercialization and reimbursement**

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

At the date of this Prospectus, the Genio® system is the only product on the market by the Company. The Genio® system received a CE-Mark in March 2019 for the treatment of obstructive sleep apnea ("OSA"). The CE-Mark cannot be construed as evidence of (statistically significant) efficacy or safety of the Genio® system. The Company is working to gain commercial market acceptance of the Genio® system in target markets and has generated only limited revenue from commercial sales of the Genio® system. The Company sold the first commercial units in July 2020. The Genio® system launched by the Company might not gain commercial acceptance in target markets. If the Company fails to gain and maintain commercial market acceptance of the Genio® system in its target markets, for instance because of insufficient price and reimbursement levels from government and third party payers, competition, the inability to demonstrate to physicians and other potential customers the benefits and cost-effectiveness 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. For an overview of the commercial market, see Part 8 - (Business), section 8.5 (*Market overview*). In addition, the Genio® system has not received marketing approval in the United States and the Company's future financial performance will depend on the successful completion of its planned pivotal study in the United States.

These and other factors present obstacles to commercial market acceptance of the Genio® system in target markets and could lead to the Company's failure, or a substantial delay, in gaining significant commercial market acceptance of the Genio® system in target markets, which could affect the Company's ability to generate revenues from sales of the system.

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

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

In many countries, payment for the Genio® system will be dependent on obtaining a "reimbursement code" for the procedure and product. Obtaining a reimbursement code can be a lengthy process (taking from months to years), that varies from country to country. Following the grant of a reimbursement code payers (e.g. national healthcare systems or health insurance companies) have to agree to provide coverage for the procedure(s) that use the Genio® system, which could be an additional hurdle for the Company. For an overview of the reimbursement landscape, see Part 8 - (Business), section 8.4 (*Reimbursement landscape*).

With global pressure on healthcare costs, payers are attempting to contain costs by, for example, limiting coverage of and the level of reimbursements for new therapies. Generally, hospitals, governments and third-party payers are increasingly exerting downward pressure and reviewing the cost-effectiveness of medical products, therapies and services. Securing adequate or attractive reimbursement often depends on the successful outcome of a medical economics study, which is a clinical study designed to demonstrate the cost effectiveness of a product or procedure. Such studies are time-consuming and costly. It is uncertain if the results of such studies will be sufficient to support a reimbursement application. The Company might therefore not be able to obtain reimbursement at satisfactory levels or at all.

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

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

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

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

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

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

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

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

The Company will need on the one hand to expand its internal sales and marketing organization, which was composed of two employees at the end of 2019, to commercialize the Genio® system in markets that the Company will target directly, which may entail risks as set out above. On the other hand, the Company may decide to target certain other markets indirectly via distributors or other arrangements. If the Company is unable to find suitable distribution partners, loses these distribution partners or if the Company's distribution partners fail to sell its products in sufficient quantities, on commercially viable terms or in a timely manner, the commercialization of the Genio® system could be materially harmed, which could prevent the Company from achieving or maintaining profitability.

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

See Part 8 – (Business), section 8.3 (*Marketing strategy and commercial objectives*) for a description of the Company's marketing strategy and commercialization efforts.

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

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

The Company's business and the business of its development and manufacturing partners and suppliers could be materially adversely affected by the effects of pandemics, epidemics or other health crises, including the

recent 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.

In March 2020, the World Health Organisation characterized COVID-19 as a pandemic, which resulted in the implementation of travel and other restrictions across the world to reduce the spread of the disease.

This exceptional situation has required exceptional measures. Governmental safety guidelines have been implemented in all Nyxoah entities. Although it cannot be excluded that COVID-19 related issues or measures may result in stoppages, interruptions, reductions or breaks in the Company's production activities, supply chain and support functions, up to and at the date of the Prospectus, COVID-19 has not resulted in any stoppage of the production activities in the Company's Tel Aviv facility, the Company's suppliers of components of the Genio® system are continuing to supply components and support functions (R&D, QA&RA) also continued, albeit with reduced capacity. Elective surgeries were on-hold as from March to August 2020 in certain geographies across Europe and Australia but are selectively re-opening.

Due to the high degree of unpredictability of COVID-19, the Company foresees challenges in training and proctoring new centers and their surgeons in the United States and Europe. Patients being less willing to travel to these centers or their travelling being restricted could become an issue and potentially impact the Company's clinical and commercial activities.

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

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

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

Taking into account its current limited financial and managerial resources, the Company will have to carefully identify which markets to target first based on parameters such as market size, market readiness, competition, and the type of product and allocate its financial and managerial resources accordingly.

In order to identify its primary target markets, the Company makes projections on the number of people by target market. These projections are derived from a variety of sources, including, but not limited to, scientific literature, governmental statistics and market research, and are highly contingent on a number of variables that are difficult to predict and may prove to be too high. If as a result of these or other factors the market for the Genio® system does not develop as currently anticipated, the Company's ability to generate revenue

could be materially adversely affected. If the Company uses its limited financial and managerial resources to promote a particular indication expansion that is not ultimately sufficiently commercially successful, this could result in a smaller population of patients who could benefit from the Genio® system than the Company anticipates which would result in lower potential revenue for the Company.

See Part 8 – (Business), section 8.3 (*Marketing strategy and commercial objectives*) for more information on the Company's marketing strategy and commercialization efforts.

### **2.3 Risks relating to the Company's financial situation**

*In the opinion of the Company, it does not currently have sufficient working capital for its present requirements, that is for at least the next 12 months following the date of this Prospectus. While in the opinion of the Company following the Offering it will have sufficient working capital to do so, the Company could require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available.*

Based on a working capital assessment, the Company expects that it will have a shortfall of approximately € 13 million by the end of the third quarter of 2021. See Part 6 – (Capitalisation and indebtedness), section 6.2 (*Working capital statement*).

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

- acceptance of the Company's 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 the Company's patents or other intellectual property rights in various jurisdictions;
- the cost of defending, in litigation or otherwise, any claims that the Company infringes third-party patents or other intellectual property rights;
- the cost 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 the Company acquires or invests in products, technologies and businesses, although the Company currently has no commitments or agreements relating to any of these types of transactions; and
- the costs of operating as a public company.

Any additional equity or debt financing that the Company raises may contain terms that are not favorable to

the Company or its shareholders. If the Company raises additional funds by selling additional Shares or other securities convertible into or exercisable or exchangeable for Shares after this Offering (including through the exercise by the Underwriters of their Over-allotment Option), the issuance of such securities will result in dilution to the Company's shareholders. The price per share at which the Company sell additional Shares or securities convertible into or exercisable or exchangeable for Shares, in future transactions may be higher or lower than the price per Share paid by investors in this Offering.

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

Furthermore, the Company cannot be certain that additional funding will be available on acceptable terms, if at all. While the ultimate overall economic impact caused by the COVID-19 pandemic may be difficult to assess or predict, it is currently resulting in significant disruption to the global financial markets. If the resulting disruptions are sustained or recurrent, they could make it more difficult for the Company to access capital, which could in the future negatively affect its ability to source required funding, which could delay or prevent it from executing its strategy as planned. If it does not have, or is not able to obtain, sufficient funds, the Company may have to delay development or commercialization of its products or license to third-parties the rights to commercialize products or technologies that the Company would otherwise seek to commercialize. The Company also may have to reduce marketing, customer support or other resources devoted to its products or cease operations.

***The Company may not be able to achieve or maintain profitability.***

The Company has incurred operating losses and negative operating cash flows in each period since it was incorporated in 2009. As of 31 December 2019, the Company had a loss brought forward of € 47.1 million. These losses have resulted primarily from costs incurred in the development of the Genio® technology, as well as from general and administrative costs associated with the Company operations and manufacturing. The Company intends to fund the continued development of its technology and the Genio® product line, to expand manufacturing capabilities, to seek further regulatory and marketing approvals for the Genio® system in order to be able to secure reimbursement by payers, to maintain, protect and expand the Company's intellectual property portfolio, to expand sales and marketing activities and to scale-up manufacturing capacities. Approval in the United States from the Food and Drug Administration ("FDA") to start the investigational device exemption ("IDE") trial (DREAM trial) was obtained on 23 June 2020. Depending on approval of the proposed study design and proposed timelines, the Company expects to obtain post-market approval by the end of 2022. The aim of the study is to support a marketing authorization from the FDA in the United States, as well as to support product reimbursement more generally. The Company also plans to conduct additional clinical studies and as a result, management expects that clinical affairs expenses will increase significantly over the next several years. These expenses, together with anticipated commercial/sales, R&D and general and administrative expenses, will likely result in the Company incurring further losses for at least the next few years.

The Company may not achieve profitability, which could impair its ability to sustain operations or obtain

any required additional funding. If the Company does achieve profitability in the future, it may not be able to sustain profitability in subsequent periods, and it may suffer net losses and/or negative operating cash flows in subsequent periods.

It is possible that the Company will experience fluctuating revenues, operating results and cash flows. In that case, as a result, period-to-period comparisons of financial results are not necessarily meaningful, and results of operations in prior periods should not be relied upon as an indication of future performance.

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

Since September 2011, the Company has received financial support from the Walloon Region in the form of recoverable cash advances and subsidies for more than € 8 million. In March 2018, in accordance with Section 27A of the Australian Industry Research and Development Act 1986, the Australian Government gave notice to the Company's Australian subsidiary of Registration for the R&D Tax Incentive from the 2017/2018 income year. This incentive represents 43.5% of the yearly eligible R&D expenditure. Since the incorporation of the Australian subsidiary, the total amount received by Nyxoah PTY LTD is AUD 0.9 million (approximately € 0.5 million).

All these subsidies and reimbursable cash advances increased the Company's financial resources to support R&D and clinical development projects. However, the Company cannot predict whether it or its subsidiaries will continue to benefit from such incentives and/or advantages and/or to what extent.

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

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

The Genio® system requires customized components and services that are currently available from a limited number of sources (see Part 8 - (Business), section 8.6.6 (*Manufacturing and supply*) and section 8.12.1 (*Supplier agreements*)). If these suppliers decide not to supply, are unable to supply, or if they provide the Company with components or services of insufficient quality, this could harm the Company's reputation and business by affecting, for example, product availability and performance. The Company's suppliers might not be able or willing to continue to provide the Company with the components or services it needs, at suitable prices or in sufficient quantity or quality. If any of the Company's existing suppliers are unable or unwilling to meet its demand for components or services, or if the services or components that they supply do not meet quality and other specifications, clinical studies or sales of the Genio® system could be delayed or halted, which could prevent the Company from achieving or maintaining profitability. For instance, where the Company relies on a single source supplier for a critical component, even if additional suppliers are available to provide a secondary source for these critical components, the addition of a new supplier to the production process generally requires extensive evaluations, testing and regulatory approval, making it difficult and costly for the Company to diversify its exposure to single source suppliers. The Company's suppliers, in turn, depend on their own suppliers and supply chain. In addition, if the Company has to switch to a replacement supplier for any of its product components or for certain services required for the production and assembly

of the Genio® system (for example, the sterilization and coating of the product components), or if the Company has to commence its own manufacturing to satisfy market demand, it may face delays, and the manufacturing and delivery of the Genio® system could be interrupted for an extended period of time, which could delay completion of its clinical studies or commercialization and prevent the Company from achieving or maintaining profitability. Alternative suppliers may be unavailable, may be unwilling to supply, may not have the necessary regulatory approvals or certifications, or may not have in place an adequate quality management system. Furthermore, modifications to a service or component made by a third-party supplier could require new approvals or certifications from the relevant regulatory authorities before the modified service or component may be used.

In addition, the Company's suppliers may discontinue their supply of components or services upon which the Company relies before the end of the product life of the Genio® system. The timing of a discontinuation may not allow the Company sufficient time to develop and obtain regulatory approval for replacement components or service before the Company exhausts its inventory. If suppliers discontinue their supply of components or services, the Company may have to pay premium prices to its suppliers to keep their production or service lines open or to obtain alternative suppliers, buy substantial inventory to last until the scheduled end of life of the Genio® system or through such time as the Company has an alternative component developed and approved by the regulatory authorities or temporarily cease supplying the Genio® system once its inventory of the affected component is exhausted.

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

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

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

The Company expects to expand its operations and grow its clinical development, manufacturing, administrative and commercial operations. This will require hiring a number of qualified clinical, scientific, commercial and additional administrative, sales and marketing personnel. Competition for skilled personnel is intense and may limit the Company's ability to hire and retain highly qualified personnel on acceptable terms or at all. Competitors may have greater financial and other resources, different risk profiles and a longer history than the Company. If the Company is unable to identify, attract, retain and motivate these highly skilled personnel, it may be unable to continue its development, commercialization or growth.

In November 2019, Enrique Vega, at that time the CEO of the Company, decided to leave the Company for personal reasons. He was replaced by Olivier Taelman who was at the time the the Company's Chief Operating and Commercial Officer.

As a retention plan, the Company offers long-term incentives to key personnel through a warrant grant program. Further, non-competing clauses are included in all employee contracts.

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

The Company relies, and will rely in the future, on third parties to conduct clinical studies, perform data collection and analysis and provide marketing, manufacturing, regulatory advice and other services that are crucial to its business. In particular, the Company's technology and product development activities or clinical studies conducted in reliance on third parties may be delayed, suspended, or terminated if (i) the third parties do not devote a sufficient amount of time or effort to the Company's activities or otherwise fail to successfully carry out their contractual duties or to meet regulatory obligations or expected deadlines, (ii) the Company replaces a third party, (iii) the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons including the loss of data; or (iv) the third party becomes bankrupt or enters into liquidation. The Company is currently not planning on relying on contract research organizations for its ongoing clinical trials (BETTER SLEEP and ELiSA), but contract research organizations might be used in its future trials.

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

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

Expedited, reliable shipping is essential to the Company's operations since the components of the Genio® system are manufactured to the Company's specifications by third-party suppliers in various jurisdictions. While the initial assembly of the different electronic components is done by different external suppliers, the final assembly is done in the Company's facility in Tel Aviv. As a result, the Company relies heavily on providers of transport services for reliable and secure point-to-point transport of the key components of the Genio® system to the Company's facility and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any components, it would be costly to replace such components in a timely manner and such occurrences, if they resulted in delays to the assembly and shipment of the completed Genio® system to customers, may damage the Company's reputation and lead to decreased demand for the Genio® system and increased cost and expense to the Company's business. In

addition, any significant increase in shipping rates could adversely affect the Company's operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services the Company uses would adversely affect the Company's ability to process orders for the Genio® system on a timely basis.

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

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

The market for sleep disordered breathing and OSA solutions is increasingly competitive. The Company's success is contingent on its ability to provide innovative and superior solutions as well as a strong value proposition for all stakeholders to achieve their health goals, and the Company's ability to achieve these goals is not certain. The Company is pioneering a new category in the care of sleep disordered breathing conditions with a system designed at the origin to treat OSA via a bilateral hypoglossal nerve stimulation system.

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

Additionally, the Company also considers, as indirect competition, invasive surgical treatment options such as uvulopalatopharyngoplasty and maxillomandibular advancement surgery and, to a lesser extent, mandibular advancement devices, which are primarily used in the treatment of mild to moderate OSA.

The Genio® therapy is approved for use as a second-line therapy in the treatment of moderate-to-severe OSA in patients who do not tolerate, refused or failed Positive Airway Pressure therapy. If one or more CPAP device manufacturers successfully develop a CPAP device that is better tolerated and demonstrates significantly higher therapy compliance, or if improvements in other second-line therapies make them more effective, cost effective, easier to use or otherwise more attractive than the Genio® system, these therapies could have a material adverse effect on the Company's sales, financial condition and results of operations.

OSA prevalence is on the rise and the Company expects increasing competition from its current competitors, which may be well established and enjoy greater resources or other strategic advantages, as well as from new entrants into the market, some of which may become significant competitors in the future.

As the markets for sleep disordered breathing and OSA grow and change, the Company expects the markets will continue to attract existing and new emerging companies that will be Company competitors, that currently engage in the fields of chronic disease management and neurostimulation, and which may choose, to venture into developing and introducing new approaches, products and services.

Any products developed by the Company's competitors that have been commercialized or are in clinical studies or in development or are developed in the future could have superior clinical results, be easier to implement clinically, be more convenient for patients, be less expensive than the Genio® system or reach commercialization sooner in certain target markets. In addition, products are generally provided at no charge during clinical studies. Entry by a competitive product into clinical studies while the Genio® system is being

commercialized could have an adverse effect on the Company's sales. For more information on the competitive landscape, see Part 8 – (Business), section 8.6.4 (*Hypoglossal nerve stimulation – competitive landscape*).

The commercial availability of any approved competing product could potentially inhibit recruitment and enrolment in the Company's clinical studies. The Company may successfully conclude its clinical studies and obtain final regulatory approval, and nevertheless may fail to compete against competitors or alternative treatments that may be available or developed for the relevant indication. Alternative treatments include drugs, devices and surgery, among others. New treatment options may emerge yielding clinical results better than or equal to those achieved with the Genio® system, possibly at a lower cost. Emergence of such new therapies may inhibit the Company's ability to develop and grow the market for the Genio® system. Furthermore, new entrants into the markets in which the Company operates could also decide to more aggressively compete on price, requiring the Company to reduce prices to maintain market share. For more information on alternative and new treatments, see Part 8 – (Business), section 8.5.3 (*Other treatment options being investigated*).

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

The Company's research and development facility and all manufacturing facilities are located in Tel Aviv, Israel. In addition, the majority of its employees and some officers are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly adversely affect the Company's business. Any armed conflicts, terrorist activities, political instability in the region or the interruption or curtailment of trade between Israel and its trading partners could adversely affect the Company's business conditions in general and harm its results of operations. The Company's commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although Israeli legislation requires the Israeli government to cover the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, the Company cannot assure that this government coverage will be maintained, or if maintained, will be sufficient to fully compensate the Company for damages incurred. Any losses or damages incurred by the Company could have a material adverse effect on its business.

## **2.6 Risks related to manufacturing**

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

The Company's revenues and other operating results will depend, in large part, on its ability to manufacture and sell the Genio® system in sufficient quantities and quality, in a timely manner, and at a cost that is economically attractive.

The Company expects to be required to significantly increase manufacturing volumes as clinical studies on the Genio® system are expanded and the Genio® system is commercialized. The capacity of the Company's facility in Tel Aviv is expected to cover the IS and ES demand for 2020 and the first and second quarter of 2021. In order to support future demand for the Genio® system, the Company would likely need to expand its manufacturing capacity, which could require opening a new facility or outsourcing to a third-party contract

manufacturing organization. Opening a new manufacturing facility could involve significant additional expenses, including for the construction of a new facility, the movement and installation of key manufacturing equipment, the modification of manufacturing processes and for the recruitment and training of new team members. In addition, the Company must also notify, and in most cases obtain approval from, regulatory authorities regarding any changes or modifications to its manufacturing facilities and processes, and the regulatory authorities might not authorize the Company to proceed or might delay the process significantly. See Part 8 – (Business), section 8.6.6 (*Manufacturing and supply*) for a description of the manufacturing capacity and third-party manufacturing.

In addition, the Company's current business expectation is that the cost of goods sold will decline over time as the cumulative volume manufactured grows. However, the Company or its suppliers might not be able to increase yields and/or decrease manufacturing costs with time, and in fact costs may increase, which could prevent the Company from achieving or maintaining profitability.

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

To ensure adequate inventory supply of the Genio® system in general and its components (e.g. for replacement, upgrade or maintenance purposes), the Company must forecast inventory needs and place orders with its suppliers based on its estimates of future demand for the Genio® system and/or its components. The Company has never commercialized its products before and its ability to accurately forecast demand for its Genio® system could be negatively affected by many factors, including failure to accurately manage the Company's expansion strategy, product introductions by competitors, an increase or decrease in customer demand for the Genio® system or for products of the Company's competitors, failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause the Company's gross margin to be adversely affected and could impair the strength of the Genio® brand. Conversely, if the Company underestimates customer demand for the Genio® system, the Company third-party contract manufacturers may not be able to deliver products to meet the Company's requirements, and this could result in damage to the Company's reputation and customer relationships. In addition, if the Company experiences a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to the Company, or at all, or suppliers or third-party manufacturers might not be able to allocate sufficient capacity in order to meet the Company's increased requirements, which could have an adverse effect on the Company's ability to meet customer demand for the Genio® system.

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

## **2.7 Legal and regulatory Risks**

***The Genio® system is still unapproved in certain significant markets, such as the United States market,***

***and seeking and obtaining regulatory approval for active implantable medical devices can be a long, expensive and uncertain process.***

Applications for prior regulatory approval in the countries where the Company intends to sell or market its products may require extensive pre-clinical, clinical and technical testing, all of which must be undertaken in accordance with the requirements of regulations established by the relevant regulatory agencies, which are complex and have become more stringent over time. The Company may be adversely affected by potential changes in government policy or legislation applicable to implantable medical devices. At the date of this Prospectus, the Company has only received regulatory approval for the European Economic Area ("EEA") Member States (through CE-Marking) for its Genio® system.

In the United States, the Company is in the early stages of a process of seeking marketing approval. The Company received an investigational device exemption ("IDE") approval from the FDA on 23 June 2020 and is in the process of formally confirming the appropriate regulatory pathway to pursue to receive marketing authorization. Even though it has received an IDE, the Genio® system may not successfully obtain marketing authorization. In addition, there may be substantial and unexpected delays in the process, for example in the initiation and completion of clinical study testing and evaluation. For more information on the importance of the United States as a significant market for the Genio® system, see Part 8 – (Business), section 8.5.4 (*Hypoglossal nerve stimulation, a proven strategy to treat OSA*) and Part 9 – (Operating and financial review), section 9.3.1 (*Regulatory approvals*).

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. The pertinent submission with the Federal Communications Commission, which is expected to be required for commercial release, will be done prior to commercialization or before the start of the pivotal IDE study and it will take approximately three months to complete the test.

For an overview of the regulatory framework, see Part 8 – (Business), section 8.7 (*Regulatory framework*).

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

The Company currently manufactures the Genio® system and has entered into relationships with third party suppliers to manufacture and supply certain components of the Genio® system. The manufacturing practices of the Company and its third-party suppliers are subject to ongoing regulation and periodic inspection. Any failure to follow and document the adherence to regulatory requirements (including having in place an adequate QMS in line with the most up-to-date standards and regulations) by the Company or its third party suppliers may lead to significant delays in the availability of the Genio® system for commercial sale or clinical studies, may result in the termination of or a hold on a clinical study, or may delay or prevent filing or approval or maintenance of marketing applications for the Genio® system.

Failure to comply with applicable regulations could also result in regulatory authorities taking various actions, including:

- levying fines and other civil or criminal penalties;
- imposing consent decrees or injunctions;
- requiring the Company to suspend or put on hold one or more of the Company's clinical studies;
- suspending or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring the Company to suspend manufacturing activities, sales, imports or exports of the Genio® system;
- requiring the Company to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving the Company;
- mandating product recalls or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

Any of the foregoing actions could be detrimental to the Company's reputation or result in significant costs or loss of revenues for the Company.

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

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

The new Medical Device Regulation also imposes a re-designation of the "**Notified Bodies**" (i.e. the organizations designated by the EEA Member State in which they are based, which are responsible for assessing whether medical devices and manufacturers of medical devices meet the applicable regulatory requirements in the EEA). To be re-designated Notified Bodies must demonstrate increased technical expertise in their scope of designation, as well as improved quality management systems. This re-designation process, has caused backlogs in the assessment of medical devices and medical device manufacturers during the transition period leading up to the May 2021 effective date of the new Medical Device Regulation.

The CE-Mark obtained in 2019 for the Company's Genio® system will remain valid until March 2024. It must be re-approved under the new Medical Device Regulation before the end of that period of time. The recertification requires the demonstration that the performance and the safety of the system has been maintained and that the system continues to meet existing regulations and standards (see Part 8 - (Business), section 8.7.1 (*Regulatory landscape in the EEA*)). Otherwise, the marketing and sale of the Genio® system in EEA Member States may be temporarily or permanently prohibited. Modifications to the Genio® system, if any, will also require approval under the new Medical Device Regulation.

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

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

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

Any delay or failure to comply with the new Medical Device Regulation could result in the sale of the Genio® system being temporarily or permanently prohibited in EEA Member States and affect the Company's reputation, business, financial condition, results of operations and prospects.

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

The Company has developed and maintains a quality management system for medical devices intended to ensure quality of the Company's products and activities. The system is designed to be in compliance with regulations in many different jurisdictions, including the Quality Systems Regulations mandated by the FDA in the United States and the requirements of the AIMD Directive in the European Union, including the international standard ISO13485 required by the countries in Europe that recognize the CE-Mark, Israel, New Zealand and Australia. See Part 8 - (Business), section 8.7 (*Regulatory framework*) for a description of the regulatory framework.

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

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

Any change or modification to a device (including changes to the manufacturing process) may require further approvals (depending on the jurisdiction) and must be made in compliance with appropriate quality system regulations (such as the quality systems regulations for the United States and the AIMD Directive and the new Medical Device Regulation for Europe), which compliance may cause interruption to or delays in the

marketing and sale of the Company's products. Regulations and laws regarding the manufacture and sale of AIMDs are subject to future changes, as are administrative interpretation and policies of regulatory agencies. If the Company fails to comply with such laws and regulations where the Company would intend to market the Genio® system, the Company could be subject to enforcement action including recall of its device, withdrawal of approval or clearance and civil and criminal penalties. If any of these events occur, it may materially and adversely affect the Company's business, financial condition, results of operations and prospects.

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

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

All medical devices have associated risks. Regulatory authorities regard active implantable medical devices ("AIMDs") as the highest risk category of medical devices and accordingly AIMDs are subject to a high level of scrutiny when seeking regulatory approval. The Genio® system was reviewed, classified and the CE-Mark was granted by the Company's European Notified Body as an AIMD. A CE-Mark in Europe indicates that the device in question is in full compliance with European legislation. Medical devices approved in the EU only need to demonstrate that they perform or will probably perform as designed and that the potential benefits outweigh potential risks. Devices approved first in the EU may be associated with an increased risk of post-marketing safety alerts and recalls. On the other hand, before FDA approval of a medical device in the US, a device must not only be shown to be safe, but also efficacious. The risk classification for the Genio® system is still under review by the U.S. Food and Drug Administration and other International Regulatory bodies. 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. For an overview of the adverse effects related to the Genio® system identified during the BLAST OSA Study, see Part 8 – (Business), section 8.6.5b (*Clinical studies and results*).

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

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

AIMDs are characterized by a complex manufacturing process, requiring adherence to demanding product specifications. The Genio® system uses many disciplines including electrical, mechanical, software, bio-materials, and other types of engineering. Device failures discovered during the clinical study phase may lead to suspension or termination of the study. 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 once regulatory approval has been obtained for the commercial distribution of the device. For example, engineers employed by the Company undertaking development or manufacturing activities may make an incorrect decision or make a decision during the engineering phase without the benefit of long-term experience, and the impact of such wrong decisions may not be felt until well into a product's life cycle. The relevant governmental authorities may require the recall of commercialized products in the event of material deficiencies, or defects in design or manufacture, or in the event that a product poses an unacceptable risk to health. The Company on its own initiative may recall a product if any material deficiency in a device is found. A government mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues.

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

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

The Genio® system is designed to affect important bodily functions and processes. As medical device manufacturer, the Company is exposed to the product liability claims arising from the Genio® system failures and malfunctioning, product use and associated surgical procedures. This risk exists even if the Genio® system is cleared or approved for commercial sale by regulatory authorities and manufactured in facilities licensed and regulated by the applicable regulatory authority. The medical device industry has historically been subject to extensive litigation over product liability claims, and the Company may face product liability suits if the Genio® system causes, or merely appears to have caused, patient injury or death. In addition, an injury that is caused by the activities of the Company's suppliers, such as those who provide the Company with components and raw materials, may be the basis for a claim against the Company. Product liability claims may be brought against the Company by patients, healthcare providers or others selling or otherwise being exposed to the Genio® system, among others. If the Company cannot successfully defend itself against product liability claims, the Company will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in one or more of the following:

- costs of litigation;
- distraction of management's attention from its primary business;
- the inability to commercialize the Genio® system or new products;
- decreased demand for the Genio® system;
- damage to the Company's reputation;

- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of sales.

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

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

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

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

The Company is subject to various fraud and abuse laws.

For instance, pursuant to the Belgian Act of 18 December 2016 and its implementing Royal Decree of 14 June 2017 (the "**Sunshine Act**"), manufacturers of medical devices are required to document and disclose all direct or indirect premiums and benefits granted to healthcare professionals, healthcare organizations and patient organizations with a practice or a registered office in Belgium. Also, under Article 10 of the Belgian Act of 25 March 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.

Upon the planned launch of operations in the United States, the Company's operations will be subject to various federal and state fraud and abuse laws. Such laws include the federal and state anti-kickback statutes, physician payment transparency laws, false claims laws and sunshine laws. These laws may affect, among other things, the Company's proposed sales and marketing and education programs and require it to implement additional internal systems for tracking certain marketing expenditures and to report to governmental authorities. In addition, the Company may be subject to patient privacy and security regulations by both the federal government and the states in which the Company conducts its business.

If the Company's operations are found to be in violation of any of the laws described above or any other

governmental regulations that apply to it, it may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of the Company's operations, the exclusion from participation in government healthcare programs and individual imprisonment.

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

The Company and certain third parties that it relies on for its operations collect and store confidential and sensitive information, and their operations are highly dependent on information technology systems, including internet-based systems, which may be vulnerable to breakdown, wrongful intrusions, data breaches and malicious attack. This information includes, among other things, intellectual property and proprietary information, the confidential information of any of the Company's future collaborators and licensees, the personal data of the Company's 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. Any attack or breach could compromise the Company's networks or those of related third parties and stored information could be accessed, publicly disclosed, lost, or stolen, resulting in legal claims or proceedings, liability (including substantial fines and penalties) under laws that protect the privacy of personal information, including GDPR, and lead to delays and impediments to the Company's development efforts, and damage to the Company's reputation. In particular, the loss of pre-clinical or clinical study data from completed, ongoing or planned studies could result in delays in the Company's regulatory approval efforts and significantly increase the Company's costs to recover or reproduce the data. When the Company launches operations in the United States, it will also need to comply with the data privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations (collectively "HIPAA"), and similar state laws, as well as other data privacy laws.

Since the Genio® system is a wireless medical device, additional complications may arise with respect to the wireless, RF, technology used for the communication between the system parts. While the Company has reviewed and determined the integrity of its system and the communication protocol, use of wireless technology imposes a risk that third parties might attempt to access the Company's system. An additional risk is related to interruption or distortion of communication by other devices that might be used in the vicinity of the system, especially when in use by the user, which might have an effect on the effectiveness of the therapy delivered by the system. Any such unauthorized access, interruption or distortion could result in legal claims or proceedings, liability (including substantial fines and penalties) under laws that protect the privacy of personal information (such as the GDPR), delays and impediments to the Company's development efforts, damage to the Company's reputation, and ineffectiveness of the therapy. In addition, procedures and safeguards must continually evolve to meet new data security challenges, and enhancing protections, and conducting investigations and remediation, may impose additional costs on the Company.

## **2.8 Risks relating to intellectual property**

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

The Company's success will depend significantly on its ability to protect its proprietary and licensed in rights, including in particular the intellectual property and trade secrets related to the Genio® system. The Company

relies on a combination of patent(s) (applications), trademarks, designs and trade secrets, and uses non-disclosure, confidentiality and other contractual agreements to protect its technology. For more information on the intellectual property policy of the Company, see Part 8 – (Business), section 8.8 (*Intellectual property*). The Company generally seeks patent protection where possible for those aspects of its technology and products that it believes provide significant competitive advantages. However, the Company may be unable to adequately protect the intellectual property rights and trade secrets related to the Genio® system or may become subject to a claim of entitlement, infringement or misappropriation that it is unable to settle on commercially acceptable terms. The Company cannot be certain that patents will be issued with respect to the Company's pending or future patent applications. In addition, the Company does not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or whether they will prevent the development of competitive patents or provide meaningful protection against competitors or against competitive technologies.

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

***The Company could become subject to intellectual property litigation.***

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

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

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

The Company relies upon unpatented confidential and proprietary information, including technical information, know-how, and other trade secrets to develop and maintain its competitive position, the Genio® system. While the Company generally enters into non-disclosure or confidentiality agreements with its employees and other third parties to protect its intellectual property and trade secrets, such agreements might be breached, or might not provide meaningful protection for the Company's trade secrets and proprietary information or adequate remedies might not be available in the event of an unauthorized use or disclosure of such information. For more information on the Company's confidentiality policy, see Part 8 – (Business), section 8.8.3 (*Confidential information and trade secrets*).

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

The Company relies on licensing agreements providing the Company exclusivity in the field of its practice. For an overview of the current licensing agreements, see Part 8 – (Business), section 8.8.1 (*Utility and design patents*) and Part 12 – (Related party transactions). While the Company has ensured through multiple robust agreements acquisition of exclusive licenses and freedom to operate for its technology, as with any agreement, under unexpected or unpredictable circumstances, these could be under a risk of being terminated despite companies' efforts and diligence in ensuring integrity of the agreement. Should the agreements be found invalid or licenses revoked and the licensor decide to sue the Company for infringement of its patents rights, this could expose the company to risks of litigation. In addition, any intellectual property litigation could force the Company to do one or more of the following: (i) stop selling the Genio® system or using technology that contains the allegedly infringing intellectual property; (ii) forfeit the opportunity to license the Company patented technology to others or to collect royalty payments based upon successful protection and assertion of its intellectual property rights against others; (iii) pay substantial damages to the party whose intellectual property rights the Company may be found to be infringing; or (iv) redesign those products that contain or utilize the allegedly infringing intellectual property.

The requirement to obtain licenses to third party intellectual property could also arise in the future. If the Company needs to license in any third-party intellectual property, it could be required to pay lump sums or royalties on its products. In addition, if the Company is required to obtain licenses to third party intellectual property, it might not be able to obtain such licenses on commercially reasonable terms or at all.

## **2.9 Risks relating to the Offered Shares and the Offering**

***The fact that no minimum amount is set for the Offering may affect the Company's investment plan and the liquidity of the Shares.***

The Company has the right to proceed with a capital increase in a reduced amount, corresponding to a number of Offered Shares that is lower than the maximum number of Offered Shares in the Offering. Since there is no minimum amount of the Offering, if not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from Subscription Commitments (as described in Part 0 - (Risk Factors), section 2.3 (*Risks relating to the Company's financial situation*), Part 4 - (Use of Proceeds), section 4.2 (*Reasons of the Offering and use of proceeds*) and Part 14

- (The Offering), section 14.2 (*Conditions and nature of the Offering*). The actual number of Shares subscribed for, or placed, will be confirmed on the Company's website and by way of a press release together with the Offering Price. As a result, a number of Shares that is lower than the maximum number of Offered Shares in the Offering could be available for trading on the market, which could limit the liquidity of the Shares. Furthermore, the Company's financial means in view of the uses of proceeds would in such case also be reduced. If this were to be the case, the Company may have to reduce its level of investments or look for further external funding.

***There has been no prior public market for the Shares and an active market for the Shares may not develop.***

Prior to the Offering, there has been no public trading market for the Shares. An active trading market for the Shares may not develop or, if developed, may not be sustained or be sufficiently liquid following the closing of the Offering. Taking into account the lock-up arrangements as described in section 15.3 (*Lock-up arrangements*), it is expected that after the Offering, approximately 15.4 per cent of the Company's Shares will be freely tradeable. Furthermore, the Offering Price is not necessarily indicative of the prices at which the Shares will subsequently trade on the stock exchange. If an active trading market is not developed or maintained, the liquidity and trading price of the Shares could be adversely affected. The degree of liquidity of the Shares may negatively impact the price at which an investor can dispose of the Shares where the investor is seeking to achieve a sale within a short timeframe.

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

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

- 19; and
- the risk factors mentioned above.

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

***Future sales of substantial amounts of Shares, or the perception that such sales could occur, could adversely affect the market value of the Shares.***

A sale of a significant number of Shares on the public markets, or the perception that such sale will occur, may adversely affect the market price of the Shares. The Company cannot make any predictions as to the sale or perception on the market price of the Shares. Subject to certain exceptions, as described in section 15.3 (*Lock-up*), (i) the current holders of shares or other securities representing more than 2% of the Company's Shares on a fully diluted basis (excluding the new Shares to be issued pursuant to the Offering) have entered into a lock up arrangement with the Underwriters with respect to certain of their Shares and other securities issued by the Company for a period of twelve months after the Listing Date, and (ii) the current holders of shares or other securities representing 2% or less of the Company's Shares on a fully diluted basis (excluding the new Shares to be issued pursuant to the Offering) have entered into a lock up arrangement with the Underwriters with respect to certain of their Shares and other securities issued by the Company for a period of six months after the Listing Date.

For example, given the fact that several existing shareholders have been investors in the Company for many years, it cannot be excluded that some of them may want to sell all or part of their Shares following the expiration of their lock-up obligations where applicable. Future potential sales of Shares by the relevant existing shareholders, or the perception that such sales could occur, may adversely affect the market price of the Shares.

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

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

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

See Part 5 – (Dividends and Dividend Policy), section 5.1 (*Dividends*) for more information on the applicable rules under Belgian law with regard to dividends.

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

Following the closing of the Offering and listing of its Shares, the Company will have a number of significant shareholders. For an overview of the Company's current significant shareholders see Part 11 – (Major Shareholders).

Currently, the existing shareholders of the Company and the Company have entered into a shareholders' agreement (the "**Shareholders' Agreement**"), containing, amongst others, terms regarding the Company's business and governance, as well as pre-emptive rights and transfer restrictions regarding the Shares. The Shareholders' Agreement will be terminated effective as of the closing of the Offering. The Company is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock up arrangements as described above). Nevertheless, they could, alone or together, have the ability to elect or dismiss directors, and, depending on how broadly the Company's other Shares are held, take certain other shareholders' decisions that require at least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such items are submitted to voting by the shareholders. Alternatively, to the extent that these shareholders have insufficient votes to impose certain shareholders' decisions, they could still have the ability to block proposed shareholders' resolutions that require at least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such decisions are submitted to voting by the shareholders. Any such voting by the shareholders may not be in accordance with the interests of the Company or the other shareholders of the Company.

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

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

### 3. IMPORTANT INFORMATION

#### 3.1 Responsibility statement

In accordance with Article 26, §1 and §2 of the Belgian Act of 11 July 2018 on the public offering of securities and the admission of securities to trading on a regulated market (the "**Prospectus Act**"), the Company, represented by its Board of Directors, assumes responsibility for the completeness and accuracy of all of the contents of this Prospectus. The Company attests that to the best of its knowledge, the information contained in the Prospectus is in accordance with the facts and that the Prospectus makes no omission likely to affect its import.

None of the Underwriters makes any representation or warranty, express or implied, as to, or assumes any responsibility for, the accuracy or completeness or verification of the information in this Prospectus, and nothing in this Prospectus is, or shall be relied upon as, a promise or representation by the Underwriters (or any of their respective officers, directors or employees), whether as to the past or the future. Accordingly, the Underwriters disclaim, to the fullest extent permitted by applicable law, any and all liability, whether arising in tort, contract or otherwise, in respect of this Prospectus or any such statement.

In making an investment decision, investors must rely on their own assessment, examination, analysis and enquiry of the Company, the terms of the Offering and the contents of this Prospectus, including the merits and risks involved. Any purchase of the Offered Shares should be based on the assessments that an investor may deem necessary, including the legal basis and consequences of the Offering, and including possible tax consequences that may apply, before deciding whether or not to invest in the Offered Shares. In addition to their own assessment of the Company and the terms of the Offering, investors should rely only on the information contained in this Prospectus, including the risk factors described herein, any supplements to this Prospectus as may be published (if any) and any notices that the Company may publish under applicable law or the relevant rules of Euronext Brussels.

Investors must also acknowledge that: (i) they have not relied on the Underwriters or any person affiliated with the Underwriters in connection with any investigation of the accuracy of any information contained in this Prospectus or their investment decision; and (ii) they have relied only on the information contained in this Prospectus, and that no person has been authorized to give any information or to make any representation concerning the Company or its subsidiaries or the Shares (other than as contained in this Prospectus) and, if given or made, any such other information or representation should not be relied upon as having been authorized by the Company or the Underwriters.

None of the Company or the Underwriters, or any of their respective representatives, is making any representation to any offeree or purchaser of the Offered Shares regarding the legality of an investment in the Offered Shares by such offeree or purchaser under the laws applicable to such offeree or purchaser. Each investor should consult with his or her own advisors as to the legal, tax, business, financial and related aspects of a purchase of the Offered Shares.

No person has been authorized to give any information or to make any representation in connection with the Offering other than those contained in this Prospectus, and, if given or made, such information or representation must not be relied upon as having been authorized. Without prejudice to the Company's obligation to publish supplements to the Prospectus when legally required (as described below), neither the

delivery of this Prospectus nor any sale made at any time after the date hereof shall, under any circumstances, create any implication that there has been no change in the Company's affairs since the date hereof or that the information set forth in this Prospectus is correct as of any time since its date.

The Underwriters are acting exclusively for the Company and no one else in connection with the Offering. They will not regard any other person (whether or not a recipient of this document) as their respective clients in relation to the Offering and will not be responsible to anyone other than the Company for providing the protections afforded to their respective clients nor for giving advice in relation to the Offering or any transaction or arrangement referred to herein.

This Prospectus is intended to provide information to potential investors in the context of and for the sole purpose of evaluating a possible investment in the Offered Shares. It contains selected and summarized information, does not express any commitment or acknowledgment or waiver, and does not create any right, express or implied, towards anyone other than a potential investor. Investors must assess, with their own advisers if necessary, whether the Offered Shares are a suitable investment for them, considering their personal income and financial situation. In case of doubt about the risk involved in investing in the Offered Shares, investors should abstain from investing in the Offered Shares.

The summaries and descriptions of legal provisions, accounting principles or comparisons of such principles, legal company forms or contractual relationships reported in the Prospectus may under no circumstances be interpreted as a basis for credit or other evaluation, or as investment, legal or tax advice for prospective investors. Prospective investors are urged to consult their own financial adviser, accountant or other advisers concerning the legal, tax, economic, financial and other aspects associated with the trading or investment in the Shares.

### **3.2 Prospectus approval**

The FSMA, as competent authority under the Prospectus Regulation, approved the English version of this Prospectus on 8 September 2020 in accordance with Article 20 of the Prospectus Regulation. The FSMA only approves this Prospectus as meeting the standard of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. The FSMA's approval does not imply any opinion by the FSMA on the suitability and the quality of the Offering or on the status of the Company and should not be considered as an endorsement of the Company that is the subject of this Prospectus nor the quality of the Offered Shares. This Prospectus has been prepared in English and translated into French. The Summary of the Prospectus has also been translated into Dutch and French. The Company is responsible for the consistency between the French, English and Dutch versions of (the Summary of the) Prospectus. Investors can rely on the French language version of this Prospectus, and its translated version, in their contractual relationship with the Company. Without prejudice to the responsibility of the Company for inconsistencies between the different language versions of the Prospectus or the summary of the Prospectus, in the case of discrepancies between the different versions of this Prospectus, the English version will prevail.

The information in this Prospectus is as of the date printed on the front cover, unless expressly stated otherwise. The delivery of this Prospectus at any time does not imply that there has been no change in the business or affairs since the date hereof or that the information contained herein is correct as of any time subsequent to the date hereof. In accordance with Article 23 of the Prospectus Regulation, in the event of a significant new factor, material mistake or inaccuracy relating to the information included in this Prospectus

which may affect the assessment of the Offered Shares, and which arises or is noted between the time when the Prospectus is approved and the closing of the Offer Period or the time when trading on Euronext Brussels begins, whichever occurs later, shall be mentioned in a supplement to the Prospectus without undue delay. Any supplement is subject to approval by the FSMA, in the same manner as this Prospectus and must be made public in the same manner as this Prospectus.

If a supplement to the Prospectus is published, investors will have the right to withdraw their orders made prior to the publication of the supplement provided that the new factor, mistake or inaccuracy referred to in the previous paragraph arose before the end of the Offering Period and the delivery of the Shares. Such withdrawal must be done within the time period set forth in the supplement (which shall not be shorter than two business days after publication of the supplement).

The distribution of this Prospectus and the Offering may, in certain jurisdictions, be restricted by law, and this Prospectus may not be used for the purpose of, or in connection with, any offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorized or to any person to whom it is unlawful to make such offer or solicitation. This Prospectus does not constitute an offer to sell, or an invitation of an offer to purchase, any Offered Shares in any jurisdiction in which such offer or invitation would be unlawful. The Company and the Underwriters require persons into whose possession this Prospectus comes to inform themselves of and observe all such restrictions. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction. None of the Company or the Underwriters accept any legal responsibility for any violation by any person, whether or not a prospective purchaser of Shares, of any such restrictions. The Company and the Underwriters reserve the right in their own absolute discretion to reject any offer to purchase Shares that the Company, the Underwriters or their respective agents believe may give rise to a breach or violation of any laws, rules or regulations.

### **3.3 Stabilization**

In connection with the Offering, Belfius Bank NV/SA or its affiliates will act as Stabilization Manager on behalf of itself and the Underwriters and may engage in transactions that stabilize, maintain or otherwise affect the price of the Shares or any options, warrants or rights with respect to, or other interest in, the Shares or other securities of the Company for up to 30 days from the Listing Date (the "**Stabilization Period**"). These activities may support the market price of the Shares at a level higher than that which might otherwise prevail. Stabilization will not be executed above the Offering Price. Such transactions may be effected on Euronext Brussels, in the over-the-counter markets or otherwise. The Stabilization Manager and its agents are not required to engage in any of these activities and, as such, there is no assurance that these activities will be undertaken; if undertaken, the Stabilization Manager or its agents may discontinue any of these activities at any time and they must terminate at the end of the 30-day period mentioned above.

During the Stabilization Period, the details of all stabilisation transactions will be made public no later than the end of the seventh daily market session following the date of execution of such transactions, in accordance with Article 6.2 of the Commission Delegated Regulation (EU) 2016/1052 of 8 March 2016 supplementing Regulation (EU) No 596/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the conditions applicable to buy-back programs and stabilization measures.

Within five business days of the end of the Stabilization Period, the following information will be made public in accordance with Article 5 of Regulation (EU) No 596/2014 of the European Parliament and of the

Council of 16 April 2014 on market abuse and Article 6.3 of the Commission Delegated Regulation (EU) 2016/1052 of 8 March 2016 supplementing Regulation (EU) No 596/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the conditions applicable to buy-back programs and stabilization measures, as well as Article 5, §2 of the Royal Decree on Primary Markets Practices: (i) whether or not stabilization was undertaken; (ii) the date at which stabilization started; (iii) the date on which stabilization last occurred; (iv) the price range within which stabilization was carried out, for each of the dates on which stabilization transactions were carried out; and (v) the final size of the Offering, including the result of the stabilization and the exercise of the Over-allotment Option, if any, and (vi) the place where the stabilization was undertaken including, where relevant, the name of the trading venue.

### **3.4 Selling restrictions and transfer restrictions**

Persons into whose hands this Prospectus comes are required by the Company and the Underwriters to comply with all applicable laws and regulations in each country or jurisdiction in or from which they purchase, offer, sell or deliver Shares or have in their possession or distribute such offering material, in all cases at their own expense. Neither the Company nor the Underwriters accept any legal responsibility for any violation by any person, whether or not a prospective subscriber or purchaser of any of the Shares, of any such restrictions.

#### **3.4.1 Notice to prospective investors in the United States**

The Offered Shares have not been and will not be registered under the U.S. Securities Act and are being offered and sold: (i) in the United States only to persons that are reasonably believed to be QIBs as defined in Rule 144A; and (ii) outside the United States in compliance with Regulation S.

Each purchaser of the Company's securities in the United States will be deemed to have represented and agreed as follows:

- i. The purchaser (a) is a qualified institutional buyer, or QIB, as defined in Rule 144A, or a broker-dealer acting for the account of a QIB, (b) is acquiring the securities for its own account or for the account of a QIB, and (c) is aware that the securities are restricted within the meaning of the U.S. Securities Act, and may not be deposited into any unrestricted depository facility, unless at the time of such deposit the securities are no longer restricted.
- ii. The purchaser is aware that such securities have not been and will not be registered under the U.S. Securities Act or with any securities regulatory authority of any state of the United States, as amended and are being offered in the United States only to QIBs in a transaction not involving any public offering in the United States within the meaning of the U.S. Securities Act.
- iii. The purchaser understands and agrees that the securities may not be offered, sold, pledged or otherwise transferred, except (a) to a person that the seller and any person acting on its behalf reasonably believe is a QIB purchasing for its own account or for the account of another QIB *or* (b) outside the United States in accordance with Regulation S under the U.S. Securities Act , *or* (c) pursuant to another exemption from registration under the U.S. Securities Act *or* (d) pursuant to an effective registration statement under the U.S. Securities Act.
- iv. The purchaser acknowledges that the Company, the Underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing acknowledgements, representations and agreements, and undertakes promptly to notify the Company and the Underwriters if, at any time prior to the purchase of the Offered Shares, any of the foregoing ceases to be true.

In addition, until the end of the 40th calendar day after the commencement of the Offering, an offer or sale of the shares within the United States by any dealer (whether or not participating in the Offering) may violate the registration requirements of the U.S. Securities Act if such offer or sale is made otherwise than in accordance with Rule 144A or another exemption from registration under the U.S. Securities Act.

The Offered Shares have not been recommended by any U.S. federal or state securities commission or regulatory authority. Furthermore, the foregoing authorities have not confirmed the accuracy or determined the adequacy of this Prospectus. Any representation to the contrary is a criminal offense in the United States.

### **3.4.2 Notice to prospective investors in the EEA and in the United Kingdom**

An offer to the public of any Offered Shares may not be made in any Member State of the EEA and the United Kingdom (each a "**Relevant State**") other than an offer to the public in Belgium unless the Prospectus has been (i) approved by the competent authority in such Relevant State or passported and (ii) published in accordance with the Prospectus Regulation. This Prospectus has been prepared on the basis that all offers of Offered Shares other than the offers contemplated in Belgium, will be made pursuant to an exemption under the Prospectus Regulation, from the requirement to produce a prospectus for offers of Offered Shares. Accordingly, any person making or intending to make any offer of Offered Shares within the EEA or the United Kingdom which are the subject of the placement contemplated in this Prospectus should only do so in circumstances in which no obligation arises for the Company or any of the Underwriters to produce a prospectus for such offer. Neither the Company nor the Underwriters have authorized, nor do the Company or the Underwriters authorize, the making of any offer of Offered Shares through any financial intermediary, other than offers made by the Underwriters which constitute the final placement of Offered Shares contemplated in this Prospectus.

The Offered Shares have not been, and will not be, offered to the public in any Relevant State, except Belgium. Notwithstanding the foregoing, an offering of the Offered Shares may be made in a Relevant State:

- a. to legal entities that are qualified investors as defined in the Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation) subject to obtaining the prior consent of the Underwriters for any such offer; or
- c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation, if applicable,

provided that no such offer of Offered Shares shall result in a requirement for the publication by the Company or any Underwriter of 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 Shares or to whom any offer is made will be deemed to have represented, warranted and agreed to and with the Underwriters and the Company that it is a "qualified investor" within the meaning of the Prospectus Regulation.

The Company, the Underwriters and their affiliates and others will rely upon the truth and accuracy of the foregoing representation, acknowledgement, and agreement. Notwithstanding the above, a person who is not a qualified investor and who has notified the Underwriters of such fact in writing may, with the consent of the Underwriters, be permitted to subscribe for Shares in the Offering.

For the purposes of this provision, the expression an "offer to the public" in relation to any Offered Shares in any Relevant State means the communication to persons in any form and by any means, presenting sufficient information on the terms of the Offering and the Offered Shares so as to enable an investor to decide to subscribe for Offered Shares, as defined in Article 2(d) of the Prospectus Regulation.

### **3.4.3 Notice to prospective investors in Switzerland**

The Offered Shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("**SIX**") or on any other stock exchange or regulated trading facility in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the Shares constitutes a prospectus or a similar notice as such terms are understood pursuant to article 652a, article 752 or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of Article 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the Offered Shares or the Offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this Prospectus nor any other offering or marketing material relating to the Offering, the Company or the Shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this Prospectus will not be filed with, and the Offering will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA. The Offering has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (the "**CISA**"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of Shares.

### **3.4.4 Notice to prospective investors in Japan**

The Shares have not been and will not be registered under the Financial Instruments and Exchange Act, as amended, or any successor legislation thereto (the "**FIEL**"). This document is not an offer of securities for sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or entity organized under the laws of Japan) or to others for reoffer or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements under the FIEL and otherwise in compliance with such law and any other applicable laws, regulations and ministerial guidelines of Japan.

### **3.4.5 Notice to prospective investors in Israel**

This Prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the "**Israeli Securities Law**"), and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this Prospectus is being distributed only to, and is directed only at, and any offer of the Offered Shares is directed only (i) at a limited number of persons (35 investors or fewer during any given 12 month period) in accordance with Section 15A(a)(1) of the Israeli Securities Law and/or (ii) to investors listed in the first schedule to the Israeli Securities Law (the "**Schedule**"), consisting primarily of joint investment in trust funds, provident funds, insurance companies, banking corporations, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and high net worth individuals, each as described in the Schedule (as it may be amended from time to time), collectively referred to as "qualified investors" (in each case purchasing for their own

account or, where permitted under the Schedule, for the accounts of their clients who are investors listed in the Schedule). Qualified investors will be required to submit written confirmation that they fall within the scope of the Schedule, and that they are aware of the consequences of such designation and agree thereto.

#### **3.4.6 Notice to prospective investors in Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission in relation to the Offering. This Prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Australian Corporations Act 2001 (the "**Corporations Act**") and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the Offered Shares may only be made to persons ("**Exempt Investors**"), who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act), or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the Offered Shares without disclosure to investors under Chapter 6D of the Corporations Act.

The Offered Shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the Offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring Offered Shares must observe such Australian on-sale restrictions.

#### **3.4.7 Notice to prospective investors in Hong Kong**

The contents of this Prospectus have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the Offering of the Shares. If you are in any doubt about any of the contents of this document, you should obtain independent professional advice.

The Shares have not been offered or sold and will not be offered or sold in Hong Kong, other than to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) and any rules made under that Ordinance.

No advertisement, invitation or document relating to the offer or sale of the Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the Shares that are or are intended to be disposed of only to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) and any rules made under that Ordinance or only to persons outside Hong Kong.

This Prospectus is confidential to the person to whom it is addressed and no person to whom a copy of this document is issued may issue, circulate, distribute, publish, reproduce or otherwise disclose (in whole or in

part) this document to any person in Hong Kong or use for any purpose in Hong Kong other than in connection with the consideration of the offer described herein by the person to whom this Prospectus is addressed.

### 3.5 Available information

This Prospectus is available to retail investors in Belgium in English and French. The Summary of the Prospectus will be made available in Dutch and French. The Prospectus will be made available to investors at no cost at the Company's registered office, located at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium and can be obtained by retail investors in Belgium at Bank Degroof Petercam NV/SA and Belfius Bank NV/SA upon request by phone: +32 2 287 95 52 (Bank Degroof Petercam NV/SA) and +32 222 12 01 and +32 222 12 02 (Dutch) (Belfius Bank NV/SA).

Subject to certain country restrictions, the Prospectus and the Summary of the Prospectus are also available to investors in English, French and Dutch (only the Summary), on the following websites: [www.nyxoah.com](http://www.nyxoah.com), [www.degroofpetercam.be/en/news/nyxoah\\_2020](http://www.degroofpetercam.be/en/news/nyxoah_2020) and [www.belfius.be/Nyxoah2020](http://www.belfius.be/Nyxoah2020). The information on the website does not form part of the Prospectus and has not been scrutinized or approved by the FSMA.

The posting of the Prospectus on the internet does not constitute an offer to sell or a solicitation of an offer to buy any of the Shares to or from any person in any jurisdiction in which it is unlawful to make such offer or solicitation to such person. The electronic version may not be copied, made available or printed for distribution. Information on the website of the Company ([www.nyxoah.com](http://www.nyxoah.com)) or any other website does not form part of the Prospectus.

The Company has filed its deed of incorporation and must file its coordinated articles of association and all other deeds that are to be published in the Annexes to the Belgian State Gazette with the clerk's office of the commercial court of Brabant Wallon where they are available to the public. The Company is registered with the register of legal entities (Brabant Wallon) under enterprise number 0817.149.675. A copy of the Company's most recent articles of association will also be available on its website.

In accordance with Belgian law, the Company must also prepare audited annual statutory and consolidated financial statements (the "**Consolidated Financial Statement**"). The audited annual statutory financial statement and the Consolidated Financial Statements, together with the report of the Board of Directors and the audit opinion of the statutory auditor, will be filed with the National Bank of Belgium ("**NBB**"), where they will be available to the public. Furthermore, as a listed company, the Company must publish a consolidated annual report (composed of the Consolidated Financial Statements to be filed with the NBB and a responsibility statement) and a half-yearly financial report (composed of interim condensed consolidated financial statement, the conclusion of the statutory auditor, if reviewed, and a responsibility statement) (the "**Half-Yearly Financial Statements**"). These reports will be made publicly available on the website of the Company.

As a listed company, the Company must also disclose "inside information," information about its shareholder structure and certain other information to the public. In accordance with the Belgian Royal Decree of 14 November 2007 relating to the obligations of issuers of financial instruments admitted to trading on a Belgian regulated market (*Koninklijk besluit betreffende de verplichtingen van emittenten van financiële instrumenten die zijn toegelaten tot de verhandeling op een Belgische gereguleerde markt/Arrêté royal relatif aux obligations des émetteurs d'instruments financiers admis aux négociations sur un marché réglementé belge*),

such information and documentation will be made available through the Company's website, press releases, the communication channels of Euronext Brussels, on STORI, or a combination of these means. All press releases published by the Company will be made available on its website.

For so long as any of the Shares are "restricted securities" as defined in Rule 144(a)(3) under the U.S. Securities Act, the Company will, during any period in which it is neither subject to Section 13 or 15(d) of the U.S. Securities Exchange Act of 1934, as amended (the "**U.S. Exchange Act**"), nor exempt from reporting under the U.S. Exchange Act pursuant to Rule 12g3-2(b) thereunder, make available to any holder or beneficial owner of such restricted securities or to any prospective purchaser of such restricted securities designated by such holder or beneficial owner, on the request of such holder, beneficial owner or prospective purchaser, the information required to be provided to such persons pursuant to Rule 144A(d)(4) under the U.S. Securities Act. The Company expects to be exempt from reporting requirements under the U.S. Exchange Act, pursuant to Rule 12g3-2(b).

### **3.6 Presentation of financial and other information**

The Company's Consolidated Financial Statements as of and for the years ended 31 December 2019, 2018 and 2017 and the Half-Yearly Financial Statements as of and for the financial period ended 30 June 2020 have been prepared in accordance with IFRS. The consolidated financial statements and the statutory financial statements as of and for the years ended 31 December 2019, 2018 and 2017 have been audited by EY Réviseurs d'Entreprises SRL. The statutory financial statements are available on the website of the NBB.

Rounding adjustments have been made in calculating some of the financial information included in this Prospectus. As a result, figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that precede them.

### **3.7 Other Information**

In this Prospectus, references to the "Company" are to Nyxoah SA and references to "we," "us" or "our" are to the Company together with its consolidated subsidiaries.

References to "Euros" or "€" are to the common currency of the member states of the EU that are part of the Eurozone. References to the "United States" or the "U.S." are to the United States of America and references to "U.S. dollars", "U.S. \$" or "\$" are to the lawful currency of the United States.

### **3.8 Industry and market data**

This Prospectus includes market share and industry data, which were obtained by us from industry publications and surveys, industry reports prepared by consultants, internal surveys and customer feedback. The market, economic and industry data have primarily been derived and extrapolated from corporate presentations of competitors, clinical publications and white papers, as well as market research reports from Data Bridge Market Research.

The third-party sources the Company has used generally state that the information they contain has been obtained from sources believed to be reliable. These third-party sources also state, however, that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on

significant assumptions. As the Company does not have access to the facts and assumptions underlying such market data, or statistical information and economic indicators contained in these third party sources, it is unable to verify such information and, while the Company believes it to be reliable, it cannot guarantee its accuracy or completeness.

However, where information has been sourced from a third party, the Company confirms that the information has been accurately reproduced and as far as the Company is aware and is able to ascertain from information published by its third party sources, no facts have been omitted which would render the reproduced information inaccurate or misleading.

In addition, certain information in this Prospectus is not based on published data obtained from independent third parties or extrapolations therefrom, but rather is based upon the Company's best estimates, which are in turn based upon information obtained from trade and business organizations and associations, consultants and other contacts within the industries in which the Company competes, information published by its competitors and its own experience and knowledge of conditions and trends in the markets in which it operates.

The Company cannot provide any assurance that any of the assumptions that it has made while compiling this data from third party sources are accurate or correctly reflect its position in the industry and none of its internal estimates have been verified by any independent sources. None of the Company or the Underwriters makes any representation or warranty as to the accuracy or completeness of this information. None of the Company nor the Underwriters have independently verified this information and, while the Company believes it to be reliable, none of the Company or the Underwriters can guarantee its accuracy.

### **3.9 Enforcement of civil liabilities**

The Company is a limited liability company incorporated under the laws of Belgium. Its registered offices and the majority of its assets are located outside the United States. In addition, most of its directors and all members of its executive management team live outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon these individuals or the Company, to enforce judgments obtained in U.S. courts against these individuals or the Company in courts outside the United States, or to enforce against these individuals or the Company, whether in original actions or in actions for the enforcement of judgments of U.S. courts, civil liabilities based solely upon U.S. federal or state 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 enforcement of judgements 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 enforced 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 purpose 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 the disputed goods 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 29 May 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.

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 and the creditor are jointly liable for the payment of the registration tax; however, the liability of the creditor is limited up to a maximum amount of half of the amount he recovers from the debtor. An exemption from such registration tax applies in respect of exequaturs of judgments rendered by courts of states that are bound by European Regulation 44/2001.

### **3.10 Forward-looking statements**

This Prospectus contains "forward-looking statements" within the meaning of the securities laws of certain jurisdictions, including statements under the captions "Summary," "Risk Factors," "Operating and Financial Review," "Industry," "Business" and in other sections. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes," "estimates," "anticipates," "expects," "intends," "may," "will," "plans," "continue," "ongoing," "potential," "predict," "project," "target," "seek" or "should" or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. These forward-looking statements appear in a number of places throughout this Prospectus. Forward-looking statements include statements regarding the Company's intentions, beliefs or current expectations concerning, among other

things, its results of operations, prospects, growth, strategies and dividend policy and the industry in which it operates. In particular, certain statements are made in this Prospectus regarding management's estimates of future growth.

By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance. Prospective investors should not place undue reliance on these forward-looking statements. Any forward-looking statements are made only as of the date of this Prospectus and the Company does not intend, and does not assume any obligation, to update forward-looking statements set forth in this Prospectus, unless required by law.

Many factors may cause the results of operations, financial condition, liquidity and the development of the industries in which the Company competes to differ materially from those expressed or implied by the forward-looking statements contained in this Prospectus.

These risks described under "*Risk Factors*" are not exhaustive. Other sections of this Prospectus describe additional factors that could adversely affect the results of operations, financial condition, liquidity and the development of the sectors in which the Company operates. New risks can emerge from time to time, and it is not possible for the Company to predict all such risks, nor can it assess the impact of all such risks on the business or the extent to which any risks, or combination of risks and other factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, prospective investors should not rely on forward-looking statements as a prediction of actual results.

## 4. USE OF PROCEEDS

### 4.1 Expenses of the Offering

The aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the Offering (including but not limited to legal publications, printing and translation of the Prospectus and Offering related documents, the compensation payable to Mr. Kezirian<sup>3</sup> and Fabian Suarez Gonzalez<sup>4</sup> as a result of the Offering (as described in Part 8 – (Business), section 8.12.6 (*Kezirian Agreement*) and Part 10 - (Management and corporate governance), section 10.4.2b (*Remuneration and compensation in 2019*), and expenses incurred by the Underwriters (which are estimated at € 44,000)) and the remuneration of the FSMA (which is estimated at € 22,000) and Euronext Brussels, is expected to amount to approximately € 4.3 million.

Additionally, assuming that the Offering Price is at the midpoint of the Price Range, the fees and commissions payable to the Underwriters by the Company are expected to be maximum (a) € 2.48 million assuming a placement of the maximum number of Offered Shares in the Offering (excluding the exercise of the Increase Option and the Over-allotment Option), (b) € 2.93 million assuming a placement of the maximum number of Offered Shares in the Offering (including the exercise in full of the Increase Option but excluding the exercise of the Over-allotment Option), or (c) € 3.44 million assuming a placement of the maximum number of Offered Shares in the Offering (including the exercise in full of the Increase Option and the Over-allotment Option).

### 4.2 Reasons of the Offering and use of proceeds

Assuming a placement of the maximum number of Offered Shares in the Offering and that the Offering Price is at the midpoint of the Price Range, the gross proceeds from the issue of the Offered Shares are estimated to be (i) approximately € 60 million in case of a placement of the maximum number of new Shares in the Offering, excluding the exercise of the Increase Option and the Over-allotment Option, (ii) approximately € 69 million in case of a placement of the maximum number of new Shares in the Offering, including the exercise in full of the Increase Option but excluding the Over-allotment Option and (iii) approximately € 79.35 million in case of a placement of the maximum number of Offered Shares in the Offering, including the exercise in full of the Increase Option and the Over-allotment Option.

Based on the aforementioned assumptions and the expenses of the Offering (see section 4.1 (*Expenses of the Offering*) above), the Company estimates to receive net proceeds of (i) approximately € 55.51 million in case of a placement of the maximum number of Offered Shares in the Offering but excluding the exercise of the Increase Option and Over-allotment Option, (ii) approximately € 64.06 million in case of a placement of the maximum number of Offered Shares in the Offering, including the exercise in full of the Increase Option but excluding the exercise of the Over-allotment Option, and (iii) approximately € 73.89 million in case of a placement of the maximum number of Offered Shares in the Offering including the exercise in full of the Increase Option and the Over-allotment Option. The principal purpose of the Offering is to obtain additional capital to support the execution of the Company strategy (as described in Part 8 – (Business), section 8.3

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<sup>3</sup> Assuming an Exit Value, i.e. the value of 100% of the Shares of the Company on a fully-diluted basis at the time of the Offering, less any costs, expenses and fees incurred by the Shareholders or the Company, equal to € 1.32.

<sup>4</sup> Assuming an Exit Value, i.e. the value equal to the average closing trading price of the Shares of the Company during the 6-month period after the end of the lock-up period following the Offering, multiplied by the number of then outstanding Shares of the Company, equal to € 0.92.

(*Marketing strategy and commercial objectives*)). In particular, the Company intends to use the net proceeds of the Offering as follows:

- €27.5 million to conduct clinical trials in the United States, in Europe and in Australia;
- €14.5 million to fund product development and research and development activities, in particular regarding the future generation of the Company's products (see Part 8 – (Business), section 8.1.5 (*Research and development*) and 8.6.7 (*Research and development*));
- to fund the marketing strategy and commercialization efforts; and
- for general corporate purposes.

See also Part 6 - (Capitalization and Indebtedness), section 6.2 (*Working capital statement*).

The Company cannot predict with certainty all of the particular uses for the proceeds from the issuance of the Offered Shares, or the amounts that it will actually spend on the uses set forth above. The amounts and timing of the Company's actual expenditures will depend upon numerous factors, including the progress, costs, timing and results of its further development of the Genio® system, regulatory or competitive developments, the net proceeds actually raised by it in the Offering, amounts received by way of revenues and the Company's operating costs and expenditures. As such, the Company's management assumes significant flexibility in applying the net proceeds from the issue of the Offered Shares and may change the allocation of these proceeds as a result of these and other contingencies. Pending the use of the proceeds from this Offering, the Company intends to invest the net proceeds in interest bearing, cash and cash equivalents instruments or short-term certificates of deposit. Furthermore, the Company has the right to proceed with a capital increase in a reduced amount, corresponding to a number of Shares lower than the maximum number of Offered Shares in the Offering. In the event that the Company would proceed with the capital increase in a reduced amount, it may be required to raise additional capital in order to meet the funding requirements of the above proposed uses.

Furthermore, as no minimum amount is set with respect to the Offering (see Part 14 - (The Offering), section 14.2 (*Conditions and nature of the Offering*) and Risk Factor 2.9 (*The fact that no minimum amount is set for the Offering may affect the Company's investment plan and the liquidity of the Shares*)), the Company has the right to proceed with a capital increase in a reduced amount, corresponding to a number of new Shares lower than the 3,871,000 Offered Shares (i.e., excluding the exercise, in part or in full, of the Increase Option) initially offered in the Offering, it being understood that, in a worst case scenario, the net proceeds of the Offering would be equal to the net proceeds from the Subscription Commitments of the Participating Investors. In the event that the net proceeds from the Offering are limited to the net proceeds from the Subscription Commitments of the Participating Investors (i.e. € 23,063,997), the Company would use these proceeds to (i) continue and finalise the BETTER SLEEP trial, (ii) continue the DREAM study and the EliSA trial, albeit at a lower pace and not having sufficient funds to finalise them, and (iii) fund (partially) the marketing strategy and commercialization efforts, albeit at a lower pace. Finalization of the DREAM study and EliSA trial, research and development activities, part of the marketing strategy and commercialization efforts would potentially be delayed until additional financing were to become available.

In the event that the Company proceeds with the capital increase in a reduced amount, it may be required to raise additional funding in order to meet the funding requirements for the DREAM study and the EliSA trial, research and development activities, and part of the marketing strategy and commercialization efforts. Such additional funding could be a combination of external financing and further shareholders' financing. See also

Risk Factor 2.3 *(In the opinion of the Company, it does not currently have sufficient working capital for its present requirements, that is for at least the next 12 months following the date of this Prospectus. While in the opinion of the Company following the Offering it will have sufficient working capital to do so, the Company could require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available) and Part 6 - (Capitalization and Indebtedness), section 6.2 (Working capital statement).*

## **5. DIVIDENDS AND DIVIDEND POLICY**

### **5.1 Dividends**

As of the closing of the Offering, all of the Shares, including the Offered Shares, will entitle the holder thereof to an equal right to participate in dividends declared after the Closing Date, in respect of the financial year ending 31 December 2020 and future years. All of the Shares participate equally in the Company's 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 the Company's Board of Directors. 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.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Company's 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 the Company's 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), 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.

In addition, pursuant to Belgian law and the Articles of Association, the Company must allocate an amount of 5% of its Belgian GAAP annual net profit (*netto-winst/bénéfices nets*) to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Company's share capital. The Company's legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Company's ability to pay out dividends to its shareholders.

Additional financial restrictions and other limitations may be contained in future credit agreements.

Assuming that the Offering Price is at the mid-point of the Price Range and all Offered Shares are placed (including the exercise in full of the Over-allotment Option and the Increase Option), the Company's share capital will amount to € 3,816,143. There will be no distributable reserves nor will there be a legal reserve, as of the closing of the Offering.

### **5.2 Dividend Policy**

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

Currently, the Company's Board of Directors expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future.

As a consequence of all of these factors, there can be no assurance as to whether dividends or similar payments will be paid out in the future nor, if they are paid, as to their amount.

## 6. CAPITALIZATION AND INDEBTEDNESS

### 6.1 Capitalization and indebtedness

The following table sets forth the Company's capitalization as of 30 June 2020 (i) on an actual basis and (ii) as adjusted to give effect to (a) the conversion in full of the Noshaq Convertible Loan, and (b) the Offering (assuming the issuance and placement in full of the maximum number of Offered Shares (i.e., including the exercise in full of the the Increase Option and the Over-allotment Option) and that the Offering Price is at the mid-point of the Price Range).

Based on expected gross proceeds of (i) approximately € 60 million in case of a placement of the maximum number of new Shares in the Offering, excluding the exercise of the Increase Option and the Over-allotment Option, (ii) approximately € 69 million in case of a placement of the maximum number of new Shares in the Offering, including the exercise in full of the Increase Option but excluding the Over-allotment Option and (iii) approximately € 79.35 million in case of a placement of the maximum number of Offered Shares in the Offering, including the exercise in full of the Increase Option and the Over-allotment Option, the Company estimates that it will receive net proceeds from the Offering of approximately € 55.51 million, € 64.06 million or € 73.89 million, respectively, following the deduction of underwriting commissions, and, generally, all administrative, legal, tax and audit expenses as well as the other costs in connection with the Offering (see section 4.1 (*Expenses of the Offering*) above).

This table should be read in conjunction with Part 7 (*Selected Consolidated Financial Information*) and Part 9 (*Operating and Financial Review*), the Consolidated Financial Statements as of 31 December 2019, 2018 and 2017, the Half-Yearly Financial Statements as of and for the financial period ended 30 June 2020 and related notes included elsewhere in this Prospectus.

The following tables set forth the Company's consolidated capitalization and net financial indebtedness as at 30 June 2020 (i) on an actual basis and (ii) as adjusted to give effect to (a) the conversion of the Noshaq Convertible Loan (see Part 8 – (Business), section 8.12.4 (*Noshaq Convertible Loan*)), (b) the Subscription Commitments, and (c) the Offering (assuming a placement of the maximum number of new Shares in the Offering (i.e., including the exercise in full of the Increase Option and of the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range).

<i>(in € 000)</i>	<b>Actual as at 30 June 2020</b>	<b>As adjusted</b>
<b>Current Debt</b>		
Guaranteed	-	-
Secured	411	411
Unguaranteed/unsecured	4,089	3,089
Total current debt	4,500	3,500
<b>Non-current Debt</b>		
Guaranteed	-	-
Secured	895	895
Unguaranteed/unsecured	7,361	7,361
Total non-current debt	8,256	8,256
<b>Total indebtedness</b>	<b>12,756</b>	<b>11,756</b>

<i>(in € 000)</i>	<b>Actual as at 30 June 2020</b>	<b>As adjusted</b>
<b>Shareholders' equity</b>		
Share capital	2,917	3,808
Share premium	72,196	115,656
Other reserves	1,011	1,011
Retained earnings	(50,713)	(50,713)
<b>Total shareholders' equity</b>	<b>25,411</b>	<b>105,762</b>

The following table details the net financial indebtedness of the Company as at 30 June 2020:

<i>(in € 000)</i>	<b>Actual as at 30 June 2020</b>	<b>As adjusted</b>
<b>Cash and cash equivalents</b>	<b>23,880</b>	<b>98,768</b>
Current financial receivables <sup>5</sup>	(1,000)	-
Current portion of non current debt	793	793
Other current financial debt	1,000	-
<i>Current financial debt</i>	<i>793</i>	<i>793</i>
<b>Net current financial indebtedness</b>	<b>(23,087)</b>	<b>(97,975)</b>
Other non current loans	8,256	8,256
<b>Net financial indebtedness</b>	<b>(14,831)</b>	<b>(89,719)</b>

## 6.2 Working capital statement

On the date of this Prospectus, the Company is of the opinion that, taking into account its available cash and cash equivalents, it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least twelve months as of the date of this Prospectus.

However, assuming a placement of the maximum number of Offered Shares in the Offering (excluding the exercise of the Increase Option and the Over-allotment Option) and that the Offering Price is at the lower end of the Price Range, the gross proceeds from the issue of the Offered Shares are estimated to be approximately € 54.19 million. Based on the Subscription Commitments, the Company is of the opinion that the proceeds of the Offering (together with its available cash and cash equivalents) will provide the Company with sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least twelve months from the date of the Prospectus, even if the Offering Price is at the lower end of the Price Range.

In case the Company would not be able to attract new funds (beyond its existing cash and cash equivalents), it expects to run out of working capital by in the second quarter of 2021. The Company's twelve-month working capital shortfall in the event the Company would not be able to attract any such additional funds and if the Company in that event maintains its current strategy and development activities, is projected to be

<sup>5</sup> Convertible loan agreement was executed on 30 June 2020, but the funds have been transferred on Nyxoah bank account on 1 July 2020.

approximately €13 million at the end of the third quarter of 2021.

In the event that the Company proceeds with the capital increase in a reduced amount (i.e., lower than the aforementioned estimated € 54.19 million gross proceeds), it may be required to raise additional funding in order to meet the funding requirements for the DREAM study and the EliSA trial, research and development activities, and part of the marketing strategy and commercialization efforts. Such additional funding could be a combination of external financing and further shareholders' financing (see also Part 4 - (Use of proceeds), section 4.2 (*Reasons of the Offering and use of proceeds*)).

## 7. SELECTED CONSOLIDATED FINANCIAL INFORMATION

The selected consolidated financial information presented below as of and for the years ended 31 December 2019, 2018 and 2017 and as of and for the financial period ended 30 June 2020 has been derived from the Consolidated Financial Statements as of and for the years ended 31 December 2019, 2018 and 2017 and the Half-Yearly Financial Statements as of and for the financial period ended 30 June 2020, respectively. The Consolidated Financial Statements as of and for the years ended 31 December 2019, 2018 and 2017 have been audited by EY Réviseurs d'Entreprises SRL. These Consolidated Financial Statements and Half-Yearly Financial Statements have been prepared in accordance with IFRS.

The selected consolidated financial information presented below should be read in conjunction with "*Operating and financial review*" included elsewhere in this Prospectus.

### 7.1 Consolidated Income Statement

<i>(in EUR 000)</i>	As of 30 June	As of 31 December		
	2020	2019	2018	2017
Revenue		-	-	-
Cost of goods sold		-	-	-
General and administrative expenses	(2,063)	(3,027)	(2,339)	(2,192)
Research and development expenses	(56)	(630)	(1,385)	(1,505)
Clinical expenses	(509)	(848)	(2,523)	(2,110)
Manufacturing expenses	(207)	(489)	(1,089)	(803)
Quality assurance and regulatory expenses	(86)	(227)	(680)	(882)
Patents Fees & Related	(107)	(267)	(594)	(533)
Therapy Development expenses	(761)	(902)	(338)	(495)
Other operating income / (expenses)	184	(126)	498	(1,623)
<b>Operating loss for the period</b>	<b>(3,605)</b>	<b>(6,516)</b>	<b>(8,450)</b>	<b>(10,143)</b>
Financial income	82	71	29	25
Financial expense	(416)	(740)	(617)	(216)
<b>Loss for the period before taxes</b>	<b>(3,939)</b>	<b>(7,185)</b>	<b>(9,038)</b>	<b>(10,334)</b>
Taxes	(24)	(70)	(41)	(37)
<b>Loss for the period</b>	<b>(3,963)</b>	<b>(7,255)</b>	<b>(9,079)</b>	<b>(10,371)</b>
<b>Loss attributable to equity holders<sup>6</sup></b>	<b>(3,963)</b>	<b>(7,255)</b>	<b>(9,079)</b>	<b>(10,371)</b>
Other comprehensive income items that may be subsequently reclassified to profit or loss (net of tax):				
Currency translation differences	(89)	168	(24)	(3)
<b>Total comprehensive loss for the year, net of tax</b>	<b>(4,052)</b>	<b>(7,087)</b>	<b>(9,103)</b>	<b>(10,374)</b>
<b>Loss attributable to equity holders<sup>7</sup></b>	<b>(4,052)</b>	<b>(7,087)</b>	<b>(9,103)</b>	<b>(10,374)</b>

<sup>6</sup> For all periods presented above, the loss is fully attributable to the Company's equity holders of as the Company does not have any non-controlling interests.

<sup>7</sup> For all periods presented above, the loss is fully attributable to the Company's equity holders of as the Company does not have any non-controlling interests.

## 7.2 Consolidated Statement of Financial Position

<i>(in EUR 000)</i>	As of 30 June	As of 31 December		
	2020	2019	2018	2017
<b>ASSETS</b>				
<b>Non-current assets</b>	<b>11,042</b>	<b>7,221</b>	<b>440</b>	<b>461</b>
Property, plant and equipment	386	322	343	369
Intangible assets	9,269	5,734	0	0
Right of use assets	1,285	1,066	0	0
Deferred tax asset	24	21	29	22
Other long-term receivables	78	78	68	70
<b>Current assets</b>	<b>27,125</b>	<b>7,974</b>	<b>17,539</b>	<b>10,684</b>
Trade receivables	30	60	64	46
Other receivables	1,428	2,048	668	529
Other current assets	1,787	11	2	4
Cash and cash equivalents	23,880	5,855	16,805	10,105
<b>Total assets</b>	<b>38,167</b>	<b>15,195</b>	<b>17,979</b>	<b>11,145</b>
<b>EQUITY AND LIABILITIES</b>				
<b>Capital and reserves</b>				
Capital	2,917	2,481	2,481	2,004
Share premium	72,196	47,668	47,668	33,143
Share based payment reserve	893	420	80	52
Currency translation reserve	118	207	39	63
Retained Earnings	(50,713)	(47,063)	(39,814)	(30,735)
<b>Total equity attributable to shareholders</b>	<b>25,411</b>	<b>3,713</b>	<b>10,454</b>	<b>4,527</b>
<b>LIABILITIES</b>				
<b>Non-current liabilities</b>	<b>8,256</b>	<b>7,911</b>	<b>5,526</b>	<b>4,869</b>
Financial debt	7,331	7,146	5,526	4,869
Lease liability	895	735	-	-
Pension Liability	30	30	-	-
<b>Current liabilities</b>	<b>4,500</b>	<b>3,571</b>	<b>1,999</b>	<b>1,749</b>
Financial debt	382	378	289	395
Lease liability	411	340	-	-
Convertible Loan	1,000	-	-	-
Trade payables	1,343	1,385	810	602
Other payables	1,364	1,468	900	752
<b>Total liabilities</b>	<b>12,756</b>	<b>11,482</b>	<b>7,525</b>	<b>6,618</b>
<b>Total equity and liabilities</b>	<b>38,167</b>	<b>15,195</b>	<b>17,979</b>	<b>11,145</b>

### 7.3 Consolidated Statement of Cash Flows

<i>(in EUR 000)</i>	As of 30 June	As of 31 December		
	2020	2019	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>				
<b>Profit/(loss) before tax for the year</b>	<b>(3,940)</b>	<b>(7,185)</b>	<b>(9,038)</b>	<b>(10,334)</b>
Adjustments for:				
Finance income	(82)	(71)	(29)	(25)
Finance costs	416	740	617	216
Depreciation and impairment of property, plant and equipment and right-of-use assets	259	433	95	87
Share-based payment transaction expense	786	346	28	24
Pension	-	30	-	-
Other non-cash items	(161)	70	63	2,277
<b>Net profit/(loss) before changes in working capital</b>	<b>(2,722)</b>	<b>(5,637)</b>	<b>(8,264)</b>	<b>(7,755)</b>
Changes in working capital:				
Increase (-)/Decrease (+) in Trade and other receivables	(1,127)	(1,385)	(155)	(161)
Increase (+)/Decrease (-) in Trade and other payables	(145)	1,143	356	(293)
<b>Cash generated from changes in operations</b>	<b>(3,994)</b>	<b>(5,879)</b>	<b>(8,063)</b>	<b>(8,209)</b>
Interests received	2	8	1	5
Interests paid	(4)	(33)	(29)	(37)
Income tax (paid)	(28)	(61)	(48)	(46)
<b>Net cash generated/(used) from operating activities</b>	<b>(4,024)</b>	<b>(5,965)</b>	<b>(8,139)</b>	<b>(8,287)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>				
Purchases of property, plant and equipment	(120)	(51)	(77)	(91)
Capitalization of intangible assets	(3,535)	(5,734)	-	-
(Increase)/Decrease of long-term deposits	-	(10)	2	-
<b>Net cash generated/(used) from investing activities</b>	<b>(3,655)</b>	<b>(5,795)</b>	<b>(75)</b>	<b>(91)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>				
Payment of principal portion of lease liabilities	(209)	(341)	-	-
Repayment of other loan	(21)	(82)	(42)	-
Recoverable cash advance received	-	1,196	226	1,213
Repayment of recoverable cash advance	-	(40)	(184)	(100)
Proceeds from Convertible Loan	1,000	-	-	-
Proceeds from issuance of shares	24,964	-	15,002	-
<b>Net cash generated/(used) from financing activities</b>	<b>25,735</b>	<b>733</b>	<b>15,002</b>	<b>1,113</b>
<b>Movement in cash and cash equivalents</b>	<b>18,056</b>	<b>(11,027)</b>	<b>6,788</b>	<b>(7,265)</b>
Effect of exchange rates on cash and cash equivalents	(31)	77	(88)	(76)
<b>Cash and cash equivalents at 1 January</b>	<b>5,855</b>	<b>16,805</b>	<b>10,105</b>	<b>17,446</b>
<b>Cash and cash equivalents at end of period</b>	<b>23,880</b>	<b>5,855</b>	<b>16,805</b>	<b>10,105</b>

## 8. BUSINESS

### 8.1 Overview

The Company is a health-technology company focused on the development and commercialization of solutions and services to treat sleep disordered breathing conditions. The Company's innovative solution platform is based on the Genio® system, a CE-Mark validated, user-centered, next generation neurostimulation therapy for OSA, the world's most common sleep disordered breathing condition that is associated with increased mortality risk<sup>8</sup> and comorbidities including cardiovascular diseases, depression and strokes.

The product is intended to be used as a second-line therapy to treat moderate-to-severe OSA patients who have failed conventional therapy, including Continuous Positive Airway Pressure ("CPAP"), which, despite its proven efficacy, has been associated with many limitations, making compliance a serious challenge. In addition, other second-line treatments, such as oral devices, are more suitable to treat mild to moderate OSA or are highly invasive.

Compared to other hypoglossal nerve stimulation technologies for the treatment of OSA (such as the CE-marked and FDA-approved Inspire and the CE-marked ImThera devices), the Genio® system is the world's first and only battery-free, minimally invasive and leadless neurostimulator implant and is capable of delivering bilateral hypoglossal nerve stimulation to keep the upper airway open. The Genio® system is a 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 left and right branches of the hypoglossal nerve.

#### 8.1.1 Large market

OSA is the most common sleep disordered breathing condition, affecting around 936 million people between 30 and 69 years of age globally, of whom 425 million suffer from moderate-to-severe OSA, requiring treatment.<sup>9</sup> 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.

OSA is a chronic disease, which affects the patient's health and quality of life. Left untreated, OSA is associated with increased mortality risk and comorbidities<sup>10</sup>, including cardiovascular diseases, depression and

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<sup>8</sup> Young T. et al: Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort. *Sleep*. 2008 Aug 1; 31(8): 1071–1078.

<sup>9</sup> Benjafield, Adam V et al. Estimation of the global prevalence and burden of obstructive sleep apnea: a literature-based analysis. *Lancet Respir Med* 2019 Published Online 9 July 2019 [http://dx.doi.org/10.1016/S2213-2600\(19\)30198-5](http://dx.doi.org/10.1016/S2213-2600(19)30198-5).

<sup>10</sup> Al Lawati NM, Patel SR, Ayas NT. Epidemiology, risk factors, and consequences of obstructive sleep apnea and short sleep duration. *Prog Cardiovasc Dis* 2009;51:285–293; Caples SM, Garcia-Touchard A, Somers VK. Sleep-disordered breathing and cardiovascular risk. *Sleep* 2007;30:291–303.

stroke. Clinical studies have shown that the mortality rate of non-treated patients suffering from OSA increases significantly over time.<sup>11</sup> Numerous studies demonstrated the correlation between efficient OSA therapy and the reduction of mortality and comorbidities.<sup>12</sup> OSA prevalence is increasing due to the ageing population and rise in obesity.

Still, OSA remains significantly underdiagnosed: in 2010, the diagnosis rate for OSA in the United States was estimated to be 15-20%, averaged at 18%.<sup>13</sup>

There are a few options available for the treatment of OSA, depending on the level of severity of the disease. These range from lifestyle changes (e.g. weight loss) to surgery.

The standard of care for the patient management and symptomatic treatment of moderate-to-severe OSA patients is CPAP (Continuous Positive Airway Pressure). The CPAP system is composed of a bedside machine pushing air at a constant or automated pressure and a mask (nasal or facial) that the patient needs to put on his/her face each night and wear all night. Studies report that a significant percentage of patients with OSA fail to adhere to prescribed CPAP therapy, with patients who discontinue the treatment citing reasons including that the treatment is uncomfortable and noisy. Studies also show that the air used in CPAP therapy can cause severe dryness in the nose and mouth for some patients, and that CPAP side effects include a sense of suffocation, nasal or oral dryness, nasal congestion, nosebleeds, and skin irritation. CPAP non-compliance has been reported in clinical trials between 29% and 83%, as referenced by recent studies.<sup>14,15</sup> A patient is considered compliant if he or she uses the CPAP machine on average at least four hours/night and five days per week. Despite the evolution of CPAP machines over the last decade, compliance with the therapy remains a major issue. The Company estimates the CPAP non-compliance rate at 35%.

In 2020, the total OSA market revenue, including diagnostics and therapeutic devices, is estimated at \$10.5 billion.<sup>16</sup>

### 8.1.2 The Genio® system

The Genio® system has been developed using a user-centric approach to offer patients a convenient alternative for the treatment of OSA that may potentially lead to increased treatment compliance. This novel solution consists of a small implantable stimulator, an activation chip with disposable patch, and a charging unit.

The implantable stimulator is a small, battery-free and leadless device that is implanted under the chin to

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<sup>11</sup> Young T. et al: Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort, *Sleep*. 2008 Aug 1; 31(8): 1071–1078.

<sup>12</sup> Campos-Rodriguez and al., Mortality in obstructive sleep apnea-hypopnea patients treated with positive airway pressure. *Chest*. 2005 Aug;128(2):624-33; Long-term effects of nasal continuous positive airway pressure therapy on cardiovascular outcomes in sleep apnea syndrome. *Chest*. 2005 Jun;127(6):2076-84.

<sup>13</sup> Harvard Medical School Division of Sleep Medicine, The Price of Fatigue - The surprising economic costs of unmanaged sleep apnea, December 2010; Van Ryswyk and al., Predictors of long-term adherence to continuous positive airway pressure in patients with obstructive sleep apnea and cardiovascular disease, *SLEEPJ*, 2019, Vol. 42, No. 10.

<sup>14</sup> Van Ryswyk and al., Predictors of long-term adherence to continuous positive airway pressure in patients with obstructive sleep apnea and cardiovascular disease, *SLEEPJ*, 2019, Vol 42, No. 10; Kribbs NB, Pack AI, Kline LR, Smith PL, Schwartz AR, Schubert NM, Redline S, Henry JN, Getsy JE, Dinges DF. Objective measurement of patterns of nasal CPAP use by patients with obstructive sleep apnea. *Am. Rev. Respir. Dis.* 1993; 147: 887–95; Sawyer AM, Gooneratne NS, Marcus CL, Ofer D, Richards KC, Weaver TE. A systematic review of CPAP adherence across age groups: clinical and empiric insights for developing CPAP adherence interventions. *Sleep Med. Rev.* 2011; 15: 343–56.; Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure therapy: the challenge to effective treatment. *Proc. Am. Thorac. Soc.* 2008; 5: 173–8.

<sup>15</sup> The reported data are based on objective measurements (CPAP machines include a real time clock to calculate patient usage of their machine).

<sup>16</sup> Data Bridge Market Research – Global Sleep Apnea Devices Market, Industry Trends and Forecast to 2024.

deliver bilateral electrical stimulation to both left and right branches of the hypoglossal nerve, causing the back of the tongue to slightly move forward, thereby keeping the upper airway open. While no studies have directly compared the effects of bilateral stimulation versus unilateral stimulation, several findings support the notion that bilateral stimulation might result in an improved response.<sup>17</sup>

In addition, compared to other available neurostimulation systems, the surgical implantation procedure of the Genio® system only requires a single incision under the chin and is therefore more straightforward, less invasive, and generally quicker. The details of the surgical approach have been published in *Laryngoscope Investigative Otolaryngology*.<sup>18</sup>

The Company has invested significant resources in clinical studies to demonstrate the safety and efficacy of the Genio® system and has also established a solid network of key opinion leaders in Europe, Australia, and the United States who support the clinical development and use of the Genio® system.

The current Genio® system builds on the learnings from two systems that the Company developed earlier. Between 2012 and 2014, the Company developed two unilateral hypoglossal nerve stimulation systems that were evaluated in two clinical trials (SAT2012A, which evaluated the safety of the first device in healthy volunteers, and SAT2014A, a feasibility study).

The clinical evidence of the Genio® system is composed of one completed "BiLateral hypoglossal nerve STimulation for treatment of Obstructive Sleep Apnea" clinical study ("**BLAST OSA**"), a prospective, open-label, non-randomized, single arm treatment study involving 27 implanted participants. The results of the BLAST OSA study were published in the *European Respiratory Journal* in October 2019.<sup>19</sup> The BLAST OSA study found that the Genio® system therapy reduced the severity of the obstructive sleep apnea condition and improved the quality of life of those persons afflicted with the condition. These data demonstrate that treatment with the Genio® system was safe and effective, and resulted in significant improvement in patients' quality of life measurements.

Following the completion of the BLAST OSA study, the Genio® system received its CE-Mark in March 2019. With the CE-Mark on a product, the manufacturer certifies (i) compliance of the design of the product with the applicable harmonized standards and essential requirements of the AIMD Directive and (ii) the QMS (including that of critical suppliers) is in conformity with the requirements under the AIMD Directive. The CE-Mark cannot be construed as evidence of (statistically significant) efficacy or safety of the Genio® system. As part of the post-market surveillance mandated by the Notified Body, the Company initiated two post-market studies (i.e. the EliSA trial and the BETTER SLEEP trial) that are designed to gather long-term safety and efficacy data (three-year follow-up) of the Genio® system in 150 patients collectively (see subsection 8.6.5 (*Clinical results and studies*) for more details on the trials). The BETTER SLEEP trial<sup>20</sup> (clinical-trial.gov identifier NCT03763682) is ongoing in Australia and New Zealand and the EliSA trial<sup>21</sup> (clinical-trials.gov identifier NCT04031040) is ongoing in Europe. The initial results from the BETTER SLEEP and

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<sup>17</sup> Heiser et al. Cross motor innervation of the hypoglossal nerve—a pilot study of predictors for successful opening of the soft palate, *Sleep and Breathing* June 2020.

<sup>18</sup> Lewis R, Pételle B, Campbell MC, et al. Implantation of the nyxoah bilateral hypoglossal nerve stimulator for obstructive sleep apnea. *Laryngoscope Investig Otolaryngol.* 2019;4(6):703-707. Published 2019 Nov 22. doi:10.1002/lio2.312.

<sup>19</sup> <https://erj.ersjournals.com/content/early/2019/09/25/13993003.01320-2019>

<sup>20</sup> Link to the study: <https://clinicaltrials.gov/ct2/show/NCT03763682?id=NCT03763682&draw=2&rank=1>

<sup>21</sup> Link to the study: <https://clinicaltrials.gov/ct2/show/NCT04031040?id=NCT04031040&draw=2&rank=1>

EliSA trials (i.e. when the results on endpoints will be available) are expected to be available in early 2021 and mid-2022, respectively.

In parallel, to support approval and reimbursement of the system in the United States, the Company received FDA approval in June 2020 to conduct a clinical trial to collect safety and effectiveness data required to support a premarket approval application or a premarket notification (De Novo) submission. The Company aims to obtain FDA approval for the Genio® system by the end of 2022 leading to an expected commercialisation in the first half of 2023.

### **8.1.3 Commercial operations**

In markets where the Genio® system is approved for marketing, the Company intends to commercialize the Genio® system using a distribution model that will be tailored by country, to maximize country specific market entrance requirements and needs. Depending on the country, in order to provide OSA patients the quickest access to the Genio® system, the Company will sell the Genio® system using either a direct sales force or indirect marketing models.

The Company intends to first commercialize the Genio® system in selected countries in Europe, with Germany as the first European market entry in 2020. Other countries include Belgium, France, Spain, the Netherlands, the United Kingdom and Switzerland. In Australia, the company expects TGA approval in Q4 2020 and has already begun reimbursement negotiations. Based on the outcome of these reimbursement discussions, a commercialization strategy is ready to be executed.

The Company currently has a market development team of five European based and five Australia and New Zealand based employees to support commercialization of the Genio® system. This team will gradually grow in line with the further roll-out of the Company's commercialization ramp up strategy.

### **8.1.4 Manufacturing and product development**

The Company has gained significant experience and expertise in the production process of the Genio® system and is building production capacity to accommodate the expected demand in the next coming years. The Company partners with third-party suppliers to manufacture all the components of the Genio® system. These suppliers have been selected through a rigorous selection process and are in close partnership with an experienced in-house team. The suppliers are also required by the Company to comply with applicable standards and regulations as well as use quality assurance processes and technologies. Certain final key manufacturing steps of parts of the Genio® system, with respect to the implant, are currently done internally by the Company's manufacturing team in the clean room at the Company's facility in Tel Aviv, Israel. The Company is also considering renting manufacturing facilities in Belgium to further scale-up its manufacturing capacity.

### **8.1.5 Research and development**

The Company will continue to invest in research and development. It intends to continuously invest in product improvements and next generation Genio® system products to further improve the Genio® system, user comfort, therapeutic effects, patient and market acceptance and additional features or services that could potentially provide opportunities for future revenue generation related to patient data.

### 8.1.6 Intellectual property

The Company's technology and products are protected by a strong and growing portfolio of intellectual property rights, including trademarks and 109 granted utility and design patents and 68 utility patent applications pending across 12 countries, and its know-how associated with the design, development and use of the Genio® system.

### 8.1.7 History

The Company was founded on 15 July 2009 by Robert Taub, who has extensive experience with Israeli companies, with the mission to develop user-centered innovative solutions for OSA. Since its inception, the Company has raised equity financing totaling approximately €79 million from several national and international investors. The most recent equity rounds were led by Coöperatieve Gilde Healthcare III Sub-Holding U.A. and Coöperatieve Gilde Healthcare III Sub-Holding 2 U.A. (hereinafter jointly “**Gilde Healthcare III**”) (2016), Cochlear (2018) and ResMed Inc (2020).

The Company is headquartered in Mont-Saint Guibert, Belgium, and has established three wholly owned subsidiaries: Nyxoah LTD, incorporated on 10 January 2008 and a subsidiary of the Company since 21 October 2009 (located in Israel and initially incorporated under the name M.L.G. Madaf G. LTD), Nyxoah PTY LTD since 1 February 2017 (located in Australia) and Nyxoah, Inc. since 14 May 2020 (located in the United States). The Company's Israeli subsidiary is responsible for the Company's research and development and manufacturing activities, its Australian subsidiary is responsible for its clinical activities and preparing further commercialisation, and its U.S. subsidiary is responsible for the execution of the IDE pivotal trial (see see Part 8 – (Business), section 8.7.2 (*Regulatory landscape in the United States*)).

### 8.1.8 The Company's vision

- Vision statement

The Company is a user-centered company seeking to provide its users with the freedom to enjoy life to its fullest by delivering reliable, durable, efficient and harmonious solutions to treat sleep disordered breathing conditions, including OSA.

The Company's vision is to create a complete platform of user-centered technologies and digital solutions to diagnose and treat sleep disordered breathing conditions. This applies not only to the OSA patient, but across the treatment paradigm, engaging in all areas related to OSA: from the patients suffering from the condition and their families, to the physicians, sleep technicians and surgeons who treat them, as well as patient groups.

The Company believes that the human centered approach will lead to a superior customer and patient experience, increasing quality of life for the patient and thus the compliance needed for the success of the therapy.

- Vision aspirations

The Company is seeking to expand innovation beyond product development, to include services for the stakeholders supporting new business models that are not based solely on the revenue generated from to the implantation of the device.

As patients using the Genio® system will be applying a Genio® Disposable Patch every night, the Company plans to develop services to deliver this disposable patch to the patients under a prescription model creating another revenue stream.

The Company's future products are expected to have the capacity to assess parameters related to patient sleep quality (e.g. snoring, movement, sleep position etc.) and the capacity to be connected to the cloud. The collected information will give the Company the power to monitor and better understand the patient's quality of sleep and respiratory status. With this knowledge, the Company aims to develop services to share relevant information with the stakeholders. For example, the Company aims to be able to regularly assess the quality of the treatment using healthcare connectivity tools. Also, it is expected that sleep specialists who treat the patients will have access to a Digital Care Management platform, enabling them to assess the patient's health status, take the best medical decision and adapt the patient therapy at any time, while invoicing their medical act to the payors.

## 8.2 Strengths

### ***First battery-free, leadless and minimally invasive neurostimulator specifically designed for bilateral hypoglossal nerve stimulation***

The Genio® system is the world's first and unique battery-free, leadless and minimally invasive neurostimulator that is capable of delivering bilateral hypoglossal nerve stimulation for OSA patients.

In contrast to competing solutions which are currently designed only for unilateral nerve stimulation, the Company's proprietary Genio® system is the only neurostimulation therapy that has specifically been designed for bilateral hypoglossal nerve stimulation. The Company believes that bilateral stimulation can lead to better therapy performance and larger therapeutic indications compared to other hypoglossal nerve stimulation-based technologies (e.g. therapeutic indications expansion to patients with BMI > 35 or patients with complete concentric collapse, currently contra-indicated for Inspire therapy). The ongoing BETTER SLEEP trial is currently investigating this latter assumption.

The surgical implantation procedure of the Genio® neurostimulator only requires a single incision under the chin. The procedure is generally quicker, more straightforward and less invasive compared to other hypoglossal nerve stimulation technologies currently on the market.

Another key advantage compared to other available neurostimulators is that it consists of only one internal device, i.e. the stimulator that is implanted while the activation chip and power source are housed in an external device. This allows for future updates of the device without requiring surgery to change the implanted device.

The Genio® system has been designed to reduce and/or eliminate risks associated with traditional pacemaker-based therapies:

- there is no lead, which prevents the risk of lead failure, or abrasion;
- there is no implantable pulse generator preventing (i) the risk of Twiddler's syndrome (i.e. a malfunction of a pacemaker due to manipulation of the device and the subsequent dislodging of the leads

from their intended location), (ii) the need for surgical replacement of the implantable pulse generator upon battery depletion and (iii) associated increased infection rates every time a surgical reintervention is required;

- only one incision (vs. two or three for competitive devices) is required and there is no tunneling (vs. one or two for competitive devices) which reduces surgical implantation time and reduces risks of infection. Additionally, the Genio® system can be an outpatient surgery (i.e. not requiring an overnight hospital stay) and the recovery time is expected to be shorter compared to competitive devices;
- the components are biocompatible so there is no risk of allergic reactions relating to the materials of the components; and
- no unnecessary stimulation is required.

The Company's product is not the first hypoglossal nerve stimulation treatment for OSA on the market and can therefore benefit from the efforts already made by competitors to educate medical professionals, patients and other market players about neurostimulation as an alternative therapy for moderate-to-severe OSA patients. For more information on the market size, see Part 8 – (Business), section 8.1.1 (*Large market*).

While hypoglossal nerve stimulation does not show a 100% responder rate and not all patients can benefit from the therapy, the Company believes that its Genio® system has the potential to have an improved therapeutic effect compared to other neurostimulation solutions and other second-line OSA therapies on the basis of the following characteristics:

- safe and effective therapy;
- high therapy compliance;
- quality of life improvement;
- specifically designed for OSA;
- minimally invasive;
- bilateral hypoglossal nerve stimulation; and
- partially external device.

#### ***First positive clinical data and a robust long-term clinical strategy***

The BLAST OSA study provides first positive safety and efficacy data of the Genio® system, demonstrating that treatment with the Genio® system resulted in a significant improvement in sleep apnea symptoms and patients' quality of life. These safety and efficacy data were associated with high therapy compliance, thus suggesting significant benefits compared to CPAP in OSA patients in terms of overall alleviation of the condition.

The Company believes that its continued clinical research will confirm these initial positive results on a longer-term basis through its EliSA trial (a post-market clinical study of the Genio® system for the treatment of OSA in adult patients). In addition, the currently ongoing BETTER SLEEP clinical study in Australia and New Zealand is expected to contribute to the expansion of the therapy indications, particularly for patients with complete concentric collapse.

#### ***Solid intellectual property position***

The Company's technology and products are protected by a strong and growing portfolio of intellectual property rights, including trademarks and 109 granted utility and design patents and 68 utility patent applications pending, across 12 countries. Furthermore, intellectual property barriers are also achieved through the design of the Genio® system. Many of the components within the Genio® system cannot be physically accessed unless the device is destroyed, and several of the components are uniquely manufactured for the Company and are not otherwise available for purchase. The Genio® system requires extensive development and manufacturing experience, and replication of the performance of the Genio® system is difficult due to the unique interaction of the system components and would require significant experience and extensive testing. The Company's proprietary software cannot be retrieved from the device.

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

The Company's Board of Directors is composed of seasoned directors with extensive industry entrepreneurship experience. In particular, Robert Taub, the Company's Executive Chairman, (co-)founded and (co-)managed several pharmaceutical and medical device companies, some of which were listed on NASDAQ. The Company's multi-disciplinary management team is composed of members with strong clinical, engineering, production, regulatory and commercial experience and expertise in bringing a product from concept phase through to commercialization. Many of the team members have experience in the medical device and life sciences sector, including at St Jude Medical Inc., Medtronic Inc., Stryker Corp and Nevro Corp.

Finally, the Board of Directors and the management are assisted by a Scientific Advisory Committee that consists of industry-relevant international key opinion leaders.

### ***Key achievements and clear path to commercialization***

The Company obtained a CE-Mark approval for the Genio® system in March 2019, meaning that its system meets the health, safety and environmental protection standards for products sold within the EEA and can be freely sold and marketed within the EEA. The Company intends to first commercialize the product in Europe, initially focusing on certain target countries that foster innovation, such as Germany, and in Australia and New Zealand.

The Company is developing clear and tailor-made reimbursement strategies, based on assessments of the local requirements of target countries.

The Company is in discussions with the FDA to agree on the regulatory and approval pathway for the Genio® system in the United States and is on track to begin a pivotal IDE clinical trial in the United States as part of the approval process.

## **8.3 Marketing strategy and commercial objectives**

### **8.3.1 Marketing strategy**

The Company intends to implement 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 and will include the following:

- raising awareness of sleep disordered breathing conditions as well as its corporate brand;
- providing education and training to medical professionals; and
- partnerships with local key opinion leaders and patient associations.

**a. Raising awareness**

In markets where the Genio® system is approved for sale, the Company intends to raise market awareness and educate the various stakeholders on sleep disordered breathing conditions, in particular OSA, as well as on the Company's corporate identity and on the Genio® system as safe and effective treatment for moderate-to-severe OSA patients.

The Company intends to engage with the following key stakeholders in the OSA therapeutic field:

- OSA patients and patient associations;
- implanting surgeons, primarily ear, nose and throat physicians, who, independent of whether they have prior expertise in OSA therapy, will be the target audience to implant the Genio® system;
- sleep centers, which may include sleep medical specialists, neurologists and pulmonologists, and which are a significant gateway to accessing OSA patients who constitute potential candidates for the Genio® system. They constitute a major OSA patient referral base for ear, nose and throat physicians;
- cardiac electrophysiologists, cardiologists, cardiovascular surgeons and dentists, which are a second OSA patient referral base for ear, nose and throat physicians; and
- reimbursement institutions and other (commercial) payors to help them reduce hurdles to treat OSA with the Genio® system by continuing to highlight the Company's robust clinical data, the economic and other advantages of increased OSA treatment compliance, and the advantages of the Genio® system compared to other hypoglossal nerve stimulation therapies currently available on the market.

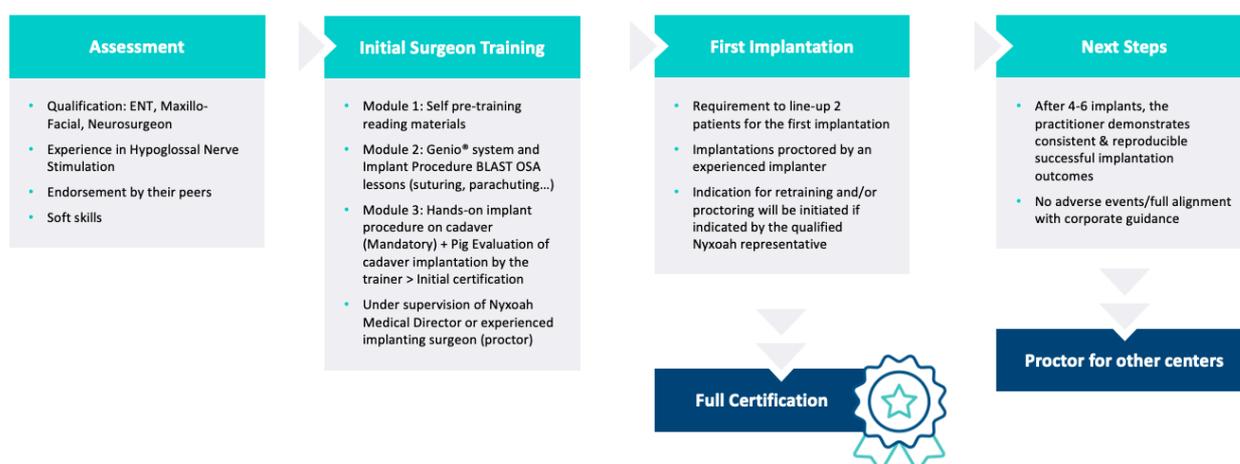
The Company also intends to continue to publish additional clinical data in various scientific journals and to be present at various conferences. The Company will also continue to invest in promotional activities using both conventional and social media including videos / testimonials provided by patients and physicians or sleep specialists in order to raise awareness of the Genio® system therapy amongst clinicians, patients, academics and other stakeholders.

**b. Education and training**

The Company has developed dedicated education and training programs leading to a certification delivered by an approved proctor. These education and training programs will 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. These education and training programs will promote a better understanding of OSA, which the Company believes will result in maximizing therapy outcomes for Genio® users, a better understanding of the technology's benefits and risks, and increasing confidence in the safety of the technology. In addition, a specific one-day education program has been developed for implanting surgeons in order to train and qualify them prior to the first implantation of a Genio® system. As at the date of this Prospectus, 16 surgeons were successfully fully trained in Europe and 9 surgeons were trained in Australia as part of BLAST OSA, EliSA and BETTER SLEEP trials.

The Company also intends to develop online and offline programs targeted towards Genio® patients to promote and increase user therapy engagement, long-term therapy observance, quality of life and wellbeing of OSA patients.

### Surgeon Certification Process



Summary overview of Nyxoah's Surgeon Certification Process

#### c. Partnerships with key opinion leaders and patient associations

The Company seeks to establish long-term partnerships with key opinion leaders and patient associations that are built on mutual trust and oriented towards the needs of its patients and customers. Fostering a culture of win-win collaborations with international and local key opinion leaders, relevant scientific societies, as well as patient associations, lies at its core and is embedded throughout the various stages of the Company's development. The Company's vision is people-centered, beginning with the center circle of OSA patients as its users through the second circle of their partners and family members affected by the manifestation of OSA and the third circle, the Company's customers (ENTs, sleep doctors and commercial payors).

### 8.3.2 Commercialization efforts

#### a. Geographical focus

The Company obtained a CE-Mark approval for the Genio® system in March 2019 and intends to first commercialize the product in Europe, Australia and New Zealand. The Company intends to focus its European commercialization activities and efforts initially on a limited number of countries that have been selected based on market access and therapy adoption for hypoglossal nerve stimulation and country-specific level of innovation.

Based on market access activities conducted over the past four years, the Company expects to obtain reimbursement and funding for the Genio® system by local health authorities in the focus countries of (listed in chronological order) Germany, Australia and New Zealand, Spain, France, the Netherlands, the Nordic countries, Belgium, UK and Switzerland. In these countries, a clear reimbursement pathway has been identified

and the Company will execute a country specific reimbursement strategy. The Company will make the Genio® system commercially available for patients through country specific innovation full funding pathways for procedures and products that would not yet be covered by an existing code, including, amongst others, device costs and procedure costs.

Although there is a general consensus about the medical necessity to treat OSA and notwithstanding the increasing number of hypoglossal nerve stimulation therapy coverage decisions (as evidenced by the Inspire case), the Company shall continue to develop further clinical evidence demonstrating a long term meaningful improvement in net health outcomes for patients meeting the specified criteria.

In 2020, the Company is working to:

- start commercializing the system in Germany under the existing hypoglossal nerve stimulation NUB (*Neue Untersuchungs- und Behandlungsmethoden*);
- obtain TGA approval in Q4 2020;
- commercialize the Genio® system in Spain, where the Company obtained funding in selected hospitals to make its first implants in Q4 2020;
- gain approval in France from the specific local innovation funding (*Forfait Innovation*) and intends to partner with leading French expert centers and build clinical evidence in order to obtain full reimbursement through the integration in the *Liste des Produits et Prestations* file. The Company is currently preparing the submission to *Forfait Innovation* and the final submission to *Forfait Innovation* is planned for the second half of 2020;
- enter into collaboration in the Netherlands with the leading HGNS center (OLVG West – Amsterdam with Prof. de Vries);
- submit the reimbursement file in Belgium. Based on the interpretation of the published clinical data by the healthcare authorities, the Genio® system could obtain either full reimbursement or will be covered as part of the innovation budget;
- attract limited patient funding in the UK through the collaboration with private hospital groups; and
- make case by case submission to local insurance companies in Switzerland.

The Company is in discussions with the FDA to agree on the regulatory pathway for the Genio® system in the United States. On 23 June 2020, the FDA approved the Company's IDE application, allowing the Company to commence its pivotal DREAM study of the Genio® system to support the system's marketing approval in the United States. Approval was granted under a Centers for Medicare & Medicaid Services (which is part of the United States Department of Health and Human Services, "CMS") category B. Category B (Non-experimental/investigational) refers to a device for which initial questions of safety and effectiveness of that device type have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type. The study is expected to start in the second half of 2020 in up to 26 centers in and outside the United States.

In parallel, the Company will actively seek new opportunities, monitor market evolution and develop dedicated tactics and plans to keep developing new markets, identify additional regions with promising market potential for the Genio® system and establish proper reimbursement pathways.

**b. Developing and focusing on Centers of Excellence**

The Company's commercial strategy is to go "deep" from a therapy penetration perspective instead of going "wide". The Company is therefore focusing its efforts on developing Centers of Excellence, where it will 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. The surgical procedure for implantation of the Genio® system will typically be performed by an ear, nose and throat surgeon, and in some cases, by a maxillo-facial surgeon or neurosurgeon.

The Company intends to focus on sleep centers as they diagnose and manage many patients who suffer from OSA, which are an important referral base for the ear, nose and throat surgeons with whom they partner.

The Company has defined qualification criteria for Centers of Excellence to ensure a successful market entry. In order to qualify as a Center of Excellence, a medical center must fulfil six out of the following eight pre-defined selection criteria:

- a large pool of patients diagnosed and treated for OSA;
- an existing relationship between the surgeon performing the implant procedure and the sleep specialist working under the same roof;
- existence of an external referral network in addition to the center's existing internal referral network;
- experience with hypoglossal nerve stimulation treatments;
- willingness to form a positive experience with the proprietary technology;
- being active and recognized as a key opinion leader in the sleep/ear, nose and throat field, demonstrated e.g. through publications and presentations at seminars;
- a potential advocate and influencer within the ear, nose and throat /sleep specialists community; and
- proctoring skills and interest, including the availability of training facilities.

It is the Company's aspiration that, within the first twelve months after a Center of Excellence is open, the Genio® system will have become the treatment of choice for the center's annual eligible population treated with a type of hypoglossal nerve stimulation treatment.

Both the sleep specialist and the surgeon who performs the implantation procedure will be part of the Centers of Excellence. Once a patient has undergone the implantation of the Genio® system, the sleep specialist will further oversee and follow-up with the patient for both activation and optimization of the treatment.

Under the Company's direct sales model, key account managers will manage all stakeholders within the Centers of Excellence in their territory. Once a critical mass of new implanted patients is reached, a key account manager will be supported by a "field sleep expert" of the Company, who will directly oversee and manage the patients' follow-up and further optimize of the treatment. Based on specific country growth, a dedicated country manager may also be hired.

### **c. Growing sales and marketing organization**

The Company currently has a market development team of five European based and five Australian and New Zealand based employees to support commercialization of the Genio® system. This team will gradually scale-up in line with market entry and access in the various countries and regions and depending on the commercialization strategy implemented in these countries and regions.

The Company intends to sell the Genio® system using a direct commercialization model. The Company will use key account managers supporting the Centers of Excellence to strengthen the referral physician network, guiding new patients to these Centers of Excellence. Once an OSA patient is selected for Genio® system therapy the key account manager will support the physician during the implant procedure. Some weeks after the implantation the key account manager will support the activation of the therapy and at a later stage the key account manager will assist with a further individual adjustment of the therapy during sleep nights to provide the patient with the optimal therapeutic effect. The Company currently estimates that one key account manager can cover around 45 to 55 new patients annually, spread over two to three implant sites, which would correspond to €1 million in revenue per year when calculated at an estimated HGNS system average selling price of €20,000. When the key account manager would reach his/her maximum span of activity, a Company field sleep expert will be added to oversee the patient therapy optimization sleep nights.

In Germany, the Company's strategy is to have a high therapy penetration level in the selected sites and therefore the Company plans to work with at least 15 implantation sites in the first years after start of commercialization.

Using the same strategy the Company is planning to enter in Belgium with three to four Centers of Excellence, the Netherlands with one to two centers, France with six to eight centers, the UK with four to six centers, Switzerland with two to four centers spread over both countries, and the Nordic countries with two to four centers in the coming two to three years depending on the speed of obtaining reimbursement.

In Spain, the Company intends to enter the market with four to six Centers of Excellence and expects to work with a distributor as market access partner due to the complexity of the regional setup of the Spanish reimbursement system. The Company is aiming to commercialize the Genio® system using the existing hospital budgets in target centers and will prepare the submission of a national funding dossier.

In Australia, the Company intends to enter the market with eight Centers of Excellence. The decision to open Centers of Excellence in Australia is multifold: (i) clinical data from Australia is extremely well perceived by the FDA and can be used as feasibility data, (ii) Centers of Excellence in Australia have previous experience in the hypoglossal nerve stimulation space with Apnex Medical Inc. and (iii) the time required to activate such centers in Australia is short compared to the European Union and the United States.

In New Zealand, the Company intends to enter the market with two Centers of Excellence and expects to work with a distributor.

The Company has not yet made a decision on its commercialization efforts in the United States, which may include establishing and gradually developing a direct sales force in the United States, working with distributors, or other forms of partnership or other models. Based on its experience gained from the commercial roll-out in Europe but also taking into account particular aspects of the local markets, the Company will determine and prepare what it believes to be the optimal commercial structure for the United States, to jump-start its entry into the United States market.

#### **8.4 Reimbursement landscape**

Nyxoah as a "Fast Follower"		Nyxoah as a "Market Leader"	
<b>Germany</b>	<ul style="list-style-type: none"> <li>German federation of public health agency (G-BA) approved Nyxoah funding through existing HGNS NUB platform</li> <li>Nyxoah and Inspire have similar proven efficacy and safety</li> <li>Nyxoah – Direct in top 15 centers of excellence</li> <li>First revenue generated in July 2020</li> </ul>	<b>France</b>	<ul style="list-style-type: none"> <li>Forfait Innovation eligibility approved by Health Authorities in February 2020 &gt; First revenue in 2021</li> <li>Nyxoah – Direct in top tier 6-8 focus CoEs</li> <li>LPP coding: 2024</li> </ul>
<b>Australia</b>	<ul style="list-style-type: none"> <li>MSAC approval for expedited review (Nyxoah can leverage Inspire clinical data) &gt; DRG coding in 2021</li> <li>Nyxoah – Direct in top tier 8 focus CoEs</li> <li>First case-by-case approval (SAS) by Ministry of Health obtained in Q1 2020</li> </ul>	<b>Spain</b>	<ul style="list-style-type: none"> <li>Obtained funding in selected hospitals leading to first implants and revenue expected in Q4 2020</li> <li>Distributor in top tier 4-6 focus CoEs</li> <li>National coverage: 2023</li> </ul>
<b>Netherlands</b>	<ul style="list-style-type: none"> <li>Top tier 1-2 focus CoEs</li> <li>Nyxoah – Direct</li> <li>"Technical variant": 2021</li> </ul>	<b>UK</b>	<ul style="list-style-type: none"> <li>Nyxoah – Direct in top tier 4-6 focus CoEs</li> <li>Private hospital budget followed by NHS coding (2023)</li> </ul>
<b>Switzerland</b>	<ul style="list-style-type: none"> <li>Top tier 2-4 focus CoEs</li> <li>Nyxoah – Direct</li> <li>Case by case submission based on existing DRG coding</li> </ul>	<b>NZ</b>	<ul style="list-style-type: none"> <li>Distributor in top tier 2 focus CoEs (Hospital budget)</li> <li>DRG coding: 2022</li> </ul>
		<b>Belgium</b>	<ul style="list-style-type: none"> <li>Nyxoah – Direct in top tier 3-4 focus CoEs</li> <li>Reimbursement dossier (LCA) / INAMI-RIZIV funding: 2023</li> </ul>
		<b>Nordics</b>	<ul style="list-style-type: none"> <li>Nyxoah – Direct in 1 focus CoE by Nordic country</li> <li>Hospital budget and HTA assessment leading to funding</li> </ul>

## 8.4.1 Reimbursement landscape in selected EEA countries

### a. Germany

In Germany, the Company expects to obtain funding based on the existing NUB coding for hypoglossal nerve stimulation systems.

Procedure code OPS 5-059.c7 is allocated for "the implantation or change of a neurostimulator with implantation or change of a neurostimulator electrode for a system for hypoglossal nerve stimulation" which triggers G-DRG 802A. In 2019, the reimbursement rate under G-DRG 802A for patients staying in the hospital for at least four days amounted to roughly €7,800.

In Germany, the "*Institut für das Entgeltsystem im Krankenhaus GmbH*", which acts as the German federal reimbursement agency, has granted the "*Neue Untersuchungs- und Behandlungsmethoden*" (NUB) Status 1 coverage for hypoglossal nerve stimulation systems. The NUB process allows for the introduction of new and innovative medical devices prior to reaching reimbursement and provides a supplemental payment for new technologies under the German reimbursement system. NUB Status 1 is the highest of four levels. Under NUB Status 1, healthcare insurances are obligated to cover the differences in treatment costs of new technologies compared to existing therapies.

The "HGNS for OSA therapy" NUB was first granted in the year 2016 and has been confirmed again for the year 2020. NUBs are by definition limited in time - they typically run until the authorities consider they have sufficient evidence to define a proper coding and pricing for the procedure and implants. Once sufficient data will be available, a new DRG code will be issued.

The Company received the final decision from the federal joint committee (G-BA) on 5 March 2020 confirming that the Genio® system is now entitled to join the existing NUB. The Company has generated its first revenue from commercial sales in Germany in July 2020.

### b. Belgium

The strategy of the Company is to build dedicated clinical evidence and expertise in leading Belgian sleep centers, in order to create a "Health Technology Assessment" dossier to integrate clinical evidence into the local reimbursement assessment requirements, while building key opinion leader endorsement and partnerships in Belgium.

In parallel, the Company will apply for special innovation funding programs, such as Limited Clinical Application and "Solidariteit" funds.

**c. France**

Currently, there is no existing code for hypoglossal nerve stimulation treatment of OSA under the French coding system - "*Liste des Produits et Prestations*". The Company will therefore apply for special innovation funding, "*Forfait Innovation*". The Company is currently preparing for the submission of the *Forfait Innovation* dossier in 2020, of which final results are expected to be made available in the first half of 2021. Through this "*Forfait Innovation*", it will run a dedicated clinical trial in order to generate clinical data to support the submission of a reimbursement dossier to the French healthcare authority, the "*Haute Autorité de Santé*". During the period of the trial, it will be able to secure funding for implanted Genio® systems (approximately 100 patients).

**d. Spain**

In Spain, national approval and coverage require a dedicated Spanish clinical registry and Health Technology Assessment including long term clinical data. Funding opportunity for the Genio® system will be based on regional budgets, negotiated by local hospitals. The Company's strategy will focus on hospitals that can use their budget to fund the therapy. The Company will establish a distributor network to support case-by-case funding submission in target local sites.

**e. The Netherlands**

In the Netherlands, there is currently an existing code (DB-C code) for hypoglossal nerve stimulation therapy for OSA. The Company is currently investigating if it will apply to the existing DB-C code or request a new one, in order to maximize local access to reimbursement.

**f. United Kingdom**

In parallel to the creation of a dedicated Health Technology Assessment to support the request for funding, the Company's strategy is to focus on privately funded hospital groups.

**g. Other countries**

In other EEA countries, coverage for the Genio® system will be driven by the integration of clinical evidence into the local reimbursement assessment requirements (Health Technology Assessment).

In countries where innovation is embraced through specific innovation budgets, the Company will apply for these.

## 8.4.2 Reimbursement landscape in the United States

The Company expects that if the Genio® system is approved for marketing in the U.S., its products would be sold to hospitals and ambulatory surgery centers, and these health care organizations, as well as the physicians and other health care professionals involved in performing the implant procedures and follow-up, would all seek reimbursement for their services from various third-party payers, such as commercial health insurance companies and government health care programs, such as Medicare and Medicaid. Separate payments would likely be sought for facilities where the implantation procedure is performed, the physicians performing the surgeries and follow-up examinations. Reimbursement approaches and rules can be very complex, and their application to health care services involving a novel implanted medical device, such as the Genio® system, is uncertain. An important part of the Company's marketing and commercialization activities would be to help identify and obtain appropriate third-party payers reimbursement for the health care provider services associated with the implantation and management of the Genio® system.

Third party payers rely upon a system of codes, including procedure codes, to identify the type of service for which reimbursement is being sought by health care providers. These codes include, among others, codes called current procedural terminology codes. Current procedural terminology codes are the responsibility of and are produced and updated by the American Medical Association. Given the novel nature of the Genio® system, the precise current procedural terminology or other codes that would be used for reimbursement purposes is not certain, although it is the Company's current belief that the implantation procedure of the Genio® Implantable Stimulator, which is part of the Genio® system, may be described by CPT code 61886, which describes the implantation of a cranial nerve stimulator. There can be no assurances, however, that Medicare or any other public or private payer would maintain this view in the event the Genio® system is, in the future, approved for marketing in the U.S., or that third party payers will determine to reimburse for Genio® system services, or if they do provide reimbursement, that it will be adequate to support the delivery of the service.

For example, Medicare will cover treatments that are considered "medically necessary" and needed to diagnose or treat a medical condition and that meet accepted standards of medical practice. Thus, the fact that a medical device has been approved for marketing by the FDA does not necessarily mean that Medicare will cover treatments involving the device. Current market research conducted by the Company generally indicates that about one-half of commercial payers would cover the Genio® system implantation when provided with twelve months of favorable randomized controlled trial data, whereas, the remaining commercial payors will require 24 months of favorable RCT data, although there can be no assurances that this will prove to be the case when, if the Genio® system is approved for marketing in the U.S., coverage determinations are actually sought. It is also noteworthy that market research conducted by the Company found that all sampled commercial payers had written "medical necessity" coverage policies with respect to the coverage of treatments for obstructive sleep apnea, with such policies setting forth certain restrictions that apply to treatment coverage in individual cases (e.g., prior authorization based on the presence of certain specified medical criteria). As a result, the Company believes that those commercial payers that do determine to cover treatment involving the Genio® system would also develop similar formal coverage policies controlling access to Genio® system treatments through coverage policies specifying certain criteria for access to reimbursement. The Company's market research also indicates that Medicare would require 24 months of favorable randomized controlled trial data for coverage, and individual state Medicaid plans would require 24 months of favorable randomized controlled trial data and generally lag behind Medicare and commercial payors.

With respect to the implantation procedure, it is generally expected that these would take place in hospital outpatient departments or ambulatory surgery centers, and both such facilities are generally reimbursed based on prospective payment systems, where (subject to certain exceptions) an aggregated, bundled rate, developed using multiple weighted factors, is intended to reimburse the facility for providing the given procedure. Fees paid to the physicians performing an implantation procedure would generally be separately reimbursed outside of the bundled rate. For example, Medicare provides reimbursement to hospitals under the hospital outpatient prospective payment system, for all its facility costs related to procedures performed in the hospital outpatient setting. By way of example only, under the hospital outpatient prospective payment system, the current national average Medicare payment to hospitals for procedures covered by CPT code 61886 is slightly in excess of \$27,000, which covers the cost of the device and of the implantation procedure to which 61886 applies. The surgeon is receiving an additional physician payment under the Medicare Physician Fee Schedule. Notably, reimbursement paid by both public and private third-party payers may also vary depending on the payment rates and other arrangements negotiated between the applicable parties. For example, managed care plans may negotiate discounted rates with hospital systems in exchange for delivering to the hospitals higher numbers of patients, and, increasingly all health care providers, such as hospitals, ambulatory surgery centers and physician groups, may take on certain risk-based payment arrangements, where reimbursement may vary depending upon the achievement of cost-savings and quality metrics, and such approaches to reimbursement - which essentially share cost-savings between third-party payers and health care providers - are expected to increase over time in the U.S. As an example of this trend, the Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015, established a new payment framework called the Quality Payment Program, under which certain eligible clinicians must participate in Medicare through either the Merit-Based Incentive Payment System or Advanced Alternative Payment Models. The Merit-Based Incentive Payment System generally modifies Medicare reimbursement to eligible clinicians to include both positive and negative payment adjustments account for, among other things, quality and cost control. Advanced Alternative Payment Models generally involve higher levels of financial and technology risk. The requirements for the Merit-Based Incentive Payment System and Advanced Alternative Payment Models performance measures continue to evolve, and as such, their implications are uncertain, but the measure underscores trends by third party payers, including Medicare, to incentivize physicians, hospitals, and systems to alter practice patterns to control health care spending.

The Company will conduct the DREAM pivotal IDE study in and outside of the United States. Based on the outcome of the DREAM IDE study, the Company aims to obtain FDA approval by the end of 2022, leading to an expected commercialisation in the first half of 2023.

#### **8.4.3 Reimbursement landscape in Australia and New Zealand**

In Australia, coverage for the Genio® system will be driven by the integration of clinical evidence, resulting into TGA approval. TGA approval can be expected in Q4 2020.

Simultaneously, negotiations with the Medical Services Advisory Committee on reimbursement have already been initiated. The Company already achieved to obtain individual patient funding through the Special Access Scheme. Once this has been granted, the Company is entitled to engage in negotiations for the Genio® system's coverage with the patient's insurance. The Special Access Scheme is not limited in numbers but every dossier shall be discussed on a case-by-case basis.

In New Zealand, following WAND registration in December 2019, Nyxoah has initiated discussions with

local potential market access and reimbursement partners for the Genio® system.

## 8.5 Market overview

### 8.5.1 Obstructive Sleep Apnea – Prevalence – Comorbidities – Economic Costs

OSA is the world’s most common sleep disordered breathing condition, occurring in up to 50% of the population in some countries and affecting around 936 million people between 30 and 69 years of age globally, of which 425 million suffer from moderate-to-severe OSA and require treatment.<sup>22</sup>

	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
<b>EUROPE</b>			
Austria	4,601,766	1,306,180	28.4%
Belgium	5,917,763	931,859	15.7%
Denmark	2,927,893	833,901	28.5%
Finland	2,894,948	853,928	29.5%
France	32,613,385	11,836,999	36.3%
Germany	43,751,645	14,393,964	32.9%
Iceland	162,564	19,136	11.8%
Ireland	2,447,445	117,487	4.8%
Italy	33,020,571	3,959,253	12.0%
Luxemburg	308,327	48,029	15.6%
Malta	225,879	36,769	16.3%
Netherlands	9,050,266	2,582,583	28.5%
Norway	2,684,446	351,443	13.1%
Portugal	5,691,681	713,458	12.5%
Spain	26,158,266	4,233,728	16.2%
Sweden	4,918,210	626,258	12.7%
Switzerland	4,518,615	1,654,232	36.6%
UK	32,936,962	1,581,374	4.8%
<b>AUSTRALIA / NEW ZEALAND</b>			
Australia	12,110,362	581,348	4.8%
New Zealand	2,256,063	68,590	3.0%
<b>UNITED STATES</b>			
USA	163,246,772	23,678,109	14.5%

Estimated moderate-to-severe OSA prevalence per country<sup>23</sup>

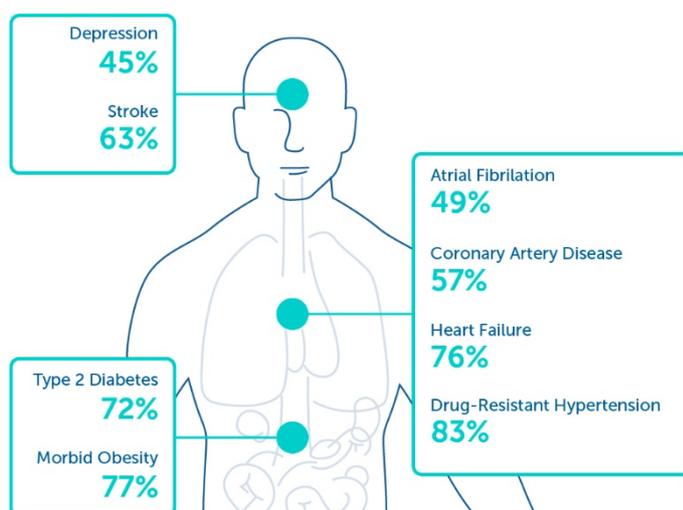
<sup>22</sup> Benjafeld, Adam V et al. Estimation of the global prevalence and burden of obstructive sleep apnea: a literature-based analysis. *Lancet Respir Med* 2019 Published Online 9 July 2019 [http://dx.doi.org/10.1016/S2213-2600\(19\)30198-5](http://dx.doi.org/10.1016/S2213-2600(19)30198-5)

<sup>23</sup> Benjafeld, Adam V et al. Estimation of the global prevalence and burden of obstructive sleep apnea: a literature-based analysis. *Lancet Respir Med* 2019 Published Online 9 July 2019 [http://dx.doi.org/10.1016/S2213-2600\(19\)30198-5](http://dx.doi.org/10.1016/S2213-2600(19)30198-5).

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 totally (apnea) blocked thereby 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.

Due to the poor quality and lack of sleep, OSA sufferers often feel tired and fatigued during the day. They have difficulties to concentrate and experience emotional stress. OSA is a severe and chronic sleep disordered breathing condition which can result in severe medical comorbidities, including cardiovascular diseases, depression, stroke, arrhythmia, obesity, hypertension, diabetes, etc.

Untreated OSA can be deadly<sup>24</sup>. Untreated OSA patients have two times<sup>25</sup> more risk of suffering stroke<sup>25</sup>, two and a half times more risk of heart failure<sup>26</sup> and five times more risk of cardiovascular mortality<sup>27</sup>. Clinical studies have shown that the mortality rate of non-treated patients suffering from OSA increases significantly over time<sup>28</sup>. Numerous studies demonstrated the correlation between efficient OSA therapy and the reduction of mortality and comorbidities.<sup>29</sup>



High prevalence in key chronic diseases<sup>30</sup>

Clinical studies have also shown that:

<sup>24</sup> Young T. et al: Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort, *Sleep*. 2008 Aug 1; 31(8): 1071–1078.

<sup>25</sup> Wake up America : a national sleep alert : report of the National Commission on Sleep Disorders Research (1994)

<sup>26</sup> Daniel Bratton. CPAP vs MA Devices and Blood Pressure in Patients With Obstructive Sleep ApneaA Systematic Review and Meta-analysis. *Jama* 2015.

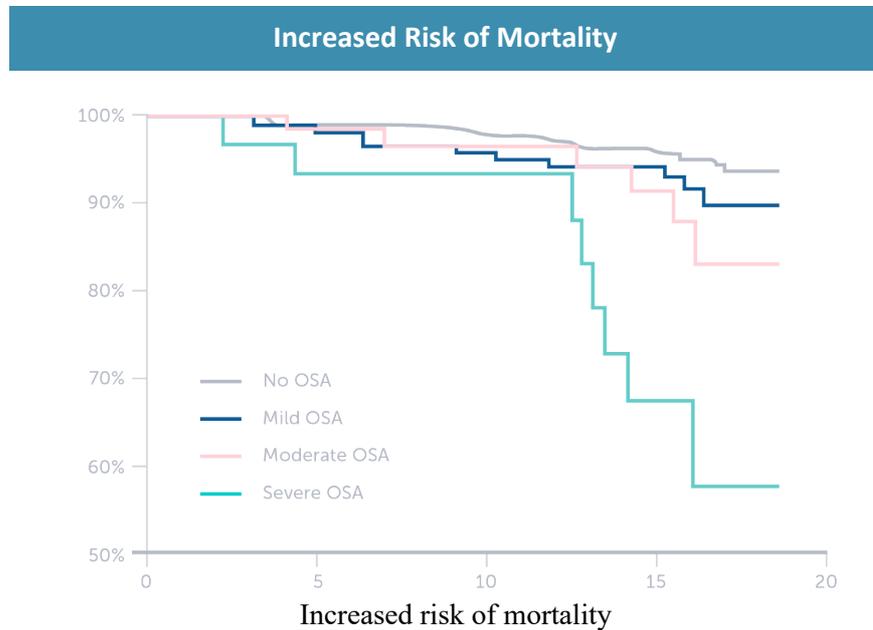
<sup>27</sup> Logan et al. J. Hypertension; O’Keefe and Patterson, *Obes Surgery*; Oldenburg et al., *Eur J Heart Failure*; Einhorn et al. *Endocrine Prac*; Bassetti et al. *Stroke*

<sup>28</sup> Young T. et al: Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort, *Sleep*. 2008 Aug 1; 31(8): 1071–1078

<sup>29</sup> Campos-Rodriguez and al., Mortality in obstructive sleep apnea-hypopnea patients treated with positive airway pressure. *Chest*. 2005 Aug;128(2):624-33; Long-term effects of nasal continuous positive airway pressure therapy on cardiovascular outcomes in sleep apnea syndrome. *Chest*. 2005 Jun;127(6):2076-84.

<sup>30</sup> Logan et al. J. Hypertension; O’Keefe and Patterson, *Obes Surgery*; Oldenburg et al, *Eur J Heart Failure*; Einhorn et al. *Endocrine Prac*; Bassetti et al. *Stroke*

- 30-50% of patients with high blood pressure also have OSA<sup>31 32</sup>
- Prevalence exceeds 70% in morbidly obese and diabetic patients<sup>33</sup>
- Up to 50% of people with OSA are not obese<sup>34</sup>



OSA prevalence is ~25% in middle aged men, ~40% in older men, and ~25% in older women.<sup>35,36</sup>

The severity of OSA is measured by the number of complete (apnea) or partial (hypopnea) airway blockages occurring for each hour of sleep, referred to as the Apnea-Hypopnea Index ("AHI").

	AHI
Normal	<5
Mild OSA	5-14
Moderate OSA	15-30
Severe OSA	>30

Moderate and severe OSA patients require a dedicated therapy according to guidelines published by sleep doctors' scientific societies such as the American Academy of Sleep Medicine.

<sup>31</sup> Logan et al. J. Hypertension; O'Keefe and Patterson, Obes Surgery; Oldenburg et al., Eur J Heart Failure; Einhorn et al. Endocrine Prac; Bassetti et al. Stroke

<sup>32</sup> Daniel Bratton. CPAP vs MA Devices and Blood Pressure in Patients With Obstructive Sleep ApneaA Systematic Review and Meta-analysis. Jama 2015

<sup>33</sup> Logan et al. J. Hypertension; O'Keefe and Patterson, Obes Surgery; Oldenburg et al., Eur J Heart Failure; Einhorn et al. Endocrine Prac; Bassetti et al. Stroke.

<sup>34</sup> Peppard PE, Young T, Barnet JH, Palta M, Hagen EW, Hla KM. Increased prevalence of sleep-disordered breathing in adults. Am J Epidemiol. 2013;177(9):1006–1014; Gray EL, McKenzie DK, Eckert DJ. Obstructive sleep apnea without obesity is common and difficult to treat: evidence for a distinct pathophysiological phenotype. J Clin Sleep Med. 2017;13(1):81–88.

<sup>35</sup> Peppard PE, Young T, Barnet JH, Palta M, Hagen EW, Hla KM. Increased prevalence of sleep-disordered breathing in adults. AmJ Epidemiol. 2013;177(9):1006–14.

<sup>36</sup> Young T, Palta M, Dempsey J, Skatrud J, Weber. The occurrence of sleep-disordered breathing among middle-aged adults. N Engl J Med. 1993 Apr 29;328(17):1230–5.

### A disruptive disorder seriously impacting lives

- A sleep condition where the muscles and soft tissues in throat and tongue relax too much and collapse
- Obstruction of airway causes cessation of breathing
- Low quality of life due to poor quality and lack of sleep
- Associated with many other adverse health consequences, including an increased risk of death

0-4	Normal Range
5-14	Mild Sleep Apnea
15-30	Moderate Sleep Apnea
>30	Severe Sleep Apnea

Apnea Hypopnea Index (AHI) is used to indicate severity of OSA and represents the number of apnea and hypopnea events per hour of sleep

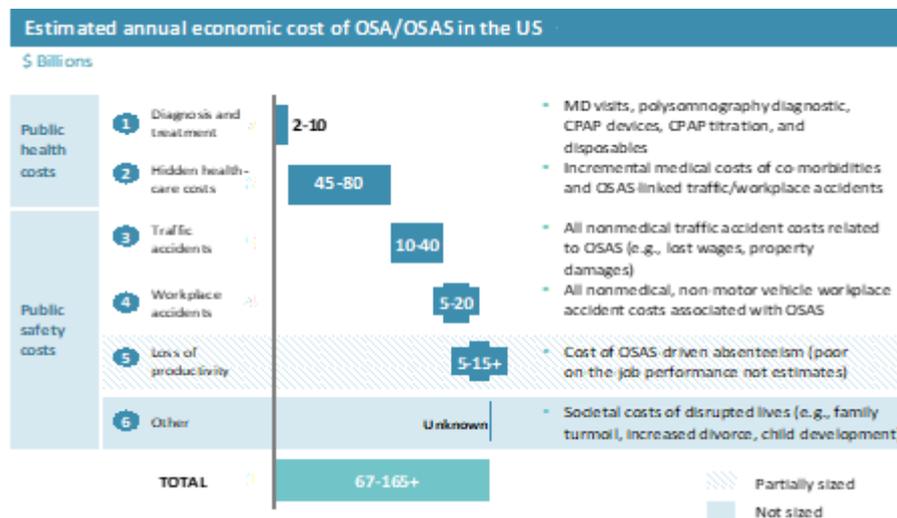
**Requires therapy due to severe health impact**



OSA – A severe disorder that significantly impacts lives

The socio-economic burden of OSA stems from both direct and indirect health costs amounting to billions of dollars. Expert reports estimate the economic cost of moderate-to-severe OSA in the United States to be \$67-165 billion annually, which 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.<sup>37</sup>

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.<sup>38</sup>



Estimated annual economic cost of OSA/OSAS<sup>39</sup> in the United States

### 8.5.2 Current treatment paradigm

<sup>37</sup> Harvard Medical School division of Sleep Medicine, The Price of Fatigue: The Surprising Economic Costs of Unmanaged Sleep Apnea, Dec 2010.

<sup>38</sup> Tregear S et al. J Clin Sleep Med 2009;5(6):573-581.

<sup>39</sup> OSAS means OSA syndrome, i.e. obstructive sleep apnea syndrome.

Since the early 1980s, various conventional treatment options have been available, depending on the level of severity of the disorder. These options range from lifestyle changes such as weight loss and medical interventions including CPAP, mandibular advancement devices and traditional surgical interventions.

**a. First-line therapy: CPAP**

CPAP is the standard line treatment in 80% of diagnosed moderate-to-severe OSA patients.<sup>40</sup> CPAP is a treatment whereby air at a constant or automated pressure is pushed into the upper airway via a mask (nasal or facial) that the patient must wear all night.

CPAP has demonstrated its efficacy in reducing AHI, as well as improving patient sleep quality and daytime sleepiness. However, the efficacy of CPAP therapy is directly correlated to the number of hours of use per night and its long-term compliance.

There are many limitations to this therapeutic option, meaning compliance is a serious challenge. Limitations include mask discomfort, mask leakage, skin irritation, claustrophobia and lack of intimacy.

In addition, the airway pressure can also cause severe dryness in the nose and mouth, resulting in side effects such as sense of suffocation, nasal/oral dryness, nasal congestion, and nosebleeds.

As a result, CPAP non-compliance has been estimated to be between 29% and 83%.<sup>41</sup> The Company estimates the CPAP non-compliance rate at 35%.

**b. Second-line therapies**

**i. Oral appliances - mandibular advancement devices**

Mandibular advancement devices, which look similar to orthodontic retainers, help keeping the airway open by bringing the jaw forward, allowing free passage of air.

However, mandibular advancement device therapy has multiple limitations, including but not limited to:

- discomfort, such as teeth and jaw pain and tooth displacement;
- need for multiple and recurrent follow-ups with the dentist to adjust or change the device;
- more suitable to treat mild to moderate OSA;
- non predictive therapy efficacy; and
- lower therapy efficacy when compared to CPAP therapy.<sup>42</sup>

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<sup>40</sup> Harvard Medical School Division of Sleep Medicine, The Price of Fatigue - The surprising economic costs of unmanaged sleep apnea, December 2010.

<sup>41</sup> Van Ryswyk and al., Predictors of long-term adherence to continuous positive airway pressure in patients with obstructive sleep apnea and cardiovascular disease, SLEEPJ, 2019, Vol. 42, No. 10; Kribbs NB, Pack AI, Kline LR, Smith PL, Schwartz AR, Schubert NM, Redline S, Henry JN, Getsy JE, Dinges DF. Objective measurement of patterns of nasal CPAP use by patients with obstructive sleep apnea. Am. Rev. Respir. Dis. 1993; 147: 887–95; Sawyer AM, Gooneratne NS, Marcus CL, Ofer D, Richards KC, Weaver TE. A systematic review of CPAP adherence across age groups: clinical and empiric insights for developing CPAP adherence interventions. Sleep Med. Rev. 2011; 15: 343–56.; Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure therapy: the challenge to effective treatment. Proc. Am. Thorac. Soc. 2008; 5: 173–8.

<sup>42</sup> Martha Schwartz, et al. Effects of CPAP and mandibular advancement device treatment in obstructive sleep apnea patients: a systematic review and meta-analysis. Sleep Breath (2018) 22:555–568

## ii. **Surgery to remove or reposition patient tissue or bone**

For patients who have difficulties with the aforementioned treatment options, surgical procedures for the nose (e.g. nasal), throat (e.g. palate, tonsils, uvula) or mandible, such as uvulopalatopharyngoplasty and maxillomandibular advancement, 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. Some procedures can last several hours, are painful and require long recuperation periods. For example, maxillomandibular advancement consists in 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 option, due to their invasiveness, cost, the high incidence of side effects and varying responder rates (30% to 60%)<sup>43</sup>.

### **8.5.3 Other treatment options being investigated**

Additional OSA treatment options have been investigated and/or developed over the past years such as positional OSA therapy (specific for the subset of OSA patients suffering from positional OSA). Also, some technologies such as tongue training (didgeridoo playing, direct electrical tongue stimulation) and drugs are in a very early stage of investigation. To date, none of these have demonstrated sustainable and positive outcomes due to lack of performance, significant patient discomfort or side effects.

### **8.5.4 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 help maintain an open airway during sleep.

The first publication in 1988 was from Japan and described the effect of transcutaneous submental stimulation with polysomnographic studies during all-night sessions.<sup>44</sup> Hypoglossal nerve stimulation emerged as an alternative approach to muscle stimulation. In 1993, studies demonstrated that hypoglossal nerve stimulation was capable of keeping the airway open during sleep in OSA patients.<sup>45</sup> The initial trial of efficacy was reported in 2001.<sup>46</sup> Over the past 15 years, hypoglossal nerve stimulation was proven to be an effective second line therapy to CPAP and was developed commercially as therapy for OSA. Inspire's 5-year STAR trial data demonstrated a 75% responder rate (defined as a decrease in AHI by at least 50% and a residual AHI of less than 20 events/h)<sup>47</sup>. Under the same definition, the ADHERE registry showed aan 81% responder

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<sup>43</sup> Shah, Janki, et al; Uvulopalatopharyngoplastyvs CN XII stimulation for treatment of obstructive sleep apnea: A single institution experience; American Journal of Otolaryngology (2018).

<sup>44</sup> Miki H, Hida W, Inoue H, et al. A new treatment for obstructive sleep apnea syndrome by electrical stimulation of submental region. *Tohoku J Exp Med.* 1988; 154:91–92.

<sup>45</sup> Decker MJ, Haaga J, Arnold JL, et al. Functional electrical stimulation and respiration during sleep. *J Appl Physiol* (1985). 1993; 75:1053–61.

<sup>46</sup> Schwartz AR, Bennett ML, Smith PL, et al. Therapeutic electrical stimulation of the hypoglossal nerve in obstructive sleep apnea. *Arch Otolaryngol Head Neck Surg.* 2001; 127:1216–23.

<sup>47</sup> Woodson, Strohl, Soose et al.; Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes; *Otolaryngology–Head and Neck Surgery* 1–9. 2018.

rate<sup>48</sup>. Various scientific societies (Netherlands, Germany, USA) already recognized the benefits of hypoglossal nerve stimulation as a therapy for moderate-to-severe OSA.<sup>49</sup>

The yearly pool of moderate-to-severe OSA patients newly eligible for hypoglossal nerve stimulation is estimated at approximately 500,000 patients in the United States and 600,000 patients in Europe and Australia/New Zealand.

The figures below give an overview of the estimated annual population eligible to hypoglossal nerve stimulation in the United States and Western Europe and the resulting business opportunity.



Notes:

*Incidence = number of new patients eligible to HGNS therapy every year*

(1) Harvard Medical School Division of Sleep Medicine, *The Price of Fatigue - The surprising economic costs of unmanaged sleep apnea*, December 2010

(2) Inspire Medical SEC filing, Form S-1, April 2018

(3) Company estimates

(4) CPAP non-adherence has been estimated between 29% and 83%, according to scientific literature. Nyxoah average to ~ 35% non-observance.

(5) Inspire Medical SEC filing, Form S-1, April 2018

Annual population eligible to hypoglossal nerve stimulation in the United States and Europe/ANZ

## 8.6 The Company's solution

### 8.6.1 Product

<sup>48</sup> Heiser C, Steffen A, Boon M, et al. Post-approval upper airway stimulation predictors of treatment effectiveness in the ADHERE registry. *Eur Respir J* 2019; 53: 1801405.

<sup>49</sup> Netherlands ZIN Scientific Committee - April 2017; German Sleep Society - Q3 2016; American AAO-HNS Society - March 2016.

The Company's proprietary Genio® system is the world's first and unique battery-free, leadless and minimally invasive neurostimulator that is capable of delivering bilateral hypoglossal nerve stimulation for patients who suffer from OSA. The Company obtained a CE-Mark for its Genio® system in March 2019, following the successful completion of the BLAST OSA clinical study whose results were published in the European Respiratory Journal in October 2019. Similar to other hypoglossal nerve stimulation therapies, the Genio® system is intended as a second line therapy for use by patients who have not tolerated, failed or refused Positive Airway Pressure ("PAP") therapy.

The Genio® system consists of five main parts:

- Implantable Stimulator – Genio® IS
- Activation Chip – Genio® AC
- Disposable Patch – Genio® DP
- Charging Unit – Genio® CU
- External Stimulator – Genio® ES (only used during implantation procedure)



Small, battery-free Implantable Stimulator (IS) implanted in the chin area

Minimally invasive and short procedure with only one incision

Bilateral nerve stimulation, unique to Nyxoah



Activation Chip (AC) with its own battery & adhesive Disposable Patch (DP)

Every night the patient will connect the Activation Chip to a new patch and position it under the chin

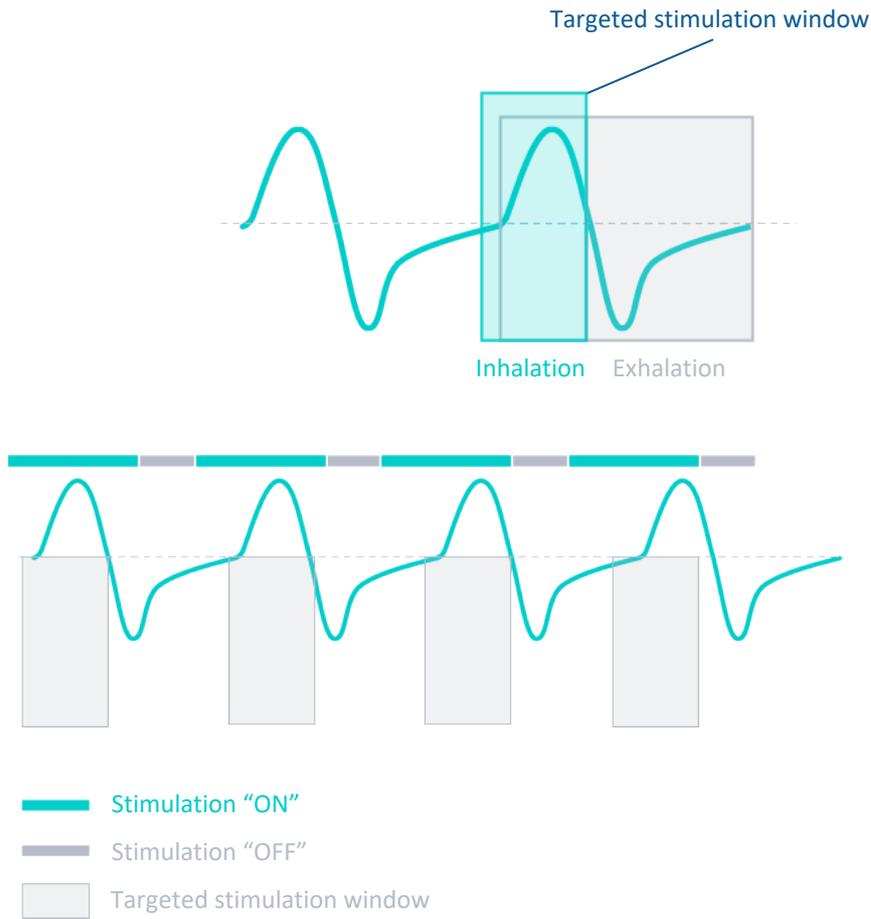


After sleep, the Activation Chip is detached and plugged to the Charging Unit (CU)

The Activation Chip is fully charged in a few hours

### Proprietary Genio® system

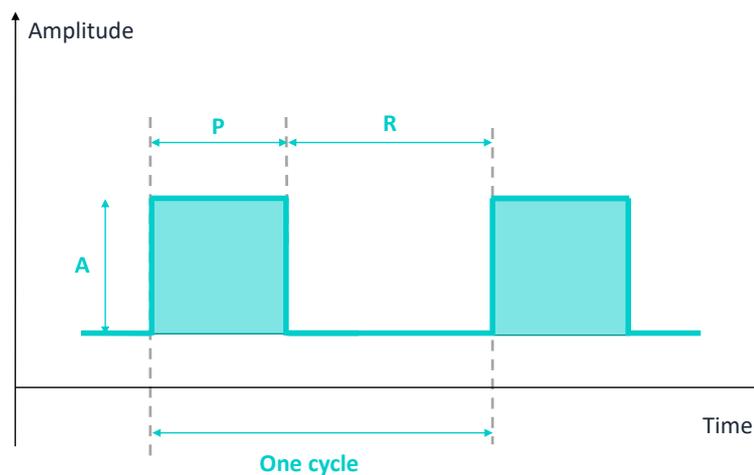
The *Implantable Stimulator* is a small saddle-like implant that consists of an antenna (the "saddle") and two "legs", each including two metal pads called electrodes. This stimulator is implanted under the chin, through a minimally invasive surgical procedure. The device is placed over the genioglossus muscle, close to the tongue's hypoglossal nerve. The pair of electrodes deliver electrical signals to both left and right branches of the hypoglossal nerve, resulting in bilateral stimulation of the nerve, which then triggers a slight forward movement of the posterior portion of the tongue. This process of stimulation and forward movement helps to maintain an open airway, thereby allowing normal breathing during sleep. The device is using a duty cycle to deliver its therapy using a cyclical pattern: (i) the train length and train interval are defined and stay the same overnight, (ii) the window of duty cycle repeats itself throughout the whole night; there is no continuous and/or synchronous stimulation, (iii) the duty cycle is designed to prevent the nerve and/or muscle fatigue as it integrates a rest period of time when the stimulation is off so they can rest.



### Genio® algorithm example

The Genio® system is a patient centric solution with stimulation parameters that are tailored to each individual patient. A patient's breathing frequency is analysed based on an initial PolySomnoGraphy (PSG) sleep exam. The stimulation starts only after 30-45 minutes, making sure the patient is asleep first, after which the stimulation gradually builds up to avoid waking up the patient.

Parameter	Description	Ranges
Pulse Amplitude (A)	Stimulation amplitude	1-100 %
Pulse Duration (P)	Duration of one stimulation pulse	50-250 $\mu$ sec
Pulse interval (R)	Interval between 2 pulses	--
Pulse Frequency (1/(P+R))	Number of pulses per second	30-50 Hz



Overview of Genio<sup>®</sup> system stimulation parameters

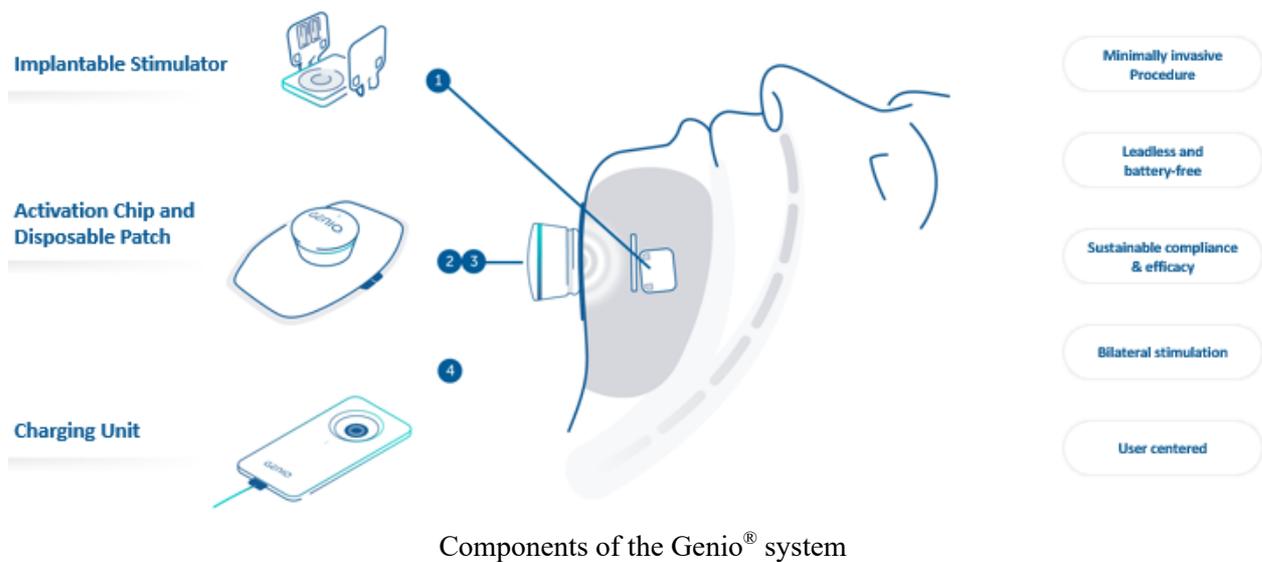
The Activation Chip constitutes the detachable power source of the implantable stimulator and is composed of the user's personalized therapy program and a battery. The design offers significant opportunities to make future updates and upgrades, or to add additional services to the Genio<sup>®</sup> system without the need for additional surgery. The Activation Chip should be charged daily after each use with the Charging Unit.

The Disposable Patch is a single-use medical grade adhesive patch placed on the skin under the chin. The Activation Chip is attached to the Disposable Patch at night, and together, they transmit energy to the Implantable Stimulator. After use, the Activation Chip can be detached from the Disposable Patch and the patch can be disposed of.

The Charging Unit and its power adapter are used to charge the Activation Chip's battery.

The External Stimulator is a disposable single-use device that is used during the surgical implantation procedure to test activation of the Implantable Stimulator ("IS") and confirm its proper placement.

The image below shows the components of the Genio<sup>®</sup> system, excluding the External Stimulator (images not true to size):



## 8.6.2 Treatment process

### a. Patient selection and implantation

The Genio® system is used to treat adult patients suffering from moderate-to-severe OSA with an AHI equal to or exceeding 15, but not exceeding 65. It is intended as a second line therapy for use by patients who have not tolerated, failed or refused PAP therapy. PAP treatment failure is defined as an inability to eliminate OSA (AHI > 15 despite PAP usage). PAP intolerance is defined as:

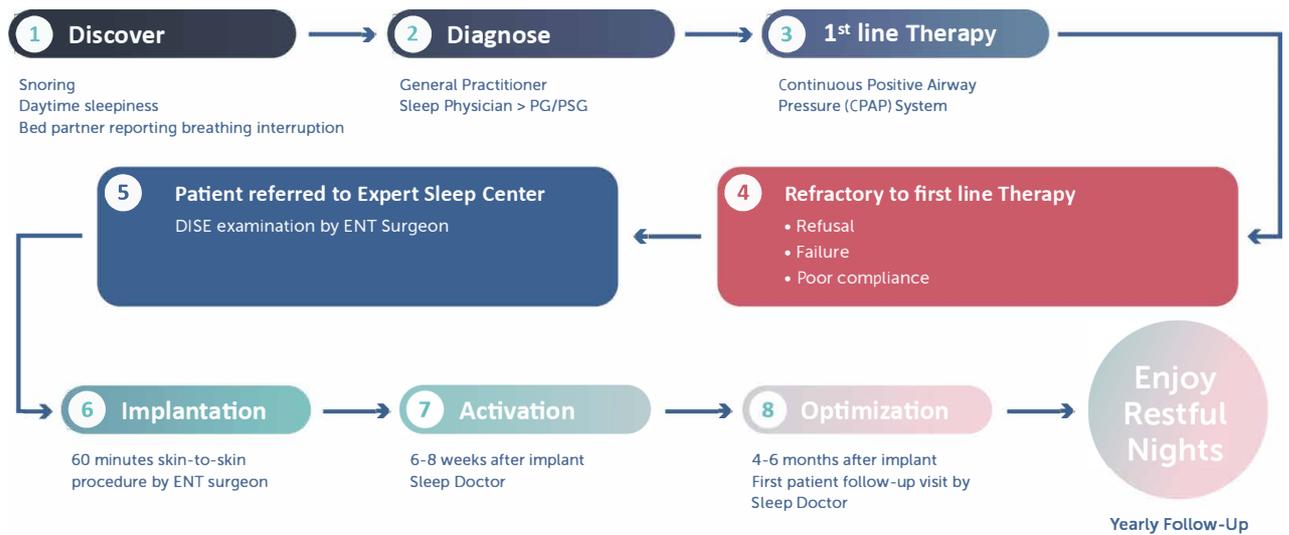
- inability to use PAP (< 5 nights per week; usage being defined as  $\geq 4$  hours per night); or
- unwillingness to continue using PAP (for example, a patient returns the CPAP system after attempting to use it).

Patients eligible for the Genio® system cannot have any anatomical characteristic that would preclude them from receiving the device. For example, patients with major craniofacial abnormalities narrowing the airway or the implantation site or that would impair the functioning of the hypoglossal nerve stimulator to treat OSA (such as congenital malformations in the larynx, tongue, or throat) will not be eligible. However, some prior surgeries to remove obstructions related to obstructive sleep apnea, such as uvulopalatopharyngoplasty, tonsillectomy or adenoidectomy, would be allowed.

Patients eligible to use the Genio® system can have a body mass index of up to 35kg/m<sup>2</sup>.

The Genio® system operates as follows:

- implantation of the Genio® IS by the surgeon;
- activation and therapy optimization of the Genio® system by the sleep specialist; and
- daily at-home activation of the Genio® system by the patient.



PG/PSG are sleep exams (Polygraphy/Polysomnography)

ENT: Ear Nose Throat surgeon

DISE: Drug Induced Sleep Endoscopy

CCC: Complete Concentric Collapse

#### Patient journey map

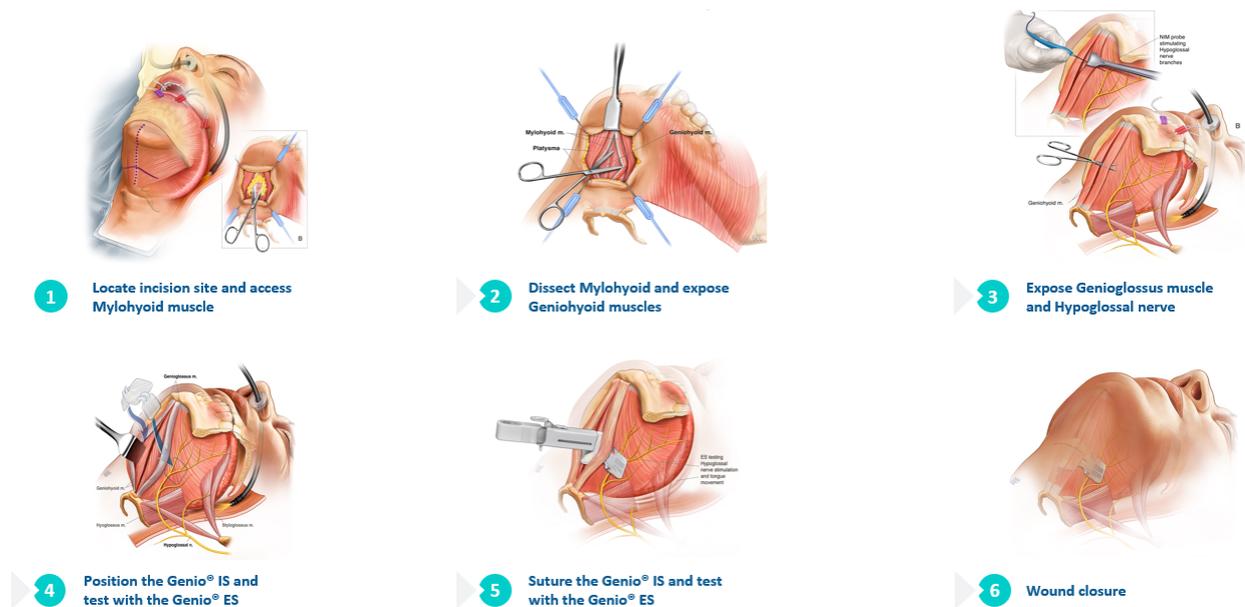
The implantation procedure of the IS is a minimally invasive procedure and is performed by a trained and certified surgeon. The procedure requires only one incision, takes about one hour to complete and is done under general anesthesia. The IS constitutes the only implanted component of the Genio® system.

The small curvilinear incision under the chin (four to six centimeters) makes the genioglossus muscle and the left and right hypoglossal nerve branches accessible for the IS.

The specific and unique design of the IS enables it to be positioned over both genioglossus muscles, with the stimulating paddle electrodes facing the medial left and right branches of the hypoglossal nerve on each muscle (the device is positioned similar to the positioning of a saddle on a horse).

During surgery, the surgeon will use the Genio® External Stimulator ("ES") to provide power to the IS to verify optimal placement of the implant and for the hypoglossal nerve stimulation. The surgeon will subsequently suture the IS to the muscle to secure proper fixation. The incision is then closed to obtain acceptable aesthetic results.

For a surgeon familiar with the procedure, the implantation procedure is expected to take about one hour. The patient will typically be discharged the same day. Approximately four to ten days after surgery, the patient will return to the hospital as an outpatient, for post-operative wound inspection. At this stage, the device is not yet activated.



## Overview of implantation procedure of the IS

### b. Activation and therapy optimization

Four to eight weeks after surgery, the patient will return to the hospital to activate the Genio® system and to receive training on how to use the different components of the device. Once activated, the patient can start using the system every night.

Following activation, the patient enters the first phase of the therapy optimization process, i.e. the acclimation period, during which the device operates using low stimulation parameters, allowing the patient to acclimate to the stimulation sensation and tongue movement.

Following successful acclimation, the second phase starts, which is aimed at reaching the patient's individual and specific therapeutic levels of stimulation. This is achieved by configuring the Activation Chip component through tailored, individual adjustments during wakeful and sleep lab studies performed in a specialized sleep lab. The goal of the wakeful titration is to identify the optimal tongue contraction characteristics (direction and intensity using nasal endoscopy). The individual adjustments to the Activation Chip allow refining of the stimulation parameters to reach optimal settings to keep the upper airway open, oxyhemoglobin saturation, and sleep continuity, all without not waking the patient.

### c. Daily home activation of the Genio® system

Following activation and therapy optimization, the patient is expected to use the system at home on a daily basis. The patient will be taught to connect the Activation Chip to the single-use Disposable Patch and then place the Disposable Patch and the attached Activation Chip on the skin under the chin prior to going to sleep.

After every night, a new Disposable Patch should be used.

The Activation Chip should be placed on the Charging Unit to recharge the battery and the Disposable Patch should be thrown away.

### 8.6.3 Potential patient benefits

The Company believes that the Genio® system will have an improved overall therapeutic effect when compared to existing hypoglossal nerve stimulation therapies and other second-line OSA therapies, due to the following potential key benefits:

- **Safe therapy:** the results from the BLAST OSA study demonstrated that the Genio® system is well tolerated with no device-related serious adverse events related to the Genio® system being reported during the course of the study. Four procedure-related serious adverse events were reported, of which an independent clinical event committee and the center adjudications concluded that such events were not related to the Genio® system. A total of 100 non-serious adverse events for 27 patients were reported which is aligned with other hypoglossal nerve stimulation devices.
- **Effective compared to no treatment:** the BLAST OSA study demonstrated a 45.6% reduction in AHI ( $p < 0.001$ ) and a decrease in the oxygen desaturation index ("**ODI**") by 48.7% ( $p < 0.001$ ), which is in line with other HNS devices reported performance at the same time stamp.
- **High therapy compliance:** BLAST OSA data reported high therapy compliance, with 91% of participants using the system more than five nights per week over a period of six months.
- **Quality of life improvement:** results from the BLAST OSA study demonstrated that patients' quality of life significantly improved as assessed using the FOSQ-10 questionnaire, with an increase in score by 1.9 units ( $p = 0.016$ ) and a decrease in the daytime sleepiness (ESS score) by 3.0 units ( $p = 0.0113$ ). In addition, the number of sleep partners who reported that their partner did not snore, or snored only softly, increased from 4% at baseline to 65%.
- **Specifically designed for OSA patients:** in contrast to other hypoglossal nerve stimulation technologies, the Genio® system has been specifically designed to treat OSA.
- **Minimally invasive:** the Genio® system only has one implantable part, which is leadless and battery-free, and which requires only one incision to implant.
- **Bilateral hypoglossal nerve stimulation:** as clinical research suggests, the Company believes that bilateral stimulation results in a stronger muscle contraction, a more symmetric tongue movement, and a wider opening of the airway as compared to unilateral stimulation whereby only one branch of the hypoglossal nerve is stimulated. The specific bilateral stimulation design also provides an extra electrode pair that can act as a back-up in case one electrode pair is not optimally placed, or if the electrode pair is not functioning.
- **Partially external device, without implanted battery:** the Activation Chip, including the user's personalized therapy program and a battery, is an external device which will facilitate future updates and upgrades of the Genio® system.

The Company expects that patients implanted with the Genio® Implantable Stimulator are eligible for MRI scan under the "MR conditional" labeling. The Company is currently in the process of defining the test plan and will then conduct all required tests for that purpose. Once this testing is complete, the results will be submitted to the Notified Body resulting in a "MR conditional" labeling.

Despite all the potential benefits listed above, stimulation of the hypoglossal nerve does not guarantee the treatment results nor that all patients will respond to the therapy given variable response to electrical activity or different mechanical displacement of the muscle in different patients. It should be noted that there is a reduced probability that hypoglossal nerve stimulation works for more (highly) obese patients.

#### **8.6.4 Hypoglossal nerve stimulation – competitive landscape**

As of the date of this Prospectus, besides the Company's Genio® system, there are two other implantable devices for hypoglossal nerve stimulation that are currently approved and available on the market in selected countries. While the Company's Genio® system has been specifically designed to treat OSA, other hypoglossal nerve stimulation technologies are based on existing implantable pulse generators (similar to pacemakers) and available leads.

##### **a. Inspire Medical**

In 2010, Inspire Medical commercially launched a neurostimulation device that delivers phasic stimulation, i.e. synchronized with the patient's breathing pattern. It is implanted under the skin of the neck and chest through three incisions (one for the internal pulse generator, one for the stimulation cuff electrode and one for the respiratory sensor) during a surgical procedure under general anesthesia. Once implanted, it is expected that the pulse generator has a lifespan of eleven years, after which time the battery must be replaced through another surgical procedure. This device is approved for use in the European Union (CE-Mark obtained in 2010) and the United States (FDA approval obtained in 2014). Inspire is listed on the NYSE since May 2018 (NYSE:INSP).

Inspire Medical's system is commercially available in Europe (including Germany, Netherlands, Spain, Switzerland) and is currently the only FDA approved hypoglossal nerve stimulation device that is being commercialized in the United States. According to information publicly disclosed by Inspire Medical, the average selling price in Q4 2019 was \$22,400 in Europe (e.g. approximately €20,000 in Germany) and \$23,800 in the United States. To date, more than 6,000 patients are implanted with the Inspire Medical system across the United States and Europe. Inspire Medical's commercial focus is on the United States and on Germany.

Inspire reported in February 2020 to have published clinical evidence evaluating their technology in more than one hundred publications, including more than 2,000 patients<sup>50</sup>.

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<sup>50</sup> Inspire company presentation - February 2020. [www.inspiresleep.com](http://www.inspiresleep.com)

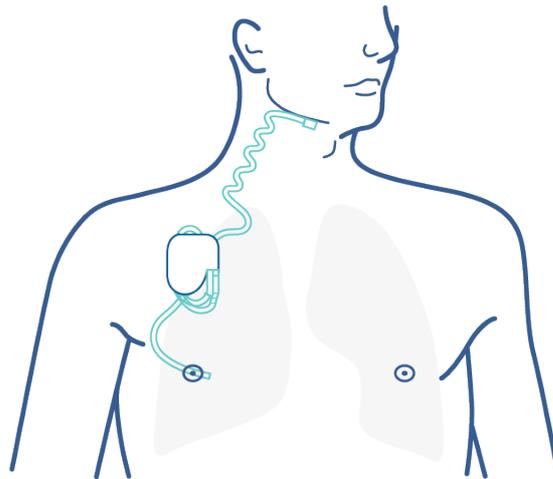


Figure XX - Overview of the Inspire Medical system

The Company believes that the Inspire Medical therapy has several limitations, including but not limited to the following:

- the therapy is based on technology that was not specifically designed to treat OSA;
- the Inspire Medical system consists of three implantable parts containing two leads and a cuff electrode (i.e. an electrode placed circularly around the nerve which implies that the nerve needs to be priorly dissected and separated from the genioglossus muscle prior to implantation in order to facilitate the placement of the cuff around the nerve). Paddle electrodes, as used by the Genio® system, only need to be placed against the hypoglossal nerves whereas cuff electrodes needs to be wrapped around the nerve. They require a precise nerve dissection and isolation making the surgery more dangerous and longer. Additionally, using cuff electrodes during an explant procedure not only renders the procedure extremely challenging but also increases the risk while adding time to the overall surgery compared to similar procedures when using paddle electrodes (i.e. no need to dissect down the nerve).;
- the synchronous stimulation is based on a complicated closed loop system requiring the implantation and tunneling of a dedicated breathing sensing lead making the system harder and riskier to implant; three incisions and two steps of subcutaneous lead tunneling (i.e. to bring a lead from the pulse generator to the neck and to bring a lead from the pulse generator to the ribs) are required with an implantation procedure of approximately 2.5 hours. The average recovery time is also expected to be longer as the Genio® system only requires one incision.
- the Inspire Medical system only provides unilateral stimulation;
- the power source of the Inspire Medical system is an implanted battery that must be replaced once depleted through a surgical procedure; and
- the implantable pulse generator is positioned subcutaneously, like a classic pacemaker, thus making the device visible and palpable.

**b. ImThera (LivaNova) Aura6000**

Since 2012, the ImThera Aura6000 (now a part of LivaNova™) is an open-loop neurostimulation device that is designed to deliver continuous, tonic stimulation to the hypoglossal nerve's main trunk. It is implanted under the skin of the neck and chest through two incisions (one for the internal pulse generator (IPG) pocket and one for the stimulation cuff electrode) during a surgical procedure under general anesthesia. Once implanted, the system is expected to have a lifespan of up to 15 years, after which the battery must be replaced

through another surgical procedure. ImThera obtained a CE-Mark for its system in 2012 and is currently conducting a clinical trial that started in 2015, intended for FDA approval. ImThera was acquired by LivaNova PLC (NASDAQ:LIVN) in December 2017.

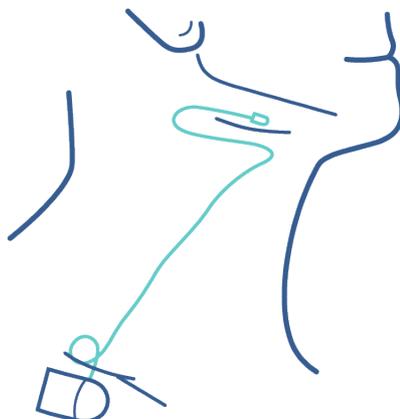


Figure XX - Overview of the ImThera Medical system

The Company believes that the ImThera therapy has several limitations, including but not limited to the following:

- the therapy is based on technology that was not specifically designed to treat OSA;
- the ImThera system consists of two implantable parts containing one lead and a cuff electrode;
- two incisions and subcutaneous lead tunneling (i.e., to bring the lead from the pulse generator to the neck) are required (approx. 2 hours implantation procedure);
- the ImThera system only provides unilateral stimulation;
- the power source of the ImThera system is an implanted rechargeable battery; and
- the implantable pulse generator is positioned subcutaneously, thus making the device visible.

**c. The Genio® system – competitive advantages**

The Company aims to reach new milestones in hypoglossal nerve stimulation therapy with its unique, proprietary Genio® system.

In contrast to other hypoglossal nerve stimulation technologies, the Genio® system has been specifically designed to treat OSA. The implanted part of the Genio® system is battery-free, leadless and only requires a minimally invasive procedure to implant. The surgical procedure for implantation under general anesthesia requires only a single incision under the chin and is therefore more straightforward and quicker (approx. 1 hour procedure). The Genio® system delivers bilateral stimulation to both left and right branches of the hypoglossal nerve whereby both sides of the tongue are stimulated simultaneously, which is expected to be more effective compared to other neurostimulation systems. The Company believes that its solution is at least comparable in efficacy but significantly less invasive than other hypoglossal nerve stimulation technologies currently available on the market or in development. The Company does not foresee any competitive disadvantages over hypoglossal nerve stimulation competitors.



Inspire

Imthera  
(LivaNova)

Implantable parts	1 – Genio® IS	3 – Pulse generator + 2 leads	2 – Pulse generator + lead
Number of incisions	1 incision	3 incisions	2 incisions
Lead(s)	0 – No lead	2 – Stimulation and breathing	1 – Stimulation
Tunneling	No tunneling	2 steps	1 step
Estimated implantation time	~ 1 hour	~ 2.5 hours	~ 2 hours
Type of stimulation	Bilateral stimulation (Left and Right)	Unilateral	Unilateral
Electrode type	Paddle electrodes	Cuff electrode	Cuff electrode
Power source	External	Implanted battery	Implanted rechargeable battery

## 8.6.5 Clinical results and studies

### a. Clinical development pathway

The clinical evidence of the Genio® system was demonstrated in the BLAST OSA study which was been successfully completed at the end of 2018. The results of the BLAST OSA study were used to support the Company's application to obtain the CE-Mark for its Genio® system from DEKRA, which was obtained in March 2019. The CE-Mark cannot be construed as evidence of (statistically significant) efficacy or safety of the Genio® system.

As part of the regulatory requirements, the Company will perform additional studies with the Genio® system (the EliSA trial and the BETTER SLEEP trial) that are designed to obtain long-term safety and efficacy data (five-year follow-up) with the Genio® system in 154 patients. The BETTER SLEEP trial (clinicaltrials.gov identifier NCT03763682) is currently ongoing in Australia and New Zealand and the EliSA trial (clinicaltrials.gov identifier NCT04031040) is currently ongoing in Europe. The results from the BETTER SLEEP and EliSA trials primary endpoints are expected to be available in early 2021 and mid-2022, respectively.

On 23 June 2020, the FDA approved the Company's IDE application, allowing the Company to commence its pivotal DREAM study of the Genio® system to support the system's marketing approval in the United States. The IDE application approval was granted under a CMS category B. Category B (Non-experimental/investigational), refers to a device for which initial questions of safety and effectiveness of that device type have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type. The study is expected to start in the second half of 2020 in up to 26 centers in and outside the United States. The Company expects to obtain post-market approval by the end of 2022 (based on an expected enrollment rate of eligible patients of 0.6 patient/center/month compared to 0.4 patient/center/month for the BLAST OSA study).

### b. Completed studies

*SAT studies with first generation system – improvements resulting in the development of the current*

## ***Genio® system***

The current Genio® system builds on what the Company has learned from two systems that the Company developed previously. Between 2012 and 2014, the Company developed two unilateral hypoglossal nerve stimulation systems (SAT systems) that were tested in two clinical trials in ten patients (SAT2012A to test the first device in patients and SAT2014A, which was a feasibility study) which were conducted in Germany and Belgium.

Patients who used the system were highly satisfied with the system and demonstrated a significant improvement in their quality of sleep and reduction in apnea events, confirming the technology's proof-of-concept. In addition, both devices were well tolerated and were shown to have good safety profiles, with only mild adverse events being reported. Moreover, in some patients the device has been implanted for over 30 months without showing any clinically relevant safety issues.

While the SAT systems functioned as intended, the SAT implants stopped working during both studies. Following these events, the Company performed a retrospective failure analysis and several Corrective and Preventative Action investigations (CAPA #2015-005 and CAPA #2015-002) were conducted in order to determine the root cause of these issues.

It was concluded that failure was related to the following issues:

1. Lack of mechanical reinforcement in the implant's antenna area
2. Inadequate implant width dimensions
3. Inadequate implant suturing technique which compromised the implant's encapsulation.

Following extensive research and development, based on the experiences gained during the previous two clinical studies with the SAT systems, the Company developed the current Genio® implant system.

The Genio® implant dimensions were adapted to fit two genioglossus muscles as per updated literature search and pre-clinical assessments. The implant has enhanced mechanical reinforcements, specifically in the antenna area, as well as dedicated suturing holes to protect the implant's encapsulation.

The Genio® implant also has two pairs of paddle electrodes, thus providing bilateral stimulation to the hypoglossal nerves. In pre-clinical experiments, the Company observed that bilateral stimulation results in a stronger muscle contraction, more symmetric tongue movement, and a wider airway opening compared to the unilateral implant. In addition, the specific bilateral stimulation design also provides redundancy, meaning that a second electrode pair acts as a safeguard in case one electrode pair is not optimally placed with regard to the hypoglossal nerve, or if an electrode pair is not functioning.

## ***BLAST OSA study***

- **BLAST OSA study design**

The BLAST OSA study was a prospective, open-label, non-randomized, multicenter, single arm study. The objective of this study was to evaluate and assess the safety, performance and initial efficacy trends of the Genio® system in adult patients with moderate-to-severe OSA, over a treatment period of five months (i.e.

six months post-surgery), with efficacy being measured by the AHI score. This trial is registered with ClinicalTrials.gov under number NCT03048604, followed the MEDDEV guidelines for clinical evaluation (conformity assessment) and is, to date, the only safety and efficacy study with a bilateral hypoglossal nerve stimulation device.

The primary safety endpoint was the incidence of serious device-related adverse events recorded during the study over a period of six months post implantation. The primary outcome measure was the change in the AHI score from baseline to six months post implantation measured by the number of events (apneas and hypopneas) per hour during an overnight sleep study using fixed therapeutic polysomnography settings during a full night period.

The secondary performance endpoint was the change in the ODI score from baseline to six months post implantation - measured by the number of desaturation episodes per hour during an overnight sleep study using fixed therapeutic polysomnography settings during a full night period.

Additional performance measures included changes in the sleep-related quality of life, evaluated by the level of daytime sleepiness using both, the Epworth Sleepiness Scale and the Functional Outcomes of Sleep Questionnaire (FOSQ-10), as well as supplementary objective measures evaluated in an in-lab polysomnography, such as therapy response rate (where response is defined, based on the Sher success criteria, as a reduction in AHI from baseline to six months of 50% or more, and an AHI score at six months of less than 20)<sup>51</sup> and a change in the percentage of time spent at an oxygen desaturation state below 90% (SaO<sub>2</sub><90%). Sleep partner-reported snoring and nightly usage of the system were also evaluated.

Patients with moderate-to-severe OSA (AHI score between 20 to 60) and aged between 21 and 75 years were eligible for enrolment if they failed, or did not tolerate, PAP treatment. The main exclusion criteria were a body mass index above 32 kg/m<sup>2</sup>, i.e. the same BMI cutoff as the one used by Inspire Medical, a complete concentric collapse at the level of the soft palate observed during a drug induced sleep endoscopy, and combined central and mixed AHI above 10 at baseline polysomnography.

Participants were included in the trial based on the 2014 scoring guidelines recommended by the American Academy of Sleep Medicine.<sup>52</sup> However, in order to allow a more direct comparison with available literature, all results presented in this document are based on the 2014 American Academy of Sleep Medicine acceptable scoring guidelines.<sup>53</sup>

All trial participants provided written, informed consents prior to participation in the study which was approved by the relevant ethics committees at all medical centers where the study was carried out.

A clinical events committee was formed to independently review any adverse events. Patients who completed the study are being monitored and followed to collect long-term safety data.

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<sup>51</sup> Sher AE, Schechtman KB, Piccirillo JF (1996) The efficacy of surgical modifications of the upper airway in adults with obstructive sleep apnea syndrome. *Sleep* 19(2):156–177.

<sup>52</sup> The AASM Manual for the scoring sleep and associated events: rules, terminology and technical specifications (v2.5).

<sup>53</sup> The AASM Manual for the scoring sleep and associated events: rules, terminology and technical specifications (v2.5).

Population and key inclusion criteria	Age 21-75	Failed, Not Tolerated or Refused PAP	Combined central/mixed AHI>10 excluded
	BMI ≤ 32	Moderate to Severe OSA – AHI 20-60	CCC of soft palate excluded
	<b>Population</b>	93 consented patients	27 implanted patients

#### Primary endpoints

- Safety: Incidence of serious device-related adverse events at 6-Month
- Performance: Change from baseline to 6-Month post implantation in the Apnea Hypopnea Index (AHI)

#### Secondary endpoint

Change from baseline to 6-Month post implantation in the Oxygen Desaturation Index (ODI)

#### Additional endpoints

- Therapy response rate – where response is defined as a reduction in AHI from baseline to 6-Month of 50% or higher and AHI at 6-months less than 20
- Change from baseline to 6-Month post implantation in percentage of time that SaO<sub>2</sub><90% as measured by in-lab PSG
- Change from baseline to 6-Month post implantation in daytime sleepiness measured with ESS
- Change from baseline to 6-Month post implantation in sleep-related quality of life, measured with FOSQ-10

## • BLAST OSA Results

The BLAST OSA results were published in the European Respiratory Journal in October 2019<sup>54</sup>.

Between 7 April 2017 and 15 February 2018, 93 study participants were enrolled in seven clinical sites in France and Australia (one site was activated in the UK but did not enroll any participants). 66 out of the 93 enrolled participants failed the additional testing post-consent and therefore did not receive an implant. PSG test results, AHI too high, too low or a patient having a non supine AHI less than 10, were the primary reason for patient exclusion (61%) and the secondary reason was exclusion due to complete concentric collapse (28%). 27 participants underwent the implantation procedure of the Genio® system. Of these participants, 63% (17/27) were men with a mean age of 55.9 ± 12.0 years and a mean body mass index of 27.4 ± 3.0 kg/m<sup>2</sup>. No patient with a AHI < 20 was enrolled. The minimum sample size was determined to detect a clinically meaningful reduction of AHI of at least 15/hour with 90% power at a 5% level of significance.

22 patients completed the protocol and the study met all primary, secondary and additional endpoints at 6 months (length of the study). Four patients prematurely left the study due to (i) procedure related infections (two patients), (ii) exclusion due to violent behavior (one patient) and (iii) sub-optimal response to stimulation at implant, which was one of the exclusion criteria (one patient) and one participant was withdrawn as the participant failed to return for the 6-month end-point visit despite numerous attempts from the centre to re-establish contact with the participant.

No serious adverse events related to the Genio® system were reported during the 6-month post-implant period and the majority of the adverse events were mild and resolved within days.

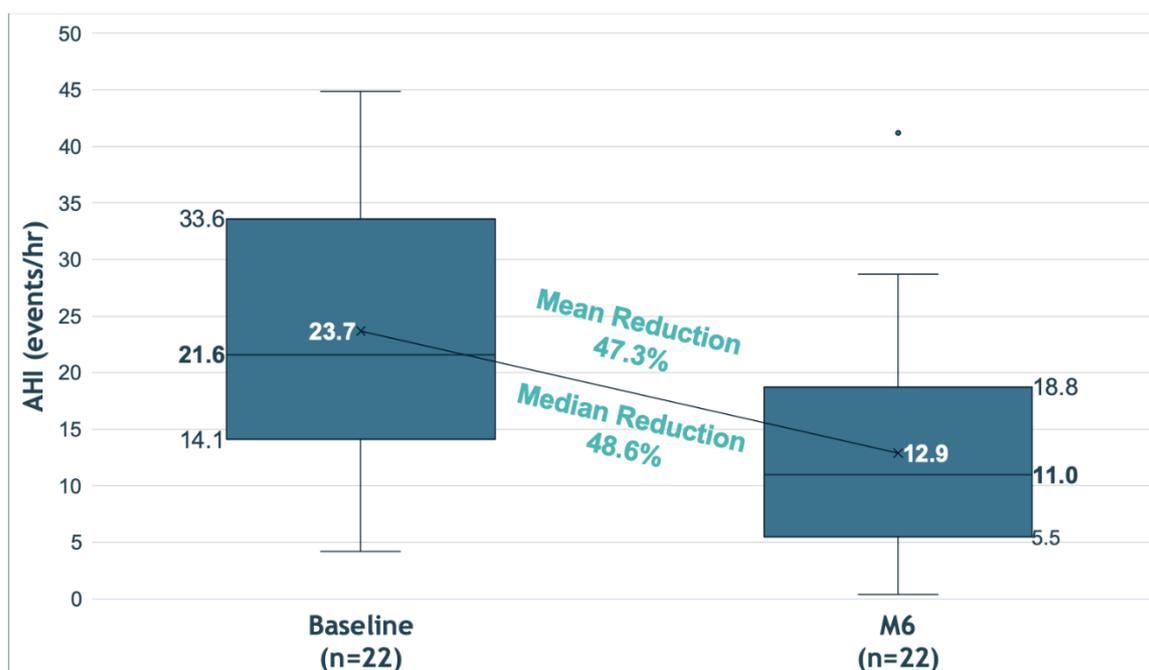
The most frequent device-related adverse event that occurred in implanted patients was a temporary and mild local skin irritation due to usage of the disposable patch (eight patients). These events were generally resolved with the application of skin lotion on the irritated skin. One of the patients had sporadic skin irritation from the patch which remained present at the 6-month visit. This irritation was resolved with the application of

<sup>54</sup> <https://erj.ersjournals.com/content/early/2019/09/25/13993003.01320-2019>.

skin lotion, but returned once the patient stopped applying the lotion. Additional common adverse events that occurred in 11% of the patients included tongue abrasion, tongue fasciculation, abnormal scarring and discomfort due to electrical stimulation. The latter was typically resolved by reprogramming the stimulation parameters.

Four serious adverse events related to the implant procedure were reported in 3 of the 27 patients implanted during the 6-month post-implant period. These included two participants, at the same hospital, who developed infections, which were related to the implantation procedure and which resulted in removal of the implanted device (one of these two patients was kept in the hospital for overnight observation). Finally, the third patient was kept in the hospital for one extra day after having exhibited difficulties swallowing post-implant. All serious adverse events were resolved without any consequences.

A significant reduction in the AHI score was demonstrated between baseline and the 6-month post-implantation visit. At the 6-months mark, participants' AHI decreased from  $23.7 \pm 12.2$  to  $12.9 \pm 10.1$ , representing a mean change of 10.8 events/hour [ $p < 0.001$ ] (mean individual percent decrease of 47.3%); the number of participants considered "responders" to the therapy, defined using the established standard for similar studies of surgical outcomes in OSA of  $\geq 50\%$  reduction in mean AHI and an AHI of  $< 20$  events $\cdot$ h $^{-1}$  when using the 2014 AASM acceptable scoring guidelines is 50%.



Boxplots of the AHI at Screening and 6-Month for patients that reached the 6-Month visit

A significant reduction in the ODI score was demonstrated between baseline and 6-month post-implantation period, dropping from a mean of  $19.1 \pm 11.2$  to  $9.8 \pm 6.9$ , representing a mean change of 9.3 events/hour [ $p < 0.001$ ].

Both the propensity for daytime sleepiness, as measured by the Epworth Sleepiness Scale, and sleep-related quality of life, as assessed using the Functional Outcomes of Sleep Questionnaire (FOSQ-10), significantly improved. The Epworth Sleepiness Scale decreased from  $11.0 \pm 5.3$  to  $8.0 \pm 5.4$ , representing a mean change

of 3.3 units [95% CI 0.8-5.7, p=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=0.0157]. FOSQ-10 reflects the quality of life of a patient. The FOSQ-10 objective is to demonstrate a change in sleep-related quality of life at the 6-month visit compared to baseline. A score greater than 17 is considered clinically significant (i.e. a good quality of life).

Outcome measures (n = 22).

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

*Data are mean (Standard Deviation) unless otherwise specified.*

*AHI = apnea hypopnea index;*

*Arousal Index = number of arousals and awakenings registered during the sleep study;*

*ODI = 4% oxygen desaturation index;*

*SaO<sub>2</sub> < 90% = proportion of the night spent at an oxygen saturation below 90%;*

*Sleep efficiency = ratio of total time spent asleep in a night compared to the total amount of time spent in bed;*

*ESS = Epworth Sleepiness Scale;*

*FOSQ10 = the 10 - item Functional Outcomes of Sleep Questionnaire;*

*\*n = 21*

The reported snoring intensity was positively impacted with 65% of the sleep partners having reported, at the 6-month post implantation visit, no or only soft snoring, compared to only 4.2% at baseline.

Compliance to the therapy during the study was high with 91% of patients having reported using the Genio® system more than 5 days a week, of whom 77% reported a nightly use of more than 5 hours per night.

Moreover, 82% of the participants were extremely or somewhat satisfied with the use of the Genio® system.<sup>55</sup>

In conclusion, the BLAST OSA study in patients with moderate-to-severe OSA demonstrated that the

<sup>55</sup> Eastwood PR, Barnes M, MacKay SG, et al. Bilateral Hypoglossal Nerve Stimulation for Treatment of Adult Obstructive Sleep Apnea. Eur Respir J 2019; <https://erj.ersjournals.com/lookup/doi/10.1183/13993003.01320-2019>

Genio® system is well-tolerated and is effective, and that it is associated with high compliance.

- **Summary of the six-months BLAST OSA results, ImThera second feasibility study, the STAR trial (Inspire Medical) results and CE-Mark (Inspire Medical) results**

The table below summarizes the publicly available clinical data on performance of all hypoglossus nerve stimulation therapies at the 6 months visit; for Inspire Medical (CE-Mark and STAR study), ImThera (second feasibility study) and the Company (BLAST OSA results).

	Inspire CE-Mark <sup>(1)</sup>		Inspire STAR Study <sup>(2)</sup>		BLAST OSA Study <sup>(3)</sup>		ImThera Study <sup>(4)</sup>	
	Baseline Mean ± SD; n	6-month Mean ± SD; n	Baseline Mean ± SD; n	6-month Mean ± SD; n	Baseline Mean ± SD; n	6-month Mean ± SD; n	Baseline Mean ± SD; n	6-month Mean ± SD; n
AHI	42.3 ± 12.9; 28	32.6 ± 17.1; 28	32.0 ± 11.8; 126	19.9 ± 16.8; 125	23.7 ± 12.2; 22	12.9 ± 10.1; 22	34.9 ± 22.5; 43	25.4 ± 23.1; 43
ODI	30.6 ± 19.8; 28	26.7 ± 20.4; 28	28.9 ± 12.0; 126	17.8 ± 16.0; 125	19.1 ± 11.2; 22	9.8 ± 6.9; 22	32.4 ± 22.3; 43	23.6 ± 22.3; 43
FOSQ	89.1 ± 23.5; 28	100.8 ± 16.9; 28	14.3 ± 3.2; 126	17.0 ± 3.1; 122	15.3 ± 3.3; 22	17.2 ± 3.0; 22	NA	NA
ESS	11.0 ± 5.0; 28	7.6 ± 4.3; 28	11.6 ± 5.0; 126	7.4 ± 4.2; 123	11.0 ± 5.34; 21	8.0 ± 5.4; 22	12.0 ± 4.8; 43	8.3 ± 4.4; 43
Percentage Sleep SaO <sub>2</sub> <90%	NA	NA	8.7 ± 10.2; 126	5.6 ± 10.5; 125	5.0 ± 6.0; 22	2.1 ± 3.0; 22		
Arousal Index (events.h <sup>-1</sup> )	NA	NA	NA	NA	28.7 ± 11.5; 22	16.0 ± 8.0; 22	42.7 ± 19.4; 43	31.6 ± 20.3; 43
Sleep Efficiency (%)	77 ± 14.7; 28	76.9 ± 12.3; 28	NA	NA	84.0 ± 10.8; 22	87.3 ± 8.9; 22	NA	NA
Responder rate (Sher Criteria) at 6-month	10 patients out of 28 (35.7%)		NA		11 patients out of 22 (50%)		15 patients out of 43 (34.9%)	

Notes:

(1) Van de Heyning P. et al: "Implanted Upper Airway Stimulation Device for Obstructive Sleep Apnea", *Laryngoscope*, 122:1626–1633, 2012.

(2) Inspire 4 – STAR Pivotal Trial Clinical Report, *Stimulation Therapy for Apnea Reduction (STAR)*; 4/30/2013, p. 76.

(3) *European Respiratory Journal* - <https://erj.ersjournals.com/content/early/2019/09/25/13993003.01320-2019>.

(4) Friedman et al., “Targeted Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea: Six-Month Results”, *The Laryngoscope*, 2016.

The table below represents the same data but as the mean variation.

	Mean variation at 6-month			
	Inspire CE-Mark n=28	Inspire STAR Study n=126	BLAST OSA Study n=22	ImThera 2 <sup>nd</sup> Feasibility Study N=43
AHI	-23.0%	-37.8%	-45.6%	-27.2%
ODI	-13.0%	-38.4%	-48.7%	-27.2%
FOSQ	13.1%	18.9%	12.4%	NA
ESS	-30.9%	-36.2%	-27.3%	-30.8%
Percentage Sleep SaO <sub>2</sub> <90%	NA	-35.6%	-58.0%	NA
Arousal In- dex (events.h <sup>-1</sup> )	NA	NA	-44.3%	-26.0%
Sleep Effi- ciency (%)	-0.1%	NA	+3.9%	NA

The Genio® Implantable Stimulator shows an improvement in all the major sleep categories (AHI, ODI and percentage of Sleep SaO<sub>2</sub><90%) in addition to the improvement in sleep related quality of life. The STAR and ImThera studies and BLAST OSA study had similar patient selection (inclusion and exclusion) criteria, supporting the comparison. The results are in line with previously published hypoglossal nerve stimulation systems’ results, from which the Genio® system offers distinct, potentially advantageous differences.

The BLAST OSA study protocol was recently amended to include a long-term safety follow-up phase. All participants, in whom the device is implanted, are therefore eligible to enroll in the long-term follow-up phase of the study in order to obtain long-term safety and efficacy data. The majority of the participants are currently 18-24 months post-implantation and all 22 participants who attended their six-month post-implantation visit agreed to enroll into the long-term follow-up study.

Of these 22 participants, six patients had their devices explanted; of these six (retrospective analyses indicated five procedure related complications and one patient that resumed strenuous physical activity before the

minimum recommended healing time. Two out of these six participants requested a replacement of their implant as they reported that they were satisfied with the therapy before the device stopped performing as intended. All explant procedures were successfully performed without any complications, and the patients were sent home without any sequelae. There was no serious device related adverse event reported at the end of the study and only 100 total non-serious adverse events, aligned with Inspire Medical's reported adverse event data. No unexpected (serious) adverse events have occurred since the CE-Mark has been obtained in the BLAST OSA study results. Following the results of the retrospective device analyses, the company updated the implantation technique so to minimize the puncturing risk. Subsequently, the updated implantation procedure was submitted to DEKRA on 12 June 2019, reviewed and approved on 2 September 2019. No other procedure related adverse event has happened since then.

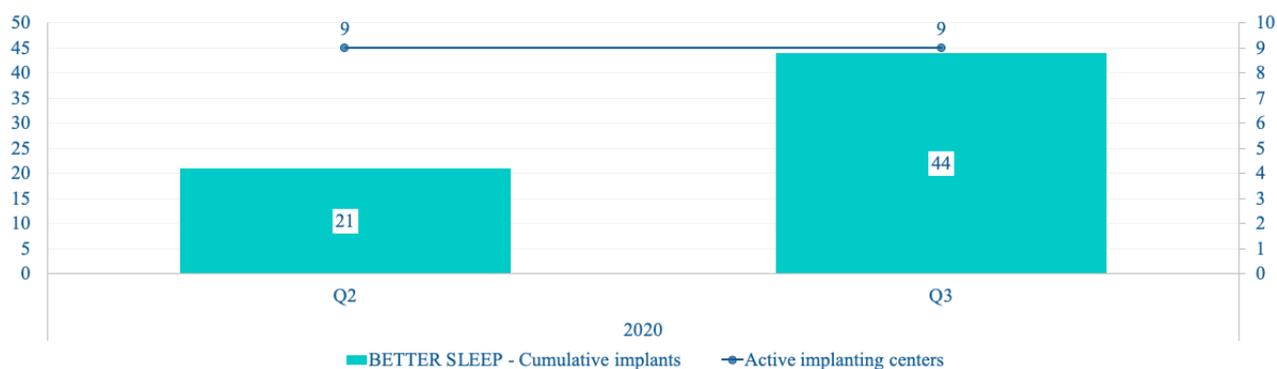
**c. Ongoing studies**

***BETTER SLEEP Study***

The BETTER SLEEP study is a multicenter, prospective, open-label, two-group study, designed to assess the safety and efficacy / performance of the Genio® system for the treatment of OSA in adult patients who either exhibit or do not exhibit a complete concentric collapse of the soft palate.

The study has been approved by the Australian and New Zealand regulatory bodies and is being conducted in nine local medical centers. The Company intends to obtain clinical evidence from a sub-group of patients who exhibit a complete concentric collapse at the soft palate level that will serve as a feasibility study for indication expansion. Since the patients who exhibit a complete concentric collapse represent 25% of the total OSA population, this could significantly increase the target market.

The study is expected to recruit 44 patients who will undergo an implantation of the Genio® system (of the 44 participants, at least 13 with complete concentric collapse will undergo the implantation procedure):



Patient recruitment BETTER SLEEP study

The study is expected to complete its enrolment phase by October 2020. The study is planned to have a 36 month follow-up and the end of trial is expected in early 2024.

As of 15 August 2020, 28 patients underwent the implantation procedure as part of the study. As at the date

of this Prospectus, one serious adverse event has been reported: due to an overnight hospitalization for a basal cell carcinoma on the left shin. The event required an overnight hospitalisation to ensure the patient's leg stayed elevated following the removal procedure. This event is not device or procedure related, and it was resolved without sequelae.

Population and key inclusion criteria	Age 21-75	Failed, Not Tolerated or Refused PAP	Combined central/mixed AHI>25% total AHI excluded
	BMI ≤ 32	Moderate to Severe OSA – AHI 15-65	Both CCC and not CCC patients included
	Target: 44 patients implanted		
Primary endpoints			
<ul style="list-style-type: none"> <li>• Safety: Incidence of serious device-related adverse events at 6-Month</li> <li>• Performance: Change from baseline to 6-Month post implantation in the Apnea Hypopnea Index (AHI)</li> </ul>			

- ***Complete concentric collapse at the soft palate level and Drug Induced Sleep Endoscopy (DISE)***

The BETTER SLEEP study aims, among other objectives, to assess whether the Company’s bilateral hypoglossal nerve stimulation has a beneficial effect in adult OSA patients suffering from complete concentric collapse at the level of the soft palate. Currently, these complete concentric collapse patients are contraindicated for Inspire therapy. If the initial results of BETTER SLEEP are positive, the Company is planning further studies in collaboration with the Notified Body in order to expand the CE-Mark indication to address an unmet need in a population that represents a significant market opportunity.

In order to diagnose complete concentric collapse, a Drug Induced Sleep Endoscopy procedure is required. During this procedure, the patient receives midazolam to artificially induce sleep, and the pharyngeal collapse patterns are visualized using a flexible fiber optic nasopharyngoscope (i.e. a soft and flexible endoscope is inserted in the patient's nose to visualize the status of the pharyngeal area to assess the level, direction and degree of the collapsed area).

During a Drug Induced Sleep Endoscopy procedure, the level (palate, oropharynx, tongue base, hypopharynx/epiglottis), the direction (anteroposterior, concentric, lateral), and the degree of collapse (none, partial, or complete) are evaluated.

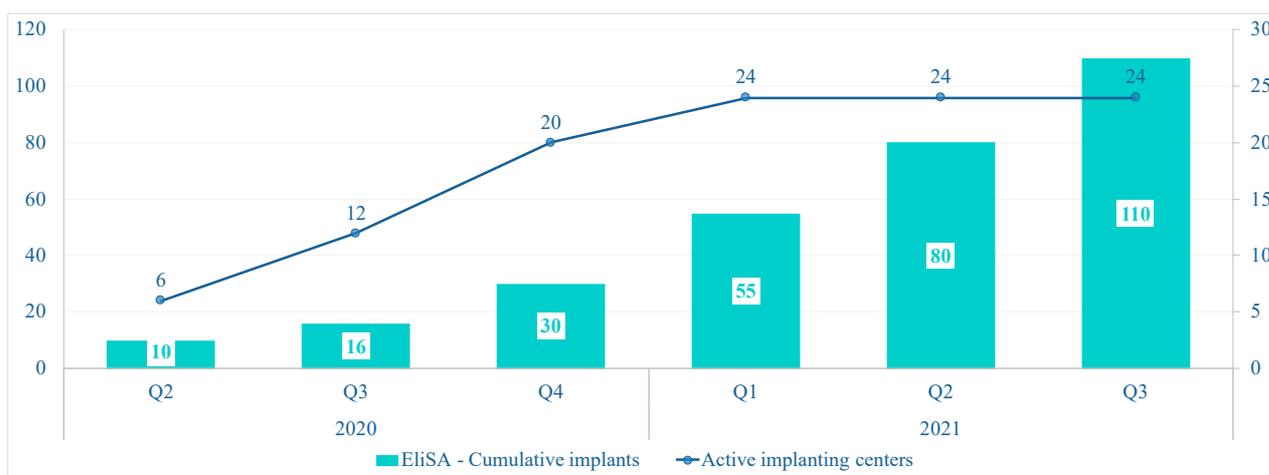
Over the last several years, the absence of complete concentric collapse at the level of the palate documented during Drug Induced Sleep Endoscopy has been used as a potential predictor of therapeutic success for OSA patients receiving hypoglossal nerve stimulation therapy, despite rising issues regarding the validity and reliability of the Drug Induced Sleep Endoscopy procedure and the logistical challenges with this procedure.

### ***ELISA Study***

After obtaining the CE-Mark for the Genio® system in March 2019, the Company initiated the EliSA post-marketing study in Europe for the treatment of OSA in adult patients with moderate-to-severe OSA, which is expected to be completed by Q3 2026.

The primary objective of this study is to confirm the long-term safety and clinical effect of the Genio® system, when used in accordance with its usage instructions, in adult patients suffering from moderate-to-severe OSA. The study is expected to follow patients implanted with the Genio® system over a period of five years.

EliSA is a multicenter prospective single arm Post Market Clinical Follow-up study and is expected to enroll at least 110 *De Novo* patients as well as participants from the BLAST OSA study. The EliSA study will enroll patients in approximately 25 investigational centers across Europe.



EliSA study implants and centers

As of 15 August 2020, 12 patients have undergone the implantation procedure as part of the study. As at the date of this Prospectus, no serious adverse events have been reported.

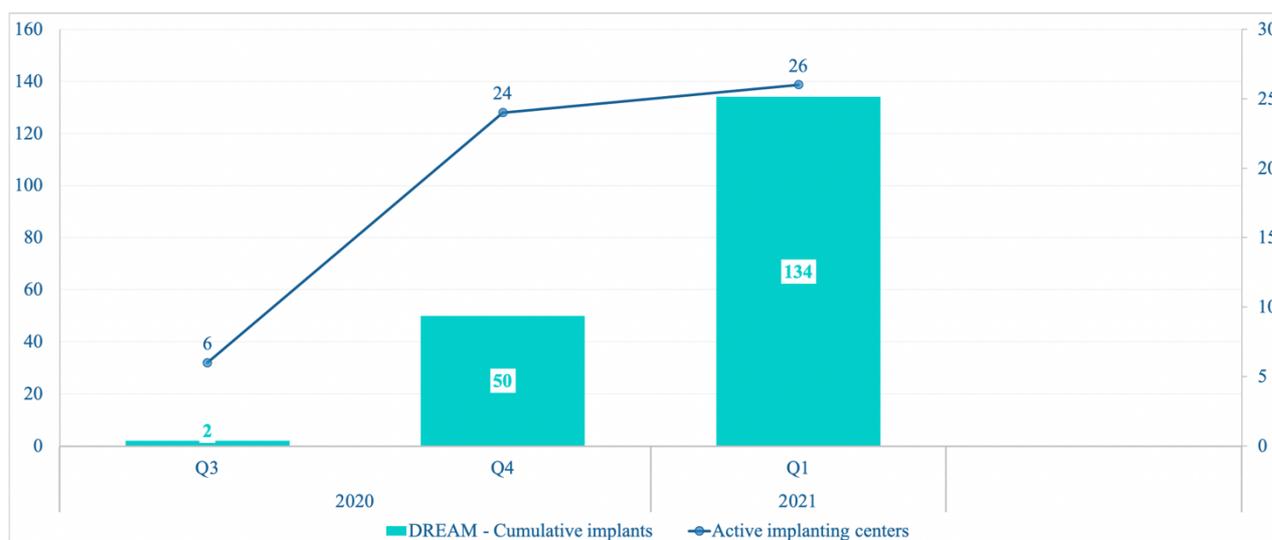
<b>Population and key inclusion criteria</b>	Age >18	Failed, Not Tolerated or Refused PAP	Combined central/mixed AHI >25% total AHI excluded
	BMI < 35	Moderate to Severe OSA – AHI 15-65	CCC of soft palate excluded
	<b>Target: 110 patients implanted</b>		
<b>Primary endpoints</b>			
<ul style="list-style-type: none"> <li>Safety: Incidence of serious device-related adverse events at 12-Month</li> <li>Performance: Change in the Apnea Hypopnea Index (AHI) and change in patient Quality of Life from baseline to 12-Month post implantation</li> </ul>			

**d. Upcoming study**

The Company will initiate a pivotal, Investigational Device Exemption (IDE) study, the DREAM study (Dual-sided hypoglossal nerve stimulation for the treatment of obstructive sleep apnea), in and outside the United States to support marketing authorization and reimbursement in the United States.

The DREAM study is a multicenter, prospective, open-label, observational study 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.

The study will enroll 134 patients with 12-month performance and safety primary endpoints who will undergo the implantation procedure in up to 26 centers worldwide (as of the date of the Prospectus, 24 centers have been selected: one in Germany, one in Belgium, four in Australia and 18 in the United States (most of which are in the Northeast and Midwest of the United States)).



The DREAM study protocol was designed using feedback from numerous experts in the sleep disorders and ear, nose and throat fields, as well as from the FDA. On 23 June 2020, the FDA approved the Company's IDE application, allowing the Company to commence its pivotal DREAM study of the Genio® system to support the system's marketing approval in the United States. Approval was granted under a CMS category B. Category B (Non-experimental/investigational), refers to a device for which initial questions of safety and effectiveness of that device type have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

<b>Population and key inclusion criteria</b>	22 < Age < 75	Failed, Not Tolerated or Refused PAP	Combined central/mixed AHI > 25% total AHI excluded
	BMI ≤ 32 kg/m <sup>2</sup>	Moderate to Severe OSA – AHI 15-65	CCC of soft palate excluded
	Target: 134 patients implanted		
<b>Co-Primary endpoints</b>			
<ul style="list-style-type: none"> <li>• Safety: Incidence of serious device-related adverse events at 12-Month</li> <li>• Performance: percentage of responders at 12 months based on Apnea Hypopnea Index (AHI4) using the Sher criteria and percentage of responders at 12 months based on ODI4 (25% reduction of ODI between baseline and 12-month visit)</li> </ul>			

As of 15 August 2020, no patient has yet undergone the implantation procedure as part of the study. As at the date of this Prospectus, no serious adverse events have been reported.

**e. Important Clinical Milestones**

The table below provides an overview of all important clinical milestones and their expected timing. All timeline assumptions are based on the Company's past clinical trial experience (amount of time needed to open centers, ethic committee submissions, average recruitment rates, contract negotiation, etc.) during the pre-CE Mark phase. The Company included a 9-month period for monitoring/analysis and FDA review of the data (150 days dedicated for the FDA de novo review).<sup>56</sup> The Company expects to benefit from the already existing hypoglossal nerve stimulation awareness and therapy embracement by the medical community (increasing average enrolment rate).

	EliSa study	Better Sleep study	DREAM study
Number of patients to enroll	110	44	134
Start of Enrolment	Sep-19	Feb-19	H2 2020
Last enrolment (expected)	Q2 2021	Oct. 2020	Mar-21
Primary Endpoint Availability (expected report)	Mid 2022	Q2 2021	End 2022
All Study Endpoints availability (expected report)	Mid 2026	Early 2024	End 2022

**8.6.6 Manufacturing and supply**

**a. Sourcing of Components**

The Company relies on third-parties to manufacture and supply all the components of the Genio® system to the Company's specifications. Outsourcing component manufacturing reduces capital investment and reduces operational expense for the Company. These suppliers are managed by experienced in-house resources and are required to comply with applicable standards and regulations as well as use quality assurance processes and technology. The Company's suppliers have undergone a rigorous selection process in which their capabilities were assessed by the Research and Development, Quality Assurance/Regulatory Affairs and Operations teams of the Company, intended to ensure that the supplied components comply with medical device standards and are produced according high-quality standards.

Most components are supplied by single-source suppliers. The Company will look for additional or replacement suppliers for the currently single-source components and intends maintaining a reasonable level of inventory of such components to enable continued production for a limited period, such as during a supplier transition phase.

**b. IS and ES manufacturing**

The Company works with third parties to manufacture and supply the components of the IS and the ES. The

<sup>56</sup> [https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request#FDA\\_Review\\_and\\_Review\\_Timeline](https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request#FDA_Review_and_Review_Timeline)

initial assembly of the different electronics components is done by different external suppliers.

The final assembly of the ES parts and the final key manufacturing step of the IS parts (the silicone molding) are done internally by the Company's manufacturing team in the clean room at the Company's facility in Tel Aviv (Israel). The capacity of the Company's facility in Tel Aviv is expected to cover the IS and ES demand for 2020 and 2021.

The Company is finalizing its plan to establish a manufacturing facility in Liège, Belgium that is expected to have enough capacity for the assembly of IS and ES parts for full year 2022 and beyond through a phased approach, manufacturing first the external device of the Genio® system by Q4 2020 followed by the IS and ES by Q3 2021. The current capacity would be tripled with this Belgian manufacturing site and provide the Company with capacity to support the implant need and start building stock. The Company may in the future rent a dedicated clean room space where the Company will install its own equipment for manufacturing and for which it will hire its own dedicated manufacturing team. In January 2020, the Company paid € 70,000. for leasehold improvements for establishing a new clean room in Belgium. This new facility is expected to be up and running before the end of 2021 and is expected to be financed by the proceeds of the Offering and non-dilutive financing.

#### **c. Activation Chip and Charging Unit manufacturing**

The Company works with third parties to manufacture and supply the electronic and plastic components of the Activation Chip and Charging Unit. The final assembly of these parts is done by the Company's manufacturing team in the Company's facility in Tel Aviv (Israel).

The Company is finalizing its plan to outsource the assembly of the Activation Chip and Charging Unit to an external supplier based in Belgium. The supplier selection and validation and start of product assembly by the selected supplier is expected before the end of Q2 2020.

#### **d. Disposable Patch manufacturing**

The manufacturing of the Disposable Patch is fully outsourced to the third party-supplier Pronat, based in Israel. The Company currently has no intention of changing the supplier for the Disposable Patch.

### **8.6.7 Research and development**

Beyond the ongoing clinical studies (EliSA and SLEEP BETTER) and the planned IDE study in the United States, the Company continues 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. Some of the improvements would include features aimed at enhancing physician's ability to monitor patient compliance and therapy efficacy. Further improvements or a next generation product may also bring additional disruptive features or services to the Genio® system, potentially opening opportunities to generate revenue from data obtained with the Genio® system.

For example, the future generation of the Company's products focuses on having the capability to assess variables related to the patient's sleep quality (like surrogates of the patient flow, snoring, movement, sleep

position etc.) and the capacity to be connected to the cloud. The collected information may enable the Company to monitor and better understand the patient's quality of sleep and respiratory status, which the Company could consider sharing with key stakeholders. For example, the Company is considering solutions to enhance patient compliance with the therapy by letting the users follow-up regarding the quality of the treatment received, on a regular basis, with healthcare connectivity tools. Also, the Company is considering 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 reimbursable) basis, to assess patient status and adjust Genio® system treatment parameters. Its location close to the airway is optimal for detection and analysis of sleep and respiratory variables.

It is the Company's intention to build a modular, flexible and scalable technology platform allowing quick and streamlined release of new features and functionalities (through software, firmware, hardware updates and upgrades) and therapy enhancement. The external Genio® system Activation Chip is expected to allow for external enhancements to the Genio® system without the need for surgical reintervention.

The Company's research and development team is currently located in Israel.

In addition to investing in product development, the Company also invests in regulatory compliance, applying the most up-to-date, harmonized and consensus standards and international regulatory requirements.

## **8.7 Regulatory framework**

The Company's products and operations are subject to extensive regulations, including those of the EU, FDA and other federal and state authorities. These regulations, for example, govern the process for achieving marketing approvals, as well as clinical trials, and once the Genio® system is cleared or approved for marketing in a jurisdiction, numerous extensive regulatory requirements will continue to apply. These will include for example, establishment registration and device listing in the EU and potentially with the FDA and the TGA, as well as continuing compliance with quality system regulations and current manufacturing best practices, such as EN ISO 13485:2016, which require manufacturers to follow defined and approved design, testing, control, documentation and other quality assurance procedures throughout the entire design and manufacturing process. Various laws and regulations also govern reimbursement relationships with third party payers, including both governmental and private health insurance plans.

With respect to marketing authorizations and quality standards, the Company obtained the CE-Mark for the Genio® system in March 2019. In addition, both the Company and the Genio® system are fully compliant with EN ISO 13485:2016 maintaining its certification as of May 2017. Further, the Genio® system and the Company were audited and approved by DEKRA, where technical dossiers and the manufacturers' quality system were fully reviewed for compliance.

In addition, the Company is registered as legal manufacturer in Belgium under Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (the "**AIMD Directive**"). It further intends to obtain approval by the Australian Government therapeutic goods administration for the Genio® system and has commenced the process for obtaining such approval and is in discussions with the FDA regarding clinical trials and approval processes for obtaining marketing authorization in the United States. In addition, the Company invests significant efforts in compliance with the most updated, harmonized and consensus standards, and with local and international regulatory

requirements.

### **8.7.1 Regulatory landscape in the EEA**

As of the date of this Prospectus, the Company's products are subject to regulation under the AIMD Directive.

On 5 April 2017 the European Parliament passed Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (the "**Medical Device Regulation**"), which repeals and replaces the EU Medical Devices Directive and the AIMD Directive. The Medical Device Regulation will come into effect and become applicable in May 2020. Nevertheless, the CE-Mark on the current Genio® system design, obtained in March 2019, is valid until March 2024. The recertification requires the demonstration that the performance and the safety of the system has been maintained and that the system continues to meet existing regulations and standards. Clinical studies shall not be required to obtain the recertification. The Company is in the process of conducting a full-gap analysis and compliance assessment in relation to the Medical Device Regulation.

### **8.7.2 Regulatory landscape in the United States**

The Genio® system is not yet approved for marketing in the United States. With respect to the process to obtain FDA approval for marketing medical devices in the United States, unless an exemption applies, each medical device commercially distributed in the U.S. will require FDA clearance or approval, based on their risk classification. Under the Food, Drug, and Cosmetic Act ("**FDCA**"), medical devices are classified into one of three classes-Class I, Class II or Class III, based on the extent of the regulatory controls necessary and sufficient to provide reasonable assurance of safety and effectiveness of the device. The three categories of devices are Class I (general controls), Class II (special controls), and Class III (premarket approval). Class I includes devices with the lowest risk to the patient. Class II and III devices are higher risk devices, which are subject to more FDA oversight to ensure the safety and effectiveness of the device, such as regarding performance standards and post-market surveillance.

In addition, while most Class I devices do not require FDA notice or approval prior to commencing marketing, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device, and Class III devices are subject to premarket approval prior to marketing. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Generally, under the 510(k) process, the manufacturer submits to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to another commercially available device that was cleared to through the 510(k) process. In addition, an alternative regulatory pathway, - the De Novo regulatory pathway under section 513(f)(2) of the FDCA - is available for devices for which general controls or general and special controls would provide a reasonable assurance of safety and effectiveness but for which a predicate device cannot be identified. Under this approach, there are two main tracks. The requester can submit a 510(k) application and receive pursuant to it an FDA determination that the device is not substantially equivalent, or the requester determines that there is no legally marketed device upon which to base a determination of substantial equivalence, thereby avoiding the need to first submit a 510(k) application. On December 7, 2018, the FDA published a proposed rule to formally establish regulations for the De Novo classification process which, if finalized, would provide further clarity, structure, and transparency on the De Novo pathway. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices,

or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are otherwise placed in Class III, requiring approval of a PMA under section 515 of the FDCA. Generally, the De Novo regulatory pathway is expected to be faster than the PMA pathway but the difference in timeframes is unknown.

The Company has not yet determined, in consultation with the FDA, which regulatory pathway it will use for this process, and it is currently considering either a PMA or a De Novo submission.

A marketing application under the PMA process, as well as under certain 510(k) and De Novo applications, will generally require supporting clinical evidence and pre-clinical data, such as animal and laboratory test results, and it is the Company's intention to conduct the DREAM study (dual-sided hypoglossal nerve stimulation for the treatment of obstructive sleep apnea), a pivotal IDE study in and outside of the United States.

On 23 June 2020, the FDA approved the Company's IDE application, allowing the Company to commence its pivotal DREAM study of the Genio® system to support the system's marketing approval in the United States. The IDE application approval was granted under a CMS category B. Category B (Non-experimental/investigational), refers to a device for which initial questions of safety and effectiveness of that device type have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type. The study is expected to start in the second half of 2020 in up to 26 centers in and outside the United States.

With respect to the conduct of clinical trials for medical devices, in the U.S clinical investigations of investigational devices to determine safety and effectiveness in connection with FDA marketing authorizations must be conducted in accordance with the FDA's IDE regulations. If the investigational device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. 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 notifies the company that the investigation may not begin.

Studies conducted under IDEs must satisfy numerous requirements, and the IDE regulations address, for example, investigational device labeling, the protection of patients through institutional review board oversight and detailed informed consent requirements, prohibitions on the promotion of the investigational device, and also specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Also, after an IDE does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials, and after a trial begins, the FDA or the institutional review board could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study patients outweigh the anticipated benefits.

The approval by the FDA of marketing authorization for a novel implanted medical device, such as the Genio® system, is subject to substantial uncertainty, and applications for the Company's product could fail

to receive regulatory approval in an initial or subsequent indication for many reasons, including but not limited to the following:

- the FDA may determine that the Company's product is not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities, or other characteristics that preclude the Company's obtaining marketing approval or prevent or limit commercial use;
- the FDA may believe that the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which the Company seek approval;
- the FDA may disagree with the Company's interpretation of data from preclinical studies or clinical trials;
- the Company may be unable to demonstrate to the FDA that a product candidate's risk-benefit ratio for a proposed indication is acceptable;
- the FDA may fail to approve the manufacturing processes, test procedures, and specifications, or facilities of third-party manufacturers with which the Company contracts for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering the Company's clinical data insufficient for approval.

Similar issues may apply with respect to regulatory authorities in other countries and jurisdictions.

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 unapproved or "off-label" uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- 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, the Company's manufacturing operations and the recall or seizure of the Company's products.

In addition, the FDA has broad enforcement powers, and determinations by the FDA of non-compliance could result in sanctions, including, but not limited to, warning letters, fines, injunctions, consent decrees, civil or criminal penalties, recalls, operating restrictions or suspensions, product seizures, delayed or denied marketing authorizations for new or modified products.

If the Genio® system is approved for marketing in the United States, the Company may also be subject to U.S. federal and state health care fraud and abuse, referral and reimbursement laws and regulations with respect to its operations. Some of these laws, referred to as "false claims laws," prohibit the submission or causing the submission of false or fraudulent claims for reimbursement to federal, state and other health care payers and programs. Other laws, referred to as "anti-kickback laws," prohibit soliciting, offering, receiving or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for, or recommending ordering, purchasing or leasing of, items or services that are paid for by federal, state and other health care payers and programs. In addition, the United States Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, each enacted in March 2010 (the "**Health Care Reform Law**"), not only increased federal oversight of private health insurance plans, and included measures to provide access to increased health coverage while also attempting to reduce government health care costs, but also included provisions to reduce fraud and abuse. Notably, the Healthcare Reform Law has and continues to face legal challenges in the United States, as well as certain rollbacks, such as regarding the repeal of its requirement that certain individuals purchase health care insurance. This includes, also, ongoing litigation seeking to invalidate some or all of the Health Care Reform Law or the manner in which it was and continues to be implemented. In December 2018, a Texas federal district court struck down the entire Healthcare Reform Law, a ruling which is being appealed, and, if upheld, could have a significant impact on the U.S. health care industry.

The U.S. fraud and abuse laws and regulations have been subject to varying interpretations, as well as heightened enforcement activity over the past few years, and significant enforcement activity has been the result of "relators," who serve as whistleblowers by filing complaints in the name of the United States (and if applicable, particular states) under federal and state false claims laws and who may receive up to 30% of total government recoveries. Penalties under fraud and abuse laws may be severe. For example, under the federal False Claims Act, violations may result in treble damages, plus civil penalties of up to \$22,927 per claim, as well as exclusion from federal health care programs and criminal penalties. Most states have adopted similar state false claims laws, and these state laws have their own penalties which may be in addition to federal False Claims Act penalties. With respect to "anti-kickback laws," violations of the federal Anti-Kickback Law may result in civil penalties of up to \$102,522 for each violation, plus up to three times the total amount of remuneration offered, paid, solicited or received, as well as exclusion from federal health care programs and criminal penalties. Furthermore, the Health Care Reform Law significantly strengthened the federal False Claims Act and the federal Anti-Kickback Law provisions, clarifying that a federal Anti-Kickback Law violation can be a basis for federal False Claims Act liability. Failure to comply with fraud and abuse laws and regulations could result in significant civil and criminal penalties and costs, including the ability to participate

in federal and state health care programs. Also, many of these laws are vague or indefinite and have not been interpreted by the courts, and have been subject to frequent modification and varied interpretation by prosecutorial and regulatory authorities, increasing the risk of noncompliance.

A Health Care Reform Law provision, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, imposes annual reporting and disclosure requirements on certain drug and medical device manufacturers and distributors, including medical device manufacturers that sell medical devices subject to premarket approval or premarket notification by the FDA, which are reimbursed by Medicare or Medicaid. This transparency law, which imposes substantial and sometimes ambiguous tracking and reporting requirements, applies to payments or other transfers of value made to certain covered recipients, including physicians and teaching hospitals, and to certain ownership interests held by physicians in the reporting entity. The U.S. Centers for Medicare and Medicaid Services publishes information from these reports on a publicly available website, including amounts transferred and physician and teaching hospital identities. While the Physician Payment Sunshine Act pre-empts similar state reporting laws, tracking and reporting may also be required to report under certain state transparency laws that address circumstances not covered by the Physician Payment Sunshine Act, and some of these state laws can be uncertain to apply.

In addition, the Health Care Reform Law includes a 2.3% excise tax on domestic sales of many medical devices by manufacturers and importers that was scheduled to begin in 2013, but a two-year moratorium suspending the imposition of the tax on device sales was imposed under the Consolidated Appropriations Act, 2016, which lasted until December 31, 2017, and on January 22, 2018 an additional two-year moratorium was imposed under Public Law No. 115-120, suspending the imposition of the tax on device sales during the period beginning January 1, 2018 and ending on December 31, 2019. In the absence of further Congressional action, the excise tax will apply to certain sales, uses, and leases of affected medical devices beginning January 1, 2020.

### **8.7.3 Regulatory landscape in Australia and New Zealand**

In New Zealand, the Genio® system (comprising all its components) has been added ("notified") to the New Zealand Medsafe WAND (Web Assisted Notification of Devices) database in December 2019. This notification is equivalent to the CE-Mark approval in the European Union and the TGA approval in Australia. The search for a sponsor (distributor) is ongoing. As soon as this task is completed, the Company will be allowed to submit tenders to supply its devices to the New Zealand public health system.

In Australia, an application for inclusion in the Australian Register of Therapeutic Goods has been submitted in Q3 2019 to the Therapeutic Goods Administration. Discussions are ongoing and approval is expected to be granted in Q4 2020.

## **8.8 Intellectual property**

The Company's intellectual property and the rights underlying the same are valuable and important in the medical device and health tech industry in which the Company operates. The Company relies heavily on its patent and design portfolio to maintain competitive technological advantage, as well as on its trademarks that support its brand identity.

The Company has 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.

The Company may, from time to time, file patent applications for inventions that may be of importance to its future business. It 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 the Company. Further, the Company may decide, from time to time, to license its intellectual property to other parties, for example, in exchange for cash, marketing collaboration, or other valuable consideration to the Company.

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

The Company's policy is that employees and contractors of the Company execute a propriety information and inventions assignment agreement, which protects proprietary information and which assigns to the Company 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 the Company's intellectual property and confidential information, and to assign to the Company new inventions related to the Company's business.

### 8.8.1 Utility and design patents

As of 1 September 2020, the Company's protection of its technology includes a strong and growing portfolio of intellectual property rights, including 122 granted utility and design patents and 61 patent applications pending, across 12 countries.

The table below provides an overview of the Company's patents and patent applications which have been granted over the recent years on a continuous basis as from 2011.

<b>Jurisdiction</b>	<b>Pending</b>	<b>Allowed/Granted</b>	<b>Total</b>
Australia	3	18	21
Canada	11	5	16
China	5	9	14
Europe	15	12	27
Hong Kong	5	0	5
Israel	5	16	21
Japan	3	3	6
United States	13	47	60
<b>Total</b>	<b>60</b>	<b>110</b>	<b>170</b>

The table below provides an overview of the Company's design rights distribution per jurisdiction.

<i>Jurisdiction</i>	<b>Implantable Stimulator</b>	<b>External Stimulator</b>	<b>Disposable Patch</b>
<i>Australia</i>	Granted	Granted	Granted
<i>China</i>	Granted	Granted	Granted
<i>Europe</i>	Granted	Granted	Granted
<i>Israel</i>	Granted		
<i>Japan</i>	Granted		
<i>United States</i>	Granted	Granted	Granted

The selection of countries in which to pursue such patent applications is based, in part, on the Company's assessments of the importance of its future markets. Securing a patent typically involves negotiation between the Company and the governmental authority that issues the patent, e.g., the United States Patent and Trademark Office or the European Patent Office. In the course of such negotiations, the examining authority may initially reject the patent application claims, for example, based on its interpretation of prior art, and, from time to time, may issue a "final" ruling rejecting certain patent application claims. The Company, in conjunction with its patent attorneys in the pertinent jurisdiction, may modify or delete claims, or accept suggested claim amendments offered by the examining authority, to secure issuance of a patent. Alternatively, the Company may continue to pursue the same or similar patent application claims by way of a continuation application, a request for continued examination, or a divisional application, depending upon the applicable jurisdiction.

The Company's intellectual property portfolio has been continuously growing and expanding since 2009, with its first international patent filings in 2010. The earliest patent of the Company will lapse in 2029 and the core patent filings of 2012, 2013 and 2014 will lapse in 2032, 2033 and 2034, respectively. The Company considers all its patents as material intellectual property. This notwithstanding, the earliest patent of the Company of 2009 is directed to diagnosis and prediction of the OSA by locating the location of the tongue. The Company will attempt to obtain USPTO PTE rights (i.e. a patent term extension under 35 U.S.C. 156 for products that undergo regulatory review before commercial marketing or use) for its key patents upon completion of its clinical studies in the United States.

The Company's core intellectual property protects its novel technology and differentiation over competitors through interlocking fencing strategy having a hierarchical structure. First, this is accomplished by patent filings to cover detailed technological concepts which are claimed across various patent families aimed at protecting similar functions and continuously evolving with the research and development activities. Second, the Company files various continuation and continuation in part applications which claim overlapping aspects within the same or parallel patent families (this broadening the technological space by reformulating the patent application over time e.g. to eventually cover products/features that might be introduced by competitors). Third, the Company applied a hierarchical patent claim structure, i.e., it filed different independent claims per patent, claiming various (hierarchically structured) technological components, such as for system and its functions, implant, its structure and components, external units such as the activation unit and power source.

As the Company continues to innovate, new patent applications may be filed from time to time, and it is anticipated that the Company's intellectual property portfolio will grow. The Company does not intend to make announcements as new patent applications are filed for commercial and competitive reasons.

In addition to patent protection, the Genio® system benefits from enhanced protection from the complexity

of its design. The device needs to be completely destroyed in order to access many of the components, including the software. Several of the components are not available on the open market, and the Genio® system software cannot be retrieved from the device.

In addition to the extensive and robust patent portfolio owned by the Company, the Company holds exclusive licenses granting the Company a fully paid-up, transferrable and sub-licensable, worldwide, irrevocable license 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 the Company by Man & Science SA (a company held and governed by Robert Taub, TOGETHER Partnership and Jürgen Hambrecht).

### 8.8.2 Trademarks

The Company uses its corporate name, Nyxoah, and associated logo as well as the tagline, in creating awareness of its expertise and in marketing its Genio® system technology. The Company uses the trademark Genio® to identify its Genio® system. The Company has obtained registration for the Nyxoah name and the Genio® trademark in seven jurisdictions around the globe.

The table below provides an overview of the Company's trademark rights distribution per jurisdiction as of 1 September 2020.

Jurisdiction	Nyxoah	Genio			Nyxoah	Nyxoah™	GENIO
Australia	Registered	Pending	Registered				
Benelux	Registered	Registered	Registered	Registered	Registered	Registered	
Canada	Registered		Registered			Registered	
China	Pending	Pending	Registered		Pending		Pending
Europe	Registered	Registered	Registered			Registered	Pending
Israel	Registered	Registered	Registered			Registered	
Japan	Registered		Registered				
United States	Registered	Registered	Registered				

### 8.8.3 Confidential information and trade secrets

The success of the Company's business depends, in part, on securing confidential information and trade secrets, generally referred to as proprietary information. The Company has implemented procedures, where appropriate, to maintain the confidentiality of its proprietary information. The Company's policy is that employees and contractors enter into confidentiality agreements with the Company, and, where appropriate, that confidentiality agreements are executed before confidential information is revealed to any third party. Confidentiality provisions are also included in consulting agreements and supplier agreements in certain cases where the consultant or supplier may be exposed to confidential information.

## 8.9 Environmental and health and safety

The Company is committed to providing a safe and healthy work environment for all its employees, contractors and visitors. This commitment also extends to ensuring that its operations do not place local communities

or the environment at risk of injury, illness or damage. The Company has not been the subject of any significant environmental prosecutions for violating environmental regulations, licenses or other requirements during the past five financial years.

## 8.10 Insurance

The Company's insurance covers number of claims and losses, including a product liability insurance to help pay for the defense of product liability lawsuits and clinical study insurance helps cover defense of lawsuits relating to products which are the subject to clinical studies. Management believes that the Company's insurance coverage is adequate in light of the potential risks that the Company faces.

## 8.11 Employees

Management believes that one of the Company's key strengths is its employee base, which has extensive know-how across research, manufacturing, quality-control, engineering, software programming and marketing and sales.

As at 30 June 2020, the Nyxoah Group employed 53.5 full-time equivalents, including white-collar employees and consultants. The following table presents a breakdown of the Company's full-time equivalents as at 30 June 2020 and 31 December 2019, 2018, 2017.

	As at 30 June	As at 31 December		
	2020	2019	2018	2017
General & Administration	6.6	5.8	7.0	6.7
IP & Trademark	-	1.0	1.0	1.0
Research & Development	8.8	10.6	11.0	9.0
Clinical & Regulatory Affairs	12.2	8.2	7.2	7.9
Quality Assurance & Regulatory	6.9	5.9	5.9	5.8
Operations	14	9.0	7.0	5.0
Therapy Development (including the sales team)	5	2.0	1.0	1.0
<b>Total</b>	<b>53.5</b>	<b>42.5</b>	<b>40.1</b>	<b>36.4</b>

As of 30 June 2020, the Company had 12.2 full-time equivalents located in Europe, 32.3 full-time equivalents located in Israel, 5 full-time equivalents located in Australia and 4 full-time equivalents located in the United States. In 2020, the Company will continue recruiting talent and the headcount is expected to increase by 45%.

In selected countries, the Company will implement a direct sales model, with key account managers in each market. The Company currently estimates that, in the years following market entry, one key account manager will be able to cover around 45 to 55 new patients annually, spread over two to three implant sites, which would correspond to €1 million in revenue per year when calculated at an estimated hypoglossal nerve stimulation system (i.e. the Inspire Hypoglossal Nerve Stimulation System) average selling price of €20,000.

As the Company intends to scale up the business within three to five years after opening and developing its Centers of Excellence, the Company expects to hire field sleep experts who will assist key account managers and be responsible for managing the therapy optimization parameters during sleep nights under observation

in sleep centers.

## **8.12 Material contracts**

### **8.12.1 Supplier agreements**

Most of the sub-components of the Genio® system, including the plastic components, batteries, printed circuit board, charger, docking station and disposable patches are sourced externally from five external suppliers.

The Company's suppliers are predominantly headquartered in Europe, the United States and Israel and range from large multinational companies to smaller private companies. In the Company's opinion, the suppliers of the critical components of the Genio® system are experienced and well-respected manufacturers with multiple customers and have existing quality control programs and registrations with the appropriate regulatory authorities.

Currently the Company's relationships with suppliers is usually on an order-by-order basis without longer term agreements. The Company will determine, going forward, whether and as of when it is appropriate to have a long term or short-term agreement in place with a supplier on a case by case basis.

### **8.12.2 Cochlear Collaboration Agreement**

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

The specific contributions and services to be used, applied and provided by both parties are further detailed in a document called "**Statement of Work**" that may be agreed upon by the parties from time to time. The initial Statement of Work was agreed upon by the Company and Cochlear on 7 November 2018. According to this Statement of Work, Cochlear would evaluate three packaging technologies (i.e. Titanium, Ceramic, and Hybrid) and support the Company in the assessment of the Company's encapsulation technologies.

The 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"<sup>57</sup>, 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, the Company could pay a break-up fee, if the decision is made to stop the collaboration with Cochlear.

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<sup>57</sup> The project steering committee consists of the following members: Fabian Suarez Gonzalez, MedTech Execs LLC (permanently represented by Donald Deyo), Jan Janssen and Catherine Picard (the two first members are appointed by the Company and the other two members by Cochlear).

On the date of this Prospectus, the objectives of the initial Statement of Work have been met. A new Statement of Work was entered into on 8 June 2020 and the Company may decide to enter into other new Statements of Work with Cochlear to continue their collaboration.

### 8.12.3 Novallia Loan

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

### 8.12.4 Noshag Convertible Loan

On 26 June 2020, the Company and Noshag SA ("**Noshag**") entered into a convertible loan agreement (the "**Noshag Convertible Loan**") pursuant to which Noshag has made available to the Company a convertible loan of € 1 million (the "**Principal Amount**"). The Company intends to apply the proceeds of the loan towards the scale-up of its manufacturing process and establishment of a manufacturing facility in the Liège region and for general corporate purposes. The outstanding portion of the Principal Amount shall bear simple, non-compounding interest at a rate of 2.50% per annum.

Under the Noshag Convertible Loan, the Offering is one of the events triggering a conversion.

Upon completion of the Offering, the outstanding Principal Amount shall be converted in full into new Shares in the Company by way of a contribution in kind of Noshag's receivable for the outstanding Principal Amount in exchange for fully paid-up new Shares at a subscription price per new Share equal to the Offering Price minus 10%. These Shares will be subject to a statutory lock-up in accordance with the provisions of the Royal Decree on Primary Market Practices.

The interest accrued on the Principal Amount is payable to Noshag in cash immediately prior to the aforementioned conversion of the outstanding Principal Amount.

### 8.12.5 Fraunhofer Agreement

On 3 May 2011, the Company and the Fraunhofer Institute for Biomedical Engineering (IBMT) ("**Fraunhofer IBTM**")<sup>58</sup> entered into an agreement pursuant to which Fraunhofer IBMT provides services with respect to the research and development of an "implantable electrostimulation system for therapy of obstructive sleep apnea" (the "**Fraunhofer Project**"). The goal of this project is to design and develop the electrostimulation system according to the requirements and specifications of the concept and according to the project plan. This initial agreement has been amended three times, most recently on 9 October 2019 in order to agree on new objectives, timelines, deliverables and fees with regard to the research and development services pro-

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<sup>58</sup> The legal entity behind Fraunhofer IBMT that signed the agreement and the amendments is Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung E. V.

vided by Fraunhofer IBMT in respect to the Fraunhofer Project. Pursuant to the latest amendment of 9 October 2019: (i) new objectives after the preliminary design phase and (ii) a new fee of € 5,500 (excl. VAT, if applicable) were set by the Company and Fraunhofer IBMT.

The contract is entered into for a definite term until the duration of the completion of the research and development of the Fraunhofer Project and contains early termination options if no essential progress in work has been achieved within a significant period of performance. Each party is also entitled to terminate this agreement with immediate effect for good cause, including the failure of Fraunhofer IBMT and the Company to agree on an adjustment of the fixed fees.

This agreement contains (i) a confidentiality clause that remains applicable for a period of up to five years after the termination of the agreement and (ii) an intellectual property rights clause according to which Fraunhofer IBTM transfers all right, title and interest in the results of the study and performance of the agreement to the Company.

#### **8.12.6 Kezirian Agreement**

The Company and Dr. Eric J. Kezirian ("**Mr. Kezirian**"), who is employed by the University of Southern California ("**USC**"), entered into a consultant agreement, dated 5 March 2014, for a definite term until 30 April 2014 (the "**Kezirian Agreement**"), pursuant to which Mr. Kezirian provides consulting services to the Company with respect to neurostimulation device development and cadaver studies. The Company or Mr. Kezirian may terminate the Kezirian Agreement without cause at any time by giving 30 days' prior written notice to the other party. The Company can also terminate this agreement for cause as further detailed in the Kezirian Agreement. Furthermore, the Kezirian Agreement contains a confidentiality clause which remains applicable for a period of up to two years after the termination of the agreement.

On 25 November 2015, the Company and Mr. Kezirian entered into an addendum to the Kezirian Agreement (the "**Kezirian Addendum**"), effective as from 22 July 2015, whereby additional services to be provided by Mr. Kezirian were added to the scope of services. The Kezirian Addendum re-activated for an indefinite term with the mutual termination rights of the Company and Mr. Kezirian as set forth in the Kezirian Agreement.

The Kezirian Addendum includes a clause stating that all intellectual property concerning all improvements, inventions, formulae, processes, techniques, knowhow and data that are related to, or useful to, the Company that result from tasks assigned by the Company to Mr. Kezirian and are related to any products and programs that are being developed by the Company, will be the exclusive property of the Company.

The Kezirian Addendum provided for compensation payable to Mr. Kezirian upon an "Exit of the Company", provided that Mr. Kezirian is not a "bad leaver" (as defined in the agreement) prior to such Exit. The Offering qualifies as an "Exit of the Company" under the Kezirian Addendum. If an Exit occurs prior to the fifth anniversary of the Kezirian Addendum (i.e. 25 November 2020), the compensation shall be equal to 0.5% of the "Exit Value", or the value of 100% of the Shares of the Company on a fully-diluted basis at the time of an Exit, less any expenses, costs and fees incurred by the Shareholders or the Company in the framework of the Exit. If the "Exit Value" of the Company is adjusted after the closing of an "Exit" for any amount (e.g. escrow hold back, working capital adjustment, earn-out payments, etc.), the compensation payable will also be adjusted.

In addition, the Kezirian Addendum permits Mr. Kezirian and USC to enter into an agreement with the Company's competitor Inspire Medical Systems Inc. with a scope of services related to the post approval study required by the FDA with respect to the safety and effectiveness of the Inspire Medical Systems Inc. implantation and treatment.

### **8.13 Legal proceedings**

There were no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Company is aware) during the previous 12 months which may have, or have had in the recent past, significant effects on the Company and/or the Company's financial position or profitability.

### **8.14 Facilities**

Nyxoah SA (the parent) operates out of a leased site in Mont-Saint-Guibert, Belgium, which gives home to its corporate, commercial, therapy development and marketing, and clinical activities. The lease for the site in Mont-Saint-Guibert, Belgium expires on 30 September 2025. The Company will be scaling up its manufacturing capacities by opening a manufacturing facility in Liège in 2020 (see Part 8 - (Business), section 8.6.6 (*Manufacturing and supply*)).

Nyxoah LTD operates out of a leased site in Tel Aviv, Israel, located at 126 Yigal Alon Street which gives home to research and development and manufacturing activities of the Company. The lease for the site in Tel Aviv, Israel expires on 30 September 2020, with the option to extend the lease for up to two two-year renewal periods. The landlord may only reject the exercise of the lease extension by the Company if the landlord plans to pull down the building to construct a new one. The landlord must provide the Company 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.

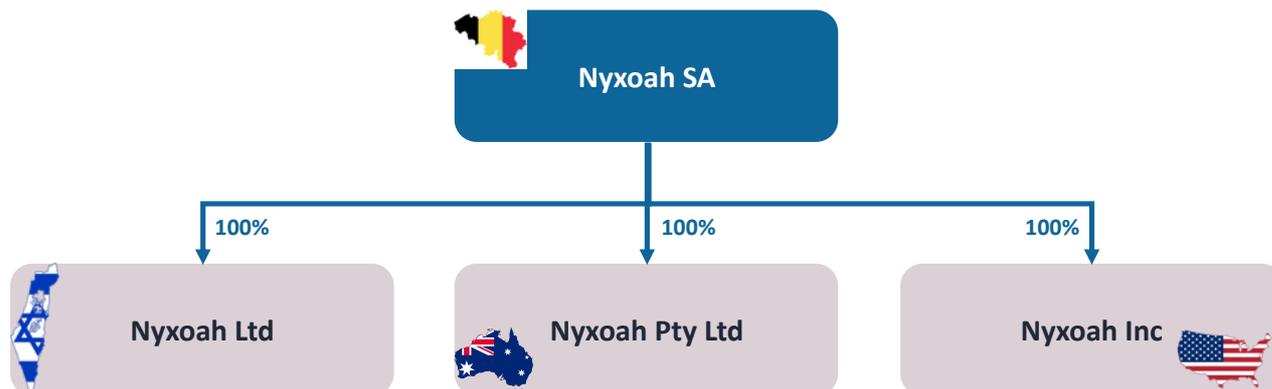
Nyxoah PTY LTD operates out of a business center in Melbourne, Australia, which gives home to clinical activities of the Company. The services agreement with the business center in Melbourne, Australia expires on 16 August 2021 or can be terminated by either party by giving 30-calender days prior notice.

### **8.15 Group structure**

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

- Nyxoah LTD (the Israeli subsidiary, incorporated on 1 January 2008 under the name M.L.G. Madaf G. LTD and a subsidiary of Nyxoah SA since 21 October 2009), which conducts research and development and manufacturing activities
- Nyxoah PTY LTD (the Australian subsidiary, incorporated on 1 February 2017), which conducts clinical activities and the preparation of commercial activities.
- Nyxoah, Inc. (the U.S. subsidiary, incorporated on 14 May 2020), which conducts clinical activities.

The following chart represents the Company's structure at the date of this Prospectus:



## 8.16 Grants and subsidies

The Company has been granted several recoverable cash advances by the Walloon Region since its 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, in essence, consist of two phases, i.e., the "research phase" and the "exploitation phase".

During the research phase, the Company receives funds from the Walloon Region based on statements of expenses. At the end of the research phase, the Company is required to decide within six months whether or not to exploit the results of any given research program. If the Company decides not to exploit the results of a program, motivates this decision and transfers to the Walloon Region all real rights on the results, then the cash advance does not have to be reimbursed. If the Company decides 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:

1. fixed repayments paid in annual amounts throughout the duration of the exploitation phase and representing in aggregate 30% of the principal amount; and
2. 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.

The Company has contracted the following recoverable cash advances with the Walloon Region:

<i>(in € 000)</i>	<b>Contractual Advances</b>	<b>Advances received</b>	<b>Amounts re- imbursed</b>
Sleep apnea device (6472)	1,600	1,600	380
First Articles (6839)	2,160	2,160	84
Clinical Trial (6840)	2,400	2,210	-
Activation chip improvements (7388)	1,467	1,467	-
<b>Total</b>	<b>7,627</b>	<b>7,437</b>	<b>464</b>

The Company has received several grants from the Walloon Region totaling € 1 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.

### **8.17 COVID-19 impact**

In March 2020, the World Health Organisation characterized COVID-19 as a pandemic. This has affected the course of business of the Company. This exceptional situation has required exceptional measures. Governmental safety guidelines have been implemented in all Nyxoah entities. Production activities have not stopped in the Tel Aviv facility. Support functions (R&D, QA&RA) also continued but with reduced capacity. Elective surgeries were on hold from March to August 2020 in certain geographies across Europe and Australia, but are selectively re-opening. Study centers and centers of excellence may not perform elective surgeries should COVID-19 cases increase locally. Although the Company is monitoring developments relating to the COVID-19 situation closely, the ultimate impact of COVID-19 on the Company's business is uncertain at this time and will depend on future developments, which are highly uncertain and cannot be predicted.

Due to the high degree of unpredictability of COVID-19, the Company foresees challenges in training and proctoring new centers and their surgeons in the United States and Europe. Patients being less willing to travel to these centers or their travelling being restricted could become an issue and potentially impact the Company's clinical and commercial activities.

## 9. OPERATING AND FINANCIAL REVIEW

*The following is a review of the Company's financial condition and results of operations as of and for the six-month periods ended 30 June 2020 and 2019 and the three years ended 31 December 2019, 2018 and 2017. This section should be read in conjunction with the section entitled "Selected Consolidated Financial Information" and the Company's audited financial statements and notes to those financial statements, included elsewhere in this Prospectus. The figures used in this section have been derived from the consolidated financial statements, which have been prepared in accordance with IFRS. Certain statements in this section are forward-looking and should be read in conjunction with "Forward-looking statements".*

### 9.1 Overview

The Company is a health-technology company focused on the development and commercialization of solutions and services to treat sleep disordered breathing conditions. The Company's Genio® system is a product addressing OSA, the world's most common sleep disordered breathing condition.

The product is intended to be used as a second-line therapy to treat moderate-to-severe OSA patients who have failed conventional therapy, including CPAP, which, despite its proven efficacy, has been associated with many limitations, making compliance a serious challenge. In addition, other second-line treatments, such as oral devices, are more suitable to treat mild to moderate OSA or are highly invasive.

Compared to other hypoglossal nerve stimulation technologies for the treatment of OSA (such as the CE-Marked and FDA-approved Inspire and the CE-Marked ImThera), the Genio® system is the world's first and only battery-free, minimally invasive and leadless neurostimulator implant and is capable of delivering bilateral hypoglossal nerve stimulation to keep the upper airway open. The Genio® system is a 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 left and right branches of the hypoglossal nerve.

OSA is the world's most common sleep disordered breathing condition, affecting around 936 million people between 30 and 69 years of age globally, of which 425 million worldwide, suffering from moderate-to-severe OSA, require treatment<sup>59</sup>. OSA is a chronic disease, which adversely affects the patients' health and quality of life. It is associated with increased mortality risk<sup>60</sup> and comorbidities, including cardiovascular diseases, depression and stroke when left untreated. Clinical studies have shown that the mortality rate of non-treated patients suffering from OSA increases significantly over time. Numerous studies demonstrated the correlation between efficient OSA therapy and the reduction of mortality and comorbidities.<sup>61</sup>

The Company obtained a CE-Mark approval for the Genio® system in March 2019, meaning that its system meets the health, safety and environmental protection standards for products sold within the EEA and can be freely sold and marketed within the EEA. The Company intends to first commercialize the product in Europe,

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<sup>59</sup> Benjafield, Adam V et al. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. *Lancet Respir Med* 2019 Published Online 9 July 2019 [http://dx.doi.org/10.1016/S2213-2600\(19\)30198-5](http://dx.doi.org/10.1016/S2213-2600(19)30198-5).

<sup>60</sup> Young T. et al: Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort. *Sleep*. 2008 Aug 1; 31(8): 1071–1078

<sup>61</sup> Campos-Rodriguez and al., Mortality in obstructive sleep apnea-hypopnea patients treated with positive airway pressure. *Chest*. 2005 Aug;128(2):624-33; Long-term effects of nasal continuous positive airway pressure therapy on cardiovascular outcomes in sleep apnea syndrome. *Chest*. 2005 Jun;127(6):2076-84.

initially focusing on certain target countries, such as Germany, which is the company's first target market, as well as in Australia and New Zealand. As far as the United States is concerned, the Company is in discussions with the FDA to agree on the regulatory pathway for the Genio® system in the United States.

The Company's commercial strategy will be tailored to suit local market needs in order to maximize therapy penetration and expansion.

## **9.2 Current trading developments and recent trends**

The Company received the final decision from the federal joint committee (G-BA) on 5 March 2020 confirming that the Genio® system is now entitled to join the existing NUB. The Company generated its first revenue from commercial sales in Germany in July 2020.

In March 2020, the World Health Organisation characterized COVID-19 as a pandemic. This has affected the course of business of the Company. This exceptional situation has required exceptional measures. Governmental safety guidelines have been implemented in all Nyxoah entities. Production activities have not stopped in the Tel Aviv facility. Support functions (R&D, QA&RA) also continued but with reduced capacity. Elective surgeries were on-hold from March to August 2020 in certain geographies across Europe and Australia but are selectively re-opening. Study centers and Centers of Excellence may not perform elective surgeries should COVID-19 cases increase locally. Although the Company is monitoring developments relating to the COVID-19 situation closely, the ultimate impact of COVID-19 on the Company's business is uncertain at this time and will depend on future developments, which are highly uncertain and cannot be predicted.

## **9.3 Factors affecting the results of operations**

### **9.3.1 Regulatory approvals**

Before the Company can begin generating revenue from sales of the Genio® system in the countries in which it intends to market and sell the system, it must receive regulatory approval in those countries. The Company obtained a CE-Mark approval for the Genio® system in March 2019 and intends to first commercialize the product in Europe, Australia and New Zealand. In Australia, the company expects TGA approval in Q4 2020. The Company intends to focus its European commercialization activities and efforts initially on a limited number of countries that have been selected based on expected market access and therapy adoption for hypoglossal nerve stimulation and openness in general to embrace innovation.

The Company believes that it is likely to receive full reimbursement from local health authorities in the following countries, on which it is focusing as its initial target markets, starting in 2020: Germany, Australia and New Zealand, Spain, France, Netherlands, Nordic countries, Belgium, UK and Switzerland. The Company will make the Genio® commercially available for patients through country-specific innovation funding pathways.

The Company is in discussions with the FDA to agree on the regulatory pathway for the Genio® system in the United States. On 23 June 2020, the FDA approved the Company's IDE application, allowing the Company to commence its pivotal DREAM study of the Genio® system to support the system's marketing ap-

proval in the United States. Approval was granted under a CMS category B. Category B (Non-experimental/investigational), refers to a device for which initial questions of safety and effectiveness of that device type have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for such type of device.

In parallel, the Company will actively seek new opportunities, monitor market evolution and develop dedicated tactics and plans to keep developing new markets, identify additional regions with promising market potential for the Genio® system and establish proper reimbursement pathways.

### **9.3.2 Revenue growth and expansion**

Based on its strategy to target selected countries in Europe, the Company started to generate revenue from sales of the Genio® system in July 2020. Future revenue growth will depend on patient and physician acceptance of the Genio® system, reimbursement coverage and the expansion of the sales and marketing organization in each market.

In markets where the Genio® system is approved for marketing, the Company intends to commercialize the Genio® system using a distribution model that will be tailored by country, to maximize country specific market entrance requirements and needs. Depending on the country, in order to provide OSA patients the quickest access to the Genio® system, the Company will sell the Genio® system using either a direct sales force or indirect marketing models.

For the direct sales force model, the Company currently estimates that, in the years following the commercialization, one key account manager will be able to cover around 45 to 55 new patients annually, spread over two to three implant sites, which would correspond to €1 million in revenue per year when calculated at an estimated hypoglossal nerve stimulation system (i.e. the Inspire Hypoglossal Nerve Stimulation System) average selling price of €20,000.

As the Company scales up the business within three to five years of opening and developing its Centers of Excellence, the Company expects to hire field sleep experts who will assist key account managers and be responsible for managing the therapy optimization parameters during sleep nights.

Based on extended internal market research and interaction with major sleep centers, the Company believes that each Center of Excellence could have, on average, 300 new moderate-to-severe OSA patients per year. Of these patients, the Company estimates that approximately 20% become eligible for hypoglossal nerve stimulation therapy. When calculating the potential number of Centers of Excellence in a country, the Company believes that on average, in a mature market, it will have one center of excellence per 1 million inhabitants. Considering that CPAP compliance and the need for alternatives exists on a global scale, no differences across regions and countries can be ascertained.

### **9.3.3 Evolution of cost base**

In line with market practice in the medical devices industry, the Company is initially targeting to generate a gross margin of at least 80% on sales of units of the Genio® system, which is slightly above margins of others in the neuromodulation field. After the commercial launch, if the Company is able to grow sales in

line with its expectations, it expects that the margin will improve over time as the production volume increases.

#### **9.3.4 Expenses related to clinical trials**

The Company has invested significant resources in clinical studies to demonstrate the safety and efficacy of the Genio® system. The Company has ongoing clinical trials in Europe, Australia and New Zealand, and expects to commence a clinical trial in the United States for FDA approval in the second half of 2020, and therefore expects to continue to have significant clinical expenses in future periods.

The duration, costs and timing of these studies, and accordingly, the Company's clinical expenses, depend on a variety of factors that include, but are not limited to the following:

- the clinical study costs per patient;
- the number of patients that participate in the clinical studies;
- the number of sites included in clinical studies and the type of site;
- the countries in which the clinical studies are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by the relevant regulatory authorities;
- the duration of any patient follow-up, and
- the timing and receipt of regulatory approvals.

In particular, in the United States, costs vary significantly across potential clinical sites. Hospital care costs are generally much more expensive in the United States than in Europe, and also vary significantly across Europe.

### **9.4 Key income statement items**

#### **9.4.1 Revenue**

During the period under review in the financial statements, the Company generated € 0.00 revenue. The Company sold the first units of the Genio® system in July 2020. Therefore, the Company will book revenue from the sales of the Genio® system in the second half of financial year 2020.

#### **9.4.2 General and administrative expenses**

The principal components of general and administrative expenses are salaries and related costs for personnel and external consultants in executive, finance, accounting, tax, audit, legal and human resources functions and their respective external advisers. General and administrative expenses also include the costs related to the general information and communication technologies as well as lease, rental, insurance and general maintenance expenses. General and administrative expenses are expected to increase as a result of becoming a public company and in line with the expansion of the Company's business.

### **9.4.3 Research and development expenses**

The Company's research and development expenses primarily include employee-related costs, such as salaries, benefits and travel expenses, of its employees, as well as costs related to external consultants and suppliers involved in the development of design of the Genio® system. Research and development expenses are expected to increase as result of the development of the next generation of the Genio® system.

In line with market practice, the Company is of the opinion that development expenditures meet the capitalization criteria as of March 2019 because the Company obtained the CE-Mark allowing it to commercialize the Genio® system in the EU market. Accordingly, development intangible assets will be recognized in the financial statements from this date.

### **9.4.4 Clinical expenses**

During the periods presented, the Company invested significant resources in clinical studies to demonstrate the safety and efficacy of the Genio® system. These costs primarily include the following:

- employee-related expenses, including the following salaries, benefits, bonuses and travel expenses;
- the cost of pre-clinical and clinical study activities performed by third parties, including hospitals, laboratories and physicians;
- the cost of outside consultants who assist with pre-clinical and clinical studies and medical affairs; and
- the cost of the Genio® systems used in the clinical studies.

The Company has ongoing clinical trials in Europe, Australia and New Zealand. It also expects to commence a clinical trial in the United States for FDA approval in the second half of 2020, and therefore expects to continue to have significant clinical expenses in future periods.

### **9.4.5 Quality assurance and regulatory expenses**

The costs of obtaining and maintaining regulatory approval for the Genio® system are included within quality assurance and regulatory expenses. Employee-related costs, such as salaries, benefits and travel expenses, of the employees are a key part of quality and regulatory expenses. The cost of regular audits and regulatory filings, internal and external costs related to testing and validation, as well as costs associated with external consultants, are also included within quality assurance and regulatory expenses. Changes in regulations or standards (including, for example, the introduction of the Medical Device Regulation) may lead to additional quality assurance and regulatory expenses.

### **9.4.6 Patents fees & related expenses**

Patents fees & related expenses consist primarily of patent prosecution costs, annuities, consulting services, costs of foreign associates and innovative initiatives. These expenses also include employee compensation, such as salaries, benefits and travel expenses.

### **9.4.7 Therapy development expenses**

The Company's therapy development team is focused on the successful penetration in targeted markets, such as Germany, Australia and New Zealand, Belgium, Spain, France, the Netherlands, the United Kingdom, the Nordic countries and Switzerland.

In addition to the direct costs associated with its therapy development team, the Company conducts promotional activities using both conventional and social media tools to raise awareness of the Genio® system among the medical community, patients and other third parties. These costs are recorded directly within therapy development expenses.

#### **9.4.8 Manufacturing expenses**

The Company completes the final assembly step of all devices and tests them at its facility in Tel Aviv. The other manufacturing steps are all sourced externally as are all sub-components such as batteries, printed circuit boards and electronic components. The Company includes the cost of producing the Genio® system (including labor expenses) in manufacturing expenses.

The Company is working to improve the manufacturing process of the Genio® system as well as reduce the cost of the system. It is exploring production cost reduction by optimizing and internalizing manufacturing processes and through the realization of purchasing efficiencies as production volumes increase.

#### **9.4.9 Net financial result**

The Company's finance costs include interest costs less interest income and also include foreign exchange gains/losses related to expenses made in currencies other than the euro.

#### **9.4.10 Income tax**

Since its inception, the Company has not made profits and, as a result, has not paid any material corporate income taxes in Belgium. The Company's accumulated tax losses can in principle be used to offset part of future tax profits. However, because of the development stage of the Company and the lack of visibility that the Company will generate taxable profits within the foreseeable future, no tax losses carried forward have been recorded as deferred tax assets in the Company's financial statements (IFRS) to date.

In Belgium, the Company benefits from the exemption from professional withholding taxes on part of the remuneration paid to scientific personnel.

On 9 February 2017, a law was approved in Belgium that allows Belgian companies to exempt 85% of their patent income from corporate income tax starting from 1 July 2016 if such income is deemed to derive from intellectual property which is internally generated. In the case of acquired intellectual property, the patent income that will be eligible for tax reduction will be reduced by the relevant depreciation on the acquired intellectual property. In the future, the Company intends to apply for the necessary ruling to optimize its corporate tax rate by benefiting to a certain extent from this favorable tax regime.

### **9.5 Operating results**

The following table details information relating to the Company's operating results for the six-month periods

ended 30 June 2020 and 2019 and the years ended 31 December 2019, 2018 and 2017.

<i>(in € 000)</i>	For the six-month period ended 30 June		For the year ended 31 December		
	2020	2019	2019	2018	2017
Revenue	-	-	-	-	-
Cost of goods sold	-	-	-	-	-
General and administrative expenses	(2,063)	(1,109)	(3,027)	(2,339)	(2,192)
Research and development expenses	(56)	(527)	(630)	(1,385)	(1,505)
Clinical expenses	(509)	(480)	(848)	(2,523)	(2,110)
Manufacturing expenses	(207)	(273)	(489)	(1,089)	(803)
Quality assurance and regulatory expenses	(86)	(204)	(227)	(680)	(882)
Patents Fees & Related	(107)	(93)	(267)	(594)	(533)
Therapy Development expenses	(761)	(319)	(902)	(338)	(495)
Other operating income / expenses	184	(184)	(126)	498	(1,623)
<b>Operating loss for the period</b>	<b>(3,605)</b>	<b>(3,189)</b>	<b>(6,516)</b>	<b>(8,450)</b>	<b>(10,143)</b>
Finance income	82	26	71	29	25
Finance expenses	(416)	(385)	(740)	(617)	(216)
<b>Loss for the period before taxes</b>	<b>(3,939)</b>	<b>(3,548)</b>	<b>(7,185)</b>	<b>(9,038)</b>	<b>(10,334)</b>
Taxes	(24)	(18)	(70)	(41)	(37)
<b>Loss for the period</b>	<b>(3,963)</b>	<b>(3,566)</b>	<b>(7,255)</b>	<b>(9,079)</b>	<b>(10,371)</b>
<b>Loss attributable to equity holders</b>	<b>(3,963)</b>	<b>(3,566)</b>	<b>(7,255)</b>	<b>(9,079)</b>	<b>(10,371)</b>
Other comprehensive income Items that may be subsequently reclassified to profit or loss					
Currency translation differences	(89)	60	168	(24)	(3)
<b>Total comprehensive loss for the year, net of tax</b>	<b>(4,052)</b>	<b>(3,506)</b>	<b>(7,087)</b>	<b>(9,103)</b>	<b>(10,374)</b>
<b>Loss attributable to equity holders</b>	<b>(4,052)</b>	<b>(3,506)</b>	<b>(7,087)</b>	<b>(9,103)</b>	<b>(10,374)</b>

### 9.5.1 Operating results for the six-month periods ended 30 June 2020 and 2019

#### a. Revenue and cost of goods sold

In the periods under review, the Company did not commercially sell any units of the Genio® system and therefore generated € 0.00 revenue.

Likewise, the Company did not manufacture any units of the Genio® system for commercial sale and therefore, the cost of goods sold is € 0.00 across the periods under review.

#### b. General and administrative expenses

General and administrative expenses for the six-month period ended 30 June 2020 increased by 86%, to €2.06 million from €1.11 million for six-month period ended 30 June 2019 as a result of an increase in staff cost and in professional services. These services are related to the February 2020 capital increase.

#### c. Research and development expenses

Before capitalization of €0.61 million and €0.76 million for the six-month period ended 30 June 2020 and 2019 respectively, research and development expenses for the six-month period ended 30 June 2020 decreased by 49%, to €0.66 million from €1.29 million for six-month period ended 30 June 2019 explained

by the fact that costs related to research and development expenses were booked in July 2020 without impacting June 2020 figures.

**d. Clinical expenses**

Before capitalization of €1.05 million and €0.52 million for the six-month period ended 30 June 2020 and 2019 respectively, clinical expenses for the six-month period ended 30 June 2020 increased by 56%, to €1.56 million from €1.00 million for six-month period ended 30 June 2019 as a result of an increase of the clinical study expenses and the increase of the clinical staff. These expenses are related to the BETTER SLEEP study in Australia, the initiation of the EliSA long-term study in Europe and the IDE submission to obtain FDA approval to start the DREAM study.

**e. Quality assurance and regulatory expenses**

Before capitalization of €0.51 million and €0.25 million for the six-month period ended 30 June 2020 and 2019 respectively, quality assurance and regulatory expenses for the six-month period ended 30 June 2020 increased by 33%, to €0.60 million from €0.45 million for six-month period ended 30 June 2019 as a result of the scaling-up of the preparation of the commercialization and of the manufacturing process.

**f. Patents fees & related expenses**

Before capitalization of €0.16 million and €0.14 million for the six-month period ended 30 June 2020 and 2019 respectively, patents fees and related expenses for the six-month period ended 30 June 2020 increased by 14%, to €0.27 million from €0.23 million for six-month period ended 30 June 2019 as a result of a slight increase in prosecution and outsourcing costs.

**g. Therapy development expenses**

Therapy development expenses for the six-month period ended 30 June 2020 increased by 138%, to €0.76 million from €0.32 million for six-month period ended 30 June 2019 as a result of an increase of staff and outsourcing costs relating to the preparation of the commercialization of the Genio® system after obtaining the CE Mark in March 2019.

**h. Manufacturing expenses**

Before capitalization of €1.20 million and € 0.36 million for the six-month period ended 30 June 2020 and 2019 respectively, manufacturing expenses for the six-month period ended 30 June 2020 increased by 124%, to € 1.41 million from € 0.63 million for six-month period ended 30 June 2019 as a result of an increase of headcount and an increase of manufacturing expenses to produce devices in order to support the clinical trials and to start the commercialization.

**i. Other operating income / expenses**

In the six-month period ended 30 June 2020, the Company had other operating income of €0.18 million. In the six-month period ended 30 June 2019, the Company had an operating loss of €0.18 million as a result of the impact of the initial measurement and re-measurement of recoverable cash advances.

## **9.5.2 Operating results for the years ended 31 December 2019, 2018, 20187**

### **a. Revenue and cost of goods sold**

In the periods under review, the Company did not commercially sell any units of the Genio® system and therefore generated € 0.00 revenue.

Likewise, the Company has not manufactured any units of the Genio® system for commercial sale and therefore, the cost of goods sold is € 0.00 across the periods under review.

### **b. General and administrative expenses**

General and administrative expenses increased by 30%, from €2.3 million in 2018 to €3.0 in 2019, mainly due to an increase of staff costs.

General and administrative expenses increased by 7%, from €2.2 million in 2017 to €2.3 million in 2018, mainly due to an increase of legal costs and an increase of office rental costs and costs related to external consultants, partially offset by the decrease of other operating expenses.

### **c. Research and development expenses**

Before capitalization of €1.7 million in 2019, Research and development expenses increased by 71% from €1.4 million in 2018 to €2.4 million in 2019 due mainly to the increase of development costs of the Genio® system.

Research and development expenses decreased by 8% in 2018, from €1.5 million in 2017 to €1.4 million in 2018. This decrease was due to a reduction of outsourced development expenses partially offset by an increase in staff costs.

### **d. Clinical expenses**

Before capitalization of €2.0 million in 2019, clinical expenses increased by 14% from €2.5 million in 2018 to €2.9 million in 2019 due mainly to an increase of consulting and contractor's fees to support clinical trials.

Clinical expenses increased by 20% in 2018, from €2.1 million in 2017 to €2.5 million in 2018. This increase was primarily due to an increase in clinical expenses related to the completion of BLAST OSA study.

### **e. Quality assurance and regulatory expenses**

These expenses decreased by 23%, from €0.9 million in 2017 to €0.7 million in 2018. Expenses in 2017 were higher because of additional work undertaken for the preparation of ISO certification for the Genio® system as well as main verification and validation testing for the Genio® System.

### **f. Patents fees & related expenses**

From 2017 to 2018, patents fees and related expenses increased by 11%, from €0.5 million to €0.6 million due to additional legal costs related to the settlement of assignment rights with one inventor.

**g. Therapy development expenses**

Therapy development expenses increased significantly in 2019, from €0.3 million in 2018 to €0.9 million in 2019. This increase was mainly due to the increase of headcount, the use of consultants to prepare reimbursement processes in each jurisdiction and the participation in conferences in order to promote the Company's technology.

These expenses decreased by 32% from €0.5 million in 2017 to €0.3 million in 2018. In 2017, the Company incurred additional costs because it engaged external consultants to determine the reimbursement process in the United States.

**h. Manufacturing expenses**

Before capitalization of €1.3 million in 2019, manufacturing expenses increased by 66% from €1.1 million in 2018 to €1.8 million in 2019 mainly due to an increase in manufacturing costs to support clinical trials.

Total manufacturing expenses increased by 36% from €0.8 million in 2017 to €1.1 million in 2018. This increase is mainly due to the increase of staff and manufacturing costs. Costs related to the manufacturing of devices (including material and supplier costs only) are detailed in the table below:

<i>(in €000)</i>	2019	2018	2017
Implantable Stimulator	686	295	206
Activation Chip	67	15	14
Disposable Patch	113	29	74
External Stimulator	37	52	8
Other	168	79	58
<b>Capitalized costs*</b>	<b>(800)</b>	<b>-</b>	<b>-</b>
<b>Total</b>	<b>271</b>	<b>470</b>	<b>360</b>

\* From March 2019, the Company recognizes development expenditure as an asset.

**i. Other operating income / expenses**

From 2018 to 2019, other operating expenses evolved changed from an income of €0.5 million to an expenses of €0.13 million mainly due to the development expenses incurred by the subsidiary in Australia. Such expenses were deducted from capitalized clinical expenses.

From 2017 to 2018, other operating expenses changed from expenses of €1.6 million to an income of €0.5 million because the Company received, in 2018, an amount of €0.4 million from grants and an amount of €0.2 million from other sources while the negative impact the reassessment of the reimbursable cash advances was limited to €0.1 million compared to €2.3 million in 2017 due to the initial recognition of the financial debt for the variable part of reimbursable cash advances.

## 9.6 Liquidity and capital resources

As of 31 December 2019, the Company had cash and cash equivalents of €5.9 million and an accumulated deficit of €47.1 million. As of 30 June 2020, the Company had cash and cash equivalents of €23.9 million and an accumulated deficit of €50.7 million. The Company's primary sources of capital to date have been from private financings and non-dilutive money from the Walloon Region:

- €78.9 million from shares issued in private placements to M. Robert Taub (founder), the late M. Uwe Washer, M. Jürgen Hambrecht and other private investors, Gilde Healthcare, S.R.I.W. SA<sup>62</sup> (the Regional Investment Company of Wallonia), Cochlear and ResMed Inc.;
- €7.4 million from reimbursable cash advances from the Walloon Region;
- €1.0 million from a convertible loan received from Noshag SA in June 2020, a governmental investment fund based in the Liège region;
- €1.0 million from subsidies from the Walloon Region; and
- €0.5 million from a subordinated loan from Novallia, a regional financing and development company.

As the Company continues to grow its business, it expects to fund its operations through multiple sources, including the funds raised in this Offering, cash flow from operations and non-dilutive financings such as reimbursable cash advances or subsidies.

## 9.7 Cash flows

The following table sets forth certain information regarding the principal items of the consolidated statement of cash flows for the six-month periods ended 30 June 2020 and 2019 and the years ended 31 December 2019, 2018 and 2017:

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<sup>62</sup> S.R.I.W. is the abbreviation of the Société Régionale d'Investissement de Wallonie.

<i>(in €000)</i>	For the six-month period ended 30 June		For the year ended 31 December		
	2020	2019	2019	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>					
<b>Profit/(loss) before tax for the year</b>	<b>(3,940)</b>	<b>(3,548)</b>	<b>(7,185)</b>	<b>(9,038)</b>	<b>(10,334)</b>
Adjustments for:					
Finance income	(82)	(26)	(71)	(29)	(25)
Finance costs	416	385	740	617	216
Depreciation and impairment of property, plant and equipment and right-of-use assets	259	206	433	95	87
Share-based payment transaction expense	786	6	346	28	24
Pension	-	-	30	-	-
Other non-cash items	(161)	226	70	63	2,277
<b>Net profit/(loss) before changes in working capital</b>	<b>(2,722)</b>	<b>(2,751)</b>	<b>(5,637)</b>	<b>(8,264)</b>	<b>(7,755)</b>
Changes in working capital:					
Increase (-)/Decrease (+) in Trade and other receivables	(1,127)	(411)	(1,385)	(155)	(161)
Increase (+)/Decrease (-) in Trade and other payables	(145)	175	1,143	356	(293)
<b>Cash generated from changes in operations</b>	<b>(3,994)</b>	<b>(2,987)</b>	<b>(5,879)</b>	<b>(8,063)</b>	<b>(8,209)</b>
Interests received	2	5	8	1	5
Interests paid	(4)	(16)	(33)	(29)	(37)
Income tax (paid)	(28)	(17)	(61)	(48)	(46)
<b>Net cash generated/(used) from operating activities</b>	<b>(4,024)</b>	<b>(3,015)</b>	<b>(5,965)</b>	<b>(8,139)</b>	<b>(8,287)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>					
Purchases of property, plant and equipment	(120)	(37)	(51)	(77)	(91)
Capitalization of intangible assets	(3,535)	(2,035)	(5,734)	-	-
(Increase)/Decrease of long-term deposits	-	(7)	(10)	2	-
<b>Net cash generated/(used) from investing activities</b>	<b>(3,655)</b>	<b>(2,079)</b>	<b>(5,795)</b>	<b>(75)</b>	<b>(91)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>					
Payment of principal portion of lease liabilities	(209)	(165)	(341)	-	-
Repayment of other loan	(21)	(42)	(82)	(42)	-
Recoverable cash advance received	-	47	1,196	226	1,213
Repayment of recoverable cash advance	-	(40)	(40)	(184)	(100)
Proceeds from Convertible Loan	1,000	-	-	-	-
Proceeds from issuance of shares	24,964	-	-	15,002	-
<b>Net cash generated/(used) from financing activities</b>	<b>25,735</b>	<b>(200)</b>	<b>733</b>	<b>15,002</b>	<b>1,113</b>
<b>Movement in cash and cash equivalents</b>	<b>18,056</b>	<b>(5,294)</b>	<b>(11,027)</b>	<b>6,788</b>	<b>(7,265)</b>
Effect of exchange rates on cash and cash equivalents	(31)	7	77	(88)	(76)
<b>Cash and cash equivalents at 1 January</b>	<b>5,855</b>	<b>16,805</b>	<b>16,805</b>	<b>10,105</b>	<b>17,446</b>
<b>Cash and cash equivalents at end of period</b>	<b>23,880</b>	<b>11,518</b>	<b>5,855</b>	<b>16,805</b>	<b>10,105</b>

### 9.7.1 Cash flow used in operating activities

Cash flow used in operating activities increased from €3.0 million for the six-month period ended 30 June 2019, to €4.0 million for the six-month period ended 30 June 2020. The increase of cash flow used in operating activities is mainly due to the increase of €1.7 million of other current assets which was offset by €0.6 million decrease in other receivables.

Cash flow used in operating activities decreased from €8.1 million in 2018 to €6.0 million in 2019, which corresponded with a general decrease in the loss before tax for the period from €9.0 million in 2018 to €7.2 million in 2019. The overall decrease in the loss before tax for the period was offset by an increase of €0.8 million in non-operating cash flow adjustments and a decrease of €0.4 million in the net working capital changes.

Cash flow used in operating activities decreased from €8.3 million in 2017 to €8.1 million in 2018, which corresponded with a general decrease in the loss before tax for the period from €10.3 million in 2017 to €9.0 million in 2018. The overall decrease in the loss before tax for the period was partially offset by a decrease in the fair value adjustment of financial debts and an increase in working capital in 2018 as compared to 2017.

### **9.7.2 Cash flow used in investing activities**

Cash flow used for investing activities increased from €2.1 million for the six-month period ended 30 June 2019 to €3.7 million for the six-month period ended 30 June 2020 due to capitalisation of development costs.

Cash flow used for investing activities increased by €5.7 million in 2019 due to initial recognition of the development expenditure as an asset.

Cash flow used for investing remained constant at €0.1 million from 2017 to 2018 because the level of investments in furniture and office equipment, leasehold improvements and laboratory equipment was stable across the two years.

### **9.7.3 Cash flow from financing activities**

Cash flow from financing activities was an outflow of €0.2 million for the six-month period ended 30 June 2019. It was in inflow of €25.7 million for the six-month period ended 30 June 2020 due to the capital increase of €25 million organized by the Company in February 2020 and the completion of €1 million convertible loan in June 2020.

Cash flow from financing activities decreased from €15.0 million in 2018 to €0.73 million in 2019 mainly due to payment of €0.3 million principal portion of lease liabilities which was offset by €1.2 million received from the Walloon Region as recoverable cash advance.

Cash flow from financing activities increased from €1.1 million in 2017 to €15.0 million in 2018 largely as a result €15.0 million in proceeds from the issuance of Shares.

### **9.8 Off-balance sheet liabilities**

The Company does not have any off-balance sheet liabilities.

### **9.9 Significant accounting policies**

These Consolidated Financial Statements as of and for the years ended 2019, 2018 and 2017 and the half-yearly financial statements as of and for the financial period ended 30 June 2020 have been prepared in accordance with the International Financial Reporting Standards ("**IFRS**") as adopted for use in the European Union. They are prepared on the assumption that the Company will continue to operate in the foreseeable future, and they have been prepared on basis of the historical cost convention.

For all periods up to and including the year ended 31 December 2019, the Company prepared its statutory financial statements in accordance with generally accepted accounting principles in Belgium ("**Belgian GAAP**"). The Company prepared its first Consolidated Financial Statements in accordance with IFRS as of and for the year ended 31 December 2016.

The preparation of the Consolidated Financial Statements and the Half-Yearly Financial Statements in accordance with IFRS as adopted in the EU 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 and the Half-Yearly Financial Statements. They are disclosed in note 2.3 of the annual financial statements for the period ending on 31 December 2019.

## 9.10 Qualitative and quantitative disclosure about financial risks

### 9.10.1 Liquidity risk

The Company manages liquidity risk by continuously monitoring forecast and actual cash flows.

The following table details the remaining contractual maturity for the Company's financial liabilities with agreed repayment periods, including both interest and principal cash flows as of 31 December 2019:

<i>(in €000)</i>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>more than 5 years</b>	<b>Total</b>
Long term debt obligations	392	828	2,043	11,470	14,733
Lease liability	353	618	91	38	1,100
Trade & other payables	2,853	-	-	-	2,853
<b>Total</b>	<b>3,598</b>	<b>1,446</b>	<b>2,134</b>	<b>11,508</b>	<b>18,686</b>

### 9.10.2 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.

### 9.10.3 Credit risk

Because of the absence of sales to third parties and therefore trade receivables, credit risk arises mainly from cash and cash equivalents and deposits with banks and financial institutions. The Company only works with international reputable commercial banks and financial institutions.

### 9.10.4 Interest rate risk

The Company is exposed to interest rate risk in respect of surplus funds held on deposit. This risk is not considered to be significant. The Company is not exposed to interest rate risk in respect of its financial instrument liabilities as the interest rate is fixed.

### 9.10.5 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 euro, the functional currency of the Company.

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 balance sheet date, the impact of which is reported as a foreign exchange gain or loss in the consolidated statements of comprehensive income.

Based on the Company's foreign currency exposures noted above, a change in foreign exchange rates (NIS and AUD) would have the following impact:

	Change in foreign exchange rate	Effect on loss (before tax)		Effect on pre-tax equity	
		NIS	AUD	NIS	AUD
2019	5%	11	39	71	127
	-5%	-11	-43	-77	-141
2018	5%	11	30	56	79
	-5%	-12	-34	-62	-87
2017	5%	10	21	47	41
	-5%	-11	-23	-52	-45

## **10. MANAGEMENT AND CORPORATE GOVERNANCE**

### **10.1 Overview**

The Company has the legal form of a limited liability company (*naamloze vennootschap/société anonyme*) organized under the laws of Belgium.

This section gives an overview of the material information concerning the Board of Directors, the executive management (as defined below), the Company's employees and its corporate governance. It is based on, and discusses, relevant provisions of Belgian law in effect as at the date of this Prospectus, the Articles of Association and the Corporate Governance Charter that will be effective as of the closing of the Offering. The full text of the Articles of Association (in French, and an unofficial English translation) and the Corporate Governance Charter (in English) will be available free of charge on the Company's website ([www.nyxoah.com](http://www.nyxoah.com)) or, during their normal business hours, at the registered office of the Company.

### **10.2 Board of Directors**

#### **10.2.1 Powers, responsibilities and functioning of the Board of Directors**

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

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

The 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 (see also subsection 10.2.4 (*Committees of the Board of Directors*) below).

The 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 for the day-to-day management of the Company. The chief executive officer reports directly to the Board of Directors.

Pursuant to the Belgian CCA and the Articles of Association, the Board of Directors must consist of at least three directors. The Company's Corporate Governance Charter provides that the composition of the Board of Directors should ensure that decisions are made in the corporate interest. It should be determined on the basis of diversity, as well as complementary skills, experience and knowledge. Pursuant to the 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.

The directors are elected by the Company's general shareholders' meeting. The term of the directors' mandates cannot exceed four years. Resigning directors can be re-elected for a new term. Proposals by the Board of Directors for the appointment or re-election of any director must be based on a recommendation by the 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 knowledge, skills, experience and mediation strength. The chairperson is responsible for the leadership and the proper and efficient functioning of the Board of Directors. On the date of this Prospectus, Mr. Robert Taub is chairperson of the Board of Directors and Mr. Olivier Taelman is the chief executive officer. If the Board of Directors envisages appointing a former chief executive officer as chairperson, it should carefully consider the positive and negative aspects of such a decision and disclose why such appointment is in the best interest of the Company.

The Board of Directors should meet as frequently as the interest of the Company requires, 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.

## 10.2.2 Composition of the Board of Directors

### a. Pre-offering Board of Directors

As of the date of this Prospectus, the Board of Directors is composed of six directors. The table below gives an overview of the members of the Company's Board of Directors and their term of office as at the date of this Prospectus:

Name	Age	Position	Start of Initial Term	Start of Current Term	End of Term
<b>Robert Taub</b>	73	Executive Chairman	15 July 2009	15 April 2014	Annual general shareholders' meeting of 2022
<b>Janke Dittmer</b>	43	Vice-chairman / Non-executive Director	29 June 2016	29 June 2016	Annual general shareholders' meeting of 2022
<b>Kevin Rakin</b>	60	Independent Non-executive Director	29 June 2016	29 June 2016	Annual general shareholders' meeting of 2022
<b>Donald Deyo*</b>	61	Independent Non-executive Director	23 May 2019	23 May 2019	Annual general shareholders' meeting of 2025
<b>Pierre Gianello</b>	63	Non-executive Director	27 March 2018	27 March 2018	Annual general shareholders' meeting of 2025
<b>Jan Janssen</b>	55	Non-executive Director	7 November 2018	7 November 2018	Annual general shareholders' meeting of 2024

Notes:

\* Acting as permanent representative of MedTech Execs LLC.

## b. Post-offering Board of Directors

With effect as of the closing of the Offering, the Board of Directors will be composed of the current six directors, an additional independent director and the chief executive officer, who will be (re-)appointed for a term of four years as of the closing of the Offering.

The table below gives an overview of the members of the Company's Board of Directors and their terms as at the closing of the Offering:

Name	Age	Position	Start of Term	End of Term
<b>Robert Taub</b>	73	Non-executive Director / Chairman of the Board of Directors	2020	Annual general shareholders' meeting of 2024
<b>Janke Dittmer</b>	43	Non-executive Director / Vice-chairman of the Board of Directors	2020	Annual general shareholders' meeting of 2024
<b>Kevin Rakin</b>	60	Independent Non-executive Director	2020	Annual general shareholders' meeting of 2024
<b>Donald Deyo</b>	61	Independent Non-executive Director	2020	Annual general shareholders' meeting of 2024
<b>Pierre Gianello</b>	63	Non-executive Director	2020	Annual general shareholders' meeting of 2024
<b>Jan Janssen</b>	55	Non-executive Director	2020	Annual general shareholders' meeting of 2024
<b>Jürgen Hambrecht</b>	74	Independent Non-executive Director	2020	Annual general shareholders' meeting of 2024
<b>Olivier Taelman</b>	49	Executive Director / CEO	2020	Annual general shareholders' meeting of 2024

## c. Biographies of members of the Board of Directors

The following paragraphs contain brief biographies of each of the pre-Offering and post-Offering members of the Company's Board of Directors, or in the case of legal entities being director, their permanent representatives.

**Robert Taub** is an investor in several pharmaceutical and medical device companies. He gained an MBA at INSEAD and held various general management and sales and marketing positions with Monsanto, Baxter Travenol Laboratories and the Revlon Health Care Group.

Mr. Taub later became an entrepreneur in the pharmaceutical and medical fields. Prior to the Company he co-founded and co-managed Octapharma, a human plasma protein company for 12 years. He also founded and managed Omrix Biopharmaceuticals throughout a NASDAQ IPO and an acquisition by Johnson & Johnson. He was an early investor and chairman of Neuroderm, a Parkinson's disease pharmaceutical company, throughout its IPO on NASDAQ and later sale to Mitsubishi-Tanabe.

**Janke Dittmer** is a General Partner at Gilde Healthcare, a transatlantic healthcare fund based in Utrecht, the Netherlands and Cambridge, United States. He has led several investments in medtech, diagnostics and digital health companies including neurostimulation company Sapiens (acquired by Medtronic for \$200m). 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 and

cofounded a Nanotech company in the Silicon Valley. He earned a PhD in Physics from the University of Cambridge and was a Post-Doc in Nanotechnology at the University of California, Berkeley.

**Kevin Rakin** is a co-founder and partner at HighCape Partners, a growth equity life sciences fund where he has served since 2013. From June 2011 to November 2012, Mr. Rakin was the President of Regenerative Medicine at Shire plc, a leading specialty biopharmaceutical company. Prior to joining Shire plc, Mr. Rakin served as the Chairman and Chief Executive Officer of Advanced BioHealing, Inc. from 2007 until its acquisition by Shire in June 2011. Mr. Rakin serves on the board of Oramed Pharmaceuticals, Inc. and on the board of a number of private companies. Mr. Rakin holds an MBA from Columbia University and received his graduate and undergraduate degrees in Commerce from the University of Cape Town, South Africa.

**Donald Deyo** is the President and CEO of LindaCare Inc. specialized in the developing and providing advanced remote digital health solutions for chronic disease. Prior to this, Mr. Deyo served as President and CEO for Fempulse Corporation, involved in developing bioelectronic medicine (neuromodulation) therapies for women's health concerns, and Medallion Therapeutic, Inc. after a 3-decade career with Medtronic, Inc., the world's largest medical device company where he served in various executive leadership roles. While with Medtronic, Mr. Deyo was 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 for \$200m). He has earned a B.Sc. in Computer Engineering and an MBA.

**Prof. Pierre Gianello** was awarded as Doctor in Medicine, Surgery and Obstetrics at the Université Catholique de Louvain (Belgium). He acquired his education in abdominal surgery at the Cliniques Universitaires Saint-Luc in Brussels and at the hospital de La Croix-Rousse de Lyon, France. He completed his post-doc training at the Massachusetts General Hospital, Harvard Medical School, Boston (United States) in the Transplant Biology Research Centre managed by Prof. David Sachs. In 1997, he 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 at Université Catholique de Louvain. He was then elected Dean of Research from 2006 to 2009 and Vice-Rector from 2009 up to 2011. He is today the general coordinator of Research of the Health Sciences Sector at the Université Catholique de Louvain, Brussels and Councilor of the vice-rector in the research and on the international stage at the Université Catholique de Louvain, Brussels. Professor Gianello is a prize-winner of about ten scientific prizes and is the author of more than 200 published manuscripts in peer reviewed scientific journals.

**Jan Janssen** is the Chief Technology Officer at Cochlear Limited, global market and technology leader in im-plant-able hearing devices. Member of the executive leadership team at Cochlear, Mr. Janssen is accountable for Research & Development, Quality, Regulatory and Business Development and is leading a team of over 500 team members. As part of his R&D accountability he leads a global team of highly qualified engineers and scientists who implement the Research and Development strategy, which encompasses identifying and developing cutting-edge technologies and commercial products. 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 in 2005 and appointed Cochlear Chief Technology Officer in 2017 with added responsibility for Business Development. In 2019 his role expanded to include executive level accountability for Quality and Regulatory Affairs at Cochlear. He has earned a M.Sc. in Micro-Electronics Engineering from KIHA and a M.Sc. in Telecommunication Engineering from KU Leuven.

**Dr. Jürgen Hambrecht**, born 1946 in Reutlingen, Germany, is married and has four children. He obtained his doctorate in Chemistry in 1975 from the University of Tübingen, Germany. Hambrecht served BASF in various responsibilities around the world for almost 45 years, lastly as Chairman of the Supervisory Board from 2014 until 2020. Hambrecht is Chairman of the Supervisory Board of Trumpf GmbH & Co. KG and Member of the Supervisory Boards of Daimler AG and Daimler Truck AG as well as of Aya Gold & Silver Inc.

**Olivier Taelman** joined the Company in July 2019 as chief operating and commercial officer and was subsequently appointed as the Company's CEO in November 2019. He holds 15+ years of experience in Medical Device Industry and seven years in the Pharmaceutical Industry working for global leading companies such as Eli Lilly and Sanofi Aventis leading specific business units. Prior to joining the Company, Mr. Taelman was responsible as Vice President Europe for market access and commercialization of SPG Neuromodulation at Autonomic Technologies treating patients with severe headache. Other important tasks in this role were the development of Key Opinion Leaders & Investor Relations management. Mr. Taelman was also part, as Business Director Neuromodulation, of the development of the European commercial structure at Nevro, a Silicon Valley Neuromodulation company active in Spinal Cord Stimulation going through a successful NASDAQ IPO, becoming a \$ 1.8 billion company. Prior to Nevro, Mr. Taelman built his Med Tech career during 9 years at Medtronic, leading seven Western European countries. Mr. Taelman holds an executive MBA from the Wharton University and won several sales awards such as Presidents club member at Medtronic and Eli Lilly.

#### **d. Additional information on the members of the Board of Directors**

Reference is made to section 10.3.5 (*Other mandates*) for an overview of the names of all companies and partnerships in which the abovementioned members of the Board of Directors are, or have been in the previous five years, a member of the administrative, management or supervisory bodies or partner at any time (excluding any mandates held within the subsidiaries of the Issuer).

Reference is made to section 10.3.6 (*Absence of convictions*) for the litigation statement concerning the members of the Board of Directors.

The business address of the pre-Offering and post-Offering members of the Company's Board of Directors is the registered office of the Company, located at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

#### **10.2.3 Share ownership and intention to participate in the Offering**

Immediately prior to the closing of the Offering, the following non-executive directors (based on the pre-Offering composition of the Board of Directors) own directly or indirectly the following Shares and/or outstanding ESOP Warrants in the Company:

Name	Function	Amount of Shares	Amount of 2016 ESOP Warrants
Kevin Rakin <sup>63</sup>	Independent Non-executive Director	43,000	54
Donald Deyo	Independent Non-executive Director	17,000	54
Pierre Gianello	Non-executive Director	/	12

The following directors are representatives of shareholders or affiliates of the shareholders of the Company leading up to this Prospectus: (i) Robert Taub is the permanent representative of MINV SA, (ii) Janke Dittmer is the general partner at Gilde Healthcare Partners B.V., an affiliate of Coöperatieve Gilde Healthcare III Sub-Holding U.A. and Coöperatieve Gilde Healthcare III Sub-Holding 2 U.A. and (iii) Jan Janssens is the Chief Technology Officer at Cochlear Limited.

Except for the Subscription Commitments that were provided by Robert Taub, Kevin Rakin and Donald Deyo (see Part 14 – (The Offering), section 14.3 (*Pre-commitments by the Participating Investors*)), the Company has not received any indication that any of its non-executive directors (based on the post-Offering composition of the Board of Directors) or, in case the non-executive directors are legal entities, their permanent representatives, intends to purchase any Offered Shares.

The Company intends to award Share-based incentives to the non-executive directors, upon advice of the remuneration committee.

For an overview of the Share and ESOP Warrants ownership of executive Directors and management team, see section 10.3.4 (*Share ownership and intention to participate in the Offering*).

#### 10.2.4 Committees of the Board of Directors

The Board of Directors has established four board committees subject to and with effect as of the closing of the Offering, 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.

##### a. Audit committee

The audit committee consists of three directors. According to the Belgian CCA, all members of the audit committee must be non-executive directors, and at least one member must be independent within the meaning of provision 3.5 of the Belgian Code on Corporate Governance. The chairperson of the audit committee is to be appointed by the members of the audit committee. Subject to and with effect as of the closing of the

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<sup>63</sup> The 43,000 Shares and 54 2019 ESOP Warrants mentioned here are the only Shares and ESOP Warrants held by Kevin Rakin. It does not include the 43,000 Shares held by Kevin L. Rakin Irrevocable Trust, of which family members of Kevin Rakin are the beneficiaries. Kevin Rakin does not control Kevin L. Rakin Irrevocable Trust and is not a beneficiary thereof.

Offering, the following directors will be the members of the audit committee: Kevin Rakin, Donald Deyo and Jürgen Hambrecht. The composition of the audit committee complies with the Belgian Code on Corporate Governance, which requires that a majority of the members of the audit committee are independent.

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

The role of the audit committee is to:

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

The audit committee should have at least four regularly scheduled meetings each year. The audit committee regularly reports to the 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 the corporate bodies of the Company, the statutory auditor must discuss, at the request of the statutory auditor, or at the request of the audit committee or of the 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 the internal financial control system of the Company.

#### **b. Remuneration committee**

The remuneration committee consists of at least three directors. 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 the Board of Directors or another non-executive director appointed by the committee. Subject to and with effect as of the closing of the Offering, the following directors will be the members of the remuneration committee: Robert Taub, Donald Deyo and Jürgen Hambrecht.

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

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.

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.

#### **c. Nomination committee**

The nomination committee consists of at least three directors. 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 the Board of Directors or another non-executive director appointed by the committee. Subject to and with effect as of the closing of the Offering, the following directors will be the members of the nomination committee: Janke Dittmer, Donald Deyo and Jürgen Hambrecht.

The role of the nomination committee is to:

- make recommendations to the Board of Directors with regard to the appointment of directors and members of the executive management;
- make recommendations to the Board in relation to the assignment of responsibilities to the executives;

- prepare plans for the orderly succession of board members;
- lead the re-appointment process of board members;
- ensure that sufficient and regular attention is paid to the succession of executives;
- ensure that appropriate talent development programmes and programmes to promote diversity in leadership are in place.

**d. Science & technology committee**

The science & technology committee consists of at least three directors. Subject to and with effect as of the closing of the Offering, the following directors will be the members of the science & technology committee: Jan Janssen, Janke Dittmer, Donald Deyo, and Pierre Gianello.

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

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

**e. Independent directors**

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.

The resolution appointing the director must mention the reasons on the basis of which the capacity of independent director is granted.

Subject to and with effect as of the closing of the Offering, Kevin Rakin, Donald Deyo, and Jürgen Hambrecht will be the Company's independent directors.

The Company is of the view that the independent directors that will enter into office at the closing of the Offering comply with each of the criteria of the Belgian CCA and Belgian Code on Corporate Governance. The Company is indeed of the opinion that, for the purposes of assessing the independence of Donald Deyo, the fees paid on a yearly basis to MedTech Execs LLC (director until closing of the Offering, permanently represented by Donald Deyo) for its membership in the project steering committee of Cochlear do not constitute a significant remuneration within the meaning of the independence criteria mentioned under d) above (see section 10.2.4e (*Committees of the Board of Directors*)). The Board of Directors will also disclose in its annual report which directors it considers to be independent directors. An independent director who ceases to satisfy the requirements of independence must immediately inform the Board of Directors thereof.

### **10.3 Executive Management Team**

#### **10.3.1 CEO**

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

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

### 10.3.2 Members of the executive management team

Subject to and with effect as of the closing of the Offering, the executive management will consist of the following members:

Name	Age	Position
<b>Olivier Taelman</b>	49	CEO
<b>Fabian Suarez Gonzalez*</b>	47	CFO

Notes:

\* Acting via ActuaRisk Consulting SRL.

**Olivier Taelman** joined the Company in July 2019 as chief operating and commercial officer and was subsequently appointed as the Company's CEO in November 2019. He holds 15+ years of experience in Medical Device Industry and seven years in the Pharmaceutical Industry working for global leading companies such as Eli Lilly and Sanofi Aventis leading specific business units. Prior to joining the Company, Mr. Taelman was responsible as Vice President Europe for market access and commercialization of SPG Neuromodulation at Autonomic Technologies treating patients with severe headache. Other important tasks in this role were the development of Key Opinion Leaders & Investor Relations management. Mr. Taelman was also part, as Business Director Neuromodulation, of the development of the European commercial structure at Nevro, a Silicon Valley Neuromodulation company active in Spinal Cord Stimulation going through a successful NASDAQ IPO, becoming a \$ 1.8 billion company. Prior to Nevro, Mr. Taelman built his Med Tech career during 9 years at Medtronic, leading seven Western European countries. Mr. Taelman holds an executive MBA from the Wharton University and won several sales awards such as Presidents club member at Medtronic and Eli Lilly.

**Fabian Suarez Gonzalez** (acting via ActuaRisk Consulting SRL) is the Company's CFO. He joined the Company in 2014 to take the leadership of the finance department and the responsibility for other functions, such as legal, infrastructure management, IT, human resources and payroll, administration and some operational responsibilities. Since he joined the Company, it raised €40M in equity and non-dilutive funding. He is an experienced executive, having held senior roles in several private equity firms between 2005 and 2014 (as a manager and/or board member), 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 for which he supervised due diligence processes related to acquisitions and asset sales. Prior to this, he served as 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.

### 10.3.3 Additional information on the members of the executive management team

Reference is made to section 10.3.5 (*Other mandates*) for an overview of the names of all companies and partnerships in which the abovementioned members of the executive management team are, or have been in the previous five years, a member of the administrative, management or supervisory bodies or partner at any time (excluding any mandates held within the subsidiaries of the Issuer).

Reference is made to section 10.3.6 (*Absence of convictions*) for the litigation statement concerning the members of the executive management team.

The business address of the members of the Company's executive management team is the registered office of the Company, located at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

### 10.3.4 Share ownership and intention to participate in the Offering

The table below provides an overview of the number of Shares and ESOP Warrants which each member of the executive management (based on the pre-Offering composition of the executive management) holds on the date of this Prospectus or that are held by him on the date of this Prospectus.

Name	Function	Number of Shares	Number of ESOP Warrants
Robert Taub	Executive Chairman	2,641,000	/
Olivier Taelman	CEO	0	1 2013 ESOP Warrant 299 2018 ESOP Warrants 320,000 2020 ESOP Warrants
Fabian Suarez*	CFO	17,000	50 2016 ESOP Warrants

Notes:

\* Acting via ActuaRisk Consulting SRL, it being understood, however, that the Shares and ESOP Warrants are held by Fabian Suarez Gonzalez personally.

For an overview of the features of the Company's ESOP Warrants plans, see also section 10.5 (*Description of the Share Incentive Plans*).

Except for the Subscription Commitment that was provided by Fabian Suarez (see Part 14 – (The Offering), section 14.3 (*Pre-commitments by the Participating Investors*)), the Company has not received any indication that any members of the executive management (based on the post-Offering composition of the executive management) intend to purchase Offered Shares.

### 10.3.5 Other mandates

Below is an overview of the companies (other than Nyxoah SA and its subsidiaries) in which the Company directors or the members of the executive management have been a partner or members of the executive, management or supervisory bodies in the past five years leading up to this Prospectus and an overview of the current mandates:

Name	Current mandates	Past mandates
Robert Taub	<ul style="list-style-type: none"> <li>• Director at MINV SA</li> <li>• Director at Man &amp; Science SA</li> <li>• Director at Robelga SPRL</li> <li>• Director at Maya Gold &amp; Silver Inc.</li> <li>• Director at LifeBond Ltd</li> <li>• Legal representative of MINV, director at Magnisense SE</li> <li>• Director at Nivelles Office Parc 3 SA</li> <li>• Director at Nivelles Office Parc 5 SA</li> <li>• Director at Nivelles Office Parc 7 SA</li> <li>• Director at Nivelles Office Parc 9 SA</li> <li>• Director at Nivelles Office Parc 11 SA</li> <li>• Director at Herpain Urbis Retail Holding SA</li> <li>• Director at Novozymatic SA</li> <li>• Director at Nivelles Service Center SA</li> <li>• Board member of HighCape Capital Acquisition Corp.</li> </ul>	<ul style="list-style-type: none"> <li>• Director at Neuroderm Ltd</li> <li>• Director at Nivelles Office Parc 1 SA</li> <li>• Director at Nivelles Office Parc 2 SA</li> <li>• Director at Nivelles Office Parc 4 SA</li> <li>• Director at Axis Gate SA</li> <li>• Director at Nivaxis Gate SA</li> </ul>
Janke Dittmer	<ul style="list-style-type: none"> <li>• General Partner at Gilde Healthcare Partners B.V.</li> <li>• Non-executive board director at Foundry Innovation &amp; Research Ltd</li> <li>• Non-executive board director at Lumeon Ltd</li> <li>• Non-executive Board Director at Big Health Ltd</li> <li>• Owner of Blue Hat Holding B.V.</li> </ul>	<ul style="list-style-type: none"> <li>• (Supervisory) board member at Sapiens Steering Brain Stimulation BV</li> <li>• Board member at Definiens AG</li> </ul>
Jan Janssen	<ul style="list-style-type: none"> <li>• Chief technology officer at Cochlear Limited</li> <li>• Board member at HEARing CRC</li> <li>• Board member at HearWorks CRC</li> </ul>	/
Pierre Gianello	<ul style="list-style-type: none"> <li>• Chairman at Pig For Live SA</li> <li>• Board member at Brussels life science incubator</li> <li>• Board member at SOPARTEC (UCL)</li> </ul>	<ul style="list-style-type: none"> <li>• Board member at “Fetus for Life” foundation</li> </ul>
Kevin Rakin	<ul style="list-style-type: none"> <li>• Board member at Cybrea Holding Company LLC</li> <li>• Board member at Aziyo Biologics, Inc.</li> <li>• Board member at Convexity Scientific, Inc.</li> <li>• Chairman of the Board at Oramed pharmaceuticals, Inc.</li> <li>• Board member of HighCape Capital Acquisition Corp.</li> </ul>	<ul style="list-style-type: none"> <li>• Board member at Tela Bio, Inc.</li> <li>• Board member at Histo-genics Corp</li> <li>• Board member at Collagen Matrix, Inc.</li> <li>• Board member at Cheetah Medical, Inc.</li> </ul>

Name	Current mandates	Past mandates
Donald Deyo	<ul style="list-style-type: none"> <li>• Chairman of the Board at LindaCare NV</li> <li>• Executive Chairman at LindaCare NV</li> <li>• President &amp; CEO at LindaCare Inc</li> </ul>	<ul style="list-style-type: none"> <li>• President, CEO and Board Member at Medallion Therapeutics, Inc</li> <li>• Board Member at Sapiens Steering Brain Stimulation BV</li> <li>• Board Member at TROD Medical</li> <li>• President, CEO and Board member at FemPulse Corporation</li> </ul>
Olivier Taelman	/	/
Fabian Suarez Gonzalez	<ul style="list-style-type: none"> <li>• Director at ActuaRisk Consulting SRL</li> <li>• Managing director at Stratimmo SPRL</li> <li>• Legal representative of ActuaRisk Consulting SRL, the chairman of the board at DeeCide SA</li> </ul>	/
Jürgen Hambrecht	<ul style="list-style-type: none"> <li>• Board member at Daimler AG</li> <li>• Board member at Daimler Truck AG</li> <li>• Chairman of the Supervisory Board Aya at TRUMPF GmbH &amp; Co. KG</li> <li>• Board member at Gold &amp; Silver Inc.</li> </ul>	<ul style="list-style-type: none"> <li>• Chairman of the Supervisory Board at BASF SE</li> <li>• Chairman of the Supervisory Board at Fuchs Petrolub SE</li> <li>• Board member at Nyxoah SA</li> </ul>

### 10.3.6 Absence of convictions

All the Company directors and the members of the executive management have declared that they have not been convicted of any fraudulent offences during the previous five years. All the Company directors and the members of the executive management have also declared that they have not been involved in any bankruptcies, receiverships, liquidations or companies put into administration in the previous five years as members of the administrative, management or supervisory bodies. All the directors and the members of the executive management have also stated that they have not been the subject of any official public incrimination and/or sanctions by statutory or regulatory authorities (including designated professional bodies) and have never been disqualified by a court from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer for at least the previous five years.

### 10.3.7 Conflicts of interest

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

legal provisions on conflicts of interest.

There are, on the date of this Prospectus, no potential conflicts of interests between any duties to the Company of the members of the Board of Directors and members of the executive management and their private interests and/or other duties other than the consultant agreement entered into with Robert Taub (see also Part 12 – Related party transactions).

There are no outstanding loans granted by the Company to any of the members of the Board of Directors and members of the executive management, nor are there any guarantees provided by the 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.

### **10.3.8 Dealing code**

With a view to preventing market abuse (insider dealing and market manipulation), the Board of Directors has established a dealing code subject to and with effect as of the closing of the Offering. The dealing code describes the declaration and conduct obligations of directors, members of the executive management, certain other employees and certain other persons with respect to transactions in Shares and other financial instruments of the Company. The dealing code sets limits on carrying out transactions in Shares and other financial instruments of the Company, and allows dealing by the above mentioned persons only during certain windows. The dealing code is attached to the Company's Corporate Governance Charter.

### **10.4 Remuneration and benefits**

The Company's remuneration policy is designed to:

- enable the Company to attract and retain talented employees;
- promote continuous improvement in the business; and
- reward performance in order to motivate employees to deliver increased shareholder value through superior business results.

The current remuneration practices in relation to the directors and members of the executive management are further described below in section 10.4.1 (*Board of Directors*) and section 10.4.2 (*CEO and other members of the executive management team*) respectively.

No service contracts have been entered into between the directors and members of the executive management and the Company (or any of its subsidiaries) which provide for benefits upon termination of employment.

The Company will prepare a remuneration policy pursuant to Article 7:89/1 CCA and intends to submit this policy to the general shareholders' meeting approving the annual accounts for the financial year ending on 31 December 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. The Company 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 the executive management will be remunerated pursuant to the current remuneration practices as described below in section 10.4.1 (*Board of Directors*) and section 10.4.2 (*CEO and other members of the executive management team*) respectively.

#### **10.4.1 Board of Directors**

##### **a. General**

Upon recommendation and proposal of the remuneration committee, the 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 during 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 prior recommendation of the remuneration committee (Article 7:92, first subsection of the Belgian CCA).

Notwithstanding points (i), and (ii) above, pursuant to the Company's Articles of Association, the Board of Directors is explicitly authorized to deviate from the provisions of article 7:91 of the Belgian CCA.

The general shareholders' meeting of the Company has not approved any of the matters referred to in paragraphs (i) to (iv) with respect to the remuneration of the directors of the Company upon closing of the Offering, except for the following matters which have been approved prior to the date of this Prospectus:

- The general shareholders' meeting approved that 2016 ESOP Warrants issued pursuant to the Company's 2016 Warrants plan can, under certain conditions, vest earlier than three years as of their grant, as referred to in paragraph (i) above.
- With respect to the matter in paragraph (iii) above, 2016 ESOP Warrants have been awarded to the following non-executive directors: Donald Deyo, Kevin Rakin and Pierre Gianello (see section 10.3.4 (*Share ownership and intention to participate in the Offering*) above).

#### **b. Remuneration and compensation in 2019 and up to August 2020**

In 2019 no remuneration or compensation was paid to the directors, other than (i) €50,000 paid to and €28,702,66 invoiced by MINV SA, the management company of Robert Taub, pursuant to the consultant agreement entered into on 26 September 2019 (see section 12 (*Related Party Transactions*) below), (ii) a monthly fee of €2,167 paid to Pierre Gianello pursuant to an employment agreement entered into with the Company on 31 January 2013 for his services as medical director provided in favor of the Company one day a week, (iii) a yearly fee €20,000 paid to MedTech Execs LLC (permanently represented by Donald Deyo) as director's fee<sup>64</sup> for its function as independent director if it is also member of the Cochlear project steering committee, and (iv) the reimbursement of out-of-pocket expenses, including travel and hotel expenses, incurred by the members of the Board of Directors in connection with their attendance of the Board of Directors' meetings or the performance of their mandate.

In the period as from 1 January 2020 until 31 August 2020 no remuneration or compensation was paid to the directors, other than (i) €50,000 to MINV SA, pursuant to the aforementioned consultant agreement entered into on 26 September 2019, (ii) a monthly salary of €3,225 paid to Pierre Gianello pursuant to his aforementioned employment agreement entered into on 31 January 2013 for his services as medical director provided in favor of the Company one day a week, and (iii) €5,781 to MedTech Execs LLC (permanently represented by Donald Deyo) as part of his yearly director's fee of €20,000 for its function as independent director if it is also member of the Cochlear project steering committee.

#### **c. Remuneration and compensation as of the closing of the Offering**

The remuneration and compensation of the directors that has been determined by the General Shareholders' Meeting as of the closing of the Offering, is as follows:

- Chairman –Non-executive director: an annual fixed fee of € 50,000.
- Independent directors: an annual fixed fee of € 25,000.
- The other non-executive directors: an annual fixed fee of € 25,000.
- The members of the audit committee, the remuneration committee and the science & technology committee will receive an additional annual fixed fee of € 2,500. The members of the nomination committee will not receive any additional fee for their membership of that committee.
- The member of the Cochlear project steering committee will receive an additional annual fixed fee of € 10,000.

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<sup>64</sup> The yearly director's fee of MedTech Execs LLC shall amount to €20,000 if MedTech Execs LLC is also a member of the Cochlear Steering Committee (see also Part 8 – (Business), section 8.12 (*Material Contracts*)). If MedTech Execs LLC is not a member of the Cochlear Steering Committee, the director's fee of MedTech Execs LLC shall be reduced to €10,000.

Olivier Taelman (CEO) is not remunerated for the performance of his mandate as executive director (without prejudice to his remuneration as CEO).

The Company also reimburses reasonable out of pocket expenses of directors (including travel and hotel expenses) incurred in performing the mandate of director.

There are currently no plans to change the aforementioned remuneration and compensation of the directors. However, the Company will continuously review the remuneration of its directors against market practice.

#### **10.4.2 CEO and other members of the executive management team**

##### **a. General**

The remuneration of the chief executive officer and the other members of the executive management is based on recommendations made by the 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 the 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 a motivated 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, the Company's 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 the Company and its shareholders. The Board of Directors will determine whether the targets for the variable remuneration of the members of the executive management, as set by the Board of Directors, are met. In the past, approval by the general shareholders' meeting has been obtained in relation to the Share incentive plans (see section 10.5 (*Description of the share incentive plans*) below).

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

- annual base salary/fee (fixed);
- participation in Share incentive plans; and
- a performance bonus.

In addition thereto, the CEO is entitled to pension benefits. The contributions by the Company to the pension scheme amount to 7.5% of its annual salary. He also benefits from a car and a health insurance.

The members of the executive management are also reimbursed for certain costs and expenses made in the performance of their function.

#### **b. Remuneration and compensation in 2019 and 2020**

Mr. Robert Taub (Executive Chairman until the closing of the Offering) has not received a remuneration for the performance of his functions as member of the executive management, but MINV SA, the management company of Robert Taub, has received fees pursuant to the consultant agreement entered into on 26 September 2019 (see section 10.4.1b (*Remuneration and compensation in 2019 and up to August 2020*) above and Part 12 (Related Party Transactions) below).

Mr. Olivier Taelman (CEO) is an employee of the Company. In 2019 the remuneration of the CEO as determined in its employment agreement dated 30 June 2019, as amended on 23 December 2019, consisted of the following main remuneration components:

- gross monthly salary of € 13,649.43;
- a bonus system equal to 30% of his base gross wage (being the sum of (i) his annual base salary, (ii) double his holiday pay and (iii) his year-end bonus)
- a monthly budget of € 1,300 (incl. VAT) for the leasing of a car;
- participation in a Share based incentive plan (266 2018 ESOP Warrants);
- pension/group insurance; and
- health insurance.

In 2020 the remuneration of the CEO consists of the following main remuneration components:

- gross annual salary of €260,000;
- a bonus system equal to €40,000 for 2020;

- a monthly budget of €1,300 (incl. VAT) for the leasing of a car;
- additional participation in a Share based incentive plan (1 2013 ESOP Warrant, 33 2018 ESOP Warrants and 320,000 2020 ESOP Warrants);
- pension/group insurance; and
- health insurance.

The employment agreement of Mr. Olivier Taelman was entered into for an indefinite period of time and can be terminated by either Mr. Olivier Taelman or the Company at any time subject to a prior notice (or the payment of an indemnity in lieu of notice) in accordance with the provisions of the Belgian Act of 3 July 1978 concerning Employment Contracts. The employment agreement can be immediately terminated by the Company in case of serious cause.

ActuaRisk Consulting SRL, the management company of Fabian Suarez Gonzalez, is the CFO of the Company. The Company and ActuaRisk Consulting SRL entered into a consulting agreement on 18 August 2014, as amended from time to time. In 2019 and up to May 2020, ActuaRisk Consulting SRL was entitled to a monthly fee of €16,500 (excl. VAT) (i.e., an annual fee of €198,000 (excl. VAT)). As of 1 May 2020, ActuaRisk Consulting SRL is entitled to an annual fee of €230,000 (excl. VAT).

ActuaRisk Consulting SRL is entitled to a success fee of €50,000 (excl. VAT) in case of closing of the Offering.

In addition, ActuaRisk Consulting SRL shall be entitled to a variable compensation that will become payable upon an "Exit of the Company", unless ActuaRisk Consulting SRL becomes a bad leaver as defined in said agreement prior to the Exit. The Offering qualifies as an "Exit of the Company" under said agreement.

This variable compensation payable by the Company in the event of an Exit, will be paid in cash and will be calculated as follows:

<b>Exit Value (€)</b>	<b>Variable compensation (in % of the Exit Value, excl. VAT)</b>
< 65,000,000	0%
≥ 65,000,000 < 300,000,000	0.35%
≥ 300,000,000	0.5%

The "**Exit Value**" pursuant to with this Offering will be equal to the closing trading price of the Shares of the Company at the time ActuaRisk Consulting SRL will invoice the Company, multiplied by the number of then outstanding Shares of the Company. ActuaRisk Consulting SRL cannot invoice the Company within the first 6 months following this Offering. If the Company is acquired through a public takeover offer, the Exit Value shall be equal to the value of 100% of the Share capital of the Company on a fully-diluted basis in the framework of such acquisition. If the Exit takes the form of 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 that is sold in the Exit (e.g. If the Exit results from a sale of 60% of the Shares, ActuaRisk Consulting SRL 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 in the different phases of the Exit.

The consulting agreement with the CFO provides that the agreement may be terminated (i) by either party with a six months' prior notice for any reason and no reason or (ii) immediately (without notice period) by the non-breaching party in case of a material breach by a party of its covenants, obligations or duties under the consulting agreement, such as gross negligence, wilful misconduct and fraud.

Fabian Suarez Gonzalez has also been granted 50 2016 ESOP Warrants.

**c. Remuneration and compensation as of closing of the Offering**

There are currently no plans to change the remuneration policy or remuneration of members of the executive management. However, the Company will continuously review the remuneration of members of the executive management against market practice.

**10.5 Description of the share incentive plans**

**10.5.1 Description**

The Company has currently outstanding ESOP Warrants pursuant to four outstanding stock based incentive plans, namely (i) the ESOP Warrants that were granted to employees, officers, directors, consultants and advisors of Nyxoah SA or its present or future subsidiaries (the "**Subsidiaries**") pursuant to the 2013 Share Incentive Plan (the "**2013 ESOP Warrants**"), (ii) the ESOP Warrants that were granted to employees, officers, directors, consultants and advisors of the Company and its Subsidiaries pursuant to the 2016 Warrants plan (the "**2016 ESOP Warrants**"), (iii) the ESOP Warrants that were granted to employees, officers, directors, consultants and advisors of the Company and its Subsidiaries pursuant to the 2018 Warrants plan (the "**2018 ESOP Warrants**") and (iv) the ESOP Warrants that were granted to employees, officers, directors, consultants and advisors of the Company and its Subsidiaries pursuant to the 2020 Warrants plan (the "**2020 ESOP Warrants**").

The following Directors and members of executive management of the Company own ESOP Warrants in the Company:

<b>Name</b>	<b>Function</b>	<b>Number of ESOP Warrants</b>	<b>Type of ESOP Warrants plans</b>
<b>Fabian Suarez Gonzalez*</b>	CFO	50	2016 ESOP Warrants
<b>Kevin Rakin</b>	Director	54	2016 ESOP Warrants
<b>Donald Deyo**</b>	Director	54	2016 ESOP Warrants
<b>Olivier Taelman</b>	CEO	1 299 320,000	2013 ESOP Warrant 2018 ESOP Warrants 2020 ESOP Warrants
<b>Pierre Gianello</b>	Director	12	2016 ESOP Warrants

Notes:

\* Acting via ActuaRisk Consulting SRL, but holding the ESOP Warrants personally.

\*\* Director as closing of the Offering and permanent representative of MedTech Execs LLC, director until closing of the

Offering. Donald Deyo holds the ESOP Warrants personally.

## 10.5.2 Currently outstanding ESOP Warrants

The number of 2013 ESOP Warrants, 2016 ESOP Warrants, 2018 ESOP Warrants and 2020 ESOP Warrants that have been granted and are still exercisable on the date of this Prospectus can be summarized as follows

Type of ESOP Warrants Plan	Number of ESOP Warrants issued	Number of ESOP Warrants lapsed, exercised or no longer available for grant	Number of ESOP Warrants outstanding	Issue date	Expiration date	Exercise Price ESOP Warrant (€)	Number and type of Shares issuable per ESOP Warrant	Aggregate number and type of Shares issuable upon exercise of outstanding ESOP Warrants
2013 ESOP Warrants <sup>65</sup>	640	479	161	03/05/2013 23/12/2014	03/05/2023 23/12/2024	2,585.51 <sup>a</sup> 5,966.59 <sup>b</sup>	500 <sup>e</sup> Common Shares per ESOP Warrant	80,500 common Shares
2016 ESOP Warrants	1,500	1018	482	3/11/2016	3/11/2026	2,585.32 <sup>c</sup>	500 <sup>e</sup> common Shares per ESOP Warrant	241,000 common Shares
2018 ESOP Warrants	525	206	319	12/12/2018	12/12/2028	3,259.91 <sup>d</sup> 5,966.59 <sup>b</sup>	500 <sup>e</sup> common Shares per ESOP Warrant	159,500 common Shares
2020 ESOP Warrants	550,000	0	550,000	21/02/2020	21/02/2030	11.94	1 common Share per ESOP Warrant	550,000 common Shares
<b>Total</b>								<b>1,031,000 common Shares</b>

Notes:

- <sup>a</sup> For ESOP Warrants granted prior to April 2020. This results in a subscription price of €5.17 (rounded) per new Share.
- <sup>b</sup> For 1 2013 ESOP Warrant and 33 2018 ESOP Warrants granted in April 2020. This results in a subscription price of €11.93 (rounded) per new Share.
- <sup>c</sup> This results in a subscription price of €5.17 (rounded) per new Share.
- <sup>d</sup> This results in a subscription price of €6.52 (rounded) per new Share.
- <sup>e</sup> Taking into account the Share Split at a ratio of 500:1 that was approved by an extraordinary shareholders' meeting on 21 February 2020, as further described in Part 13 - (Description of share capital and articles of association), section 13.3.2 (*Changes in the share capital since January 2016*).

## 10.5.3 Terms of the 2013 ESOP Warrants

The key features of the 2013 ESOP Warrants can be summarized as follows:

<sup>65</sup> The Company has issued 340 2013 ESOP Warrants at the Company's extraordinary general meeting of 3 May 2013 and 300 2013 ESOP Warrants at the Company's extraordinary general meeting of 23 December 2014.

- The 2013 ESOP Warrants could be granted to the employees, officers, directors, consultants and advisors of the Company and its present or future subsidiaries. *In casu*, the majority of the 2013 ESOP Warrants were granted to employees.
- The 2013 ESOP Warrants are in registered form.
- The 2013 ESOP Warrants issued on 3 May 2013 may only be transferred in accordance with the Company's Articles of Association while the 2013 ESOP Warrants issued on 23 December 2014 may not be sold, assigned, transferred, pledged or otherwise encumbered by the holder of the 2013 ESOP Warrants either voluntarily, by operation of law or otherwise.
- Each 2013 ESOP Warrant can be exercised for 500 new Shares, taking into account the Share Split at a 500:1 ratio that was decided by an extraordinary shareholders' meeting on 21 February 2020.
- As set forth in the 2013 ESOP Warrants plan, in the event of a stock split of the Shares, the Company shall appropriately adjust (i) the number and class of the securities of the Company available pursuant to the 2013 ESOP Warrants plan and (ii) the number and class of securities of the Company and exercise price per Share subject to each outstanding 2013 ESOP Warrant. The adjustments shall be made to the extent that the board shall determine, in good faith, that such adjustment is necessary and appropriate.
- The 340 2013 ESOP Warrants issued on 3 May 2013 were granted for €1 each while the 300 2013 ESOP Warrants issued on 23 December 2014 were granted for free, i.e. no consideration is due upon the grant of the ESOP Warrants.
- Pursuant to the terms of the 2013 ESOP Plan, the 2013 ESOP Warrants have a duration of ten years as of their issuance. However, the respective warrant agreements relating to the grant of the 2013 ESOP Warrant stipulate a contractual expiration period of five years as of the grant. The five year period as from granting shall in no case exceed the ten year period as from issuance.
- According to the vesting schedule included in each 2013 ESOP Warrant agreement entered into with the relevant beneficiaries, 34 % of the 2013 ESOP Warrants granted vest upon the date of grant, after which the balance of 2013 ESOP Warrants will vest in equal parts on the anniversary date of 2013 ESOP Warrants agreement such that 100% of the 2013 ESOP Warrants agreement are vested on the second anniversary of the relevant 2013 ESOP Warrant agreement. Furthermore, each 2013 ESOP Warrant agreement states that the vesting of the 2013 ESOP Warrants is accelerated in the event of a merger or sale of the Company to an unaffiliated third party prior to 100% vesting of said warrants.
- Save as provided otherwise in the relevant 2013 ESOP Warrant agreement, the 2013 ESOP Warrant the vesting will stop if the beneficiary is no longer an employee, officer, director, consultant or advisor of the Company or any of its Subsidiaries.
- The 2013 ESOP Warrants can be exercised by the beneficiary at any time during the year.
- As further set forth in the relevant 2013 ESOP Warrant agreement, in case of a termination of the relationship between the beneficiary and the Company, the exercise period of the 2013 ESOP Warrants may vary depending on the circumstances under which the relationship between the beneficiary and the Company or its Subsidiary is terminated (e.g. discharge for cause, death, disability, etc.)
- The terms and conditions of the 2013 ESOP Warrants are governed by the laws of Belgium.

#### **10.5.4 Terms of the 2016 ESOP Warrants**

The key features of the 2016 ESOP Warrants can be summarized as follows:

- The 2016 ESOP Warrants could be granted to the employees, officers, directors, consultants and advisors of the Company or its Subsidiaries. *In casu*, the majority of the 2016 ESOP Warrants were

granted to employees.

- The 2016 ESOP Warrants are in registered form.
- 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. 2016 ESOP Warrants that have been pledged or encumbered in violation of the preceding shall become automatically null and void.
- Each 2016 ESOP Warrant can be exercised for 500 new Shares, taking into account the Share Split at a 500:1 ratio that was decided by an extraordinary shareholders' meeting on 21 February 2020.
- As set forth in the 2016 ESOP Warrants plan, in the event of a stock split of the Shares, the number of Shares to be issued upon the exercise of the 2016 ESOP Warrant shall be adjusted so that the holder of the 2016 ESOP Warrants shall be entitled to receive the number of common Shares upon exercise of the 2016 ESOP Warrants that such holder would have owned or have been entitled to receive had these 2016 ESOP Warrants been exercised immediately prior to the stock split of the Shares.
- The 2016 ESOP Warrants are granted for free, i.e. no consideration is due upon the grant of the ESOP Warrants.
- Pursuant to the terms of the 2016 ESOP Warrants plan, the 2016 ESOP Warrants have a duration of ten years as of their issuance. However, the respective warrant agreements relating to the grant of the 2016 ESOP Warrant stipulate a contractual expiration period of five years as from the grant of the 2016 ESOP Warrants. The five year period as from granting shall in no case exceed the ten year period as from issuance.
- Save as provided otherwise by the Board of Directors (i) one third of the 2016 ESOP Warrants granted to and accepted by a beneficiary (whereby fractions of warrants will be rounded down) shall be deemed definitively vested on the date of the granting of the warrants, (ii) one third of the warrants granted and accepted by a beneficiary (whereby fractions of warrants will be rounded down) shall be deemed definitely 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 beneficiary shall be deemed definitely vested on the second anniversary of the date of the relevant grant of the relevant warrants, it being understood that the Board of Directors can also decide to modify the vesting conditions after the granting of the 2016 ESOP Warrants, provided that the rights of the holder of the 2016 ESOP Warrants may not be restricted without the latter's consent.
- On the condition that the 2016 ESOP Warrants are vested, the 2016 ESOP Warrants can be exercised during the following periods: (i) 1 March until 31 March; (ii) 1 May until 31 May; and (iii) 1 September until 30 September of each year during which the 2016 ESOP Warrants are valid and exercisable. The 2016 ESOP Warrants will immediately vest and be exercisable during at least ten business days prior to an IPO or deemed liquidation event (e.g. transaction resulting in a change of control, merger, etc.). Consequently the 2016 ESOP Warrants will immediately vest and be exercisable ten business days prior to the closing of the Offering.
- As further set forth in the 2016 ESOP Warrants plan, in case of a termination of the relationship between the beneficiary and the Company, the exercise period and/or vesting period of the 2016 ESOP Warrants may vary depending on the circumstances under which the relationship between the beneficiary and the Company or its Subsidiary is terminated (e.g. end of mandate, discharge for cause, death, disability, etc.)
- The terms and conditions of the 2016 ESOP Warrants are governed by the laws of Belgium.

### 10.5.5 Terms of the 2018 ESOP Warrants

The key features of the 2018 ESOP Warrants can be summarized as follows:

- The 2018 ESOP Warrants could be granted to the employees, officers, directors, consultants and advisors of the Company or its Subsidiaries. *In casu*, the majority of the 2018 ESOP Warrants are granted to employees.
- The 2018 ESOP Warrants are in registered form.
- 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. 2018 ESOP Warrants that have been pledged or encumbered in violation of the preceding shall become automatically null and void.
- Each 2018 ESOP Warrant can be exercised for 500 new Shares, taking into account the Share Split at a 500:1 ratio that was decided by an extraordinary shareholders' meeting on 21 February 2020.
- As set forth in the 2018 ESOP Warrants plan, in the event of a stock split of the Shares, the number of Shares to be issued upon the exercise of the 2018 ESOP Warrant shall be adjusted so that the holder of the 2018 ESOP Warrants shall be entitled to receive the number of common Shares upon exercise of the 2018 ESOP Warrants that such holder would have owned of have been entitled to receive had these 2018 ESOP Warrants been exercised immediately prior to the stock of split of the Shares.
- The 2018 ESOP Warrants are granted for free, i.e. no consideration is due upon the grant of the ESOP Warrants.
- Pursuant to the terms of the 2018 ESOP Warrants plan, the 2018 ESOP Warrants have a duration of ten years as of their issuance. However, the respective warrant agreements relating to the grant of the 2018 ESOP Warrants stipulate a contractual expiration period of five years as from the grant of the 2018 ESOP Warrants. The five year period as from granting shall in no case exceed the ten year period as from issuance.
- Save as provided otherwise by the Board of Directors (i) one third of the 2018 ESOP Warrants granted to and accepted by a beneficiary (whereby fractions of warrants will be rounded down) shall be deemed definitively vested on the date of the granting of the warrants, (ii) one third of the warrants granted an accepted by a beneficiary (whereby fractions of warrants will be rounded down) shall be deemed definitely vested on the first anniversary of the dated of the relevant grant of the relevant warrants and (iii) the remainder of the warrants granted to and accepted by a beneficiary shall be deemed definitely vested on the second anniversary of the date of the relevant grant of the relevant warrants, it being understood that the Board of Directors can also decide to modify the vesting conditions after the granting of the 2018 ESOP Warrants, provided that the rights of the holder of the 2018 ESOP Warrants may not be restricted without the latter's consent.
- On the condition that the 2018 ESOP Warrants are vested, the 2018 ESOP Warrants can be exercised during the following periods: (i) 1 March until 31 March; (ii) 1 May until 31 May; and (iii) 1 September until 30 September of each year during which the 2018 ESOP Warrants are valid and exercisable. The 2018 ESOP Warrants will immediately vest and be exercisable during at least ten business days prior to an IPO or deemed liquidation event (e.g. transaction resulting in a change of control, merger, etc.). Consequently the 2018 ESOP Warrants will immediately vest and be exercisable ten business days prior to the closing of the Offering.
- As further set forth in the 2018 ESOP Warrant Plan, in case of a termination of the relationship

between the beneficiary and the Company, the exercise period and/or vesting period of the 2018 ESOP Warrants may vary depending on the circumstances under which the relationship between the beneficiary and the Company or its Subsidiary is terminated (e.g. end of mandate, discharge for cause, death, disability, etc.)

- The terms and conditions of the 2018 ESOP Warrants are governed by the laws of Belgium.

#### **10.5.6 Terms of the 2020 ESOP Warrants**

The key features of the 2020 ESOP Warrants can be summarized as follows:

- The 2020 ESOP Warrants could be granted to the employees, officers, directors, consultants and advisors of the Company or its Subsidiaries.
- The 2020 ESOP Warrants are in registered form.
- 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. 2020 ESOP Warrants that have been pledged or encumbered in violation of the preceding shall become automatically null and void.
- Each 2020 ESOP Warrant can be exercised for one new Share.
- As set forth in the 2020 ESOP Warrants plan, in the event of a stock split of the Shares, the number of Shares to be issued upon the exercise of the 2020 ESOP Warrant shall be adjusted so that the holder of the 2020 ESOP Warrants shall be entitled to receive the number of common Shares upon exercise of the 2020 ESOP Warrants that such holder would have owned of have been entitled to receive had these 2020 ESOP Warrants been exercised immediately prior to the stock of split of the Shares.
- The 2020 ESOP Warrants are granted for free, i.e. no consideration is due upon the grant of the ESOP Warrants.
- Pursuant to the terms of the 2020 ESOP Plan, the 2020 ESOP Warrants have a duration of ten years as of their issuance.
- Save as provided otherwise by the Board of Directors (i) one third of the 2020 ESOP Warrants granted to and accepted by a beneficiary (whereby fractions of warrants will be rounded down) shall be deemed definitively vested on the date of the granting of the warrants, (ii) one third of the warrants granted and accepted by a beneficiary (whereby fractions of warrants will 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 beneficiary shall be deemed definitively vested on the second anniversary of the date of the relevant grant of the relevant warrants, it being understood that the Board of Directors can also decide to modify the vesting conditions after the granting of the 2020 ESOP Warrants, provided that the rights of the holder of the 2020 ESOP Warrants may not be restricted without the latter's consent.
- On the condition that the 2020 ESOP Warrants are vested, the 2020 ESOP Warrants can be exercised during the following periods: (i) 1 March until 31 March; (ii) 1 May until 31 May; and (iii) 1 September until 30 September of each year during which the 2020 ESOP Warrants are valid and exercisable. The 2020 ESOP Warrants will immediately vest and be exercisable during at least ten business days prior to an IPO or deemed liquidation event (e.g. transaction resulting in a change of control, merger, etc.).
- As further set forth in the 2020 ESOP Warrant Plan, in case of a termination of the relationship

between the beneficiary and the Company, the exercise period and/or vesting period of the 2020 ESOP Warrants may vary depending on the circumstances under which the relationship between the beneficiary and the Company or its Subsidiary is terminated (e.g. end of mandate, discharge for cause, death, disability, etc.)

- The terms and conditions of the 2020 ESOP Warrants are governed by the laws of Belgium.

## **10.6 Corporate Governance Code**

The Company has adopted a corporate governance charter that is in line with the Belgian Code on Corporate Governance and that will enter into force upon the closing of the Offering. The Company's Board of Directors approved the charter on 26 August 2020, subject to and with effect as of the closing of the Offering. The Corporate Governance Charter describes the main aspects of the corporate governance of the Company, including its governance structure, the terms of reference of the Board of Directors and its committees and other important topics. The Corporate Governance Charter must be read together with the Articles of Association.

The Company will apply the ten corporate governance principles contained in the Belgian Code on Corporate Governance and will 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 the size of the Company. The Audit Committee will regularly assess the need for the creation of an independent internal audit function and, where appropriate, will call upon external persons to conduct specific internal audit assignments and will inform the Board of Directors of their outcome.
- On the date of this Prospectus, Share options have been granted to non-executive directors and the Company does not exclude to award Share-based incentives to the non-executive directors, upon advice of the remuneration committee, in the future. This is contrary to provision 7.6 of the Belgian Code on Corporate Governance that provides that no stock options should be granted to non-executive board members. The Company believes 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 the Company to limit the portion of remuneration in cash that the Company would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. The Company is of the opinion that granting non-executive directors the opportunity to be remunerated in part in Share-based incentives rather than all in cash enables the non-executive directors to link their effective remuneration to the performance of the Company and to strengthen the alignment of their interests with the interests of the Company's shareholders. This is in the interest of the Company and its stakeholders. Furthermore, this is customary for directors active in companies in the life sciences industry. In any event, the Company intends that the portion of the remuneration payable in Share options will be limited and shall ensure, in accordance with provision 7.6 of the Belgian Code on Corporate Governance, that non-executive Board members shall receive part of their remuneration in the form of Company's 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 the Board of Directors do not receive part of their remuneration in the form of Shares. This deviation is explained by the fact that the interests of the non-executive members of the Board of Directors are currently considered to be sufficiently oriented to the creation of long-term value for the Company, also considering the fact that some of them already hold Shares and some of them already hold ESOP Warrants, the value of which is based on the value of the Shares (see section 10.2.3 (*Share ownership and intention to participate in the Offering*) and section 10.5 (*Description of the share incentive plans*). Therefore, the 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. The Company's Board of Directors has been explicitly authorized in the Company's Articles of Association to deviate from this rule in connection with stock based incentive plans, compensations, awards and issuances to employees, directors and service providers of the Company and/or its subsidiaries (from time to time). The Company is of the opinion that this allows for more flexibility when structuring Share-based awards. For example, it is customary for share incentive plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.
- In deviation of provision 7.9 of the Belgian Code on Corporate Governance, no minimum threshold of Shares to be held by members of the executive management team is set. This deviation is explained by the fact that the interests of the members of the executive management team are currently considered to be sufficiently oriented to the creation of long-term value for the Company, also considering the fact that some of them already hold Shares and some of them already hold ESOP Warrants, the value of which is based on the value of the Shares (see section 10.3.4 (*Share ownership and intention to participate in the Offering*) and section 10.5 (*Description of the share incentive plans*). 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. The Board of Directors intends to update the Corporate Governance Charter as often as required to reflect changes to the Company's corporate governance.

The Articles of Association and the Corporate Governance Charter will be made available on the Company's website ([www.nyxoah.com](http://www.nyxoah.com)) and can be obtained free of charge at the Company's registered office after closing of the Offering.

## 11. MAJOR SHAREHOLDERS

### 11.1 Overview

The following table presents (i) the undiluted ownership of the Shares (a) immediately prior to the closing of the Offering, (b) immediately after the closing of the Offering assuming a placement of the maximum number of Offered Shares in the Offering (but excluding the exercise of the Increase Option and the Over-allotment Option) and conversion in full of the outstanding principal amount under the Noshaq Convertible Loan into new Shares at a subscription price per new Share equal to the Offering Price minus 10%, and (c) immediately after the closing of the Offering assuming a placement of the maximum number of Offered Shares in the Offering (and including the exercise in full of the Increase Option and the Over-allotment Option) and conversion in full of the outstanding principal amount under the Noshaq Convertible Loan<sup>66</sup> into new Shares at a subscription price per new Share equal to the Offering Price minus 10% and (ii) the fully diluted ownership of the Shares immediately after the closing of the Offering assuming a placement of the maximum number of Offered Shares in the Offering (and including the exercise in full of the Increase Option and the Over-allotment Option) and conversion in full of the out-standing principal amount under the Noshaq Convertible Loan into new Shares at a subscription price per new Share equal to the Offering Price minus 10%. For the purposes of the below table it has also been assumed that (a) the Offering Price is at the mid-point of the Price Range, (b) the existing shareholders and Participating Investors will not participate in the Offering in addition to the Subscription Commitments that were provided by the Participating Investors (see also Part 14 (The Offering), section 14.3 (*Pre-commitments by the Participating Investors*)), and (c) the Participating Investors will be allocated new Shares for the full amount of their Subscription Commitments. The persons holding less than 3% of the outstanding Shares prior to the closing of the Offering have been presented under "others".

It is the Company's current belief that, as on the Closing Date, the Company will not be controlled in the sense of Article 1:14 Belgian CCA.

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<sup>66</sup> For more information on the Noshaq Convertible Loan, see Part 8 – (Business), section 8.12.4 (*Noshaq Convertible Loan*).

<i>Shareholder or Participating Investor</i>	<i>Shares owned before the closing of the Offering, on a undiluted basis<sup>67</sup></i>		<i>Shares owned assuming full placement of the Offered Shares (excluding the exercise of the Over-allotment Option and the Increase Option) and conversion of the Noshaq Convertible Loan, on an undiluted basis</i>		<i>Shares owned assuming full placement of the Offered Shares (including the exercise in full of the Over-allotment Option and the Increase Option) and conversion of the Noshaq Convertible Loan, on an undiluted basis</i>		<i>Shares owned assuming full placement of the Offered Shares (including the exercise in full of the Over-allotment Option and the Increase Option) and conversion of the Noshaq Convertible Loan, on a fully diluted basis<sup>68</sup></i>	
	<i>Number</i>	<i>%</i>	<i>Number</i>	<i>%</i>	<i>Number</i>	<i>%</i>	<i>Number</i>	<i>%</i>
Cochlear Investments Pty Ltd <sup>69</sup>	3,653,500	21.46	3,976,080	18.96	3,976,080	17.90	3,976,080	17.10
TOGETHER Partnership <sup>70</sup>	2,366,500	13.90	2,540,693	12.12	2,540,693	11.44	2,540,693	10.93
Robert Taub + MINV SA <sup>71</sup>	2,641,000	15.51	2,834,548	13.52	2,834,548	12.76	2,834,548	12.19
Coöperatieve Gilde Healthcare III Sub-Holding U.A. and Coöperatieve Gilde Healthcare III Sub-Holding 2 U.A.	3,095,000	18.18	3,288,548	15.69	3,288,548	14.80	3,288,548	14.14
Jürgen Hambrecht	973,500	5.72	1,054,145	5.03	1,054,145	4.75	1,054,145	4.53
ResMed Inc.	755,000	4.44	798,032	3.81	798,032	3.59	798,032	3.43
Others <sup>72</sup>	3,539,000	20.79	3,780,735	18.03	3,780,735	17.02	3,780,735	16.26
Free float	0 <sup>73</sup>	0.00	2,157,205	10.29	3,405,602	15.33	3,405,602	14.64
<b>TOTAL</b>	<b>17,023,500</b>		<b>20,966,184</b>		<b>22,214,581</b>		<b>23,254,581</b>	
<b>ESOP</b>	<b>1,031,000<sup>74</sup></b>		<b>1,031,000</b>		<b>1,031,000</b>		<b>0</b>	

<sup>67</sup> The number of Shares reflects the aggregate number of Shares held by the relevant shareholder after giving effect to the Share Consolidation and Share Split as further described in section 13.3.2 (*Changes in the share capital since January 2016*) and refers to common Shares.

<sup>68</sup> Assumes the exercise in full of existing ESOP Warrants.

<sup>69</sup> Cochlear Investments Pty Ltd is 100% held by Cochlear Limited.

<sup>70</sup> Ms. Anneliese Monden is the controlling shareholder of TOGETHER Partnership.

<sup>71</sup> MINV SA is owned by the Civil Partnership Romata whose shareholding is the following: 99,99% (usufruct) and 0,01% (bare ownership) of the shares are held by Robert Taub and 0,01% (usufruct) and 99,99% (bare ownership) of the shares are held by Ulla Taub.

<sup>72</sup> Existing shareholders whose shareholding does not exceed 3%.

<sup>73</sup> There is no free float before the closing of the Offering.

<sup>74</sup> Calculated as the number of ESOP Warrants that are granted and outstanding on the date of this Prospectus, multiplied by the number of Shares that will be issued upon exercise of all such ESOP Warrants.

The following table compares the net asset value per Share as of 31 December 2019 to the Offering Price per Share:

<b>Net asset value per outstanding Share as of 30 June 2020<sup>75</sup>, on an <i>undiluted</i> basis</b>	<b>Offering Price, assuming it is at the midpoint of the Price Range</b>
€ 1.66	€ 15.50

## 11.2 Other information

All of the Shares have the same voting rights. The major shareholders of the Company do not have different voting rights per Share. For further details of the Company's share capital, see Part 13 – (Description of share capital and articles of association).

On 21 February 2020, the Company and certain of the existing shareholders of the Company entered into the Shareholders' Agreement, which sets out certain arrangements regarding the operation of, the management of and the shareholding in the Company, which replaces the shareholders' agreement dated 5 October 2018, following the subscription of Shares by ResMed Inc. The Shareholders' Agreement will be terminated effective as of the closing of the Offering. The Company is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock up arrangements as described in Part 15 – (Plan of distribution), section 15.3 (*Lock-up*)).

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<sup>75</sup> Determined on the basis of unaudited, non-consolidated, interim financial information prepared in accordance with Belgian GAAP for the six month period ended 30 June 2020 (being € 28,203,641.82) and taking into account only the 16,979,000 Shares that were outstanding on that date.

## 12. RELATED-PARTY TRANSACTIONS

As part of its business, the Company has entered into several transactions with related parties, including certain of its principal shareholders. The following is a summary of the Company's most significant transactions with related parties for the period covered by the historical financial information and as of the date hereof. For further details on related party transactions, see note 2.34 to the annual financial statements for the period ending on 31 December 2019.

- Currently, the existing shareholders of the Company and the Company itself have entered into a Shareholders' Agreement containing, amongst others, terms regarding the Company's business and governance, as well as pre-emption rights and transfer restrictions regarding the Shares. The Shareholders' Agreement was entered into on 21 February 2020, replacing the shareholders' agreement dated 5 October 2018. The Shareholders' Agreement will be terminated effective as of the closing of the Offering. The Company is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock up arrangements as described in Part 15 – (Plan of distribution), section 15.3 (*Lock-up arrangements*)).
- On 7 November 2018, the Company and Cochlear, a major shareholder of the Company, entered into a collaboration agreement to further develop and progress commercialization of implantable treatments for sleep disordered breathing. A new Statement of Work was entered into on 8 June 2020 and the Company may decide to enter into other new Statements of Work with Cochlear to continue their collaboration (see Part 8 – (Business), section 8.12 (*Material contracts*) for further information).
- The Company, Man & Science SA (a company held and controlled by Robert Taub, TOGETHER Partnership and Jürgen Hambrecht), Cephalix SA<sup>76</sup>, Glucobel SA, Surgical Electronics SA and Dr. Adi Mashiach have entered into a multiparty agreement<sup>77</sup> regarding their respective ownership and licensing rights in relation to multiple inventions, including but not limited to inventions generally related to implantable flexible neuro-stimulators and inventions for specific medical indications including sleep disordered breathing, head pain, glucose monitoring, hypertension and other indications. This agreement provides that (i) the Company fully owns all rights in relation to the inventions specifically related to the sleep disordered breathing field and (ii) Man & Science SA is the owner of the generic inventions and granted a fully paid-up, exclusive and worldwide, license with respect to these inventions to several parties, including the Company in the field of sleep disordered breathing. On 23 June 2016, the Company, Cephalix SA, Surgical Electronics SA, and Man & Science SA entered into a confirmatory addendum, aiming to confirm that (i) the Company fully owns all rights in relation to the inventions specifically related to the sleep disordered breathing field as further detailed in the agreement, (ii) Man & Science SA granted an exclusive, worldwide, fully paid-up, royalty free and transferable license to the Company in the "Shared Patents" in the Sleep Disordered Breathing field inventions and (iii) the Company granted an exclusive, fully paid-up, royalty free, transferable license to use the patents as listed in the schedules to the agreement outside the sleep disordered breathing field, namely to Cephalix SA in the head pain field, Surgical Electronics SA in

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<sup>76</sup> Pursuant to a notarial deed of 19 December 2018, Man & Science SA was merged into Cephalix SA, which resulted in a transfer under universal title of all assets and liabilities of Man & Science SA to Cephalix SA. At the same time Cephalix SA changed its corporate name to Man & Science SA.

<sup>77</sup> This agreement is undated.

the hypertension field and Man & Science SA outside the head pain field and the hypertension field.

- The Company and MINV SA ("**MINV**"), a company under the control of Robert Taub, Executive Chairman and major shareholder of the Company, have entered into a consultant agreement, dated 26 September 2019, pursuant to which MINV provides consultancy services regarding the neurostimulation system of the Company, including (i) support the Company's management in the business development activities of the Company and (ii) actively help the Company's management during the investor roadshows of the Company, amongst others, in the framework of the Offering. The Company will pay MINV for extraordinary services in connection with an initial public offering process and business development activities rendered over a period from mid-2019 through mid-2020 at a total fee of €100.000, half of which is payable in 2019 and the balance in 2020. This consultant agreement was entered into for a definite term of six months starting from the date of execution of the consultant agreement and has expired. However, this agreement contains a confidentiality clause which remains applicable for a period of up to ten years after the termination of the agreement and stipulates that all intellectual and other proprietary rights in the invention, modification, discovery, design, development, improvement, method, process, formula, data, technique, know-how, secret or intellectual property right whatsoever that will come into existence in relation to the services performed on behalf of the Company will, upon creation, discovery, or receipt, be the exclusive property of the Company.
- The Company and ActuaRisk Consulting SRL, a company owned by Fabian Suarez Gonzalez, have entered into a consulting agreement, dated 18 August 2014 (amended from time to time), pursuant to which Fabian Suarez Gonzalez as representative of ActuaRisk Consulting SRL provides advisory services as CFO to the Company. See Part 10 – (Management and Corporate Governance), section 10.4 (*Remuneration and Benefits*) for further information on this agreement.
- Since the local government (i.e. Walloon Region), through its investment fund S.R.I.W. SA<sup>78</sup>, is a Shareholder of the Company and given the extent of financing received by the Company from the Walloon Region under the form of recoverable cash advances (see Part 8 – (Business), section 8.16 (*Grants and subsidies*)) the Company also considers the local government as a related party.

Other than these agreements, the Company has not undertaken any related party transactions except the compensation paid to its board of directors and executive management other than those described above (see also Part 10 – (Management and corporate governance), section 10.4 (*Remuneration and benefits*), subsection 10.4.1 (*Board of Directors*)). See also Part 11– (Major shareholders)).

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<sup>78</sup> S.R.I.W. is the abbreviation of the Société Régionale d'Investissement de Wallonie.

## **13. DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION**

### **13.1 General**

The Company has the legal form of a limited liability company (*naamloze vennootschap/société anonyme*) authorized under the laws of Belgium. Pursuant to the provisions of the Belgian CCA, the liability of the shareholders of the Company is in principle limited to the amount of their respective committed contribution to the capital of the Company. The Company is registered with the legal entities register (Brabant Wallon) under enterprise number 0817.149.675 and its legal entity identifier ("LEI") is 5493002O1ESKZ18OXR80 - Nyxoah SA. The Company's registered office is located at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert (Belgium).

This section summarizes information relating to the Company's share capital, certain material rights of its shareholders under Belgian law and the Articles of Association. The contents of this section are derived primarily from the Articles of Association, which were adopted by the general shareholders' meeting of 7 September 2020, and which will enter into force subject to and effective as of the closing of the Offering.

The description provided hereafter is only a summary and does not purport to provide a complete overview of the Articles of Association or the relevant provisions of Belgian law. Neither should it be considered as legal advice regarding these matters.

### **13.2 Corporate Purpose**

The corporate purpose of the Company is set forth in article 3 of the Articles of Association. The corporate purpose reads (in translation from the French original text) as follows:

*"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 realization thereof."*

### **13.3 Share Capital and Shares**

#### **13.3.1 Current share capital and Shares**

On the date of this Prospectus, the share capital of the Company amounts to € 2,924,315.71 and is fully paid-up. It is represented by 17,023,500 Shares, each without nominal value and representing the same *pro rata* fraction of the share capital. In addition, there are a number of outstanding ESOP Warrants that are exercisable for ordinary Shares (see also section 10.5.2 (*Currently outstanding ESOP Warrants*)).

This Prospectus does not provide any information with respect to the 230 Ant-dilution warrants issued on 28 June 2016 (the "**AD Warrants**") and the 300 series B2 anti-dilution warrants (the "**Series B2 AD Warrants**") issued on 4 October 2018 since the AD Warrants and the Series B2 AD Warrants have been cancelled pursuant to the decision of the extraordinary shareholders' meeting of the Company held on 21 February 2020.

### 13.3.2 Changes in the share capital since January 2016

The changes to the Company's actual share capital since 1 January 2016 can be 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
29/06/2016	Capital Increase <sup>79</sup>	719,224.50	7,032	Pre-ferred 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
5/10/2018	Capital <sup>80</sup> Increase	159,014.44	1,534	Pre-ferred 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
7/11/ 2018	Capital Increase	318,028.88	3,068	Pre-ferred B2 Shares	3,259.91 / 103.66	2,481,296.61	Total: 23,938 7,637 common Shares 4,061 preferred A Shares 7,638 preferred B Shares 4,602 preferred B2 Shares
21/02/2020	Share Consolidation (as described below)	NA	NA	NA	NA	2,481,296.61	29,758 common Shares
21/02/2020	Capital Increase (as further described below)	435,372	4,200	com- mon Shares	5,966.59 / 103.66	2,916,670.61	33,958 common Shares
21/02/2020	Share Split with a ratio of 500:1 (as described below)	NA	NA	com- mon Shares	NA	2,916,670.61	16,979,000 common Shares
07/09/2020	Exercise of ESOP Warrants	7,645.10	44,500	com- mon shares	5.17 / 0.1718	2,924,315.71	17,023,500 common shares

<sup>79</sup> A new category of registered preferred shares (Preferred B Shares) was created and 688 ordinary shares were converted to 606 Preferred B Shares.

<sup>80</sup> A new category of registered preferred shares (Preferred B2 Shares) was created.

On 21 February 2020, an extraordinary shareholders' meeting approved, inter alia, the following transactions (i) the conversion of all existing Series A Preferred Shares, Series B Preferred Shares and Series B2 Preferred Shares in common shares (the "**Share Consolidation**") in accordance with a subscription agreement into on 12 February 2020 between the Company, the at that date existing shareholders of the Company and a new investor ResMed Inc., (ii) the cancellation of the outstanding Series B Anti-Dilution Warrants and Series B2 Anti-Dilution Warrants (see section 13.3.4b (*Anti-Dilution warrants*)), (iii) the increase of the registered capital in an amount of € 435,372 (exclusive of an issuance premium of € 24,624,293.88) in order to bring the registered capital from € 2,481,298.61 to € 2,916,670.61 by issuance of 4,200 new Shares at a subscription price per Share of € 5,966.59 (rounded) (the "**Capital Increase**") and (iv) a split of all Shares existing after the Share Consolidation and Capital Increase into several Shares at a 500:1 ratio to reduce the value per individual Share of the Company in view of the Offering (the "**Share Split**").

### **13.3.3 Capital increase upon closing of the Offering**

Subject to and with effect as of the closing of the Offering, the Company's share capital will be increased as a result the issuance of the Offered Shares placed in the Offering.

In view hereof, upon closing of the Offering, assuming a placement of the maximum number of Offered Shares in the Offering (but excluding the exercise of the Over-allotment Option and the Increase Option) and that the Offering Price is at the midpoint of the Price Range (i.e. € 15.50), the Company's share capital will amount to € 3,601,668.82 as of the closing of the Offering, represented by 20,894,500 ordinary Shares, each with a fractional value of ca. € 0.17 and each representing the same pro rata fraction of the share capital. Assuming a placement of the maximum number of Offered Shares in the Offering (including the exercise of the Over-allotment Option and the Increase Option), the Company's share capital will amount to € 3,816,143 as of the closing of the Offering, represented by 22,142,897 Shares, each with a fractional value of ca. € 0.17 and each representing the same pro rata fraction of the share capital.

The aforementioned transactions have been approved by the extraordinary general shareholders' meeting of the Company held on 7 September 2020. The same extraordinary general shareholders' meeting also resolved, subject to and with effect of the closing of the Offering to issue a warrant, called "Over-allotment Option", which the Company may offer to the Stabilization Manager (see also section 13.3.4c (*Over-allotment Option*) below).

### **13.3.4 Outstanding warrants**

#### **a. Share-based incentive plans**

The Company has currently outstanding ESOP Warrants pursuant to four outstanding stock based incentive plans, i.e. the 2013 ESOP Warrants, the 2016 ESOP Warrants, the 2018 ESOP Warrants and the 2020 ESOP Warrants as further described in section 10.5 (*Description of the share incentive plans*).

#### **b. Anti-Dilution warrants**

The Company has issued the AD Warrants and the Series B2 AD Warrants. However, the AD Warrants and the Series B2 AD Warrants have been cancelled upon pursuant to the decision of the extraordinary general

shareholders' meeting of the Company held on 21 February 2020.

### **c. Over-allotment Option**

On 7 September 2020, the extraordinary general shareholders' meeting of the Company resolved to issue the Over-allotment Option, in the form of a warrant. The Over-allotment Option is expected to be granted to the Stabilization Manager, acting on behalf of the Underwriters, in connection with the Offering. The Over-allotment Option can only be exercised by the Stabilization Manager, acting on behalf of the Underwriters, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the Offered Shares subscribed for in the Offering at the Offering Price to cover over-allotments or short positions, if any, in connection with the Offering. The Over-allotment Option will only be exercisable for a period of 30 calendar days following the Listing Date, after which they will automatically expire. See Part 15 – (Plan of Distribution), section 15.4 (*Over-allotment Option and price*).

## **13.4 Currency**

The Company's Shares do not have a nominal value, but each reflect the same fraction of the Company's share capital, which is denominated in euro.

## **13.5 Form and transferability of the Shares**

Upon closing of the Offering, all of the Shares will belong to the same class of securities and will be in registered or dematerialized form. A register of registered Shares (which may be held in electronic form) is maintained at the Company's registered office. It may be consulted by any holder of Shares. A dematerialized Share will be represented by an entry on a personal account of the owner or holder, with a recognized account holder or clearing and settlement institution. Holders of Shares may elect, at any time, to have their registered Shares converted into dematerialized Shares, and *vice versa*, at their own expense.

The Shares are freely transferable. This is without prejudice to certain restrictions that may apply pursuant to applicable securities laws requirements which are further described in section 13.7 (*Legislation and Jurisdiction*). In addition, certain existing securities holders entered into contractual restrictions. See Part 15 - (Plan of distribution), section 15.3 (*Lock-up*).

## **13.6 Rights attached to the Shares**

### **13.6.1 Voting rights attached to the Shares**

Each shareholder of the Company is entitled to one vote per Share. Shareholders may vote by proxy, subject to the rules described below in subsection 13.6.2 (*Right to Attend and Vote at Shareholders' Meetings*), subsection 13.6.2f (*Voting by proxy or remote voting*). 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 of the Company;
- 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 the Company on the date of the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified the Company 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.

Pursuant to the Belgian CCA, the voting rights attached to Shares owned by the Company, as the case may be, are suspended. Generally, the general shareholders' meeting has sole authority with respect to:

- the approval of the annual financial statements of the Company;
- the distribution of profits (except interim dividends (see subsection 13.6.3 (*Dividend Rights*) below);
- the appointment (at the proposal of the Board of Directors and upon recommendation by the nomination committee) and dismissal of directors of the Company;
- the appointment (at the proposal of the Board of Directors and upon recommendation by the audit committee) and dismissal of the statutory auditor of the Company;
- the granting of release from liability to the directors and the statutory auditor of the Company;
- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate;
- the advisory vote on the remuneration report included in the annual report of the Board of Directors and the determination of the following features of the remuneration or compensation of directors, members of the executive management and certain other executives (as the case may be): (i) in relation to the remuneration of executive and non-executive directors, 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, (ii) in relation to the remuneration of executive directors, 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, (iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration, and (iv) any service agreements to be entered into with executive directors, members of the executive management and other executives providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration committee, eighteen months' remuneration);
- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other reorganizations of the Company; and
- the approval of amendments to the articles of association.

## **13.6.2 Right to Attend and Vote at Shareholders' Meetings**

### **a. Annual General Shareholders' Meetings**

The annual general shareholders' meeting is held at the registered office of the 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 the 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 the 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) (see also subsection 13.6.1 (*Voting rights attached to the Shares*) above).

#### **b. Special and extraordinary General Shareholders' Meetings**

The board of directors or the statutory auditor (or the liquidators, if appropriate) may, whenever the interest of the 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 the Company's share capital so request. Shareholders that do not hold at least 10% of the Company's share capital do not have the right to have the general shareholders' meeting convened.

#### **c. Right to request items to be added to the agenda and ask questions at the Shareholders' Meeting**

Shareholders who hold alone or together with other shareholders at least 3% of the Company's share capital have the right to put additional items on the agenda of a general shareholders' meeting that has been convened and to table draft resolutions in relation to items that have been or are to be included in the agenda. This right does not apply to general shareholders' meetings that are being convened on the grounds that the quorum was not met at the first duly convened meeting (see subsection 13.6.2g (*Quorum and majorities*) below). Shareholders wishing to exercise this right must prove on the date of their request that they own at least 3% of the outstanding share capital. The ownership must be based, for dematerialized Shares, on a certificate issued by the applicable settlement institution for the Shares concerned, or by a certified account holder, confirming the number of Shares that have been registered in the name of the relevant shareholders and, for registered Shares, on a certificate of registration of the relevant Shares in the share register book of the Company. In addition, the shareholder concerned must register for the meeting concerned with at least 3% of the outstanding share capital (see also subsection 13.6.2e (*Formalities to attend the general shareholders' meeting*) above). A request to put additional items on the agenda and/or to table draft resolutions must be submit-

ted in writing, and must contain, in the event of an additional agenda item, the text of the agenda item concerned and, in the event of a new draft resolution, the text of the draft resolution. The request must reach the Company at the latest on the twenty second calendar day preceding the date of the general shareholders' meeting concerned. If the Company receives a request, it will have to publish at the latest on the fifteenth calendar day preceding the general shareholders' meeting an update of the agenda of the meeting with the additional agenda items and draft resolutions.

#### **d. Notices convening the Shareholders' Meeting**

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 the 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 the 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 subsection 13.6.2 a (*Annual General Shareholders' Meetings*) 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 the Company ([www.nyxoah.com](http://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 subsection 13.6.2g (*Quorum and majorities*).

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 the Company (if any), and, as the case may be, to the directors and statutory auditor of the

Company.

**e. Formalities to attend the general shareholders' meeting**

All holders of Shares, warrants, profit-sharing certificates, non-voting Shares, bonds, subscription rights or other securities issued by the Company, as the case may be, and all holders of certificates issued with the cooperation of the 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 the Company must satisfy two criteria: being registered as holder of securities on the registration date for the meeting, and notify the 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 the 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 the Company must be further described in the notice convening the general shareholders' meeting.

**f. Voting by proxy or remote voting**

Each shareholder has, subject to compliance with the requirements set forth above under subsection 13.6.2e (*Formalities to attend the general shareholders' meeting*), 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 the Company. The signed original paper or electronic form must be received by the 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 the Company. The original signed paper form must be received by the 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.

The 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. The 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, as explained above under subsection 13.6.2e (*Formalities to attend the general shareholders' meeting*).

Holders of shares without voting rights, profit-sharing certificates without voting rights, convertible bonds, warrants or certificates issued with the cooperation of the Company may attend the general shareholders' meeting, but only with an advisory vote.

#### **g. Quorum and majorities**

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

#### **h. Right to ask questions**

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 the 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, as explained above under subsection 13.6.2e (*Formalities to attend the general shareholders' meeting*).

### **13.6.3 Dividend Rights**

As of the closing of the Offering, all of the Shares, including the Offered Shares, will entitle the holder thereof to an equal right to participate in dividends declared after the Closing Date, in respect of the financial year ending 31 December 2020 and future years. All of the Shares will participate equally in the Company's 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 the 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, the 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.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Company's 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 the Company's 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), 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.

In addition, pursuant to Belgian law and the Articles of Association, the Company must allocate an amount of 5% of its Belgian GAAP annual net profit (*netto-winst/bénéfices nets*) to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Company's share capital. The Company's legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Company's ability to pay out dividends to its shareholders. Furthermore, additional financial restrictions and other limitations may be contained in future credit agreements.

For further information in relation to the Company's dividend policy, see Part 5 – (Dividends and dividend policy).

### **13.6.4 Rights regarding liquidation**

The Company can only be dissolved by a shareholders' resolution passed with a majority of at least 75% of the votes cast at an extraordinary general shareholders' meeting where at least 50% of the share capital is present or represented.

Pursuant to article 7:228 of the Belgian CCA, if, as a result of losses incurred, the ratio of the 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 the Company or the continuation of the Company, in which case the Board of Directors must propose measures to redress the 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 the Company, provided that at least 50% of the Company's share capital is present or represented at the meeting.

If, as a result of losses incurred, the ratio of the 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 the Company.

Pursuant to article 7:229 of the Belgian CCA, if the amount of the Company's net assets has dropped below €61,500, any interested party is entitled to request the competent court to dissolve the Company. The court can order the dissolution of the Company or grant a grace period within which the Company is to remedy the situation.

If the 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 (see also Part 0 – (Risk factors), section 2.3 (*Risks relating to the Company's financial situation*) (*The Company may not be able to achieve or maintain profitability*)).

### **13.6.5 Changes to the Share Capital**

#### **a. Change to the share capital decided by the shareholders**

In principle, changes to the share capital are decided by the shareholders. The general shareholders' meeting may at any time decide to increase or reduce the share capital of the Company. Such resolution must satisfy the quorum and majority requirements that apply to an amendment of the articles of association, as described above under subsection 13.6.2 (*Right to Attend and Vote at Shareholders' Meetings*), subsection 13.6.2g (*Quorum and majorities*).

#### **b. Capital increases decided by the Board of Directors**

Subject to the same quorum and majority requirements, the general shareholders' meeting may authorize the board of directors, within certain limits, to increase the Company's share capital without any further approval of the shareholders. This is the so-called authorized capital. This authorization needs to be limited in time (i.e. it can only be granted for a renewable period of maximum five years) and scope (i.e. the authorized

capital may not exceed the amount of the registered capital at the time of the authorization).

On 7 September 2020, the Company's general shareholders' meeting authorized, subject to and with effect as from the closing of the Offering, the Board of Directors to increase the share capital of the Company within the framework of the authorized capital with a maximum of 100% of its amount as at the closing of the Offering. The Company's general shareholders' meeting decided that the Board of Directors, when exercising its powers under the authorized capital, will be authorized to restrict or cancel the statutory preferential subscription rights of the shareholders (within the meaning of article 7:188 and following of the Belgian CCA). See also subsection 13.6.5c (*Preferential subscription right*) below. This authorization includes the restriction or suppression of preferential subscription rights for the benefit of one or more specific persons (whether or not employees of the Company or its subsidiaries) and the authority to increase the Company's capital after having been notified by the FSMA that the Company is the subject of a public takeover bid (see section 13.7.2 (*Public takeover bids*)).

The authorization is valid for a term of five years as from the date of the publication of the authorization in the Annexes to the Belgian State Gazette (*Belgisch Staatsblad/Moniteur belge*).

#### **c. Preferential subscription right**

In the event of a capital increase for cash with the issue of new Shares, or in the event of an issue of 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.

The general shareholders' meeting may decide to limit or cancel these preferential subscription rights, subject to special reporting requirements. Such decision by the general shareholders' meeting needs to satisfy the same quorum and majority requirements as the decision to increase the Company's share capital.

The shareholders may also decide to authorize the 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 the Board of Directors to increase the share capital of the Company through contributions in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the financial instruments of the Company. The Company's general shareholders' meeting did not grant such express authorization to the Board of Directors.

#### **d. Acquisition of own Shares**

The Company may acquire, pledge and dispose of its own shares, profit certificates or associated certificates at the conditions provided for by articles 7:215 and following of the Belgian CCA. These conditions include a prior special shareholders' resolution approved by at least 75% of the votes validly cast at a general shareholders' meeting (whereby abstentions are not included in the numerator nor in the denominator) where at least 50% of the share capital and at least 50% of the profit certificates, if any, are present or represented.

Furthermore, shares can only be acquired with funds that would otherwise be available for distribution as a dividend to the shareholders and the transaction must pertain to fully paid-up shares or associated certificates. Finally, an offer to purchase shares must be made by way of an offer to all shareholders under the same conditions. Shares can also be acquired by the Company without offer to all shareholders under the same conditions, provided that the acquisition of the shares is effected in the central order book of the regulated market of Euronext Brussels or, if the transaction is not effected via the central order book, provided that the price offered for the Shares is lower than or equal to the highest independent bid price in the central order book of the regulated market of Euronext Brussels at that time.

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

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

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

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

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

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

## **13.7 Legislation and Jurisdiction**

### **13.7.1 Notification 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 the 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 the 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 the Company; and
- where the 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. The 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 the 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](http://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. The Company is required to publicly disclose any notifications received regarding increases or decreases in a shareholder's ownership of the 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 the Company's website ([www.nyxoah.com](http://www.nyxoah.com)).

### 13.7.2 Public takeover bids

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

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 the Company or that such party holds a larger stake than the person holding 30% of the voting securities or (ii) in case of a capital increase with preferential subscription rights decided by the Company's general shareholders' meeting.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose significant shareholdings (see subsection 13.7.1 (*Notification of significant shareholdings*) above) and merger control, that may apply towards the Company and which may create hurdles to an unsolicited tender offer, merger, change in management or other change in control. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of the Shares. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their Shares at a premium.

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

On 7 September 2020, the general shareholders' meeting expressly authorized the board of directors to increase the Company's capital after having been notified by the FSMA that the Company is the subject of a public takeover bid (see also section 13.6 (*Rights attached to the Shares*), subsection 13.6.5 (*Changes to the Share Capital*), subsection 13.6.5b (*Capital increases decided by the Board of Directors*)).

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

### **13.7.3 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 the 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, the 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.

#### **13.7.4 Sell-out right**

Within three months after the end of an acceptance period related to a public takeover bid, holders of voting securities or of securities giving access to voting rights may require the offeror, acting alone or in concert, who owns at least 95% of the voting capital and 95% of the voting securities in a public company following a takeover bid, to buy their securities from them at the price of the bid, on the condition that, in case of a voluntary takeover offer, the offeror has acquired, through the acceptance of the bid, securities representing at least 90% of the voting capital subject to the takeover bid.

#### **13.7.5 Royal Decree on Primary Market Practices**

Pursuant to Article 11 of the Royal Decree on Primary Market Practices, any natural or legal person who, in the year preceding the first admission of shares to trading on a Belgian regulated market or on a Belgian multilateral trading facility, has acquired shares outside the framework of a public offer at a price lower than the price of the public offer made at the same time as the admission of the shares concerned to trading, may not transfer those shares for one year after such admission, except in the case of a transfer leading to an obligation to launch a takeover bid, or if the shares are contributed or transferred in the framework of a takeover bid. This prohibition is subject to certain exemptions as further clarified in the aforementioned article.

## 14. THE OFFERING

### 14.1 Timetable

Certain key dates in connection with the Offering are summarized in the following table. These are all anticipated dates, which are subject to any unforeseen circumstances and to an early closing of the Offering Period.

Date	Event
9 September 2020, 9:00 a.m. CET	Expected start of the Offering Period
21 September 2020, 4:00 p.m. CET	Expected end of the Offering Period for Retail Investors
22 September 2020, 4:00 p.m. CET	Expected end of the Offering Period for Institutional Investors <sup>81</sup>
23 September 2020	Expected publication of the Offering Price and results of the Offering and communication of allocations
24 September 2020	Expected Listing Date (listing and start of “if-and-when-issued-and/or-delivered” trading)
25 September 2020	Expected Closing Date (payment, settlement and delivery of the Offered Shares)
24 October 2020	Expected last possible exercise date of the Over-allotment Option <sup>82</sup>

### 14.2 Conditions and nature of the Offering

The Offering consists of: (i) an initial public offering to retail and institutional investors in Belgium; (ii) a placement in the United States to persons that are reasonably believed to be QIBs as defined in Rule 144A under the U.S. Securities Act; and (iii) placements to certain qualified and/or institutional investors in the rest of the world outside the United States and Belgium and the United States. The Offering outside the United States will be made in compliance with Regulation S under the U.S. Securities Act. Private Placements may take place in member states of the EEA pursuant to an exemption under the Prospectus Regulation. The Offering is an offering of up to 3,871,000 new Shares in the Company. This aggregate number of 3,871,000 initially offered new Shares sold in the Offering may, pursuant to an exercise of the Increase Option, be increased by up to 15% to 4,451,650 new Shares (see section 14.16 (*Increase Option*)).

The Stabilization Manager, acting on behalf of the Underwriters, is expected to be granted by the Company the Over-allotment Option, in the form of a warrant, which entitles the Stabilization Manager, acting on behalf of the Underwriters, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the new Shares subscribed for in the Offering (including the new Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) at the Offering Price to cover over-allotments or short

<sup>81</sup> In the event of an early closing or extension of the Offering Period, these dates will be amended and published in the same manner as the announcement of the start of the Offering Period. If the Offering Period is extended with more than five business days, this will also be published in a supplement to the Prospectus.

<sup>82</sup> To enable the Stabilization Manager, acting on behalf of the Underwriters, to cover over-allotments or short positions, if any, resulting from the over-allotment, if any (for further information, see section 15.4 (*Over-allotment Option and price*)).

positions, if any, in connection with the Offering.

The Underwriters are Bank Degroof Petercam NV/SA and Belfius Bank NV/SA. See Part 15 – (Plan of distribution).

The actual number of new Shares issued by the Company in the Offering will only be determined after the Offering Period and will be published in the financial press and by way of a press release of the Company, simultaneously with the publication of the Offering Price and the allocation of Shares to Retail Investors. Such publication is currently expected to be made on or about 23 September 2020 and in any event no later than the first business day after the end of the Offering Period.

There is no minimum amount for the Offering. If not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from Subscription Commitments. The Company reserves the right to withdraw the Offering or suspend the Offering Period (see section 14.9 (*Withdrawal of the Offering or suspension of the Offering Period*) below) or to reduce the maximum number of Offered Shares at any time prior to the allocation of the Offered Shares. Any withdrawal of the Offering will be published in the financial press, by means of a press release, through electronic information services such as Reuters or Bloomberg. To the extent required, also a supplement will be published. In the event of a withdrawal of the Offering, all orders received will automatically be cancelled and withdrawn, and investors will not have any claim to the delivery of the Offered Shares or any compensation. A reduction in the number of Offered Shares prior to expiry of the Offering Period will be published in the financial press, by means of a press release, through electronic information services such as Reuters or Bloomberg, and in a supplement to the Prospectus. A supplement to the Prospectus shall be published in case of an early closing of the Offering Period without placement of the total number of Offered Shares. In the event of a publication of a supplement to the Prospectus, investors will have the right to withdraw their orders made prior to the publication of the supplement (see section 14.10 (*Right to withdraw*) below). Investors withdrawing their order will not have any claim to the delivery of the Offered Shares or any compensation.

### **14.3 Pre-commitments by the Participating Investors**

The Participating Investors have, by way of Subscription Commitments, irrevocably and conditional only on closing of the Offering, committed themselves to subscribe for new Shares in the Offering for a total aggregate amount of € 23,064,000, of which:

- the following existing shareholders have committed in aggregate € 17,364,000: Cochlear Investments PTY LTD, Robert Taub, Coöperative Gilde Healthcare III Sub-Holding U.A., Coöperative Gilde Healthcare III Sub-Holding 2 U.A., TOGETHER partnership, Jürgen Hambrecht, ResMed Inc, Jean-Marc Heynderickx, George Ortiz, PG Invest / Co Fide Capital, Michael Goossens, Ludo Schellens & Ria Brullemans, Pierre André, Pierre-Yves André, TrustCapital NV, Hilde Famaey, Kevin Rakin, Kevin L. Rakin Irrevocable Trust, Donald Deyo, and Fabian Suarez.
- the following new investors have committed in aggregate € 5,700,000 : SFPI – FPIM SA/NV, Roland Berger, Stefan Hambrecht, and Globe CP GmbH.

In the event of over-subscription of the Offering, in principle the Subscription Commitments of the Participating Investors in cash for an amount of approximately € 9,768,000 can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering, whereas the Subscription Commitments for the remaining amount shall not be reduced but be allocated entirely. However, the Company will allocate to Participating Investors that are existing shareholders a number of Offered Shares for an

aggregate amount of at least € 15,000,000. See also section 14.11 (*Allocation*).

#### 14.4 Offering Price

The Offering Price will be a single price in euro, exclusive of the Belgian tax on stock exchange transactions, if applicable (see Part 16 – (Taxation), section 16.2.3 (*Belgian tax on stock exchange transactions*)), and costs, if any, charged by financial intermediaries for the submission of applications, will apply to all investors, whether Retail Investors or Institutional Investors.

The Offering Price will be determined within the Price Range on the basis of a book-building process in which only Institutional Investors can participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time.

The Price Range has been determined by the Company in agreement with the Underwriters, taking into account market conditions and factors including but not limited to:

- the condition of the financial markets;
- the Company's financial position;
- qualitative assessment of the demand for the Offered Shares; and
- all other factors deemed relevant.

The Company reserves the right to increase or decrease the lower limit of the Price Range or to decrease the upper limit of the Price Range. If the Price Range is narrowed through an increase of the lower limit and/or a decrease of the upper limit, or if the Price Range is narrowed to a single price, the change will be published in the financial press and by means of a press release, through electronic information services such as Reuters or Bloomberg. Other changes to the Price Range will also be published in the financial press and by means of a press release, through electronic information services, as well as in a supplement to the Prospectus. Investors who have submitted subscription orders will not be notified individually by the Company. Although the Company has no obligation to notify the investors, the financial intermediaries are required to contact the investor individually. The Offering Price for investors shall not, however, exceed the higher end of the Price Range. In the event of a publication of a supplement to the Prospectus, investors will have the right to withdraw their orders made prior to the publication of the supplement (see section 14.10 (*Right to withdraw*) below).

Retail Investors in Belgium can only acquire the Offered Shares at the Offering Price and are legally bound to acquire the number of Offered Shares indicated in their subscription order at the Offering Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void, or (ii) in the event of the publication of a supplement to the Prospectus, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement (see section 14.10 (*Right to withdraw*) below).

As set out Part 10 (Management and corporate Governance) – section 10.5 (*Description of the share incentive plans*), certain directors, members of executive management, officers, employees and consultants of Nyxoah hold ESOP Warrants, pursuant to which they are entitled to subscribe to new Shares (subject to the terms and

conditions of the relevant ESOP Warrants) at a subscription price per new Shares (ranging from €5.17 to €11.94) which is significantly lower than the Price Range.

#### **14.5 Dilution resulting from the Offering**

See table in Part 11 – (Major Shareholders), section 11.1 (*Overview*).

#### **14.6 Offering Period**

The Offering Period will begin on 9 September 2020 and is expected to close no later than 4:00 p.m. (CET) on 22 September 2020, subject to the possibility of an early closing or extension, provided that the Offering Period will in any event be open for at least six business days. The Prospectus will be made available as of the first calendar day of the Offering Period. The Offering Period can be closed, at the earliest, six business days after the start of the Offering Period and, hence, prospective investors can submit their orders at least during six business days after the start of the Offering Period. However, in accordance with the possibility provided for in Article 3, §2 of the Royal Decree on Primary Market Practices, we expect the subscription period for the retail offering to end at 4:00 pm on 21 September 2020, the day before the end of the institutional bookbuilding period, due to the timing and logistical constraints associated with the centralization of the subscriptions placed by Retail Investors with the Joint Bookrunners and with other financial institutions.

Any extension or early closing of the Offering Period will be announced by means of a press release by the Company, and the dates for each of pricing, allocation, publication of the Offering Price and the results of the Offering, "as-if-and-when-issued-and/or-delivered" trading and closing of the Offering will in such case be adjusted accordingly.

In the event the Offering Period is extended with more than five business days, this will be published in a supplement to the Prospectus. Investors who have already agreed to subscribe for the Offered Shares before the supplement is published will have the right, exercisable within at least two business days after the publication of the supplement, to withdraw their subscription orders, provided that the significant new development, material mistake or inaccuracy referred to above arose before the closing of the Offering or the delivery of the Offered Shares. The Offering Period can only be closed earlier in case of a coordinated action between the Underwriters. In the event the Offering Period is extended with five business days or less, this will only be announced by means of a press release by the Company. Prospective investors can submit their subscription orders during the Offering Period. Taking into account the fact that the Offering Period may be closed early, investors are invited to submit their applications as promptly as possible.

The timeline, validity and form of instructions to financial intermediaries in relation to the subscription for or purchase of Shares will be determined by each financial intermediary in accordance with its usual procedures or as otherwise notified to the investors. The Company is not liable for any action or failure to act by a financial intermediary in connection with any subscription or purchase, or purported subscription or purchase, of Shares.

Subscription orders by Retail Investors in Belgium may be submitted at the counters of Bank Degroof Patercam NV/SA and Belfius Bank NV/SA, at no cost to the investor or alternatively through other than the aforementioned intermediaries. Applications are not binding upon the Company or the Underwriters as long as they have not been accepted (Part 14 - (The Offering), section 14.11 (*Allocation*)).

Investors wishing to place purchase orders for the Offered Shares through intermediaries other than Bank Degroof Petercam NV/SA and Belfius Bank NV/SA in Belgium should request details of the costs which these intermediaries may charge, which they will have to pay themselves.

To be valid, the subscription orders must be submitted no later than 4:00 p.m. (CET) on 21 September 2020 (for Retail Investors) and no later than 4:00 p.m. (CET) on 22 September 2020 for Institutional Investors, unless the Offering Period is closed earlier or extended, in which case the subscription orders must be submitted no later than 4:00 p.m. (CET) at such earlier or extended closing date of the Offering Period.

#### **14.7 Retail Investors**

Retail Investor shall mean an individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a qualified investor (*gekwalificeerde belegger/investisseur qualifié*) as defined in article 2, e) of the Prospectus Regulation.

Retail Investors must indicate in their subscription orders the number of Offered Shares they are committing to subscribe for. Every order must be expressed in number of Offered Shares with no indication of price and shall be deemed placed at the Offering Price. Only one application per Retail Investor will be accepted. If the Underwriters determine, or have reason to believe, that a single Retail Investor has submitted several subscription orders, through one or more intermediaries, they may disregard such subscription orders. There is no minimum or maximum amount or number of Offered Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below in section 14.11 (*Allocation*).

Belfius Bank NV/SA will act as centralization agent for subscription orders by Retail Investors.

#### **14.8 Institutional Investors**

Institutional Investors must indicate in their subscription orders the number of Offered Shares or an amount they are committing to subscribe for, and the prices at which they are making such subscription orders during the book-building period. There is no minimum or maximum amount or number of Offered Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below in section 14.11 (*Allocation*). Only Institutional Investors can participate in the book-building process during the Offering Period.

#### **14.9 Withdrawal of the Offering or suspension of the Offering Period**

The Company reserves the right to withdraw the Offering or suspend the Offering Period should the Underwriting Agreement not be signed. Furthermore, the Company reserves the right to withdraw or suspend the Offering if the Underwriting Agreement is terminated in the foreseen circumstances as described in the Underwriting Agreement (see Part 15 – (Plan of Distribution), section 15.1 (*Underwriting*)). Such withdrawal of the Offering or the suspension of the Offering Period can occur up to the closing of the Offering. The Company also reserves the right to withdraw the Offering or suspend the Offering Period if the Board of Directors following recommendations from the Underwriters, acknowledges that the quality and quantity of the subscriptions received is such that the Offering cannot be closed in the interest of the Company. Any

withdrawal of the Offering or suspension of the Offering Period will be published in the financial press, by means of a press release, through electronic information services such as Reuters or Bloomberg. To the extent required, a supplement will also be published. In the event of a withdrawal of the Offering, all orders received will automatically be cancelled and withdrawn, and investors will not have any claim to the delivery of the Offered Shares or any compensation. The amounts already paid by the prospective investors will be reimbursed within three business days, without, however, being entitled to interest on this amount or to any form of compensation for any reason whatsoever. In the event of withdrawal of the Offering or suspension of the Offering Period, the Company will also be able to withdraw the application for admission to trading of all Shares on the regulated market Euronext Brussels, and will immediately notify Euronext Brussels NV of this.

#### **14.10 Right to withdraw**

Retail Investors in Belgium can only acquire the Offered Shares at the Offering Price and are legally bound to acquire the number of Offered Shares indicated in their subscription order at the Offering Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void, or (ii) in the event of the publication of a supplement to the Prospectus, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement.

In accordance with article 23 (1) of the Prospectus Regulation, in the event of a significant new development, or material mistake or inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the Offered Shares during the period between the date of approval of the Prospectus and the Listing Date, a supplement to this Prospectus shall be published. Any supplement is subject to approval by the FSMA, in the same manner as this Prospectus and must be made public in the same manner as this Prospectus.

Investors who have already agreed to subscribe for the Offered Shares before the supplement is published will have the right, exercisable within at least two business days after the publication of the supplement, to withdraw their subscription orders, provided that the significant new development, material mistake or inaccuracy referred to above arose before the closing of the Offering or the delivery of the Offered Shares. The financial intermediaries shall contact each investor individually on the day of the publication of a supplement.

A supplement to this Prospectus will be published in accordance with article 23 of the Prospectus Regulation (i) in the event the Offering Price is set below the lower end of the Price Range, (ii) if the Price Range is changed (other than in the event of a narrowing of the Price Range through an increase of the lower limit and/or a decrease of the upper limit of the Price Range), (iii) if the Offering Period is extended with more than five business days, (iv) if the maximum number of Offered Shares is reduced, including due to an early closing of the Offering Period without placement of the total number of new Shares, (v) if the Underwriting Agreement is not executed or is executed but subsequently terminated or (vi) to the extent required, if the Offering is withdrawn or the Offering Period is suspended.

#### **14.11 Allocation**

The number of Offered Shares allotted to investors will be determined at the end of the Offering Period by the Company in agreement with the Underwriters on the basis of the respective demand of both Retail Investors and Institutional Investors and on the quantitative, and, for Institutional Investors only, the qualitative

analysis of the order book, in accordance with Belgian regulations relating to allocation to Retail Investors and Institutional Investors as set forth below.

In accordance with Belgian regulations, a minimum of 10% of the Offered Shares shall be allocated to Retail Investors, subject to sufficient retail demand. However, the proportion of Offered Shares allocated to Retail Investors may be increased or decreased in an equal manner if subscription orders received from them exceed or do not reach, respectively, 10% of the Offered Shares effectively allocated.

In case of over-subscription of the Offered Shares reserved for Retail Investors, the allocation to Retail Investors will be made on the basis of objective and quantitative allocation criteria, whereby all Retail Investors will be treated equally. The criteria used for this purpose are the preferential treatment of applications submitted by Retail Investors at the counters of Bank Degroof Petercam NV/SA and Belfius Bank NV/SA in Belgium, and the number of Shares for which applications are submitted by Retail Investors.

The results of the Offering, the allocation for Retail Investors, the Offering Price, and the allocation criteria (in case of over-subscription) will be announced by the Company on or about 23 September 2020 and in any event no later than the first business day after the end of the Offering Period. In the event of the over-allotment of Offered Shares, the Underwriters will use reasonable efforts to deliver the newly issued Shares to individual persons residing in Belgium and to investors subject to Belgian income tax on legal entities (*rechtspersonenbelasting/impôt des personnes morales*), in this order of priority. No tax on stock exchange transactions is due on the subscription for newly issued Shares, but such tax could be due on the subscription for existing Shares (see Part 16 – (Taxation), section 16.2.3 (*Belgian tax on stock exchange transactions*)). The manner for refunding amounts paid in excess by financial intermediaries in relation to the subscription for or purchase of Shares will be determined by each financial intermediary in accordance with its usual procedures or as otherwise notified to the investors.

In the event of over-subscription of the Offering, in principle the Subscription Commitments of the Participating Investors in cash for an amount of approximately € 9,768,000 can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering, whereas the Subscription Commitments for the remaining amount shall not be reduced but be allocated entirely. However, the Company will allocate to Participating Investors that are existing shareholders a number of Offered Shares for an aggregate amount of at least € 15,000,000. See also section 14.3 (*Pre-commitments by the Participating Investors*).

#### **14.12 Payment and taxes**

The Offering Price must be paid by the investors in full, in euro, together with any applicable stock exchange taxes and costs. No tax on stock exchange transactions is due on the subscription for newly issued Shares. For further information about applicable taxes, see Part 16 – (Taxation), section 16.2 (*Belgian taxation of dividends on Shares*).

The payment date for the Offered Shares, which is also the Closing Date is expected to be 25 September 2020 unless the Offering Period is closed earlier or extended. The Offering Price must be paid by investors by authorizing their financial institutions to debit their bank accounts with such amount for value on the Closing Date.

#### **14.13 Form of the Offered Shares and delivery**

From their issue date, the Offered Shares will be subject to all provisions of the Articles of Association. The Offered Shares shall be of the same class as existing ordinary Shares, including as to voting and dividend rights, and will be profit sharing as from any distribution in respect of which the relevant record date or due date falls on or after the date of their issuance, including any distributions in relation to the financial year that started on and after 1 January 2020, as the case may be. The rights attached to the Shares are described in Part 13 – (Description of Share capital and Articles of Association), section 13.6 (*Rights attached to the Shares*).

All Offered Shares will be delivered in dematerialized (book-entry) form only, and will be credited on or around the Closing Date to investors' securities accounts via Euroclear Belgium. By way of exception to the foregoing, the Offered Shares that will be issued to Participating Investors pursuant to the Pre-commitments (unless the Participating Investor has an existing client relationship and securities account with Bank Degroof Petercam NV/SA or Belfius Bank NV/SA and has opted to have such Offered Shares delivered in dematerialized (book-entry) form and credited on such securities account), will be delivered in registered form on or about their issuance.

Investors who, after delivery, wish to have their Shares registered, should request that the Company record the Shares in the Company's share register.

Holders of registered Shares may request that their registered Shares be converted into dematerialized Shares and *vice versa*. Any costs incurred in connection with the conversion of Shares into another form will be borne by the shareholders.

All Offered Shares will be fully paid-up upon their delivery and freely transferable, subject to what is set forth under Part 15 – (Plan of distribution).

#### **14.14 Trading and listing on Euronext Brussels**

An application has been made for the listing and admission to trading on the regulated market of Euronext Brussels of all Shares, including the Offered Shares and the Shares to be issued pursuant to the conversion of the Noshaq Convertible Loan. The Shares are expected to be listed under the symbol "NYXH" with ISIN code BE0974358906.

Trading is expected to commence on or about 24 September 2020 (unless in case of early closing or extension of the Offering Period) and will start at the latest on the Closing Date, when the Offered Shares are delivered to investors.

As of the Listing Date until the Closing Date and delivery of the Offered Shares, the Shares will be traded on the regulated market of Euronext Brussels on an "as-if-and-when issued and/or delivered" basis. Investors who wish to effect transactions in Shares prior to the Closing Date, whether such transactions are effected on the regulated market of Euronext Brussels or otherwise, should be aware that the issuance and delivery of the Offered Shares may not take place on the expected Closing Date, or at all, if certain conditions or events referred to in the Underwriting Agreement (as defined below) are not satisfied or waived or do not occur on or prior to such date.

Euronext Brussels may annul all transactions effected in the Shares if the Offered Shares are not delivered on the Closing Date. Euronext Brussels cannot be held liable for any damage arising from the listing and trading on an "if-and-when-issued-and/or-delivered" basis as of the Listing Date until the expected Closing Date.

#### **14.15 Share Lending**

Mr. Robert Taub is expected to agree to lend to the Stabilization Manager (acting on behalf of the Underwriters) a number of Shares equal to up to 15% of the number of new Shares subscribed for in the Offering (including the new Shares subscribed for pursuant to the effective exercise of the Increase Option, if any), in order to enable the Stabilization Manager to settle any over-allotments.

#### **14.16 Increase Option**

Depending on the volume of demand, the 3,871,000 initially offered new Shares sold in the Offering may be increased by up to 15% to 4,451,650 new Shares. Any decision to exercise the Increase Option will be communicated at the latest on the date of announcement of the Offering Price, which is currently expected to be on or around 23 September 2020. To the extent that the Increase Option has been exercised and subject to entering into the Underwriting Agreement, the Underwriters will severally (and not jointly, nor jointly and severally) subscribe to such additional new Shares in the same proportion as set forth in the table in section 15.1 (*Underwriting*).

#### **14.17 Authorizations**

This Prospectus and the participation of the Company in the Offering were approved by the Board of Directors of the Company on 7 September 2020. The issuance of the Offered Shares and required amendments to the Articles of Association, both of which are subject to the condition precedent of the closing of the Offering, were approved by the shareholders of the Company at its extraordinary general shareholders' meeting held on 7 September 2020.

#### **14.18 Jurisdiction and Competent Courts**

The Offering is subject to Belgian law and the courts of Brussels are exclusively competent to adjudicate any and all disputes with investors concerning the Offering.

## 15. PLAN OF DISTRIBUTION

### 15.1 Underwriting

The Underwriters are Bank Degroof Petercam NV/SA, having its registered office at Rue de l'Industrie 44, 1040 Brussels (Belgium), registered with the Crossroad Bank for Enterprises under the number 0403.212.172 (Brussels) and Belfius Bank NV/SA, having its registered office at Place Charles Rogier 11, 1210 Brussels and registered with the Crossroad Bank for Enterprises under the number 0403.201.185 (Brussels).

The Underwriters are expected (but have no obligation) to enter into an underwriting agreement (the "**Underwriting Agreement**"), upon the determination of the Offering Price, which is expected to take place on or about 23 September 2020. The entering into the Underwriting Agreement may depend on various factors including, but not limited to, market conditions and the results of the book-building process.

Subject to the terms and conditions to be set forth in the Underwriting Agreement, the Underwriters will severally (and not jointly, nor jointly and severally) agree to subscribe for the following percentage of the total number of new Shares (including the new Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) less those new Shares subscribed for by certain Participating Investors pursuant to a Subscription Commitment (the "**Underwritten Shares**"), in their own name but for the account of the relevant subscribers in the Offering to whom those Underwritten Shares have been allocated:

<b>Underwriters</b>	<b>Percentage of Underwritten Shares to be subscribed for</b>
<b>Bank Degroof Petercam NV/SA</b>	52.5%
<b>Belfius Bank NV/SA</b>	47.5%
<b>Total percentage of Underwritten Shares to be subscribed for</b>	100%

The Underwriters shall have no obligation to underwrite any of the Underwritten Shares prior to the execution of the Underwriting Agreement (and then only in accordance with the terms and subject to the conditions set forth therein). The Underwriters have not committed to subscribe for any of the Shares that will not be subscribed for by investors in the Offering ("*soft underwriting*").

Immediately after receipt of the Underwritten Shares, the Underwriters will deliver such Underwritten Shares to the relevant subscribers in the Offering against payment of the Subscription Price therefor.

In the Underwriting Agreement, the Company will make certain customary representations and warranties and the Company will agree to indemnify each of the Underwriters against certain liabilities in connection with the Offering, including liability under the U.S. Securities Act. If the Underwriting Agreement is not entered into, a supplement to the Prospectus to this effect will be published.

The Underwriting Agreement will provide that each Underwriter shall have the right to terminate the Underwriting Agreement before the realization of the capital increase in relation to the Offering, if: (i) any statement in any offering document is, or has become, or has been discovered to be, inaccurate or misleading in any material respect, or any matter has arisen which would, if the offering documents were to be issued at such time, constitute a material inaccuracy or omission from such offering document; (ii) any matter has arisen

which would, in the reasonable opinion of the Joint Global Coordinators, require under the Euronext Legal Framework the publication of a supplement to the Prospectus or a supplement or addendum to the other offer documents and the relevant Joint Global Coordinator has not explicitly confirmed to the Company at the occasion of the publication of such addendum that it would waive such condition, (iii) the approval for the admission of the Shares to listing and trading on Euronext Brussels has been withdrawn or refused, (iv) there has been a breach by the Company or its subsidiaries of any of the representations and warranties given in relation to it or its subsidiaries and contained in the Underwriting Agreement, or the Company has not complied with its covenants and undertakings set forth in the Underwriting Agreement; (v) any of the Underwriters would default in performing its underwriting obligations under the Underwriting Agreement (it being specified that the termination rights in that case accrue to the non-defaulting Underwriter(s) only); (vi) any Joint Global Coordinator would terminate the Agreement in accordance with the termination events set forth in the Underwriting Agreement; (vii) in the reasonable opinion of the Joint Global Coordinators, there shall have been or it is likely that there will be a material adverse effect; (viii) any of the conditions precedent has not been satisfied, such as (a) the performance of the Participating Investors pursuant to the Subscription Commitments or (b) the delivery of the closing documents; (ix) the Company fails to issue at the relevant date(s) the number of Shares that it is obliged to issue under the Underwriting Agreement; or (x) there has been a force majeure event. Following termination of the Underwriting Agreement by an Underwriter, the other Underwriter will be authorized but is not obliged to further proceed with the Offering and the performance of the Underwriting Agreement without the involvement of the Underwriter who terminated the Underwriting Agreement.

In the event that the Underwriting Agreement is not executed or is executed but subsequently terminated, a supplement to this Prospectus shall be published. After publication of the supplement, the subscriptions for the Offered Shares will automatically be cancelled and withdrawn, and subscribers will not have any claim to delivery of the Offered Shares or to any compensation.

Assuming that the Offering Price is at the midpoint of the Price Range, the fees and commissions payable to the Underwriters by the Company are expected to be maximum of (a) € 2.48 million, assuming a placement of the maximum number of Offered Shares in the Offering (excluding the exercise of the Increase Option and the Over-allotment Option), (b) € 2.93 million, assuming a placement of the maximum number of Offered Shares in the Offering (including the exercise in full of the Increase Option but excluding the exercise of the Over-allotment Option), or (c) € 3.44 million, assuming a placement of the maximum number of Offered Shares in the Offering (including the exercise in full of the Increase Option and the Over-allotment Option).

## **15.2 Standstill**

The Company is expected to agree pursuant to the Underwriting Agreement (which is expected to be entered into on or about 23 September 2020) that it will not, and it will procure that none of its affiliates will, for a period as from the date of the Underwriting Agreement until 360 days after the Closing Date, otherwise than with the prior written consent of the Joint Global Coordinators (which will not be unreasonably withheld or delayed): (i) issue, offer, sell, contract to sell or otherwise transfer, (attempt to) dispose of, lend, or solicit any offer to buy (or publicly announce such action), directly or indirectly, any Shares or securities of the Company that are substantially similar to the Shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, Shares or any such substantially similar securities, (ii) grant or issue any options, warrants, convertible or exchangeable securities, other guaranty, or other rights to subscribe for or purchase Shares in the Company, or enter into any swap, hedge or

other arrangement pursuant to which the economic consequences of its ownership of Shares is transferred to any other person or entity, in whole or in part, whether any such transaction is to be settled by delivery of Shares or such other securities, or cash or otherwise, or to enter into any contract (including derivative transactions) or commitment with like effect, or (iii) submit to its shareholders or any other body a proposal to effect any of the foregoing. The foregoing undertaking shall not apply in relation to (1) the new Shares, (2) the Over-allotment Option, (3) the Shares (to be) issued upon exercise of the Over-allotment Option, (4) the new Shares (to be) issued upon the exercise of warrants, conversion rights or options that are outstanding or are contemplated to be issued as described in the Prospectus, (5) the granting of warrants or options under employee stock option plans or under warrant or option plans, provided that the total amount of outstanding warrants or options, including the ESOP Warrants outstanding at the date of the Underwriting Agreement, shall not, at any given time, during the period of 360 days from the Closing Date exceed 12.5% of the total number of all outstanding Shares (on a fully diluted basis), and (6) any share issue component in relation to a licensing or acquisition transaction.

### 15.3 Lock-up arrangements

The current holders of Shares or certain other securities of the Company have entered into a lock up arrangement with the Underwriters in respect of (i) any of their Shares in the Company prior to the Offering and (ii) all their securities issued or agreed to by the Company that are convertible into or exercisable or exchangeable for Shares of the Company (including the shares into which such securities are converted, exercised or exchanged) (together the "**Locked Securities**"). The definition of Locked Securities does not include any of the new Shares that will be subscribed for in the Offering at the Offering Price pursuant to the Subscription Commitments or otherwise, and any of the new Shares that will be subscribed after the closing of the Offering pursuant to the exercise of ESOP Warrants.

Pursuant to the lock up arrangement, the current holders of Locked Securities will not voluntarily do any of the following (a) for a period six months after the Listing Date for current holders of Locked Securities representing 2% or less of the Shares on a fully diluted basis (excluding the new Shares to be issued pursuant to the Offering), or (b) for a period of twelve months for current holders of Locked Securities representing more than 2% of the Company's Shares on a fully diluted basis (excluding the new Shares to be issued pursuant to the Offering): (i) directly or indirectly, conditionally or unconditionally, issue, offer, pledge, exchange, lend, assign by way of security, grant any right "in rem", deliver or market, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or lend or otherwise transfer or dispose of any of their Locked Securities, (ii) enter into any swap, any arrangement, any derivative transaction or issue any instruments that transfer (conditionally or unconditionally, now or in the future) to a third party all or part of the economic risk, benefits, rights or ownership of any Locked Securities, or (iii) publicly announce such an intention to effect any such transaction.

Subject to certain conditions, the restrictions do not prohibit the holders of Locked Securities from (i) accepting a public takeover or tender offer on all of the Shares or other securities of the Company, giving an irrevocable commitment to accept such an offer, or disposing of Locked Securities to an offeror or potential offeror during the period of such an offer or pursuant to a squeeze-out; (ii) proceeding with any transfer required by law, regulation or a court of competent jurisdiction; (iii) transferring Locked Securities to the legal successor pursuant to the merger, liquidation, concursus, de-merger, transfer of a division or of a business as a whole of such holder (in the event the holder is a legal person), provided that each such transferee

shall continue to be bound by the restrictions for the remaining period of the restrictions; (iii) transferring Locked Securities to the legal successors pursuant to (a) the death of such holder (in the event the holder is a natural person) or (b) the a merger, liquidation, concursus, de-merger, transfer of a division or transfer of a business as a whole of such holder (in the event the holder is a legal person), provided that each such transferee shall continue to be bound by the restrictions for the remaining period of the restrictions; (iv) lending a number of Locked Shares to one of the Joint Global Coordinators in the framework of the Offering; (v) transferring Locked Securities to the person for the economic benefit of which the relevant holder currently holds the Locked Securities as escrow agent, trustee or in a similar capacity, (vi) any transfer of Locked Securities to an ascendant, descendant or spouse or an affiliate of the current holder, (vii) any pledge of the Locked Securities to a financial institution securing a mortgage or loan entered into by such holder.

Furthermore, during the second six-month period following after the Listing Date, the lock-up restrictions shall not apply to transfers approved by the Joint Global Coordinators on a discretionary basis. In case of such proposed transfers representing at least 5% of the Locked Securities, the transferors shall need to agree a coordinated transfer process with the Joint Global Coordinators.

#### **15.4 Over-allotment Option and price stabilization**

In connection with the Offering, Belfius Bank NV/SA will act as Stabilization Manager on behalf of the Underwriters and may engage in transactions that stabilize, maintain or otherwise affect the price of the Shares or any options, warrants or rights with respect to, or other interest in, the Shares or other securities of the Company for up to 30 calendar days from the Listing Date. These activities may support the market price of the Shares at a level higher than that which might otherwise prevail. Stabilization will not be executed above the Offering Price. Such transactions may be effected on the regulated market of Euronext Brussels, in the over-the-counter markets or otherwise. The Stabilization Manager and its agents are not required to engage in any of these activities and, as such, there is no assurance that these activities will be undertaken; if undertaken, the Stabilization Manager or its agents may discontinue any of these activities at any time and they must terminate at the end of the 30-calendar day period mentioned above.

Under the possible stabilization measures, investors may, in addition to the new Shares being offered, be allocated up to 15% of the new Shares subscribed for in the Offering (including the new Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) as additional Shares as part of the allocation of the Shares to be placed. Within the scope of a possible over-allotment, the additional Shares will be provided for the account of the Stabilization Manager, acting on behalf of the Underwriters, in the form of a securities loan from Robert Taub.

The Company is expected to grant to the Stabilization Manager, acting on behalf of the Underwriters, an Over-allotment Option, in the form of a warrant, which will entitle the Stabilization Manager, acting on behalf of the Underwriters, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the new Shares subscribed for in the Offering at the Offering Price to cover over-allotments or short positions, if any, in connection with the Offering.

The Stabilization Manager may elect to reduce any short position by exercising all or part of the Over-allotment Option. The Over-allotment Option will be exercisable for a period of 30 calendar days from the Listing Date. The Over-allotment Option will be exercisable in whole or in part, and in one or in several times, to

cover over-allotments or short positions, if any. The possibility to over-allot Shares in the Offering and to exercise the Over-allotment Option will exist whether or not the Offering is fully subscribed.

If the Stabilization Manager creates a short position in the Shares in connection with the Offering (i.e. over-allot additional Shares), they may reduce that short position by purchasing Shares or by exercising all or part of the Over-allotment Option. Purchases of Shares to stabilize the trading price or to reduce a short position may cause the price of the Shares to be higher than it might be in the absence of such purchases. Neither the Company, nor the Underwriters make any representation or prediction as to the direction or the magnitude of any effect that the transactions described above may have on the price of the Shares.

During the Stabilization Period, the details of all stabilisation transactions will be made public no later than the end of the seventh daily market session following the date of execution of such transactions, in accordance with Article 6.2 of the Commission Delegated Regulation (EU) 2016/1052 of 8 March 2016 supplementing Regulation (EU) No 596/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the conditions applicable to buy-back programs and stabilization measures.

Within five business days of the end of the Stabilization Period, the following information will be made public in accordance with Article 5 of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse and Article 6.3 of the Commission Delegated Regulation (EU) 2016/1052 of 8 March 2016 supplementing Regulation (EU) No 596/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the conditions applicable to buy-back programs and stabilization measures, as well as Article 5, §2 of the Royal Decree on Primary Markets Practices: (i) whether or not stabilization was undertaken; (ii) the date at which stabilization started; (iii) the date on which stabilization last occurred; (iv) the price range within which stabilization was carried out, for each of the dates on which stabilization transactions were carried out; and (v) the final size of the Offering, including the result of the stabilization and the exercise of the Over-allotment Option, if any, and (vi) the place where the stabilization was undertaken including, where relevant, the name of the trading venue.

## **15.5 Interests in the Offering**

In connection with the Offering, each of the Underwriters and any of their respective affiliates, acting as an investor for its own account, may take up Offered Shares in the Offering and in that capacity may retain, purchase or sell for its own account such securities and any Shares or related investments and may offer or sell such Shares or other investments otherwise than in connection with the Offering. For more information on the fees and commissions of the Underwriters payable by the Company in connection with the Offering, see section 15.1 (*Underwriting*). Accordingly, references in the Prospectus to Shares being offered or placed should be read as including any offering or placement of Offered Shares to any of the Underwriters or any of their respective affiliates acting in such capacity. None of the Underwriters intend to disclose the extent of any such investment or transactions otherwise than in accordance with any legal or regulatory obligation to do so. In addition, certain of the Underwriters or their affiliates may enter into financing arrangements (including swaps) with investors in connection with which such Underwriters (or their affiliates) may from time to time acquire, hold or dispose of Shares.

As of the date of this Prospectus, the only contractual relationships between the respective Underwriters and the Company relate to this Offering. Certain of the Underwriters and/or their respective affiliates may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and

ancillary activities in the ordinary course of their business with the Company or any parties related to it, in respect of which they may, in the past have received, or in the future receive, customary fees and commissions. As a result of these transactions, these parties may have interests that may not be aligned, or could possibly conflict with the interests of investors.

Pursuant to the consulting agreement between the Company and ActuaRisk Consulting SRL (CFO of the Company and represented by Fabian Suarez Gonzales), ActuaRisk Consulting SRL shall be entitled to a variable compensation that will become payable upon an "Exit of the Company". The Offering qualifies as an "Exit of the Company" under said agreement. ActuaRisk Consulting SRL shall also be entitled to a success fee of €50,000 (excl. VAT) in case of closing of the Offering. See also Part 10 - (Management and corporate governance), section 10.4.2b (*Remuneration and compensation in 2019*).

As set out Part 10 (Management and corporate Governance) – section 10.5 (*Description of the share incentive plans*), certain directors, members of executive management, officers, employees and consultants of Nyxoah hold ESOP Warrants, pursuant to which they are entitled to subscribe to new Shares. Certain of these ESOP Warrants will immediately vest and be exercisable ten business days prior to the closing of the Offering.

## **15.6 No public offering outside Belgium**

No public offer is being made and no action has been or will be taken that would, or is intended to, permit a public offering of the Offered Shares, or the possession, circulation or distribution of this Prospectus or any other material relating to the Offered Shares, in any country or jurisdiction, other than Belgium, where any such action for that purpose is required. Accordingly, the Offered Shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other offering material or advertisements in connection with the Offered Shares may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of such country or jurisdiction. Purchasers of the Offered Shares may be required to pay stamp taxes and other charges in accordance with the laws and practices of the country of purchase in addition to the Offering Price.

## **16. TAXATION**

### **16.1 Belgian taxation**

The paragraphs below present a summary of certain Belgian federal income tax consequences of the ownership and disposal of the Shares by an investor that acquires such Shares in connection with this Offering. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this Prospectus, all of which are subject to change, including changes that could have retroactive effect. Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below. The tax legislation of the investor's EEA Member State may have an impact on the income received from the Shares.

This summary does not purport to address all tax consequences of the investment in, ownership in and disposal of the 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. This summary 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. This summary does not address the tax regime applicable to Shares held by Belgian tax residents through a fixed basis or a permanent establishment situated outside Belgium. This summary does in principle not address the local taxes that may be due in connection with an investment in the Shares, other than Belgian local surcharges which generally vary from 0% to 9% of the investor's income tax liability.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (i.e. an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (i.e. a corporate entity that has its statutory seat in Belgium (unless it can be demonstrated that the tax residence of the company is situated in another State than Belgium), or a corporate entity that has its main establishment, its administrative seat or seat of management in Belgium), an Organization for Financing Pensions subject to Belgian corporate income tax (i.e. a Belgian pension fund incorporated under the form of an Organization for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (i.e. a legal entity other than a company subject to Belgian corporate income tax, that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium). A non-resident is any person that is not a Belgian resident.

Investors should consult their own advisers regarding the tax consequences of an investment in the Shares in the light of their particular circumstances, including the effect of any state, local or other national laws.

### **16.2 Belgian taxation of dividends on Shares**

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the Shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the Belgian CCA is not treated as a dividend distribution to the extent that such repayment is imputed to the fiscal capital. This fiscal capital includes, in principle, the actual paid-up statutory share capital and, subject to certain conditions, the paid-up issuance premiums and the cash amounts subscribed to

at the time of the issue of profit sharing certificates. Note that Article 18 of the Belgian Income Tax Code ("ITC") was amended by the Act of 25 December 2017. As a consequence, for any decision of capital reduction taken as from 1 January 2018 in accordance with the Belgian CCA, the amount of the capital reduction will be deemed to be derived proportionally (a) from the fiscal capital of the Company, on the one hand and (b) on the other hand, from the total of (i) certain taxed reserves incorporated in the capital of the Company, (ii) certain taxed reserves not incorporated into the capital of the Company and (iii) certain untaxed reserves incorporated into the capital of the Company (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.

Belgian withholding tax of 30% is normally levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions.

In case of redemption of the Shares, the redemption gain (i.e. the redemption proceeds after deduction of the portion of fiscal capital represented by the redeemed Shares) will be treated as a dividend 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 Euronext or a similar stock exchange and meets certain conditions. In case of liquidation of the Company, the liquidation gain (i.e. the amount distributed in excess of the fiscal capital) will in principle be subject to Belgian withholding tax at a rate of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions.

### **16.2.1 Belgian income tax**

#### **a. Belgian resident individuals**

For Belgian resident individuals who acquire and hold the Shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless elect to report the dividends in their personal income tax return. Where such individual opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% withholding tax rate on dividends or at the progressive personal income tax rates applicable to the taxpayer's overall declared income (local surcharges will not apply). In addition, if the dividends are reported, the dividend withholding tax levied 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, provided that the dividend distribution does not result in a reduction in value of or a capital loss on the Shares. This condition is not applicable if the individual can demonstrate that he has held the Shares in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends.

For dividends paid or attributed as of 1 January 2018, an exemption from personal income tax could in principle be claimed by Belgian resident individuals in their personal income tax return for a first tranche of dividend income up to the amount of €812 (for income year 2020) per year and per taxpayer, subject to certain formalities. 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.

For Belgian resident individuals who acquire and hold the Shares for professional purposes, the Belgian withholding tax does not fully discharge their personal income tax liability. Dividends received must be reported by the investor and will, in such case, be taxable at the investor's personal income tax rate increased with local surcharges. Belgian withholding tax levied 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: (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 the investor can demonstrate that he has held the full legal ownership of the Shares for an uninterrupted period of twelve months prior to the attribution of the dividends.

**b. Belgian resident companies**

**i. Withholding tax**

Dividends distributed to a Belgian resident company will be exempt from Belgian withholding tax provided that the Belgian resident company holds, upon payment or attribution of the dividends, at least 10% of the share capital of the Company and such minimum participation is held or will be held during an uninterrupted period of at least one year. In order to benefit from this exemption, the Belgian resident company must provide the Company or its paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions. If the Belgian resident company holds the required minimum participation for less than one year, at the time the dividends are paid on or attributed to the Shares, the Company 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 the Company or its paying agent if the one-year period has expired or if its shareholding will drop below 10% of the share capital of the Company before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the Belgian resident company.

**ii. Corporate income tax**

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) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 25% as of assessment year 2021 for financial years starting on or after 1 January 2020. Subject to certain conditions, a reduced corporate income tax rate of 20% as of assessment year 2021 (i.e. for financial years starting on or after 1 January 2020) may apply for small companies (as defined by Article 1:24, §1 to §6 of the Belgian CCA) on the first bracket of €100,000 of taxable profits.

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, 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 (a) if the company can demonstrate that it has held the Shares in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends; or (b) if, during said period, the Shares never belonged to a taxpayer other than a Belgian resident company or a

non-resident company which has, in an uninterrupted manner, invested the Shares in a permanent establishment ("**PE**") in Belgium.

As a general rule, Belgian resident companies can (subject to certain conditions and limitations) deduct 100% of gross dividends received from their 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 €2,500,000 (it being understood that only one out of the two tests must be satisfied); (2) the Shares have been held or will be held in full 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 ITC (the "**Article 203 ITC Taxation Condition**") are met (together, the "**Conditions for the application of the dividend received deduction regime**"). The Conditions for the application of the dividend received deduction regime depend on a factual analysis, upon each distribution, and for this reason the availability of this regime should be verified upon each distribution.

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.

### c. **Organizations for financing pensions**

For organizations for financing pensions (the "**OFPs**"), i.e. Belgian pension funds incorporated under the form of an OFP (*organismen voor de financiering van pensioenen/organismes de financement de pensions*) within the meaning of Article 8 of the Belgian Law 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 OFPs corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due.

The Belgian Parliament recently adopted a law pursuant to which 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.

**d. Other Belgian resident legal entities subject to Belgian legal entities tax**

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their Belgian income tax liability.

**e. Non-resident individuals or non-resident companies**

**i. Non-resident income tax**

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 PE.

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 personal or corporate income tax rate, as appropriate. Belgian withholding tax levied at source may be credited against non-resident personal 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 at the time the dividends are paid or attributed 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 twelve months prior to the attribution of the dividends or (b) with regard to non-resident companies only, if, during said 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 PE.

Non-resident companies that have attributed the Shares to 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 subsection (b) (Belgian resident companies). 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.

**ii. 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 newly introduced tax exemption with respect to ordinary dividends in an amount of up to €812 (amount applicable for income year 2020) per year and per taxpayer. 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 dividends up to the amount of € 812 (amount applicable for income year 2020) 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 such an amount could in principle be reclaimed by filing a request thereto addressed to the general advisor of the foreign affairs department of the FPS Finance (*adviseur-generaal van het Centrum Buitenland/conseiller général du Centre Etrangers*). 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 which are determined in Article 206/1 of the Belgian Royal Decree implementing the Belgian Income Tax Code.

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 ITC 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 organization must then forward that certificate to the Company or its paying agent.

The Belgian Parliament recently adopted a law pursuant to which a pension fund 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 be rejected, unless counterproof is provided by the OFP that the arrangement or series of arrangements are genuine.

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 the share capital of the Company 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 the Company or its 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, the Company must levy the withholding tax but does not need to transfer it to the Belgian Treasury provided that the non-resident company provides the Company or its 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 the Company or its paying agent when the one-year

period has expired or if its shareholding drops below 10% of the Company's share capital before the end of the one-year 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 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 the Company's share capital but with an acquisition value of at least €2,500,000; (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 the Company or its 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 31 December of the year preceding the year during which the dividend is paid or attributed.

Belgian dividend withholding tax is subject to such relief as may be available under applicable tax treaty provisions. Belgium has concluded tax treaties with more than 95 countries, reducing the dividend withholding tax rate to a rate between 0% to 20% for residents of those countries, depending on conditions, among others, related to the size of the shareholding and certain identification formalities. Such reduction may be obtained either directly at source or through a refund of taxes withheld in excess of the applicable treaty rate.

Prospective holders of Shares should consult their own tax advisers to determine whether they qualify for a reduction in withholding tax upon payment or attribution of dividends, and, if so, to understand the procedural requirements for obtaining a reduced withholding tax upon the payment of dividends or for making claims for reimbursement.

## 16.2.2 Belgian taxation of capital gains and losses on Shares

### a. Belgian resident individuals

In principle, 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 in principle not tax deductible.

However, capital gains realized by a Belgian resident individual are taxable at 33% (plus local surcharges) if the capital gain on the Shares is deemed to be realized outside the scope of the normal management of the individual's private estate (e.g. in case of speculation). Capital losses are, however, not tax deductible.

Moreover, capital gains realized by Belgian resident individuals on the disposal of the Shares, outside the exercise of a professional activity, to a non-resident company (or 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 the Company (i.e. a shareholding of more than 25% in the Company). Capital losses are, however, not tax deductible in such event.

Capital gains realized by Belgian resident individuals upon redemption of the Shares or upon liquidation of the Company will generally be taxable as a dividend. See section 16.2 (*Belgian taxation of dividends on Shares*). In the case of a redemption of the Shares followed by their annulment, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed Shares) will be treated as a dividend 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 case of liquidation of the Company, any amounts distributed in excess of the fiscal capital will in principle be subject to a 30% withholding tax, subject to such relief as may be available under applicable domestic or treaty provisions.

Belgian resident individuals who hold the Shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realized upon the disposal of the Shares, except for: (i) capital gains on Shares realized in the framework of the cessation of activities, which are taxable at a separate rate of 10% or 16.5% (depending on the circumstances); or (ii) Shares held for more than five years, which are taxable at 16.5% 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.

### b. Belgian resident companies

Belgian resident companies are in principle not subject to Belgian corporate income tax on capital 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,

the capital gains realized upon the disposal of the Shares by Belgian resident companies are taxable at the standard corporate income tax rate of 25% (as of assessment year 2021 for financial years starting on or after 1 January 2020) or, if applicable, the reduced rate of 20% (as of assessment year 2021 for financial years starting on or after 1 January 2020) for small companies, as defined by Article 1:24 of the Belgian CCA.

Capital gains realized by Belgian resident companies upon the redemption of Shares by the Company or upon the liquidation of the Company will, in principle, be subject to the same taxation regime as dividends (see above).

Capital losses on the Shares incurred by Belgian resident companies are as a general rule not tax deductible.

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. As of assessment year 2021, for financial years starting on or after 1 January 2020, the capital gains on such Shares are taxable at the ordinary corporate income tax rate of 25%, unless the reduced corporate income tax rate of 20% applies (*supra*), and the capital losses on such Shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

**c. Belgian resident organizations for financing pensions**

Capital gains on the Shares realized by OFPs within the meaning of Article 8 of the Belgian Act of 27 October 2006 are in principle exempt from corporate income tax and capital losses are not tax deductible.

Capital gains realized by Belgian OFPs upon the redemption of ordinary shares or upon the liquidation of the Company will in principle be taxed as dividends.

**d. Other Belgian resident legal entities subject to Belgian legal entities tax**

Capital gains realized upon disposal of the Shares by Belgian resident legal entities are in principle not subject to Belgian income tax.

Capital gains realized upon disposal of (part of) a substantial participation in a Belgian company (i.e., a participation representing more than 25% of the share capital of the Company 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 realized by Belgian resident legal entities upon the redemption of Shares or upon the liquidation of the Company will, in principle, be taxed as dividends (see above).

Capital losses on Shares incurred by Belgian resident legal entities are generally not tax deductible.

**e. Non-resident individuals**

Capital gains realized on the Shares by a non-resident individual that has not held the Shares in connection with a business conducted in Belgium through a fixed base in Belgium are in principle not subject to taxation, unless in the following cases if such capital gains are obtained or received in Belgium:

- the gains are deemed to be realized outside the scope of the normal management of the individual's private estate. In such case, the capital gains have to be reported in a non-resident tax return for the income year during which the gain has been realized and may be taxable in Belgium; or
- the gains originate from the disposal of (part of) a substantial participation in a Belgian company (being a participation representing more than 25% of the share capital of the Company at any time during the last five years prior to the disposal) 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 of the EEA. Then, the realized capital gains may, under certain circumstances, give rise to a 16.5% tax (plus local surcharges).

However, Belgium has concluded tax treaties with more than 95 countries which generally provide for a full exemption from Belgian capital gains taxation on such gains realized by residents of those countries. Capital losses are generally not tax deductible.

Capital gains realized by Belgian non-resident individuals upon the redemption of Shares or upon the liquidation of the Company will generally be taxable as a dividend (see above).

Capital gains will be taxable at the ordinary progressive income tax rates and capital losses will be tax deductible, if those gains or losses are realized on Shares by a non-resident individual that holds Shares in connection with a business conducted in Belgium through a fixed base in Belgium.

#### **f. Non-resident companies or entities**

Capital gains realized by non-resident companies or other non-resident entities that hold the Shares in connection with a business conducted in Belgium through a PE are generally subject to the same regime as Belgian resident companies or other Belgian resident legal entities subject to Belgian legal entities tax.

Capital gains realized by non-resident companies or non-resident entities upon redemption of the Shares or upon liquidation of the Company will, in principle, be subject to the same taxation regime as dividends (see above).

### **16.2.3 Belgian tax on stock exchange transactions and tax on repurchase transactions**

The purchase and the sale and any other acquisition or transfer for consideration of the Shares (secondary market transactions) is subject to the tax on stock exchange transactions as mentioned in articles 120 and following the Belgian Code of 2 March 1927 on miscellaneous duties and taxes (*wetboek van 2 maart 1927 diverse rechten en taksen/Code du 2 mars 1927 des droits et taxes divers ("CMDT")*) (hereafter referred to as the "**Tax on Stock Exchange Transactions**") if (i) it is executed in Belgium through a professional intermediary, or (ii) deemed to be executed 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 in Belgium, or legal entities for the account of their seat or establishment in Belgium (both, a "**Belgian Investor**"). No Tax on Stock Exchange Transactions is due on the issuance of the Shares (i.e. primary market transactions).

The Tax on Stock Exchange Transactions is levied at a rate of 0.35% of the purchase price. This tax is however limited to a maximum of €1,600 per transaction and per party.

In addition, the tax on repurchase transactions (tax on a sale combined with a forward purchase) as mentioned in articles 138 and following CMDT (*taks op de reporten/taxe sur les reports*) (the "**Tax on Repurchase Transactions**") is levied at a rate of 0.085%, capped at €1,600 per transaction and per party, in case a professional intermediary acts for either party in a secondary market transaction.

For both the Tax on Stock Exchange Transactions and the Tax on Repurchase Transactions, the tax is due separately by each party to the transaction, i.e. the seller (transferor) and the purchaser (transferee), and is collected by the professional intermediary.

However, if the intermediary is established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. 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 (*borderel/bordereau*), 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-today listing, numbered in series. Alternatively, professional intermediaries established outside of Belgium could, subject to certain conditions and formalities, appoint a stock exchange tax representative in Belgium in accordance with article 126/3 CMDT ("**Stock Exchange Tax Representative**"). Such Stock Exchange Tax Representative will then be liable towards the Belgian Treasury for the Tax on Stock Exchange Transactions 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 (*borderel/bordereau*) 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.

An exemption is available for exempt persons acting for their own account, including investors who are Belgian non-residents provided they deliver an affidavit to the financial intermediary in Belgium confirming their non-resident status and certain Belgian institutional investors, as defined in Article 126<sup>1</sup>, 2° CMDT for the tax on stock exchange transactions and Article 139, §2 of the same code for the tax on repurchase transactions.

The EU Commission adopted on 14 February 2013 the Draft Directive on a Financial Transaction Tax, or FTT (see below). The Draft Directive currently 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). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

#### **16.2.4 Common Reporting Standard**

Following recent international developments, the exchange of information will be governed by the Common Reporting Standard ("**CRS**").

On 3 September 2020, 109 jurisdictions had signed the multilateral competent authority agreement ("**MCAA**"), which 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 50 jurisdictions 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, one jurisdiction as from 2019 and 6 jurisdictions as from 2020. 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.

Belgium has implemented the DAC2 and respectively the CRS by the Act of 16 December 2015 regulating the exchange of financial account information between Belgian financial institutions and the FPS Finances in the framework of automatic information exchange at the international level and for tax purposes ("**Act of 16 December 2015**").

The Shares are subject to DAC2 and to the Act of 16 December 2015. Under DAC2 and the Act of 16 December 2015, Belgian financial institutions holding the Shares for tax residents in another CRS contracting state shall report financial information regarding the Shares (e.g. in relation to income and gross proceeds) to the Belgian competent authority, who shall communicate the information to the competent authority of the state of the tax residence of the beneficial owner.

As a result of the Act 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 (including Austria, irrespective of the fact that the automatic exchange of information by Austria towards other EU Member States is only foreseen as of income year 2017), (ii) as of income year 2014 (first information exchange in 2016) towards the United States and (iii), with respect to any other non-EU States that have signed the MCAA, as of the respective date determined by Royal Decree.

In a Royal Decree of 14 June 2017, as amended, it was determined that the automatic provision of information has to be provided as from 2017 (for the 2016 financial year) for a first list of eighteen foreign jurisdictions, as from 2018 (for the 2017 financial year) for a second list of 44 jurisdictions, as from 2019 (for the 2018 financial year) for another jurisdiction and as from 2020 (for the 2019 financial year) for a fourth list of 6 jurisdictions.

Investors who are in any doubt as to their position should consult their professional advisers.

### **16.2.5 The proposed Financial Transaction Tax**

On 14 February 2013, the European Commission adopted a Draft Directive implementing enhanced cooperation in the area of financial transaction tax in Belgium, Germany, Estonia, Greece, Spain, France, Italy, Austria, Portugal, Slovenia and Slovakia (the "**Participating Member States**"). However, on 16 March 2016 Estonia formally withdrew from the group of states willing to introduce the FTT.

The proposed FTT has a 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 is exempt from financial transaction tax in the current Draft Directive. This means that the issuance and subscription of the Shares should not become subject to financial transaction tax. The target date of 30 June 2016, for expected full agreement on a proposed FTT, mentioned in a statement dated 3 June 2016, has not been met and there is no specification available of a new target adoption date.

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.

As a result, investors may be faced with additional transaction costs if the FTT is introduced in its current form. The rate for financial instruments is a minimum of 0.1% of the purchase price (or market value if greater). Nevertheless, the effective rate will be higher as each financial institution party is separately liable for the tax, so transactions between two financial institutions will be taxed twice.

The Draft Directive provides that 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.

The FTT proposal remains subject to negotiation between the participating Member States. It may therefore be altered prior to any implementation, the timing of which remains unclear. Additional Member States may decide to participate. Prospective investors are strongly advised to seek their own professional advice in relation to the FTT.

### **16.3 U.S. Federal Income Tax Considerations**

#### **16.3.1 General**

This section describes certain U.S. federal income tax consequences to U.S. Shareholders of acquiring, owning, and disposing of the Shares. It applies only to U.S. Shareholders who acquire their ordinary Shares in the initial offering through this Prospectus and who hold such Shares as capital assets for U.S. federal income tax purposes. This section does not apply to a shareholder who is member of a special class of shareholders subject to special U.S. tax rules, including:

- a dealer in securities;
- a real estate investment trust or regulated investment company;
- a trader in securities that elects to use a mark-to-market method of accounting for securities holdings;
- a tax-exempt organization;
- a tax-deferred account, including an "individual retirement account" or "Roth IRA";
- a bank or other financial institution, or a life insurance company;
- a person that actually or constructively owns 10% or more of either the voting power or the value of the Shares;
- a person that holds Shares as part of a straddle or a hedging, integrated or conversion transaction;
- a former citizen or long term resident of the United States;
- a U.S. Shareholder (as defined below) whose functional currency is not the U.S. dollar.

This section is based on the U.S. Internal Revenue Code of 1986, as amended, its legislative history, existing and proposed U.S. Treasury Regulations, published rulings and court decisions, as well as the Convention Between the Government of the United States of America and 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* (the "**Treaty**"), all as of the date hereof and all subject to change, possibly on a retroactive basis. No ruling will be sought from the U.S. tax authority in any respect of this discussion and no assurance can be given that the U.S. tax authority will not assert a position different to that expressed herein.

A Shareholder is a "U.S. Shareholder" if such Shareholder is a beneficial owner of Shares and if such Shareholder is, 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 whose income is subject to U.S. federal income tax regardless of its source, or
- a trust, if (1) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons are authorized to control all substantial decisions of the trust or (2) such trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

If a partnership (including any entity treated as a partnership for U.S. federal income tax purposes) is a Shareholder, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. A Shareholder that is a partnership, and partners in such partnership, should consult their own tax advisors regarding the tax consequences of acquiring, owning and disposing of the Shares.

**Shareholders should consult their own tax advisors regarding the U.S. federal, state and local and other tax consequences of acquiring, owning and disposing of Shares in their particular circumstances.**

This discussion addresses only U.S. federal income taxation of U.S. Shareholders. Shareholders should consult their own tax advisors as to potential application of U.S. state and local tax laws, any other U.S. tax laws (such as the gift, alternative minimum, or estate tax) and other U.S. laws and foreign laws, including the laws of the Kingdom of Belgium.

This discussion is addressed only to U.S. Shareholders. If you are not a U.S. Shareholder, please consult your own tax advisors as to the consequences of acquiring, owning and disposing of the Shares of the Company.

### **16.3.2 Taxation of U.S. Shareholders**

#### **a. Passive Foreign Investment Company Considerations**

The Company believes that, based on its expected income operations and assets, the Shares are likely to be treated as stock of a passive foreign investment company (a "PFIC") for U.S. federal income tax purposes for its current taxable year and for the foreseeable future. This conclusion is a factual determination made on an annual basis, and it is possible that the Company's income and assets may, in some taxable year in the future, allow the Company to make a differing conclusion.

In general, the Company will be a PFIC with respect to a U.S. Shareholder if for any taxable year of the Company in which Shares are held by such U.S. Shareholder:

- at least 75% of the Company's gross income for the taxable year is "passive income"; or
- at least 50% of the value, determined on the basis of a quarterly average, of the Company's gross assets is attributable to assets that produce or are held for the production of "passive income."

For purposes of the PFIC rules, "passive income" generally includes dividends, interest, royalties, rents (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from the disposition of assets that produce passive income. Cash is generally treated as an asset that produces passive income. If a foreign corporation owns at least 25% by value of the stock of another corporation, the foreign 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. Moreover, Shares will be treated as stock of a PFIC with respect to a U.S. Shareholder if the Company is a PFIC at any time during the period in which such U.S. Shareholder holds the Shares, even if the Company ceases to be treated as a PFIC, unless certain special elections are made.

If the Company is treated as a PFIC, and a U.S. Shareholder does not make one of the elections described below, such U.S. Shareholder will be subject to special tax rules with respect to:

- any gain realized on the sale or other disposition of Shares; and
- any excess distribution that the Company makes to such U.S. Shareholder (generally, any distributions during a single taxable year that are greater than 125% of the average annual distributions received by such U.S. Shareholder in respect of its Shares during the three preceding taxable years or, if shorter, such U.S. Shareholder's holding period for its Shares).

Under these rules:

- the gain or excess distribution will be allocated ratably over the U.S. Shareholder's holding period for its Shares;

- the amount allocated to the taxable year in which the U.S. Shareholder realized the gain or excess distribution will be taxed as ordinary income;
- the amount allocated to each prior year, with certain exceptions, will be taxed at the highest tax rate in effect applicable to ordinary income for the applicable class of taxpayers for that year; and
- the interest charge generally applicable to underpayments of tax will be imposed in respect of the tax attributable to each prior year.

Assuming the Company is a PFIC, the general tax treatment for U.S. Shareholders described above would apply to indirect distributions and gains deemed to be realized by U.S. Shareholders in respect of any of the Company's subsidiaries that are also PFICs. The Company believes that the Company and its subsidiaries are likely to be PFICs for the current taxable year of each such subsidiary.

#### **b. QEF Election**

The special PFIC tax rules described above will not apply to a U.S. Shareholder who elects to have the Company treated as a "qualified electing fund" with respect to such U.S. Shareholder (such election, a "**QEF election**") and the Company provides certain required information to U.S. Shareholders to give effect to such election. The Company intends to provide U.S. Shareholders with such information as may be required to make a QEF election effective.

If you are a U.S. Shareholder that makes a QEF election, you will be currently taxable on your pro rata share of the Company's ordinary earnings and net capital gain, at ordinary income and capital gain rates, respectively, for each of the Company's taxable years, regardless of whether or not you receive distributions. Your basis in the Shares will be increased to reflect taxed but undistributed income. Distributions of income that had been taxed previously will result in a corresponding reduction of basis in the Shares and will not be taxed again as a distribution to you.

#### **c. Mark-to-Market Election**

If the Company is determined to be a PFIC and the Shares are treated as marketable stock, a U.S. Shareholder may make a mark-to-market election with respect to its Shares requiring the U.S. Shareholder to currently include any appreciation in its Shares in its income as ordinary income on an annual basis to avoid gain and excess distributions being treated as earned ratably over the U.S. Shareholder's holding period (and therefore, also avoiding the application of the interest charge described above). However, a mark-to-market election will generally not be available unless the Shares are regularly traded on a qualified exchange and, further, would not mitigate the adverse implications of PFIC status with respect to any subsidiaries of the Company. The Company cannot guarantee that its Shares will be traded on a qualified exchange or be sufficiently traded on such an exchange, and thus, the Company cannot guarantee its Shares would be treated as marketable stock.

If the Company is treated as a PFIC for any taxable year with respect to a U.S. Shareholder and a QEF election is not in effect, such U.S. Shareholder may be able to make a deemed sale election if the Company ceases to be treated as a PFIC in subsequent taxable years. The effect of the deemed sale is generally to "purge" the Company's stock of its characterization as stock of a PFIC, and thereafter, such Company stock generally would not be treated as stock of a PFIC with respect to such U.S. Shareholder, provided that the

Company does not become a PFIC again in a subsequent taxable year. Upon making a deemed sale election with respect to the Company's stock, generally such electing U.S. Shareholder would be treated as having sold all of such U.S. Shareholder's stock in the Company for its fair market value on the last day of the Company's last taxable year during which the Company was treated as a PFIC, and such deemed sale generally would be treated as a taxable disposition that is subject to the PFIC tax rules described above. The U.S. Shareholder's holding period in the non-PFIC Shares would be treated as beginning on the day following the deemed sale for purposes of the PFIC rules. U.S. Shareholders should consult their own tax advisors as to the availability and consequences of a deemed sale election.

A U.S. Shareholder must generally file an IRS Form 8621 ("Information Return by a Shareholder of a Passive Foreign Investment Company") with its U.S. federal income tax return for any taxable year in which the Company is a PFIC with respect to such U.S. Shareholder. U.S. Shareholders are urged to consult their own tax advisors concerning the filing of IRS Form 8621.

#### **d. Taxation of Dividends**

Notwithstanding any election a U.S. Shareholder makes with regard to its Shares (discussed above), dividends received from the Company will not constitute qualified dividend income taxable at long-term capital gains rates for a non-corporate U.S. Shareholder if the Company is a PFIC either in the taxable year of the distribution or the preceding taxable year. Moreover, such U.S. Shareholder's Shares will continue to be treated as stock in a PFIC if the Company was a PFIC at any time during such U.S. Shareholder's holding period in its Shares, even if the Company is not currently a PFIC (unless a deemed sale election is made to purge characterization of a U.S. Shareholder's Shares as stock of a PFIC, as discussed above). Dividends that a U.S. Shareholder receives that do not constitute qualified dividend income are not eligible for taxation at the preferential rate of taxation under current law applicable to qualified dividend income. Instead, such U.S. Shareholder will be subject to U.S. federal income tax at rates applicable to ordinary income on the gross amount of any such distribution treated as a dividend.

Dividends are taxable to U.S. Shareholders as ordinary income when such dividends are received, actually or constructively. Such dividends will not be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations.

The amount of a dividend distribution that U.S. Shareholders must include in their income as a U.S. Shareholder will be the U.S. dollar value of the euro payments made, determined at the spot euro/U.S. dollar rate on the date the dividend distribution is includible in such U.S. Shareholder's income, regardless of whether the payment is in fact converted into U.S. dollars. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date a dividend payment is included in taxable income to the date the payment is converted into U.S. dollars will be treated as ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. The currency gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes. If dividends received in euros are converted into U.S. dollars on the day they are received, the U.S. Shareholder generally will not be required to recognize foreign currency gain or loss in respect of the dividend income.

#### **e. Foreign Tax Credits**

With respect to any dividends paid to U.S. Shareholders, such U.S. Shareholders must include any Belgian tax withheld from the dividend payment in the gross amount of such dividend even though it was not received. Subject to certain limitations, Belgian tax withheld in accordance with the Treaty and paid over to Belgium will be creditable or deductible against a U.S. Shareholder's United States federal income tax liability. Special rules apply in determining the foreign tax credit limitation with respect to dividends that are subject to the maximum 15% tax rate. To the extent a refund of the tax withheld is available to a U.S. Shareholder under Belgian law or under the Treaty, the amount of tax withheld that is refundable will not be eligible for credit against such U.S. Shareholder's United States federal income tax liability.

A U.S. Shareholder may make an election to treat all foreign taxes paid as deductible expenses in computing taxable income, rather than as a credit against tax, subject to generally applicable limitations. Such an election, once made, applies to all foreign taxes paid for the taxable year subject to the election. The rules governing foreign tax credits are complex and, therefore, U.S. Shareholders are strongly encouraged to consult their own tax advisors to determine whether they are subject to any special rules that may limit their ability to make effective use of foreign tax credits and whether or not an election would be appropriate based on their particular circumstances.

**f. Taxation of Capital Gains**

If the PFIC rules discussed above were not to apply, when a U.S. Shareholder sells or otherwise disposes of its Shares, such U.S. Shareholder generally will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference between the U.S. dollar value of the amount realized and such U.S. Shareholder's tax basis, determined in U.S. dollars, in its Shares. Capital gain of a non-corporate U.S. Shareholder is generally taxed at a preferential rate of taxation under current law where the Shareholder has a holding period greater than one year. Such gain or loss will generally be income or loss from sources within the United States for foreign tax credit limitation purposes. The deductibility of capital losses is subject to certain limitations.

**g. Net Investment Income Tax**

Subject to certain limitations, an additional tax of 3.8% is imposed on the "net investment income" of certain U.S. Shareholders who are citizens and resident aliens, and on the undistributed "net investment income" of certain estates and trusts. Among other items, "net investment income" generally would include dividends paid on Shares and certain net gain from the sale or other taxable disposition of Shares, less certain deductions. U.S. Shareholders should consult their own tax advisors concerning the effect, if any, of this net investment income tax on holding Shares in their particular circumstances.

**h. Backup Withholding and Information Reporting**

For a non-corporate U.S. Shareholder, information reporting requirements, on Internal Revenue Service Form 1099, generally will apply to:

- dividend payments or other taxable distributions made to such U.S. Shareholder within the United States or by a U.S. payor; and
- the payment of proceeds to such U.S. Shareholder from the sale of Shares effected at a U.S. office of a broker.

Additionally, backup withholding may apply to such payments to a non-corporate U.S. Shareholder that fails to provide an accurate taxpayer identification number, is notified by the Internal Revenue Service that such non-corporate U.S. Shareholder has failed to report all interest and dividends required to be shown on its U.S. federal income tax returns, or in certain circumstances, fails to comply with applicable certification requirements. Certain U.S. Shareholders (including, among others, corporations) are not subject to backup withholding.

Backup withholding is not an additional tax. A non-corporate U.S. Shareholder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed such Shareholder's U.S. federal income tax liability by timely filing a refund claim with the Internal Revenue Service.

**i. Disclosure of Information with respect to Foreign Financial Assets**

Certain U.S. Shareholders who hold any interest in "specified foreign financial assets," including the Shares, during such U.S. Shareholders' taxable year must attach to their U.S. federal income tax return for such year certain information with respect to each asset (IRS Form 8938 "Statement of Specified Foreign Financial Assets") if the aggregate value of all of such assets exceeds \$50,000 on the last day of the tax year or more than \$75,000 at any time during the tax year (or a higher dollar amount prescribed by the Internal Revenue Service). For this purpose, a "specified foreign financial asset" includes any depositary, custodial or other financial account maintained by a foreign financial institution, and certain assets that are not held in an account maintained by a financial institution, including any stock or security issued by a person other than a U.S. person. Penalties apply for failure to furnish the required information. U.S. Shareholders should consult their own tax advisers concerning any obligation that they may have to furnish information to the Internal Revenue Service as a result of holding the Shares.

**The above discussion is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of the Shares.**

## **17. LEGAL MATTERS**

Certain legal matters in connection with this Offering have been passed upon for the Company by NautaDutilh BV/SRL with respect to the laws of Belgium and by Proskauer Rose LLP with respect to the laws of the United States. Certain legal matters in connection with this Offering have been passed upon for the Underwriters by Baker & McKenzie CVBA/SCRL with respect to the laws of Belgium and by Baker & McKenzie LLP with respect to the laws of the United States.

## **18. GENERAL INFORMATION**

### **18.1 Domicile, Legal Form and Incorporation**

The Company is a public 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 Wallon) under enterprise number 0817.149.675. The Company's registered office is in Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium. The Company's telephone number is +32 10 22 23 55. The Company's Legal Entity Identifier (LEI) is 5493002O1ESKZ18OXR80 - Nyxoah SA. The Company's website is [www.nyxoah.com](http://www.nyxoah.com).

### **18.2 Statutory Auditor**

The Company's statutory auditor is EY Réviseurs d'Entreprises SRL, with registered office at De Kleetlaan 2, 1831 Diegem, Belgium, represented by Carlo-Sébastien D'Addario, auditor. EY Réviseurs d'Entreprises SRL is a member of the *Instituut van de Bedrijfsrevisoren/Institut des Réviseurs d'Enterprises*. The Company's statutory auditor has been appointed effective as from 23 May 2019 for the statutory term of three years by the Company's extraordinary general shareholders' meeting held on 23 May 2019. Belgian law limits the auditor's liability to €3 million (for a non-listed company) and €12 million (for a listed company) for tasks reserved to auditors by Belgian law or in accordance with Belgian law, such as auditing financial statements such as those described above, other than liability due to fraud or other deliberate breach of duty.

The Company's Consolidated Financial Statements as of 31 December 2019, 2018 and 2017 have been audited by EY Réviseurs d'Entreprises SRL, who rendered an unqualified opinion on these Consolidated Financial Statements.

EY Réviseurs d'Entreprises SRL has consented to the inclusion of its reports in this Prospectus in the form and context in which they appear and has at the date of this Prospectus not withdrawn its consent.

### **18.3 No Significant change**

As at the date of this Prospectus, there has been no significant change in the financial performance, the financial position and the trading position of the Group since 30 June 2020. See section 9.2 (*Current trading developments and recent trends*) for further information on the Group's current trading and recent developments.

### **18.4 Options or preferential rights in respect of shares**

Save as disclosed in section 8.12.4 (*Noshaq Convertible Loan*) and section 10.5 (*Description of the share incentive plans*), the Company is not party to any contract or arrangement (or contemplated contract or arrangement), whereby an option or preferential right of any kind is (or is proposed to be) given to any person to subscribe for any securities in the Company.

### **18.5 Available Documents**

Subject to any applicable securities laws, copies of the following documents will be available and can be

obtained free of charge from the Company's website ([www.nyxoah.com](http://www.nyxoah.com)) and, during their normal business hours, at the registered office of the Company and Joint Global Coordinators from the date of this Prospectus until at least the Closing Date:

- this Prospectus;
- the Articles of Association;
- the Consolidated Financial Statements as of 31 December 2017, 2018 and 2019; and
- Half-Yearly Financial Statements as of 30 June 2020.

## **18.6 Incorporation by Reference**

The Articles of Association (the official French version and an English translation thereof) are incorporated in this Prospectus by reference and, as such, form part of this Prospectus. The Articles of Association can be obtained free of charge from the Company's website ([www.nyxoah.com](http://www.nyxoah.com)).

## **18.7 No Incorporation of Website**

Prospective investors should only rely on the information that is provided in this Prospectus or incorporated by reference into this Prospectus. No other documents or information, including the contents of the Company's website ([www.nyxoah.com](http://www.nyxoah.com)), including any websites accessible from hyperlinks on such website or any websites of any subsidiary, associated company and joint venture of the Company, form part of, and/or are incorporated by reference into, this Prospectus. The information on the Company's website has not been scrutinized or approved by the FSMA.

## 19. GLOSSARY OF SELECTED TERMS

<b>2013 ESOP Warrants</b>	The Share options (subscription rights) that were granted to employees, officers, directors, consultants and advisors of the Company or its Subsidiaries pursuant to the 2013 Share Incentive Plan.
<b>2016 ESOP Warrants</b>	The Share options (subscription rights) that were granted to employees, officers, directors, consultants and advisors of the Company or its Subsidiaries pursuant to the 2016 Warrants plan.
<b>2018 ESOP Warrants</b>	The Share options (subscription rights) that were granted to employees, officers, directors, consultants and advisors of the Company or its Subsidiaries pursuant to the 2018 Warrants plan.
<b>2020 ESOP Warrants</b>	The Shares options (subscription rights) which the Company has created, to be granted to employees, officers, directors, consultants and advisors of the Company and its Subsidiaries, pursuant to the 2020 Warrants plan.
<b>Act of 16 December 2015</b>	The Act of 16 December 2015 regulating the exchange of financial account information between Belgian financial institutions and the FPS Finances in the framework of automatic information exchange at the international level and for tax purposes.
<b>AD Warrants</b>	The 230 anti-dilution warrants issued by the Company on 28 June 2016.
<b>AHI</b>	The Apnea-Hypopnea Index, an index used to indicate the severity of sleep apnea.
<b>AIMD</b>	Active implantable medical device.
<b>AIMD Directive</b>	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices and subsequent amendments, which have been repealed and replaced on 5 April 2017 by the Medical Devices Regulation.

<b>Article 203 ITC Taxation Condition</b>	The conditions relating to the taxation of the underlying distributed income, as described in article 203 ITC.
<b>Articles of Association</b>	The articles of association of the Company, which were adopted by the general shareholders' meeting of 7 September 2020, and which will enter into force subject to and effective as of the closing of the Offering.
<b>Belgian CCA</b>	The Belgian Code of Companies and Associations.
<b>Belgian GAAP</b>	Belgian generally accepted accounting principles, which refers to the financial reporting framework applicable in Belgium.
<b>Belgian Investor</b>	Private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium.
<b>Belgian Takeover Act</b>	The Belgian Act of 1 April 2007 on public takeover bids, as amended.
<b>Belgian Takeover Decree</b>	The Belgian Royal Decree of 27 April 2007 on public takeover bids, as amended.
<b>BLAST OSA</b>	Bilateral hypoglossal nerve stimulation for treatment of obstructive sleep apnea.
<b>Board of Directors</b>	The board of directors of the Company.
<b>CE-Mark</b>	A mandatory conformance mark on active implantable medical devices placed on the market in the EEA (and Switzerland based on mutual recognition).
<b>CISA</b>	The Swiss Federal Act on Collective Investment Schemes.
<b>Closing Date</b>	The date of payment, settlement and delivery of the Offered Shares, which is expected to take place on 25 September 2020.
<b>CMDT</b>	The Belgian Code of 2 March 1927 on miscellaneous duties and taxes.

<b>Company</b>	Nyxoah SA.
<b>Conditions for the application of the dividend received deduction regime</b>	(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 €2,500,000 (it being understood that only one out of the two tests must be satisfied); (2) the Shares have been held or will be held in full 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 ITC.
<b>Consolidated Financial Statement</b>	The audited consolidated financial statements of the Company.
<b>Corporations Act</b>	The Australian Corporations Act 2001.
<b>Corporate Governance Charter</b>	The corporate governance charter of the Company.
<b>CMS</b>	Centers for Medicare & Medicaid Services, which is part of the United States Department of Health and Human Services.
<b>CPAP</b>	Continuous positive airway pressure.
<b>DAC2</b>	Directive 2014/107/EU on administrative cooperation in direct taxation.
<b>DEKRA</b>	DEKRA Certification B.V, a certification company recognized as a Notified Body by the European Commission.
<b>Draft Directive</b>	The proposal for a Council Directive on a common financial transaction tax adopted by the EU Commission on 14 February 2013.
<b>EEA</b>	European Economic Area.
<b>ES</b>	The Genio® External Stimulator.
<b>ESOP Warrants</b>	The 2013 ESOP Warrants, the 2016 ESOP Warrants, the 2018 ESOP Warrants and the 2020 ESOP Warrants.
<b>EU</b>	The European Union.
<b>Euronext Legal Framework</b>	The (relevant parts of the) rule book of Euronext Brussels together with any law or regulation in relation to Euronext

Brussels, the admission thereto, listing and trading thereon, and/or transactions thereon or the offering of shares in Belgium, including (without limitation) (i) the Belgian CCA, (ii) the Prospectus Regulation, (iii) Commission Delegated Regulation (EU) 2019/979 supplementing Regulation (EU) 2017/1129 with regard to regulatory technical standards on key financial information in the summary of a prospectus, the publication and classification of prospectuses, advertisements for securities, supplements to a prospectus, and the notification portal, and repealing Commission delegated regulation (EU) No 382/2014 and Commission delegated regulation (EU) 2016/30, (iv) Commission Delegated Regulation (EU) 2019/980 of 14 March 2019 supplementing Regulation (EU) 2017/1129 of the European Parliament and of the Council as regards the format, content, scrutiny and approval of the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Commission Regulation (EC) No 809/2004, (v) the Belgian Act of 2 August 2002 on the supervision of the financial sector and the financial services, (vi) the Prospectus Act, and any regulations, laws, royal decrees and other rules further executing or implementing such laws, as amended from time to time), and the interpretations, guidelines or recommendations provided by the FSMA and the European Securities and Markets Authority.

**Euros, € or EUR**

The common currency of the member states of the EU that are part of the Eurozone.

**Exempt Investors**

Persons who are "sophisticated investors" within the meaning of section 708(8) of the Corporations Act.

**FDA**

The U.S. Food and Drug Administration.

**FDCA**

Food Drugs and Cosmetics Act.

**FIEL**

The Japanese Financial Instruments and Exchange Act, as amended.

**FSMA**

The Belgian Financial Services and Market Authority.

**FTT**

Financial transaction tax.

<b>GDPR</b>	Regulation (EU) 2016/679 of the European Parliament and of the Council of 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.
<b>Health Care Reform Act</b>	The United States Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, each enacted in March 2010.
<b>HIPAA</b>	The Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations.
<b>HNS</b>	Hypoglossal nerve stimulation.
<b>IDE</b>	An investigational device exemption provided by the FDA, which allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.
<b>IFRS</b>	The International Financial Reporting Standards as adopted by the EU.
<b>Investigator</b>	The physician at each clinical study center maintaining overall responsibility for conduct of the clinical study.
<b>IPO</b>	Initial public offering of shares.
<b>IS</b>	The Genio® Implantable Stimulator.
<b>Israeli Securities Law</b>	The Israeli Securities Law 5728-1968, as amended and the rules and regulations promulgated thereunder from time to time.
<b>ITC</b>	Belgian Income Tax Code.
<b>Joint Bookrunners</b>	Bank Degroof Petercam NV/SA and Belfius Bank NV/SA.
<b>Joint Global Coordinators</b>	Bank Degroof Petercam NV/SA and Belfius Bank NV/SA.
<b>Law of 16 December 2015</b>	The law of 16 December 2015 regulating the exchange of financial account information between Belgian financial institutions and the FPS Finances in the framework of automatic

information exchange at the international level and for tax purposes.

**Listing Date**

The date on which trading of the Shares on Euronext Brussels commences, on an "if-and-when-issued and/or delivered" basis, which is expected to be on or about 24 September 2020.

**Locked Securities**

Any of the Shares of the current shareholder in the Company prior to the Offering, and all their securities or rights issued or agreed to by the Company that are convertible into or exercisable or exchangeable for Shares of the Company (including the shares into which such securities or rights are converted, exercised or exchanged) which are subject to a lock up arrangement.

**MCAA**

The multilateral competent authority agreement, signed on 29 October 2014 by 51 jurisdictions, which 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.

**Medical Device Regulation**

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

**Member State**

Any member state of the European Economic Area.

**NBB**

The National Bank of Belgium.

**Noshaq Convertible Loan**

The € 1.0 million convertible loan agreement entered into between Noshaq SA (as lender) and the Company (as borrower) on 26 June 2020.

**Notified Bodies**

Organizations which are responsible for assessing whether manufacturers of medical devices and medical devices meet the applicable regulatory requirements in the EEA.

**ODI**

The oxygen desaturation index.

**Offered Shares**

The Shares being offered by the Company during the Offering.

<b>Offering</b>	The initial offering by the Company of up to 3,871,000 new Shares, with no nominal value, of the Company, as may be increased pursuant to the exercise of the Increase Option.
<b>Offering Period</b>	The period starting on 9 September 2020 and expected to end no later than 4:00 pm (CET) on 21 September 2020 (for Retail Investors) and no later than 4:00 pm (CET) on 22 September 2020 (for Institutional Investors).
<b>Offering Price</b>	The price per Offered Share.
<b>OFP</b>	Organization for financing pensions.
<b>OSA</b>	Obstructive sleep apnea.
<b>Over-allotment Option</b>	A warrant to purchase additional new shares in a number equal to up to 15% of the number of Shares subscribed for in the Offering at the Offering Price to cover over-allotments or short positions, if any, in connection with the Offering.
<b>PAP</b>	Positive airway pressure.
<b>Parent-Subsidiary Directive</b>	Council Directive 2011/96/EU of 30 November 2011 on the common system of taxation applicable in the case of parent companies and subsidiaries of different Member States.
<b>Participating Member States</b>	The participating Member States under the Draft Directive implementing enhanced cooperation in the area of financial transaction tax adopted by the European Commission on 14 February 2013, i.e. Belgium, Germany, Estonia, Greece, Spain, France, Italy, Austria, Portugal, Slovenia and Slovakia.
<b>PE</b>	Permanent establishment.
<b>Price Range</b>	Between € 14.00 and € 17.00 per Offered Share.
<b>Prospectus</b>	This prospectus.

<b>Prospectus Act</b>	The Belgian Act of 11 July 2018 on the public offering of securities and the admission of securities to trading on a regulated market.
<b>Prospectus Regulation</b>	Regulation 2017/1129 of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market.
<b>QIB</b>	Qualified institutional buyers, as defined in Rule 144A under the U.S. Securities Act.
<b>Regulation S</b>	Regulation S under the U.S. Securities Act.
<b>Relevant State</b>	Any Member State of the EEA, except for Belgium, and the United Kingdom.
<b>Relevant Persons</b>	Investment professionals falling within article 19(5), or falling within section 49(2)(a) to (d) (" <i>high net worth; unincorporated associations, etc.</i> "), of the U.K. Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or other persons to whom such investment or investment activity may lawfully be made available.
<b>ResMed Inc.</b>	A Delaware corporation, organized and existing under the laws of the State of Delaware, United States, with its principal offices at 9001 Spectrum Center Blvd., San Diego, CA 92123.
<b>Retail Investor</b>	An individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a qualified investor ( <i>gekwalficeerde belegger/investisseur qualifié</i> ) as defined in article 2, e) of the Prospectus Regulation.
<b>Royal Decree on Primary Market Practices</b>	The Belgian Royal Decree of 17 May 2007 on primary market practices.
<b>Series B2 AD Warrants</b>	The 240 anti-dilution warrants issued by the Company on 4 October 2018.
<b>Shares</b>	The Shares in the Company.
<b>SIX</b>	The SIX Swiss Exchange.

<b>Stabilization Manager</b>	Belfius Bank NV/SA.
<b>Stabilization Period</b>	The period up to 30 days from the Listing Date.
<b>Stock Exchange Tax Representative</b>	Stock exchange tax representative appointed in Belgium in accordance with article 126/3 CMDT.
<b>Subsidiaries</b>	The present or future subsidiaries of the Company.
<b>Sunshine Act</b>	The Belgian Act of 18 December 2016 and its implementing Royal Decree of 14 June 2017.
<b>Tax on Stock Exchange Transactions</b>	The tax on stock exchange transactions as mentioned in articles 120 and following of the Belgian Code of 2 March 1927 on miscellaneous duties and taxes.
<b>TGA</b>	The Australian Therapeutic Goods Administration.
<b>U.S. dollars, U.S. or \$</b>	The lawful currency of the United States.
<b>U.S. Exchange Act</b>	The U.S. Securities Exchange Act of 1934, as amended.
<b>U.S. Securities Act</b>	The U.S. Securities Act of 1933, as amended.
<b>Underwriters</b>	Bank Degroof Petercam NV/SA and Belfius Bank NV/SA.
<b>Underwriting Agreement</b>	The underwriting agreement which is expected to be entered into on or about 23 September 2020 between the Company and the Underwriters.
<b>Underwritten Shares</b>	The total number of new Shares less those new Shares subscribed for by certain Participating Investors pursuant to a Subscription Commitment which the Underwriters will severally (and not jointly, nor jointly and severally) agree to subscribe to and procure payment for, subject to the terms and conditions to be set forth in the Underwriting Agreement.

## 20. NYXOAH GROUP CONSOLIDATED FINANCIAL STATEMENTS

### 20.1 CONSOLIDATED FINANCIAL STATEMENTS AS OF 31 DECEMBER 2019, 2018 AND 2017 AND FOR THE YEAR THEN ENDED

#### 1 Consolidated Financial Statements as of 31 December 2019, 2018 and 2017 and for the year then ended

##### 1.1 Independent auditor's on the consolidated financial statements 2019, 2018 and 2017



EY Bedrijfsrevisoren  
EY Réviseurs d'Entreprises  
De Kleetlaan 2  
B - 1831 Diegem

Tel: +32 (0) 2 774 91 11  
ey.com

#### Independent auditor's report to the general meeting of Nyxoah SA for the year ended 31 December 2019, 31 December 2018, 31 December 2017

As required by law and the Company's articles of association, we report to you as statutory auditor of Nyxoah SA (the "Company") and its subsidiaries (together the "Group"). This report includes our opinion on the consolidated statement of financial position as at 31 December 2019, 31 December 2018 and 31 December 2017, the consolidated income statement and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year ended 31 December 2019, 31 December 2018 and 31 December 2017 and the disclosures (all elements together the "Consolidated Financial Statements") as well as our report on other legal and regulatory requirements. These two reports are considered one report and are inseparable.

We have been appointed as statutory auditor by the shareholders' meeting of 23 May 2019, in accordance with the proposition by the Board of Directors. Our mandate expires at the shareholders' meeting that will deliberate on the Consolidated Financial Statements for the year ending 31 December 2021. We performed the audit of the Consolidated Financial Statements of the Group during 4 consecutive years.

#### Report on the audit of the Consolidated Financial Statements

##### Unqualified opinion

We have audited the Consolidated Financial Statements of Nyxoah SA, that comprise the consolidated statement of financial position on 31 December 2019, 2018 and 2017, the consolidated income statement and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for these years and the disclosures, which show a consolidated statement of financial position total of € thousand 15,195 for the year ended 2019, of € thousand 17,979 for the year ended 2018 and of € thousand 11,145 for the year ended 2017 and of which the consolidated income statement shows a loss for the year of € thousand 7,255 for the year ended 2019, of € thousand 9,079 for the year ended 2018 and of € thousand 10.371 for the year ended 2017.

In our opinion, the Consolidated Financial Statements give a true and fair view of the consolidated net equity and financial position as at 31 December 2019, 31 December 2018, and 31 December 2017, and of its consolidated results for the years then ended, prepared in accordance with the International Financial Reporting Standards as adopted by the European Union ("IFRS") and with applicable legal and regulatory requirements in Belgium.

##### Basis for the unqualified opinion

We conducted our audit in accordance with International Standards on Auditing ("ISAs"). Our responsibilities under those standards are further described in the "Our responsibilities for the audit of the Consolidated Financial Statements" section of our report.

We have complied with all ethical requirements that are relevant to our audit of the Consolidated Financial Statements in Belgium, including those with respect to independence.

We have obtained from the Board of Directors and the officials of the Company the explanations and information necessary for the performance of our audit and we believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

##### Material uncertainty related to going concern

We draw attention to Note 3.6.1 of the Consolidated Financial Statements where management describes the uncertainties related to the evolution of the medium-term cash position of the Company in connection with the financing of the development activities of the The Genio® system. These events or conditions, along with other matters as set forth in Note 3.6.1, indicate that the Company needs to seek new sources of

financing and that material uncertainty with this respect may cast doubt on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

### **Responsibilities of the Board of Directors for the preparation of the Consolidated Financial Statements**

The Board of Directors is responsible for the preparation of the Consolidated Financial Statements that give a true and fair view in accordance with IFRS and with applicable legal and regulatory requirements in Belgium and for such internal controls relevant to the preparation of the Consolidated Financial Statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of Consolidated Financial Statements, the Board of Directors is responsible for assessing the Company's ability to continue as a going concern, and provide, if applicable, information on matters impacting going concern. The Board of Directors should prepare the financial statements using the going concern basis of accounting, unless the Board of Directors either intends to liquidate the Company or to cease business operations, or has no realistic alternative but to do so.

### **Our responsibilities for the audit of the Consolidated Financial Statements**

Our objectives are to obtain reasonable assurance whether the Consolidated Financial Statements are free from material misstatement, whether due to fraud or error, and to express an opinion on these Consolidated Financial Statements based on our audit. Reasonable assurance is a high level of assurance, but not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these Consolidated Financial Statements.

As part of an audit in accordance with ISAs, we exercise professional judgment and we maintain professional skepticism throughout the audit. We also perform the following tasks:

- ▶ identification and assessment of the risks of material misstatement of the Consolidated Financial Statements, whether due to fraud or error, the planning and execution of audit procedures to respond to these risks and obtain audit evidence which is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting material misstatements resulting from fraud is higher than when such misstatements result from errors, since fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- ▶ obtaining insight in the system of internal controls that are relevant for the audit and with the objective to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control;
- ▶ evaluating the selected and applied accounting policies, and evaluating the reasonability of the accounting estimates and related disclosures made by the Board of Directors as well as the underlying information given by the Board of Directors;
- ▶ conclude on the appropriateness of the Board of Directors' use of the going-concern basis of accounting, and based on the audit evidence obtained, whether or not a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's or Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the Consolidated Financial Statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the Company to cease to continue as a going-concern;
- ▶ evaluating the overall presentation, structure and content of the Consolidated Financial Statements, and evaluating whether the Consolidated Financial Statements reflect a true and fair view of the underlying transactions and events.

We communicate with the Board of Directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the audits of the subsidiaries. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities.

We provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the Consolidated Financial Statements.

## **Report on other legal and regulatory requirements**

### **Responsibilities of the Board of Directors**

The Board of Directors is responsible for the preparation and the content of the Board of Directors' report on the Consolidated Financial Statements.

### **Responsibilities of the auditor**

In the context of our mandate and in accordance with the additional standard to the ISAs applicable in Belgium, it is our responsibility to verify, in all material respects, the Board of Directors' report on the Consolidated Financial Statements, as well as to report on these matters.

### **Aspects relating to Board of Directors' report**

In our opinion, after carrying out specific procedures on the Board of Directors' report, the Board of Directors' report is consistent with the Consolidated Financial Statements and has been prepared in accordance with article 3:32 of the Code of companies and associations (former article 119 of the Belgian Company code).

In the context of our audit of the Consolidated Financial Statements, we are also responsible to consider whether, based on the information that we became aware of during the performance of our audit, the Board of Directors' report contains any material inconsistencies or contains information that is inaccurate or otherwise misleading. In light of the work performed, there are no material inconsistencies to be reported. In addition, we do not provide any assurance regarding the Board of Directors' report and other information included in the annual report.

### **Independence matters**

Our audit firm and our network have not performed any services that are not compatible with the audit of the Consolidated Financial Statements and have remained independent of the Company during the course of our mandate.

The fees related to additional services which are compatible with the audit of the Consolidated Financial Statements as referred to in article 3:65 of the Code of companies and associations were duly itemized and valued in the notes to the Consolidated Financial Statements.

Diegem, 30 June 2020

EY Bedrijfsrevisoren BV  
Statutory auditor  
Represented by



Vincent Etienne \*  
Partner  
\*Acting on behalf of a SRL

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## 1.2 Consolidated Statement of Financial Position

<i>(in EUR 000)</i>	Notes	As of and for the year ended 31 December		
		2019	2018	2017
<b>ASSETS</b>				
<b>Non-current assets</b>				
Property, plant and equipment	2.8	322	343	369
Intangible assets	2.9	5,734	-	-
Right of use assets	2.10	1,066	-	-
Deferred tax asset	2.31	21	29	22
Other long-term receivables		78	68	70
		<b>7,221</b>	<b>440</b>	<b>461</b>
<b>Current assets</b>				
Trade receivables		60	64	46
Other receivables	2.11	2,048	668	529
Other current assets	2.12	11	2	4
Cash and cash equivalents	2.13	5,855	16,805	10,105
		<b>7,974</b>	<b>17,539</b>	<b>10,684</b>
<b>Total assets</b>		<b>15,195</b>	<b>17,979</b>	<b>11,145</b>
<b>EQUITY AND LIABILITIES</b>				
<b>Capital and reserves</b>				
Capital	2.14	2,481	2,481	2,004
Share premium	2.14	47,668	47,668	33,143
Share based payment reserve	2.15	420	80	52
Currency translation reserve	2.14	207	39	63
Retained Earnings	2.14	(47,063)	(39,814)	(30,735)
<b>Total equity attributable to shareholders</b>		<b>3,713</b>	<b>10,454</b>	<b>4,527</b>
<b>LIABILITIES</b>				
<b>Non-current liabilities</b>				
Financial debt	2.16	7,146	5,526	4,869
Lease liability	2.10	735	-	-
Pension Liability	2.28	30	-	-
		<b>7,911</b>	<b>5,526</b>	<b>4,869</b>
<b>Current liabilities</b>				
Financial debt	2.16	378	289	395
Lease liability	2.10	340	-	-
Trade payables	2.17	1,385	810	602
Other payables	2.18	1,468	900	752
		<b>3,571</b>	<b>1,999</b>	<b>1,749</b>
<b>Total liabilities</b>		<b>11,482</b>	<b>7,525</b>	<b>6,618</b>
<b>Total equity and liabilities</b>		<b>15,195</b>	<b>17,979</b>	<b>11,145</b>

### 1.3 Consolidated Income Statement and Other Comprehensive Income

		<b>For the year ended 31 December</b>		
<i>(in EUR 000)</i>	<b>Notes</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Revenue	2.19	-	-	-
Cost of goods sold	2.19	-	-	-
General and administrative expenses	2.20	(3,027)	(2,339)	(2,192)
Research and development expenses	2.21	(630)	(1,385)	(1,505)
Clinical expenses	2.22	(848)	(2,523)	(2,110)
Manufacturing expenses	2.23	(489)	(1,089)	(803)
Quality assurance and regulatory expenses	2.24	(227)	(680)	(882)
Patents Fees & Related	2.25	(267)	(594)	(533)
Therapy Development expenses	2.25	(902)	(338)	(495)
Other operating income / (expenses)	2.26	(126)	498	(1,623)
<b>Operating loss for the period</b>		<b>(6,516)</b>	<b>(8,450)</b>	<b>(10,143)</b>
Financial income	2.29	71	29	25
Financial expense	2.30	(740)	(617)	(216)
<b>Loss for the period before taxes</b>		<b>(7,185)</b>	<b>(9,038)</b>	<b>(10,334)</b>
Taxes	2.31	(70)	(41)	(37)
<b>Loss for the period</b>		<b>(7,255)</b>	<b>(9,079)</b>	<b>(10,371)</b>
<b>Loss attributable to equity holders<sup>83</sup></b>		<b>(7,255)</b>	<b>(9,079)</b>	<b>(10,371)</b>
Other comprehensive income				
Items that may be subsequently reclassified to profit or loss (net of tax)				
Currency translation differences		168	(24)	(3)
<b>Total comprehensive loss for the year, net of tax</b>		<b>(7,087)</b>	<b>(9,103)</b>	<b>(10,374)</b>
<b>Loss attributable to equity holders<sup>1</sup></b>		<b>(7,087)</b>	<b>(9,103)</b>	<b>(10,374)</b>
Basic Earnings Per Share (in EUR) <sup>84</sup>	2.32	(0.488)	(0.740)	(0.906)
Diluted Earnings Per Share (in EUR) <sup>85</sup>	2.32	(0.488)	(0.740)	(0.906)

<sup>83</sup> For the years ending 31 December 2019, 2018 and 2017, the loss is fully attributable to equity holders of the Company as the Company does not have any non-controlling interests.

<sup>84</sup> Based on pro forma number of shares reflecting resolution approved by the Shareholders' Meeting on 12 February 2020 – see notes 2.32 and 2.35.

<sup>85</sup> Based on pro forma number of shares reflecting resolution approved by the Shareholders' Meeting on 12 February 2020 – see notes 2.32 and 2.35.

## 1.4 Consolidated Statement of Changes in Equity

<i>(in EUR 000)</i>	Notes	Capital	Share premium	Attributable to owners of the parent			Total
				Share based payment reserve	Currency translation reserve	Retained earnings	
<b>Balance at 1 January 2017</b>	<b>2.14</b>	<b>2,004</b>	<b>33,143</b>	<b>28</b>	<b>66</b>	<b>(20,364)</b>	<b>14,877</b>
Profit/(loss) for the year				-		(10,371)	(10,371)
Other comprehensive income for the year					(3)	-	(3)
<b>Total comprehensive income for the year</b>		-	-		<b>(3)</b>	<b>(10,371)</b>	<b>(10,374)</b>
Equity-settled share-based payment plan	2.15			24			24
<b>Total transactions with owners of the Company recognized directly in equity</b>		-	-	<b>24</b>		-	<b>24</b>
<b>Balance at 31 December 2017</b>	<b>2.14</b>	<b>2,004</b>	<b>33,143</b>	<b>52</b>	<b>63</b>	<b>(30,735)</b>	<b>4,527</b>
<b>Balance at 1 January 2018</b>	<b>2.14</b>	<b>2,004</b>	<b>33,143</b>	<b>52</b>	<b>63</b>	<b>(30,735)</b>	<b>4,527</b>
Profit/(loss) for the year						(9,079)	(9,079)
Other comprehensive income for the year					(24)		(24)
<b>Total comprehensive income for the year</b>					<b>(24)</b>	<b>(9,079)</b>	<b>(9,103)</b>
Equity-settled share-based payment plan	2.15			28			28
Issuance of shares	2.14	477	14,525				15,002
<b>Total transactions with owners of the Company recognized directly in equity</b>		<b>477</b>	<b>14,525</b>	<b>28</b>			<b>15,030</b>
<b>Balance at 31 December 2018</b>	<b>2.14</b>	<b>2,481</b>	<b>47,668</b>	<b>80</b>	<b>39</b>	<b>(39,814)</b>	<b>10,454</b>
<b>Balance at 1 January 2019</b>	<b>2.14</b>	<b>2,481</b>	<b>47,668</b>	<b>80</b>	<b>39</b>	<b>(39,814)</b>	<b>10,454</b>
Profit/(loss) for the year						(7,255)	(7,255)
Other comprehensive income for the year					168		168
<b>Total comprehensive income for the year</b>					<b>168</b>	<b>(7,255)</b>	<b>(7,087)</b>
Equity-settled share-based payment plan							
Granted during the year	2.15			346			346
Cancelled and forfeited during the year	2.15			(6)		6	
<b>Total transactions with owners of the Company recognized directly in equity</b>				<b>340</b>		<b>6</b>	<b>346</b>
<b>Balance at 31 December 2019</b>	<b>2.14</b>	<b>2,481</b>	<b>47,668</b>	<b>420</b>	<b>207</b>	<b>(47,063)</b>	<b>3,713</b>

## 1.5 Consolidated Statement of Cash Flows

<i>(in EUR 000)</i>	Notes	For the year ended 31 December		
		2019	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>				
<b>Profit/(loss) before tax for the year</b>		<b>(7,185)</b>	<b>(9,038)</b>	<b>(10,334)</b>
Adjustments for:				
Finance income	2.29	(71)	(29)	(25)
Finance expenses	2.30	740	617	216
Depreciation and impairment of property, plant and equipment and right-of-use assets	2.8, 2.10	433	95	87
Share-based payment transaction expense	2.15	346	28	24
Pension	2.28	30	-	-
Other non-cash items <sup>86</sup>	2.26, 2.31	70	63	2,277
<b>Cash generated before changes in working capital</b>		<b>(5,637)</b>	<b>(8,264)</b>	<b>(7,755)</b>
Changes in working capital:				
Increase (-)/Decrease (+) in Trade and other receivables		(1,385)	(155)	(161)
Increase (+)/Decrease (-) in Trade and other payables		1,143	356	(293)
<b>Cash generated from changes in operations</b>		<b>(5,879)</b>	<b>(8,063)</b>	<b>(8,209)</b>
Interests received	2.29	8	1	5
Interests paid	2.30	(33)	(29)	(37)
Income tax (paid)	2.31	(61)	(48)	(46)
<b>Net cash generated/(used) from operating activities</b>		<b>(5,965)</b>	<b>(8,139)</b>	<b>(8,287)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>				
Purchases of property, plant and equipment	2.8	(51)	(77)	(91)
Capitalization of intangible assets	2.9	(5,734)	-	-
(Increase)/Decrease of long-term deposits		(10)	2	-
<b>Net cash generated/(used) from investing activities</b>		<b>(5,795)</b>	<b>(75)</b>	<b>(91)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>				
Payment of principal portion of lease liabilities	2.10	(341)	-	-
Repayment of other loan	2.16.2	(82)	(42)	-
Recoverable cash advance received	2.16.1	1,196	226	1,213
Repayment of recoverable cash advance	2.16.1	(40)	(184)	(100)
Proceeds from issuance of shares	2.14	-	15,002	-
<b>Net cash generated/(used) from financing activities</b>		<b>733</b>	<b>15,002</b>	<b>1,113</b>
<b>Movement in cash and cash equivalents</b>		<b>(11,027)</b>	<b>6,788</b>	<b>(7,265)</b>
Effect of exchange rates on cash and cash equivalents		77	(88)	(76)
<b>Cash and cash equivalents at 1 January</b>	2.13	<b>16,805</b>	<b>10,105</b>	<b>17,446</b>
<b>Cash and cash equivalents at 31 December</b>	2.13	<b>5,855</b>	<b>16,805</b>	<b>10,105</b>

<sup>86</sup> The other non-cash items include (i) the impact of the initial measurement and re-measurement of recoverable cash advances (see notes 2.16, 2.26) and (ii) the evolution of the deferred tax assets.

## 2 Notes to the Consolidated Financial Statements as of 31 December 2019, 2018 and 2017 and for the year then ended

### 2.1 General Information

Nyxoah SA (the “Company”) is a public 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 health-technology company focused on the development and commercialization of solutions and services to treat sleep disordered breathing conditions. The Company's innovative solution platform is based on the user-centered Genio® system, a CE-mark validated, user-centered, next generation neurostimulation therapy for OSA, the world’s most common sleep disordered breathing condition that 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 Obstructive Sleep Apnea (“OSA”) patients who have failed 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.

OSA is the most common sleep disordered breathing condition, affecting around 936 million people globally, of whom 425 million suffer from moderate to severe OSA, requiring treatment<sup>87</sup>. 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 two wholly owned subsidiaries: Nyxoah Ltd, a subsidiary of the Company since 21 October 2009 (located in Israel and incorporated on 10 January 2008 under the name M.L.G. Madaf G. Ltd) and Nyxoah Pty Ltd since 1 February 2017 (located in Australia). It is not required to prepare consolidated financial statements for any of the periods stated under Belgian GAAP.

This Consolidated Financial Statements, creating a comprehensive set with comparative data covering three years as required under the Prospectus Regulation, have been authorized for issue on 30 June 2020 by the Board of Directors of the Company.

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<sup>87</sup> Benjafield, Adam V et al. Estimation of the global prevalence and burden of obstructive sleep apnea: a literature-based analysis. *Lancet Respir Med* 2019 Published Online 9 July 2019 [http://dx.doi.org/10.1016/S2213-2600\(19\)30198-5](http://dx.doi.org/10.1016/S2213-2600(19)30198-5).

## **2.2 Declaration of compliance**

In application of European Regulation 1606/2002 of 19 July 2002, the Consolidated Financial Statements of the Company are prepared in conformity with the International Financial Reporting Standards (IFRS) published by the International Accounting Standard Board (IASB), as adopted by the EU on the date of the closure of the accounts by the Board of Directors, which are applicable as at 31 December 2019, 2018 and 2017 respectively.

## **2.3 Significant accounting policies**

### **2.3.1 Basis of Preparation and Going Concern**

#### *Basis of preparation*

These Consolidated Financial Statements have been prepared in accordance with the IFRS as adopted for use in the European Union. They are prepared on the assumption that Nyxoah will continue to operate in the foreseeable future.

The Consolidated Financial Statements are presented in Euro (EUR) and all values are rounded to the nearest thousand (KEUR), 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 2.6.

#### *Going concern principle*

The Consolidated Financial Statements have been prepared on a going concern basis. Please refer to note 2.6.1 for the detailed explanation of the going concern.

### **2.3.2 Consolidation**

The Consolidated Financial Statements comprise the financial statements of the Company and its subsidiaries as at 31 December 2019, 2018 and 2017.

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

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

### **2.3.3 New and amended standards and interpretations applicable**

#### **2.3.3.1 For the annual period beginning after 1 January 2019**

The Company applied for the first-time certain standards and amendments, which are effective for annual periods beginning on or after 1 January 2019. The Company has not early adopted any other standard,

interpretation or amendment that has been issued but is not yet effective. With the exception of the adoption of IFRS 16, the new standards and amendments that apply for the first time in 2019, do not have a material impact on the Consolidated Financial Statements of the Company:

*(a) IFRS 16 Leases, applicable for annual periods beginning on or after 1 January 2019*

The Company adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of 1 January 2019. Under this method, the standard is applied retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application. The Company elected to use the transition practical expedient not to reassess whether a contract is, or contains, a lease at 1 January 2019. Instead, the Company applied the standard only to contracts that were previously identified as leases applying IAS 17 and IFRIC 4 at the date of initial application. The Company also elected to use the recognition exemptions for lease contracts that, at the commencement date, have a lease term of 12 months or less and do not contain a purchase option ('short-term leases'), and lease contracts for which the underlying asset is of low value ('low-value assets').

Upon adoption of IFRS 16, the Company applied a single recognition and measurement approach for all leases that it is the lessee, except for short-term leases and leases of low-value assets. The Group recognized lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets. The Company has leases of certain office equipment (i.e., personal computers, printing and photocopying machines) that are considered of low value.

*Leases where the Company acts as a lessor*

Not applicable

*Leases previously accounted for as operating leases*

The Company recognized right-of-use assets and lease liabilities for those leases previously classified as operating leases, except for short-term leases and leases of low-value assets. Lease liabilities were recognized based on the present value of the remaining lease payments, discounted using the incremental borrowing rate at the date of initial application. Incremental borrowing rates are between 1% to 1.5% for offices and 1.95% for cars.

The Company also applied the available practical expedients wherein it:

- used a single discount rate to a portfolio of leases with reasonably similar characteristics;
- relied on its assessment of whether leases are onerous immediately before the date of initial application;
- applied the short-term leases exemptions to leases with lease term that ends within 12 months of the date of initial application;
- excluded the initial direct costs from the measurement of the right-of-use asset at the date of initial application.

Based on the above, right-of-use assets and related lease liabilities have been recognized and presented separately in the statement of financial position. The impact as at 1 January 2019 amounted to KEUR 1,323. The lease liabilities as at 1 January 2019 can be reconciled to the operating lease commitments as of 31 December 2018 as follows:

Operating lease commitments as at 31 December 2018	1,477
Discounting effect	(40)
Commitments relating to leases of low-value assets and short-term leases	(114)
<u>Lease liabilities as at 1 January 2019</u>	<u>1,323</u>

The new accounting policy is further detailed in note 2.3.16. Evolution in 2019 of the right-of-use assets and lease liabilities are presented in note 2.10.

- (b) *IFRIC 23 Uncertainty over Income Tax Treatments, applicable for annual periods beginning on or after 1 January 2019;*
- (c) *IFRS 9 Amendments Prepayment Features with Negative Compensation, applicable for annual periods beginning on or after 1 January 2019;*
- (d) *IAS 28 Amendments Long-term Interests in Associates and Joint Ventures, applicable for annual periods beginning on or after 1 January 2019;*
- (e) *IAS 19 Amendments Plan Amendment, Curtailment, or Settlement, applicable for annual periods beginning on or after 1 January 2019; IFRS 17 Insurance Contracts, applicable for annual periods beginning on or after 1 January 2021;*
- (f) *Annual improvements to IFRS Standards 2015-2017 Cycle, applicable for annual periods beginning on or after 1 January 2019.*

### 2.3.3.2 For the annual period beginning after 1 January 2020

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

- Amendments to References to the Conceptual Framework in IFRS Standards, effective 1 January 2020
- Amendments to IFRS 3 Business Combinations – Definition of a business, effective 1 January 2020
- Amendments to IFRS 9 Financial Instruments and IFRS 7 Financial Instruments: Disclosures - Interest Rate Benchmark Reform
- Amendments to IAS 39 Financial Instruments: Recognition and measurement and IFRS 7 Financial Instruments: Disclosures - Interest Rate Benchmark Reform
- IFRS 17 Insurance Contracts, effective 1 January 2021
- Amendments to IAS 1 Presentation of Financial Statements and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors – Definition of material, effective 1 January 2020
- Amendments to References to the Conceptual Framework in IFRS Standards

#### (a) Amendments to References to the Conceptual Framework in IFRS Standards

Amendments to References to the Conceptual Framework in IFRS Standards sets out the amendments to affected standards, except to IFRS 3 Business Combinations and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors, in order to update references to the Conceptual Framework. In most cases, the standard references are updated to refer to the Conceptual Framework. These amendments are effective for reporting periods beginning on or after 1 January 2020.

#### (b) Amendments to IFRS 3 Business Combinations – Definition of a business

The narrow-scope amendments clarify how to determine whether an acquired set of activities and assets is a business or not. The amendments clarify the minimum requirements for a business; remove the assessment of whether market participants are capable of replacing any missing elements; add guidance to help entities assess whether an acquired process is substantive; narrow the definitions of a business and of outputs; and introduce an optional fair value concentration test.

Companies are required to apply the amended definition of a business to acquisitions that occur on or after 1 January 2020. Earlier application is permitted.

**(c) Amendments to IFRS 9 Financial Instruments and IFRS 7 Financial Instruments: Disclosures - Interest Rate Benchmark Reform**

The amendments modify some specific hedge accounting requirements to provide relief from potential effects of the uncertainty caused by the IBOR reform. In addition, the amendments require companies to provide additional information to investors about their hedging relationships which are directly affected by these uncertainties. The amendments apply to all hedging relationships that are directly affected by interest rate benchmark reform. Application of the reliefs is mandatory. The first three reliefs provide for:

- The assessment of whether a forecast transaction (or component thereof) is highly probable
- Assessing when to reclassify the amount in the cash flow hedge reserve to profit and loss
- The assessment of the economic relationship between the hedged item and the hedging instrument

The fourth relief provides that, for a benchmark component of interest rate risk that is affected by IBOR reform, the requirement that the risk component is separately identifiable need be met only at the inception of the hedging relationship.

The effective date of the amendments is for annual periods beginning on or after 1 January 2020, with early application permitted. The requirements must be applied retrospectively. However, any hedge relationships that have previously been de-designated cannot be reinstated upon application, nor can any hedge relationships be designated with the benefit of hindsight. Since the Company does not have hedge accounting, the Company will not be affected by these amendments on the date of transition.

**(d) Amendments to IAS 39 Financial Instruments: Recognition and measurement and IFRS 7 Financial Instruments: Disclosures - Interest Rate Benchmark Reform**

The amendments modify some specific hedge accounting requirements to provide relief from potential effects of the uncertainty caused by the IBOR reform. In addition, the amendments require companies to provide additional information to investors about their hedging relationships which are directly affected by these uncertainties.

The corresponding amendments to IAS 39 Financial Instruments: Recognition and Measurement are consistent with those amendments for IFRS 9, but with the following differences:

- For the prospective assessment of hedge effectiveness, it is assumed that the benchmark on which the hedged cash flows are based (whether or not it is contractually specified) and/or the benchmark on which the cash flows of the hedging instrument are based, are not altered as a result of IBOR reform.
- For the retrospective assessment of hedge effectiveness, to allow the hedge to pass the assessment even if the actual results of the hedge are temporarily outside the 80%-125% range, during the period of uncertainty arising from IBOR reform.
- For a hedge of a benchmark portion (rather than a risk component under IFRS 9) of interest rate risk that is affected by IBOR reform, the requirement that the portion is separately identifiable need be met only at the inception of the hedge.

The effective date of the amendments is for annual periods beginning on or after 1 January 2020, with early application permitted. The requirements must be applied retrospectively. However, any hedge relationships

that have previously been de-designated cannot be reinstated upon application, nor can any hedge relationships be designated with the benefit of hindsight. Since the Company does not have hedge accounting, the Company will not be affected by these amendments on the date of transition.

**(e) IFRS 17 Insurance contracts**

IFRS 17, a comprehensive new accounting standard for insurance contracts covering recognition and measurement, presentation and disclosure, will replace IFRS 4 Insurance Contracts. IFRS 17 applies to all types of insurance contracts (i.e., life, non-life, direct insurance and re-insurance), regardless of the type of entities that issue them, as well as to certain guarantees and financial instruments with discretionary participation features. A few scope exceptions will apply. The overall objective of IFRS 17 is to provide an accounting model for insurance contracts that is more useful and consistent for insurers. In contrast to the requirements in IFRS 4, which are largely based on grandfathering previous local accounting policies, IFRS 17 provides a comprehensive model for insurance contracts,

The core of IFRS 17 is the general model, supplemented by a specific adaptation for contracts with direct participation features (the variable fee approach) and a simplified approach (the premium allocation approach) mainly for short-duration contracts.

IFRS 17 is effective for reporting periods beginning on or after 1 January 2021, with comparative figures required. Early application is permitted, provided the entity also applies IFRS 9 and IFRS 15 on or before the date it first applies IFRS 17. This standard is not applicable to the Company.

**(f) Amendments to IAS 1 Presentation of Financial Statements and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors – Definition of material**

The amended definition of material clarifies that the materiality assessment will need to take into account how primary users could reasonably be expected to be influenced in making economic decisions.

The amendments clarify that the assessment of materiality will depend on the nature or magnitude of information. The amendments also clarify that, in assessing whether information could reasonably be expected to influence decisions of the primary users, an entity must consider the characteristics of those users as well as its own circumstances.

The amendments to IAS 1 and IAS 8 are required to be applied for annual periods beginning on or after 1 January 2020. The amendments must be applied prospectively and earlier application is permitted. Since the Company's current practice is in line with the amendments, the Group does not expect any effect on its Consolidated Financial Statements.

### **2.3.4 Foreign Currency Translations**

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

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

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

## **2.3.5 Intangible Assets**

### **2.3.5.1 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.

For the years ended 31 December 2017 and 2018 respectively, the Company is of the opinion that none of the projects met the recognition criteria.

Following initial recognition of the development expenditure as an asset in 2019 triggered by obtaining CE mark in March of the same year, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Development costs primarily include employee compensation and outsourced development expenses. Amortization of the asset begins when development is complete and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in cost of sales. During the period of development, the asset is tested for impairment annually.

## **2.3.6 Property, Plant and Equipment**

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

Property, plant and equipment are recorded 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.

### **2.3.7 Impairment of Intangible Assets and Property, Plant and Equipment**

At each reporting date, the Company assesses whether there is an indication that tangible and intangible assets may be impaired. If an indication of impairment exists, or when annual impairment testing is required in the case of intangible assets with an indefinite useful life or intangible assets not yet available 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.

In assessing value in use, the estimated future 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.

As the Company currently does not generate significant cash-inflows, the recoverable amount of an asset is therefore determined on basis of its fair value less cost to sell.

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.

### **2.3.8 Financial assets and liabilities**

Financial assets and financial liabilities are recognized when the Company becomes a party to the contractual provisions of the instruments.

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.

#### **2.3.8.1 Financial Assets**

The Company has mainly financial assets measured at amortized cost which are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market, mainly financial assets measured at amortized cost include trade receivables and other receivables which 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. The Company's financial assets include cash and cash equivalents, trade receivable, and other long term and current receivables.

### *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.

### **2.3.8.2 Financial Liabilities**

After initial recognition, financial liabilities are subsequently 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. The Company’s financial liabilities include non-current liabilities (financial debt and other non-current liabilities) and current liabilities (trade and other payables).

### *Derecognition*

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

### **2.3.9 Fair value measurement**

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

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

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

### **2.3.10 Equity Instruments**

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

### **2.3.11 Cash and Cash Equivalents**

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

### **2.3.12 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.

#### *Deferred Income Tax*

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

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

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

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

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

### **2.3.13 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 Defined Contribution pension scheme for its employees. In the view of the minimum legal returns guaranteed under such scheme, those plans qualify as Defined Benefits plans. Such pension scheme is treated in accordance with IAS 19 “Employee Benefits” as a defined benefit plan. For defined benefit plans, the amount recognized in the Statement of financial position as a net liability (asset) corresponds to the difference between the present value of future obligations and the fair value of the plan assets.

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

### **2.3.14 Share-Based Compensation**

Certain employees receive remuneration, as compensation for services rendered, in the form of equity-settled share-based compensation. 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.

### **2.3.15 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.

### **2.3.16 Leases**

Before the application of IFRS 16, i.e. for financial years 2017 and 2018, IAS 17 was applied to lease contracts. A financial lease was a lease which transferred substantially all risks and rewards of ownership to the lessee. All other leases were recognized as operating leases. The Company was only involved in operating leases as a lessee which were straight line expensed over the lease term.

AS from 1<sup>st</sup> January 2019, IFRS 16 supersedes IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases-Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. The standard sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to recognize most leases on the statement of financial position.

The new accounting policy of the Group upon adoption of IFRS 16 is as follows:

- **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.
- **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.
  
- **Significant judgement in determining the lease term of contracts with renewal options:**  
The Group determines the lease term as the non-cancellable term of the lease, together with any periods covered by an option to extend the lease if it is reasonably certain to be exercised, or any periods covered by an option to terminate the lease, if it is reasonably certain not to be exercised.

### **2.3.17 Revenue**

The Company will develop accounting policies when it will begin to generate material revenues.

### **2.3.18 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.

## **2.4 Capital Management**

Capital comprises equity attributable to shareholders, borrowings and cash and cash equivalents. 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'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 Company monitors capital regularly to ensure that the legal capital requirements are met and may propose capital increases to the Shareholders' Meeting to ensure the necessary capital remains intact.

## **2.5 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

Because of the absence of sales to third parties and therefore trade receivables, credit risk arises mainly from 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 Walloon Region and there is no 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, primarily the US dollar ("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.

Currency	2019 rates		2018 rates		2017 rates	
	Closing	Average	Closing	Average	Closing	Average
NIS	3.87700	3.99220	4.28383	4.23833	4.16960	4.23209
AUD	1.60102	1.61057	1.62456	1.57996	1.5486	1.4731

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 and AUD would have the following impact:

	Change in foreign exchange rate	Effect on loss (before tax)		Effect on pretax equity	
		NIS	AUD	NIS	AUD
2019	5%	11	39	71	127
	-5%	-11	-43	-77	-141
2018	5%	11	30	56	79
	-5%	-12	-34	-62	-87
2017	5%	10	21	47	41
	-5%	-11	-23	-52	-45

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.

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 31 December are as follows:

(in EUR 000)	2019			2018		2017	
	Lease Liability	Financial Debt	Trade & Other Payable	Financial Debt	Trade & Other Payable	Financial Debt	Trade & Other Payable
Less than 1 year	353	392	2,853	531	1,710	413	1,354
1-5 years	709	2,871		1,936		1,495	
5+ years	38	11,470		10,002		10,355	
<b>TOTAL</b>	<b>1,100</b>	<b>14,733</b>	<b>2,853</b>	<b>12,469</b>	<b>1,710</b>	<b>12,263</b>	<b>1,345</b>

### 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 ongoing 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 2.3.9 for information on the valuation of non-current liabilities.

(in EUR 000)	Carrying value			Fair value		
	2019	2018	2017	2019	2018	2017
<b>Financial Assets</b>						
Other long-term receivables (level 3)	78	68	70	78	68	70
Trade and other receivables (level 3)	2,107	732	575	2,107	732	575
Other current assets (level 3)	11	2	4	11	2	4
Cash and cash equivalents (level 1)	5,855	16,805	10,105	5,855	16,805	10,105
<b>Financial liabilities</b>						
Financial debt (level 3)	376	458	500	321	412	437
Lease liability (level 3)	1,075	-	-	1,075	-	-
Recoverable cash advances (level 3)	7,148	5,357	4,764	7,148	5,357	4,764
Trade and other payables (level 3)	2,853	1,710	1,354	2,853	1,710	1,354

## 2.6 Critical Accounting Estimates and Assumptions

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

### 2.6.1 Critical Judgments

#### *Going Concern*

The Company strengthened its cash position in February 2020 following a capital increase of €25,059,665.88. However, given significant clinical activities (including the launch of the US study), the start of commercialization in Europe and Australia/New Zealand, the continuation of research and development projects, the Board of Directors analysed the evolution of the cash position until 31 December 2021 with a view to ensuring that it was sufficient to meet the Company's commitments up to that date. Based on the assumptions made by the Board of Directors regarding expected cash inflows and outflows over the next 18 months, this analysis indicates that the Company's cash position would be negative as of June 30, 2021. Inherent uncertainties in these forecasts may have an impact on when the Company's cash position will actually become negative.

These forecasts do not include financing alternatives currently under consideration by the Board of Directors. In this context, the Board of Directors is aware that the continuity of Company's operations depends on its ability to find these new sources of funding and that there are uncertainties in this regard.

### 2.6.2 Critical Accounting Estimates and Assumptions

#### *Recoverable Cash Advances*

The Company benefits from recoverable cash advances granted by the Walloon Region. These are in substance financial liabilities of the Company towards the Walloon 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 Walloon Region.

Based on these estimates, it may be concluded that the amount of the cash advance that the Company has received from the Walloon 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.

For the year ended 31 December 2016, it was too early for management to foresee future sales. As such, no liability was recorded in the financial statements with respect to the variable refundable part. For years ended 31 December 2017, 2018 and 2019, management could foresee in a more probable manner the future sales. At that point, management 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%. Refer also to note 2.16.

### *Research and Development Expenses*

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 31 December 2019, for the first time the Company capitalized amount of development costs of KEUR 5,734. This amount includes costs related to the development of the Genio® System which received CE Mark approval in March 2019. Therefore, the Company is of the opinion that, from March 2019, development expenditures do meet capitalization criteria. Accordingly, the costs incurred after this date have been recognized in the Statement of financial position (see note 2.9).

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. Moreover, the yearly impairment test of the capitalized development expenses requires critical estimates, judgements and assumptions which are further detailed in note 2.9.

### *Share-Based Payments*

The Company has equity-settled share-based payment plans in place. Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which is dependent on the terms and conditions of the option plan. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them. The assumptions and models used for estimating the fair-value for share-based payment transactions are disclosed in note 2.15.

### *Deferred Tax Assets*

As a result of significant losses incurred by the Company, the Company incurs tax losses that can be carried forward. Moreover, in the near future, the Company will continue investing in its clinical studies, R&D activities and commercial launch of the Genio® system in Europe, Australia, New Zealand and the United States meaning that no significant profits are expected in the near future. Therefore, no deferred tax asset on the tax losses has been recognized at this stage.

## **2.7 Subsidiaries**

For all three years ended as at 31 December 2019, 2018 and 2017 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.

## 2.8 Property Plant and Equipment

<i>(in EUR 000)</i>	Furniture and office equipment	Leasehold improvements	Laboratory equipment	Total
<b>Period ended 31 December 2017</b>				
Opening Gross value	347	163	84	594
Additions	50	4	37	91
<b>Gross value at 31/12/2017</b>	<b>397</b>	<b>167</b>	<b>121</b>	<b>685</b>
Opening accumulated depreciation	(161)	(31)	(18)	(210)
Depreciation charge	(59)	(20)	(8)	(87)
<b>Depreciation at 31/12/2017</b>	<b>(220)</b>	<b>(51)</b>	<b>(26)</b>	<b>(297)</b>
Opening Exchange differences	(5)	(1)	(1)	(7)
Exchange differences	(5)	(3)	(4)	(12)
<b>Exchange differences at 31/12/2017</b>	<b>(10)</b>	<b>(4)</b>	<b>(5)</b>	<b>(19)</b>
<b>Net book amount at 31/12/2017</b>	<b>167</b>	<b>112</b>	<b>90</b>	<b>369</b>
<b>Period ended 31 December 2018</b>				
Opening Gross value	397	167	121	685
Additions	42	23	12	77
<b>Gross value at 31/12/2018</b>	<b>439</b>	<b>190</b>	<b>133</b>	<b>762</b>
Opening accumulated depreciation	(220)	(51)	(26)	(297)
Depreciation charge	(63)	(21)	(11)	(95)
<b>Depreciation at 31/12/2018</b>	<b>(283)</b>	<b>(72)</b>	<b>(37)</b>	<b>(392)</b>
Opening Exchange differences	(10)	(4)	(5)	(19)
Exchange differences	(3)	(3)	(2)	(8)
<b>Exchange differences at 31/12/2018</b>	<b>(13)</b>	<b>(7)</b>	<b>(7)</b>	<b>(27)</b>
<b>Net book amount at 31/12/2018</b>	<b>143</b>	<b>111</b>	<b>89</b>	<b>343</b>
<b>Period ended 31 December 2019</b>				
Opening Gross value	439	190	133	762
Additions	48	-	3	51
<b>Gross value at 31/12/2019</b>	<b>487</b>	<b>190</b>	<b>136</b>	<b>813</b>
Opening accumulated depreciation	(283)	(72)	(37)	(392)
Depreciation charge	(64)	(24)	(12)	(100)
<b>Depreciation at 31/12/2019</b>	<b>(347)</b>	<b>(96)</b>	<b>(49)</b>	<b>(492)</b>
Opening Exchange differences	(13)	(7)	(7)	(27)
Exchange differences	10	9	9	28
<b>Exchange differences at 31/12/2019</b>	<b>(3)</b>	<b>2</b>	<b>2</b>	<b>1</b>
<b>Net book amount at 31/12/2019</b>	<b>137</b>	<b>96</b>	<b>89</b>	<b>322</b>

In 2019, 2018 and 2017 acquisitions were mainly related to laboratory equipment, IT and office equipment, and leasehold improvements. In 2018, offices in Tel-Aviv were extended, increasing the expenses related to leasehold improvements.

The yearly depreciation charge amounts to KEUR 100 in 2019, KEUR 95 in 2018 and KEUR 87 in 2017.

## 2.9 Intangible assets

<i>(in EUR 000)</i>	<b>Development Cost</b>	<b>Patents and licenses</b>	<b>Total</b>
<b>Cost</b>			
At 1 January 2017	-	-	-
Additions	-	-	-
<b>At 31 December 2017</b>	-	-	-
Additions	-	-	-
<b>At 31 December 2018</b>	-	-	-
Additions	5,311	335	5,646
<b>At 31 December 2019</b>	<b>5,311</b>	<b>335</b>	<b>5,646</b>
<b>Amortization</b>			
At 1 January 2017	-	-	-
Amortization	-	-	-
<b>At 31 December 2018</b>	-	-	-
Amortization	-	-	-
<b>At 31 December 2019</b>	-	-	-
Opening Exchange differences	-	-	-
Exchange differences	88	-	88
<b>Exchange differences at 31/12/2019</b>	<b>88</b>	-	<b>88</b>
<b>Net book value</b>			
At 31 December 2017	-	-	-
At 31 December 2018	-	-	-
<b>At 31 December 2019</b>	<b>5,399</b>	<b>335</b>	<b>5,734</b>

There is only one development project: The Genio® system. Refer to note 2.1.

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. As the Company currently does not generate significant cash-inflows, the recoverable amount of the intangible asset is determined on basis of its fair value less cost to sell.

The Company considers the relationship between the fair value of outstanding shares and the book value of its equity in order to assess the need for impairment. Currently, the Genio® system is the unique product line developed by the Company. Therefore, the fair value of the outstanding shares was estimated from the financial terms agreed in December 2019 for a capital increase organized by the Company and completed in February 2020 (see note 2.35 Subsequent events). On this basis, the Company concluded that this valuation derived from this share issuance is significantly above the book value of its equity, and therefore no impairment is required on intangible assets.

## 2.10 Right-of-use assets and lease liabilities

The Company has lease contracts for buildings and vehicles used in its operations. Leases of building generally have lease terms between four and nine years, while motor vehicles generally have lease terms of five years. The Company's obligations under its leases are secured by the lessor's title to the leased assets. Generally, the Company is restricted from assigning and subleasing the leased assets and some contracts require the Company to maintain certain financial ratios.

The Company also has certain leases of office equipment with low value. The Company applies the "short-term lease" and "lease of low-value assets" recognition exemptions for these leases.

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

<i>(in EUR 000)</i>	<b>Building</b>	<b>Motor vehicles</b>	<b>Total</b>
<b>Gross value</b>			
As of January 1, 2019 - Adoption of IFRS 16	1,131	192	1,323
Addition	-	-	-
<b>Gross value at 31/12/2019</b>	<b>1,131</b>	<b>192</b>	<b>1,323</b>
<b>Depreciation</b>			
As of January 1, 2019	-	-	-
Depreciation of the year	(281)	(52)	(333)
<b>Depreciation at 31/12/2019</b>	<b>(281)</b>	<b>(52)</b>	<b>(333)</b>
Opening exchange difference	-	-	-
Exchange difference	76	-	76
<b>Exchange difference</b>	<b>76</b>	<b>-</b>	<b>76</b>
<b>Net value at 31/12/2019</b>	<b>926</b>	<b>140</b>	<b>1,066</b>

The carrying amounts of lease liabilities and the movements during the period is as follows:

<i>(in EUR 000)</i>	
<b>As at January 1, 2019 – Adoption of IFRS 16</b>	<b>1,323</b>
Addition	0
Accretion of interest	17
Payments	(341)
Exchange difference	76
<b>Net value at 31/12/2019</b>	<b>1,075</b>
<i>Non-Current</i>	735
<i>Current</i>	340
<b>Net value at 31/12/2019</b>	<b>1,075</b>

The maturity analysis of lease liabilities is disclosed in note 2.3.16, the table hereunder details the amounts recognized in profit or loss:

<i>(in EUR 000)</i>	<b>31/12/2019</b>
Depreciation expense of right-of-use assets	333
Interest charge on lease liabilities	17
Rent expenses (note 2.20)	115

## 2.11 Other receivables

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Recoverable cash advance receivable	1,100	-	-
R&D Incentive receivable (Australia)	495	373	268
VAT receivable	153	136	118
Current tax receivable	30	18	115
Other	270	141	28
<b>Total Other receivables</b>	<b>2,048</b>	<b>668</b>	<b>529</b>

The recoverable cash advance is related to the Walloon Region who confirmed a final payment of KEUR 1,100 in connection with the convention 7388. Payment has been received in January 2020.

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

Current tax receivable relates to excess prepayment of corporate income tax in Israel.

In 2019, the caption “Other” includes an amount of KEUR 124 from “Man&Science S.A” co-owned by a non-executive Director (see note 2.34) and a credit note of KEUR 121 to be received from a service provider. The later explain the increase from 2018 to 2019.

## 2.12 Other Current Assets

Other current assets relate to prepaid expenses which amount to KEUR 11 at 31 December 2019, KEUR 2 as at 31 December 2018 and KEUR 4 as at 31 December 2017.

## 2.13 Cash and Cash Equivalents

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Short term deposit	28	844	290
Three months term deposit	363	352	-
Current accounts	5,463	15,606	9,810
Petty Cash	1	3	5
<b>Total Cash and cash equivalents</b>	<b>5,855</b>	<b>16,805</b>	<b>10,105</b>

## 2.14 Capital, Share Premium, Reserves

### 2.14.1 Capital and share premium

As of 31 December 2017, the share capital of the Company amounts to EUR 2,004,255 represented by 19,336 shares, and the share premium to EUR 33,142,943. As of 31 December 2018 and 2019, the share capital of

the Company amounts to EUR 2,481,299, represented by 23,938 shares, and the share premium amounts to EUR 47,668,005.

Evolution of the share capital and share premium over the last three years is as follows:

<i>(Number of shares except otherwise stated)</i>	<b>Number of Shares</b>	<b>Par value (EUR)</b>	<b>Share Capital</b>	<b>Share Premium</b>
<b>1 January 2017</b>	19,336	103.66	2,004	33,143
Capital increase of preferred shares	-	-	-	-
Capital increase through exercise of options	-	-	-	-
<b>31 December 2017</b>	19,336	103.66	2,004	33,143
Capital increase of preferred shares	4,602	103.66	477	14,525
Capital increase through exercise of options	-	-	-	-
<b>31 December 2018</b>	23,938	103.66	2,481	47,668
Capital increase of preferred shares	-	-	-	-
Capital increase through exercise of options	-	-	-	-
<b>31 December 2019</b>	23,938	103.66	2,481	47,668

At the extraordinary Shareholders' Meeting of the Company held on 5 October 2018, the following operations were decided:

- A creation of a new category of shares (the Preferred type B2 shares).
- A capital increase of EUR 477,043 by the creation of 4,602 new shares (Preferred type B2 shares). These new shares have been issued at a unit price of EUR 3,259.91, from which EUR 103.66 has been registered as share capital and the difference as share premium, i.e. EUR 3,156.25.
- Issuance of 300 anti-dilutive warrants which gives right to the owner to subscribe to new Preferred type B2 shares if the Company issue additional shares at an issue price lower than EUR 3,259.91 before the earlier of a liquidation event or 5 years.

#### 2.14.2 Categories of existing shares

As at 31 December 2019, there are four categories of shares, including 3 types of preferred shares. Preferred shares have 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. Shares outstanding by categories of shares were as follows:

	<b>Common Shares</b>	<b>Preferred A shares</b>	<b>Preferred B shares</b>	<b>Preferred B2 shares</b>	<b>Total</b>
<b>1 January 2017</b>	7,637	4,061	7,638	-	19,336
Capital increase of preferred shares	-	-	-	-	-
Capital increase through exercise of options	-	-	-	-	-
<b>31 December 2017</b>	7,637	4,061	7,638	-	19,336
Capital increase of preferred shares	-	-	-	4,602	4,602
Capital increase through exercise of options	-	-	-	-	-
<b>31 December 2018</b>	7,637	4,061	7,638	4,602	23,938
Capital increase of preferred shares	-	-	-	-	-
Capital increase through exercise of options	-	-	-	-	-
<b>31 December 2019</b>	7,637	4,061	7,638	4,602	23,938

In connection with the capital increase of 12 February 2020 (see note 2.35 Subsequent events), 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 a result of this conversion, the

capital of the Company represented by 23,938 existing shares with different rights as of 31 December 2019 will be represented by 29,758 common shares with the same rights. Following a share split decided the same day of 500:1, number of common shares will amount to 14,879,000 (before capital increase achieved on 12 February 2020).

### **2.14.3 Reserves**

In addition to share capital and share premium, shareholders' equity includes retained earnings and other reserves.

For periods up to and including the year ended 31 December 2015, the Company did not prepare Consolidated Financial Statements and only prepared its financial statements in accordance with local generally accepted accounting principle (Local GAAP). In this context, Retained earnings and Share payment reserves as at 1 January 2017 as presented in the Consolidated Statement of Changes in Equity includes the following:

- A negative amount of KEUR -4,243 reflecting the adjustments made at the transition date to restate local GAAP financial statements to IFRS accounting policies. These adjustments primarily related to R&D costs (KEUR -6,138), recoverable cash advances (KEUR -896) and subsidies (KEUR 2,791).
- Share-based payment transaction reserve used to recognize the value of equity-settled share-based payment transactions provided to employees as part of their remuneration (see note 2.15). The impact of this adjustment amounted to KEUR 28 as at 1 January 2017.

## **2.15 Share-Based Compensation**

The Company currently has four outstanding share-based incentive plans, including (i) the 2013 warrants plan (the 2013 Plan), (ii) the amendment of the 2013 warrants plan (the 2013 Plan AD), (iii) the 2016 warrants plan (the 2016 Plan), (iv) and the 2018 warrants plan (the 2018 Plan). AS disclosed in note 2.35 Subsequent events, the shareholders' meeting of the Company at 12 February 2020 has decided to achieve a share split in a ratio of 500:1. While such share split will also apply to warrants, the current disclosure provides indication on warrant before the impact the share split decided in 2020.

### **2.15.1 Description of the 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. These warrants are valid until 3 May 2023. 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 EUR 2.585,51. The key features of the warrants granted under the 2013 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 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.

#### *(b) 2013 Plan AD*

At the Company's extraordinary shareholders' meeting of December 23<sup>rd</sup> 2014, a further 300 warrants were approved for issuance, under the same conditions as the 2013 Plan, with a term of 5 years.

639 warrants under both the 2013 Plan and the 2013 Plan AD were fully granted throughout the years 2014, 2015 and 2016. Considering the cancelled, forfeited and exercised warrants:

- 539 warrants are still outstanding as at December 31, 2017.
- 539 warrants are still outstanding as at December 31, 2018.
- 416 warrants are still outstanding as at December 31, 2019.

*(c) 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. Under this plan, up to 1.500 warrants can be issued. By consequence, the Company can issue up to 1.500 common shares if all warrants are exercised.

The total amount of warrant owners cannot exceed 150 individuals. The warrants are and will stay nominative. The exercise price of each warrant cannot be less than EUR 2,585.32. The key features of the warrants granted under the 2016 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 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. Considering the cancelled, forfeited and exercised warrants under the 2016 Plan,

- 1,190 warrants are still outstanding as at December 31, 2017
- 1,485 warrants are still outstanding as at December 31, 2018
- 1,485 warrants are still outstanding as at December 31, 2019

*(d) 2018 Plan*

On 12 December 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. 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. The warrants are and will stay nominative. The exercise price of each warrant cannot be less than EUR 3,259.91. The key features of the warrants granted under the 2018 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 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.

In 2019, 492 warrants out of the 525 warrants were granted and 106 warrants were forfeited during the year. As at 31 December 2019, 33 warrants were yet to be issued in relation with the 2018 Plan. Considering the cancelled, forfeited and exercised warrants under the 2018 Plan, 386 warrants are still outstanding as at 31 December 2019.

### 2.15.2 Accounting for Share-Based Payment

The fair value of the plan is expensed over the vesting period. The share-based compensation expense recognized in the income statement was KEUR 346 for the year ended 31 December 2019, KEUR 28 for the year ended 31 December 2018 and KEUR 24 for the year ended 31 December 2017.

Movements during the year (in unit):

	Number of option (in units)	Weighted average exercise price in EUR
Outstanding 31/12/16	1,549	2,585.39
Granted during 2017	195	2,585.32
Forfeited during 2017	(15)	2,585.32
Exercised during 2017	0	n.a.
<b>Outstanding 31/12/17</b>	<b>1,729</b>	<b>2,585.38</b>
Granted during 2018	295	2,585.32
Forfeited during 2018	-	n.a.
Exercised during 2018	-	n.a.
Expired during 2018	-	n.a.
<b>Outstanding 31/12/18</b>	<b>2,024</b>	<b>2,585.37</b>
Granted during 2019	492	3,259.91
Forfeited during 2019	(184)	2,974.46
Exercised during 2019	-	-
Expired during 2019	(45)	2,585.51
<b>Outstanding 31/12/19</b>	<b>2,287</b>	<b>2,699.06</b>

The table hereunder details the number of exercisable (vested) warrants and their weighted average exercised price:

	<b>2019</b>	<b>2018</b>	<b>2017</b>
Number of exercisable (vested) warrants	1,940	1,807	1,193
Weighted average exercised price	2,630.57	2,585.38	2,585.39

The fair value of each option or subscription right is estimated on the date of grant using the Black & Scholes model. The expected life of the share options is based on current expectations and is not necessarily indicative of exercise patterns that may occur. The expected volatility reflects the assumption based on a Damodaran sample (2016), which includes 254 Companies from the Healthcare Products sector is indicative of future trends, which may not necessarily be the actual outcome.

The weighted average remaining contractual life for the share options outstanding as at 31 December was 2.5 in 2019, 2.99 in 2018 and 3.70 in 2017.

The weighted average fair value of options granted during the year was EUR 2,620.27 in 2019, EUR 51.78 in 2018 and EUR 18.74 in 2017 as follows:

**Year ended December 31, 2017**

	<u>2016 Plan</u>	<u>2018 Plan</u>
Number of shares granted	195	n.a.
Weighted average fair values at the measurement date	18.74	n.a.
Dividend yield	0.0%	n.a.
Expected volatility	62.20%	n.a.
Risk-free interest rate	0.77%	n.a.
Expected life of share options/SARs (years)	3	n.a.
Weighted average share price (€)	412.18	n.a.
Exercise price	2,585.32	n.a.
Model used	B&S	n.a.

**Year ended December 31, 2018**

	<u>2016 Plan</u>	<u>2018 Plan</u>
Number of shares granted	295	n.a.
Weighted average fair values at the measurement date	51.78	n.a.
Dividend yield	0.0%	n.a.
Expected volatility	66.92%	n.a.
Risk-free interest rate	0.35%	n.a.
Expected life of share options/SARs (years)	3	n.a.
Weighted average share price (€)	546.00	n.a.
Exercise price	2,585.32	n.a.
Model used	B&S	n.a.

**Year ended December 31, 2019**

	<u>2016 Plan</u>	<u>2018 Plan</u>
Number of shares granted	n.a.	492
Weighted average fair values at the measurement date	n.a.	2,620.27
Dividend yield	n.a.	0.0%
Expected volatility	n.a.	56.32%
Risk-free interest rate	n.a.	(0.20%)
Expected life of share options/SARs (years)	n.a.	3
Weighted average share price (€)	n.a.	5,122
Exercise price	n.a.	3,259.91
Model used	n.a.	B&S

**2.16 Financial Debt**

Financial debt consists of recoverable cash advances and other loan. Related amounts can be summarized as follows:

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Recoverable cash advances – Non-current	6,874	5,172	4,431
Recoverable cash advances – Current	274	185	333
<b>Total Recoverable cash advances</b>	<b>7,148</b>	<b>5,357</b>	<b>4,764</b>
Other loan – Non-current	272	354	438
Other loan – Current	104	104	62
<b>Total Other loan</b>	<b>376</b>	<b>458</b>	<b>500</b>
Non-current	7,146	5,526	4,869
Current	378	289	395
<b>Total Financial debt</b>	<b>7,524</b>	<b>5,815</b>	<b>5,264</b>

## 2.16.1 Financial debt related to recoverable cash advances

### 2.16.1.1 Background information

The Company receives the support from 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. 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 advance received, depending on the level and the timing of the sales.

At inception, recoverable cash advances are recognized as financial liability at fair value when received. To determine the fair value of the cash advances received, the Company estimates future cash outflows it will have to support considering (i) assumptions regarding the probability of success of the research programs benefiting from the cash advance including 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 recalculate 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 the probability 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.

#### 2.16.1.2 Recoverable cash advances received

As at 31 December 2019, the details of recoverable cash advances received can be summarized as follows:

<i>(in EUR 000)</i>	<b>Contractual Advances</b>	<b>Advances received</b>	<b>Amounts reimbursed</b>
Sleep apnea device (6472)	1,600	1,600	380
First Articles (6839)	2,160	2,160	84
Clinical Trial (6840)	2,400	2,210	-
Activation chip improvements (7388)	1,467	1,467	-
<b>Total</b>	<b>7,627</b>	<b>7,437</b>	<b>464</b>

- The Convention 6472 “Sleep apnea device” for a total amount of KEUR 1,600 was signed in 2011. The total amount of the advance has been received before 1 January 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 KEUR 380 (excluding interests) out of which KEUR 40 in 2019, KEUR 100 in 2018 and KEUR 100 in 2017.
- The Convention 6839 “First Articles” for a total amount of KEUR 2,160 was signed on December 5, 2012. At 1 January 2015, the advance received amounted to KEUR 1,934. The outstanding amount of K€ 226 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 (KEUR 84 excluding interests). The Region has informed the Company that the fixed reimbursement related to 2019 will be due in 2020.
- The Convention 6840 “Clinical Trial” for a total amount of KEUR 2,400 was signed on December 6, 2012. At 31 December 2019, the advance received amounted to KEUR 2,210, of which KEUR 96 in 2019 and KEUR 1,214 in 2017. 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 KEUR 1,467 was signed in December 2015. During 2016, an amount of KEUR 367 was received as part of this advance. The Company has now received the remaining balance of KEUR 1,100. 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. The Region has informed the Company that the fixed reimbursement which was contractually due as from 2019 is postponed to 2020.

### 2.16.1.3 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.

Prior to 31 December 2016, it was too early for management to foresee future sales. As such, no liability was recorded in the financial statements with respect to the variable part. Only the fixed reimbursement (30% of the advance) was therefore recognized as financial debt using a discount rate of 5%. As from 2017, management could foresee more accurately future sales and therefore 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:

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Recoverable cash advances received	7,437	6,240	6,014
Amounts to be reimbursed (2 times)	14,874	12,480	12,028
Amounts reimbursed at year-end (interests included)	(517)	(469)	(265)
<b>Total Recoverable cash advances (undiscounted)</b>	<b>14,357</b>	<b>12,011</b>	<b>11,763</b>

Based on expected timing of sales and after discounting, the financial debt related to the recoverable cash advances is as follows:

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Contract 6472	1,296	1,201	1,108
Contract 6839	2,115	1,783	1,612
Contract 6840	2,232	1,953	1,675
Contract 7388	1,505	420	369
<b>Total Recoverable cash advances</b>	<b>7,148</b>	<b>5,357</b>	<b>4,764</b>

Non-current	6,874	5,172	4,431
Current	274	185	333
<b>Total Recoverable cash advances</b>	<b>7,148</b>	<b>5,357</b>	<b>4,764</b>

The amounts recorded under Current caption correspond to the sales-independent amounts (fixed repayment) estimated to be repaid to the Walloon Region in the next 12 months period. The estimated sales-independent (variable repay) above 12 months as well as sales-dependent reimbursements (variable) are recorded under Non-current.

Changes in the recoverable cash advances can be summarized as follows:

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
As of January 1	5,357	4,764	1,300
Advances received	1,196	226	1,213
Advances reimbursed (excluding interests)	(40)	(184)	(100)
Initial measurement and re-measurement	60	70	2,286
Discounting impact	575	481	65
As of December 31	<b>7,148</b>	<b>5,357</b>	<b>4,764</b>

As the Company made a significant remeasurement at the end of 2017, the impact of the discounting, which is included in financial expenses, becomes significant in 2019 and 2018. The initial measurement and re-measurement are included in other operating income/expenses.

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<sup>88</sup> of +/- 25% and in the discount rates of +/- 25%. The table hereunder details the sensitivity results:

Fair Value of Liabilities as of end of 2019 (in EUR 000)	Variation of revenue projections			
	Variation of discount rates*	-25%	0%	25%
-25%		8,140	8,393	8,555
0%		6,879	7,148	7,326
+25%		5,868	6,142	6,324

\* 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.

### 2.16.2 Other Financial Liabilities

The Company has contracted a loan of KEUR 500 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 KEUR 376 at 31 December 2019, KEUR 458 at 31 December 2018 and KEUR 500 at 31 December 2017.

<sup>88</sup> Changes in revenue projections can be due to changes in the timing of revenues, changes in product pricing, etc

## 2.17 Trade Payables

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Payables	1,174	606	389
Invoices to be received	211	204	213
<b>Total Trade payables</b>	<b>1,385</b>	<b>810</b>	<b>602</b>

The increase of the trade payables between 2019, 2018 and 2017 is mainly due to increase in general activities. The Company normally settles its trade payable in 30 days.

## 2.18 Other Payables

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Holiday pay accrual	243	316	257
Salary	381	270	220
Accrued expenses	687	250	220
Other	157	64	55
<b>Total Other payables</b>	<b>1,468</b>	<b>900</b>	<b>752</b>

The increase of the accrued expenses in 2019, compared to 2018 and 2017, is mainly due to hospital services for the clinical trials in Australia.

## 2.19 Revenue and costs of goods sold

The Company is still in phase of development. As such there is no revenue and costs of goods sold for the fiscal years ended 31 December 2019, 2018 and 2017 respectively.

## 2.20 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.

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Staff costs	1,327	725	719
Consulting and contractors' fees	534	487	425
Legal fees	42	257	65
Rent	115	329	289
Facilities	67	94	113
Depreciation and amortization expense	415	76	73
ICT	151	130	162
Travel	186	131	121
Other expenses	190	110	225
<b>Total General and Administrative expenses</b>	<b>3,027</b>	<b>2,339</b>	<b>2,192</b>

General and administrative expenses increased by 30% from KEUR 2,339 in 2018 to KEUR 3,027 in 2019 due mainly to an increase of staff costs. In 2019, the Company applied for the first time IFRS 16 (refer to note 2.10), this explains the decrease in rent while depreciation and amortization expenses increased.

The increase by 7%, from KEUR 2,192 in 2017 to KEUR 2,339 in 2018 is mainly due to an increase of legal fees. Increases in rental expenses and external consultants are partially offset by decrease in other expenses.

## 2.21 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.

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Staff costs	1,252	1,046	976
Consulting and contractors' fees	11	48	3
Outsourced developments	1,054	209	468
Depreciation and amortization expense	16	16	17
Travel	33	52	37
Other	9	14	4
Capitalized costs	(1,745)	-	-
<b>Total Research and development expenses</b>	<b>630</b>	<b>1,385</b>	<b>1,505</b>

Before capitalization of KEUR 1,745 in 2019, Research and development expenses increased by 71% from KEUR 1,385 in 2018 to KEUR 2,375 in 2019 due mainly to the increase of development costs of the Genio® system.

The decrease by 8%, from KEUR 1,505 in 2017 to KEUR 1,385 in 2018 was due to a reduction of outsourced development expenses partially offsets by an increase in staff costs.

## 2.22 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.

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Staff costs	921	800	822
Consulting and contractors' fees	474	210	227
Clinical activities	1,190	1,189	698
Travel	182	247	275
Other	114	77	88
Capitalized costs	(2,033)	-	-
<b>Total Clinical expenses</b>	<b>848</b>	<b>2,523</b>	<b>2,110</b>

Before capitalization of KEUR 2,033 in 2019, clinical expenses increased by 14% from KEUR 2,523 in 2018 to KEUR 2,881 in 2019 due mainly to an increase of consulting and contractor's fees to support clinical trials.

The increase of 20%, from KEUR 2,110 in 2017 to KEUR 2,523 in 2018 was primarily due to an increase in clinical expenses related to the completion of BLAST OSA study.

### 2.23 Manufacturing expenses

Manufacturing and operation expenses consist primarily of acquisition costs of the components of the Genio® system, scrap and inventory obsolescence as well as distribution-related expenses such as logistics and shipping costs.

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Staff costs	613	533	318
Consulting and contractors' fees	-	8	73
Manufacturing	1,071	470	360
Travel	41	30	24
Other	87	48	28
Capitalized costs	(1,323)	-	-
<b>Total Manufacturing expenses</b>	<b>489</b>	<b>1,089</b>	<b>803</b>

Before capitalization of KEUR 1,323 in 2019, manufacturing expenses increased by 66% from KEUR 1,089 in 2018 to KEUR 1,812 in 2019 mainly due to an increase of manufacturing costs (see below) to support clinical trials.

The increase by 36% from KEUR 803 in 2017 to KEUR 1,089 in 2018 was due mainly to the increase of staff and manufacturing costs.

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

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Implantable stimulator	686	295	206
Activation chip	67	15	14
Disposable patch	113	29	74
External stimulator	37	52	8
Other	168	79	58
Capitalized costs	(800)	-	-
<b>Total</b>	<b>271</b>	<b>470</b>	<b>360</b>

## 2.24 Quality Assurance and Regulatory expenses

Quality assurance and regulatory expenses consist primarily of quality control, quality assurance and regulatory expenses. These expenses include employee compensation, consulting, testing and travel expenses related to the QA/RA department.

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Staff costs	353	361	294
Consulting and contractors' fees	400	174	267
QA & regulatory	148	113	289
Travel	27	30	26
Other	-	2	6
Capitalized costs	(701)	-	-
<b>Total Quality Assurance and Regulatory expenses</b>	<b>227</b>	<b>680</b>	<b>882</b>

Before capitalization of KEUR 701 in 2019, Quality assurance and regulatory expenses increased by 36% from KEUR 680 in 2018 to KEUR 928 in 2019 due mainly to an increase of consulting and contractors' fees associated to new projects related to the optimization of manufacturing processes.

The decrease of 23%, from €0.9 million in 2017 to €0.7 million in 2018 is explained by the fact that expenses in 2017 were higher because of additional work undertaken for the preparation of ISO certification for the Genio® system as well as main verification and validation testing for the Genio® System.

## 2.25 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 fees and related expenses were not capitalized following an accounting policy similar to the one applied to development expenses.

Before capitalization of KEUR 335 in 2019, patents fees and related expenses remained similar, KEUR 594 in 2018 compared to KEUR 602 in 2019.

From 2017 to 2018, Patents fees & related expenses increased by 11%, from KEUR 533 to KEUR 594 due to additional legal costs related to the settlement of assignment rights with one inventor.

### Therapy development expenses

Therapy development expenses consist primarily of compensation for personnel, spending related to market access and reimbursement activities. Other therapy development expenses include training physicians, travel expenses, conferences and consulting services.

Therapy development expenses increased by 267% from KEUR 338 in 2018 to KEUR 902 in 2019 mainly due to the increase of headcount, the use of consultants for the preparation of reimbursement files and the participation to congresses to promote Nyxoah technology.

These expenses decreased by 32% from KEUR 495 in 2017 to KEUR 338 in 2018. In 2017, the Company incurred additional costs because it engaged external consultants for a reimbursement study in the United States.

## 2.26 Other Operating Income / (Expenses)

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Recoverable cash advances			
- Initial measurement and re-measurement	(61)	(70)	(2,286)
R&D Incentives (Australia)	425	383	281
Other income/(expenses)	3	185	382
Capitalization of R&D Incentive	(493)	-	-
<b>Total Other Operating Income/(Expenses)</b>	<b>(126)</b>	<b>498</b>	<b>(1,623)</b>

The impact of the recoverable cash advances is further detailed in note 2.16. It includes the impact of the initial measurement and re-measurement of the financial debt. The significant impact in 2017 is due to the initial recognition of the variable part of the reimbursement of cash advances received.

The R&D Incentive (Australia) relates to incentive to be received on development expenses incurred by the subsidiary in Australia. The 2019 R&D incentive (KEUR 493) has been deducted from the clinical expenses capitalized.

The caption “Other income/(expenses)” included a refund of income taxes of employees dedicated to research and development activities (KEUR 134) in 2018 and various grant received from the Region and the European Commission to support the Company for costs relating to pattern, market strategy, etc. (KEUR 204).

## 2.27 Employee Benefits

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Salaries	3,625	2,498	2,324
Social charges	518	357	314
Fringe benefits	153	292	279
Defined contribution plan (see note 2.30)	258	180	160
Holiday pay	99	217	213
Share-based payment (see note 2.17)	346	28	24
Other	127	178	155
<b>Total employee benefits</b>	<b>5,126</b>	<b>3,750</b>	<b>3,469</b>
General and administrative expenses	1,327	725	719
Research & Development costs	1,252	1,046	976
Clinical expenses	921	800	822
Operation & Manufacturing expenses	613	533	318
QA expenses	353	361	294
Other expenses (therapy development, patents, etc.)	660	285	340
<b>Total employee benefits</b>	<b>5,126</b>	<b>3,750</b>	<b>3,469</b>

As at 31 December 2019, the Nyxoah Group employed 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 31 December 2019, 2018 and 2017.

	As at 31 December		
	2019	2018	2017
General & Administration	5.8	7.0	6.7
IP & Trademark	1.0	1.0	1.0
Research & Development	10.6	11.0	9.0
Clinical & Regulatory Affairs	8.2	7.2	7.9
Quality Assurance & Regulatory	5.9	5.9	5.8
Operations	9.0	7.0	5.0
Therapy Development (including the sales team)	2.0	1.0	1.0
Total	42.5	40.1	36.4

As of 31 December 2019, the Company had 10.2 full-time equivalents located in Belgium, 28.3 full-time equivalents located in Israel and 4 full-time equivalents located in Australia.

## 2.28 Pension Schemes

The Company offers Defined Contribution Plan funded through group insurances to its employees of the Belgian entity with a minimum return guaranteed by law. The contributions to this plan amount to minimum 7.0% of the salary, partly paid by the employer and partly by the employees. The total expense recognized in the consolidated income statement for contributions made under this plan amount to KEUR 228 in 2019, KEUR 180 in 2018 and KEUR 160 in 2017. As explained hereafter, the Define Contribution Plan qualifies as Defined Benefit Plan under IFRS. As a result, a provision of KEUR 30 has also been recorded for the net benefit obligation in 2019.

As a consequence of the law of 18 December 2015, minimum returns guaranteed by the employers are as follows:

- For the contributions paid as from 1 January 2016, a new variable return based on OLO rates comprised between 1.75% and 3.75%. The rate is currently set to 1.75%.
- For the contributions paid until end December 2015, the previously applicable legal returns of 3.75% on employee contributions and 3.25% on employer contributions continue to apply until retirement date of the participants.

The insurance companies managing these plans for the Company also guarantee a minimum return on the reserves as well as on future contributions for some portions of the plan. They have evolved as follows: 4.75% until 1998, 3.25% from 1999 till 2012 and between 0.50% and 2.25% since 2013. They are currently set between 0.50% and 1.50%. The assets of the plan are entirely managed by external insurance companies said “qualifying third party” which do not have any link with the Company.

The average maturity of the Belgian plan is between 8 and 15 years as at 31 December 2019. In view of the minimum legal returns guaranteed, this Defined Contribution Plan qualifies as Defined Benefit Plan under IFRS. Indeed, it induces a financial risk for the Company during periods of declining market interest rates when the returns guaranteed by the insurance companies are lower than the minimum legal returns, which is currently the case. In this case, the intervention of the insurance company is limited, and the Company shall fund the balance between the return delivered by the insurance company and the legal return.

A complete actuarial calculation has been performed for this plan by external actuaries based on the “Projected Unit Credit Method without future contribution” according to the IAS 19.115 as follows:

- Projection of the minimum return guaranteed by the law till the retirement date and discounting of this amount with the discount rate used for the valuation (rate of high-quality corporate bonds);
- The discounted net obligation is the maximum between this discounted projection and the projection of the accrued reserves discounted at the discount rate used for the valuation (rate of high-quality corporate bonds).

The net defined benefit obligation was established at KEUR 30 as of December 31 2019. No further disclosures were made as the amount was deemed immaterial.

## 2.29 Financial Income

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Interests	8	1	2
Exchange differences	63	28	23
<b>Total Financial income</b>	<b>71</b>	<b>29</b>	<b>25</b>

## 2.30 Financial Expense

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Recoverable cash advances, Discounting	575	481	65
Interest and bank charges	33	29	37
Interest on lease liabilities	17	-	-
Exchange differences	115	107	114
<b>Total Financial expense</b>	<b>740</b>	<b>617</b>	<b>216</b>

The discounting impact of the recoverable cash advances is further detailed in note 2.16 above.

## 2.31 Taxes

The major components of income tax expense for the years ended 31 December 2019, 2018 and 2017 are as follows:

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Current tax	(61)	(48)	(47)
Deferred tax Income/(Expense)	(9)	7	10
<b>Total Income Tax Expenses</b>	<b>(70)</b>	<b>(41)</b>	<b>(37)</b>

Current tax mainly relates to income tax paid by the subsidiary in Israel, which is the only entity generating profits, other entities having no taxable income. 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) KEUR(9) in 2019, KEUR 7 in 2018 and KEUR 10 in 2017 and deferred tax assets KEUR 21 in 2019, KEUR 29 in 2018 and KEUR 22 in 2017.

The income tax expenses can be reconciled to the Company's Belgian statutory income tax rate of 29.58% (33.99% in 2017) as follows:

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Pre-Tax Book Income /(loss)	(7,185)	(9,038)	(10,334)
Company Statutory Income Tax Rate	29.58%	29.58%	33.99%
Income Tax at Company Statutory Tax Rate:	2,125	2,673	3 513
Unrecognized DTA on tax losses and temporary differences	(2,204)	(2,743)	(3,568)
Foreign Tax Rate Differential	38	34	21
Other temporary differences	(30)	(5)	(3)
Income Tax at Company Effective Tax Rate	(70)	(41)	(37)
Company Effective Income Tax Rate	(0.98%)	(0.45%)	(0.36%)

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. While these are immaterial for the Australian entity, the Belgian entity has tax losses for some MEUR 44.1 as at 31 December 2019 but also has recoverable temporary differences (MEUR 5.4 on valuation of recoverable cash advances and MEUR 2 taxed reserves). 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.

### **2.32 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 21 February 2020. As explained in note 2.35 Subsequent events, all existing preferred shares were converted into common shares, and then a share split of 500:1 was approved by the shareholders' meeting. Applying this split to the existing shares as of 31 December 2019 provides the following information:

	<b>2019</b>	<b>2018</b>	<b>2017</b>
<i>As at 31 December, before conversion and share split</i>			
Outstanding shares at year-end (common and preferred shares)	23,938	23,938	19,336
Weighted average number of shares outstanding	23,938	20,433	19,336
Outstanding warrants	2,287	2,024	1,729

	2019	2018	2017
<i>As at 31 December, after conversion but before share split</i>			
Outstanding shares at year-end (common shares only)	29,758	29,758	22,883
Weighted average number of shares outstanding	29,758	24,522	22,883
Outstanding warrants	2,287	2,024	1,729
<i>As at 31 December, after conversion and share split</i>			
Outstanding shares at year-end (common shares only)	14,879,000	14,879,000	11,441,500
Weighted average number of shares outstanding	14,879,000	12,261,000	11,441,500
Number of Shares resulting of the exercise of outstanding warrants	1,143,500	1,012,000	864,500

Basic and Diluted EPS, based on weighted average number of shares outstanding after conversion and share split are as follows:

	2019	2018	2017
Loss of year attributable to equity holders (in EUR)	(7,255,000)	(9,079,000)	(10,371,000)
Weighted average number of shares outstanding (in units)	14,879,000	12,261,000	11,441,500
<b>Basic earnings per share in EUR (EUR/unit)</b>	<b>(0.488)</b>	<b>(0.740)</b>	<b>(0.906)</b>
<b>Diluted earnings per share in EUR (EUR/unit)</b>	<b>(0.488)</b>	<b>(0.740)</b>	<b>(0.906)</b>

## 2.33 Commitments

### 2.33.1 Capital Commitments

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

### 2.33.2 Operating Leases

For 2017 and 2018, the Company has entered into operating leases in relation to its offices as well as in relation to employee cars for which the average lease term is 48 months.

For 2019, leases for offices and employee cars are capitalized following the adoption of IFRS 16. The short term and low value leases of the year are not material.

The Company's future payments as per 31 December under its leasing contracts are summarized in the table below:

<i>(in EUR 000)</i>	2019	2018	2017
Within 1 year	115	365	325
Between 1 and 5 years	35	1,029	
More than 5 years	-	83	137
<b>Total</b>	<b>150</b>	<b>1,477</b>	<b>1,802</b>

Payments under operating leases recognized as an expense:

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Expense	115	331	261
<b>Total</b>	<b>115</b>	<b>331</b>	<b>261</b>

### 2.34 Related Party Transactions

Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes.

#### 2.34.1 Remuneration of Key Management

The remuneration of the senior management consists of the remuneration of the CEO of the Company:

<i>(in EUR 000)</i>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Short-term remuneration & compensation	612	346	325
Long-term remuneration & compensation	-	-	-
Share based payment	231	14	14
<b>Total</b>	<b>842</b>	<b>360</b>	<b>339</b>

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 KEUR 579.

In 2019, 2018 and 2017, ActuaRisk Consulting, a company owned by a management member, invoiced Nyxoah S.A for amount of KEUR 234, KEUR180 and KEUR 180, respectively for consulting services.

No loans or other guarantees have been given to a member of the executive management team.

#### 2.34.2 Transactions with Non-Executive Directors and Shareholders

Two non-executive Directors have received each 54 share options under the 2016 Plan (see note 2.15). In 2018, the Shareholder's Meeting has approved the grant of 106 share options to one non-executive Director.

Nyxoah S.A. paid in 2018, on behalf of Man & Science, a company co-owned by a non-executive Director, KEUR 124 for the settlement of an IP rights transfer with a third party (refer to note 2.11). This amount has not yet been recovered as of 31 December 2019.

In 2019, 2018 and 2017, the Company charged "Man & Science S.A" for consulting fee related to the intellectual property KEUR 6, KEUR 6 and KEUR 1 respectively.

In 2019, MINV S.A., a company owned by a non-executive Director invoiced Nyxoah S.A. for consulting services a total amount of KEUR 79.

In 2019, Cochlear, a company which is shareholder of Nyxoah S.A., invoiced Nyxoah S.A. for a total amount of KEUR 839 for the development of the Genio® system.

In 2019, 2018 and 2017, Gilde Healthcare, a company which is shareholder of Nyxoah S.A., invoiced Nyxoah S.A for a total amount of KEUR 2, KEUR 2 and KEUR 1 respectively for travel costs related to the Board of Directors.

In 2019, 2018 and 2017, Medtech Execs LLC, a company owned by a non-executive Director invoiced Nyxoah S.A. KEUR 31, KEUR 12 and KEUR 28 respectively for consulting services and board remuneration.

Christopher Smith, as non-executive director, has invoiced the Company for consulting services and board remuneration for a total amount of KEUR 9 in 2019 and KEUR 4 in 2018.

### **2.35 Events after the Balance-Sheet Date**

On 12 February 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 KEUR 25,060 (including share premium) in exchange for 4,200 new shares in the Company.

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

- i. the conversion of all preferred shares into common shares,
- ii. the cancellation of the outstanding Series B Anti-Dilution Warrants and Series B2 Anti-Dilution Warrants,
- iii. a share split at a 500:1 ratio to reduce the value per individual share of the Company,
- iv. the adoption of a revised version of the articles of association,
- v. the adoption of a new share incentive plan with issuance of five hundred fifty thousand (550,000) warrants.

Note 2.32 reflects the impact of the conversion and the share split on the existing outstanding shares as of 31 December 2019.

In March 2020, the World Health Organisation characterized COVID-19 as a pandemic. This has affected the course of business of the Company. This exceptional situation has required exceptional measures. Governmental safety guidelines have been implemented in all Nyxoah entities. Production activities have not stopped in the Tel Aviv facility. Support functions (R&D, QA&RA) also continued but with reduced capacity. Elective surgeries were on hold from March to August 2020 in certain geographies across Europe and Australia, but are selectively re-opening. Study centers and centers of excellence may not perform elective surgeries should COVID-19 cases increase locally. Although the Company is monitoring developments relating to the COVID-19 situation closely, the ultimate impact of COVID-19 on the Company's business is uncertain at this time and will depend on future developments, which are highly uncertain and cannot be predicted.

Due to the high degree of unpredictability of COVID-19, the Company foresees challenges in training and proctoring new centers and their surgeons in the United States and Europe. Patients being less willing to travel to these centers or their travelling being restricted, could become an issue and potentially impact the Company's clinical and commercial activities.

At the end of June 2020, the Company and Noshaq, a governmental investment fund, agreed on the terms of €1 million convertible loan.

### **2.36 Statutory Auditor Services and Performance of Exceptional Activities or Execution of Special Instructions Performed by the Auditor**

Ernst & Young Réviseurs d'Entreprises SCRL, organized and existing under the laws of Belgium, with registered office at De Kleetlaan 2, 1831 Diegem, Belgium has been appointed as the statutory auditor of the Company for a term of 3 years ending immediately at the approval by the shareholders' meeting of the financial statements for the year ended 31 December 2018. Re-appointment of the statutory auditor has been decided by the General Assembly of Shareholders dated 23 May 2019. The new mandate of 3 years ends at the approval by the shareholders' meeting of the financial statements for the year ended 31 December 2021.

The Company expensed in fees to the auditor KEUR 97 in 2019, KEUR 67 in 2018 and KEUR 33 in 2017. The fees are broken down as follows:

- Audit fee for statutory and consolidated financials: KEUR 76 in 2019, KEUR 50 in 2018 and KEUR 32 in 2017.
- Tax consulting services: KEUR 9 in 2019, KEUR 3 in 2018 and KEUR 2 in 2017.
- Capital increase and other related reports: KEUR 12 in 2019 and KEUR 14 in 2018.

## 20.2 UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS AS AT AND FOR THE SIX-MONTH PERIODS ENDING 30 JUNE 2019 AND 2020

### 1 Interim condensed consolidated Financial Statements for the six-month period ended 30 June

#### 1.1 Independent auditor's review report on the interim financial statements as at 30 June 2020



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#### **Report of the statutory auditor to the shareholders of Nyxoah SA on the review of the interim condensed consolidated financial statements as of 30 June 2020 and for the 6 month period then ended**

##### Introduction

We have reviewed the accompanying interim condensed consolidated statement of financial position of Nyxoah SA (the "Company"), and its subsidiaries (collectively referred to as "the Group") as at 30 June 2020 and the related interim condensed consolidated income statement and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the 6 month period then ended, and explanatory notes, collectively, the "Interim Condensed Consolidated Financial Statements". These statements show a consolidated statement of financial position total of € thousand 38,167 as at 30 June 2020 and a consolidated loss for the 6 month period then ended of € thousand 4,052. Management is responsible for the preparation and presentation of these Interim Condensed Consolidated Financial Statements in accordance with International Financial Reporting Standard IAS 34 *Interim Financial Reporting* ("IAS 34") as adopted for use in the European Union. Our responsibility is to express a conclusion on these Interim Condensed Consolidated Financial Statements based on our review.

##### Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements 2410 "*Review of Interim Financial Information Performed by the Independent Auditor of the Entity*" applicable to review engagements. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with the International Standards on Auditing and, consequently, does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.



*Report of the statutory auditor dated 7<sup>th</sup> September 2020 on the interim condensed consolidated financial statements of Nyxoah SA for the 6 month period ended 30 June 2020 (continued)*

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the accompanying Interim Condensed Consolidated Financial Statements as at 30 June 2020 and for the 6 month period then ended are not prepared, in all material respects, in accordance with IAS 34.

### Material uncertainty related to going concern

We draw attention to Note 2.2.1 of the Interim Condensed Consolidated Financial Statements that describes the uncertainties related to the evolution of the medium-term cash position of the Company in connection with the financing of the development activities of the The Genio® system. These events or conditions, along with Covid-19 matters and other matters as set forth in Note 2.2.1, indicate that the Company needs to seek new sources of financing and that material uncertainty with this respect may cast doubt on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

Diegem, 7<sup>th</sup> September 2020

EY Réviseurs d'Entreprises SRL  
Statutory auditor  
represented by

Carlo-Sébastien D'Addario\*  
Partner  
\*Acting on behalf of a BV/SRL

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## 1.2 Interim condensed consolidated statement of financial position

<i>(in EUR 000)</i>	Note	30/06/2020	31/12/2019
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	2.4	386	322
Intangible assets	2.5	9,269	5,734
Right of use assets		1,285	1,066
Deferred tax asset		24	21
Other long-term receivables		78	78
		<b>11,042</b>	<b>7,221</b>
<b>Current assets</b>			
Trade receivables		30	60
Other receivables		1,428	2,048
Other current assets	2.6	1,787	11
Cash and cash equivalents		23,880	5,855
		<b>27,125</b>	<b>7,974</b>
<b>Total assets</b>		<b>38,167</b>	<b>15,195</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Capital and reserves</b>			
Capital	2.7	2,917	2,481
Share premium	2.7	72,196	47,668
Share based payment reserve	2.8	893	420
Currency translation reserve		118	207
Retained Earnings		(50,713)	(47,063)
<b>Total equity attributable to shareholders</b>		<b>25,411</b>	<b>3,713</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Financial debt	2.9	7,331	7,146
Lease liability		895	735
Pension Liability		30	30
		<b>8,256</b>	<b>7,911</b>
<b>Current liabilities</b>			
Financial debt	2.9	382	378
Lease liability		411	340
Convertible Loan	2.10	1,000	-
Trade payables		1,343	1,385
Other payables		1,364	1,468
		<b>4,500</b>	<b>3,571</b>
<b>Total liabilities</b>		<b>12,756</b>	<b>11,482</b>
<b>Total equity and liabilities</b>		<b>38,167</b>	<b>15,195</b>

### 1.3 Interim condensed consolidated Income Statement and Other Comprehensive Income for the six-month period ended June 30th

(in EUR 000)

	Note	2020	2019
Revenue		-	-
Cost of goods sold		-	-
General and administrative expenses	2.11	(2,063)	(1,109)
Research and development expenses	2.11	(56)	(527)
Clinical expenses	2.11	(509)	(480)
Manufacturing expenses	2.11	(207)	(273)
Quality assurance and regulatory expenses	2.11	(86)	(204)
Patents Fees & Related	2.11	(107)	(93)
Therapy Development expenses	2.11	(761)	(319)
Other operating income/(expenses)		184	(184)
<b>Operating loss for the period</b>		<b>(3,605)</b>	<b>(3,189)</b>
Financial income		82	26
Financial expense		(416)	(385)
<b>Loss for the period before taxes</b>		<b>(3,939)</b>	<b>(3,548)</b>
Taxes		(24)	(18)
<b>Loss for the period</b>		<b>(3,963)</b>	<b>(3,566)</b>
<b>Loss attributable to equity holders<sup>89</sup></b>		<b>(3,963)</b>	<b>(3,566)</b>
Other comprehensive income			
Items that may be subsequently reclassified to profit or loss (net of tax)			
Currency translation differences		(89)	60
<b>Total comprehensive loss for the year, net of tax</b>		<b>(4,052)</b>	<b>(3,506)</b>
<b>Loss attributable to equity holders<sup>1</sup></b>		<b>(4,052)</b>	<b>(3,506)</b>
Basic Earnings Per Share (in EUR) <sup>90</sup>	2.12	(0.242)	(0.239)
Diluted Earnings Per Share (in EUR)	2.12	(0.242)	(0.239)

<sup>89</sup> For the periods ending 30 June 2020, 2019, the loss is fully attributable to equity holders of the Company as the Company does not have any non-controlling interests.

<sup>90</sup> Based on number of shares after the share split reflecting resolution approved by the Shareholders' Meeting on 12 February 2020 – see Notes 2.7 and 2.12.

#### 1.4 Interim condensed consolidated statement of changes in equity for the six-month period ended June 30<sup>th</sup>

<i>(in EUR 000)</i>	Notes	Share capital	Share premium	Share based payment reserve	Currency translation reserve	Retained earnings	Total
<b>Balance at 1 January 2019</b>		2,481	47,668	80	39	(39,814)	10,454
Profit/(loss) for the period						(3,566)	(3,566)
Other comprehensive income for the year					60		60
<b>Total comprehensive income for the period</b>					<b>60</b>	<b>(3,566)</b>	<b>(3,506)</b>
Cancelled and forfeited during the period						6	6
<b>Total transactions with owners of the Company recognized directly in equity</b>						<b>6</b>	<b>6</b>
<b>Balance at 30 June 2019</b>		<b>2,481</b>	<b>47,668</b>	<b>80</b>	<b>99</b>	<b>(43,374)</b>	<b>6,954</b>
<i>(in EUR 000)</i>	Notes	Share capital	Share premium	Share based payment reserve	Currency translation reserve	Retained earnings	Total
<b>Balance at 1 January 2020</b>		2,481	47,668	420	207	(47,063)	3,713
Profit/(loss) for the period						(3,963)	(3,963)
Other comprehensive income for the year					(89)		(89)
<b>Total comprehensive income for the period</b>					<b>(89)</b>	<b>(3,963)</b>	<b>(4,052)</b>
Equity-settled share-based payment plan							
Granted during the period				786			786
Cancelled and forfeited during the period	2.8			(313)		313	
Issuance of shares	2.7	436	24,624				25,060
Transaction costs			(96)				(96)
<b>Total transactions with owners of the Company recognized directly in equity</b>		<b>436</b>	<b>24,528</b>	<b>473</b>		<b>313</b>	<b>25,750</b>
<b>Balance at 30 June 2020</b>		<b>2,917</b>	<b>72,196</b>	<b>893</b>	<b>118</b>	<b>(50,713)</b>	<b>25,411</b>

## 1.5 Interim condensed consolidated statement of cash flow for the six-month period ended June 30<sup>th</sup>

<i>(in EUR 000)</i>	Notes	2020	2019
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
<b>Profit/(loss) before tax for the year</b>		<b>(3,940)</b>	<b>(3,548)</b>
Adjustments for:			
Finance income		(82)	(26)
Finance costs		416	385
Depreciation and impairment of property, plant and equipment and right-of-use assets	2.4	259	206
Share-based payment transaction expense		786	6
Other non-cash items <sup>91</sup>		(161)	226
Pension		-	-
<b>Cash generated before changes in working capital</b>		<b>(2,722)</b>	<b>(2,751)</b>
Changes in working capital:			
Increase (-)/Decrease (+) in Trade and other receivables		(1,127)	(411)
Increase (+)/Decrease (-) in Trade and other payables		(145)	175
<b>Cash generated from changes in operations</b>		<b>(3,994)</b>	<b>(2,987)</b>
Interests received		2	5
Interests paid		(4)	(16)
Income tax (paid)		(28)	(17)
<b>Net cash generated/(used) from operating activities</b>		<b>(4,024)</b>	<b>(3,015)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchases of property, plant and equipment	2.4	(120)	(37)
Capitalization of intangible assets	2.5	(3,535)	(2,035)
(Increase)/Decrease of long-term deposits		-	(7)
<b>Net cash generated/(used) from investing activities</b>		<b>(3,655)</b>	<b>(2,079)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Payment of principal portion of lease liabilities		(209)	(165)
Repayment of other loan	2.9.2	(21)	(42)
Recoverable cash advance received	2.9.1	-	47
Repayment of recoverable cash advance	2.9.1	-	(40)
Proceeds from Convertible Loan	2.10	1,000	-
Proceeds from issuance of shares	2.7	24,964	-
<b>Net cash generated/(used) from financing activities</b>		<b>25,735</b>	<b>(200)</b>
<b>Movement in cash and cash equivalents</b>		<b>18,056</b>	<b>(5,294)</b>
Effect of exchange rates on cash and cash equivalents		(31)	7
<b>Cash and cash equivalents at 1 January</b>		<b>5,855</b>	<b>16,805</b>
<b>Cash and cash equivalents at 30 June</b>		<b>23,880</b>	<b>11,518</b>

<sup>91</sup> The other non-cash items include (i) the impact of the initial measurement and re-measurement of recoverable cash advances (see note 2.9.1) and (ii) the evolution of the deferred tax assets and (iii) the loss on the derecognition (IFRS 16).

## 2 Notes to the Consolidated Financial Statements for the six-month period ended 30 June

### 2.1 General Information

Nyxoah SA (the “Company”) is a public 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 health-technology company focused on the development and commercialization of solutions and services to treat sleep disordered breathing conditions. The Company's innovative solution platform is based on the user-centered Genio® system, a CE-mark validated, user-centered, next generation neurostimulation therapy for OSA, the world’s most common sleep disordered breathing condition that 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 Obstructive Sleep Apnea (“OSA”) patients who have failed 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.

OSA is the most common sleep disordered breathing condition, affecting around 936 million people globally, of whom 425 million suffer from moderate to severe OSA, requiring treatment<sup>92</sup>. 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 21 October 2009 (located in Israel and incorporated on 10 January 2008 under the name M.L.G. Madaf G. Ltd), Nyxoah Pty Ltd since 1 February 2017 (located in Australia) and Nyxoah Inc. since 14 May 2020 (located in the USA). It is not required to prepare consolidated financial statements for any of the periods stated under Belgian GAAP.

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<sup>92</sup> Benjafield, Adam V et al. Estimation of the global prevalence and burden of obstructive sleep apnea: a literature-based analysis. *Lancet Respir Med* 2019 Published Online 9 July 2019 [http://dx.doi.org/10.1016/S2213-2600\(19\)30198-5](http://dx.doi.org/10.1016/S2213-2600(19)30198-5).

## 2.2 Significant accounting policies

### 2.2.1 Basis of Preparation and Going Concern

#### Basis of preparation

The Company's condensed consolidated financial statements for the six month period ended June 30, 2020 have been prepared in accordance with International Accounting Standard 34 – Interim Financial Reporting as endorsed by the European Union (“IFRS”) and should be read in conjunction with the Company's last annual consolidated financial statements as at and for the year ended 31 December 2019.

The significant accounting policies used in the preparation of the interim condensed 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 31 December 2019.

The Consolidated Financial Statements are presented in Euro (EUR) and all values are rounded to the nearest thousand (KEUR), 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. The critical accounting estimates used in the preparation of the interim condensed 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 31 December 2019.

#### Going concern principle

The Interim Financial Statements have been prepared on a going concern basis. The Company strengthened its cash position during the six-month period ended on 30 June 2020 with a capital increase of €25,059,665.88 and a convertible loan from Noshq in an amount of €1,000,000.00.

In addition, the Company is actively involved in additional capital and financing in the short term. However, given significant clinical activities (including the launch of the US study), the start of commercialization in Europe and Australia/New Zealand, the continuation of research and development projects, the Board of Directors analysed the evolution of the cash position through 31 December 2021 with a view to ensuring that it is sufficient to meet the Company's commitments up to that date. Based on the assumptions made by the Board of Directors regarding expected cash inflows and outflows over the next 12 months, this analysis indicates that the Company's cash position would be negative as of 30 June 2021. Inherent uncertainties in these forecasts may have an impact on when the Company's cash position will actually become negative.

These forecasts do not include financing alternatives currently under consideration by the Board of Directors. In this context, the Board of Directors is aware that the continuity of Company's operations depends on its ability to find these new sources of funding and that there are material uncertainties in this regard.

#### COVID-19 matters

In March 2020, World Health Organization characterized COVID-19 as a pandemic. This will affect the course of business of the Company. Based on the information available today, management has no knowledge of financial impacts on the Interim condensed consolidated Financial Statements as of 30 June 2020.

However, we disclose hereafter an overview of risks our Company may face in 2020 and the foreseeable future. Governmental safety guidelines have been implemented in all Nyxoah entities (Belgium, Israel, Australia and the United States of America). Production activities did not stop in the Tel Aviv facility. Supportive functions (R&D, QA&RA) also continued, but with reduced capacity. Elective surgeries were on-hold from March to May and are selectively re-opening in Australia and Europe. From a financial viewpoint, the Company is well financed after the capital increase of February 2020 and the Noshaq convertible loan. Therefore, management does not expect any problem related to liquidity or working capital in 2020.

### **2.2.2 New and amended standards and interpretations applicable**

#### *For the period beginning after 1 January 2020*

The accounting policies adopted in the preparation of the Interim condensed 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 31 December 2019, except for the adoption of new standards effective as of 1 January 2020. 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 2020, but do not have an impact on the Interim condensed consolidated Financial Statements of the Company:

- Amendments to IAS 1 Presentation of Financial Statements and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors – Definition of material, effective 1 January 2020  
Amendments to References to the Conceptual Framework in IFRS Standards;
- Amendments to References to the Conceptual Framework in IFRS Standards, effective 1 January 2020;
- Amendments to IFRS 3 Business Combinations – Definition of a business, effective 1 January 2020;
- Amendments to IFRS 9 Financial Instruments and IFRS 7 Financial Instruments: Disclosures - Interest Rate Benchmark Reform;
- Amendments to IAS 39 Financial Instruments: Recognition and measurement and IFRS 7 Financial Instruments: Disclosures - Interest Rate Benchmark Reform;
- Amendments to IAS 1 Presentation of Financial Statements and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors – Definition of material, effective 1 January 2020  
Amendments to References to the Conceptual Framework in IFRS Standards.

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

- IFRS 17 Insurance Contracts;
- Amendments to IAS 1: Classification of Liabilities as Current or Non-current
- Reference to the Conceptual Framework – Amendments to IFRS 3
- Property, Plant and Equipment: Proceeds before Intended Use – Amendments to IAS 16
- Onerous Contracts – Costs of Fulfilling a Contract – Amendments to IAS 37
- IFRS 1 First-time Adoption of International Financial Reporting Standards – Subsidiary as a first-time adopter
- IFRS 9 Financial Instruments – Fees in the '10 per cent' test for derecognition of financial liabilities
- IAS 41 Agriculture – Taxation in fair value measurements

### **2.2.3 Convertible Loan**

The Company identified two components included in the convertible loan agreement: a host loan and an embedded derivative failing the equity classification. IAS 32 requires the fair value of those embedded non-equity derivative features to be determined and included in the liability component when split accounting is applied. Both the host loan and the embedded derivatives are subject to the normal requirement of IFRS 9 to be accounted for separately.

IFRS 9 suggests a 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.

The Company elected to use the simplification method. Until conversion and at each reporting date, the Company reevaluates 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.

Please refer to note 2.10.

### **2.3 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.

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 100 USD.

### **2.4 Property Plant and Equipment**

During the period of first six- months of 2020, acquisitions were mainly related to furniture and office equipment, and leasehold improvements. In January 2020, the Company paid KEUR70 for leasehold improvements for establishing a new clean room in Belgium.

The half-yearly depreciation charge amounts to KEUR 88 in 2020, KEUR 46 in 2019.

### **2.5 Intangible assets**

There is only one development project: The Genio® system. Refer to note 2.1.

<i>(in EUR 000)</i>	<b>Development Cost</b>	<b>Patents and licenses</b>	<b>Total</b>
<b>Cost</b>			
At 1 January 2019	-	-	-
Additions	1,889	139	2,028
<b>At 30 June 2019</b>	<b>1,889</b>	<b>139</b>	<b>2,028</b>
Additions	3,422	196	3,618
<b>At 31 December 2019</b>	<b>5,311</b>	<b>335</b>	<b>5,646</b>
Additions	3,366	158	3,524
<b>At 30 June 2020</b>	<b>8,677</b>	<b>493</b>	<b>9,170</b>
<b>Amortization</b>			
At 1 January 2019	-	-	-
At 30 June 2019	-	-	-
At 31 December 2019	-	-	-
At 30 June 2020	-	-	-
<b>Exchange differences</b>			
At 1 January 2019	-	-	-
<b>Exchange differences at 30/06/2019</b>	<b>7</b>	<b>-</b>	<b>7</b>
Exchange differences	81	-	81
<b>Exchange differences at 31/12/2019</b>	<b>88</b>	<b>-</b>	<b>88</b>
Exchange differences	11	-	11
<b>Exchange differences at 30/06/2020</b>	<b>99</b>	<b>-</b>	<b>99</b>
<b>Net book value</b>			
<i>At 1 January 2019</i>	<i>-</i>	<i>-</i>	<i>-</i>
<i>At 30 June 2019</i>	<i>1,896</i>	<i>139</i>	<i>2,035</i>
<i>At 31 December 2019</i>	<i>5,399</i>	<i>335</i>	<i>5,734</i>
<i>At 30 June 2020</i>	<i>8,776</i>	<i>493</i>	<i>9,269</i>

## 2.6 Other current assets

<i>(in EUR 000)</i>	<b>30/06/2020</b>	<b>31/12/2019</b>
Convertible loan to be received	1,000	-
Prepaid transaction costs	765	-
Other prepaid	22	11
<b>Total other current assets</b>	<b>1,787</b>	<b>11</b>

Prepaid transaction costs were incurred in anticipation of a potential issuance of equity instruments. 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 them in the income statement if the issuance of equity is aborted.

For the Convertible loan, please refer to 2.102.10.

## 2.7 Capital, Share Premium, Reserves

Evolution of the share capital and share premium over the last three years is as follows:

<i>(Number of shares except otherwise stated)</i>	<b>Number of Shares</b>	<b>Par value (EUR)</b>	<b>Share Capital</b>	<b>Share Premium</b>
31 December 2019	23,938	103.66	2,481	47,668
21 February 2020 - after conversion of preferred shares	29,758		2,481	47,668
21 February 2020 - Capital increase of common shares	4,200	103.66	436	24,624
21 February 2020 - before share split	33,958	85.89	2,917	72,292
21 February 2020 - after share split	16,979,000	0.17	2,917	72,292

On 12 February 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 KEUR 25,060 (including share premium) in exchange for 4,200 new shares in the Company.

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

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

## 2.8 Share-Based Compensation

As of 30 June 2020, the Company has four outstanding share-based incentive plans, including (i) the 2013 warrants plan (the 2013 Plan), (ii) the 2016 warrants plan (the 2016 Plan), (iii) 2018 warrants plan (the 2018 Plan), and (iv) 2020 warrants plan (the 2020 plan). The Company had a shareholders' meeting on 12 February 2020, where it was decided to achieve a share split in a ratio of 500:1. Upon pursuant to the decision of the extraordinary general meeting that was held on the same shareholders' meeting, the AD Warrants were cancelled.

### 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. The warrants are and will stay nominative. 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 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 at 30 June 2020, 550,000 warrants had been granted to employees and directors in 2020.

Number of shares granted	550,000
Dividend yield	0.0%
Expected volatility	56.32%
Risk-free interest rate	(0.20%)
Expected life of share options (years)	3
Weighted average share price (€)	10.20
Exercise price (€)	11.94
Model used	B&S

The weighted average fair value of the options granted during the six months ended 30 June 2020 was 3.30 (year ended 31 December 2019: 2,620.27).

For the six months ended 30 June 2020, the Company has recognized KEUR 786 of share-based payment expense in the statement of profit or loss.

## 2.9 Financial Debt

Financial debt consists of recoverable cash advances and other loans. Related amounts can be summarized as follows:

<i>(in EUR 000)</i>	30/06/2020	31/12/2019
Recoverable cash advances – Non-current	7,060	6,874
Recoverable cash advances – Current	298	274
<b>Total Recoverable cash advances</b>	<b>7,358</b>	<b>7,148</b>
Other loan – Non-current	271	272
Other loan – Current	84	104
<b>Total Other loan</b>	<b>355</b>	<b>376</b>
Non-current	7,331	7,146
Current	382	378
<b>Total Financial debt</b>	<b>7,713</b>	<b>7,524</b>

The fair value of each class of financial assets and liabilities approximates the carrying values as of 30 June 2020.

### 2.9.1 Financial debt related to recoverable cash advances

#### 2.9.1.1 Recoverable cash advances received

As of 30 June 2020 and 31 December 2019, the details of recoverable cash advances received can be summarized as follows:

<i>(in EUR 000)</i>	<b>Contractual Advances</b>	<b>Advances received</b>	<b>Amounts reimbursed</b>
Sleep apnea device (6472)	1,600	1,600	380
First Articles (6839)	2,160	2,160	84
Clinical Trial (6840)	2,400	2,210	-
Activation chip improvements (7388)	1,467	1,467	-
<b>Total</b>	<b>7,627</b>	<b>7,437</b>	<b>464</b>

During the period of the first six month of 2020, the Company did not receive or pay any new amounts.

### 2.9.1.2 Evolution of the financial debt in the financial statements

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 twice the amount received as detailed in the table below:

<i>(in EUR 000)</i>	<b>30/06/2020</b>	<b>31/12/2019</b>
Recoverable cash advances received	7,437	7,437
Amounts to be reimbursed (2 times)	14,874	14,874
Amounts reimbursed at period -end (interests included)	(517)	(517)
<b>Total Recoverable cash advances (undiscounted)</b>	<b>14,357</b>	<b>14,357</b>

Based on expected timing of sales and after discounting, the financial debt related to the recoverable cash advances is as follows:

<i>(in EUR 000)</i>	<b>30/06/2020</b>	<b>31/12/2019</b>
Contract 6472	1,346	1,296
Contract 6839	2,170	2,115
Contract 6840	2,293	2,232
Contract 7388	1,549	1,505
<b>Total Recoverable cash advances</b>	<b>7,358</b>	<b>7,148</b>
Non-current	7,060	6,874
Current	298	274
<b>Total Recoverable cash advances</b>	<b>7,358</b>	<b>7,148</b>

The amounts recorded under current caption correspond to the sales-independent amounts (fixed repayment) estimated to be repaid to the Walloon Region in the next twelve months period. The estimated sales-dependent (variable repay) above twelve months as well as sales-dependent reimbursements (variable) are recorded under Non-current.

Changes in the recoverable cash advances can be summarized as follows:

<i>(in EUR 000)</i>	<b>30/06/2020</b>	<b>31/12/2019</b>
As of 1 January	7,148	5,357
Advances received	-	1,196
Advances reimbursed (excluding interests)	-	(40)
Initial measurement and re-measurement	(176)	60
Discounting impact	386	575
<b>Total Recoverable cash advances</b>	<b>7,358</b>	<b>7,148</b>

## 2.9.2 Other Financial Liabilities

The Company contracted a loan of KEUR 500 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 KEUR 355 at 30 June 2020 and KEUR 376 at 31 December 2019. During the first six months of 2020, the Company paid KEUR 21 as a repayable of the loan.

## 2.10 Convertible Loan

On 26 June 2020, the Company and Noshaq SA ("Noshaq") entered into a convertible loan agreement pursuant to which Noshaq made available to the Company a convertible loan for a total amount of €1 million (the "Principal Amount"). The Company intends to apply the proceeds of the loan towards the scale-up of its manufacturing process and establishment of a manufacturing facility in the Liège region and for general corporate purposes. The outstanding portion of the Principal Amount shall bear simple, non-compounding interest at a rate of 2.50% per annum.

Under the Noshaq Convertible Loan, there are three situations that would trigger a mandatory conversion of the loan into shares:

- Initial Public Offering
- Qualifying Financing: a capital increase by the Company in an aggregate amount (including issuance premium, if any) of at least twenty million euro (KEUR 20,000) against issuance of ordinary or preferred shares
- Trade sale: the sale of more than fifty percent (50%) of the outstanding shares in the Company to a third party that is not yet a shareholder of the Company prior to the trade sale.

In the event that no mandatory conversion has taken place on or prior to the second anniversary of date of the loan, Nyxoah shall 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 conversion of the loan, either optional or mandatory, will always result in the issuance of a variable number of shares of the Company.

It was assessed that, due to the imminent conversion, the fair value of the total contract is KEUR 1,000 accounted for as a current liability.

## 2.11 Operating Loss

The table hereunder details the operating expenses for the six-month periods ended 30 June 2020 and 2019 and the entire financial year ended 30 December 2019.

<i>(in EUR 000)</i>	<b>Total Cost</b>	<b>Capitalized</b>	<b>Operating Loss for the period</b>
General and administrative expenses	1,109	-	1,109
Research and development expenses	1,287	(760)	527
Clinical expenses	1,003	(523)	480
Manufacturing expenses	629	(356)	273
Quality assurance and regulatory expenses	454	(250)	204
Patents Fees & Related	232	(139)	93
Therapy Development expenses	319	-	319
Other operating expenses/(income)	184	-	184
<b>As of June 30, 2019</b>	<b>5,217</b>	<b>(2,028)</b>	<b>3,189</b>
General and administrative expenses	1,918	-	1,918
Research and development expenses	1,083	(980)	103
Clinical expenses	1,392	(1,024)	368
Manufacturing expenses	1,182	(966)	216
Quality assurance and regulatory expenses	475	(452)	23
Patents Fees & Related	370	(196)	174
Therapy Development expenses	583	-	583
Other operating expenses/(income)	(58)	-	(58)
<b>As of December 31, 2019</b>	<b>12,162</b>	<b>(5,646)</b>	<b>6,516</b>

<i>(in EUR 000)</i>	<b>Total Cost</b>	<b>Capitalized</b>	<b>Operating Loss for the period</b>
General and administrative expenses	2,063	-	2,063
Research and development expenses	662	(606)	56
Clinical expenses	1,559	(1,050)	509
Manufacturing expenses	1,407	(1,200)	207
Quality assurance and regulatory expenses	596	(510)	86
Patents Fees & Related	265	(158)	107
Therapy Development expenses	761	-	761
Other operating expenses/(income)	(184)	-	(184)
<b>As of June 30, 2020</b>	<b>7,129</b>	<b>(3,524)</b>	<b>3,605</b>

## 2.12 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 21 February 2020. As explained in note 2.7 capital and share premium, all existing preferred shares were converted into common shares, and then a share split of 500:1 was approved by the shareholders' meeting.

<i>As at 30 June</i>	<b>2020</b>	<b>2019</b>
Outstanding shares at end of period (common and preferred shares)	16,979,000	14,879,000
Weighted average number of shares outstanding	16,387,287	14,879,000
Number of shares after exercise of outstanding warrants	1,126,000	989,500

Basic and Diluted EPS, based on weighted average number of shares outstanding after conversion and share split are as follows:

	<b>30/06/2020</b>	<b>30/06/2019</b>
Loss of period attributable to equity holders (in EUR)	(3,963,266)	(3,565,876)
Weighted average number of shares outstanding (in units)	16,387,287	14,879,000
<b>Basic earnings per share in EUR (EUR/unit)</b>	<b>(0.242)</b>	<b>(0.239)</b>
<b>Diluted earnings per share in EUR (EUR/unit)</b>	<b>(0.242)</b>	<b>(0.239)</b>

## 2.13 Related Party Transactions

Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes.

### 2.13.1 Remuneration of Key Management

The remuneration of the senior management consists of the remuneration of the CEO of the Company:

<i>(in EUR 000)</i>	<b>30/06/2020</b>	<b>30/06/2019</b>
Short-term remuneration & compensation	225	191
Long-term remuneration & compensation	-	-
Share based payment	468	-
<b>Total</b>	<b>693</b>	<b>191</b>

From September 2016 to November 2019, Mr. Enrique Vega served as the Company's CEO. In November 2019, Mr. Olivier Taelman was appointed as CEO of the Company.

During the first six months of 2020 and 2019, ActuaRisk Consulting, a company owned by a management member, invoiced Nyxoah S.A for amount of KEUR 144 and KEUR 137, respectively for consulting services.

No loans or other guarantees have been given to a member of the executive management team.

### 2.13.2 Transactions with Non-Executive Directors and Shareholders

<i>(in EUR 000)</i>	<b>30/06/2020</b>		<b>30/06/2019</b>	
	<b>Consulting Services</b>	<b>Board Remuneration</b>	<b>Consulting Services</b>	<b>Board Remuneration</b>
MINV S.A.	50	-	21	-
Medtech Execs LLC	-	7	-	10
Christopher Smith	-	-	-	11
Man & Science	2	-	-	-
<b>Total</b>	<b>52</b>	<b>7</b>	<b>21</b>	<b>21</b>

## 2.14 Events after the Balance-Sheet Date

In July 2020, the Company generated its first sale of two implantable and external stimulators.

Nyxoah is currently raising additional funds through an Initial Public Offering on Euronext Brussels.

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