Nyxoah

January 2022





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# **Experienced Board And Management Team**



**Robert Taub**Founder, Chairman

- Serial entrepreneur in the pharmaceutical and medical fields
- Co-founded and co-managed Octapharma Human plasma protein company
- Founded and managed Omrix Biopharmaceuticals NASDAQ IPO, followed by the acquisition by J&J
- Early investor and chairman of Neuroderm, a Parkinson's disease pharmaceutical company – IPO on NASDAQ and later sale to Mitsubishi-Tanabe



Olivier Taelman

- Experienced Medtech leader
- 7 years in pharmaceutical healthcare at Eli Lilly and Sanofi Aventis leading specific Business Units
- 18 years within the field of Medtech neuromodulation at Medtronic, managing EMEA at Stryker NeuroVascular and serving a neuromodulation company Nevro where he was responsible for building the European business during the successful NASDAQ IPO
- Joined Nyxoah in July 2019 as Chief Operating and Commercial Officer, subsequently being appointed as CEO in November 2019.



**Loïc Moreau**CFO

- Experienced Finance leader
- 13 years in Pharmaceutical healthcare at GSK with roles in Corporate Development/ M&A (UK), Finance R&D (UK) or Country CFO where he notably led and structured the various support functions for GSK business in France (€1bn+ turnover)
- Started his career at EY (external audit) followed by PwC (Corporate Finance)
- Joined Nyxoah in 2022 to take the leadership of the finance department.



# **Experienced Management Team**



**Bruno Onkelinx** CTO

- Has 25 years of experience in highly regulated industries with the last 15 years at Cochlear.
- At Cochlear he built successful teams while managing international research & development and manufacturing operations across Europe-Belgium and the US-Colorado.



**An Moonen** General Counsel

- Joined Nyxoah in December 2020 as General Counsel, bringing over 20 years of experience
- Was involved in various strategic licensing, financing and M&A transactions, including TiGenix' Nasdaq IPO



**Jey Subbaroyan** VP Clinical Affairs

- Hs 14 years of experience in clinical and preclinical neuromodulation research in the fields of urology, migraine, spinal cord injury...
- Has successfully executed multiple clinical studies across the US, Europe and Australia managing diverse global teams



Nathalie Gilat VP RA – GM Israel

- Has over 14 years of experience in global clinical & regulatory affairs
- Joined Nyxoah in 2014 and played a key role in its initial clinical studies obtaining CE mark and achieving regulatory milestones in the US



**Rémi Renard**VP Market Development
& Education

- Has over 15 years of experience in Sales and Marketing
- Has held multiple sales and marketing positions in medical device firms, mostly in the Cardiac Rhythm Management and OSA fields at Resmed, Boston Scientific and St. Jude Medical



**Dorit Nahari** VP QA

- Has 13 years of experience in process manufacturing and quality management in highly regulated industries
- Has successfully led both small and large groups in numerous manufacturing aspects including routine production, implementation of process changes, qualifications of new manufacturing sites and preparation to regulatory audits



Patrick Tompkins
VP US Operations

- Has over 20 years of executive leadership experience in the medical device space
- Has previous commercial leadership experience, both in the cardiac and neuro fields, the last 13 years with neuromodulation companies, including St. Jude Medical



Jeremy Feffer
VP Investor Relations &
Corporate Communications

- Has 20 years of experience in healthcare capital markets as a sell-side equity research analyst and an investor relations advisor.
- As an IR Director at LifeSci Advisors, he developed and executed comprehensive capital markets, corporate access, and messaging strategies for pre-IPO and publicly-traded healthcare companies.

# Large and Underpenetrated Global OSA and HGNS Market Opportunity

# **Worldwide Obstructive Sleep Apnea Prevalence**

### 936 Million

936M individuals (30-69 year) are estimated to suffer from OSA<sup>1</sup>

### 425 Million

- 425M suffer from moderate to severe OSA, requiring therapy<sup>1</sup>
- Increasing prevalence of OSA due to rise in obesity

### 20%

Only 20% OSA patients are diagnosed<sup>2</sup>

# Undiagnosed OSA 80%

### 1. Benjafield, Adam V et al. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. Lancet Respir Med 2019

# **Hypoglossal Nerve Stimulation Market Opportunity**

### >1 million eligible annually in key geographies

- US: 510,000 eligible patients annually
- Europe: 500,000 eligible patients annually

### < 25,000 received HGNS as treatment

- First HGNS CE-Mark approval in 2010 FDA authorization in 2014
- Low awareness on neurostimulation as an OSA solution
- Limited reimbursement

### +62% CAGR HGNS revenue 2016 - 20203

- Endorsed by the global sleep and ENT medical communities
- Accepted by US/EU payors
- Embraced by OSA patient association groups



<sup>2.</sup> Harvard Medical School Division of Sleep Medicine, The Price of Fatigue - The surprising economic costs of unmanaged sleep apnea, December 2010

<sup>3.</sup> Presents annual revenue growth for Inspire Medical. Inspire Medical corporate presentation – February 2021

# **Our Vision: Improving Lives through Restful Nights**

A disruptive patient-centered solution TODAY...

Single incision procedure

Leadless and battery-free

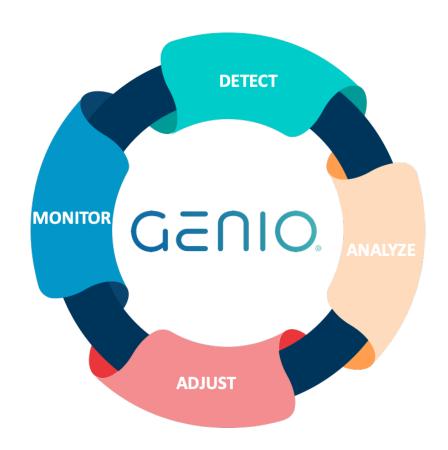
Full-body 1.5T and 3T MRI compatible

**Bilateral stimulation** 

CCC FDA breakthrough designation CCC indication in Europe

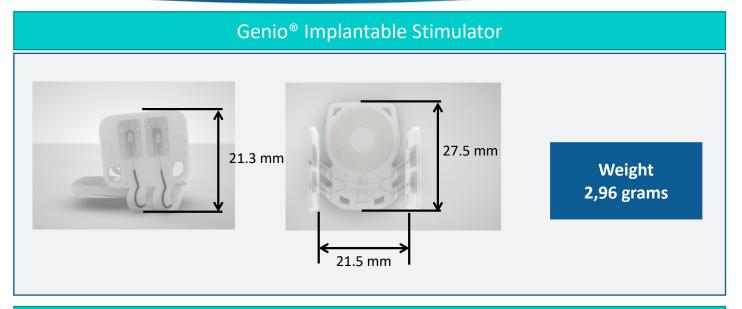
**Scalable platform** 

... An intelligent MedTech solution TOMORROW





# **Genio® Dimensions**









# The Genio® System – Addressing Unmet Physician Needs

## **Physician**

### Single procedure

 Extended operative time is associated with increased risk of surgical site infection<sup>13</sup>

### Leadless

Up to 25% failure rate of percutaneous leads after 5Y<sup>14</sup>

### **External power-source**

 Device replacement and revision procedures are associated with a twoto four-fold higher risk of infection<sup>15</sup>

### **Bilateral stimulation**

- Genio<sup>®</sup> indicated for non-CCC and CCC patients
- No need for a DISE to exclude CCC at the soft palate level

	Nyxoah.	Sleep Apnea Innovation	LivaNova W IMTHERA
Implantable parts	1 – Genio <sup>®</sup> IS	3 – Pulse generator + 2 leads	2 – Pulse generator + lead
Number of incisions	1 incision	At least 2 incisions	2 incisions
Lead(s)	0 – No lead	2 – Stimulation and breathing	1 – Stimulation
Tunneling	No tunneling	At least 1 step	1 step
Power source	External	Implanted battery	Implanted battery

1 hour

2.5 hours

**Estimated implantation** 



2 hours

<sup>13.</sup> Cheng et al. Prolonged Operative Duration Increases Risk of Surgical Site Infections: A Systematic Review. Surg Infect (Larchmt). 2017 Aug 1; 18(6): 722-735

<sup>14.</sup> Schultz et al. Neuromodulation. SCS —The Implantable Systems Performance Registry (ISPR) 2016 Dec; 19(8): 857–863

<sup>15.</sup> Döring et al. The Diagnosis and Treatment of Pacemaker-Associated Infection. Disch Arztebl Int. 2018 Jun; 115(26): 445–452

# The Genio® System – Addressing Unmet Patient Needs

### **Patient**

### **User-centric**

 No bulky pulse generator under the skin / Only one discreet scar in the chin fold

# Indicated for CCC and non-CCC patients

• CCC prevalence is superior to 35% in OSA patients

### **External power-source & Chip**

- No need for surgical reintervention due to battery depletion
- Simple and straight forward upgrades through external chip

### MRI compatibility

- >40 Million MRI scans performed in 2020 in OSA patients<sup>17</sup>
- 60% MRI scans are performed in the thorax/abdominal area<sup>17</sup>
- 40% MRI scans are 3T<sup>17</sup>



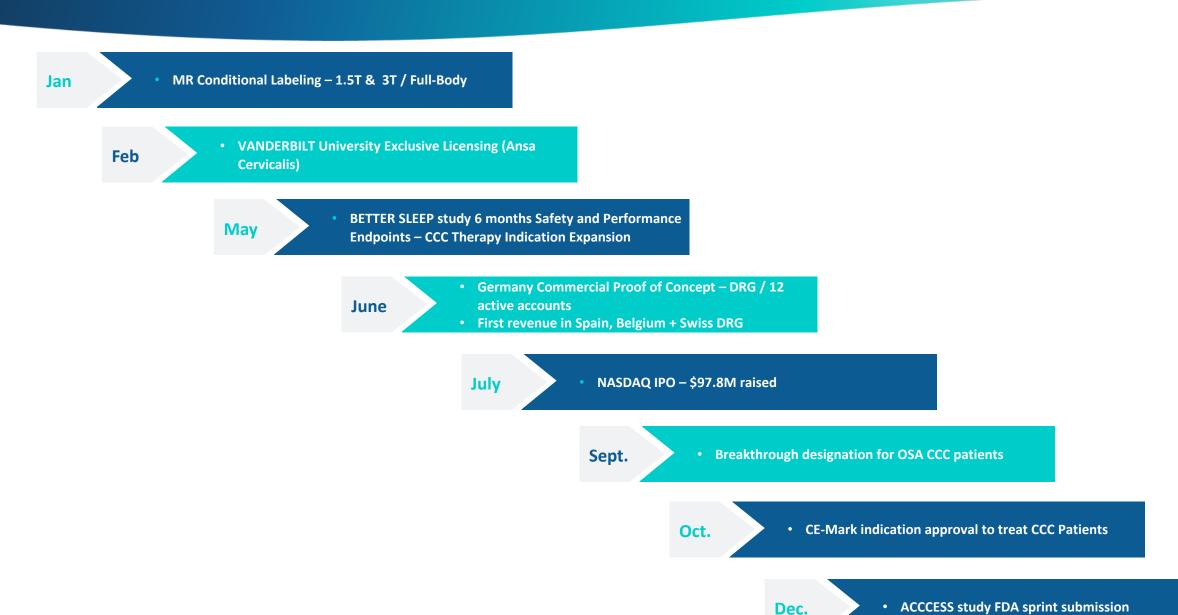




Number of scars	1 – in the chin fold	At least 2 scars	2 scars
Power source	External	Implantable Pulse Gen	Implantable Pulse Gen
Stimulation	Bilateral	Unilateral	Unilateral
MR conditional labelling	Full-body 1.5T and 3T	Extremities only 1.5T only	No



# Key Achievements – Execution Focus



# **Clinical Strategy – Building Robust Clinical Evidence**

**CE-Mark** 

Demonstrate long-term safety and efficacy

Expand Genio® therapeutic indications

FDA market authorization

CCC FDA market authorization

### BLAST OSA – 27 patients

- 2 publications
- CE mark approval in 2019



- 20 EU centers in 5 countries
- 5-year follow-up

### **BETTER SLEEP – 42 patients**

- 9 ANZ centers
- CCC represented 43% of study cohort

### DREAM – 134 patients

- FDA approved IDE pivotal trial in 2020
- 22 enrolling sites in the US and International

### ACCCESS – # patients TBD

 # US centers and # patients to be discussed with FDA



Investigative Otolaryngology

**Enrolment completed by end 2022** 

Trial Reaches its Primary Endpoints @ M6

Ongoing – Implants to be completed end Q1 2022

FDA sprint submission completed in December 2021

# **DREAM trial – IDE Pivotal Trial**

Population and key inclusion criteria

22 < Age < 75 Failed, did not tolerate or refused PAP

Combined central/mixed AHI>25% total AHI

excluded

BMI  $\leq$  32 kg/m<sup>2</sup>

Moderate to severe OSA – AHI 15-65

CCC of soft palate excluded

Target: 134 patients implanted

### **Safety and Performance**

- Safety: Incidence of device-related serious adverse events at 12 months
- Co-primary effectiveness endpoints: 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)

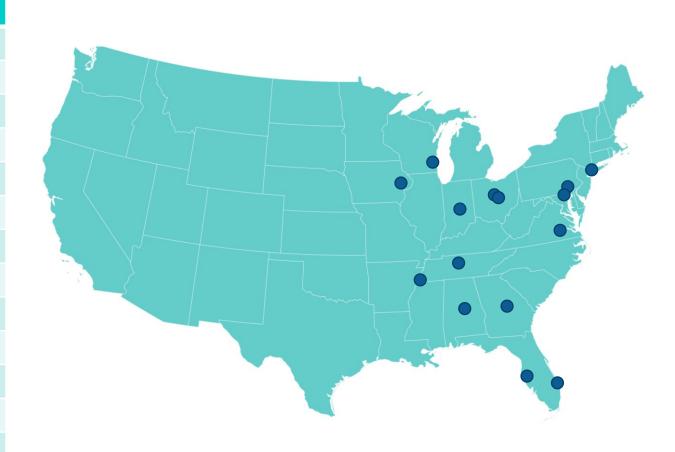
Status

- FDA approved IDE pivotal trial in June 2020 Up to 25 participating sites
- 15 US sites activated, screening, enrolling and implanting patients
- 7 International sites activated, screening, enrolling and implanting patients
- Mix of large academic centers & private practices, all HGNS experienced



# **DREAM Study – US Active Sites**

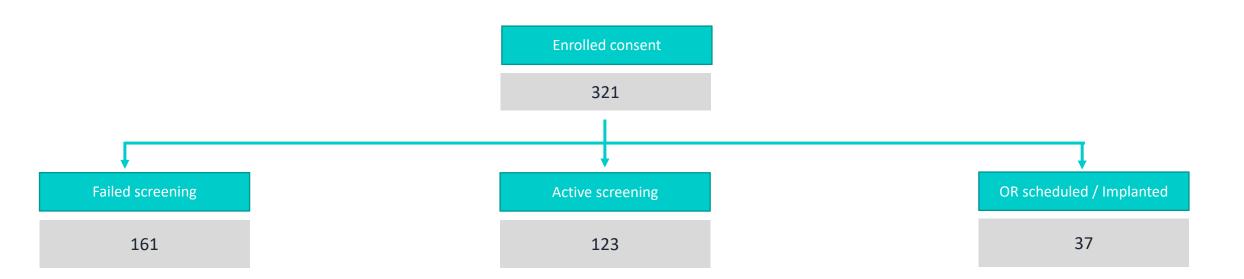
Principal Investigator	Institution & Location	
Kirk P. Withrow MD	UAB, Birmingham, AL	
Samuel Mickelson MD, FACS	Advanced ENT, Atlanta, GA	
Colin Huntley MD & Maurits S. Boon MD	Thomas Jefferson Philadelphia, PA	
Tapan A. Padhya MD	USF, Tampa General MC, Tampa, FL	
Marion Boyd Gillespie MD	UT, Memphis, TN	
Melyssa K. Hancock MD	ENT & AAF, Boca Raton, FL	
Tod C. Huntley MD	CENTA, Carmel, IN	
Raj C. Dedhia MD, MSCR	Penn, Philadelphia, PA	
Maria Suurna MD	Cornell, Manhattan, NY	
Doug Van Daele MD	Univ Iowa, Iowa City, IA	
B. Tucker Woodson MD	MCW, Milwaukee, WI	
David Kent MD	VUMC, Nashville, TN	
Asim Roy MD	OSMI, Dublin, OH	
Ulysses Magalang MD	OSU, Columbus, OH	
Ryan Nord MD	VCU, Richmond VA	



**United States** 



# DREAM IDE Trial – Status Update (Week 3 January 2022)



- Status
  - Patient drop out (54%) from Enrolled to Implant driven by DISE, PSG, BMI
  - Projected implants completion by end Q1 2022
- US commercialization expected end 2023
  - 12 months data on full study cohort (134 patients)
  - Regulatory path clarity (De Novo vs. PMA) based on 6 months safety data



# **Commercial Leadership Through Focused Execution**

# Go Deep versus Go Wide

# Recognized by medical community for expertise and high level of care Center of Excellence Clinical & Administrative leadership Commitment to education and clinical evidence building Center of Excellence

## **EU Market Access**

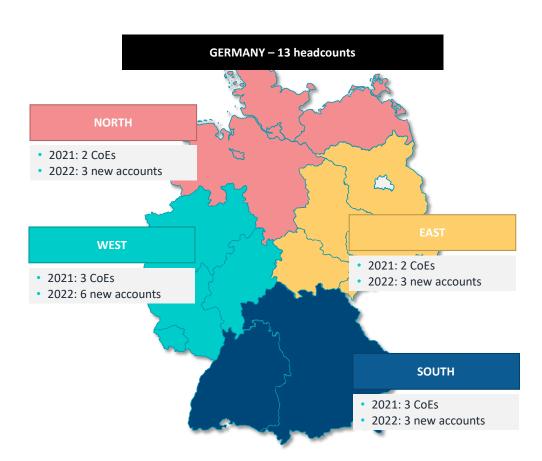
### Nyxoah – EU reimbursed countries

- Germany 2021: Dedicated DRG code
- Switzerland 2021: Dedicated DRG code
- Spain 2021: Funding through hospital budget

### Nyxoah – EU expected reimbursement

- The Netherlands
- Belgium
- Nordics

# **Germany - Proof of concept**



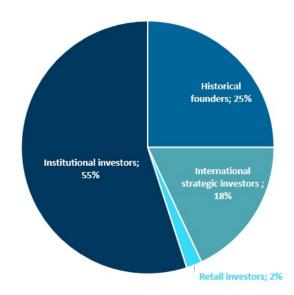


# **High Quality and Diverse International Shareholder Base**

# **Euronext IPO**



- September 2020
- Base offering & over-allotment: €85M (\$100M)



# **Nasdaq IPO**



- July 2021
- Base offering & over-allotment: \$97.8M

# **Current Shareholder Base**

**Historical Shareholders** 

- Robert Taub
- Together Partnership
- Jürgen Hambrecht

**International strategics** 





**US Institutional** 













**EU** Institutional





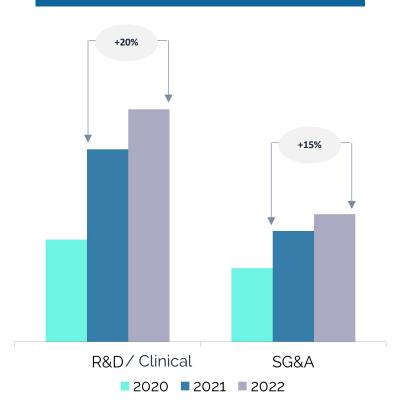




# Strong Cash Position Supports Clinical and Commercial Priorities in 2022 and Beyond

# **Strong Cash Position** June 2021, cash position €79M Nasdaq IPO proceeds €75M Post IPO cash position: €154M

# **Operating Expense Growth (in €)**



- Operating expenses to increase by ~19% in 2022
- R&D/Clinical to represent 2/3 of 2022 expenses driven by DREAM enrollment completion, EliSA study progress, and ACCCESS study commencement
- SG&A drivers include increased commercial efforts in Germany to achieve market leadership and scale-up of corporate functions



# Thank you

Q&A

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