# **Nyxoah Investor Presentation**

**May 2024** 



# **Forward-Looking Statements**

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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
Chief Executive Officer

- · 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**Chief Financial Officer

- 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.



>\$10bn US HGNS Market Opportunity with <5% Penetration and Established Reimbursement



Genio® - A Breakthrough and Disruptive Hypoglossal Nerve Stimulation Solution



**Proof-of-Concept European Commercialization** 



De-risked Pivotal Study with a US Launch in 2024 and CCC Label Expansion in 2026



# 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
- Significant OSA comorbidities, including cardiovascular disease and type II diabetes

#### 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

#### ~60,000 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

#### +67% CAGR HGNS revenue 2017 - 20233

- 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 2024

# The Genio® System An innovative and unique solution

Mode of Action

Genio® system

Hypoglossal nerve stimulation

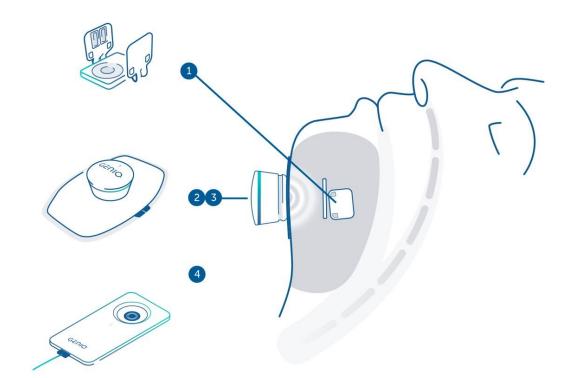
Genioglossus Maintaining open airway

Genio System Components

**Implantable Stimulator** 

Wearable

**Charging Unit** 





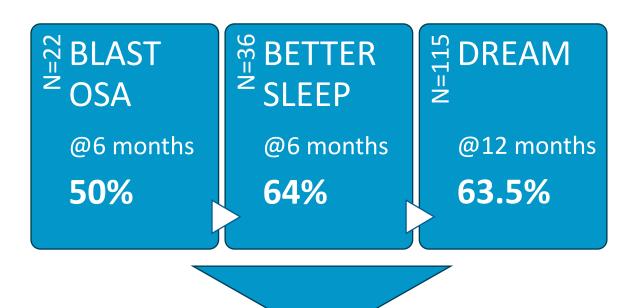
# **Clinical Strategy Overview**

## **Growing Body of Clinical & Real-life Evidence**

BLAST OSA	CE Mark
BETTER SLEEP	CCC label – Europe
Elisa	Long term data – Europe
DREAM	IDE Pivotal Study – US
ACCCESS	CCC IDE Pivotal Study – US
Commercial	European sales

~500 patients implanted and >125 doctors trained with Genio in clinical studies and commercially

## **AHI Responder Rates**



BETTER SLEEP led to CCC label expansion in Europe and Breakthrough Device Designation in the US – CCC patients represent 30% of OSA patients, currently contraindicated for HGNS in US



# DREAM U.S. Pivotal Study Study design & endpoints

### Design

- n=115
- Pivotal, multi-center, prospective, open-label study
- Safety and performance of bilateral HGNS system in adult patients
- Patients must sleep supine for at least 60 minutes at their 12-month PSG

## **Endpoints**

**Efficacy** 

- Co-Primary AHI responder rate, per the Sher criteria, at 12 months
- Co-Primary ODI responder rate at 12 months
- Secondary Median reduction in AHI from baseline to 12 months

Safety

- Incidence of device-related serious adverse events (SAEs)\*
- Adjudicated by an independent clinical events committee (CEC)

#### **Baseline Characteristics**

- Mean Baseline AHI: 28.0 events/h
- Mean Baseline ODI: 27.0 events/h
- Mean BMI: 28.5 kg/m<sup>2</sup>

#### AHI responder – Sher criteria

 AHI reduction of at least 50% from baseline on the 12month PSG

#### **AND**

 AHI score of less than 20 events per hour on the 12month PSG

#### **ODI** responder

 ODI reduction of at least 25% from baseline on the 12month PSG



<sup>\*</sup>All assessments from consent (safety) or baseline (efficacy) to 12 months post-implant

# **DREAM – IDE Pivotal Study**

# Achieved primary efficacy endpoints on ITT basis

## **Efficacy Results**

## **Co-Primary Endpoints – Intent to Treat**

- AHI Responder Rate 63.5% (p=0.002)
- ODI Responder Rate 71.3% (p<0.001)</li>



Median 12-month AHI Reduction – 70.8%

### **Sleep Position**

Similar AHI reductions in supine and non-supine sleeping positions

### Compliance

85% compliance rate



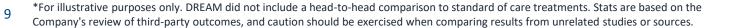
- Achieved co-primary endpoints on an Intent To Treat basis
- Results in-line with standard of care\*

 AHI reduction, which is clinically relevant, in-line with standard of care

 Will evaluate pursuing a unique label claim that Genio is usable in both sleeping positions

Believed to reflect patient comfort and satisfaction





# DREAM – IDE Pivotal Study Favorable safety results

# **Safety Results**

#### **Serious Adverse Events – SAEs**

- 11 SAEs in ten subjects resulting in an SAE rate of 8.7%
- Out of the 11 SAEs
  - 3 device-related SAEs Device-related SAE rate: 2.6%
  - 3 explants

## **Key Takeaway**

Safety results compare favorably to standard of care\*



# **US Commercialization Strategy**



#### **Smart Follower**

Smart follower strategy to leverage landscape established by monopoly player:

- Targeting a now firmly established subspecialty within ENT that provides device-forward treatments vs. traditional suture- and excision-based procedures.
- Leveraging business processes already streamlined at high-volume physician offices and sleep centers.
- Payers acknowledge the role of hypoglossal nerve stimulation in the OSA treatment algorithm and the supporting evidence around category outcomes.



### **Patients At The Center**

Address unmet patient needs with a premium choice for treatment of OSA:

- Bilateral stimulation to address both genioglossus muscles—not just one side.
- Battery-free implant that does not require follow-on procedures to replace generators.
- Designed to treat regardless of sleep position (claim pending based on supine analysis of DREAM study results).
- Single incision procedure



## **Scalable Approach**

- Focus on top ENT accounts, which comprise a majority of accounts and are geographically concentrated
- Targeted DTC at critical points along the patient journey.
- Launch with scalable processes and division of labor, gradually transitioning standard titration to sleep specialists.
- Complement prior work done in coding and payment with coverage support via prior authorization and interim codes until a new code is established.



# **Genio Expected to Capture approx. 50% Market Share** *Independent 25 Clinician Survey*

## **Guidepoint Survey**

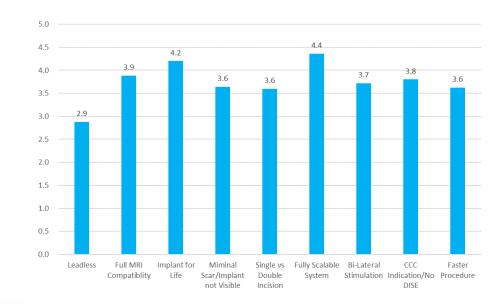
- Sample size 25 clinicians
  - 12 US ENTs + 4 German ENTs
  - 9 US Sleep Specialists

## **Driving features in Genio adoption**

- Scalability Latest-and-greatest technology with no extra surgery
- No implantable battery No need to replace depleted battery
- 1.5T & 3T full-body MRI compatibility Peace of mind
- No CCC diagnosis required with CCC label expansion No DISE
- Single-incision Less trauma and faster procedure

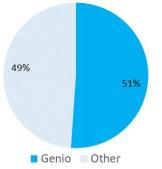
### Physician Profile

- Clinicians at least "somewhat familiar" with Genio and Inspire systems
- ENTs/Sleep Specialists Average annual HGNS implants/referrals = 40 / 47

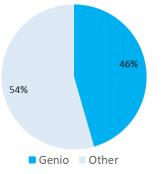


## **Genio Mix upon US availability**

**US ENTs - n=12** 

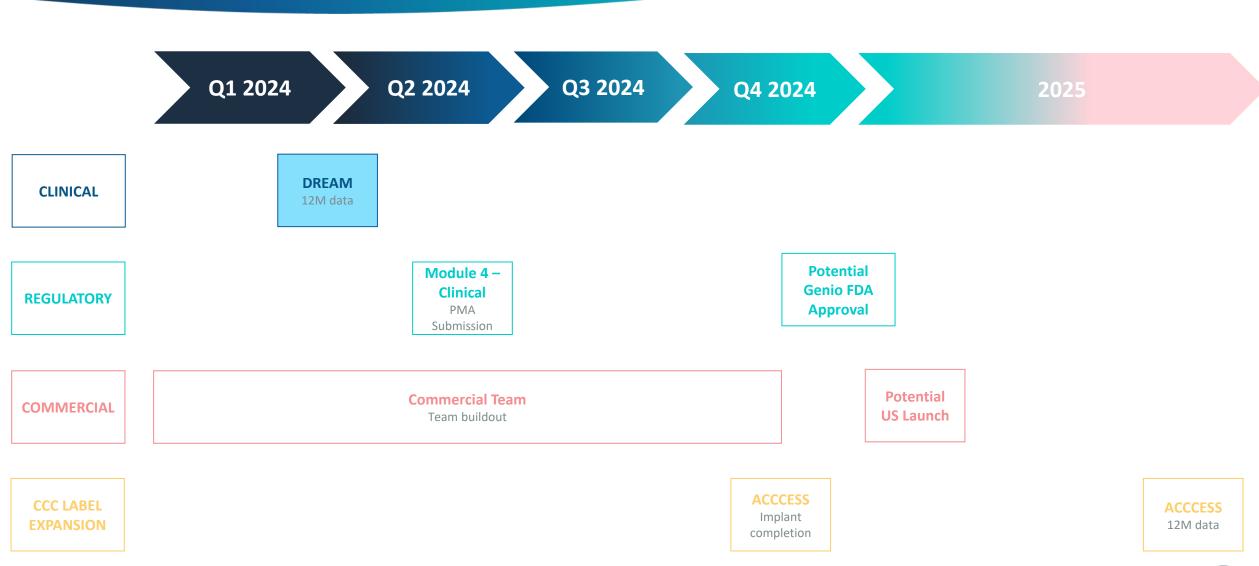


US Sleep Experts – n=9





# 2024 – 2025 Key Anticipated Milestones



# Cash of €44.3mm with a Runway into Late-2024

### **Current Shareholder Base**

# **Historical Shareholders**

- Robert Taub
- Together Partnership
- Jürgen Hambrecht

**International Strategics** 





**US Institutional** 









## **EU Institutional**









