# **Company Overview** June 2025



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Our vision is to make sleep simple.

Nyxoah is a MedTech company with a unique neuromodulation solution for Obstructive Sleep Apnea, putting the patient first.



# Nyxoah's Blueprint for Success



Focused on Rapidly Growing, Underpenetrated \$10 Billion US Obstructive Sleep Apnea (OSA) Annual Market Opportunity



Breakthrough Treatment For OSA With Unique Bilateral Mode of Action



Compelling Clinical Evidence Through DREAM IDE Study Demonstrating Safety and Efficacy Data of Genio<sup>®</sup> Therapy



Proof-of-Concept European Commercialization



Upon FDA Approval – We Expect to be the 2<sup>nd</sup> PMA Device on the Market for Hypoglossal Nerve Stimulation: Experienced Leadership and Launch Team in Place Obstructive Sleep Apnea (OSA) is a common, chronic disorder where the upper airway repeatedly collapses during sleep, interrupting breathing. Beyond significant quality of life impacts, poorly treated OSA can lead to severe health complications.



#### **Existing Therapeutic OSA Solutions Have Significant Limitations**

#### Standard of Care First Line Therapy: Continuous Positive Airway Pressure (CPAP)



- Therapy efficacy dependent of patient compliance – "Dose / Response effect"<sup>7</sup>
- Compliance definition: At least 4 hours/night for 5 nights/week)<sup>7</sup>
- CPAP non-compliance estimated to be
- <sup>6</sup> between 29% and 83%<sup>7, 8, 9</sup>

#### **Mandibular Advancement Devices**

- Only suitable for mild to moderate OSA
- Non-predictive therapy efficacy
- High out-of-pocket cost to patient

#### Unilateral Hypoglossal Nerve Stimulation (UHGNS)

- Suitable for moderate to severe OSA<sup>11</sup>
- 2 3 incisions during implant procedure
- 21.4% severe adverse event rate<sup>12</sup>
- Additional surgical procedures for battery replacement and upgrades<sup>11</sup>
- Device and/or leads sometimes visible after implant

#### **Traditional Surgery**

- Highly invasive and remains last resort
- Success rate from 30% to 60%<sup>13</sup>
- High incidence of side effects
- Often cannot be reversed



OSA is a medical condition that impacts over 54 million patients in the U.S. representing a \$10 billion annual market opportunity. Despite this, current HGNS therapies lack widespread adoption with less than 100,000 patients implanted to date.





90K HGNS Implants To Date

# 

Make Sleep Simple

## 1.5T & 3T FULL-BODY MRI COMPATIBLE

## **BATTERY-FREE IMPLANT**

## STIMULATOR NOT VISIBLE AFTER INSERTION





# **SLEEP WEARABLE**

- Convenient, travel-friendly design
- Externally powers the system





# INTUITIVE APP

Nyxoal

Track sleep progressAdjust stimulation

# **Empowers the Patient to Help Drive Compliance**

# **DREAM Clinical Study**

#### **Compelling Clinical Evidence** US Pivotal DREAM Study Achieved Safety and Efficacy Endpoints



#### Achieved Co-Primary Endpoints

#### Serious Adverse Events – 8.7% SAE Rate

Serious Adverse Events	Related to Device	Related to Implant	Unrelated to Device and/or Implant
Asthenia and Hypoesthesia			2
Atrial Fibrillation			1
Device Dislocation	2		
Device Extrusion	1		
Left Bundle Branch Block		1	
Dysphagia		2	
Epistaxis		1	
Incision Site Hematoma		1	
TOTAL: 11	3	5	3

Most Common AEs	m (n, %)
Application Site Irritation	28 (21, 18.3%)
Dysphagia	19 (18, 15.7%)
Incision Site Swelling	18 (17, 14.8%)
Medical Device Discomfort	12 (10, 8.7%)

AHI Responder definition: Minimum 50% reduction in the 4% Apnea-Hypopnea Index (AHI<sub>4%</sub>) from baseline AND final AHI of less than 20 events/h

14 ODI Responder definition: Minimum 25% reduction in the 4% Oxygen Desaturation Index ( $ODI_{4\%}$ )



#### Additional DREAM Efficacy Endpoints

#### Overall 70.8% Median AHI Reduction at 12 Months

#### 66.6% Median AHI Reduction in Supine at 12 Months

#### 82% of Patients with AHI Below 15 at 12 Months



#### Change in SUPINE AHI (4%)\*

(mean ± Standard deviation)



#### AHI at 12-Month Visit (% of Patients)





# Commercialization

#### **Commercialization – International Markets**

#### **Germany – Commercial Proof of Concept**

#### Reimbursement

- DRG code established in 2021, dedicated to Hypoglossal Nerve Stimulation
- Both Genio and UHGNS use similar code 5.059.C7

#### **Smart Follower Strategy**

- Genio quickly embraced in Tier 1 accounts as an alternative to UHGNS
- 25% Market Share within 24 months after launch

#### Focused DTC and Sleep Hubs Program

- Focused DTC investment resulting in 40% growth of implants in 2024
- Dedicated sleep hub program

#### **Selective International Expansion**

#### National Coverage – Dedicated DRG

- Germany
- Switzerland
- UK

#### **Hospital Budget**

- Spain
- Italy
- Finland

#### **Case-by-Case Insurance Coverage**

- United Arab Emirates Q1 2025
- Kuwait Q2 2025
- Singapore Q3 2025



#### **US** Commercialization

#### Reimbursement

- Expect to use an established CPT code recognized by payers for the OSA indication at launch (64568)
- Worked closely with the American Academy of Otolaryngology (AAO) on strategy
- Participating in the FDA's Early Payer Feedback Program

#### Smart Follower Strategy – 2-pronged approach

- Focus on high volume UHGNS implanting accounts
  - Market research suggests that physicians and patients are seeking an alternative UHGNS
- Drive referrals from sleep physicians who currently manage a high number of patients, supported by focused DTC investments

#### **US Launch Team in Place**

- Commercial organization of 50 people ready for limited release
  - 25 Territory Managers Hired and fully trained
- Dedicated team supporting preauthorization efforts



#### At U.S. Launch: Intend to Cover ~30% of Current U.S. HGNS Market With 25 Experienced Territory Managers

Cedar Rapids •

Minneapolis

Kansas City

Grand Rapids •

Indianapolis •

Chicago (2)

Upstate NY

Jacksonville

• Miami

Tampa

Newark

• Philadelphia

Detroit

Columbus

• Knoxville

• Atlanta

#### Initial U.S. Launch Markets:

Seattle

San Diego

#### **Territory Manager Profile**

## >10 Years Average Experience

## **44%** Prior HGNS Experience

# **100%** Experience in ENT or

Neuromodulation

#### **Previous Employers**

**S** Inspire.

Saluda MEDICAL Medtronic



Axonics





• Denver

Salt Lake City

#### Nyxoah's Expected Growth Path Forward





## Nyxoah's Strategy for Success



#### **Business Poised for Scaled Execution**

- Proven clinical efficacy with DREAM study data
- Successful commercial proof of concept in Germany
- Establishing leadership in new markets (UK, Middle East)
- Supply chain infrastructure in place



#### Unlocking a \$10B Market Opportunity

- Highly differentiated HGNS solution
- Reimbursement pathway identified
- US commercial team trained and ready for launch
- Strengthening clinical evidence to reinforce differentiation

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#### **DREAM Study Design Details**

#### 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
- All assessments from consent (safety) or baseline (efficacy) to 12 months post-implant
- All safety events were adjudicated by an independent Clinical Events Committee (CEC)

#### **BASELINE CHARACTERISTICS**

- Mean
- Mean Baseline AHI: 28.0 events/h
- Mean Baseline ODI: 27.0 events/h
- Mean BMI: 28.5 kg/m2

#### **EFFICACY ENDPOINTS**

- Co-Primary AHI responder rate at 12 months per the Sher criteria (AHI reduction of at least 50% from baseline on the 12-month PSG and AHI score of less than 20 events per hour on the 12-month PSG)
- Co-Primary ODI responder rate at 12 months (ODI reduction of at least 25% from baseline on the 12-month PSG)
- Secondary Median reduction in AHI from baseline to 12 months

#### SAFETY ENDPOINTS

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

