

Nyxoah Company Overview

October 2024



Forward-Looking Statements

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Nyxoah's Blueprint for Success



- \$10 Billion US HGNS Market Opportunity
- 8% Market Penetration
- Established HGNS Reimbursement



Breakthrough Treatment For Obstructive Sleep Apnea With Unique Bilateral Mode of Action



Compelling Clinical Evidence Through DREAM IDE Study Demonstrating Safety and Efficacy of Genio[®] Therapy



Proof-of-Concept European Commercialization

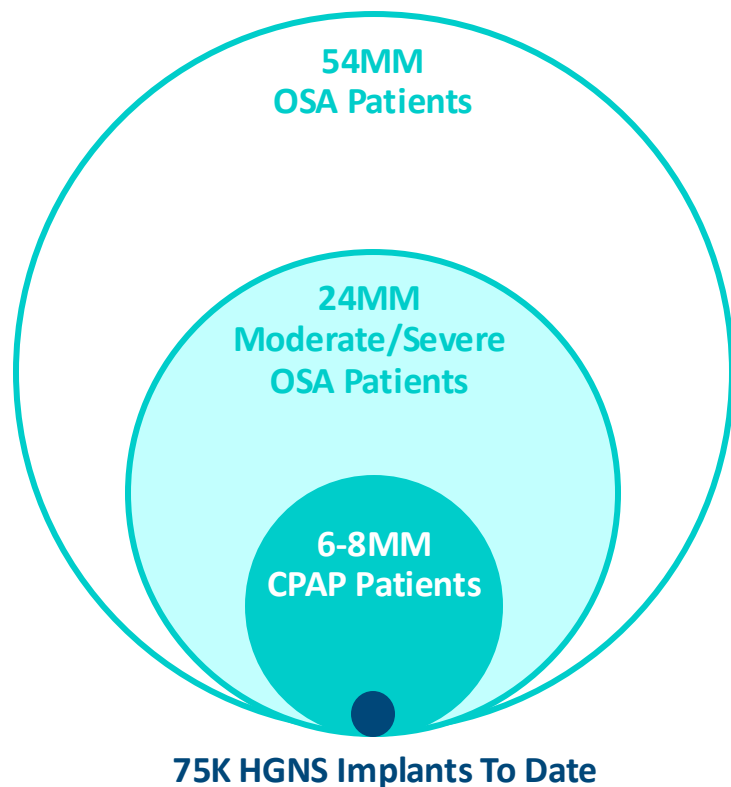


On the Verge of FDA Approval with US Commercialization Planned in Early 2025

The US Market Opportunity for Hypoglossal Nerve Stimulation

Currently, 97% of HGNS revenue is generated in the U.S.

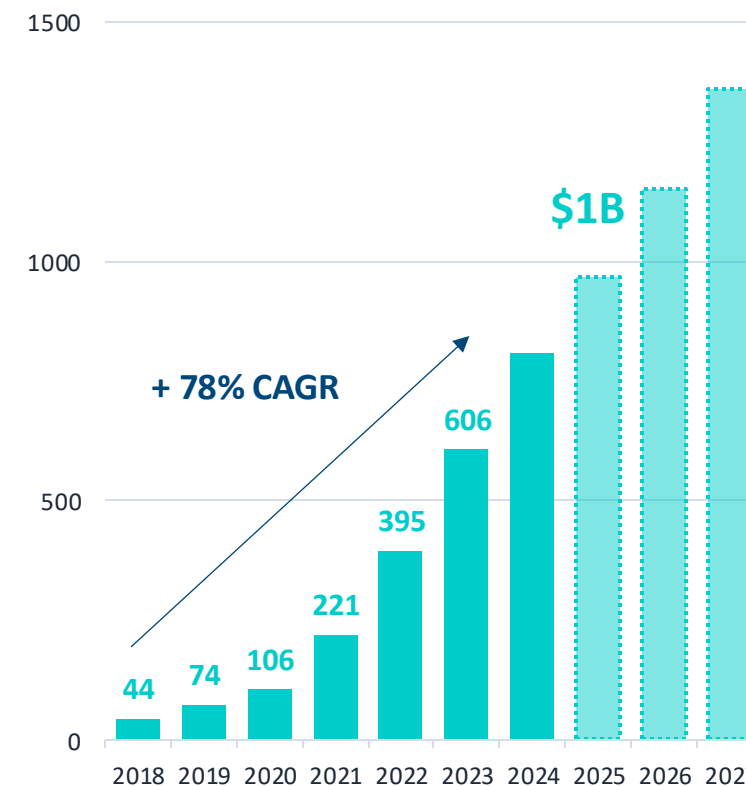
Many More OSA Patients Need Help



HGNS Has Not Yet Focused On Where OSA Patients Are

Specialty	# of US Clinicians	Current HGNS Industry Focus
Primary Care Providers	295,000	Low
Pulmonologists (primary specialty)	4,900	Low
Sleep Doctors (at 2,500 centers)	7,500	Low to Moderate
Sleep-Focused ENT Surgeons	1,300	High

Market Poised For Robust Growth



Sources: 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. 2. ResMed, 3. Inspire company reports, 4. Associated Professional Sleep Societies, 5. American Medical Association Physician Professional Database 2022.

Genio® Therapy

A breakthrough solution with unique bilateral mode of action

Implantable Stimulator

- Lead-less, battery-free stimulator inserted through a single incision
- Delivers bilateral hypoglossal nerve stimulation, which contracts the genioglossus muscle to maintain an open airway in any sleep position
- Genio implant not visible with full-body MRI compatibility up to 3T

Wearable

- Externally powers the stimulator
- Conduit for feature upgrades without the need for additional procedures to upgrade or replace a generator

Patient App

- Puts control in the hands of patients (within limits set by a health care professional)
- Provides feedback on therapy usage



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.

Experienced Executive Leadership Team



Bruno Onkelinx
Chief Technology Officer

- 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.



Dr. Maurits S. Boon
Chief Medical Officer

- Has 24 years of academic and clinical career focused on treating OSA.
- Dual boarded in Otolaryngology - Head and Neck Surgery and is one of the pioneers in the use of HNS therapy.



Maggie McGowan
Chief HR Officer

- Has 18 years of experience as global HR leader in the life sciences sector, in both biotech and pharmaceutical organizations.
- Has established a strong reputation for driving organizational success through innovative and people-centered HR strategies.



Jey Subbaroyan
Chief Clinical Officer

- Has 14 years of experience in clinical and pre-clinical 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.



Ashlea Mittelstaedt
Chief Strategy Officer

- Has 20 years of operating experience in medical device with a focus on marketing, pipeline development, and commercial operations across a wide range of healthcare solutions.
- Over 30 years of market research experience with a focus on voice of clinical customers and patients.



Scott Holstine
Chief Commercial Officer

- Has over 26 years of experience in the medical device industry with a proven track record in U.S. product launches, building and leading commercial organizations trademarked by strong operational execution.



Francis Kim
Chief Regulatory & Quality Officer

- Has more than 25 years of experience in the highly regulated medical device sector.
- In his responsibility as a leader in Quality and Regulatory, Francis introduced several innovative products to the market.



Rémi Renard
Chief of Staff

- Has 20 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.



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DREAM Results

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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
- **Supine sleep time required: ≥60 minutes at 12 months**
- **AHI range between 15 and 65, BMI<32**

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/m²

Achieved Co-Primary Endpoints on an ITT basis

- AHI Responder Rate – 63.5% (p=0.002)
- ODI Responder Rate – 71.3% (p<0.001)

AHI responder – 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

ODI responder

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



Safety Set – ITT	Responder Rate M12	p value
AHI4	63.5% (73/115)	0.002
ODI4	71.3% (82/115)	< 0.001

Full Analysis – m-ITT	Responder Rate M12	p value
AHI4	66.4% (73/110)	< 0.001
ODI4	74.5% (82/110)	< 0.001

Per Protocol – PP	Responder Rate M12	p value
AHI4	81.8% (72/88)	0.001
ODI4	92.0% (81/88)	< 0.001

Safety results compare favorably vs. standard of care*

- Serious Adverse Events (SAEs) definition follows FDA guidelines
- All events were adjudicated by an independent Clinical Events Committee (CEC)
- 11 SAEs in ten subjects resulting in an SAE rate of 8.7%
 - **3 device-related adverse events**

Serious Adverse Events & Most Common Adverse Events

SAE	Related to Device	Related to Procedure	Unrelated to Device and/or Procedure
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

Description of AE	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%)

Key Differentiating Data vs. Unilateral HNS

AHI improvements are independent from the sleep position

- Median AHI change of 71.0% in supine sleep
- Median AHI change of 66.6% in non supine sleep
- Median AHI change of 70.8% in all positions

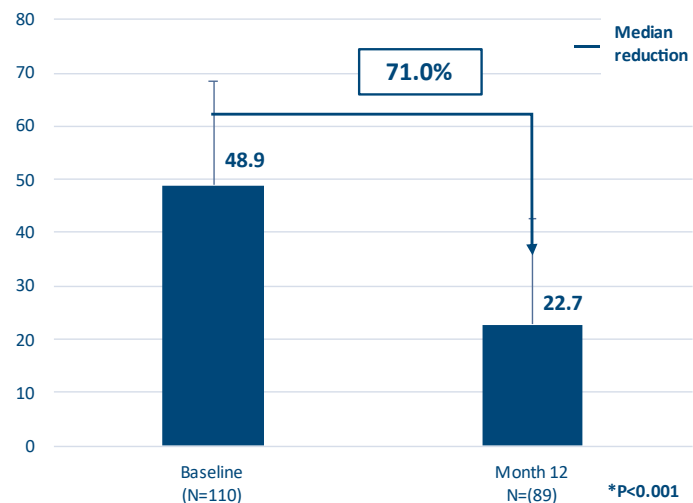
Submitted a unique label claim that Genio is usable in any sleeping position

Therapy impact on AHI at 12 months

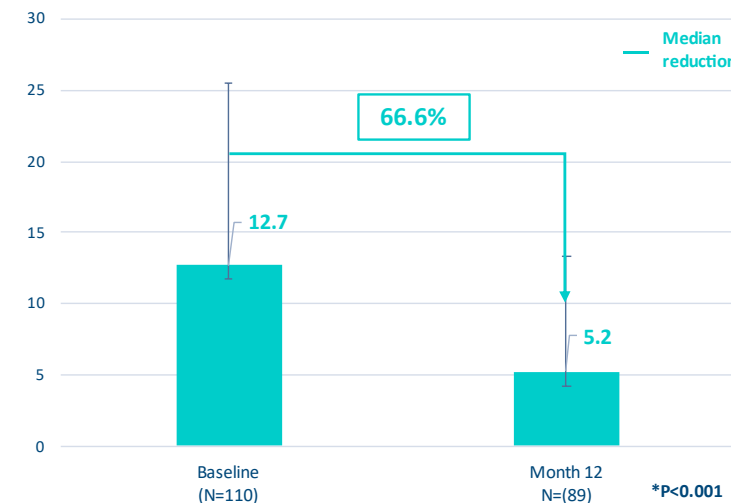
- 82.0% patients had an AHI below 15 at 12 months
- 67.4% patients had an AHI below 10 at 12 months

Patients with AHI below 15 have equivalent cardiovascular risks to the non-OSA population

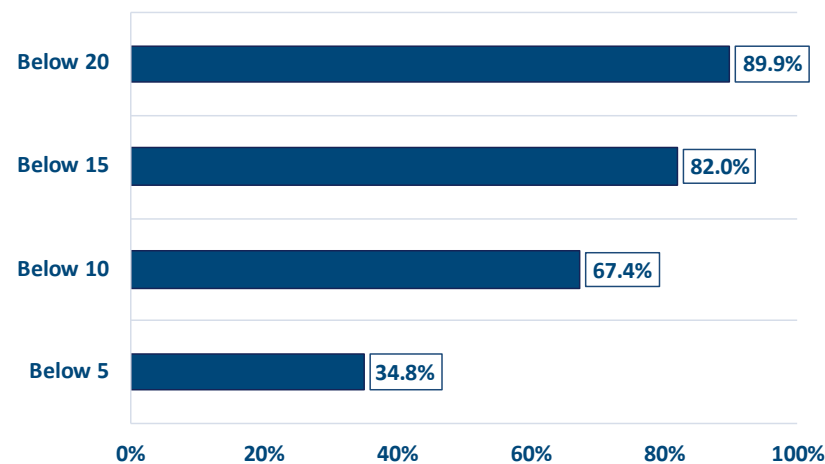
Mean change in SUPINE AHI*



Mean change in NON-SUPINE AHI*



AHI at 12-M visit – % Patients

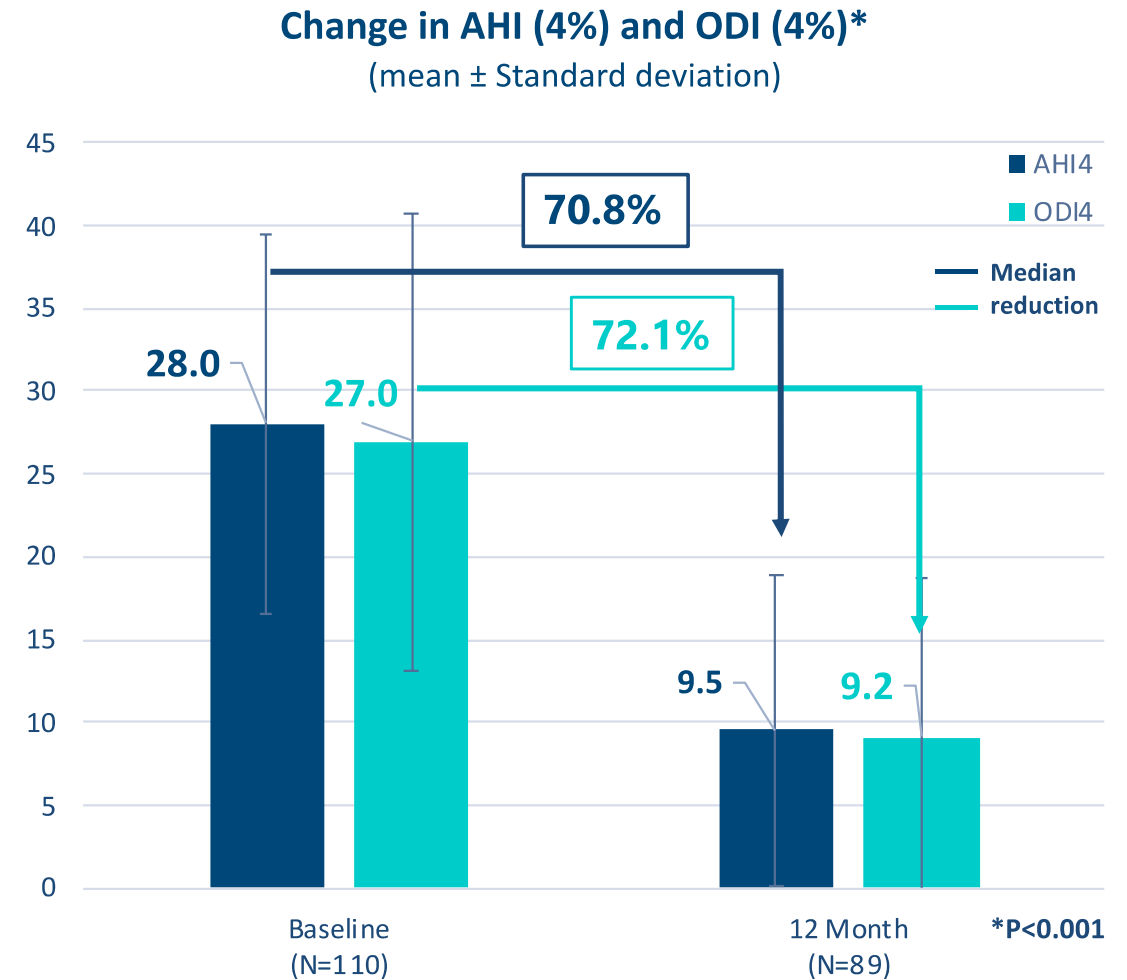


AHI Reduction

- Clinically meaningful 70.8% median AHI reduction at 12 months compared with baseline

ODI Reduction

- Clinically meaningful 72.1% median ODI at 12 months compared with baseline



Clinically significant improvements in quality-of-life outcomes

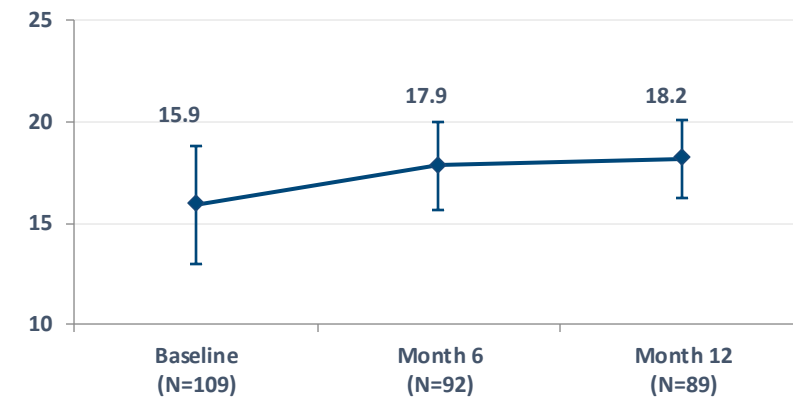
Functional Outcomes of Sleep Questionnaire (FOSQ)

- Significant mean increase of 2.3 points at 12 months vs. baseline

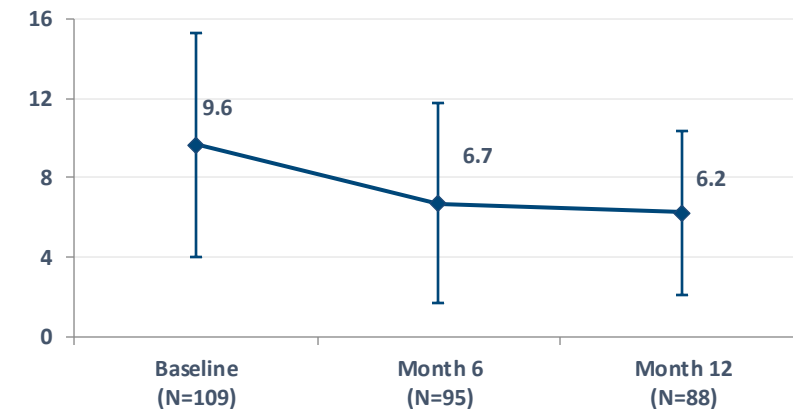
Epworth Sleepiness Score

- Significant mean reduction of 3.4 points at 12 months vs. baseline

FOSQ-10 total score by visit
(mean \pm Standard deviation)



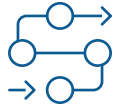
ESS total score by visit
(mean \pm Standard deviation)



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US Launch

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Smart Follower

Break the HGNS monopoly

- Targeting the now firmly established subspecialty of sleep surgeons—a highly concentrated group in ENT growing their practices through device-forward treatment.
- Leveraging business processes already streamlined at high-volume physician offices with referral pathways from 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

Make Genio the patient's preference

- Bilateral stimulation to address both sides of the genioglossus muscle to maintain an open airway regardless of sleep position
- Lead-less, battery-free implant inserted via a single incision that does not require follow-on procedures to replace generators
- Genio device not visible after implant
- Full-body MRI compatible up to 3T
- Patient app that empowers patient to adjust therapy and see their treatment success



Playbook for Scalability

Carve a fast track to profitability

- Focus on top-tier, geographically concentrated ENT accounts, and strengthening their sleep referral network
- Target DTC at critical points along the patient journey.
- Launch with sustainable processes that make business simple for stakeholders, then add geographies following initial success.
- Complement prior work done in coding and payment with coverage support via prior authorization and interim codes until a new code is established.
- EBITDA profitability expected around \$300M revenue run rate

Genio US Launch Success Factors



Experienced talent with track records of success and the right mindset—with US-based leadership



Commercial launch team focused on selected geographies, bolstered by market access, marketing, and commercial operations expertise



Developing sustainable traction in the US as a premium option to take share and accelerate market growth



Keeping the patient at the center to ensure the right patient gets the right therapy for the best outcomes

2024-2025 Key Milestones



CLINICAL EVIDENCE

DREAM
12M data

REGULATORY

All PMA
Modules
Submitted

Interactive Review with FDA

Expected FDA
Approval of Genio

COMMERCIAL

US Commercial Launch Readiness

Planned
US Launch

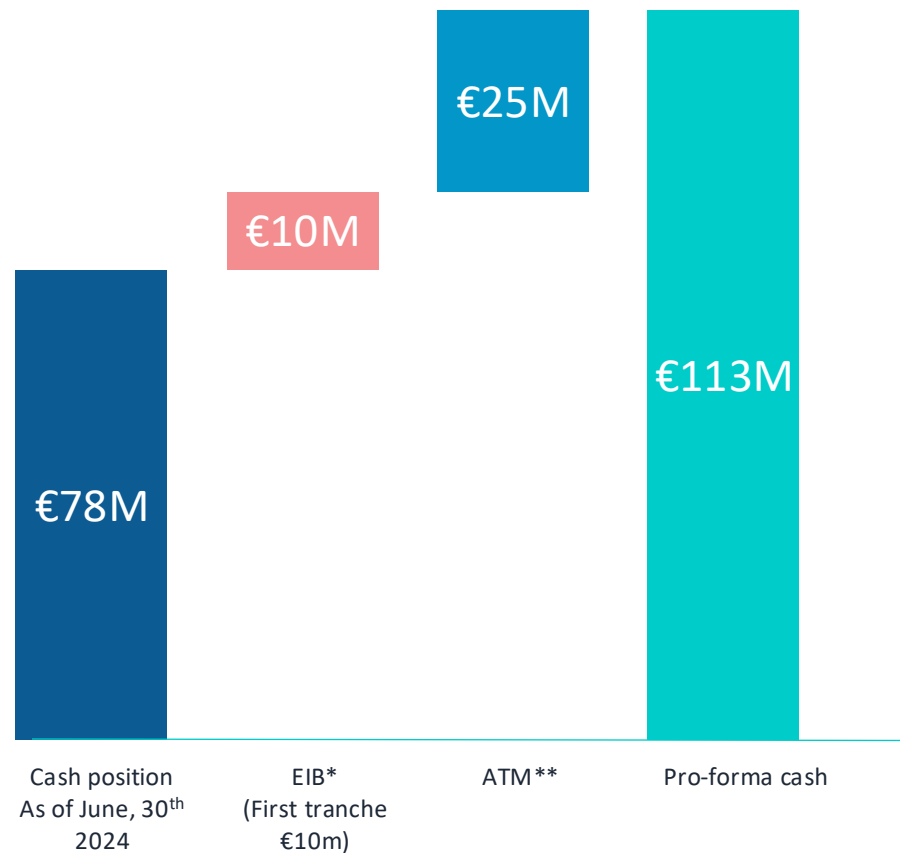
Further Geographic
Expansion

LABEL EXPANSION

Complete Concentric Collapse in the US
Ansa Cervicalis Stimulation

Solid Investor Base Provides Cash Runway Into Second Half 2026

Cash Runway into H2 2026



* On July 3rd 2024, the European Investment Bank (EIB) granted Nyxoah a facility of up to €37.5m of which of €10m was drawn down in July 2024

** On October 7, 2024 Nyxoah raised \$27M (€25M) in gross proceeds pursuant to the \$50M at-the-market offering

Shareholders Base

