

# Nyxoah

August 2022

Nyxoah 

# Forward-Looking Statements

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# Investment Highlights

## Significant Underpenetrated Global OSA Market Opportunity

- 425m moderate-to-severe OSA patients globally eligible for treatment
- >1m OSA patients eligible for HGNS treatment annually in US and Europe
- HGNS treatment solution now fully accepted by physicians and payors

## Innovative Patient-Centric Technology

- Single-incision procedure with a scalable technology platform
- Bilateral stimulation with external power source and no lead tunneling
- Full-body 1.5T and 3.0T MRI compatibility

## Growing Body of Strong Clinical Data

- BETTER SLEEP demonstrated safety and efficacy in both non-CCC and CCC patients
- DREAM IDE pivotal trial to secure US regulatory approval in H1 2024
- ACCESS IDE study to secure US approval for CCC patients in early 2025

## Targeted Commercial Strategy

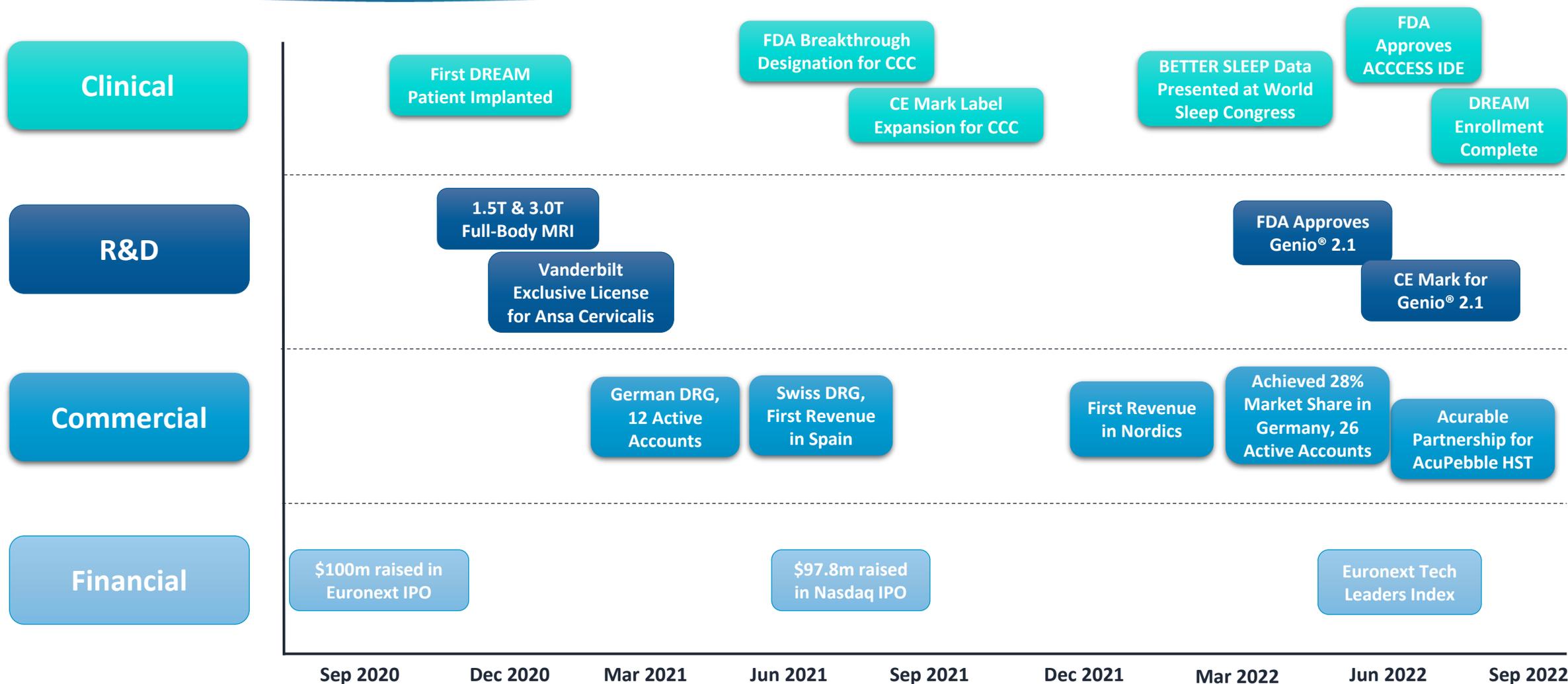
- CE Mark with first European sales in 2021
- Commercial proof of concept through expected market leadership in Germany in Q4 2022
- US pre-commercial activities focused on market access and payor coverage

## Healthy Financial Position

- Dual-listed (NYXH) company trading on Nasdaq and EuroNext stock exchanges
- €123 million cash balance after two successful IPOs, which brought in top tier investors
- Ample liquidity to fund key R&D, clinical, and commercial priorities into 2024

# Executing on Our Strategic Priorities

Euronext IPO-Present



# 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.

# Large and Underpenetrated Global OSA and HGNS Market Opportunity

## Worldwide Obstructive Sleep Apnea Prevalence

936 Million

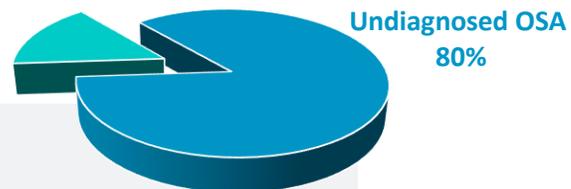
- 936M individuals (30-69 year) are estimated to suffer from OSA<sup>1</sup>

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>



## 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

+70% CAGR HGNS revenue 2016 – 2021<sup>3</sup>

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

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

3. Presents annual revenue growth for Inspire Medical. Inspire Medical corporate presentation – February 2022

# A Disruptive Patient-Centric Solution TODAY...

Single incision procedure

Leadless and battery-free

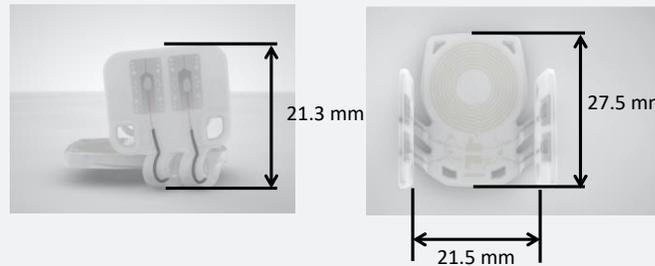
Full-body 1.5T and 3T MRI compatible

Bilateral stimulation

CCC FDA breakthrough designation  
CCC indication in Europe

Scalable platform

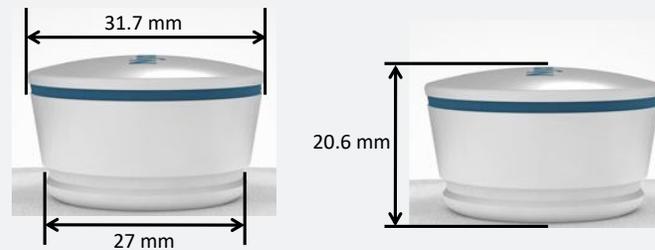
## Genio® Implantable Stimulator



Weight  
2,96 grams



## Genio® Activation Chip



Weight  
12 grams



# Our Vision: Improving Lives Through Restful Nights

## Connectivity & Remote Care

- Connectivity with remote smartphone application
- Cloud based access for patients and physicians



## Patient Engagement

- Feedback to / from the patient for optimized compliance & comfort



## Predictable Outcomes & Auto-Titration

- Patient acclimation through amplitude adjustment @ home
- Sensors for adaptive therapy & auto-titration



# The Genio® Duty Cycle Approach to Hypoglossal Nerve Stimulation

## The Genio® proprietary Duty Cycle algorithm

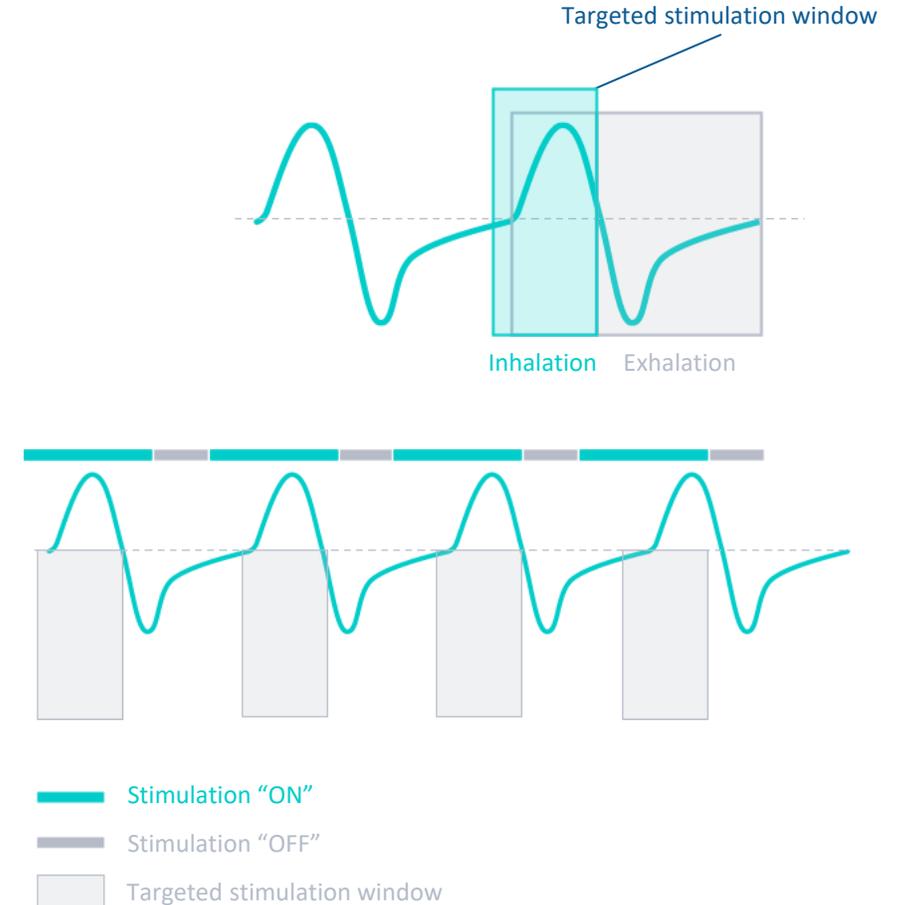
### 1 Respects the patient physiological breathing

- The patient breathing frequency is used as a reference to adjust the stimulation cycle

### 2 Ensures a timely and efficient stimulation, through Duty Cycle

- Genio® Duty Cycle algorithm: alternance of ON/OFF stimulation phases in a cyclical pattern
- The cyclical “ON” phase overlaps with the target window (end of expiration + early inspiration) to deliver a timely stimulation
- The “OFF” phase prevents the occurrence of nerve and muscle fatigue

#### Genio® algorithm example



# The Genio® System – Addressing Unmet Patient and Physician Needs

## Single incision 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

## External power-source

- Device replacement and revision procedures are associated with a two- to four-fold higher risk of infection

## Bilateral stimulation

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

## MRI compatibility

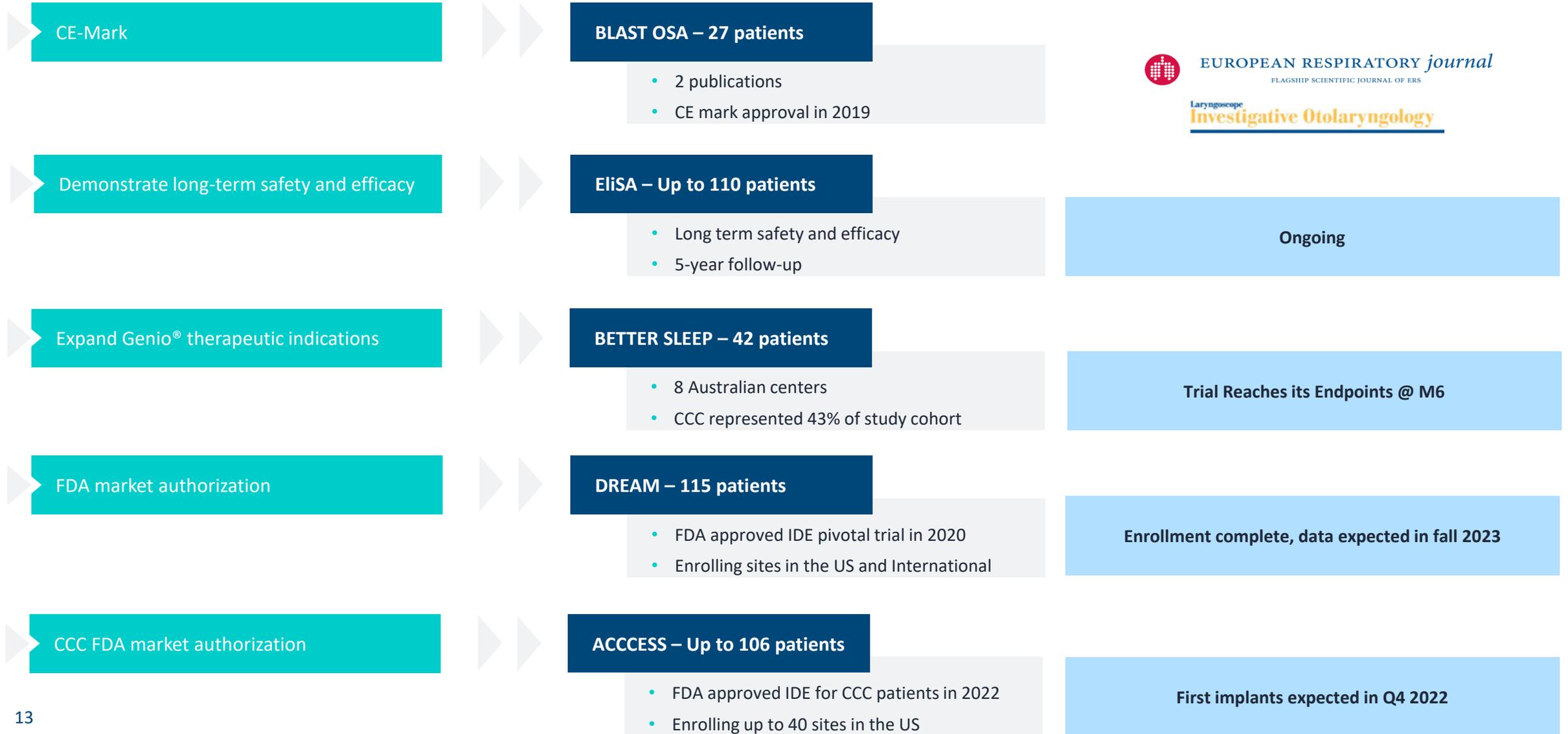
- >40 Million MRI scans performed in 2020 in OSA patients<sup>17</sup>
- 60% MRI scans are performed in the thorax/abdominal area<sup>17</sup>
- 40% MRI scans are 3T



	Nyxoah	Inspire	LivaNova
Implantable parts	1 – Genio® IS	3 – Pulse generator + 2 leads	2 – Pulse generator + lead
Number of incisions	1 incision	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
Estimated implantation time	1 hour	2.5 hours	2 hours
MR conditional labeling	Full-body 1.5T and 3.0T	1.5T only	No

# Clinical Strategy

## Building Robust Clinical Evidence



EUROPEAN RESPIRATORY *journal*  
FLAGSHIP SCIENTIFIC JOURNAL OF ERS

Laryngoscope  
**Investigative Otolaryngology**

# BETTER SLEEP Study – Demonstrated Efficacy for Both Non-CCC and CCC Patients

Population and key inclusion criteria	22 < Age < 75	Multicenter, prospective, open-label, two group study	With and without complete concentric collapse (CCC)
	BMI < 32 kg / m <sup>2</sup>	Moderate to Severe OSA – AHI 15-65	Failed, did not tolerate, or refused PAP
	Target: 42 patients		

## Safety and Performance

- Safety: Incidence of device-related serious adverse events (SAEs)
- Efficacy Endpoints
  - Primary: Mean reduction in AHI (4% oxygen desaturation, AHI<sub>4%</sub>) for the entire cohort
  - Exploratory: Mean reduction in AHI4 for the CCC subgroup
  - Secondary: Mean reduction in oxygen desaturation index scored at 4% desaturation (ODI<sub>4%</sub>) for the entire cohort

# BETTER SLEEP

## Responder Rate – Sher Criteria

- 36 patients completed polysomnography at month 6
- Responder defined according to the Sher criteria<sup>22</sup> ( $\geq 50\%$  reduction in AHI and AHI less than 20)
- Strong responder rates help de-risk DREAM U.S. IDE study

	AHI <sub>4%</sub> Responder Rate – Sher Criteria –
CCC & Non-CCC – n=36	64%
CCC – n=15	60%
Non-CCC – n=21	67%

Results subject to final review and validation

## BETTER SLEEP

### *Improvement in AHI<sub>4%</sub> in Responders*

- >70% reduction in AHI<sub>4%</sub> in responders in both CCC and non-CCC population
- Presence of “Super Responders” in both CCC and non-CCC cohorts provides additional validation

AHI responders	– AHI <sub>4%</sub> – Mean % reduction at 6 months
Entire cohort (n=23)	73.4%
CCC cohort (n=9)	71.1%
Non-CCC cohort (n=14)	74.9%

BETTER SLEEP – Data from the entire cohort

### Europe

- CE Mark label expansion to include CCC patients in Europe
- CE-Mark Instructions for use: *“The Genio® system is indicated to treat patients suffering from moderate to severe OSA with and without Complete Concentric Collapse (CCC) at the soft palate level”*
- No DISE required to assess presence of CCC at the soft palate level

### United States

- Genio® received “Breakthrough Device Designation” in the US for CCC patients
- ACCESS IDE approved, first patients expected to be implanted in Q4 2022
- FDA approval expected in early 2025

# DREAM Study – IDE Pivotal Trial

<b>Population and key inclusion criteria</b>	22 < Age < 75	Failed, did not tolerate, 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
	<b>Target: 115 patients</b>		

## Safety and Performance

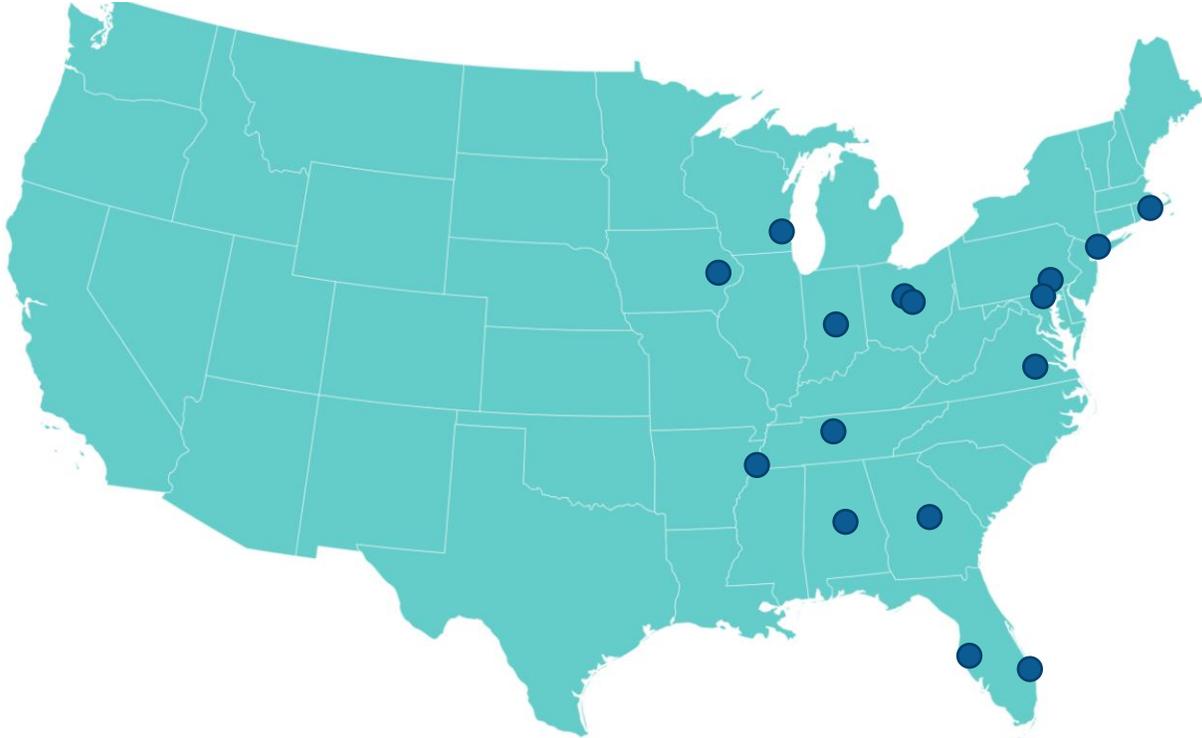
- Safety: Incidence of device-related serious adverse events at 12 months
- Co-primary effectiveness endpoints: Percentage of responders at 12 months based on Apnea Hypopnea Index (AHI4%) using the Sher criteria and percentage of responders at 12 months based on ODI4% (25% reduction of ODI between baseline and 12-month visit)

## Status

- FDA approved IDE pivotal trial in June 2020
- 20 US sites activated, screening, enrolling and implanting patients
- Mix of large academic centers & private practices, all HGNS experienced
- Enrollment complete

# 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
Phillip A. Huyett, MD	Massachusetts Eye and Ear, Boston, MA
B. Tucker Woodson MD	MCW, Milwaukee, WI
David Kent MD	VUMC, Nashville, TN
Asim Roy MD	OSMI, Dublin, OH
Ulysses Magalang MD & Eugene Chio MD	OSU, Columbus, OH
Ryan Nord MD	VCU, Richmond VA



United States



# ACCESS Study – IDE Trial to Gain US Approval for CCC Patients

Population and key inclusion criteria	22 < Age < 75	Failed, did not tolerate, or refused PAP	Central / Mixed Events < 25% of Total
	BMI < 32 kg / m <sup>2</sup>	Moderate to Severe OSA – AHI 15-65	
	<b>Target: Up to 106 patients</b>		

## Safety and Performance

- Safety: Incidence of device-related serious adverse events through 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 ODI4 between baseline and 12-month visit)

## Status

- FDA approved IDE pivotal trial in July 2022 – up to 40 participating sites
- Mix of large US academic centers & private practices, all HGNS experienced
- First patients expected to be implanted in Q4 2022
- FDA approval expected in early 2025

# Commercial Leadership Through Focused Execution

## Go Deep versus Go Wide



### Stakeholders

- ENT implant surgeon
  - Quality implant
- Sleep physician
  - Patient phenotyping
  - Patient outcomes
- Referral network
  - GPs, cardiologists

## EU Market Access

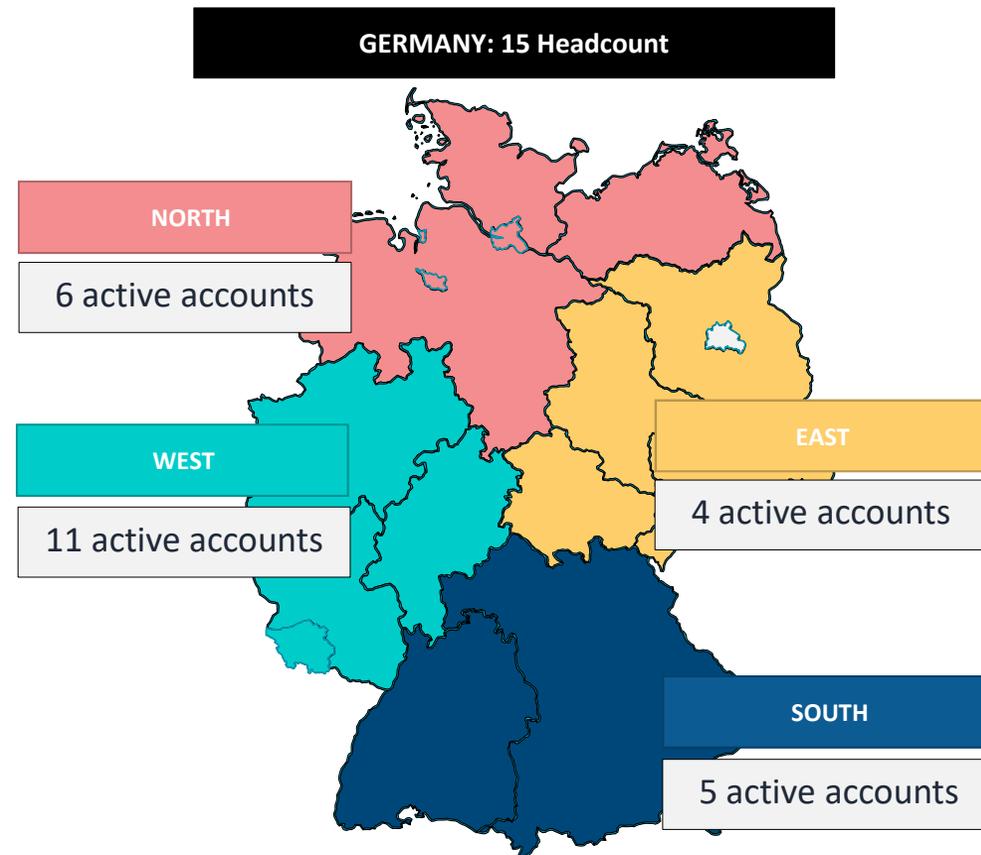
### Nyxoah – EU reimbursed countries

- Germany – 2021: Dedicated DRG
- Switzerland – 2021: Dedicated DRG code
- Spain – 2021: Funding through hospital budget
- Finland -- 2022

### Nyxoah – EU reimbursement opportunities

- The Netherlands
- Belgium
- Italy
- France
- United Kingdom
- Nordic Countries

## Germany - Proof of concept



# Acurable Home Sleep Test German Partnership

## *AcuPebble Aligns with Nyxoah's Patient-First Mission Statement*

### A Next-Generation Home Sleep Test

- CE Mark and FDA clearance
- High specificity and sensitivity for AHI and ODI, which is validated by a randomized study [published in the BMJ Open](#)

### Patient-Centric Design

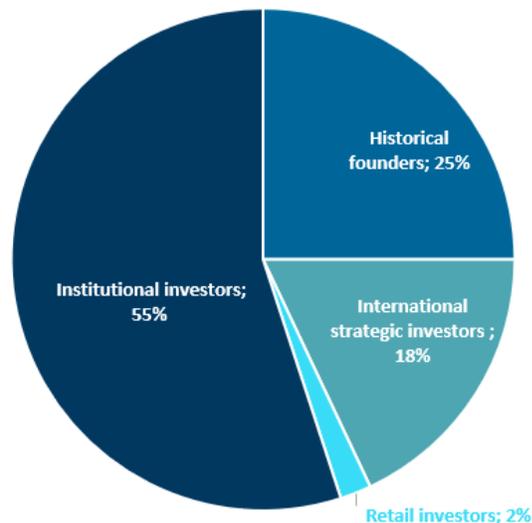
- **Highly accurate** – >93% and >91% specificity and sensitivity for AHI and ODI compared to gold-standard polygraphy
- **Easy to use** – patients download APP and follow simple instructions
- **Comfortable** – small system worn at the base of neck at night
- **Reusable** – can be used for routine monitoring, including on multiple consecutive nights
- **Novel form factor** – aligns with trend towards wearable technology

**With AcuPebble and Genio, Nyxoah can now offer patients and clinicians the most cutting edge OSA home sleep diagnosis and treatment solutions**

# High Quality and Diverse International Shareholder Base

## Euronext IPO EURONEXT

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



## Nasdaq IPO

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

## Current Shareholder Base (as of 3/31/22)

### Historical Shareholders

- Robert Taub
- Together Partnership
- Jürgen Hambrecht

### International Strategics



### US Institutional

**BlackRock**

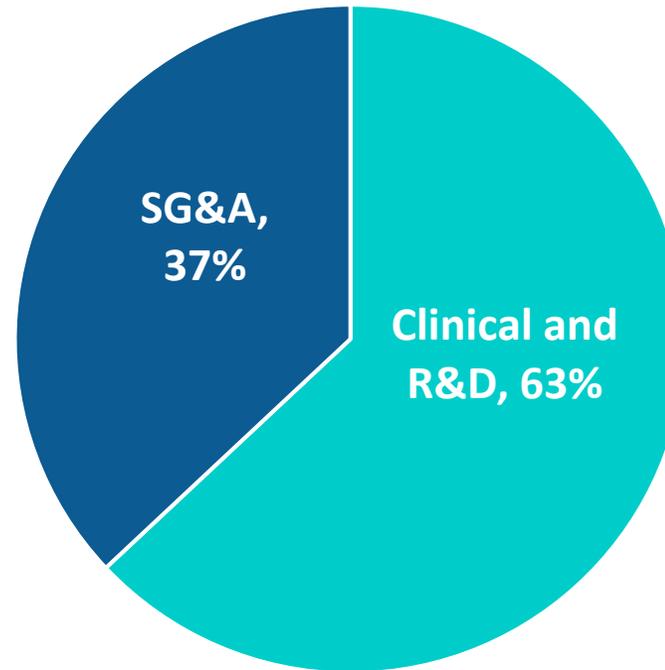
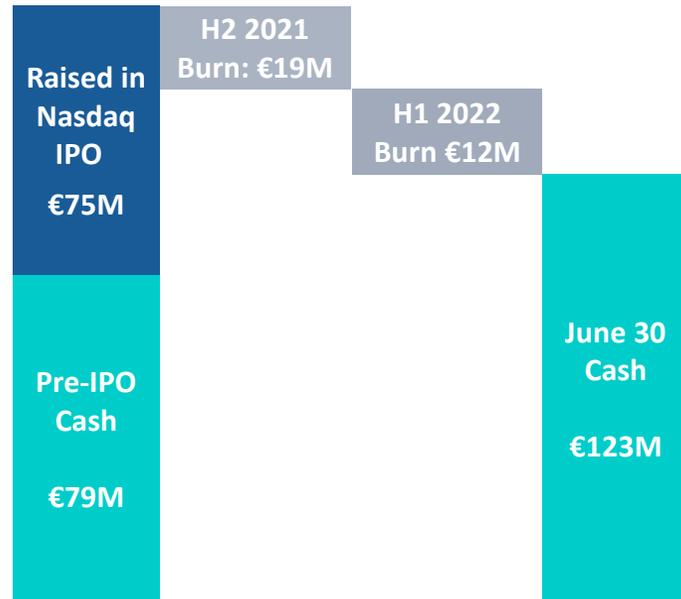


### EU Institutional



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

## Strong Cash Position - €123M



- R&D/Clinical to represent >60% of 2022 expenses driven by DREAM enrollment completion, EliSA study progress, and ACCESS 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

[www.nyxoah.com](http://www.nyxoah.com)

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Nyxoah 