

# **Santhera Pharmaceuticals H1 Results Presentation**

6 months Ending 30 June 2025

23 September 2025

# Santhera speakers today



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# Santhera Pharmaceuticals

A fully integrated  
commercial stage  
biopharmaceutical  
company

## SIX Swiss Exchange listed company (SANN)

- Global headquarters near Basel (Switzerland)
- About 110 employees; will remain <150 employees

## AGAMREE® is a differentiated product in Duchenne muscular dystrophy (DMD)

- A unique dissociative corticosteroid which maintains powerful anti-inflammatory properties of traditional steroids but with an improved safety profile

## Global rollout underway – positive market reception

- Approvals by five authorities (U.S., EU, UK, CN, HK)
- Own commercialization of AGAMREE in Western European countries, with first launches in 2024 in Germany and Austria and in the UK in 2025
- Launched in the U.S. by partner Catalyst

## Financing in place for next steps

- New financing in September 2025 raising approximately CHF 20 Mio
- Cash runway to cash-flow break-even in mid 2026
- Cash at the 30 June 2025 of CHF 18.4 Mio

# DMD is lifelong neuromuscular disorder characterized by progressive loss of muscle strength and function

1. **No cure** and high medical need
2. **Onset at age 3-5 years** and life expectancy in the late 20s to mid-30s
3. **Progressive muscle weakness** needing chronic treatment
4. **Loss of ambulation** in early teenage years followed by respiratory failure and cardiac complications



# Current therapies with intrinsic limitations: too late – too little – too soon

## Today's standard of care:

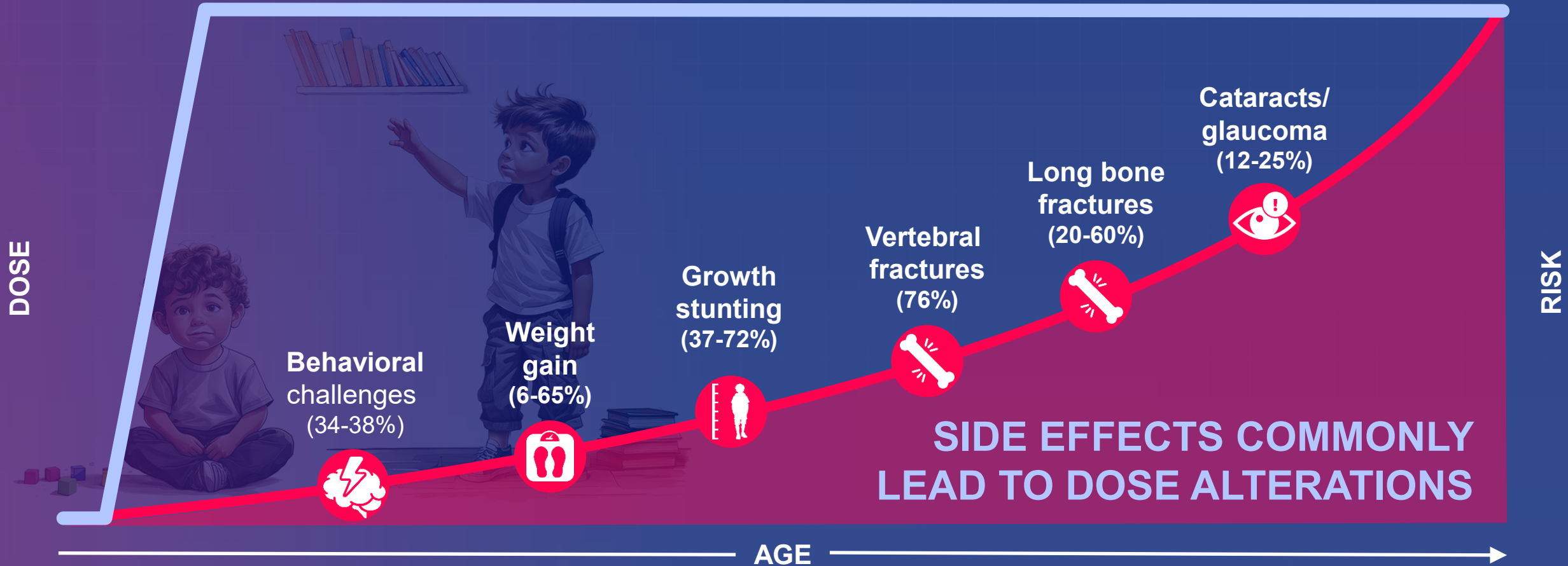
- Corticosteroids are the standard of care in combination with other treatments
- Corticosteroids can delay disease progression by 2-3 years
- Corticosteroids have limitations due to serious side-effects

## Today's problem:

- Start too late
- Dose too little
- Stop too soon



# Managing side effects and improving tolerability remain key challenges with traditional corticosteroids



# AGAMREE® (vamorolone)

## A better foundational therapy

### AGAMREE addresses limitations of standard corticosteroid therapy

- Retained anti-inflammatory action and efficacy
- Reduction of steroid-associated side effects related to:
  - growth
  - bone health
  - behavior
- May have additional benefits – Heart health

### AGAMREE allows patients to stay:

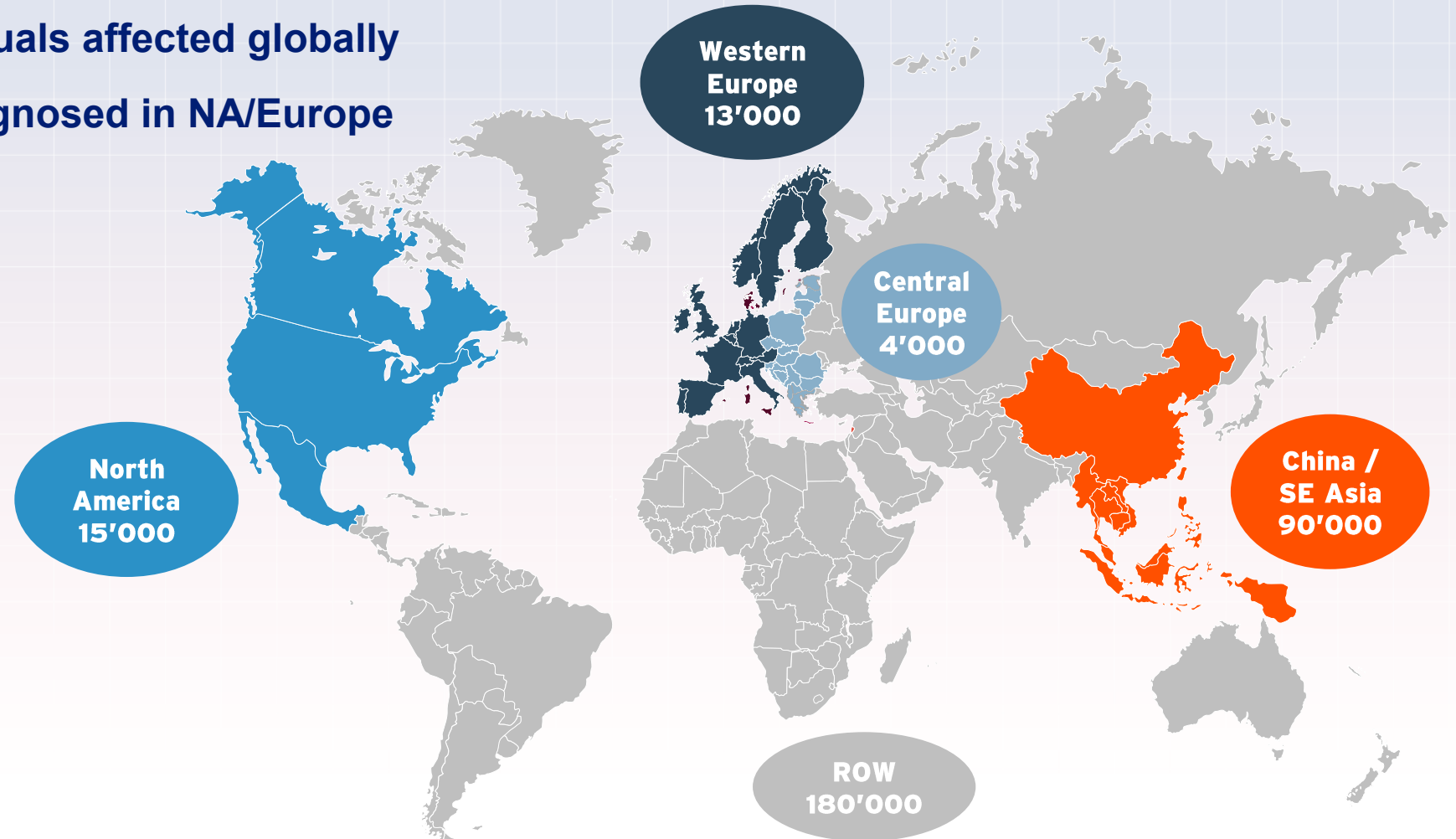
- On time
- On dose
- On treatment



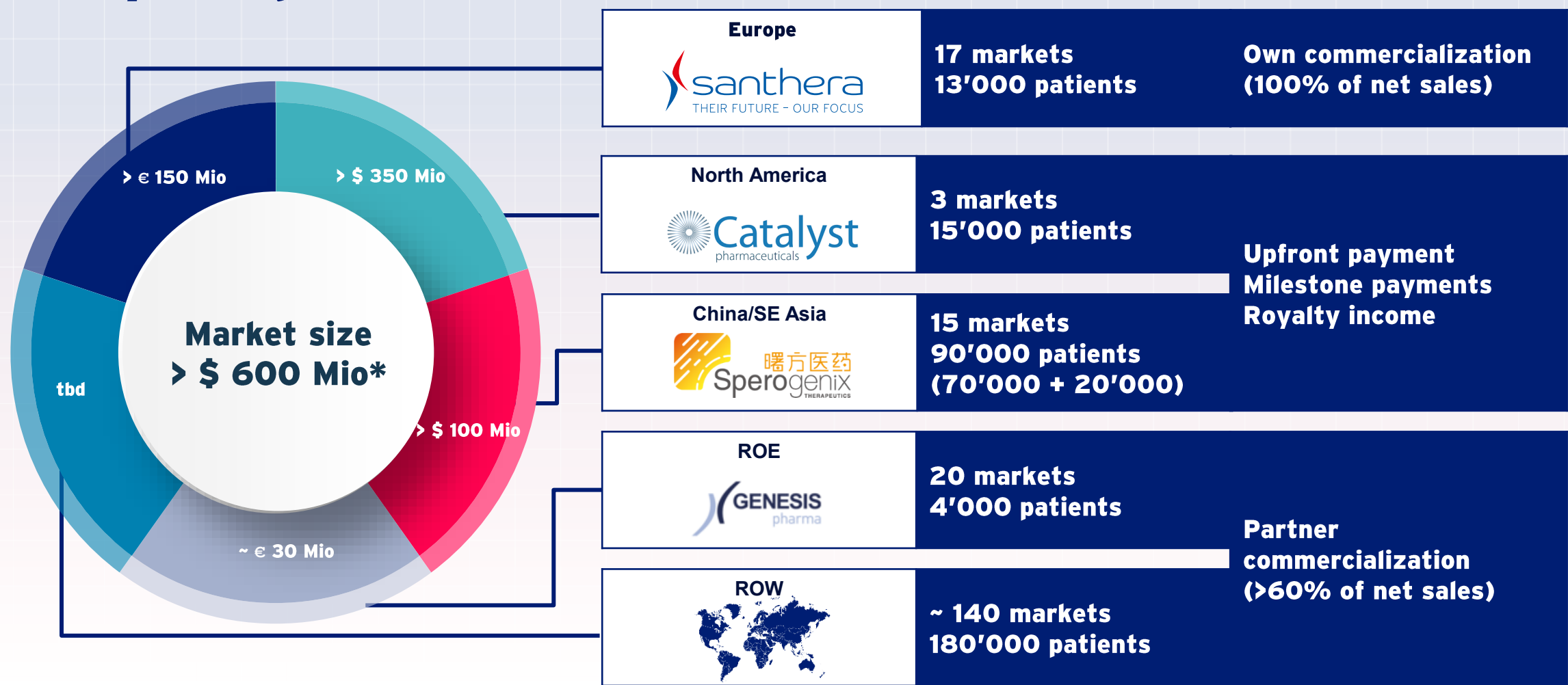


# DMD is one of the largest rare disease markets with a clearly defined patient group

- Around 300'000 individuals affected globally
- 90% of patients are diagnosed in NA/Europe
- 50-75% of patients on steroid treatment
- Patients are treated in specialized centers
- HCPs familiar with steroid usage



# Global DMD market opportunity with substantial runway for growth



\* Santhera estimates

# Operational highlights – 6 months ending 30 June 2025 (including post period)

1

## Germany and Austria growing strongly:

- Approximately 40% of steroid using DMD patients in Germany now treated with AGAMREE
- Austria becomes first country to have >50% market share\*

2

## Other EU direct markets progressing well:

- UK launched in Q2 with growing demand. Home delivery program commenced mid Q3 to streamline access and reduce admin burden
- Further launches expected through Q4 2025 and into 2026

3

## Strong partner sales with Catalyst continues

- Reported H1 2025 sales of USD 49.4 Mio
- 2025 revenue guidance: USD 100-110 Mio
- Sales >USD 100 Mio would trigger a USD 12.5 Mio milestone payment to Santhera

4

## Sperogenix partnership in China:

- Early access program continued in 2025 with commencement of non-reimbursed commercial rollout in September
- Increased expectations for demand in 2025/2026

5

## Rollout in other territories:

- Distribution agreements signed for five Gulf Cooperation Council (GCC) countries, India and Türkiye post period end
- Remains active to continue to drive geographical expansion through distribution partners

6

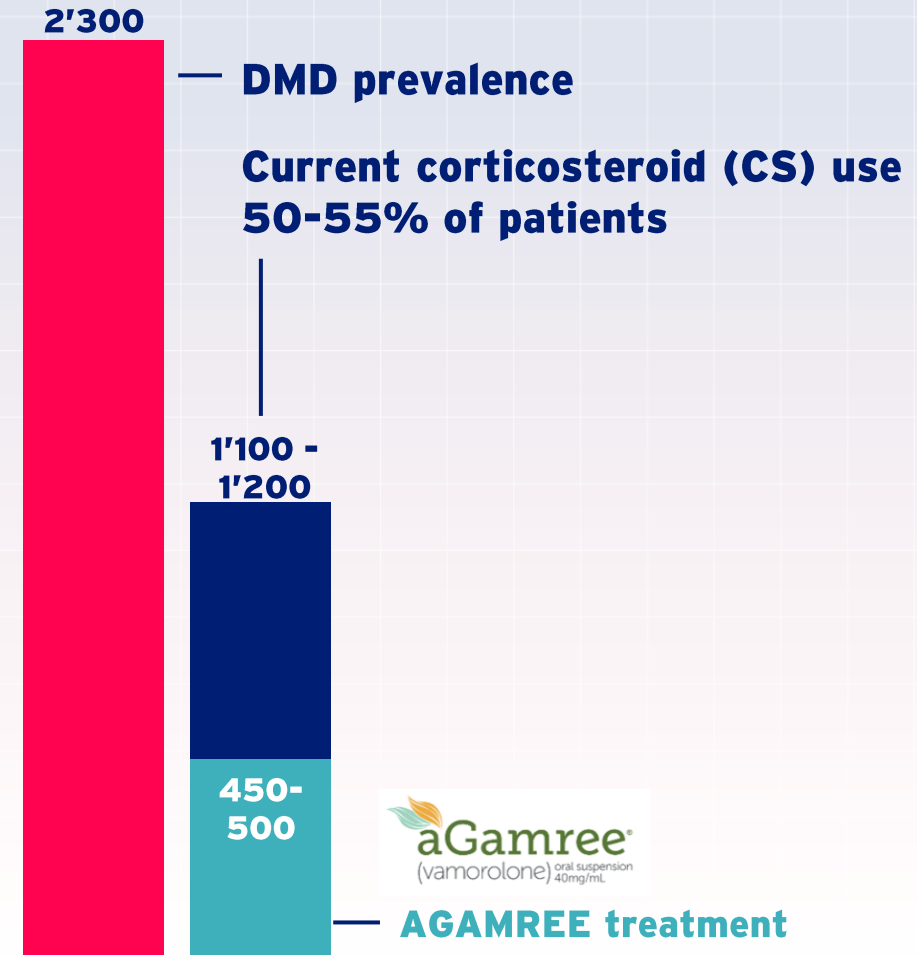
## Executive and Board changes:

- Catherine Isted joined Santhera as CFO in February
- Dr. Melanie Rolli joined the Santhera Board in May, replacing Dr. Otto Schwarz

# Rapid adoption of AGAMREE® by patients and payers in Germany & Austria

## Strong uptake of AGAMREE

- In Germany approximately **40%** of steroid using DMD patients now treated with AGAMREE
  - newly diagnosed aged 4-5
  - switchers aged 6-12
  - increasing number of older DMD patients
- In Austria **>50%** of steroid using DMD patients now treated with AGAMREE
- No clinical trial sites/experience prior to launch
- Federal price in Germany EUR 3'612.50 (per 100ml bottle) as per German formula
- Germany is the reference market for several other countries





# Key European launches progressing

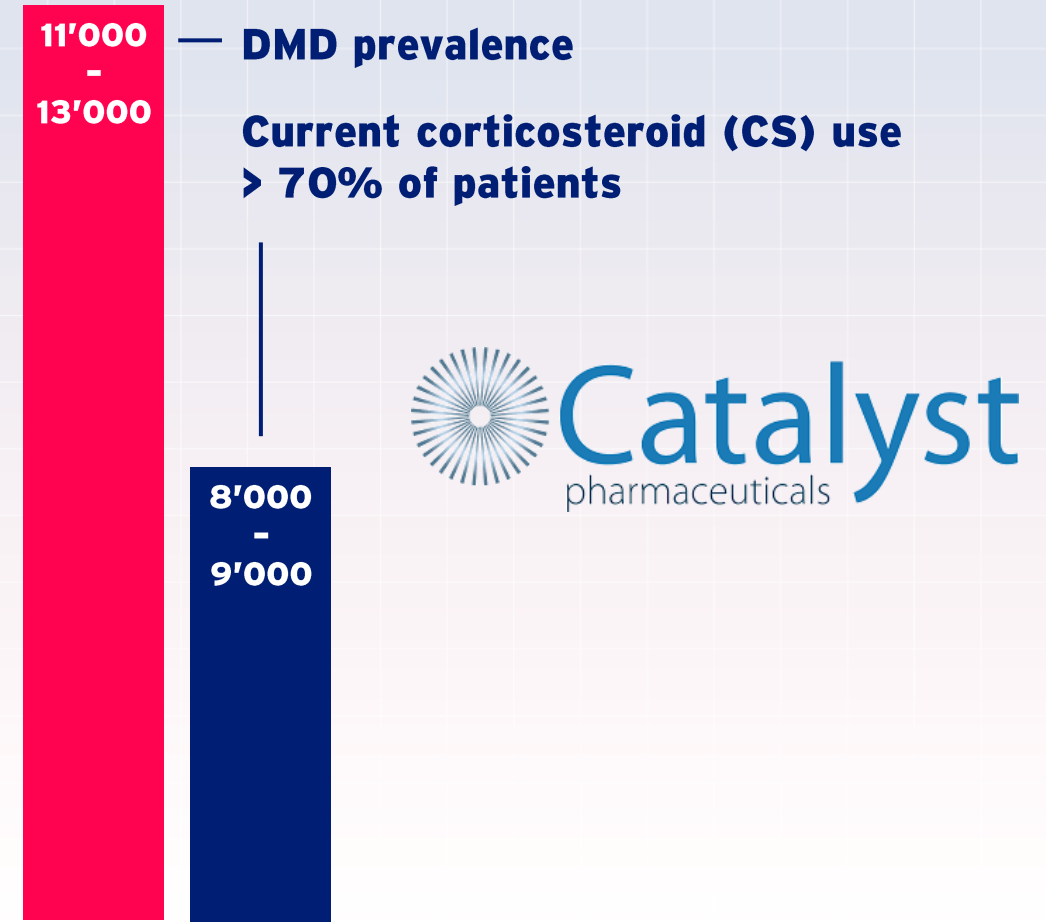
			2024				2025				2026		
		Status	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	H1	H2	
PHASE 1	Germany / Austria	Launched	Launch	Pricing negotiations			✓						
	UK	Launched	Pricing negotiations			✓		Launch					
PHASE 2	Spain	Submitted		NPP*	Pricing negotiations								
	Italy	Submission Q1 2025				NPP*	Pricing negotiations						
	Nordic	Submitted					Pricing negotiations						
	Benelux	In preparation		NPP*			Pricing negotiations						
PHASE 3	France	Submitted	Pricing negotiations							TBD			
	Switzerland	Reg. submitted	Regulatory submission and pricing & reimbursement										
	Other Europe	Ongoing	Launch preparations										

\*Named Patient Program


# Successful rollout by Catalyst in the US continues

## H1 sales of AGAMREE grew to USD 49.4 Mio

- H1 sales already ahead of FY 2024 sales of USD 46 Mio
- Catalyst 2025 guidance for AGAMREE: Net sales of USD 100-110 Mio
- Sales of >USD 100 Mio within the year leads to a milestone payable to Santhera of USD 12.5 Mio



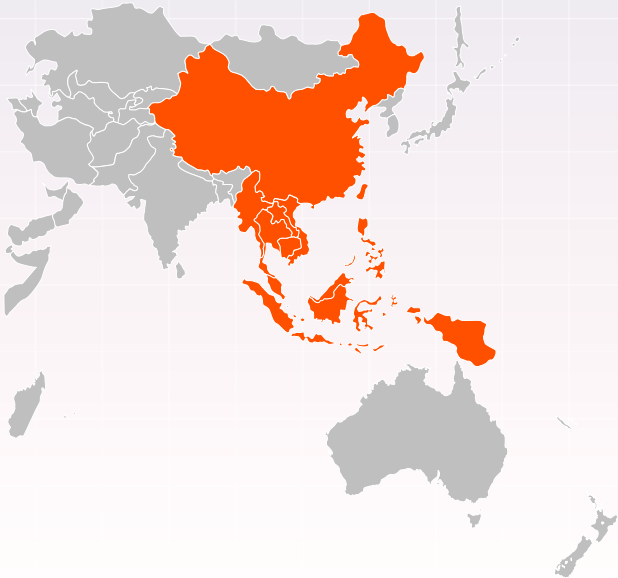
# China progressing as commercial launch commences

	2023		2024				2025		2026	
	Q3	Q4	Q1	Q2	Q3	Q4	H1	H2	H1	H2
			Filing Mar 27			Approval Dec	✓	Soft Launch	Launch	



## Reaching patients in China

- Early access program (EAP) in Hainan province was launched in June 2024
- Commercial launch in the non-reimbursed market commenced in September 2025
- More than 250 DMD patients treated to date
- Demand expectations increased for 2025/2026, leading Santhera to bring forward inventory plans



# Financial highlights - 6 months ending 30 June 2025

1

**Total revenues: CHF 24.0 Mio** (H1 2024: CHF 14.1 Mio), 70% growth driven by revenue from strong product sales in launched markets in addition to royalty and products supply revenue

2

**Product sales: CHF 11.6 Mio** (H1 2024: CHF 6.6 Mio), an increase of 76%, driven by the continued success of AGAMREE in Germany and Austria in addition to first contributions from the UK post the April 2025 launch

3

**Sales from US and Chinese partners: CHF 12.4 Mio** (H1 2024: CHF 7.6 Mio) reflecting a 63% increase in royalty, milestone and product supply revenues in the period

4

**Global sales (including partners) >USD 100 Mio in four consecutive quarters**, which triggers USD 20 Mio milestone payment in COS

5

**Operating expenses: CHF 27.3 Mio** (H1 2024: CHF 26.7 Mio) with increased Sales and Marketing offset by decrease in R&D

6

**Operating loss: CHF 35.4 Mio** (H1 2024: CHF 17.7 Mio loss. Excluding the USD 25 Mio (CHF 20.3 Mio) milestone, operating loss was reduced by CHF 2.6 Mio

7

**Financing: CHF 20 Mio secured**

USD 13 Mio royalty and CHF 10 Mio convertible bond financing secured to provide additional growth capital

8

**Cash and cash equivalents June 30, 2025: CHF 18.4 Mio** (FY 2024: CHF 40.9 Mio). Cash-flow break-even guidance maintained for mid-2026



# Financing: September 2024 gross funds c. CHF 20 Mio



## Convertible loan extension: (Highbridge Capital Management)

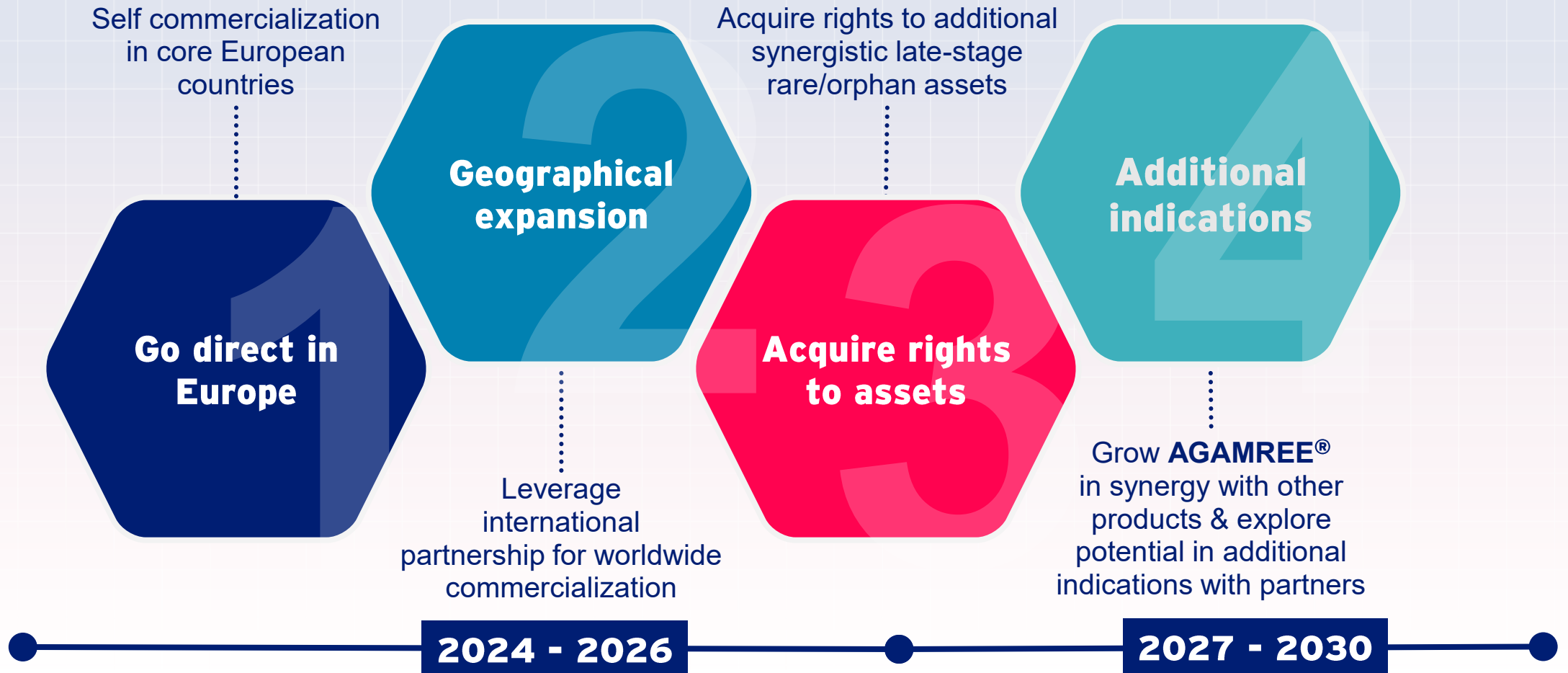
- Highbridge will provide an additional CHF 10 million via a new convertible note with the existing CHF 7 million convertible bond exchanging, at parity
- The new convertible bond will have a three-year maturity, with a conversion price set at a 10% premium to the intraday VWAP on the 23 September
- The Company will issue Highbridge approximately 110,000 shares as consideration for Highbridge agreeing to increased flexibility in relation to the CHF 35 million four-year term loan signed in August 2024

## Royalty monetization agreement: (R-Bridge - Affiliate of CBC Group)

- Santhera to receive USD 13 Mio in return for the 25% of net royalties not currently under the existing R-Bridge agreement and relates to income streams from agreements with Catalyst (US) & Sperogenix (China)
- As with the earlier agreement once cap is met, all royalty payments revert to Santhera and Santhera retains certain rights to buy back the royalty income stream
- This agreement is in addition to the Aug 24 agreement where the Company received USD 30 Mio (and up to USD 38 Mio) for 75% of future net royalty income streams from agreements with Catalyst and Sperogenix
- Milestones received from Catalyst and Sperogenix are excluded from the agreement and continue to be fully received by Santhera

- **New 2025 revenue guidance:** FY revenues in excess of CHF 65-70 Mio
- **2028 revenue outlook:** EUR 150 Mio – including direct and partnered markets, and royalty income from North America and China, but excluding potential milestones payments received from partners
- **2030 revenue outlook (direct markets):** Expect > EUR 150 Mio of sales in own direct markets (excludes distributor and licensed market revenues/royalties/milestones)
- **Operating expenses (SG&A and R&D) 2025 and going forward on constant portfolio basis:** CHF 50-55 Mio – this excludes non-cash share compensation

# Clear strategy with four pillars of revenue generation



# We have everything in place to successfully serve the DMD market



**A differentiated product with worldwide rights**



**A clear growth strategy**



**A strong & growing partner network**



**A nimble organization with expertise**



**Funded to projected cash-breakeven**

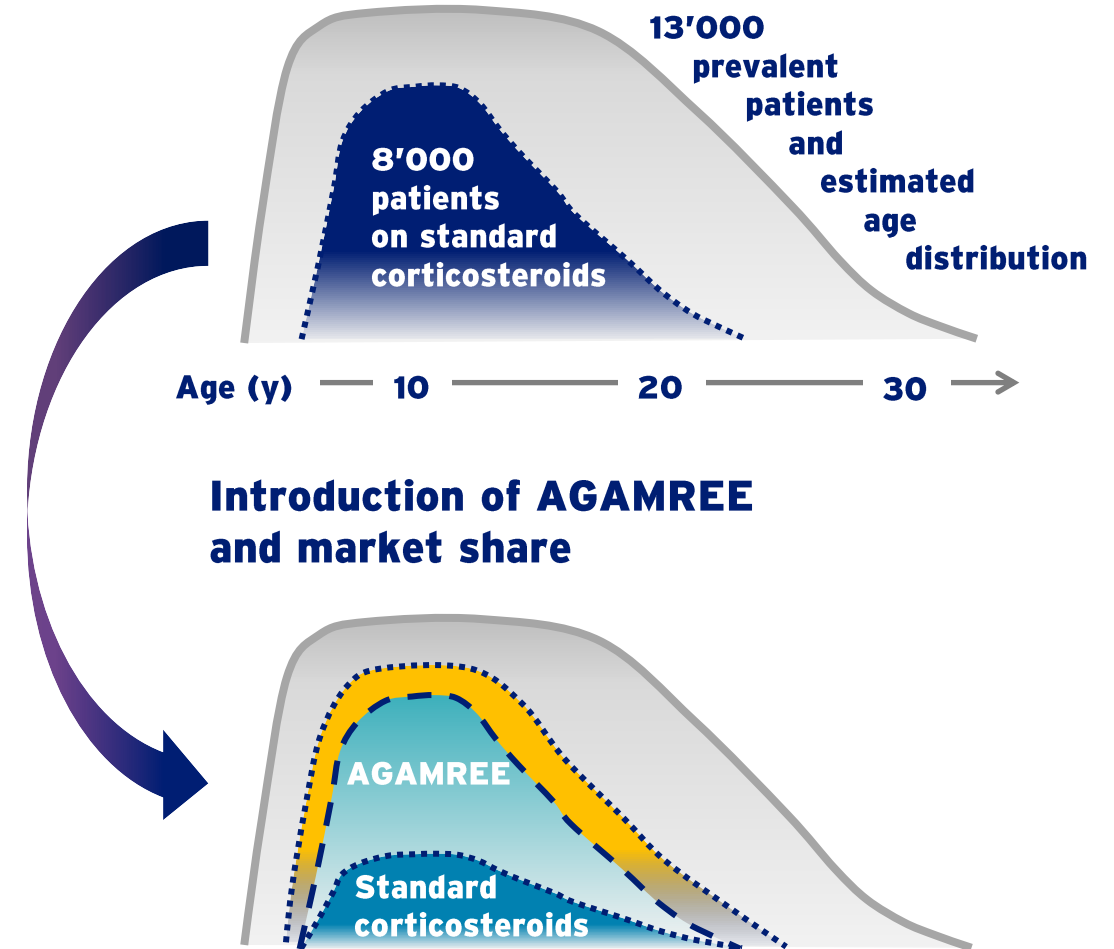
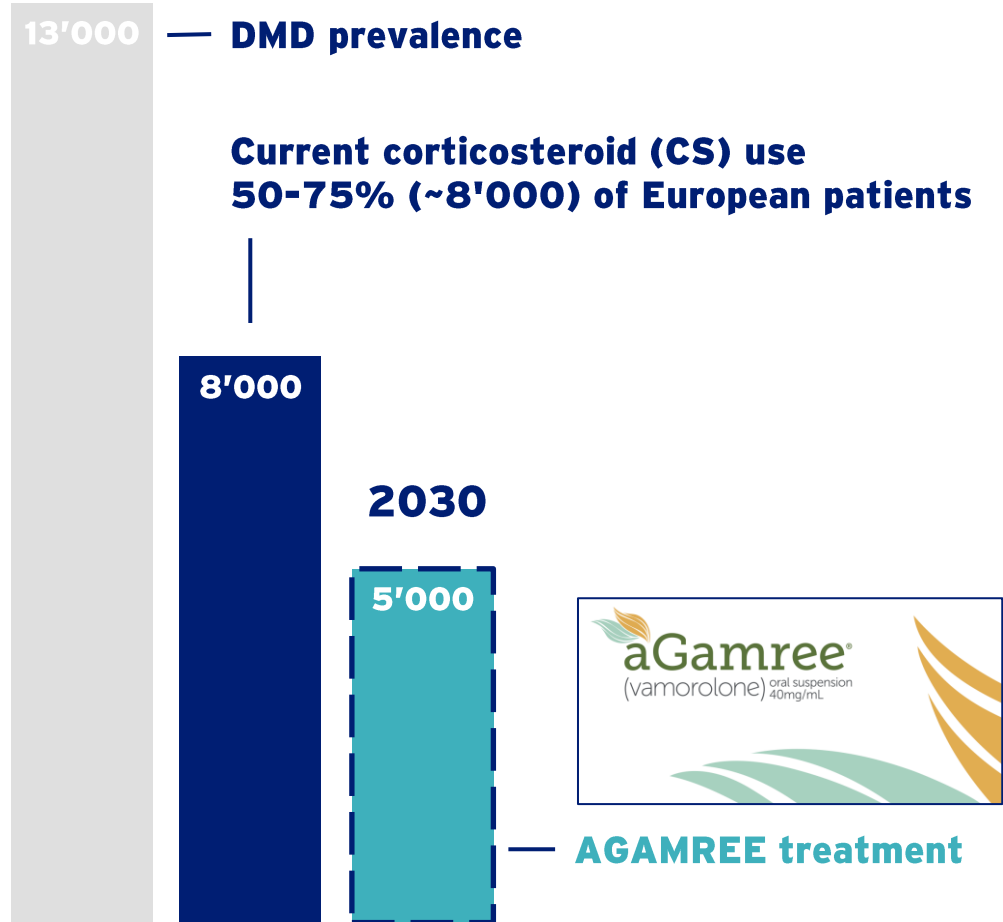


# **Thank you**

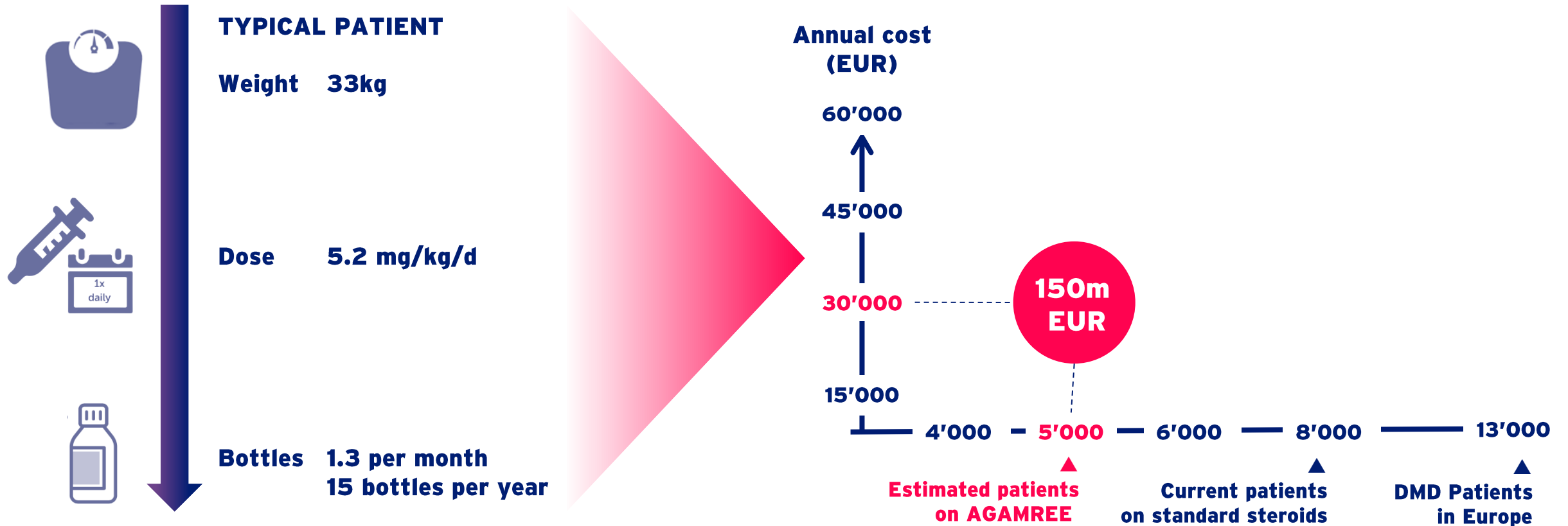
**For your time**

# **APPENDIX**

# Targeting 5'000 patients on AGAMREE® in Santhera European territory by 2030



# Expected peak sales of EUR >150 million in Santhera territory in 2030



Assumption based on patients treated,  
average weight, dose and price per bottle

# We are expanding manufacturing capacity

## Additional manufacturing sites in development:

- **Q4 2025:** First supply ready from second CMO
- **Ensures supply** for geographical expansion
- **Provides redundancy** and security of supply
- **Streamlines** supply chain & reduces lead time
- **Reduces** manufacturing cost and working capital



Catalyst Pharmaceuticals evaluates second manufacturer in US

Sperogenix Therapeutics plans for local manufacturing until 2029 (latest)



# Further geographic expansion targeted

**Santhera is actively pursuing further international partnerships with focus on:**

**Opportunity for additional mid-to long-term revenue and profitability with limited investment**

## **Step 1:**

- Turkey ✓✓
- GCC ✓✓
- Brazil/LatAm

## **Step 2:**

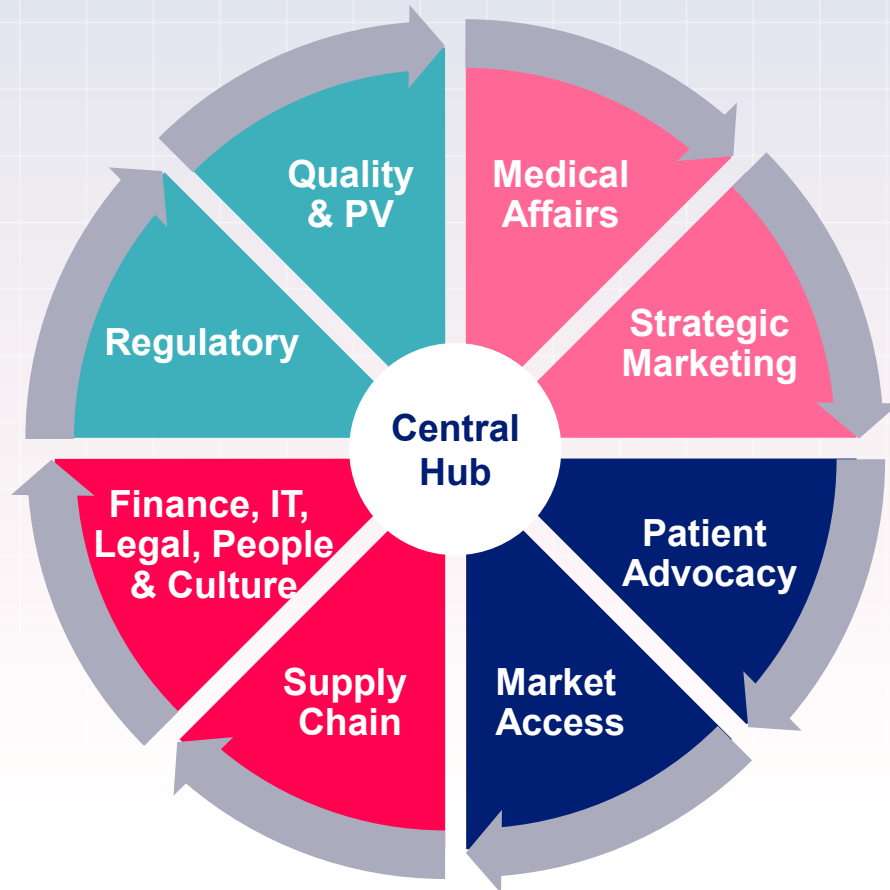
- S. Korea
- Australia/NZ
- India ✓
- Japan
- Russia tbd

**We are prioritizing countries based on market opportunity.**



# Nimble commercial set-up supports markets

Headquarters functions support own country teams, licensing and commercialization partners



## License Partners

- Catalyst (North America)
- Sperogenix (Greater China/SEA)

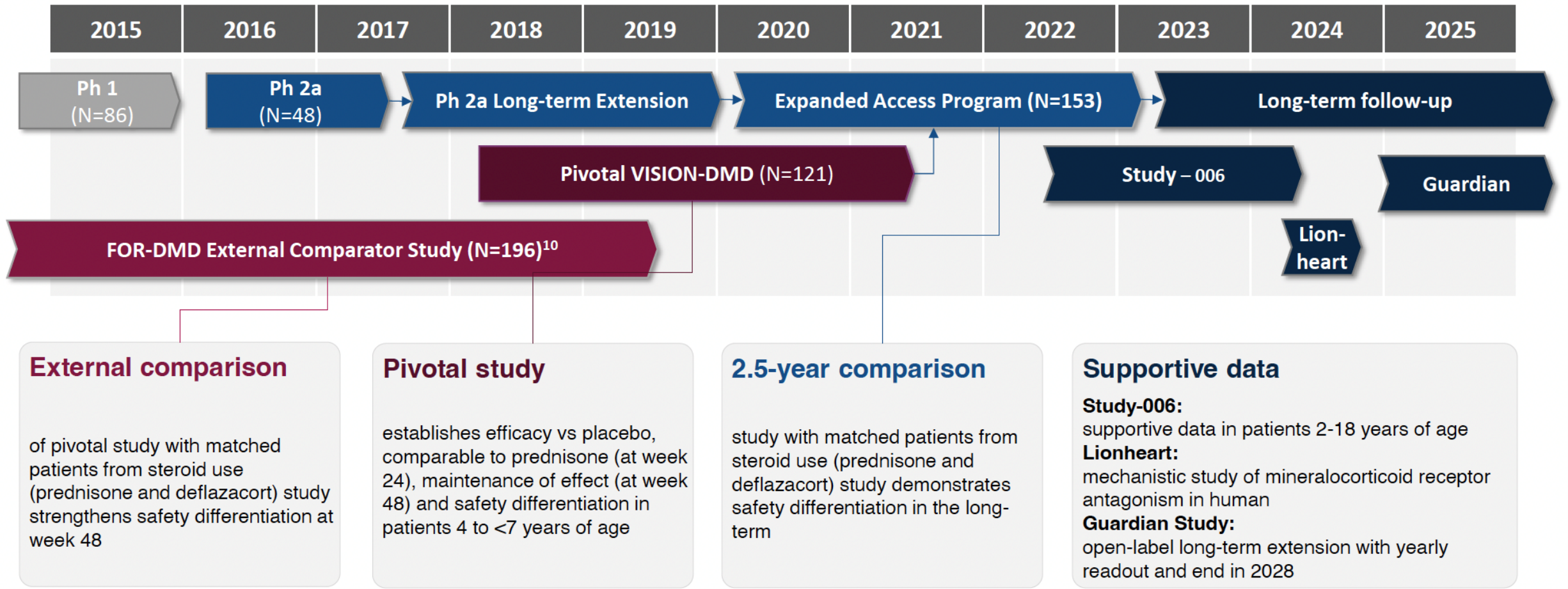
## Santhera

- Germany, Austria, Switzerland
- United Kingdom, Ireland
- France
- Italy
- Spain, Portugal
- Benelux
- Nordics

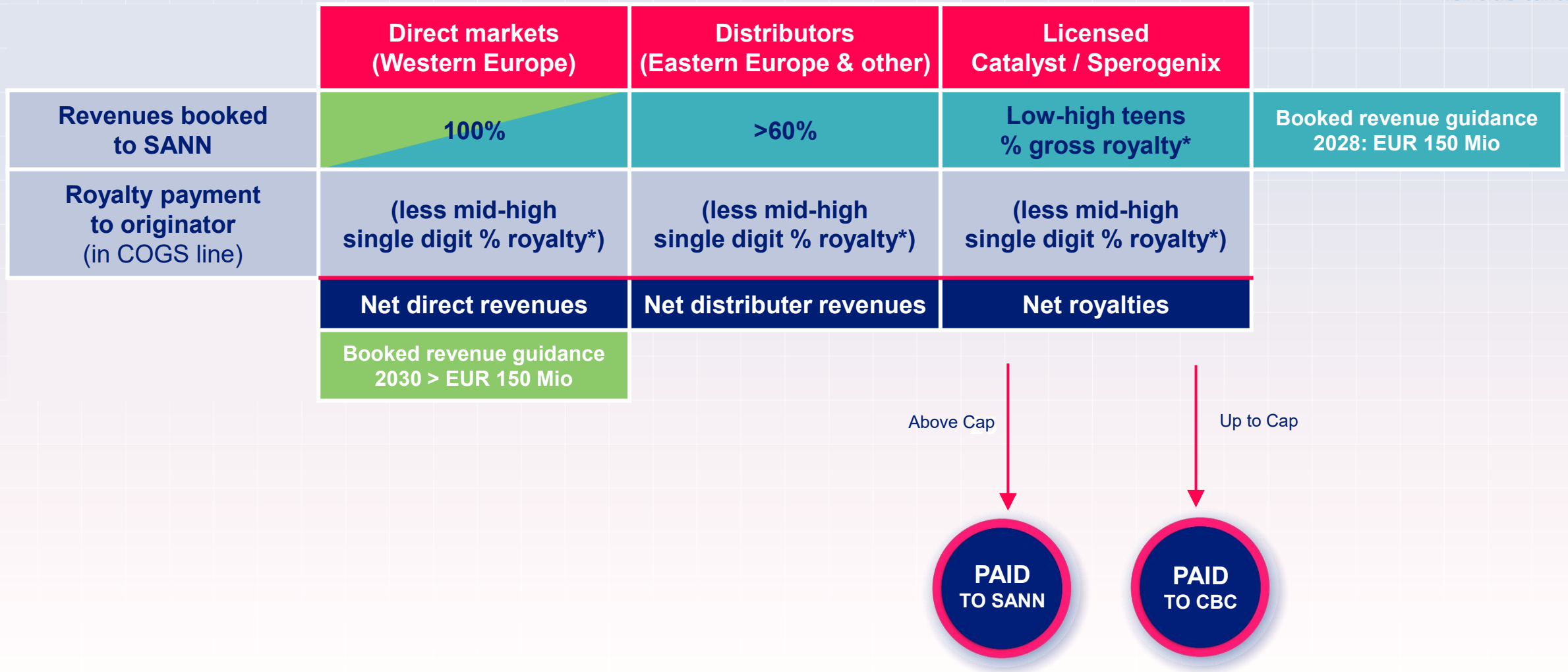
## Commercial Partners

- Genesis (20 European countries)
- Megapharm (IL), ASTE (Qatar), Clinigen (International/Named Patient)

# Our data builds on over 200 patient-years exposure from more than 200 boys treated for up to 7 years



# Summary revenue/royalty stream



# Executive Management Team



**Dario Eklund**  
Chief Executive Officer



**Catherine Isted**  
Chief Financial Officer



**Dr. Oliver P.  
Kronenberg**  
Chief Legal Officer and  
Secretary to the Board



**Dr. Shabir Hasham**  
Chief Medical Officer



**Marc Schrader**  
Chief Technology Officer



**Dr. Geert-Jan van  
Daal**  
Chief Commercial Officer