



**Conference Call  
Presentation  
Q1 2024**

Lund, April 18, 2024



# Forward-looking statements

This presentation may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future. Some of these forward-looking statements, by their nature, could have an impact on Hansa Biopharma's business, financial condition and results of operations [or that of its parent, affiliate, or subsidiary companies]. Terms such as "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to, changes in implementation of Hansa Biopharma's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Hansa Biopharma's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize imlifidase if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Hansa Biopharma's potential market and industry; the ability to develop new products and enhance existing products; the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

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# Strong commercial performance in the first quarter; Raised SEK ~372m (USD ~34.6m) in a directed share issue

## 1 Q1: Second consecutive quarter with solid IDEFIRIX product sales

- ✓ **SEK 47m in IDEFIRIX product sales**
  - Growth supported by U.K., Germany and France
  - Expect utilization in new centers and repeat use to drive sales continued sales growth in 2024
- ✓ **IDEFIRIX has achieved market access in 75% of the European transplant market**
  - Ongoing HTA processes in 11 countries
- ✓ **Cash runway extended into 2026**
  - Directed share issue was subscribed by international healthcare specialist investors
- ✓ **Evan Ballantyne joined Hansa as CFO**
  - Evan brings more than 30 years of international experience in life sciences

## 2 Pipeline: Clinical programs continue to progress as planned

- ✓ **Anti-GBM disease:**
  - Enrollment in pivotal Phase 3 50% complete;
- ✓ **Kidney Transplantation:**
  - ConfIdeS (Phase 3): Randomization completion mid-2024
  - European Post Approval Study: More than a doubling of patients treated in the last six months
- ✓ **Guillian-Barré Syndrome:**
  - Contextualized efficacy data from Phase 2 (exp 2024)
- ✓ **HNSA-5487:**
  - Further analysis around endpoints from Phase 1 to be completed in 2024 incl. selection of lead indication
- ✓ **SRP-9001-104 imlifidase in DMD:**
  - First high-level data read-out from Phase 1b (exp 2024)

# Continued progress against our key launch metrics led by in-market growth

## Market Building

7  
-

Medical guidelines implemented on a national level in 7 countries



## Market Access

14  
10

Market access secured in 14 European markets or 75% of the European transplant market

## Patient Identification

36  
8

Post Approval Study ~72% into completion

## Transplant Center Readiness & Use

~50  
25

~50 clinics are IDEFIRIX "ready" to treat patients

11  
8

Ongoing HTA processes in 11 countries; most recently in Ireland

✓

Eurotransplant:  
Two patients treated in the ET desensitization program; Patient assessment continues

25  
15

25 centers with clinical experience in transplantation incl. 17 centers that had repeat usage

Major markets to support growth going forward: France, U.K., Germany, Spain and Italy



# Strong momentum in ConfideS trial: More than 20% increase in activated sites during Q1 will accelerate randomization

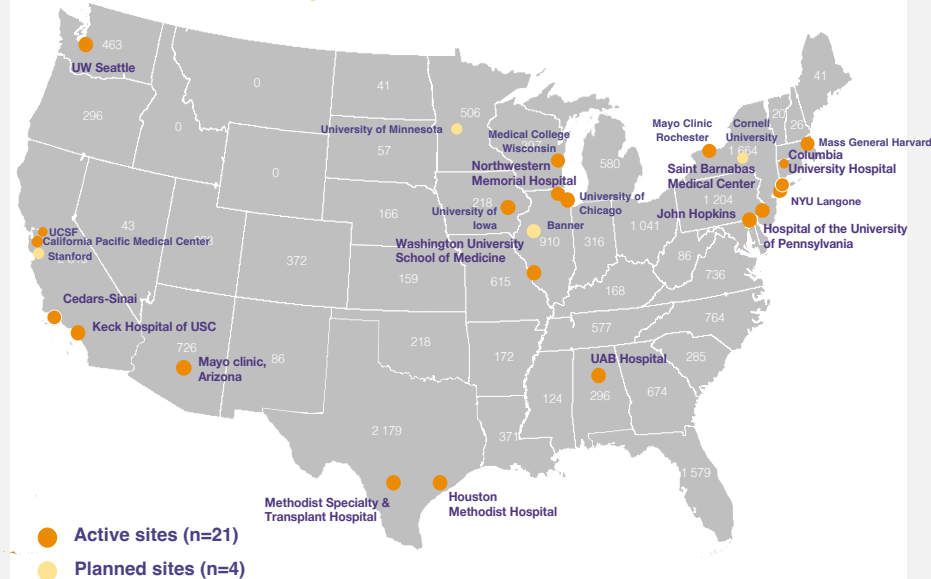
ConfideS phase 3 trial will further advance potential for imlifidase to address unmet need in desensitization

## U.S. ConfideS

### Phase 3

- Continue enrollment beyond 64 patients
- Currently 122 patients screened and enrolled
- 49 out of 64 targeted patients randomized
- Four additional clinics activated in Q1, increasing total number of recruiting clinics to 21 sites to accelerate randomization
- Randomization expected to complete mid-2024
- BLA filing in 2025

Involved ConfideS sites cover more than 20% of total transplantation volumes in the U.S<sup>1</sup>



<sup>1</sup>Organ Procurement & Transplantation Network, OPTN (2023)

# Significant progress in anti-GBM trial underpins potential for imlifidase in autoimmune disease

## First in class IgG cleaving enzyme

Unique antibody cleaving enzyme

Rapid onset of action

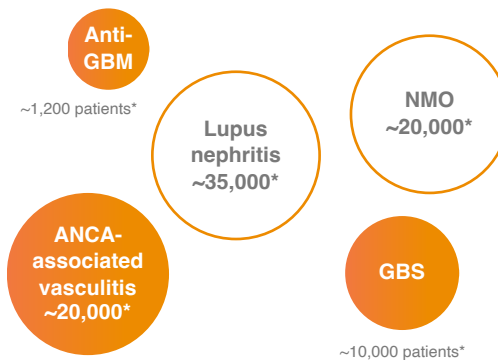
Targets IgG and inhibits IgG-mediated immune response

## Anti-GBM as catalyst to enter autoimmune

- A rare acute autoimmune disease affecting 1,200 people in US and Europe annually
- SoC (PLEX, steroids etc.) deemed insufficient
- PoC: Encouraging data from Phase 2 trial published in *JASN*
- Phase 3 study in 50 patients; 50% enrolled after 10 months

## Opportunity to expand into several IgG mediated autoimmune conditions

Potential indication universe (not exhaustive)



**Combination and stand-alone**

- Potential autoimmune indications (currently not pursued)
- Clinical programs

\*Total disease populations in EU & US, based on prevalence and population data

# Strong momentum across the pipeline in areas of high unmet need

## Phase 1

### HNSA-5487 (Lead from NiceR)



- Encouraging first read-out
- Ongoing collection of immunogenicity data in 2024

### Pre-treatment Gene Therapy Duchenne



- Study initiated in Dec'23
- First high-level data read-out from Phase 1 expected in 2024

## Phase 2

### Antibody Mediated Rejection (AMR)



- Primary endpoint met
- Plans to publish in peer-reviewed journal (2024)

### Guillain-Barré syndrome (GBS)



- Positive high-level data
- Further analysis in 2024 to contextualize efficacy data

### ANCA-associated vasculitis\*



- 10 patients to be enrolled
- 1/3 into completion

• Patients enrolled  
• Patients remaining

## Phase 3

### US ConfIdES Study in kidney



- 122 patients enrolled;
- 49 of 64 patients randomized
- Randomization to complete mid'24

### Post Approval Study in kidney



- 50 patients to be enrolled
- 72% into completion
- Study to complete by 2025

### Anti-GBM disease



- 50 patients to be enrolled
- 50% enrollment
- Complete enrollment in 2025

• Patients enrolled  
• Patients remaining

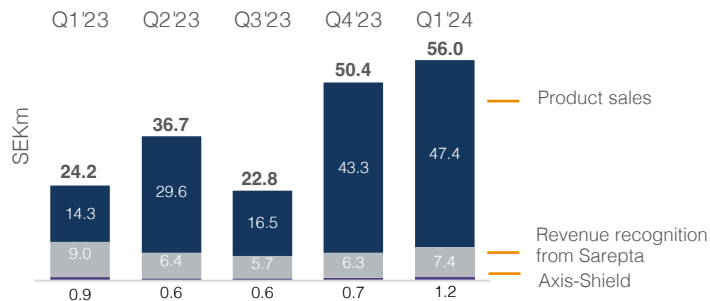
- Next generation enzymes
- Gene Therapy
- Autoimmune / Allograft
- Transplantation



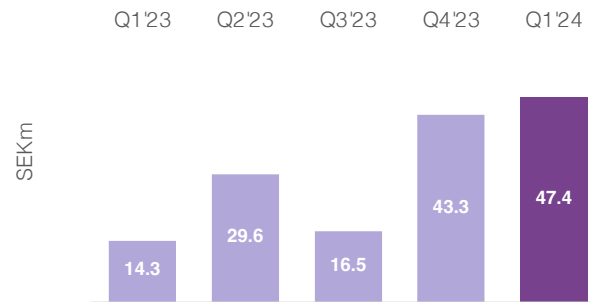
# Strong commercial performance with total Q1 revenue of SEK 56m including product sales of SEK 47m

Product sales improved +9% vs Q4 2023 and +231% vs Q1 2023;  
Growth driven by uptake in U.K., France and Germany

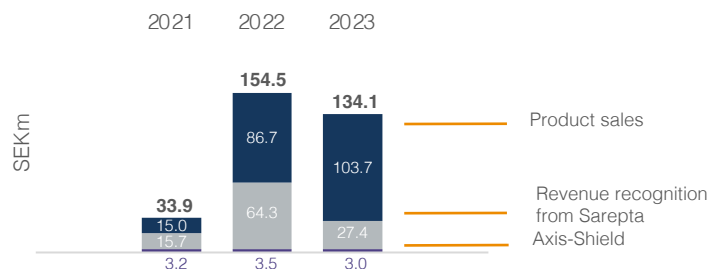
### Revenue (Q/Q)



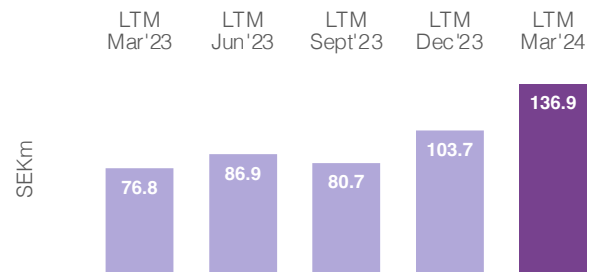
### Product Sales (Q/Q)



### Revenue (12M/12M)



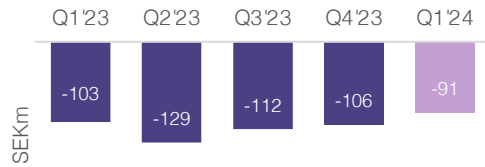
### Product Sales Rolling (Last 12 months)



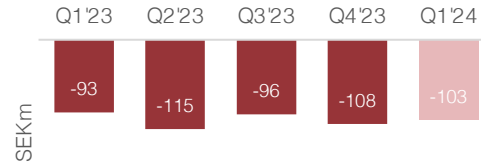


# Continued investments in commercialization and R&D activities

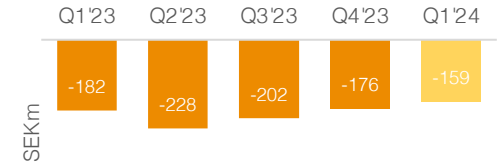
## SG&A expenses (Q/Q)



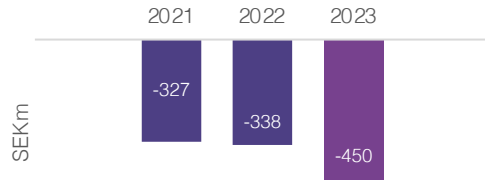
## R&D expenses (Q/Q)



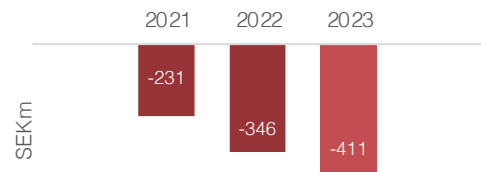
## Operating loss (Q/Q)



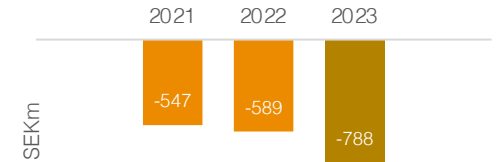
## SG&A expenses (12M/12M)



## R&D expenses (12M/12M)

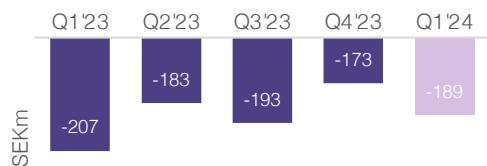


## Operating loss (12M/12M)

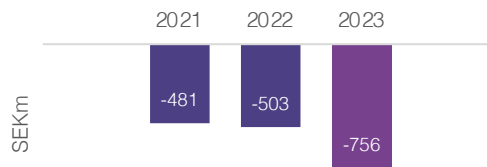


# Extended our cash runway into 2026 through a USD 34.6m directed share issue

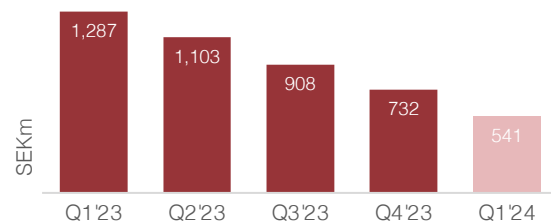
### Operating cash flow (Q/Q)



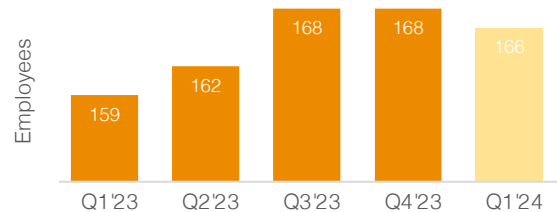
### Operating cash flow (12M/12M)



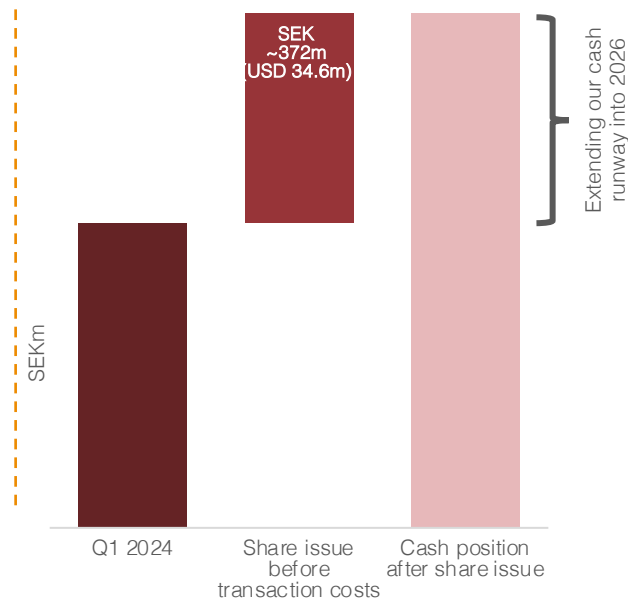
### Cash & short-term investments (Q/Q)



### Number of employees (Q/Q)



### Cash position post recent directed share issue



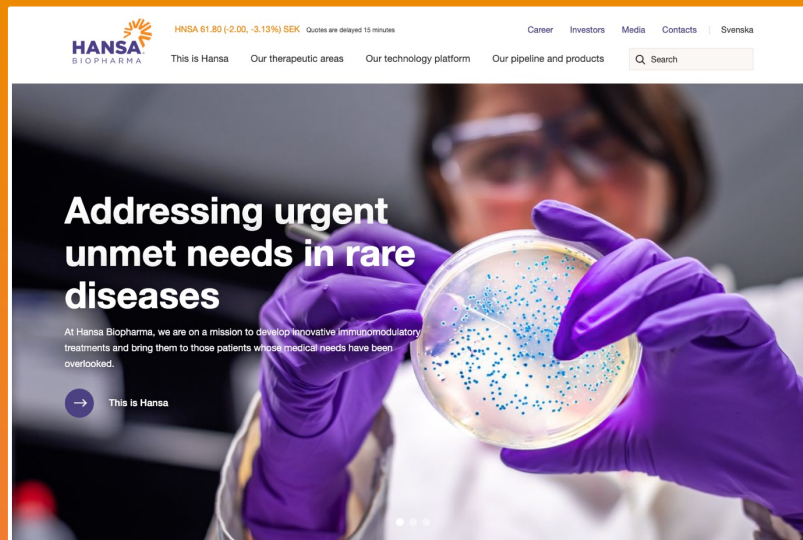
# Q4 2023 achievements and upcoming milestones 2024/25

2023	2024	2025
Q4 2023		
<ul style="list-style-type: none"> <li>✓ <b>HNSA-5487 (Lead NiceR candidate):</b> High-level data readout from Phase 1</li> <li>✓ <b>Long-term follow-up (Kidney tx):</b> 5-year data readout</li> <li>✓ <b>GBS Phase 2:</b> First data readout</li> <li>✓ <b>AMR Phase 2:</b> Full data readout</li> <li>✓ <b>Sarepta DMD pre-treatment Phase 1b:</b> Commenced clinical study</li> </ul>	<ul style="list-style-type: none"> <li>- <b>GBS Phase 2:</b> Outcome of comparative efficacy analysis</li> <li>- <b>Genethon Crigler-Najjar Phase 1/2:</b> Initiate clinical study with imlifidase prior to GNT-0003</li> <li>- <b>HNSA-5487 (Lead NiceR candidate):</b> Further analysis around endpoints to be completed in 2024 incl. lead indication</li> <li>- <b>U.S. ConfideS (Kidney tx) Phase 3:</b> Complete randomization</li> <li>- <b>Sarepta imlifidase in phase 1b in DMD:</b> First high level data read-out from phase 1b</li> </ul>	<ul style="list-style-type: none"> <li>- <b>U.S. ConfideS (Kidney tx) Phase 3:</b> BLA submission</li> <li>- <b>Anti-GBM disease Phase 3:</b> Complete enrolment</li> </ul>

# Q&A

... at Hansa Biopharma, we envision a world where all patients with rare immunologic diseases can lead long and healthy lives...

Visit our website  
[hansabiopharma.com](https://hansabiopharma.com)



# Broad clinical pipeline in transplantation, autoimmune diseases, and gene therapy

Project	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Partner	Next Anticipated Milestone
Imilifidase	EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Planned	Completed	Ongoing		EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	U.S. "ConfIdes": Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Ongoing				Completion of randomization (64 patients) mid 2024
	GOOD-IDES-02: Anti-GBM antibody disease	Completed	Completed	Completed	Ongoing				Complete enrollment (50 patients)
	16-HMedIdes-12: Active Antibody Mediated Rejection (AMR)	Completed	Completed	Completed					Plans to do sub-analysis for publication in peer-reviewed journal
	15-HMedIdes-09: Guillain-Barré Syndrome (GBS)	Completed	Completed	Ongoing					Comparative efficacy analysis 2024
	Investigator-initiated trial in ANCA-associated vasculitis <sup>3</sup>	Completed	Completed	Ongoing					Complete enrollment (10 patients)
	SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD)	Completed	Phase 1b					Sarepta Therapeutics	Complete enrollment
	Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)	Ongoing						Sarepta Therapeutics	Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease	Ongoing						AskBio	Preclinical research
Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome	Ongoing						Genethon	Preclinical research	
HNSA-5487	NICE-01 phase 1: HNSA-5487 – Lead candidate from the NiceR program	Completed	Ongoing						Further analysis around endpoints from Phase 1 to be completed in 2024 incl. selection of lead indication

Completed
  Ongoing
  Planned
  Post approval study running in parallel with commercial launch

<sup>1</sup> Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)

<sup>2</sup> Lorant et al., American Journal of Transplantation and 03+04 studies (Jordan et al., New England Journal of Medicine)

<sup>3</sup> Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

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## Calendar and events

**Apr 18, 2024 Interim Report for January-March 2024**

Apr 22, 2024 ABG Road Show, Stockholm

May 14, 2024 Capital One Biotech Disruptors Event, New York City

May 27, 2024 Carnegie Reverse Road Show, Lund

June 11, 2024 ABG Digital Autoimmunity, Transplantation, and Inflammation Seminar

**June 27, 2024 2024 Annual General Meeting**

**July 18, 2024 Half-year Report January-June 2024**

Sept 19, 2024 Pareto Securities' Annual Healthcare Conference, Stockholm

**Oct 24, 2024 Interim Report for January-September 2024**



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