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Redeye Theme: Regenerative Medicine & Cell Therapy

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HANSA BIOPHARMA

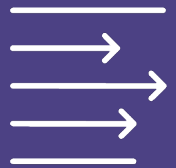
Hansa Biopharma today

A successful track record and a promising future…

A validated technology

- Commercial stage biotech company
- Approval in kidney transplantation (EU)
- Market Access in 14 European markets
- PoC in autoimmune diseases
- Three partnerships in gene therapy

Broad clinical pipeline



- Imlifidase being investigated in seven ongoing clinical programs in transplantation and autoimmune disease
- Ongoing clinical study in gene therapy
- HNSA-5487: Encouraging data from phase I first-in-human trial

Skilled and experienced team

- A high-performance organization with 20 years on average in life science
- Purpose driven culture
- Headquartered in Lund, Sweden (168 employees Dec'23)
- Operations in both EU and the US

Financial position

- Hansa is financed into 2025
- Market cap (SEK): ~2bn (Feb. 2023)
- Listed on Nasdaq Stockholm
- 20,000 shareholders
- Foreign ownership make up ~43%

3

Hansa enters 2024 in a strong position to successfully execute on our key priorities

1 Q4: Strong commercial performance

- ✓ **Strong revenue generation in Q4 2023**
  - SEK 43m in Idefirix product sales
  - Growth supported by U.K., Germany, and Spain
- ✓ **Commercial partnership with NewBridge**
  - Covering MENA in kidney transplantation
- ✓ **Market Access for Idefirix® in Slovenia**
- ✓ **Initiated restructuring program**
  - Will provide SEK 75-85m in annual savings

2 Pipeline: Encouraging read-outs across several indications

- ✓ **AMR:** Full data from AMR phase 2 study
- ✓ **GBS:** Positive high-level phase 2 data
- ✓ **Anti-GBM:** Positive momentum continues
- ✓ **HNSA-5487:** Encouraging high-level P1 data
- ✓ **Kidney Transplantation:**
  - ConfIdeS: Randomization completion mid-2024
  - Sustained positive outcomes out to year 5
- ✓ **SRP-9001-104 imlifidase in DMD:**
  - Initiation of phase 1 study mid-December 2023

Our unique antibody cleaving enzyme technology may have relevance across a range of indications

Targeting rare IgG mediated diseases

Auto-immune diseases

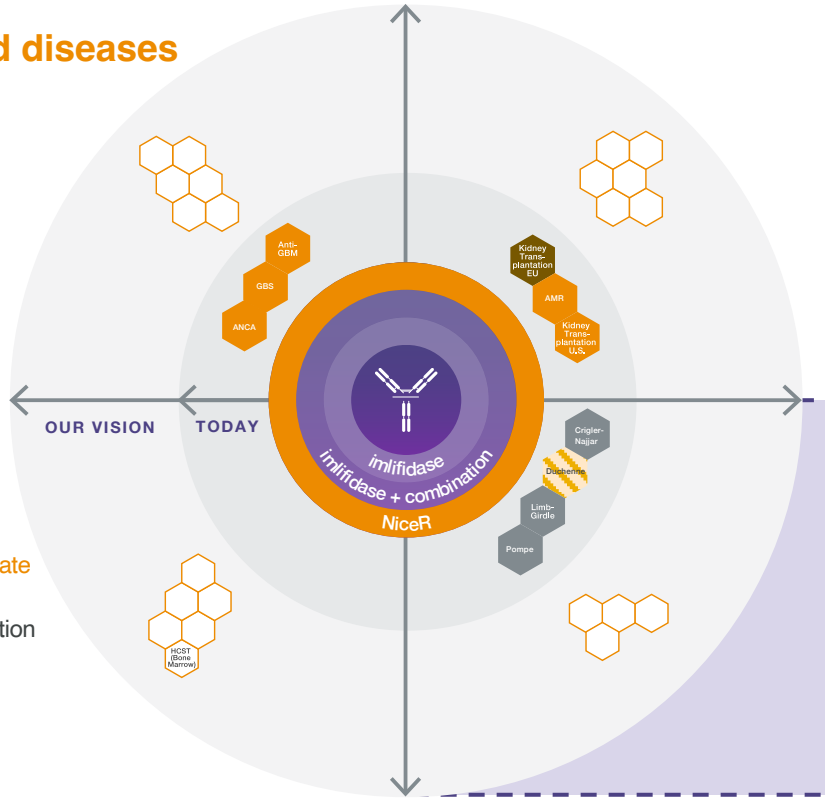
Anti-GBM disease paves the way for development in other autoimmune diseases

- Rapidly progressive glomerulonephritis
- Neurological disorders
- Skin and blood disorders

New therapies

IgG-cleaving enzymes to enable or even potentiate cancer therapy

- Allogenic stem cell (bone marrow) transplantation (HSCT)



Transplantation

Shaping a new standard for desensitization will help enable new indications in transplantations

- Antibody mediated rejection (AMR) in kidney transplantation
- Other transplantation types

Gene therapy

Exploring opportunities in gene therapy

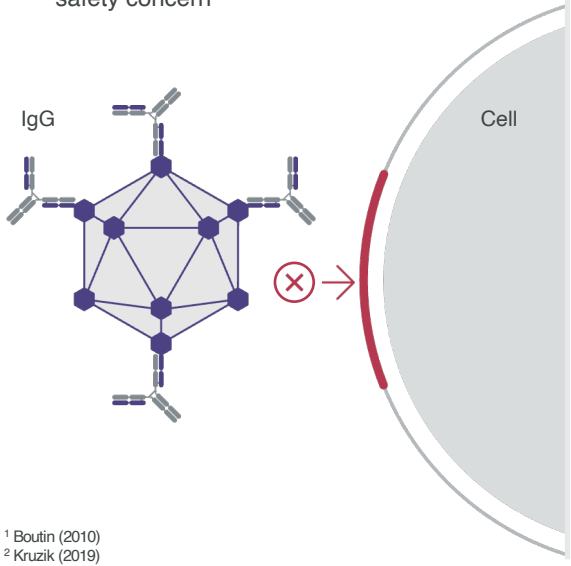
- Encouraging preclinical data published in Nature
- Validation through collaborations with Sarepta, AskBio, and Genethon
- Wide indication landscape beyond

Regulatory approval (conditional) | Clinical development | Planned clinical trial | Partnership (preclinical development) | Preclinical development | Potential indications (currently not pursued)

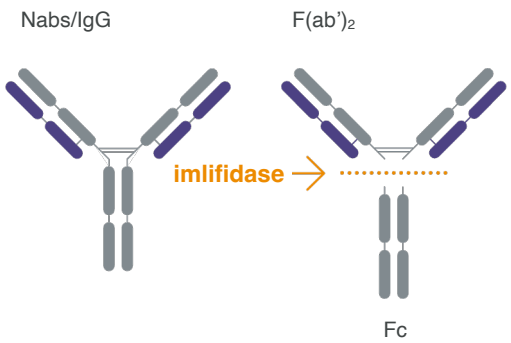
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

Between approximately 5%-70%[1,2] of patients considered for gene therapy treatment carry neutralizing anti-AAV antibodies forming a barrier for treatment eligibility

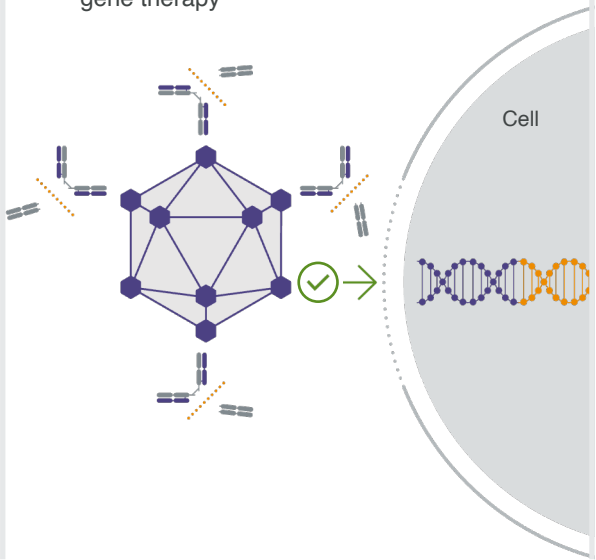
1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



2 Imlifidase is a unique IgG antibody-cleaving enzyme that cleaves IgG at the hinge region with extremely high specificity



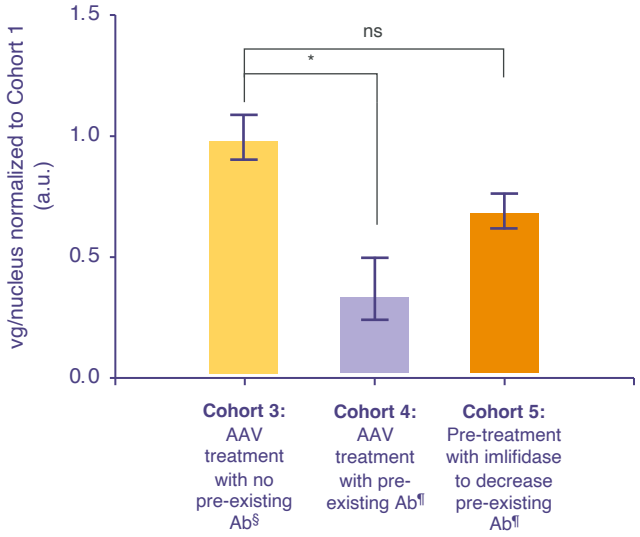
3 The idea is to eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy



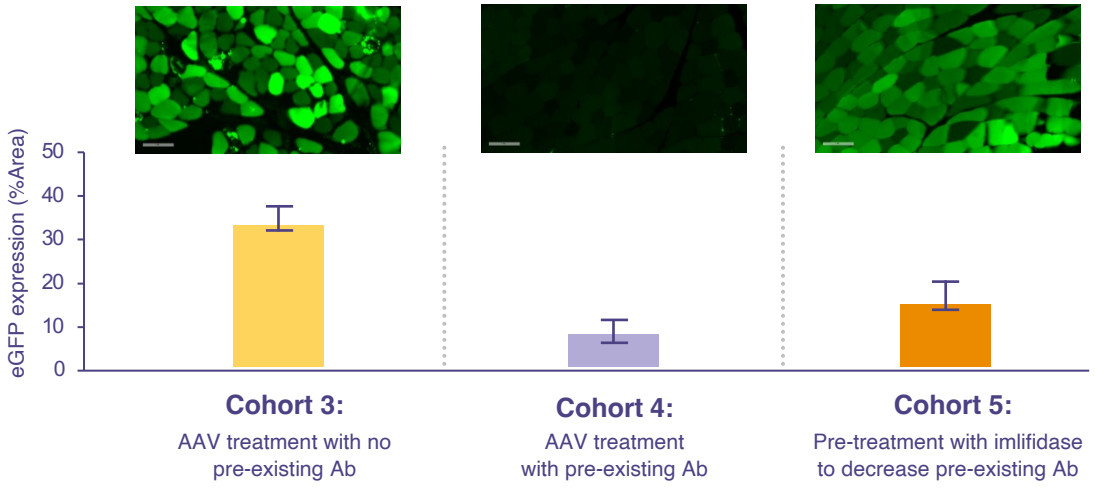
[1] Boutin (2010)
[2] Kruzik (2019)

Imlifidase pre-treatment decreases pre-existing antibodies and enhances transduction and transgene expression in NHPs

Transduction†



Expression in Skeletal Muscle‡



*P<0.05. †Data are represented as mean ± SEM and analyzed by one-way ANOVA followed by post-hoc analysis with Dunnett's multiple comparison test . ‡Data are represented as the mean ± SEM for the percent area for all of the muscle tissues analyzed at terminal necropsy. §AAVrh74 titer ≤1:400. ¶AAVrh74 titer 1:800–1:1600.

AAV, adeno-associated virus; AAVrh74, adeno-associated virus rhesus isolate serotype 74; Ab, antibody; a.u., arbitrary units; eGFP, enhanced green fluorescent protein; NHP, non-human primate; ns, not significant; vg, viral genome.

Global exclusive agreements with three partners in gene therapy

To develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications

Partner	Indication exclusivity	Collaborative research, development and commercialization
SAREPTA THERAPEUTICS	**Duchenne Muscular Dystrophy (DMD)** 1/3,500 to 5,000 male births worldwide	Antibody cleaving enzyme technology → Preclinical Development ✓ → Initiated Clinical Development ✓ → Regulatory Approvals → Commercialization
SAREPTA THERAPEUTICS	**Limb-Girdle Muscular Dystrophy** Global prevalence of ~1.6 per 100k individuals	Antibody cleaving enzyme technology → Preclinical Development ✓ → Clinical Development → Regulatory Approvals → Commercialization
AskBio	**Pompe disease** Approximate incidence is 1 per 40,000 births, or ~200 per year in the US + EU	Antibody cleaving enzyme technology → Preclinical Development ✓ → Clinical Development Phase 1/2 study (feasibility)
GENETHON CURE THROUGH INNOVATION	**Crigler-Najjar syndrome** Approximately incidence is 0.6-1 case per one million people or 600 patients in Europe and the U.S	Antibody cleaving enzyme technology → Preclinical Development ✓ → Clinical Development Phase 1/2 study (feasibility)

Exclusive option for AskBio to negotiate a potential full development and commercialization agreement

The initial agreement is focused on research and development

The companies will consider a subsequent agreement for commercialization at a later stage

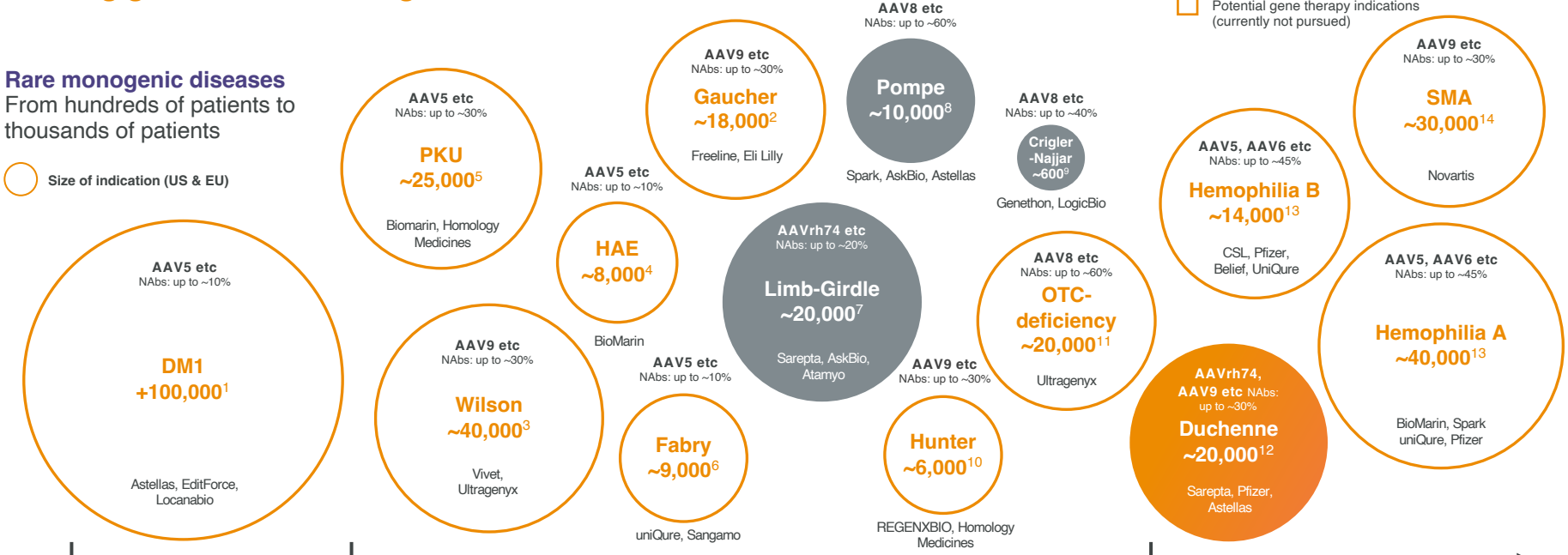
Systemic gene therapy is an emerging opportunity

with a focus on the potential to correct diseases causing genes in rare monogenic diseases

Rare monogenic diseases
From hundreds of patients to thousands of patients

Size of indication (US & EU)

Preclinical programs with Sarepta, AskBio and Genethon
Ongoing clinical study with Sarepta
Potential gene therapy indications (currently not pursued)



Numbers are estimated based on population and prevalence

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Duchenne muscular dystrophy (DMD) is progressive and causes irreversible muscle damage and loss of function

Incidences

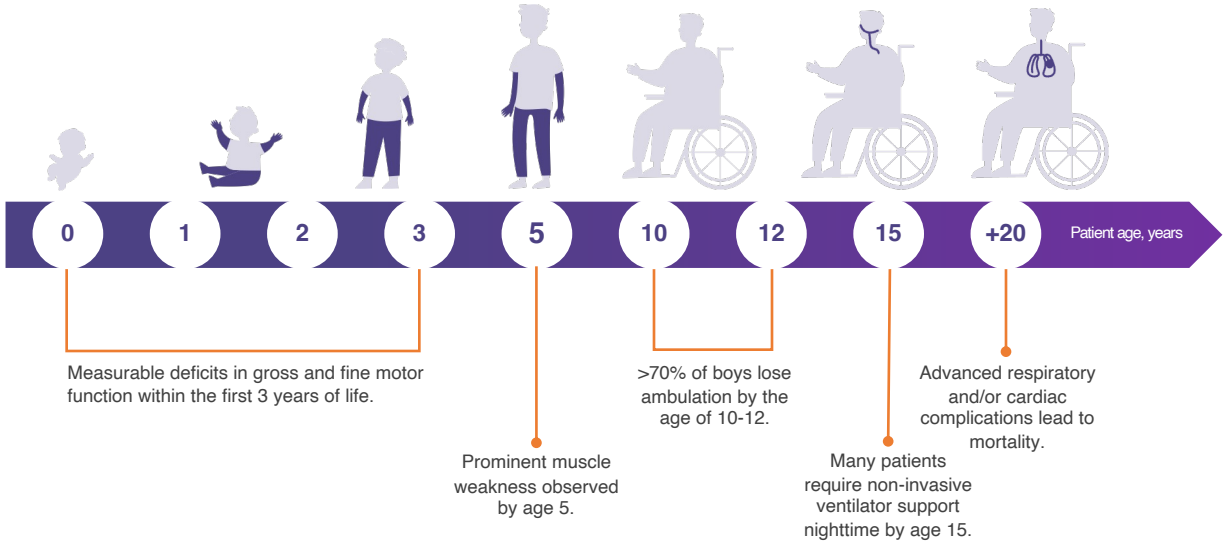
1 in **3,500** to **5,000**
male births worldwide

~14% have pre-existing IgG antibodies to rh74

High unmet need

- DMD is a rare, fatal neuromuscular genetic disease
- Muscle weakness noticeable by age 3-5, and most patients use a wheelchair by the time they are 12, many require respiratory aid by late teens.
- Life expectancy 26-30 years

DMD signs at early age, with most patients using a wheelchair by age 12



Source:
Sarepta Therapeutics, https://www.sarepta.com/ [Accessed 2023-06-13]


HANSA
BIOPHARMA

2023 achievements and upcoming milestones 2024/25

2023

Q4 2023

- **HNSA-5487 (Lead NiceR candidate):** High-level data readout from Phase 1
- **Long-term follow-up (Kidney tx):** 5-year data readout
- **GBS Phase 2:** First data readout
- **AMR Phase 2:** Full data readout
- **Sarepta DMD pre-treatment Phase 1b:** Commence clinical study

2024

- **GBS Phase 2:** Outcome of comparative efficacy analysis
- **Genethon Crigler-Najjar Phase 1/2:** Initiate clinical study with imlifidase prior to GNT-0003
- **HNSA-5487 (Lead NiceR candidate):** Further analysis around endpoints to be completed in 2024 incl. lead indication
- **U.S. ConfIdeS (Kidney tx) Phase 3:** Complete randomization
- **Sarepta imlifidase in phase 1b in DMD:** First high level data read-out from phase 1b

2025

- **U.S. ConfIdeS (Kidney tx) Phase 3:** BLA submission
- **Anti-GBM disease Phase 3:** Complete enrolment

Contact our Investor Relations and Corporate Affairs team

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Calendar and events

Feb 14, 2024 Redeye Cell Therapy & Growth Day, Stockholm

Feb 28, 2024 Ökonomisk Ugebrev Life Science Event, Copenhagen

March 4-5, 2024 TD Cowen Healthcare Conference, Boston

March 6, 2024 Life Sciencedagen, Sahlgrenska Universitetssjukhuset Gothenburg

Mar 20, 2024 Annual Report 2023

April 8-11, 2024 Needham Healthcare Conference (virtual)

April 16-17, 2024 Van Lanschot Kempen Life Science Conference, Amsterdam

Apr 18, 2024 Interim Report for January-March 2024

June 27, 2024 2024 Annual General Meeting

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

Oct 24, 2024 Interim Report for January-September 2024