HANSA BIOPHARMA

Conference Call Presentation

Interim report January – September 2023

Lund, October 26, 2023

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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Continued progress with our strategic priorities

1 Q3: Continued progress against our key launch metrics

- Anticipate sales growth in coming periods as positive first outcomes leads to repeat usage
- Several agreements in new markets and increased access to organs to support growth
- Continued progress against key launch metrics; Sales to remain volatile we reach scale
- First patients selected for treatment through Eurotransplant's new pilot program
- ESOT Congress: 600+ attendees from the transplant community attended Hans-sponsored symposium

2 Advancing the pipeline

- Anti-GBM: Good momentum in pivotal phase 3
- ANCA: New IIT phase 2 initiated
- HNSA 5487: Encouraging high-level data from phase 1 trial in healthy volunteers
- Kidney Transplantation:
  - ConfIdeS: Randomization completion mid-2024 (BLA submission expected in 2025)
  - Sustained positive outcomes in 5 year follow up study

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The long-term market uptake of Idefirix is highly dependent on successful early experiences in patients

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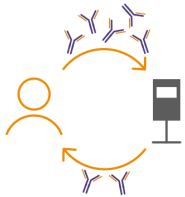
For decades, medical practice (SoC) in transplantation has been predicated on compatibility as modalities came with certain limitations

PLEX

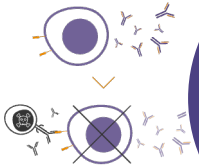


Plasmapheresis immunoadsorption
Mechanically removes antibodies from circulation

IVIg

immunoglobulins
IVIg/SCIg contains healthy antibodies that replaces pathogenic antibodies

B-cells



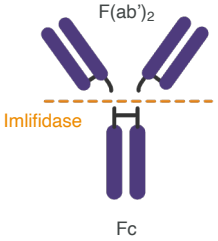
B-cell depleting mAbs
Lowering antibody levels through B-cell elimination

1950s → 1980s → 1990s

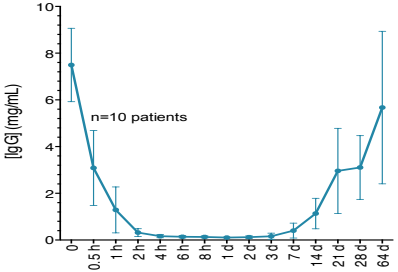
..with Idefirix we are changing the entire ecosystem in transplantation

Idefirix addresses the limitations of these other modalities and is the first and only approved drug to enable incompatible kidney transplants

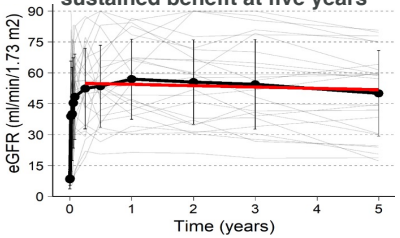
Idefirix antibody-cleaving enzyme



Inactivates IgG in 2-6 hours creating an IgG-free window



Long term data confirms sustained benefit at five years



Continued progress against key launch metrics; Major markets to support growth going forward

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Market Development

5 | -

Medical guidelines issued by ESOT

National level

600+

ESOT Congress: Hansa-sponsored symposium with participation from >600

Market Access

13 | 9

Market access secured in 13 key European markets incl. EU4+UK

10 | 8

Ongoing HTA processes in ten countries incl. Portugal and Switzerland

Patient Identification

16 | 2

Post Approval Study ~1/3 into completion

✓

Eurotransplant: First patients selected for new desensitization program

Transplant Center Readiness & Use

~50 | 25

~50 clinics are Idefirix "ready" to treat patients

20+ | 10

20+ centers have treated patients overall

Major markets to support growth going forward

France (repeat usage); Market expansion into new markets incl. U.K., Germany, Spain and Italy

Oct 2023 | Oct 2022

Eurotransplant Desensitization Program set to transform desensitization across eight European membership countries

First patients selected for treatment through the Desensitization Program

Eurotransplant

Donor age <65

Acceptable Mismatch (AM) Program

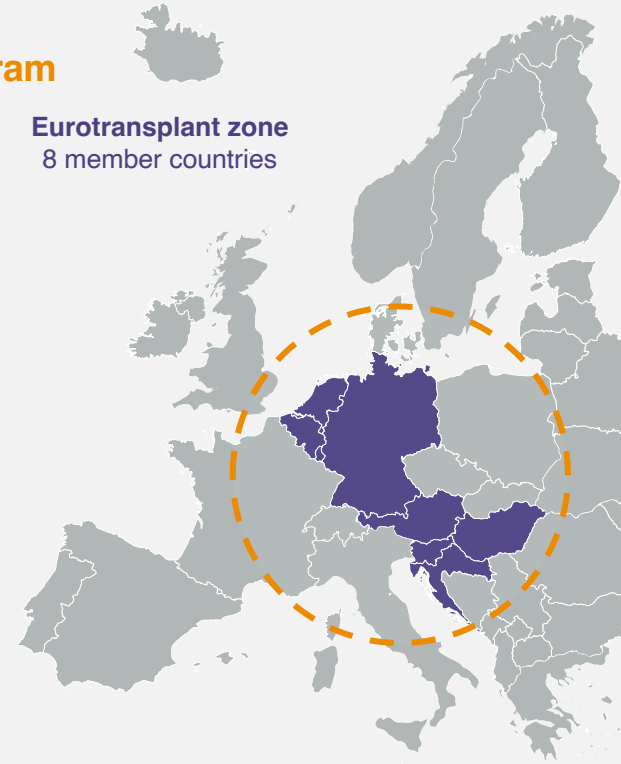
Eurotransplant Kidney Allocation System (ETKAS)

Incompatible patients

Desensitization Program
(imlifidase tier)

Inclusion Criteria:
2 years on ETKAS waitlist +
3 years in AM program

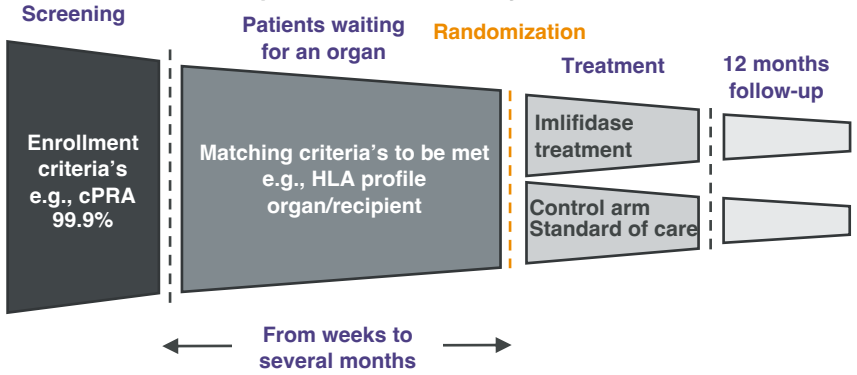
Pilot
idefirix
imlifidase
20 patients with the longest waiting time



Potential to disrupt transplantation care in the U.S. with imlifidase

~2,500 highly sensitized patients that have not been transplanted despite prioritization points on the waitlist

Increasing patient enrollment and number of active sites to complete randomization by mid-2024



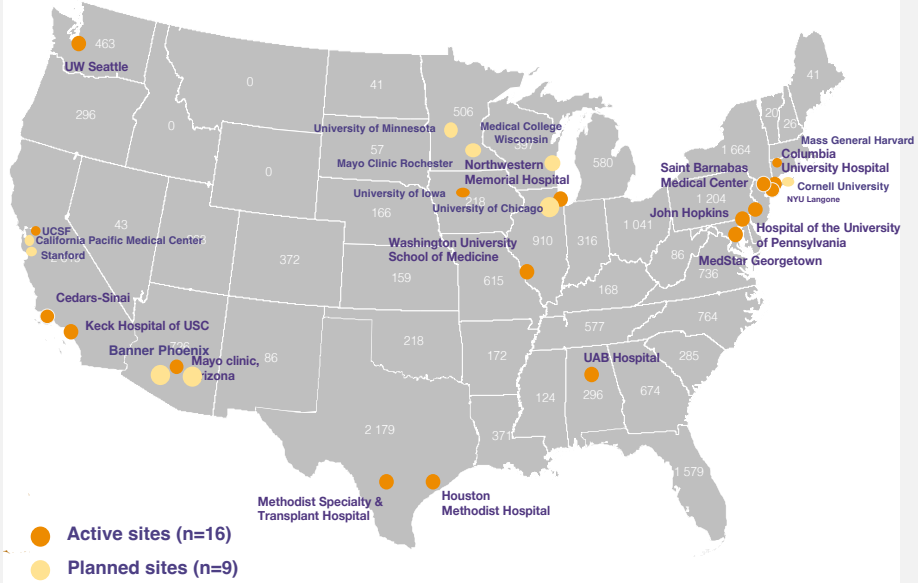
Phase 3

U.S. ConfIdeS

- Continue enrollment beyond 64 patients; Currently 87 patients screened and enrolled and more than half of the targeted patients randomized
- Expansion of no sites from currently 16 to 25 to accelerate randomization
- Randomization expected to be completed Mid-2024 with BLA filing under the accelerated approval path in 2025

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

Involved ConfIdeS sites cover more than 20% of total transplantation volumes in the U.S[1]



[1]Organ Procurement & Transplantation Network, OPTN (2023)

Long term data confirms sustained benefit at five years in graft survival and overall patient survival

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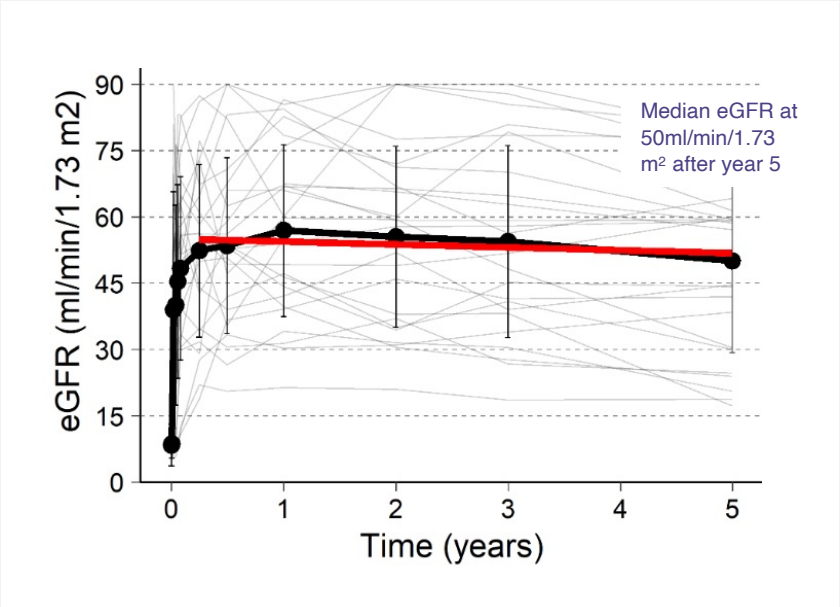
Results is a continuation of the 3-year data

- After 5 years graft survival (death censored) was 82%, in line with outcomes seen at 3-years post-transplant
- Patient survival rate was 90%[1]
- At five years kidney function measured by mean estimated glomerular filtration rate (eGFR) was 50 ml/min/m^2 at year 5
- The 5-year data is a continuation of the analysis at 3-years of crossmatch positive patients published in the *American Journal of Transplantation*
- Further data from extended pool analysis expected in 2024

[1] Three deaths occurring between six months and one year, and no deaths occurring between one and five years (not related to imlifidase)

Stable long-term outcomes on graft survival and patient survival



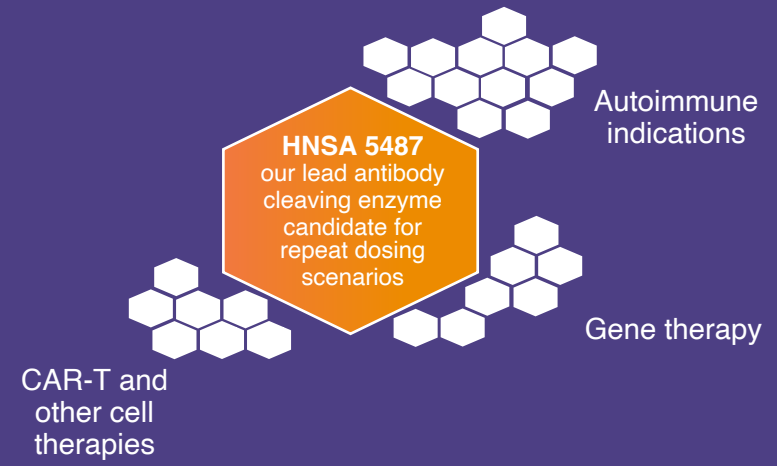
Encouraging high-level results for HNSA-5487 first in human trial

Lower immunogenicity would potentially allow for repeat dosing in a range of IgG-driven indications

High-level results from 36 healthy volunteers

- Study design: Double blind, randomized, placebo-controlled trial evaluating safety, tolerability, PK and PD of SAD of HNSA-5487
- Demonstrated tolerability and safety
- Pharmacodynamics (PD) showed a fast and complete cleavage of IgG to $F(ab')_2$ and Fc-fragments with increasing doses
- Pharmacokinetics (PK) was in line with expectations
- Further analysis around endpoints and immunogenicity profile to be completed in 2024 incl. selection of lead indication

Potential indication universe for HNSA-5487



Continued momentum with seven clinical programs in areas of high unmet need

New clinical program in DMD planned for Q4

Phase 1

HNSA-5487 (Lead from NiceR)

Completed

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

Pre-treatment Gene Therapy Duchenne

Not started

- Partnered with Sarepta
- Initiate clinical study (phase 1b) in a small patient group Q4'23

Phase 2

Antibody Mediated Rejection (AMR)

Completed

- Positive topline data on primary endpoint announced Nov 2022
- Full data read-out in Q4 2023

Guillain-Barré syndrome (GBS)

Completed

- Safety and tolerability data expected in Q4 2023
- Matched control data expected in 2024

ANCA-associated vasculitis

Patients enrolled
Patients remaining

- First three patients treated out of a target of ten in investigator-initiated Phase 2 study

Phase 3

US ConfIdeS Study in kidney

Overenrolled

- 87 patients enrolled; more than half of 64 targeted patients randomized
- Randomization to complete mid'24
- BLA submission 2025

Post Approval Study in kidney

- 50 patients to be enrolled at 20-25 clinics in Europe
- ~1/3 into completion. Study to complete by the end of 2025

Anti-GBM disease

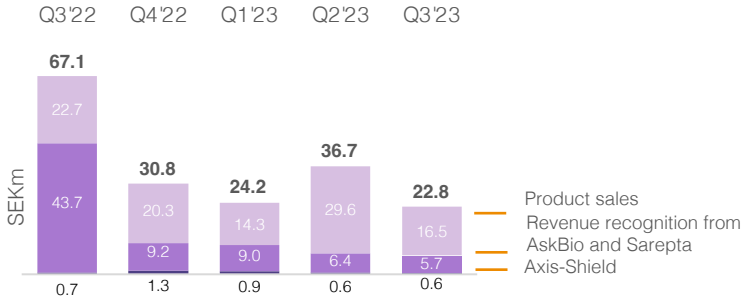
Patients enrolled
Patients remaining

- 50 patients to be enrolled at 30-40 sites (25 active sites)
- Granted orphan drug designation (FDA, EMA)

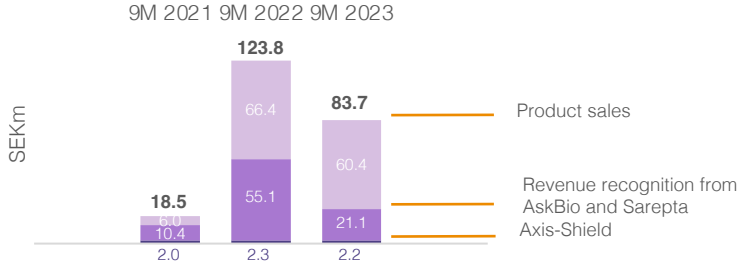
Next generation enzymes
Gene Therapy
Autoimmune / Allograft
Transplantation

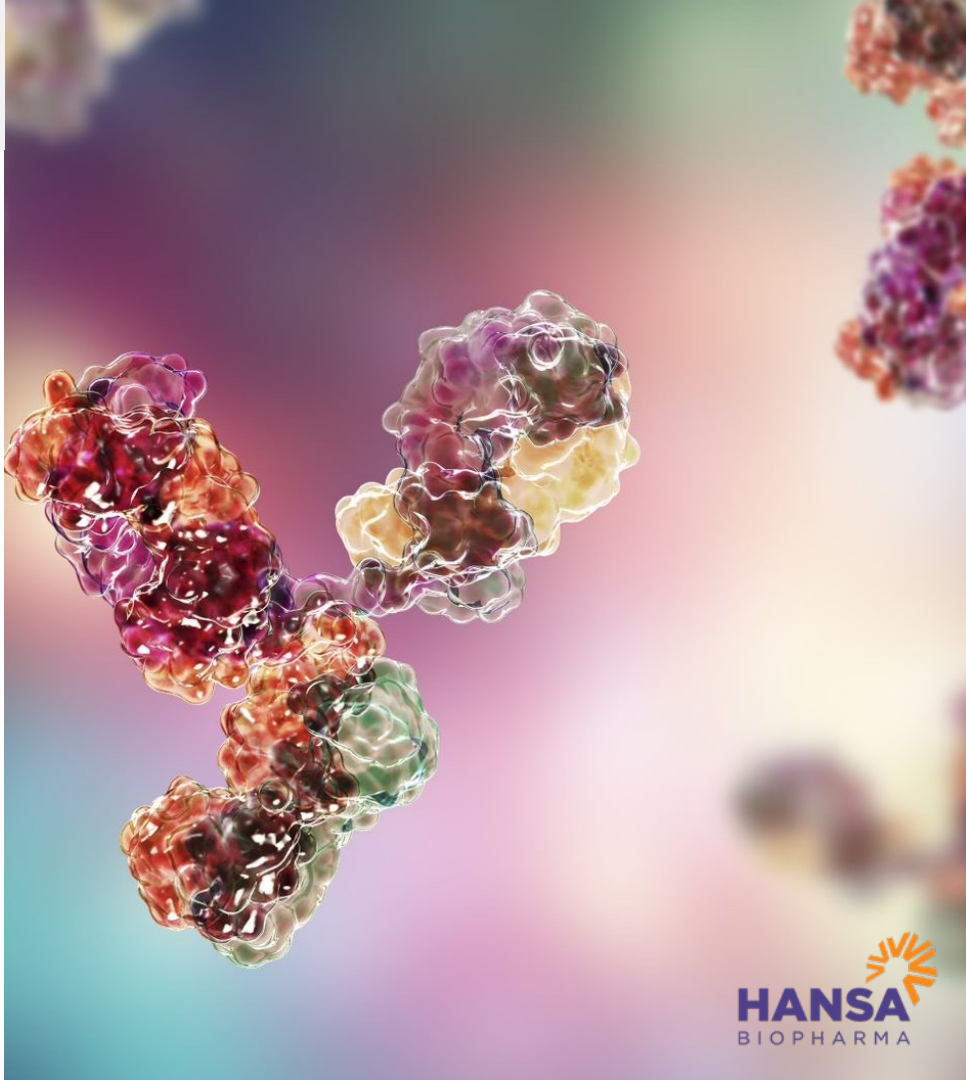
Q3 2023 Revenue amounted to SEK ~23m including SEK ~17m in product sales

Revenue (Q/Q)



Revenue (9M/9M)





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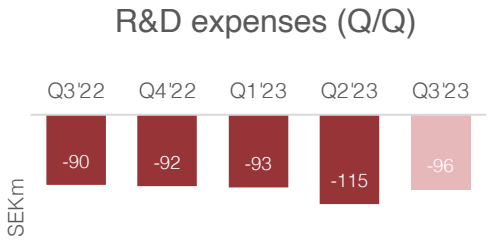
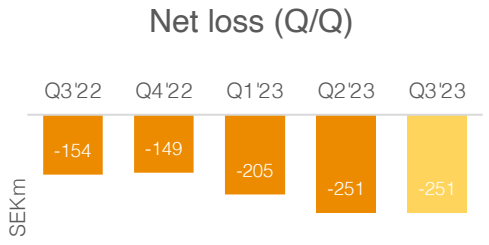
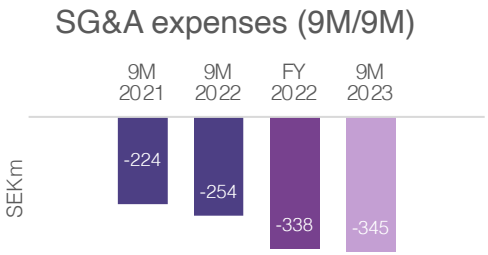
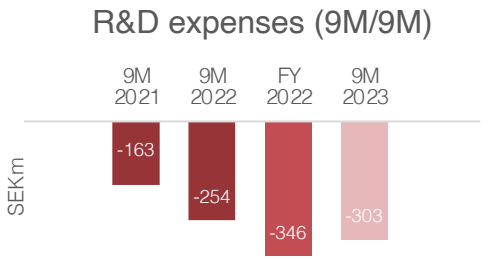
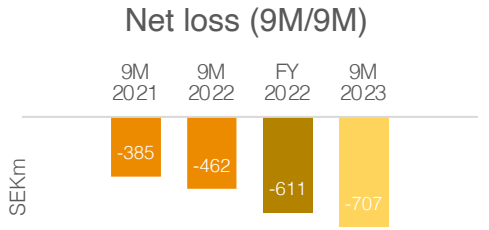
Continued investments in commercialization and R&D activities











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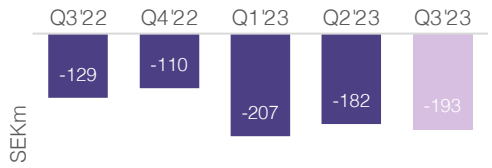
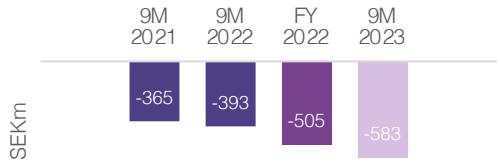
With current cash position and projected burn-rate, Hansa's operations are financed into 2025

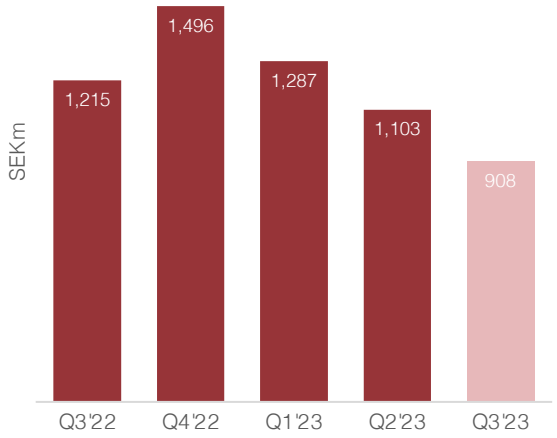
Operating cash flow (Q/Q)



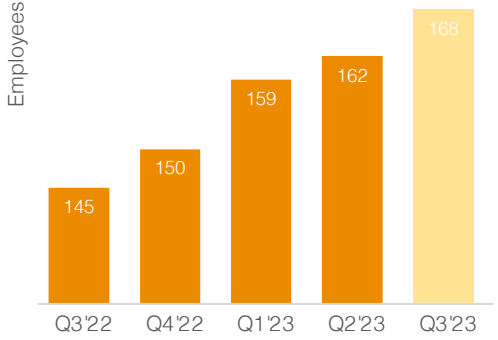
Operating cash flow (9M/9M)



Cash & short-term investments (Q/Q)



Number of employees (Q/Q)



Achieved and upcoming milestones

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2023

9M 2023

- ✓ **U.S. ConfIdeS (Kidney tx) Phase 3:** Continued enrollment beyond 64 patients
- ✓ **Anti-GBM disease Phase 3:** First patient enrolled
- ✓ **GBS Phase 2:** Complete enrollment
- ✓ **ANCA-associated vasculitis Phase 2:** First patient enrolled
- ✓ **HNSA-5487 (Lead NiceR candidate):** Initiate Phase 1 study
- ✓ **Genethon Crigler-Najjar:** Initiate preclinical study with imlifidase prior to GNT-0003

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 the comparative efficacy analysis to IGOS data
- **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

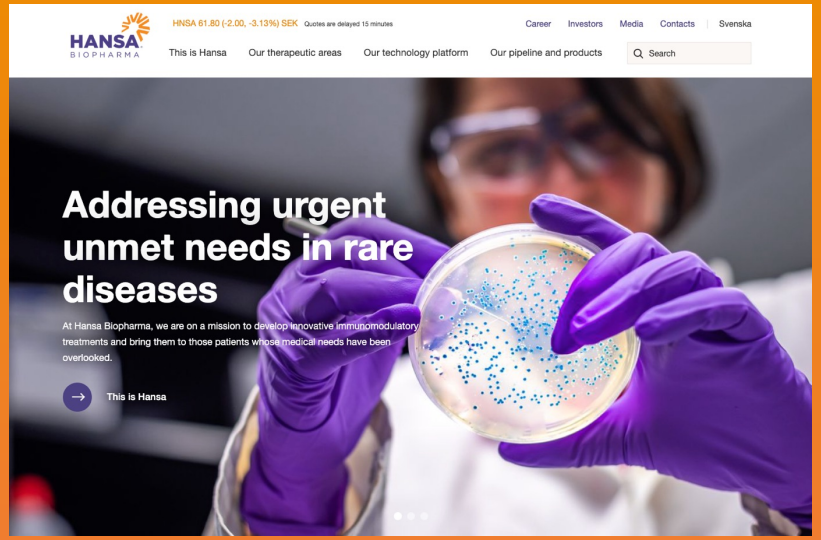
2025

- **U.S. ConfIdeS (Kidney tx) Phase 3:** BLA submission

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



Broad clinical pipeline in transplantation and autoimmune diseases

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Project	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Partner	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients[1,2]								EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	US: Kidney transplantation in highly sensitized patients[1,2]								Completion of randomization (64 patients) mid 2024
	Anti-GBM antibody disease[3]								Complete enrollment (50 patients)
	Antibody mediated rejection in kidney transplantation (AMR)								Full data read out H2 2023
	Guillain-Barré syndrome (GBS)								Topline data H2 2023 / Comparative efficacy analysis 2024
	ANCA-associated vasculitis[4]								Complete enrollment (10 patients)
	Pre-treatment ahead of gene therapy in Duchenne		Phase 1b					**Sarepta Therapeutics**	Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle							**Sarepta Therapeutics**	Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease							**AskBio**	Preclinical research
	Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome							**Genethon**	Preclinical research
HNSA-5487	Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR)								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

[1] Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)
[2] Lorant et al., American Journal of Transplantation and 03+04 studies (Jordan et al., New England Journal of Medicine)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund, Sweden
[4] Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

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Calendar and events

Oct 26, 2023	**Interim Report for January-September 2023**
Nov 21, 2023	SEB Healthcare Seminar 2023, Stockholm
Nov 23, 2023	Redeye Life Science Day, Stockholm
Dec 6, 2023	Carlsquare Life Science Investor Day, Stockholm
Dec 14, 2023	Redeye Investor Forum, Gothenburg
Jan 8, 2024	JPM week, San Francisco
Feb 2, 2024	**Full-year Report for January-December 2023**
Feb 28, 2024	Ökonomisk Ugebrev Life Science Event, Cph
Mar 20, 2024	**Annual Report 2023**
Apr 17, 2024	**Interim Report for January-March 2024**
July 17, 2024	**Half-year Report January-June 2024**
Oct 23, 2024	**Interim Report for January-September 2024**

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