



BIOPHARMA

Conference Call  
Presentation

Interim report January – March 2023  
*Lund, April 20, 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.

The factors set forth above are not exhaustive and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment, and it is not possible to predict all factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

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# Q1 progress on key deliverables

Our mission is to become a global leader in rare diseases

## 1 European launch of Idefirix® progresses as planned

- ✓ Repeat business of Idefirix® at first clinics
- ✓ Market Access secured in Spain completing access in the five of the largest European markets
- ✓ Expanded commercialization partnership with Medison Pharma in the Baltics

## 2 Exciting pipeline advances

- ✓ Guillain-Barré Syndrome (GBS): Phase 2 study enrolment completion
- ✓ HNSA-5487: Clinical study initiated with our next generation enzyme in healthy volunteers
- ✓ U.S. ConfldeS study: 62/64 patients enrolled; adding more centers in the U.S.

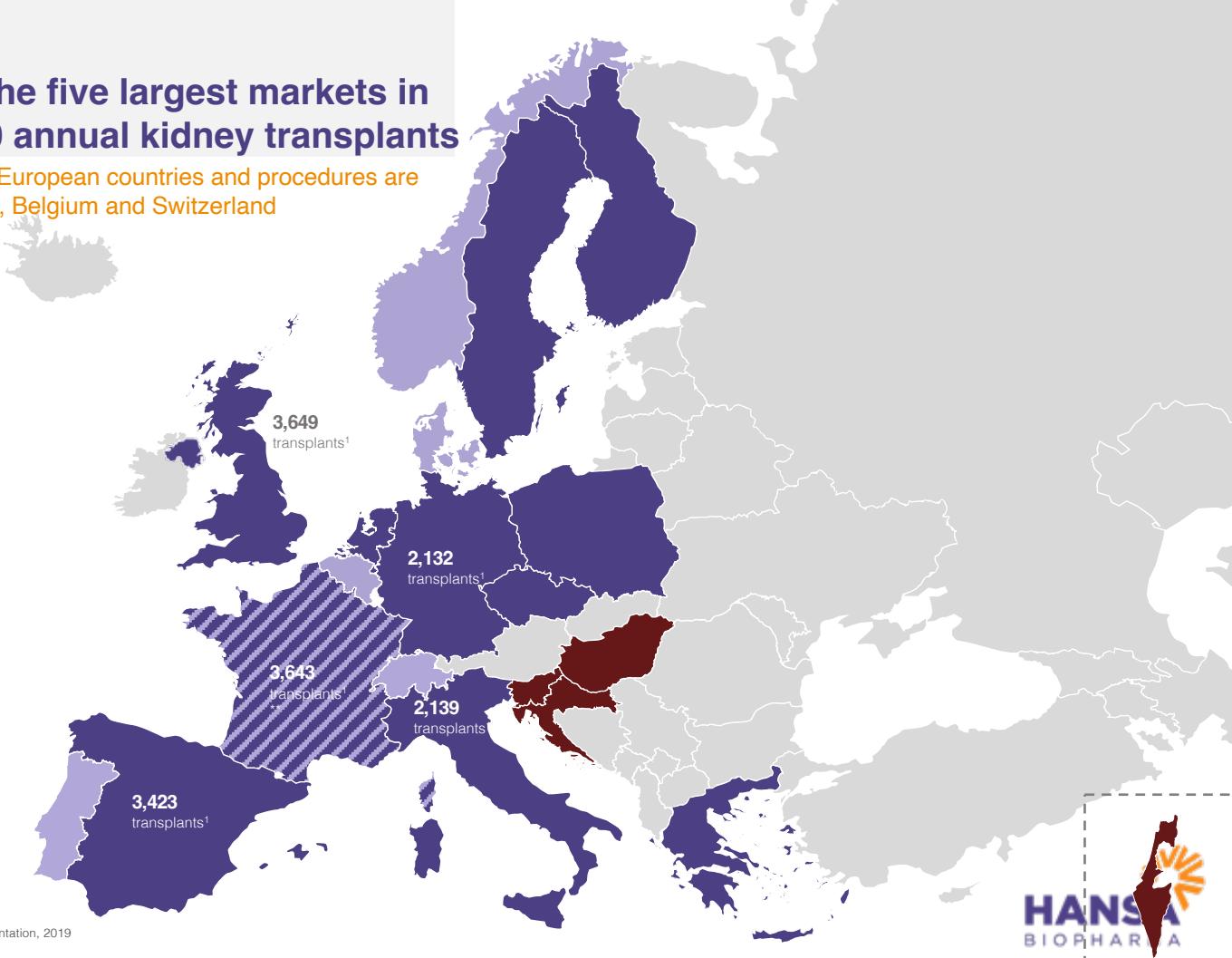
## 3 Performance continues at pace

- ✓ Total Q1 revenue - SEK 24m incl. SEK 14m in product sales and SEK 9.9m in revenue recognition from partnerships
- ✓ Cash position - SEK 1.287m end of Q1'23; Hansa financed into 2025
- ✓ Matthew Shaulis - appointed new CCO and U.S. President

# Market Access secured in the five largest markets in Europe representing 15,000 annual kidney transplants

Market access has now been secured in 12 European countries and procedures are ongoing in eight countries including Portugal, Belgium and Switzerland

- Health Technology Assessments (HTA) dossiers submitted
- Reimbursed Early Access Program
- Pricing & reimbursement obtained (country or clinic level)
- Territories covered commercially by Medison Pharma



<sup>1</sup>Annual kidney transplants 2019 (pre-Corona)

\*Transplantation data is from Global Observatory on Donation and Transplantation, 2019

\*\*Pricing & reimbursement obtained in France on an early access basis

# Exciting pipeline advances potential new medicines in areas of high unmet need

## Antibody Mediated Rejection (AMR)

Phase 2

- 30/30 patients enrolled
- Demonstrated a statistically significantly superior capacity to rapidly reduce levels of DSAs compared to PLEX (SoC)
- Full data read out expected H2 2023



## Guillain-Barré Syndrome (GBS)

Phase 2

- 30/30 patients enrolled
- Topline data expected H2 2023
- Full data following comparative efficacy analysis with the IGOS database
- Full data expected 2024



## Anti-GBM

Phase 3

- Open-label, randomised controlled study
- 50 patients to be treated to with imilifidase and SoC or SoC, alone
- Kidney function evaluated as primary endpoint
- First patient dosed H1 2023



## U.S. ConfideS

Phase 3

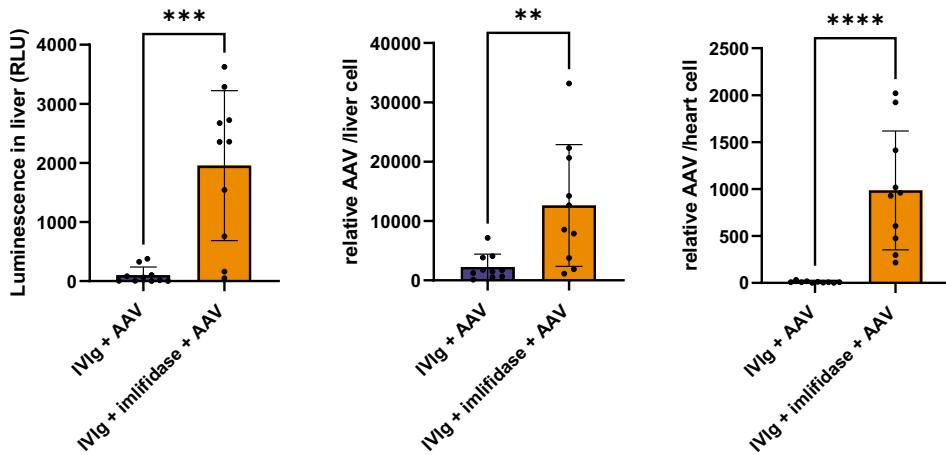
- 62/64 patients enrolled for randomization
- 13 centers open for recruitment; Hansa expects to add additional centers up to a total of 20
- Hansa will continue enrollment to accelerate randomization
- Enrollment completion expected in H1 2023; Randomization expected to be complete H2 2023



## Imlifidase facilitates transduction of AAV8 in a mouse model

Imlifidase treatment neutralises the inhibitory effect of IgG and facilitates AAV8 transduction in target cells

In severe combined immunodeficient (SCID) mice immunised with human IgG, the AAV transduction is significantly improved in the presence of imlifidase compared to without imlifidase



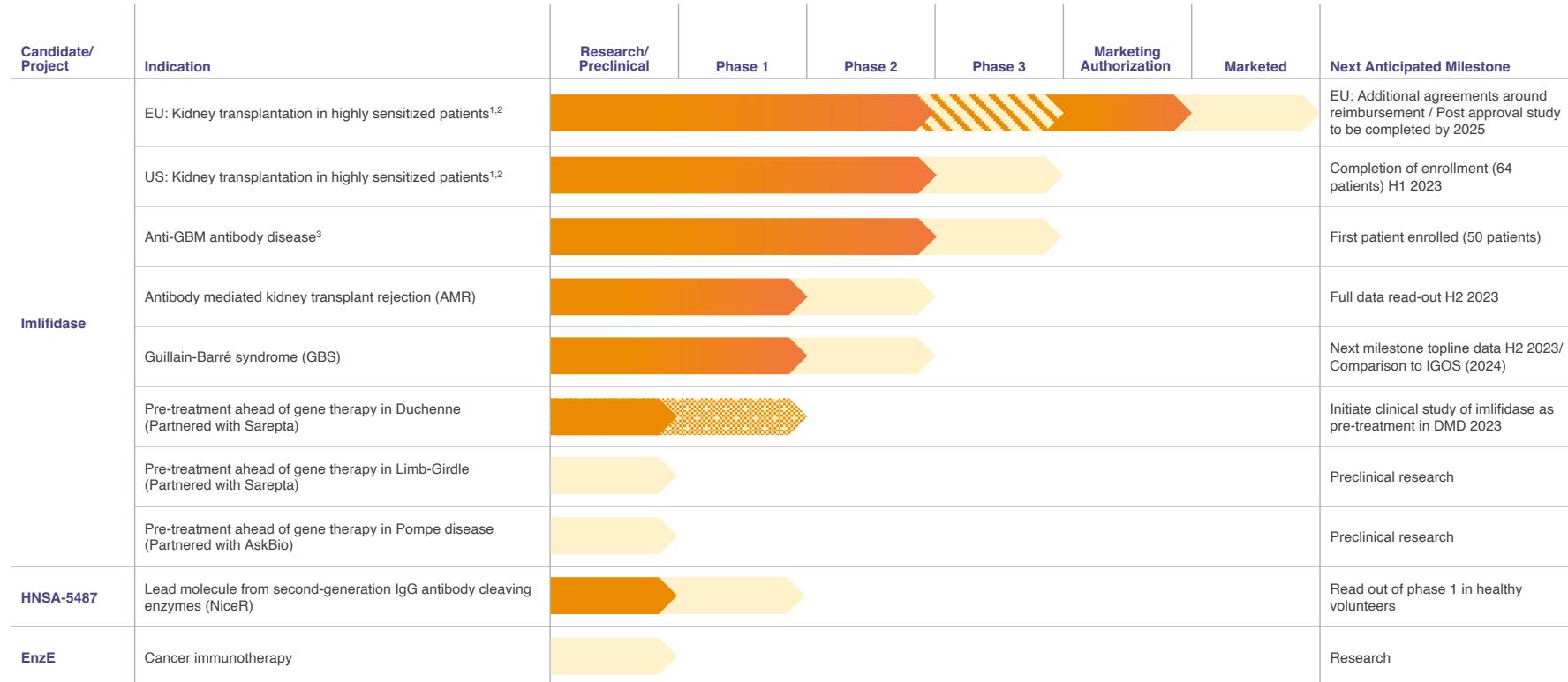
Mice administered with IVIg and AAV8 viral vectors in the absence or presence of imifidase. Transgene luciferase expression is measured in liver lysates as relative luminescence units (RLU) (a). Transduction was measured in both liver (b) and heart (c) by qPCR analysis of total DNA and calculated as the relative AAV8 genomes/cell using primers specific for viral genomes (ITR) and normalised against a mice reference gene (actin). Mann-Whitney test were performed to evaluate the significance of the difference between the two groups, \*\* $p<0.01$ , \*\*\* $p<0.001$ , \*\*\*\* $p<0.0001$ . Data is presented as mean  $\pm$  SD, n=10.

Imlifidase has previously been highlighted in *Nature Medicine*<sup>1</sup> with encouraging outcome

Leborgne et al. Nat Med (2020)

<sup>1</sup> Nature Medicine <https://doi.org/10.1038/s41591-020-0911-7>

# Broad clinical pipeline in transplantation and autoimmune diseases


<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 Mårten Segelmark, Professor at the universities in Linköping and Lund

 Completed

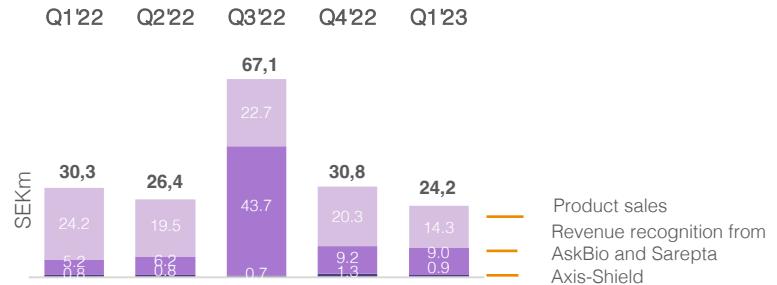
 Planned

 Ongoing

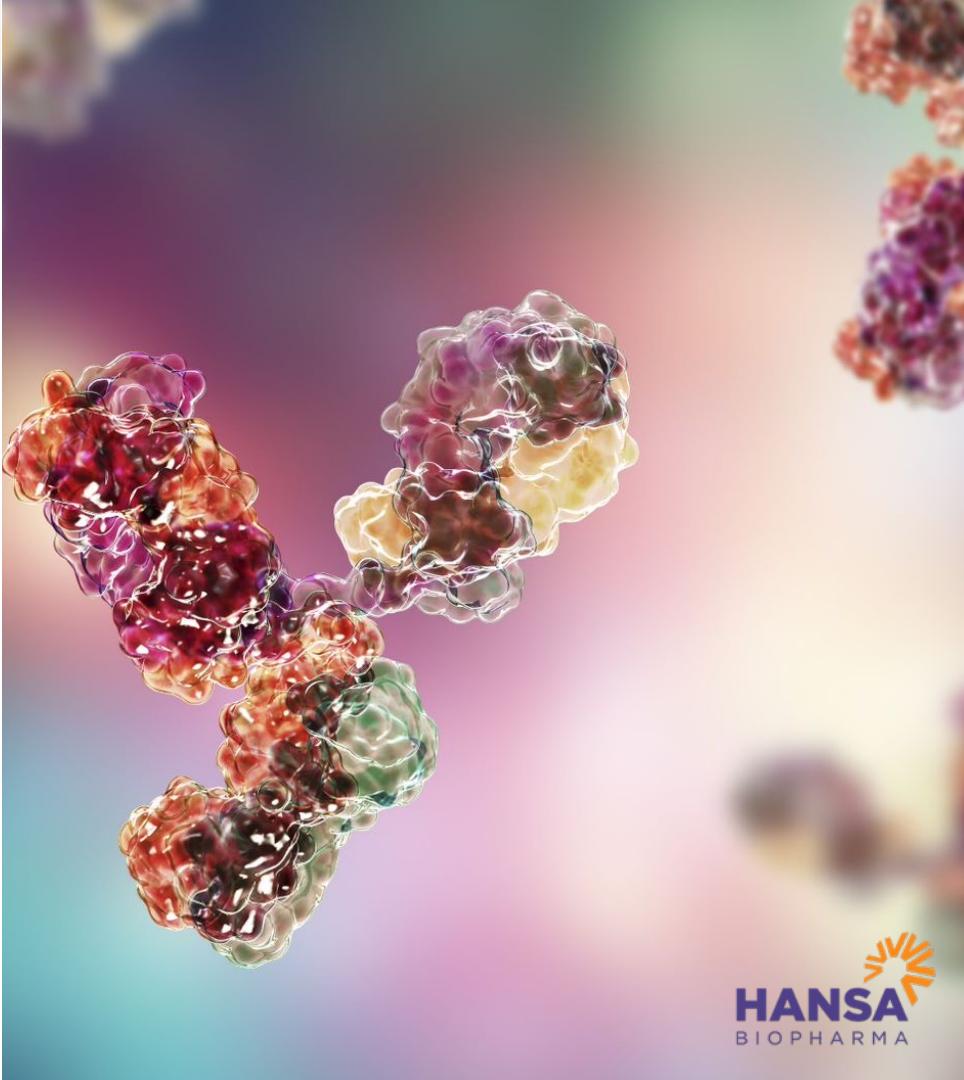
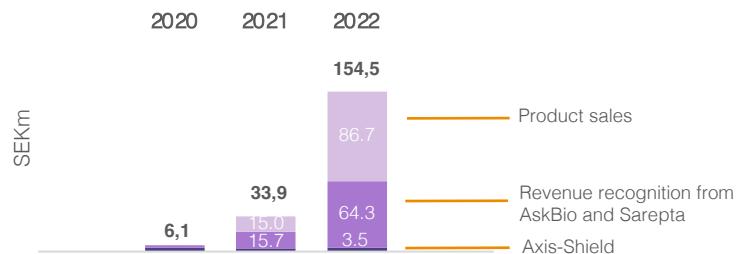
 Post approval study running in parallel with commercial launch

## Q1 2023 Revenue amounted to SEK 24m including SEK 14m in product sales

Revenue (Q/Q)



Revenue (12M/12M)

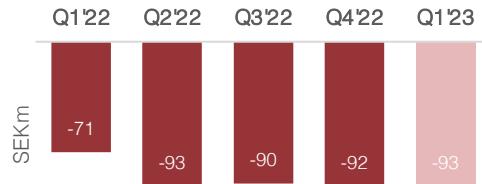


## Continued investments in our commercialization and R&D activities

SG&A expenses (Q/Q)



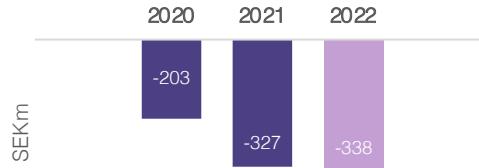
R&D expenses (Q/Q)



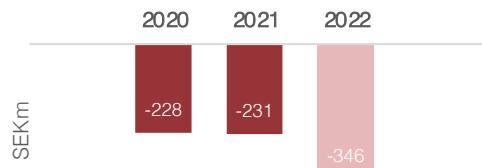
Net loss (Q/Q)



SG&A expenses (12M/12M)



R&D expenses (12M/12M)

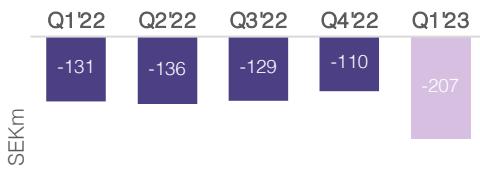


Net loss (12M/12M)

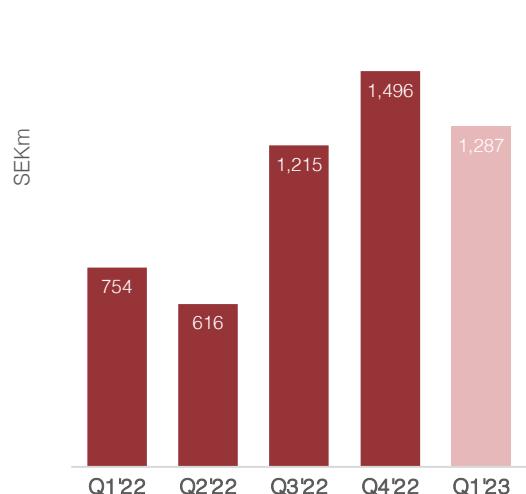


# With current cash position and projected burn-rate, Hansa's operations are financed into 2025

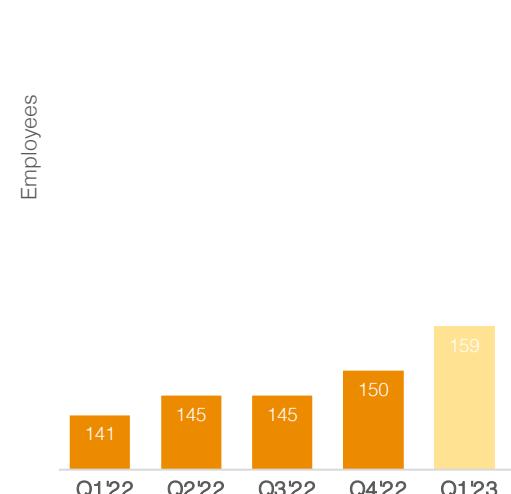
Operating cash flow (Q/Q)



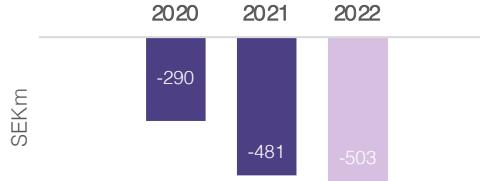
Cash & short-term investments (Q/Q)



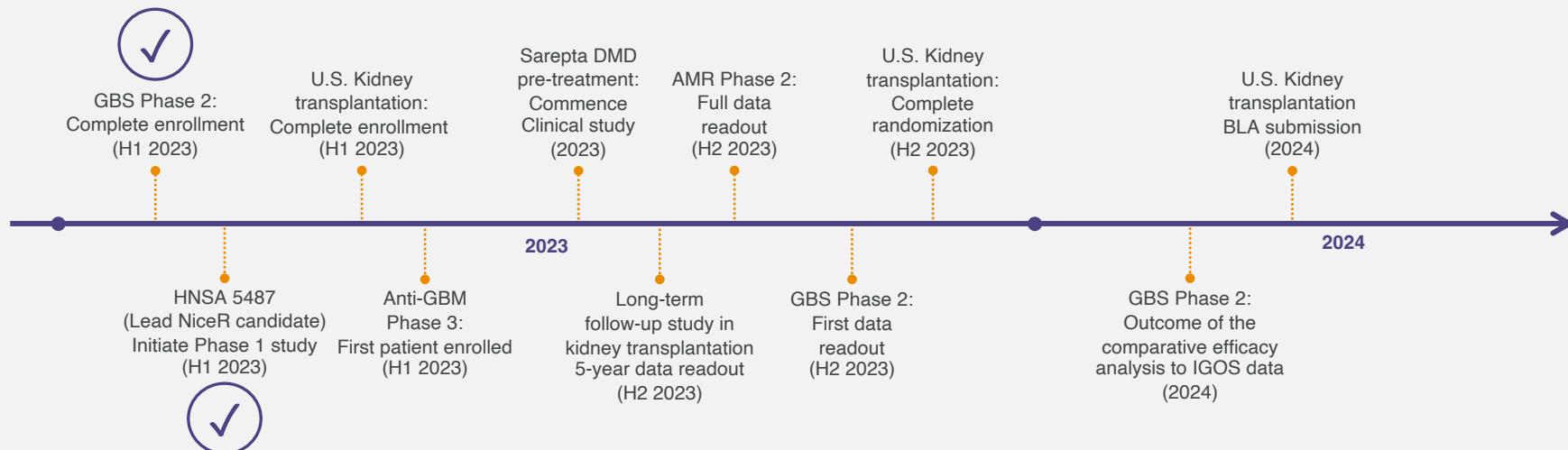
Number of employees (Q/Q)



Operating cash flow (12M/12M)



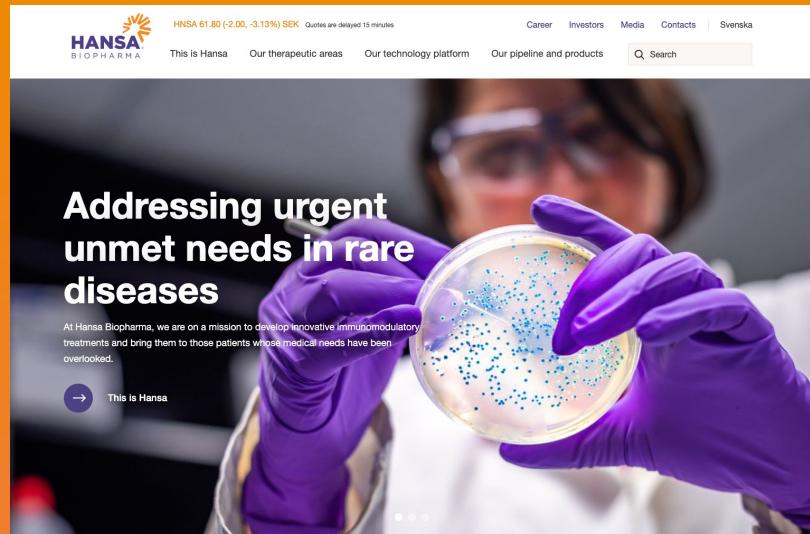
# Key near term milestones



# Q & A

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

Visit our new web site  
[www.hansabiopharma.com](http://www.hansabiopharma.com)



# Contact our Investor Relations and Corporate Affairs team

## Contact



**Klaus Sindahl**

VP, Head of Investor Relations

Mobile: +46 (0) 709-298 269

Email: klaus.sindahl@hansabiopharma.com



**Stephanie Kenney, VP Global Corporate Affairs**

VP, Corporate Affairs

Mobile: +1 (484) 319 2802

E-mail: stephanie.kenney@hansabiopharma.com

## Calendar and events

|                |  |
|----------------|--|
| April 20, 2023 | Redeye Investor Forum, Gothenburg                |
| April 21 2023  | Redeye Lunch presentation, Stockholm             |
| April 25 2023  | Kempen Life Sciences Conference 2023, Amsterdam  |
| May 9, 2023    | Midcap Canada event (virtual)                    |
| May 11, 2023   | Erik Penser Company Day, Malmö                   |
| May 11, 2023   | Redeye Investor forum, Malmö                     |
| May 25, 2023   | Erik Penser Company Day, Stockholm               |
| June 14, 2023  | Annual General Meeting                           |
| July 20, 2023  | Half-year Report for January-June 2023           |
| Aug 24, 2023   | Erik Penser Company Day, Stockholm               |
| Sept 7, 2023   | CITI Annual BioPharma Conference, Boston         |
| Sept 11, 2023  | MorganStanley Global Healthcare Conference, NYC  |
| Sept 14, 2023  | Pareto Annual Healthcare Conference, Stockholm   |
| Oct 19, 2023   | Interim Report for January-September 2023        |
| Nov 22, 2023   | Ökonomisk Ugebrev Life Science event, Copenhagen |

