



## Conference Call Presentation

Year-end Report Jan-Dec 2022

*Lund, February 2, 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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## Total 2022 revenue of SEK 155m; Cash runway extended into 2025; Market Access secured in Italy and Czech Republic; Reported positive Phase 2 top-line data in AMR

### Highlights for the fourth quarter of 2022

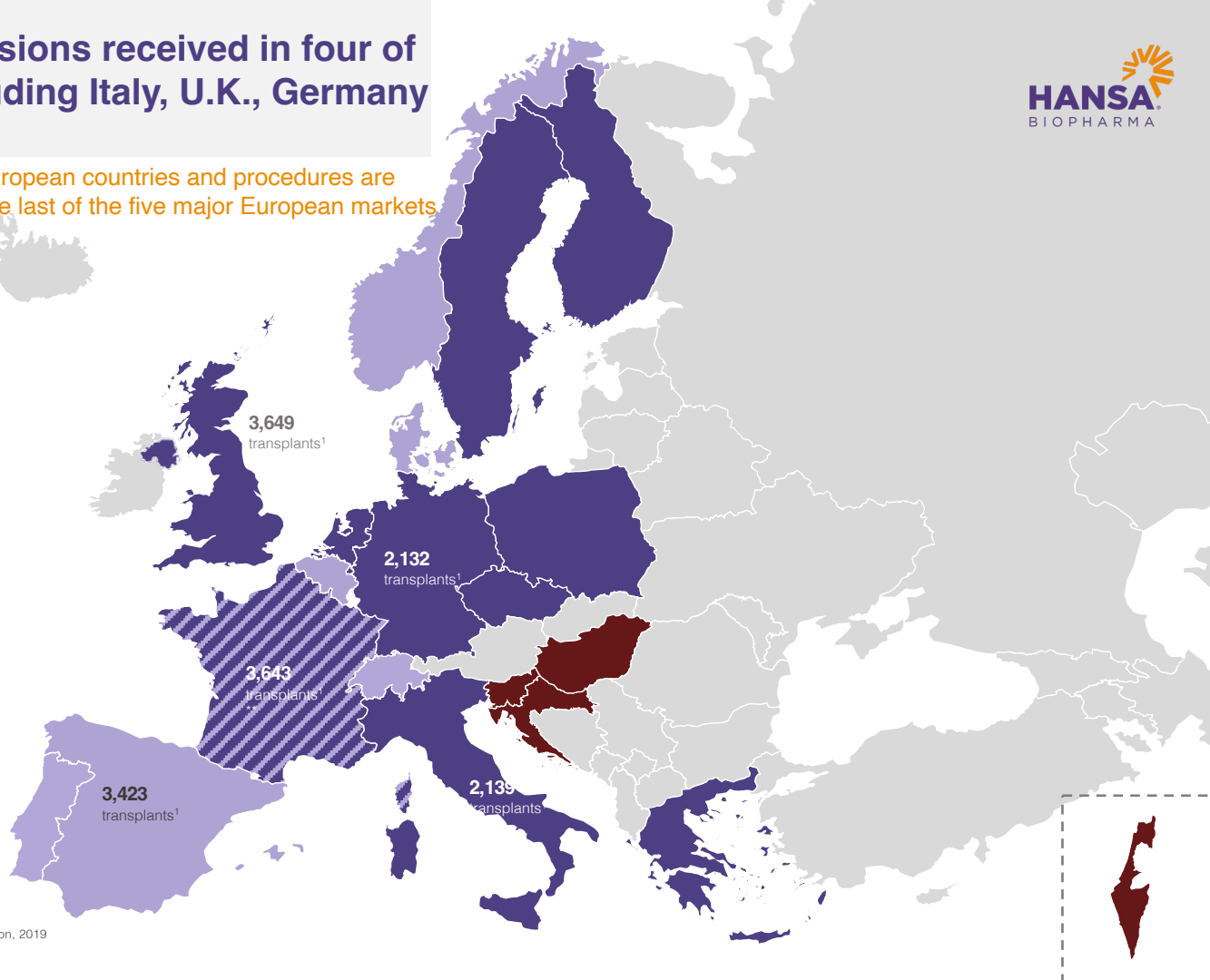
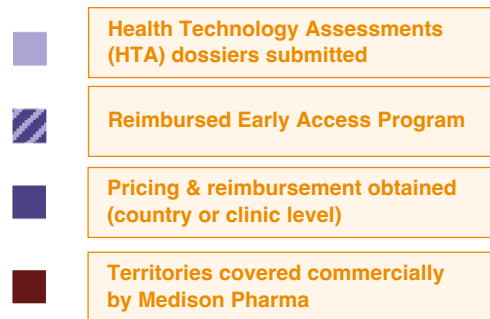
- ✓ **Idefix launch in Europe is progressing as planned**
  - Total Q4 revenue of SEK 31m including SEK 20m in product sales and SEK 11m under our agreements with Sarepta and AskBio
  - Positive reimbursement decisions received in Italy and Czech Republic; Market access secured in 11 European countries and procedures are ongoing in nine countries including Spain
  - U.K. imlifidase guidelines published by British Transplant Society; Guidelines in line with the NICE and SMC recommendations, from patient selection to transplant and post-transplant patient management and protocols
  - Distribution agreement signed with iQone Healthcare to cover Switzerland
- ✓ **Clinical and pre-clinical pipeline**
  - AMR: Positive topline data from the imlifidase phase 2 study in antibody mediated rejection (AMR) episodes post kidney transplantation
  - Anti-GBM: First sites initiated in the pivotal global phase 3 study
  - GBS: 25/30 patients enrolled in the GBS phase 2 study; Completion of enrollment in the GBS trial is anticipated for H1 2023, as previously guided
  - U.S. ConfldeS study: 51/64 patients enrolled; Hansa expect to further increase the enrollment capacity to accelerate the study. Based on this, Hansa aims to completion of enrollment in H1 2023, while completion of randomization is expected in H2 2023. BLA submission is expected in 2024 as previously guided
  - NiceR: IND enabling tox studies completed; A Clinical Trial Application was approved to initiate clinical study in the first half of 2023
  - Plans to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD in 2023
- ✓ **\$40 million raised in direct share issue; Cash runway extended into 2025**
  - Transaction targeting U.S. and other international healthcare specialist investors





## Positive reimbursement decisions received in four of the five largest markets including Italy, U.K., Germany and France (early access)

Market access has now been secured in 11 European countries and procedures are ongoing in nine countries including Spain as the last of the five major European markets



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

<sup>\*</sup>Transplantation data is from Global Observatory on Donation and Transplantation, 2019

<sup>\*\*</sup>Pricing & reimbursement obtained in France on an early access basis



# Continuous progress in our ongoing clinical programs

Enrollment status  
Feb 1, 2023

## Antibody Mediated Rejection Phase 2 study

- 30/30 patients enrolled in the AMR phase 2 study
- Data readout demonstrates a statistically significantly superior capacity of imlifidase to rapidly reduce levels of DSAs compared to plasma exchange (SoC) in the five days following the start of the treatment
- Full data read out expected H2 2023, which will determine the path forward for imlifidase in patients with active AMR

## Guillain-Barré Syndrome Phase 2 study

- 25/30 patients enrolled in the GBS program
- 10 centers are active and open for recruitment;
- Aim to complete enrollment of GBS patients H1 2023, as previously guided
- Aim to communicate first high-level data read out in H2 2023

Enrollment status  
Feb 1, 2023

## Anti-GBM Phase 3 study

- New pivotal Phase 3 study initiated in first sites in the U.S. and U.K end of 2022 as previously guided
- Open-label, randomised controlled study targeting 50 patients to be treated to with imlifidase and SoC or SoC, alone
- Kidney function will be evaluated as the primary endpoint
- First patient expected to be dosed H1 2023

## U.S. ConfldeS Phase 3 study

Randomized, controlled trial in highly sensitized kidney transplant patients

- 51/64 patients enrolled for randomization
- 13 centers active and open for recruitment; continuously adding new clinics, with a goal of at least 20, to further increase enrollment capacity.
- Expect to complete enrollment H1 2023 and complete randomization in H2 2023
- BLA submission is expected in 2024 under the accelerated approval path, as previously guided













■ Patients enrolled  
■ Patients remaining

■ Patients enrolled  
■ Patients remaining



# Broad clinical pipeline in transplantation and auto-immune diseases

Candidate/ Project	Indication	Research/ Preclinical	Phase 1	Potentially Pivotal/ Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>							EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>							Completion of enrollment (64 patients) H1 2023
	Anti-GBM antibody disease <sup>3</sup>							First patient enrolled (50 patients)
	Antibody mediated kidney transplant rejection (AMR)							Full data read-out H2 2023
	Guillain-Barré syndrome (GBS)							Completion of enrollment (30 patients) H1 '23
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)							Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)							Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)							Preclinical research
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology							Initiate Phase I study of HNSA-5487 (Lead NiceR candidate) H1 2023
EnzE	Cancer immunotherapy							Research

<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

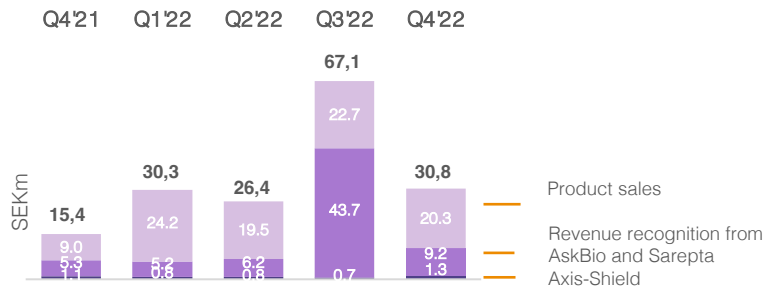
 Ongoing

 Post approval study running in parallel with commercial launch

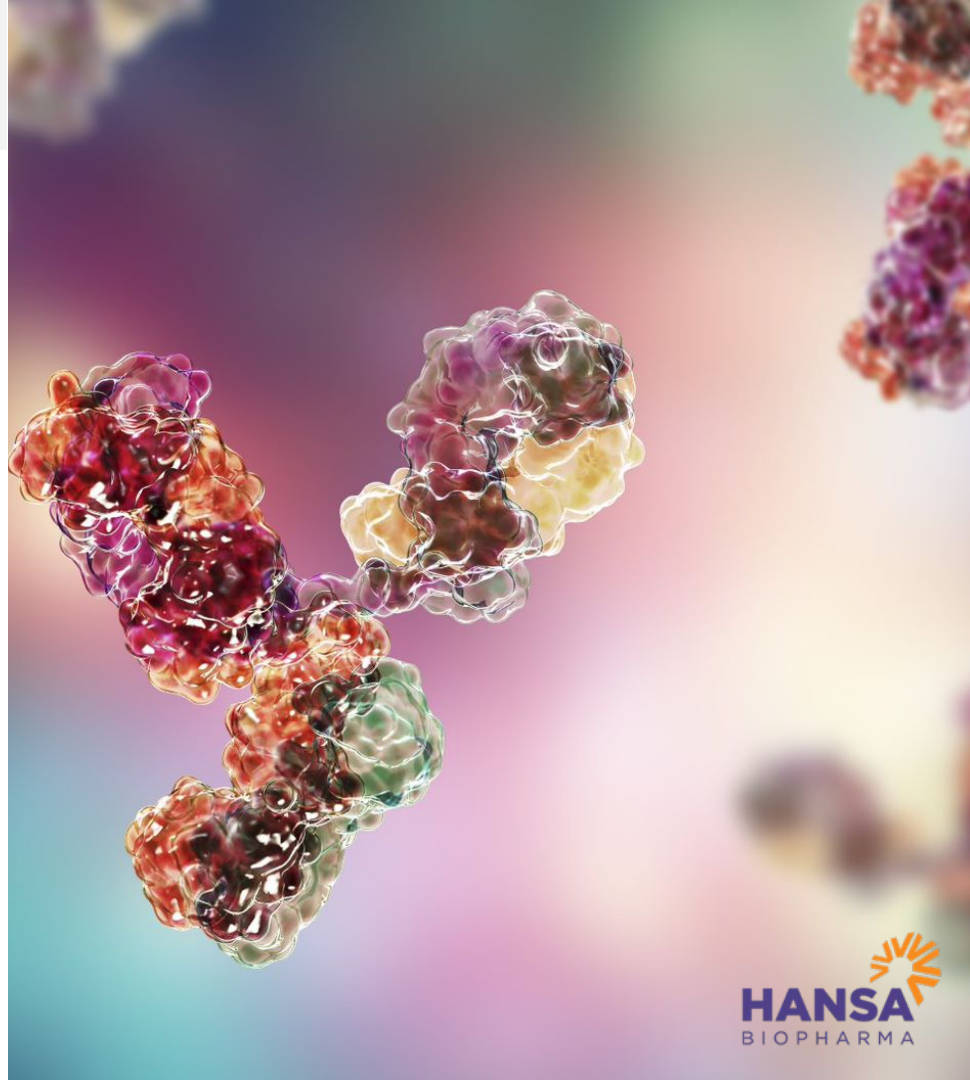
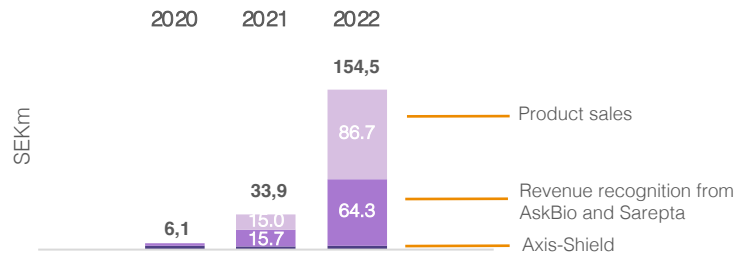


**Total 2022 revenue of SEK 155m;  
Q4 2022 Revenue amounted to SEK 31m  
including SEK 20m in product sales**

Revenue (Q/Q)



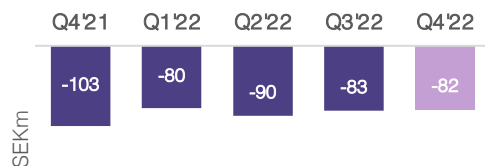
Revenue (12M/12M)



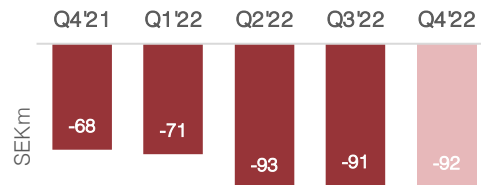


**For 2022 SG&A amounted to SEK 336m, while R&D costs amounted to SEK 346m, as Hansa continues to invest in commercial and pipeline activities**

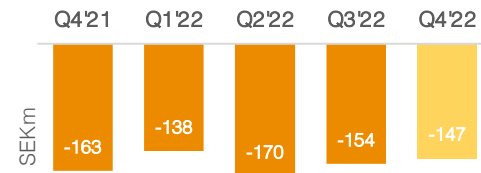
SG&A expenses (Q/Q)



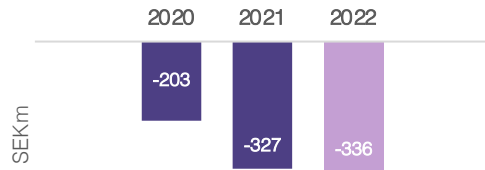
R&D expenses (Q/Q)



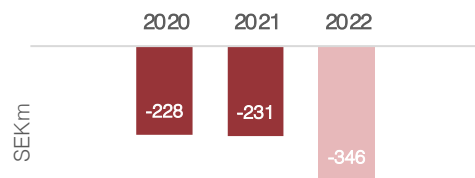
Net loss (Q/Q)



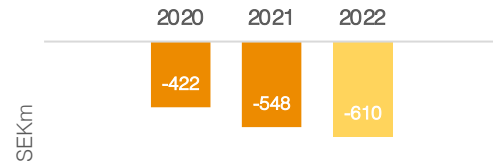
SG&A expenses (12M/12M)



R&D expenses (12M/12M)

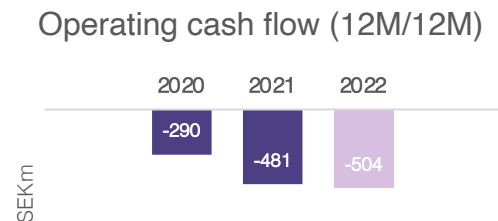
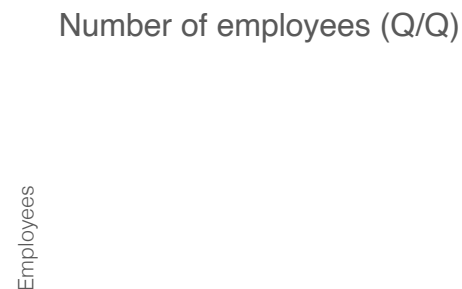
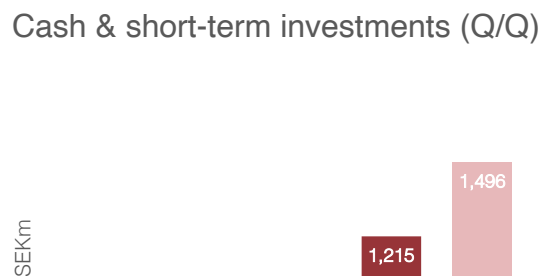
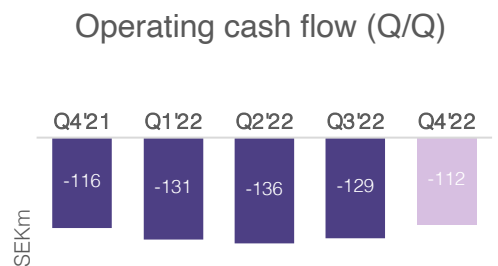


Net loss (12M/12M)



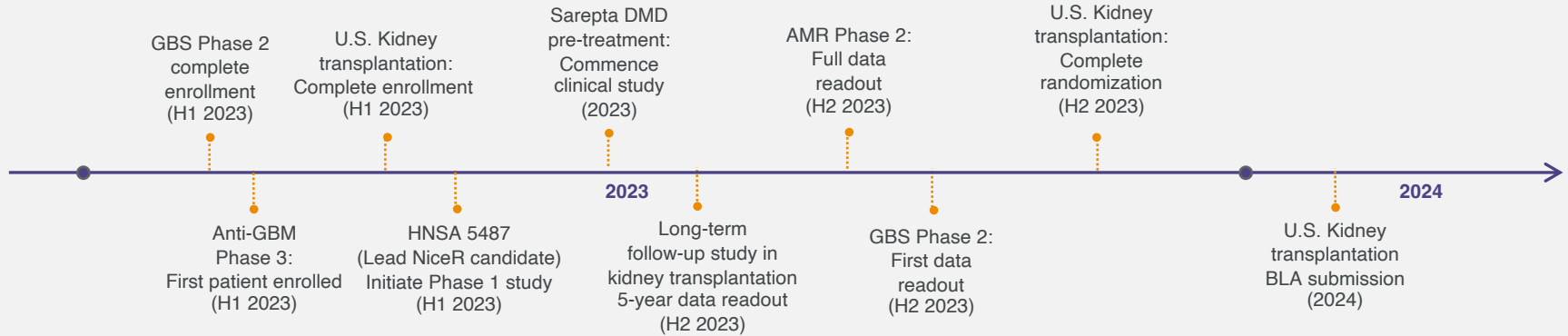


## Hansa's cash runway now extends into 2025 as a result of a non-dilutive debt-financing of USD ~70m in July 2022 and an equity financing of USD ~40m in December 2022





# Near term milestones

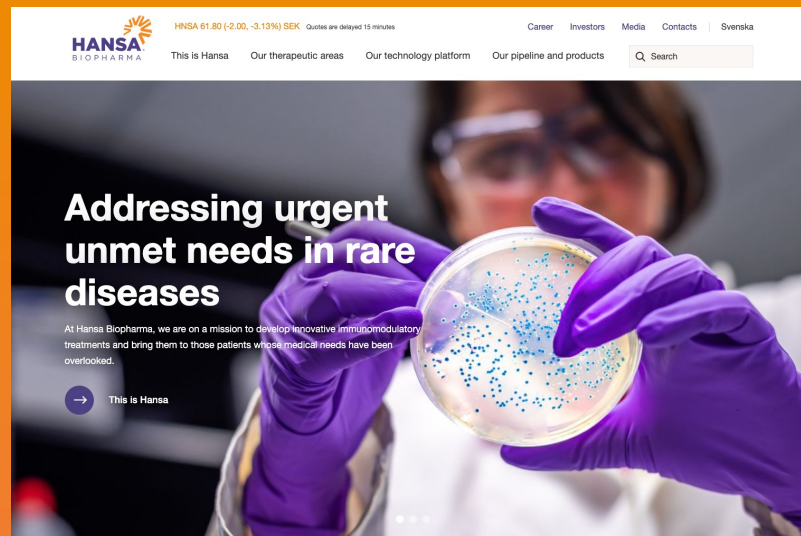




# Q&A

... 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)





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## Calendar and events

Feb 9, 2023	Mid-cap event, Frankfurt
Feb 23, 2023	Erik Penser Healthcare seminar, Stockholm
Mar 7, 2023	Redeye Healthcare seminar: Commercialization, Stockholm
Mar 8, 2023	Cowen Healthcare Conference, Boston
Mar 16, 2023	Carnegie Nordic Healthcare Seminar 2023, Stockholm
<b>Mar 30, 2023</b>	<b>2022 Annual Report</b>
April 4, 2023	Guggenheim Healthcare Talks Rare Disease Days, virtual
<b>April 20, 2023</b>	<b>Interim Report for January-March 2023</b>
April 20, 2023	Redeye Investor Forum, Gothenburg
April 21, 2023	Redeye Lunch presentation, Stockholm
April 25, 2023	Kempner Life Sciences Conference 2023, Amsterdam
May 11, 2023	Erik Penser Company Day, Malmö
May 11, 2023	Redeye Investor forum, Malmö
May 25, 2023	Erik Penser Company Day, Stockholm
<b>June 14, 2023</b>	<b>Annual General Meeting</b>
<b>July 20, 2023</b>	<b>Half-year Report for January-June 2023</b>
Aug 24, 2023	Erik Penser Company Day, Stockholm
Sept 7, 2023	CITI Annual BioPharma Conference, Boston
Sept 11, 2023	MorganStanley Global Healthcare Conference, NYC
<b>Oct 19, 2023</b>	<b>Interim Report for January-September 2023</b>
Nov 22, 2023	Ökonomisk Ugebrev Life Science event, Copenhagen



