



# HANSA

BIOPHARMA

## Conference Call Presentation

Interim Report Q1 2022

*Lund, April 21, 2022*



# 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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# Solid sales growth reported in Q1'22; Market access secured in Germany and France; Marketing authorization granted in Israel

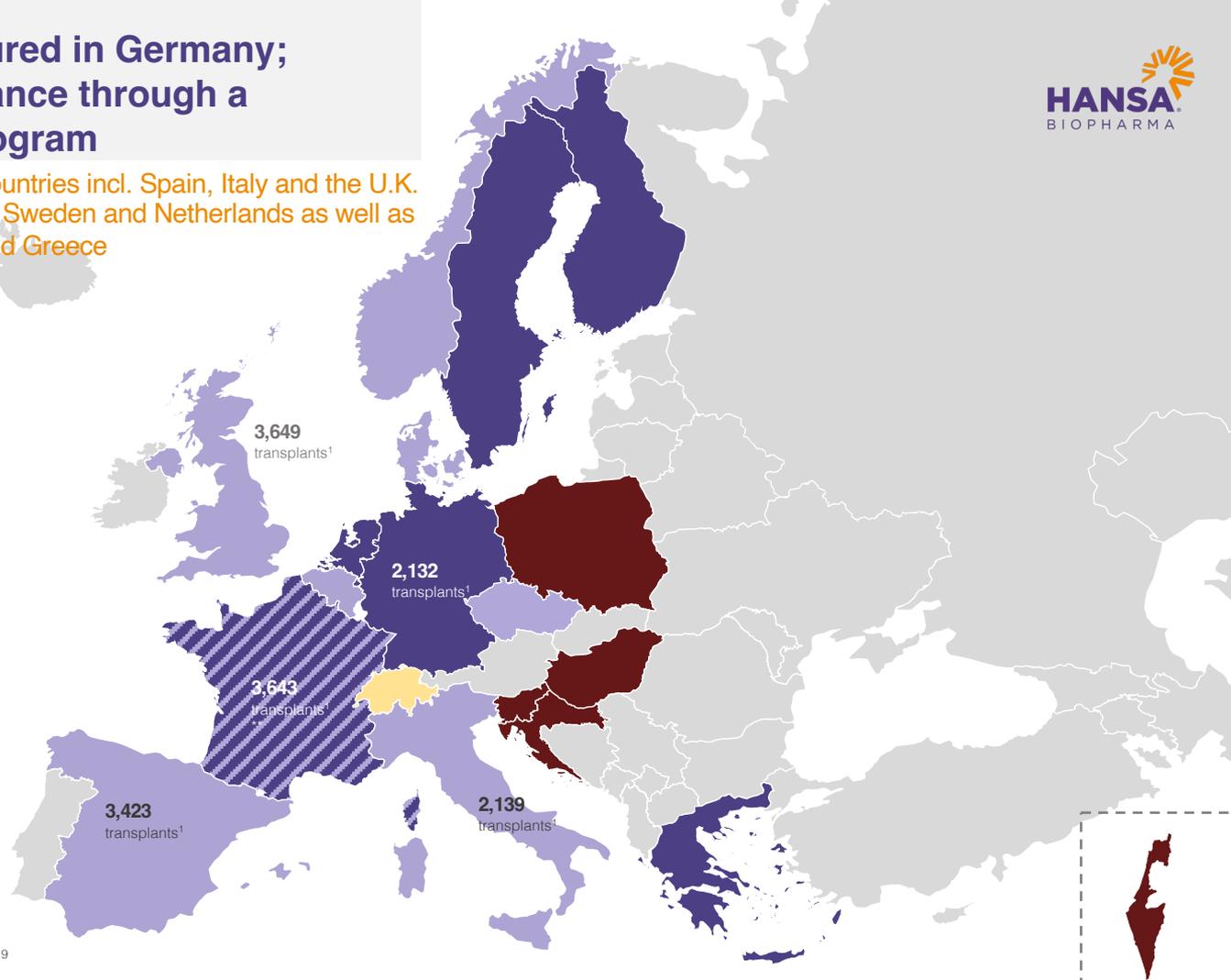
## Highlights for the first quarter of 2022

- ✓ Launch activities and market access efforts in EU progressing as planned
  - Solid sales growth in Q1 with SEK 24.2m in product sales; Total revenue of SEK 30.3m
  - Full commercial access secured in Germany on negotiated terms, while market access is granted in France through a reimbursed Early Access Program
  - Market access procedures are ongoing in 11 countries, incl. Spain, Italy and the U.K.
  - Marketing authorization granted for Idefirix® in Israel
- ✓ Key data from a Phase 2 program in anti-GBM patients highlighted in JASN
- ✓ Clinical pipeline
  - Anti-GBM: U.S. FDA has accepted Hansa's Investigational New Drug (IND) application to proceed with a Phase 3 study of imlifidase in 50 anti-GBM patients across U.S. and EU. First patient expected to be enrolled in 2022
  - U.S. ConfIdaS: Patient enrollment on track for completion second half 2022
  - AMR: Patient enrollment on track for completion first half 2022
  - GBS: 16/30 patients enrolled in the GBS phase 2 study; Significant initiatives implemented to support the completion of enrollment of GBS patients in H2 2022
- ✓ Agreement with AskBio (subsidiary of Bayer AG) to evaluate feasibility of imlifidase ahead of gene therapy in Pompe disease
- ✓ Cash position of SEK 754 million end of Q1'22; Hansa is financed into 2023



# Full commercial access secured in Germany; Market access granted in France through a reimbursed Early Access Program

Market access procedures ongoing in 11 countries incl. Spain, Italy and the U.K.  
During 2021 market access was secured in Sweden and Netherlands as well as  
on an individual hospital basis in Finland and Greece



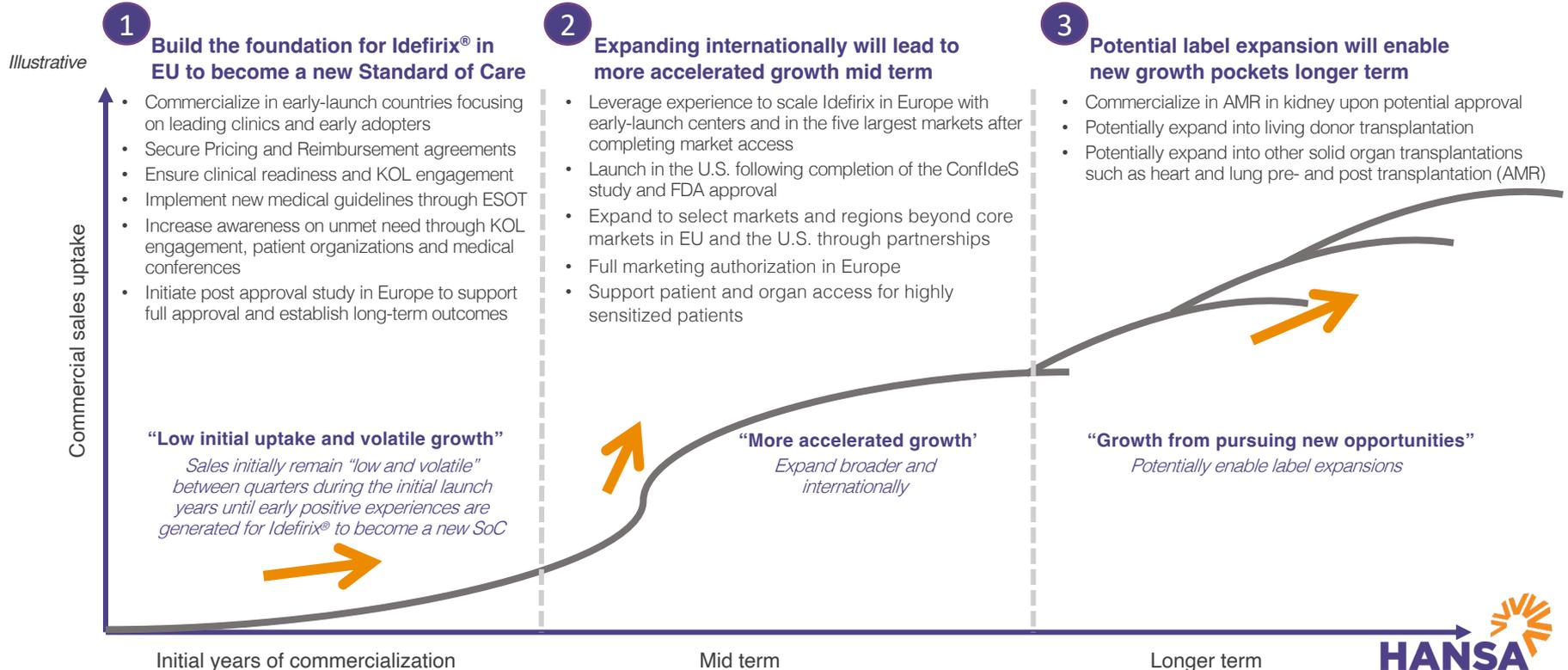
<sup>1</sup>Annual kidney transplantations 2019 (pre-Corona)

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

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

# Our center focused and sequenced launch process will help build the foundation for Idefirix® to become a new Standard of Care in transplantation

Idefirix® is the first and only approved treatment in Europe for desensitization treatment of highly sensitized kidney transplant patients. The long-term market uptake is highly dependent on successful early experiences in key early adopter centers





# Continuous progress in our ongoing clinical Programs

Enrollment status  
April 20, 2022

## Antibody Mediated Rejection Phase 2 study

- 28/30 patients enrolled in the AMR phase 2 study
- Completion of enrollment expected H1 2022\*
- First data read out expected in H2 2022\*



- Patients enrolled
- Patients remaining

## Guillain-Barré Syndrome Phase 2 study

- 16/30 patients enrolled in the GBS phase 2 study
- Enrollment rate has been affected by the COVID-19 pandemic. Significant initiatives are implemented to support the completion of enrollment incl. simplification of the protocol, addition of two new sites and supporting hiring of staff at the clinics
- Completion of enrollment expected in H2 2022\*
- First data read out expected in H1 2023



- Patients enrolled
- Patients remaining

Enrollment status  
April 20, 2022

## Anti-GBM Phase 3 study

- U.S. FDA has accepted Hansa's Investigational New Drug (IND) application to proceed with a Phase 3 study
- The planned study will commence this year\* targeting 50 patients across the U.S. and Europe



- Patients enrolled
- Patients remaining

## U.S. ConfldeS Phase 3 study

- Randomized, controlled trial in highly sensitized kidney transplant patients across 12-15 centers
- 16/64 patients enrolled for randomization
  - Nine centers are active and open for recruitment
  - Completion of enrollment expected H2 2022\*



- Patients enrolled
- Patients remaining

*\*Guidance assumes no further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.*

# Broad clinical pipeline in transplantation and auto-immune diseases

Candidate/ Program	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Conditional approval based on Phase 2 data	Completed	Marketed (*)	EU: Additional agreements around reimbursement from H2'21
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Ongoing			Completion of enrollment (64 patients) H2'22
	Anti-GBM antibody disease <sup>3</sup>	Completed	Completed	Completed	Planned			Pivotal Phase 3 study expected to commence in 2022 (50 patients)
	Antibody mediated kidney transplant rejection (AMR)	Completed	Completed	Ongoing				Completion of enrollment (30 patients) H1 2022
	Guillain-Barré syndrome (GBS)	Completed	Completed	Ongoing				Completion of enrollment (30 patients) H2 2022
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)	Ongoing						Preclinical phase
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)	Ongoing						Preclinical phase
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)	Ongoing						Preclinical phase
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	Ongoing						Completion of GLP toxicology studies in 2022
EnzE	Cancer immunotherapy	Ongoing						Research phase

<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

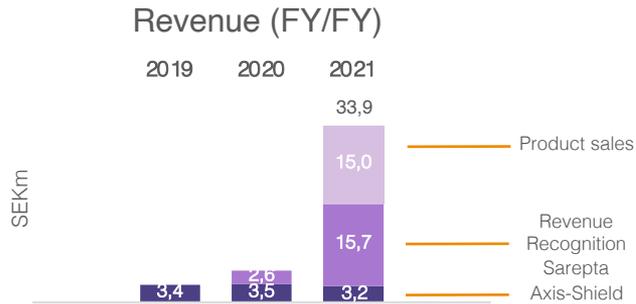
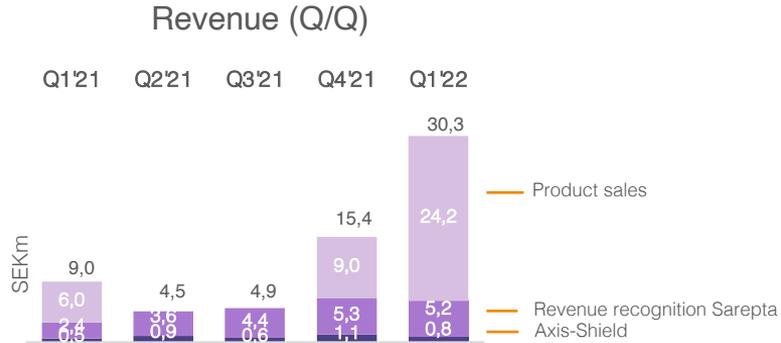
(\*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch

Completed Ongoing

Planned

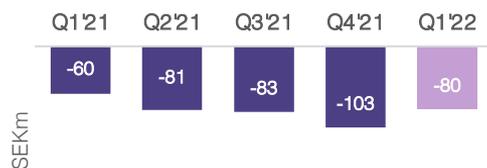
Conditional approval based on Phase 2 data

# Solid sales growth in Q1'2022 - product sales of SEK 24.2m



# Continued investments in our commercialization and pipeline

## SG&A expenses (Q/Q)



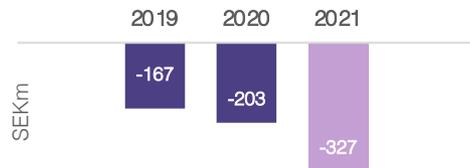
## R&D expenses (Q/Q)



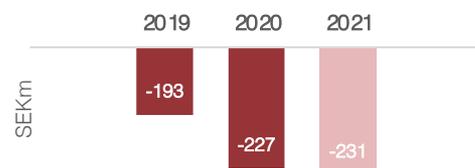
## Net loss (Q/Q)



## SG&A expenses (FY/FY)



## R&D expenses (FY/FY)

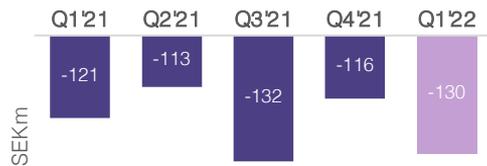


## Net loss (FY/FY)

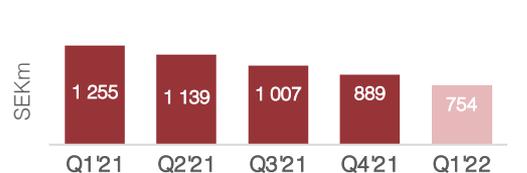


# With current cash position and projected burn-rate, Hansa's operations are financed into 2023

### Operating cash flow (Q/Q)



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



### Shareholders' equity (Q/Q)



### Operating cash flow (FY/FY)



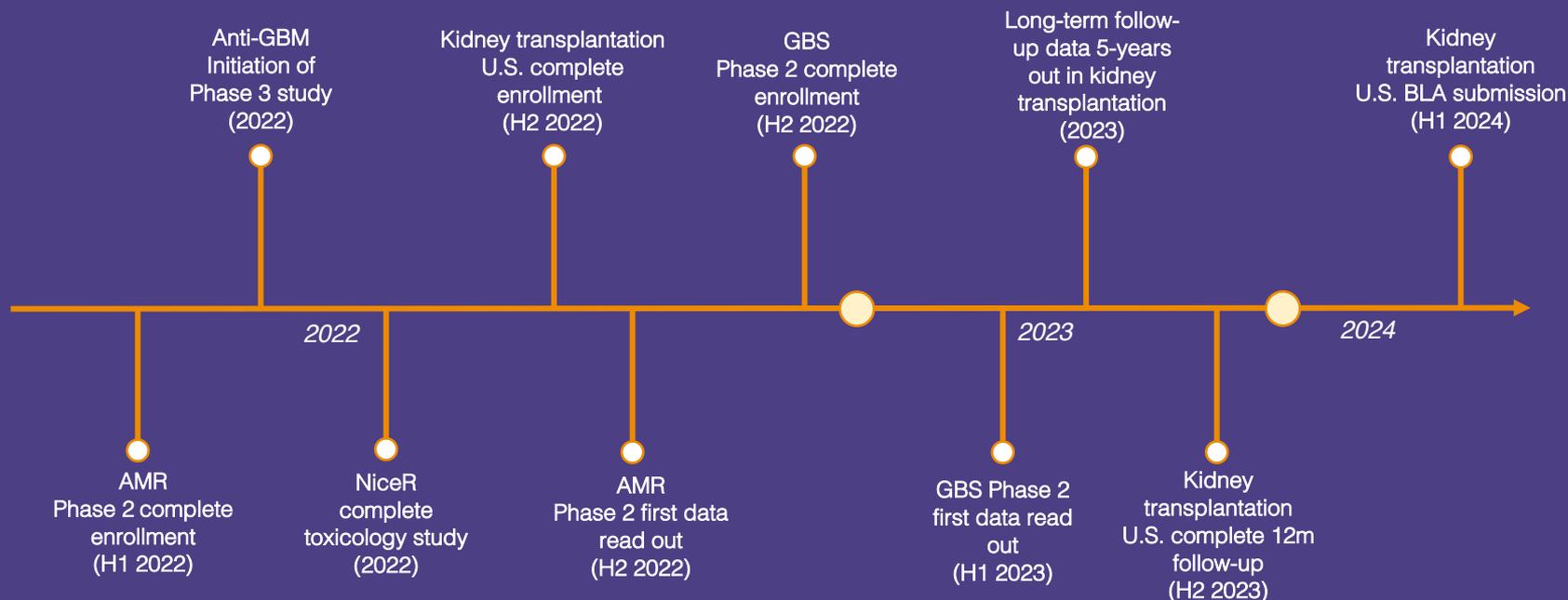
### Number of employees (Q/Q)



\* incl. USD 10 mio (SEK ~90 mio) upfront from Sarepta

# Upcoming milestones

Milestones subject to potential COVID-19 impact



Guidance assumes no persistent impact or further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.

# Q&A

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

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

The screenshot shows the Hansa Biopharma website homepage. At the top right, it displays the stock price: HNSA 246.60 (-5.20, -2.06%) SEK. The navigation menu includes: THIS IS HANSA, INNOVATION & FOCUS, INVESTORS & MEDIA, CAREERS, CONTACTS, EN, SE, and a search icon. The main content area features the 'Our Why' section with a quote: "We are leveraging our cutting-edge science to develop lifesaving and life altering therapies for patients with rare immunological diseases." attributed to Søren Tøstrup, President and CEO. On the right side, there is a portrait of a woman wearing glasses. Below the 'Our Why' section, there is a 'Latest news' section with a date of Jul 08, 2020, and a headline: 'Regulatory press release: Hansa Biopharma announces successful completion of SEK 1.1bn'. A small note below the headline reads: 'SEK 1.1bn completion of SEK 1.1bn and release'. To the right of the news section, there is a caption for the woman: 'Stephanie Patient and relative | The Netherlands'.

# Corporate Contacts

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



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## Calendar and events

April 21 2022

April 27 2022

May 15 2022

May 16 2022

June 16 2022

July 12 2022

July 21 2022

Aug 9 2022

Aug 10 2022

Sept 7 2022

Sept 7-8 2022

Oct 20 2022

Nov 23 2022

Kempen Life Sciences Conference 2022, Amsterdam

Redeye Orphan Drugs 2022, Stockholm

ABG Life Science Summit 2022, Stockholm

European Midcap Event, Copenhagen

Annual General Meeting 2022

William Blair's Biotech Focus Conference 2022, New York

Half year 2022 report

BTIG Biotechnology Conference 2022, New York

Canaccord Annual Growth Conference, Boston

Pareto annual Healthcare Conference 2022, Stockholm

Citi's 17th Annual BioPharma Conference, Boston

Interim Report for January-September 2022

Økonomisk Ugebrev Life Science conference, Copenhagen

