HANSA BIOPHARMA

Conference Call Presentation

Interim Report Q3 2022

Lund, October 20, 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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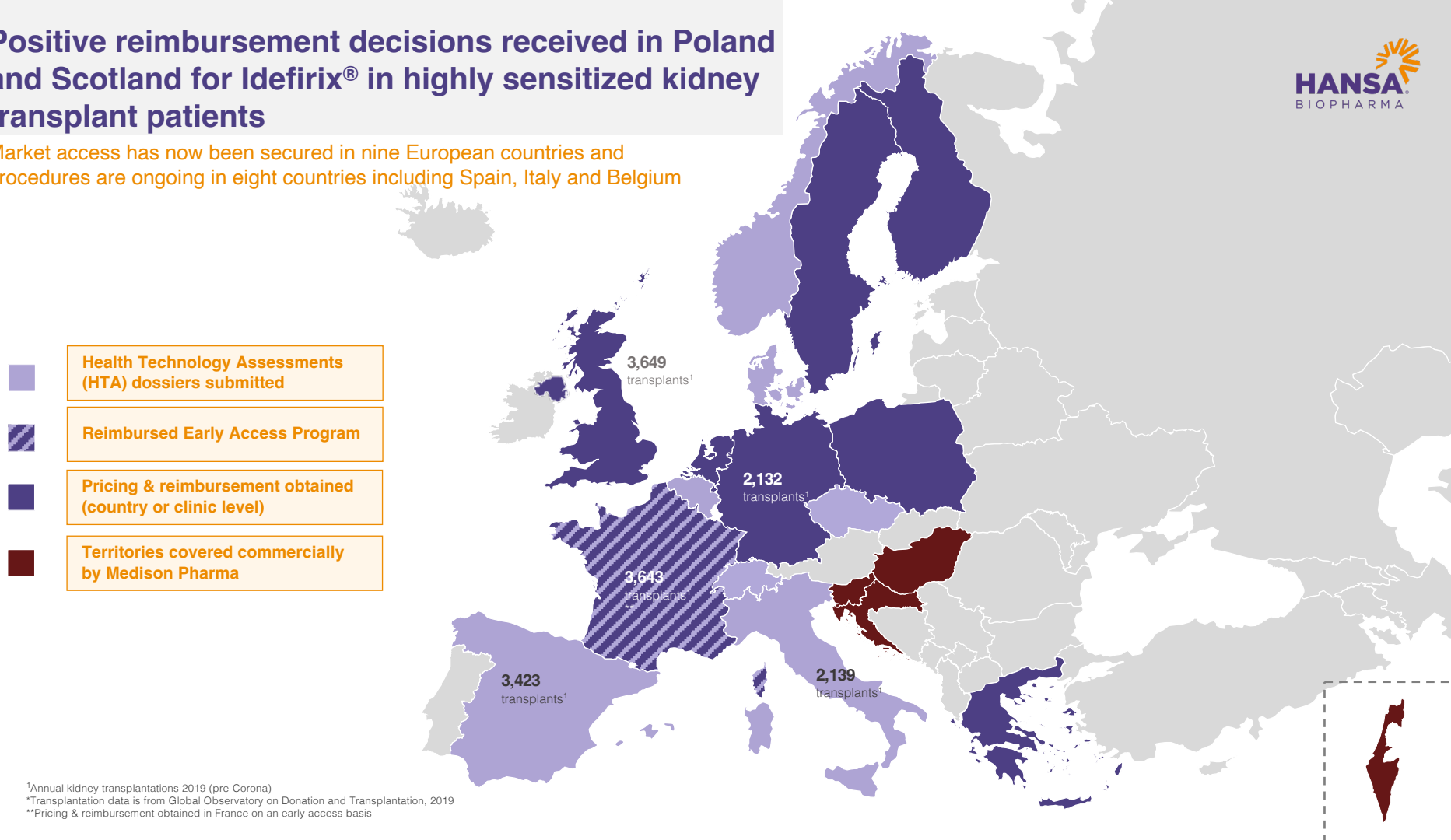
Positive reimbursement decisions received in Poland and Scotland; $70 million raised in non-dilutive financing; ESOT guidelines published in *Transplant International*

Highlights for the third quarter of 2022

- ✓ Launch activities and market access efforts in EU progressing as planned
  - Total Q3 revenue of SEK 67m including SEK 23m in product sales and SEK 44m under our agreements with Sarepta and AskBio
  - Positive reimbursement decisions received in Poland and Scotland for Idefirix®
  - Market access has now been secured in nine European countries and procedures are ongoing in eight countries including Spain, Italy and Belgium
  - The European Society for Organ Transplantation's (ESOT) guidelines for desensitization treatment of highly sensitized kidney transplant patients published in *Transplant International*.
  - First patient treated in the post-authorization efficacy study (PAES) of imlifidase in highly sensitized kidney transplant patients, at Vall d'Hebron Hospital, Barcelona.
- ✓ Clinical pipeline
  - U.S. ConfIdeS Study in kidney transplantation: 39/64 patients enrolled
  - Anti-GBM: Expect to commence Phase 3 study later this year, as previously guided
  - AMR: Patient enrollment completed; First data read-out expected in H2'22
  - GBS: 20/30 patients enrolled in the GBS phase 2 study; Higher infection rates are expected as the winter season approaches as well as additional measures will be implemented to accelerate recruitment in the coming months. Completion of enrollment in the GBS trail is anticipated H2 2022/H1 2023
- ✓ Great Place to Work® certification for the 3rd consecutive year
- ✓ $70 million raised in non-dilutive financing
  - Transaction supports the continued development of Hansa's antibody-cleaving enzyme technology platform while extending the cash runway through 2024

Positive reimbursement decisions received in Poland and Scotland for Idefirix® in highly sensitized kidney transplant patients

Market access has now been secured in nine European countries and procedures are ongoing in eight countries including Spain, Italy and Belgium



[1]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

The European Society for Organ Transplantation's (ESOT) guidelines for desensitization treatment of highly sensitized patients published in *Transplant International* in August 2022

Guidelines represent first international consensus on a management pathway for highly sensitized patients

- The European guidelines document is a result of an expert working group, led by Professor Nizam Mamode M.D. Professor of Transplant Surgery, previously at Guys and St Thomas Hospital, London, and supported by other leading experts in the transplantation field.[1]
- Guidelines include imlifidase and provide a new clinical practice tool for healthcare professionals and represent the first international consensus on a management pathway for highly sensitized patients.
- Guidelines articulate the variability in definitions, approaches, outcomes as well as the perceived success of HLA-related transplantations
- Hansa Biopharma sponsors desensitization workstream as part of ESOT's educational programs, via an educational grant

Transplant International

https://www.frontierspartnerships.org/articles/10.3389/ti.2022.10511/full


GUIDELINES
published: 10 August 2022
doi: 10.3389/ti.2022.10511

ESOT | Transplant International

European Guideline for the Management of Kidney Transplant Patients With HLA Antibodies: By the European Society for Organ Transplantation Working Group

Nizam Mamode[1]*, Oriol Bestard[2], Frans Claas[3,4], Lucrezia Furian[5], Siân Griffin[6], Christophe Legendre[7], Liset Pengel[8] and Maarten Naesens[9]

[1]Department of Transplantation, Guys Hospital, London, United Kingdom, [2]Department of Nephrology and Kidney Transplantation, Vall d'Hebron University Hospital, Barcelona, Spain, [3]Department of Immunology, Leiden University Medical Center, Leiden, Netherlands, [4]Department of Surgical Gastroenterological and Oncological Sciences, University Hospital of Padua, Padua, Italy, [5]Department of Nephrology, University Hospital of Wales, Cardiff, United Kingdom, [6]Centre for Evidence in Transplantation, University of Oxford, Oxford, United Kingdom, [7]Department of Microbiology, Immunology and Transplantation, KU Leuven, Leuven, Belgium

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This guideline, from a European Society of Organ Transplantation (ESOT) working group, concerns the management of kidney transplant patients with HLA antibodies. Sensitization should be defined using a virtual parameter such as calculated Reaction Frequency (cRF), which assesses HLA antibodies derived from the actual organ donor population. Highly sensitized patients should be prioritized in kidney allocation schemes and linking allocation schemes may increase opportunities. The use of the ENGAGE 5 ((Bestard et al., Transpl Int, 2021, 34: 1005–1018) system and online calculators for assessing risk is recommended. The Eurotransplant Acceptable Mismatch program should be extended. If strategies for finding a compatible kidney are very unlikely to yield a desensitization may be considered and should be performed with plasma adsorption, supplemented with MiG and/or anti-CD20 antibody. imlifidase, may offer alternatives. Few studies compare HLA on the waiting list, and comparisons of exchange programs (KEP) should d donors, as well as highly

[1]Mamode N, Bestard O, Claas F, Furian L, Griffin S, Legendre C, Pengel L and Naesens M (2022) European Guideline for the Management of Kidney Transplant Patients With HLA Antibodies: By the European Society for Organ Transplantation Working Group. Transpl Int 35:10511. doi: 10.3389/ti.2022.10511

Continuous progress in our ongoing clinical programs

Enrollment status
Oct 19, 2022

Antibody Mediated Rejection Phase 2 study

- 30/30 patients enrolled in the AMR phase 2 study
- Enrollment completed May 2022
- First data read out expected toward the end of 2022*
- Data from the Phase 2 program will determine the path forward for imlifidase in patients with active AMR episodes

- Patients enrolled
- Patients remaining

Guillain-Barré Syndrome Phase 2 study

- 20/30 patients enrolled in the GBS program
- Ten centers are active and open for recruitment; Additional measures will be implemented to accelerate recruitment in the coming months.
- Aim to complete enrollment of GBS patients H2'22/H1'23
- Enrollment expected to be boosted from higher infection rates during winter season, while increased capacity at the enrollment sites is also expected to support a faster enrollment
- Aim to communicate first high-level data read out in H2 2023

Enrollment status
Oct 19, 2022

- Patients enrolled
- Patients remaining

Anti-GBM Phase 3 study

- FDA has accepted Hansa's Investigational New Drug (IND) application to proceed with a pivotal global Phase 3 study
- Aim to commence the planned anti-GBM study later this year, as previously guided. Study will target 50 patients*

- Patients enrolled
- Patients remaining

U.S. ConfIdeS Phase 3 study

Randomized, controlled trial in highly sensitized kidney transplant patients across up to 15 centers

- 39/64 patients enrolled for randomization
- Aim to complete of enrollment expected toward end of 2022
- Aim to complete randomization n the first half 2023
- BLA submission is expected in 2024 under the accelerated approval path

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

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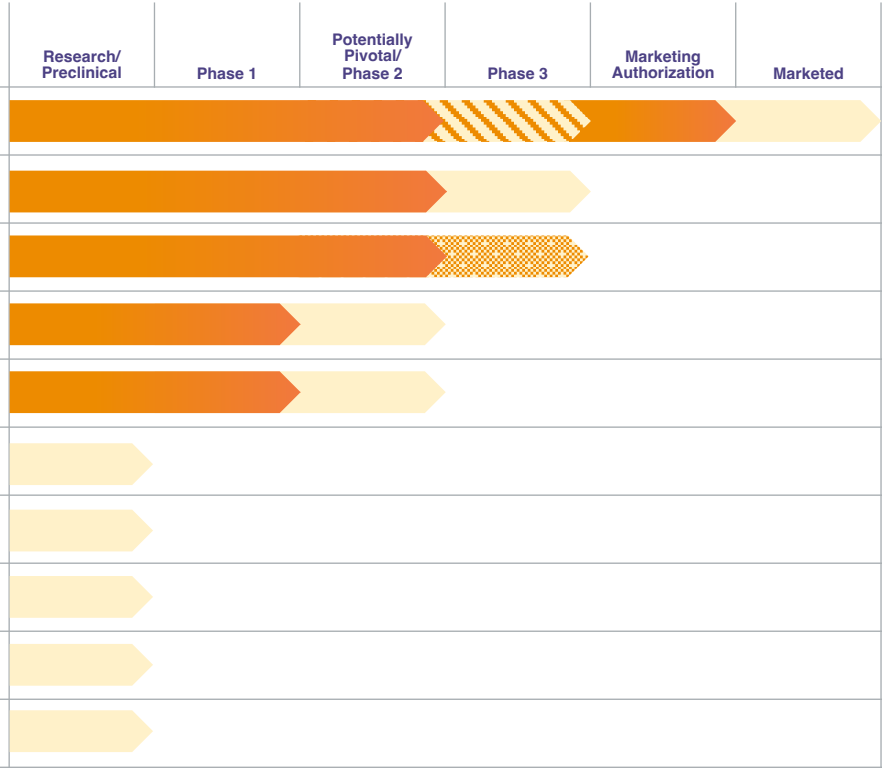
Broad clinical pipeline in transplantation and auto-immune diseases

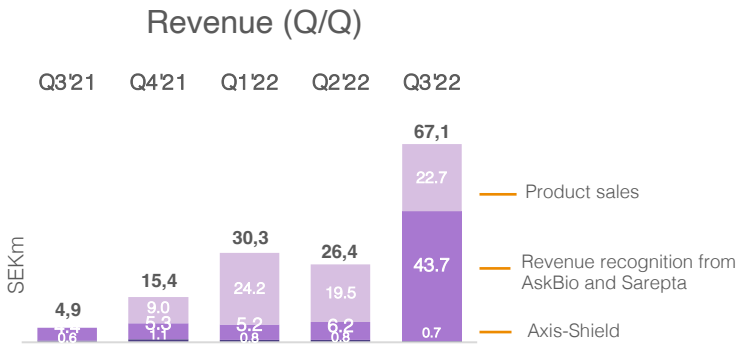
Candidate/ Project	Indication	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients[1,2]	EU: Additional agreements around reimbursement from H2'21
	US: Kidney transplantation in highly sensitized patients[1,2]	Completion of enrollment (64 patients) H2'22
	Anti-GBM antibody disease[3]	Pivotal Phase 3 study expected to commence in 2022 (50 patients)
	Antibody mediated kidney transplant rejection (AMR)	First data read-out H2 2022
	Guillain-Barré syndrome (GBS)	Completion of enrollment (30 patients) H2'22/H1'23
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)	Preclinical research
	Pre-treatment ahead of gene therapy in Duchenne (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	Completion of GLP toxicology studies in 2022
EnzE	Cancer immunotherapy	Research

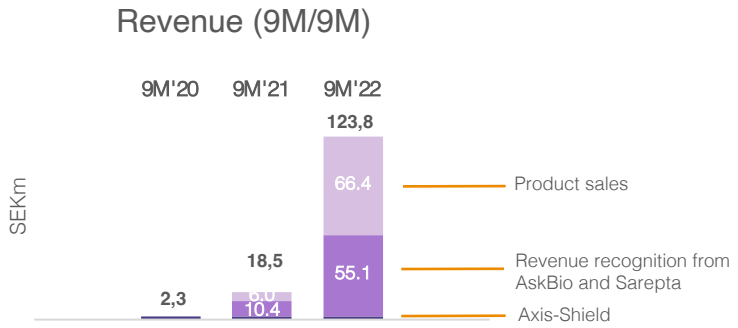


[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7)
[2] Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping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

Completed
Planned
Ongoing
Post approval study running in parallel with commercial launch

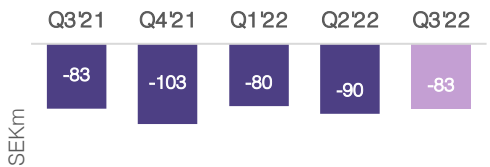
Total Revenue amounted to SEK 67m in the third quarter including SEK 23m in product sales



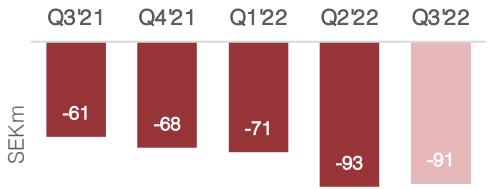


Continued investments in commercialization and our pipeline

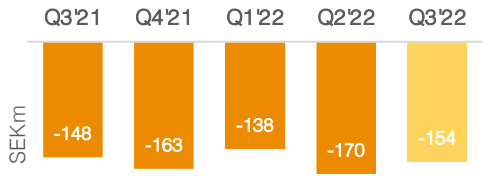
SG&A expenses (Q/Q)



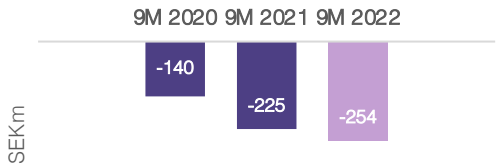
R&D expenses (Q/Q)



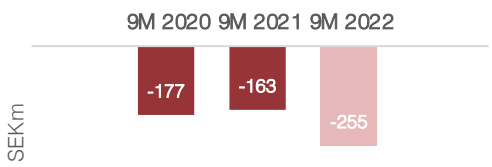
Net loss (Q/Q)



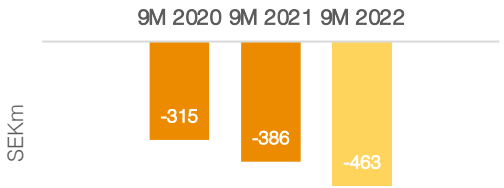
SG&A expenses (9M/9M)



R&D expenses (9M/9M)

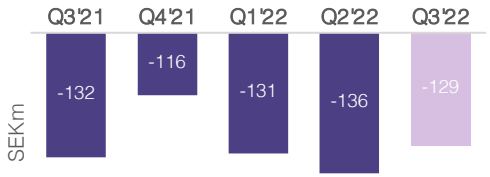


Net loss (9M/9M)

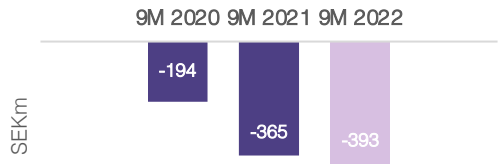


With recent financing transaction secured Hansa's cash runway has extended through 2024

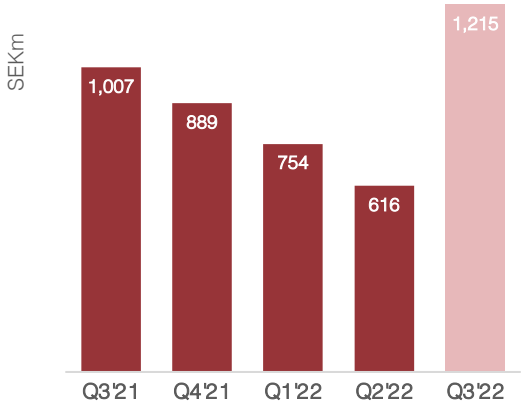
Operating cash flow (Q/Q)



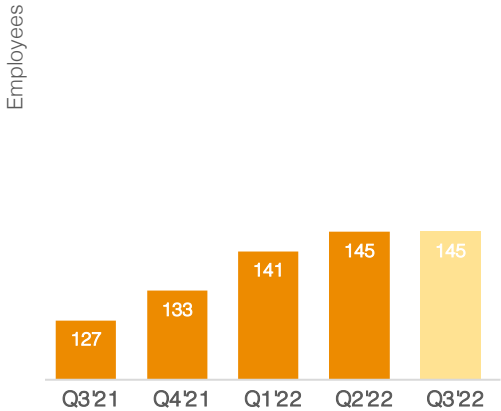
Operating cash flow (9M/9M)



Cash & short-term investments (Q/Q)

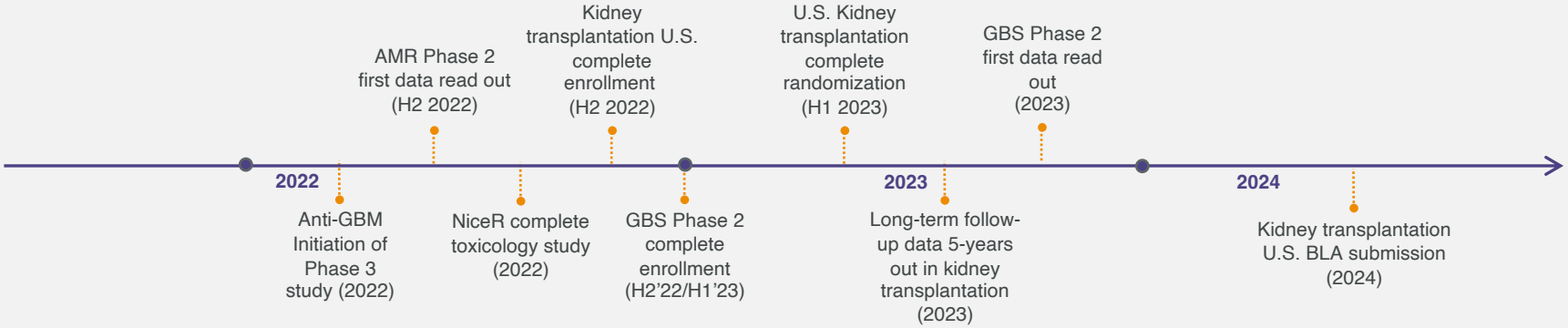


Number of employees (Q/Q)



Upcoming milestones

Milestones subject to potential COVID-19 impact

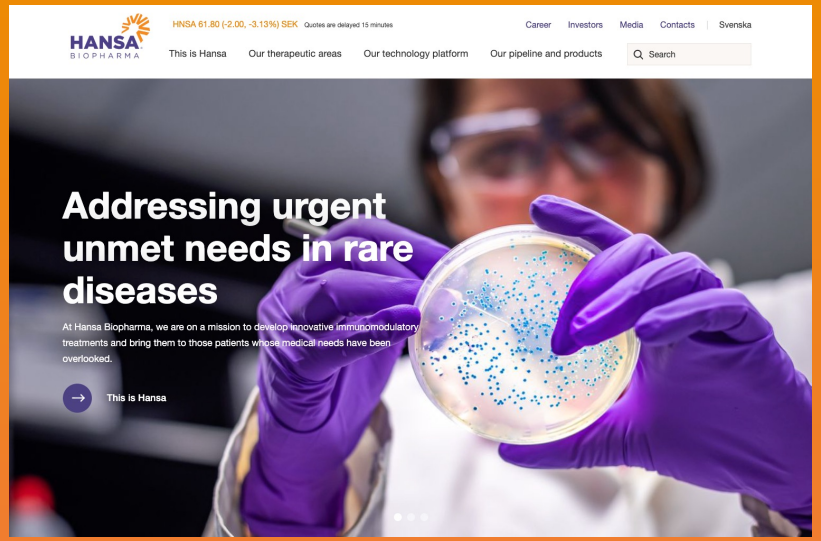


Guidance assumes no persistent impact or further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.

Q&A

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

Visit our new web site
www.hansabiopharma.com



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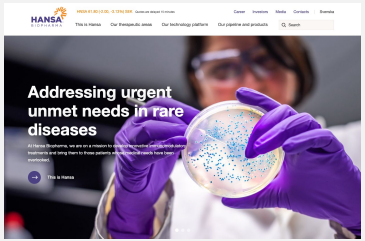

Visit our new web site
www.hansabiopharma.com

Calendar and events

Oct 20, 2022	Redeye After Work presentation, Gothenburg
Oct 21, 2022	Redeye Lunch presentation, Stockholm
Oct 26, 2022	Økonomisk Ugebrev Life Science Conference, Copenhagen
Oct 27, 2022	HCA Capital Expert call on the commercial progress/launch strategy
Nov 10-11, 2022	Bryan, Garnier & Co non-deal road show Paris & London
Nov 22, 2022	Bryan, Garnier & Co KOL Expert call on kidney transplantation (virtual)
Nov 23, 2022	SEB Healthcare Seminar 2022, Stockholm
Nov 24, 2022	Redeye Life Science Day, Stockholm
Dec 1, 2022	Erik Penser Banks Temadag - Health Care, Stockholm
Dec 2, 2022	Geneva Corporate Access Midcap Event, Geneva
Dec 15, 2022	DNB Nordic Healthcare Conference, Oslo
Jan 9, 2023	JPM Week, San Francisco
Feb 2, 2023	Interim Report for January-December 2022
Mar 14, 2023	Carnegie Nordic Healthcare Seminar 2023
Mar 30, 2023	2022 Annual Report
April 20, 2023	Interim Report for January-March 2023
June 14, 2023	2023 Annual General Meeting
July 20, 2023	Half-year Report for January-June 2023
Oct 19, 2023	Interim Report for January-September 2023


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