



HANSA

BIOPHARMA

Conference Call
Presentation
Year-end Report 2021

Lund, February 3, 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.

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Solid progress across the business as Hansa concludes 2021

Highlights for the fourth quarter of 2021

- ✓ **Launch and market access efforts in Europe progressing as planned**
 - Market access procedures are ongoing in 14 countries
 - Health Technology Assessment dossier for Spain submitted during January 2022, which completes HTA filings in all of the five largest markets in Europe
- ✓ **New commercialization partnership with Medison Pharma in certain countries in Central Eastern Europe and Israel**
- ✓ **First patients enrolled into the pivotal U.S. ConfIdaS study**
- ✓ **Clinical pipeline**
 - Anti-GBM: New Phase 3 to commence in 2022 with 50 patients across U.S. and EU following a pre-IND meeting with the U.S. FDA
 - AMR: Patient enrollment on track for completion first half 2022 as previously guided
 - GBS: 15/30 patients enrolled in the GBS phase 2 study
- ✓ **Year-end cash position of SEK 889 million (USD 98m)**
 - Hansa financed into 2023, as previously guided

Events after the reporting period

- ✓ **Agreement with AskBio (subsidiary of Bayer AG) to evaluate feasibility of imlifidase ahead of gene therapy in Pompe disease**
- ✓ **Hansa to explore allogeneic hematopoietic stem cell transplantation**



Progress with commercial metrics; Market access procedures ongoing in fourteen countries

Pricing and Reimbursement processes on track;
Completion of HTA filings in EU4+UK

ESOT workstream formed with leading
experts to advance clinical guidelines in
desensitization

Pricing and Reimbursement

4

- ✓ Agreements on funding obtained:
 - Sweden
 - Netherlands
 - Finland (on a hospital basis)
 - Greece (on a hospital basis)
- ✓ Additional milestones
 - Preparing for market access in additional international markets beyond Europe and the U.S. (e.g. Israel)
 - Pursuing select early access opportunities

Market access procedures

14

- ✓ Market access procedures are ongoing in fourteen countries
 - Sweden
 - Netherlands
 - Finland
 - Norway
 - Denmark*
 - France
 - Belgium
 - UK
 - Germany
 - Italy
 - Scotland
 - Israel
 - Greece
 - Spain
- ✓ Health Technology Assessment (HTA) dossier for Spain was submitted during January 2022, completing HTA filings in all of the five largest markets in Europe.

* In Denmark, the HTA has been pre-submitted

Clinical readiness

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- ✓ 10 priority centers ready to take on patients, including:
 - Uppsala, Sweden
 - Erasmus, Rotterdam
 - University Hospital, Helsinki
- ✓ Hansa to continue to work closely with additional priority centers on clinical readiness
- ✓ Growing number of highly sensitized patient candidates identified and prioritized for incompatible kidney transplantations in the coming months

Awareness

- ✓ Over 30 experts engaged and committed to operationalizing HLA-incompatible kidney transplants for some of their highly sensitized patients.
- ✓ European Society for Organ Transplantation (ESOT) workstream formed and continuing its work on advancing clinical guidelines in the field of desensitization.

New multiregional commercialization partnership with Medison Pharma

Partnership will cover Poland, Croatia, Hungary and Slovenia in addition to Israel

- Multiregional agreement for Medison to commercialize Idefirix® for kidney transplants in certain countries in Central Eastern Europe and Israel
- The commercialization is based on current conditional marketing authorization for Europe and pending marketing authorization by Israel's Ministry of Health
- An application for marketing authorization for desensitization treatment in kidney transplant was filed in Israel in June 2021; if granted would make Israel the first market outside of Europe where imlifidase is commercialized
- Hansa and Medison will be working together to obtain pricing and reimbursement as required depending on the country

MEDISON

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Collaboration with AskBio to evaluate imlifidase in gene therapy targeting Pompe disease

Feasibility program to evaluate imlifidase as pre-treatment ahead of gene therapy in Pompe disease for patients with pre-existing neutralizing antibodies (NAbs) to adeno-associated virus (AAV)



Hansa's key resources and deliverables

- Imlifidase validated with positive clinical efficacy and safety data as well as European approval
- Significant know-how around antibody cleaving enzymes
- Clear path to U.S. approval (kidney transplant)
- Hansa supplies material and provides additional support

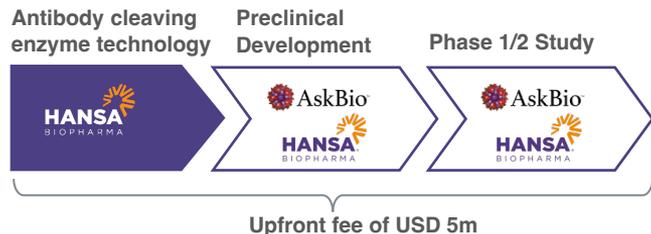


Fully owned subsidiary of Bayer AG

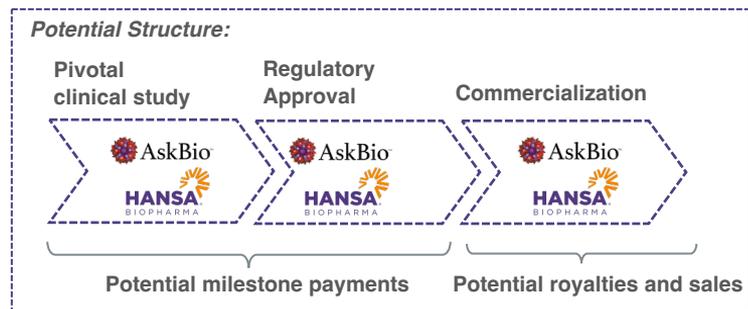
AskBio's key resources and deliverables

- Early innovator in the Gene Therapy space with AAV platform and ongoing clinical stage Pompe disease program
- Conducts pre-clinical and clinical trials according to agreed plan

Current agreement scoped around a feasibility program which covers preclinical work and a Phase 1/2 study



Exclusive option for AskBio to negotiate a potential full development and commercialization agreement



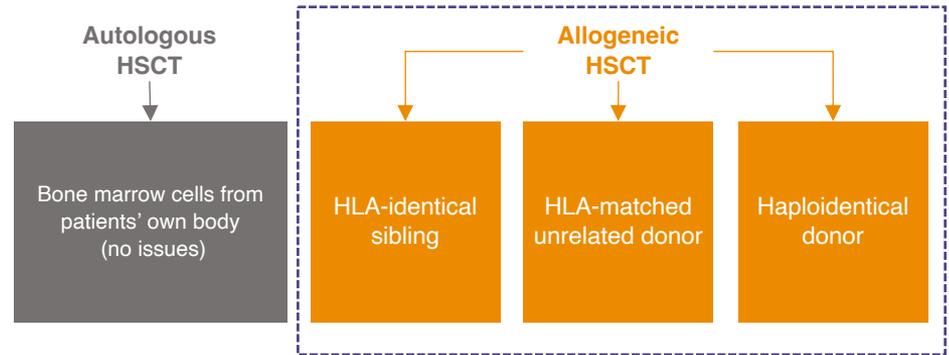
Exploring potential use of imlifidase in allogeneic hematopoietic stem cell transplantation (HSCT)

Desensitization treatment of patients with high levels of donor specific antibodies (DSA) prior to allogeneic HSCT transplant is a challenge; Imlifidase may have the potential to inactivate DSAs prior to transplantation

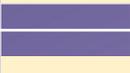
Transplantations are often acutely needed, which reduces the time available to find an adequately matched donor

- Haploidentical donors (e.g. parents, children) are often available and transplant outcome is good (e.g. engraftment, graft survival, survival)
- However, presence of donor specific antibodies (DSAs) have a negative impact on transplant outcome² (e.g. graft failure and survival) Prevalence of DSAs in allogeneic HSCT is typically between 10-21%¹
- There are currently no approved drugs to manage patients with high levels of DSAs and current desensitization methods are inadequate, thus preventing patients from having a potentially life-saving HSCT
- Consensus recommendations published¹ by the EBMT³ on testing, monitoring and treatment of patients with donor specific antibodies recommend to desensitize all patients with DSAs
- Imlifidase may have the potential to transform the standard of care by enabling clinicians to inactivate DSAs prior to transplantation

Pre-existing DSAs may result in primary graft failure and poor survival after allogeneic hematopoietic stem cell transplantations



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 ^{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)							Completion of enrollment (30 patients) H1 2022
	Guillain-Barré syndrome (GBS)							Timeline guidance under review
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)							Preclinical phase
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)							Preclinical phase
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)							Preclinical phase
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology							Completion of GLP toxicology studies in 2022
EnzE	Cancer immunotherapy							Research phase

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

*) 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

Ongoing Clinical Programs

Fourth quarter highlights

- First patients enrolled in the pivotal U.S. ConfIdeS study in kidney transplant
- Alignment with FDA on a Phase 3 study of imlifidase in anti-GBM patients
- AMR: Patient enrollment on track for completion first half 2022, as previously guided
- GBS: Timeline for completion of enrollment under review due to the direct and indirect effects of the escalating pandemic

Enrollment status
Feb 2, 2022

Antibody Mediated Rejection

- 23/30 patients enrolled in the AMR phase 2 study
- Completion of enrollment expected H1 2022* as previously guided
- First data read out expected in H2 2022*



- Patients enrolled
- Patients remaining

Guillain-Barré Syndrome

- 15/30 patients enrolled in the GBS phase 2 study
- GBS enrollment timeline under review given the difficulty of predicting enrollment due to the direct and indirect effects of the escalating pandemic
- Hansa expects to update its guidance for completion of enrollment in GBS in April 2022



- Patients enrolled
- Patients remaining

Enrollment status
Feb 2, 2022

Anti-GBM

- Alignment with FDA on a pivotal Phase 3 study of imlifidase in anti-GBM patients
- The planned study will target approximately 50 patients with anti-GBM disease across the U.S. and Europe
- The first patient is expected to be enrolled in 2022*



- Patients enrolled
- Patients remaining

U.S. randomized control trial, "ConfIdeS"

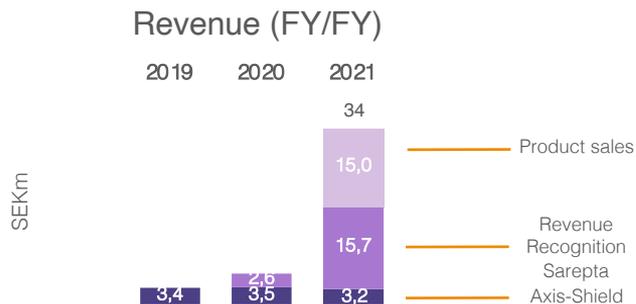
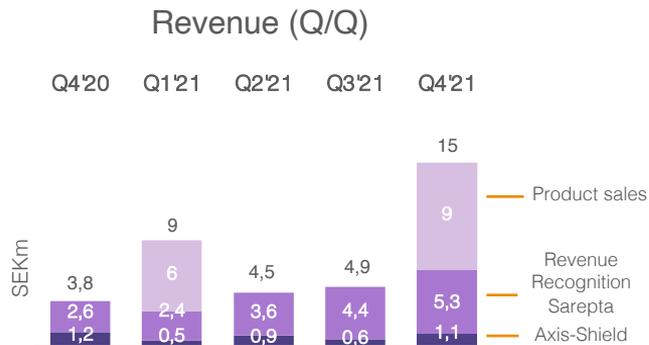
- 2/64 patients enrolled in the phase 3 "ConfIdeS" study
- First patients enrolled at Columbia University (NY) at the end of Dec 2021
- Five centers are active and open for enrollment
- Completion of enrollment expected H2 2022*
- Completion of 12 months follow-up expected H2 2023*



- 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.

Revenue amounted to SEK 15m for Q4'21 and SEK 34m for FY'21



Continued investments in our commercialization and pipeline

SG&A expenses (Q/Q)



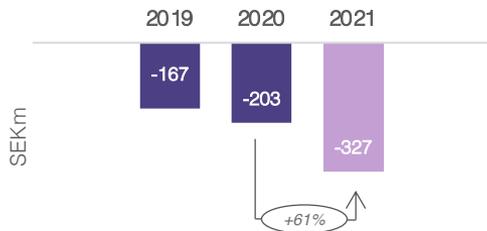
R&D expenses (Q/Q)



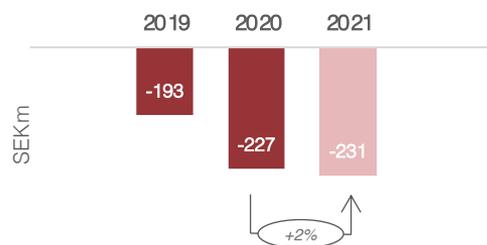
Net loss (Q/Q)



SG&A expenses (FY/FY)



R&D expenses (FY/FY)



Net loss (FY/FY)

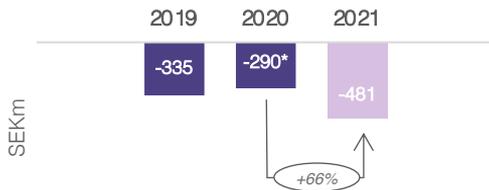


With current cash position and projected burn-rate, operations is financed into 2023

Operating cash flow (Q/Q)

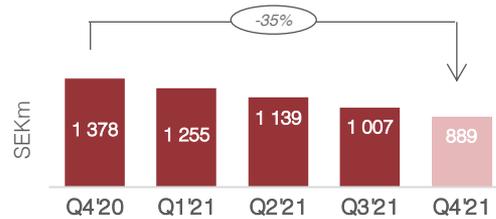


Operating cash flow (FY/FY)

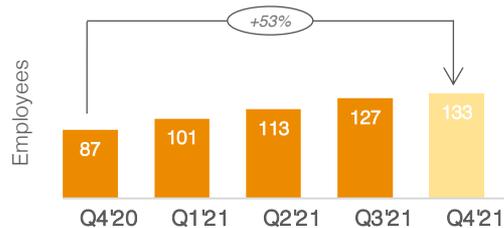


* incl. USD 10 mio (SEK ~90 mio) upfront from Sarepta

Cash & short-term investments (Q/Q)



Number of employees (Q/Q)

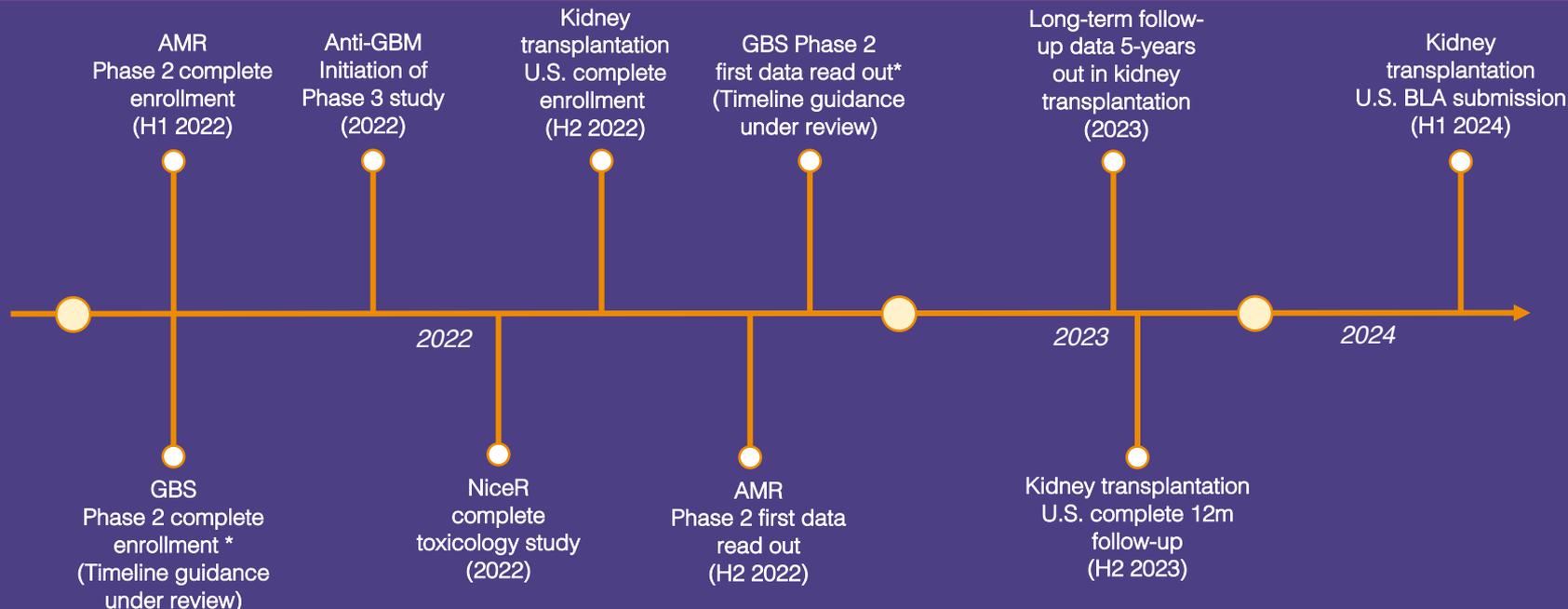


Shareholders' equity (Q/Q)



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.

*GBS: Given the current difficulty of predicting enrollment due to the direct and indirect effects of the persistent and even escalating pandemic, Hansa expects to update its guidance for completion of enrollment in GBS in April 2022

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

HANSA BIOPHARMA

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HANSA 246.60 (-5.20, -2.06%) SEK

Our Why

"We are leveraging our cutting-edge science to develop lifesaving and life altering therapies for patients with rare immunological diseases."

Søren Tøstrup, President and CEO

Latest news

Jul 08, 2020
Regulatory press release
Hansa Biopharma announces successful completion of SEK 1.1bn
RISK: 1/21 (evaluation of risk) Use and release.

Stephanie
Patient and relative | The Netherlands

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Calendar and events

Feb 3 2022

Year-End report for Jan - Dec 2021

Mar 10 2022

Erik Penser Bolagsdag, Stockholm

Mar 10 2022

Redeye Investor Forum, Gothenburg

Mar 15 2022

Carnegie Healthcare Seminar 2022, Stockholm

Mar 31 2022

Redeye Investor Forum, Malmö

April 7 2022

Annual Report 2021

April 21 2022

Interim Report for January-March 2022

April 21 2022

Kempen Life Sciences Conference 2022, Amsterdam

April 27 2022

Redeye Orphan Drugs 2022, Stockholm

May 2022

RBC Global Healthcare Conference 2022, New York City

May 18 2022

ABG ABGSC Life Science Summit 2022, Stockholm

June 16 2022

Annual General Meeting 2022

July 21 2022

Half year 2022 report

Oct 20 2022

Interim Report for January-September 2022

