



Conference Call
Presentation
Jan-Dec 2019

Lund, February 6, 2020



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Solid pipeline advancement. Clear regulatory path in the US; EMA process on track

Highlights for the fourth quarter 2019

- Hansa Biopharma's transformation into a commercial-stage biopharmaceutical company continues according to plan
- Imlifidase in kidney transplantation
 - EMA process on track with Day 120 responses submitted; CHMP opinion expected in the second quarter of 2020
 - Agreement on a clear regulatory path with the FDA. Hansa to conduct a randomized, controlled clinical study in a well-defined population with the highest unmet medical in the context of the US Kidney Allocation System
- Solid pipeline advancements
 - Enrollment in the investigator initiated anti-GBM study completed; Completion marks an important milestone for the Company's advancement into auto-immune diseases
 - First two patients treated in GBS; Enrollment progressing in AMR
- CSO, Christian Kjellman to also assume COO role to lead a focused and integrated launch strategy targeting leading transplantation centers in Europe
- Cash position stood at SEK 601m (~USD 60m) end of Dec 2019; Hansa Biopharma is financed into 2021



EMA review process on track; Agreement with the FDA on a clear regulatory path forward in the US

Imlifidase in kidney transplantation

Europe (EMA)

- Regulatory review process progressing as expected; Day 120 answers submitted on December 20, 2019
- Opinion from Committee for Medicinal Products for Human Use (CHMP) expected during the second quarter of 2020
- Decision by European Commission expected during the summer of 2020

U.S. (FDA)

- Agreement with FDA to conduct a randomized, controlled clinical study in approximately 50 highly sensitized kidney patients ($\geq 99.9\%$ cPRA) using eGFR (kidney function) after 12 months as a surrogate endpoint
- Results from this clinical study could support BLA submission by 2023 under the accelerated approval pathway

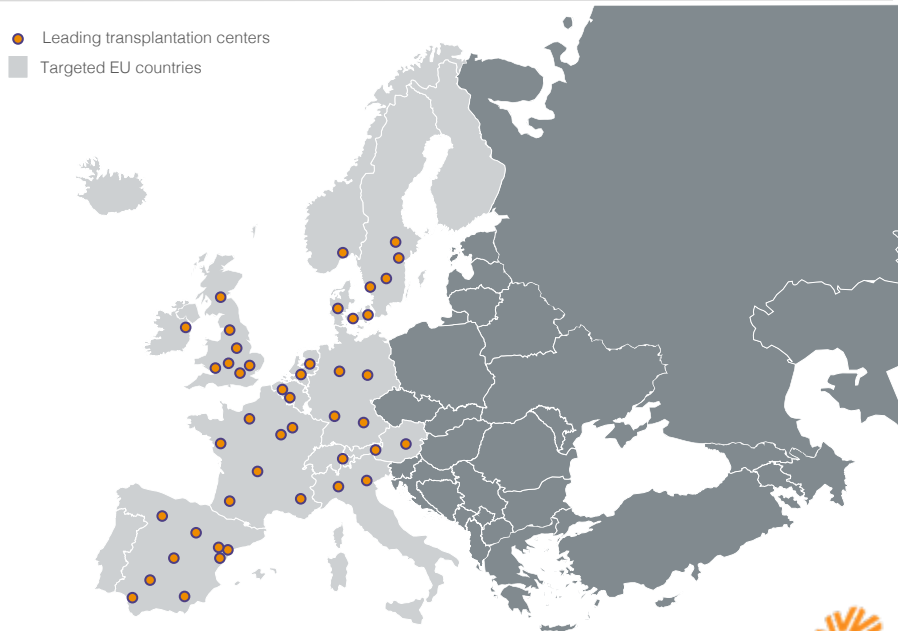


Focused launch strategy targeting leading kidney transplantation centers to ensure positive experience

Potential EU launch under conditional approval

- A sequenced and focused strategy to launch imlifidase
 - Well defined and concentrated target audience
 - Center-focused launch strategy targeting leading clinics with the potential to become early adopters
 - Key to secure early positive experience in right patients; sales ramp-up as leading centers and clinicians gain experience
- Building awareness and Key Opinion Leader advocacy through Medical Science Liaisons (MSLs) in key European markets
- Post-approval study to be initiated following potential marketing authorization - an opportunity to generate relevant experience and broaden out the experience with imlifidase

EU launch will focus on leading transplantation centers



Enrollment in Anti-GBM completed; First two patients treated in GBS and AMR respectively

Ongoing studies evaluating safety and efficacy

Enrollment



Anti-GBM (investigator-initiated study)

- 15/15 patients enrolled in anti-GBM across 5 European countries
- First data read-out expected in Q3 2020



Antibody Mediated Rejection

- 2/30 patients treated with imlifidase in AMR. 6/8 sites have been initiated to recruit patients in the US, Europe and Australia
- Enrollment expected to be completed H2 2020



Guillain-Barré Syndrome

- 2/30 patients enrolled. 6/10 sites are recruiting patients across France, UK and the Netherlands
- Enrollment expected to be completed in H1 2021

■ Patients enrolled
■ Patients left



Broad pipeline in transplantation and auto-immune diseases

Candidate / Projecting	Indication	Research/ Preclinical	Phase 1 ¹	Potentially Pivotal program/ Phase 2 ²	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	Kidney transplantation in highly sensitized patients				*)		EU: CHMP Opinion US: Initiation of clinical study to support BLA submission in 2023
	Anti-GBM antibody disease (investigator-initiated study)						Data read-out Q3 2020
	Antibody mediated kidney transplant rejection (AMR)						Complete enrolment
	Guillain-Barré syndrome						Complete enrolment
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology						Development of CMC process / Tox studies
EnzE	Cancer immunotherapy						Research phase



Completed



Ongoing

¹ Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7).

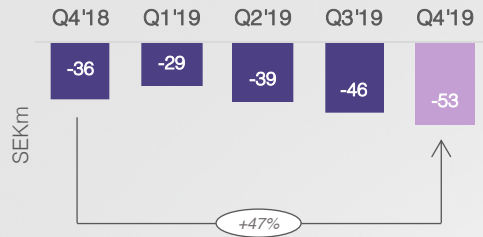
² Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)

*) EMA: In imlifidase for kidney transplantation we have filed for conditional approval after completion of phase 2.
A post-approval study would need to be executed in case of approval.

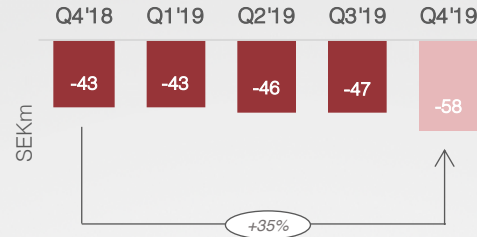
FDA: Agreement with the FDA on a regulatory path forward in the US. New clinical study to support BLA submission by 2023

SG&A and R&D spending increase in preparation for potential conditional approval in EU and pipeline advancement

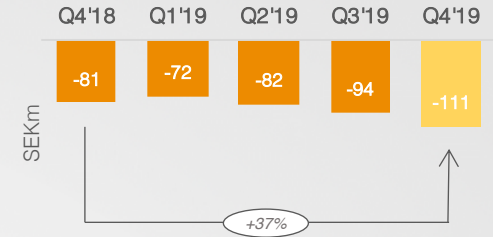
SG&A expenses (Q/Q)



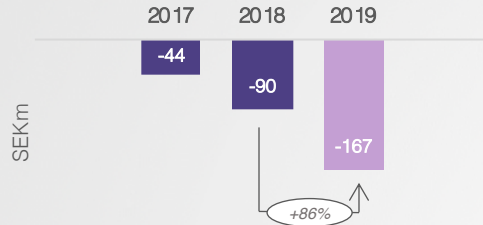
R&D expenses (Q/Q)



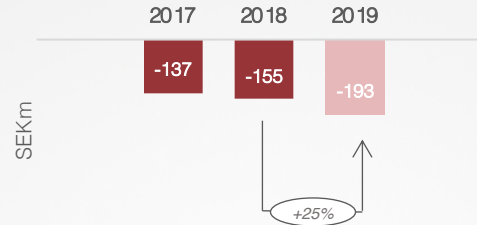
Net loss (Q/Q)



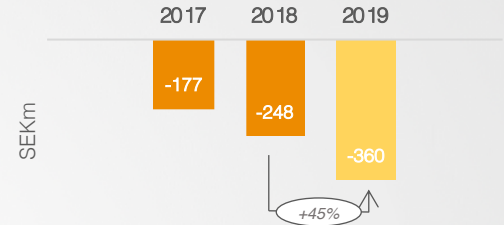
SG&A expenses (Y/Y)



R&D expenses (Y/Y)

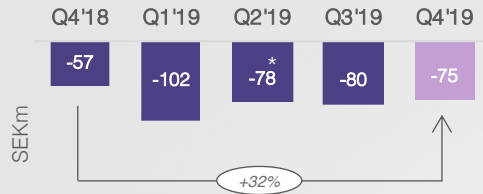


Net loss (Y/Y)

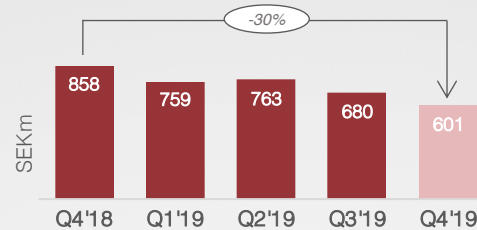


Cash position stood at SEK 601m (~USD 60m) at year-end 2019; Hansa Biopharma is financed into 2021

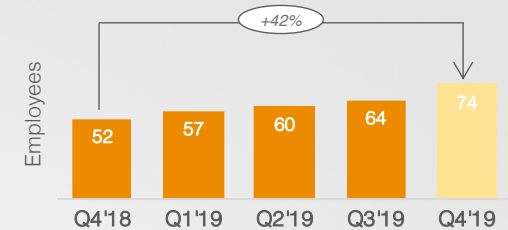
Operating cash flow (Q/Q)



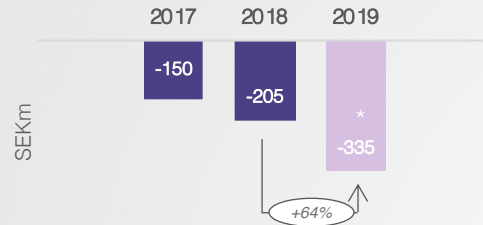
Cash & short term investments (Q/Q)



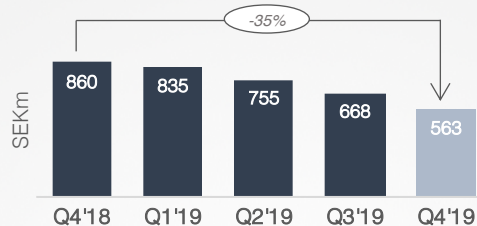
Number of employees (Q/Q)



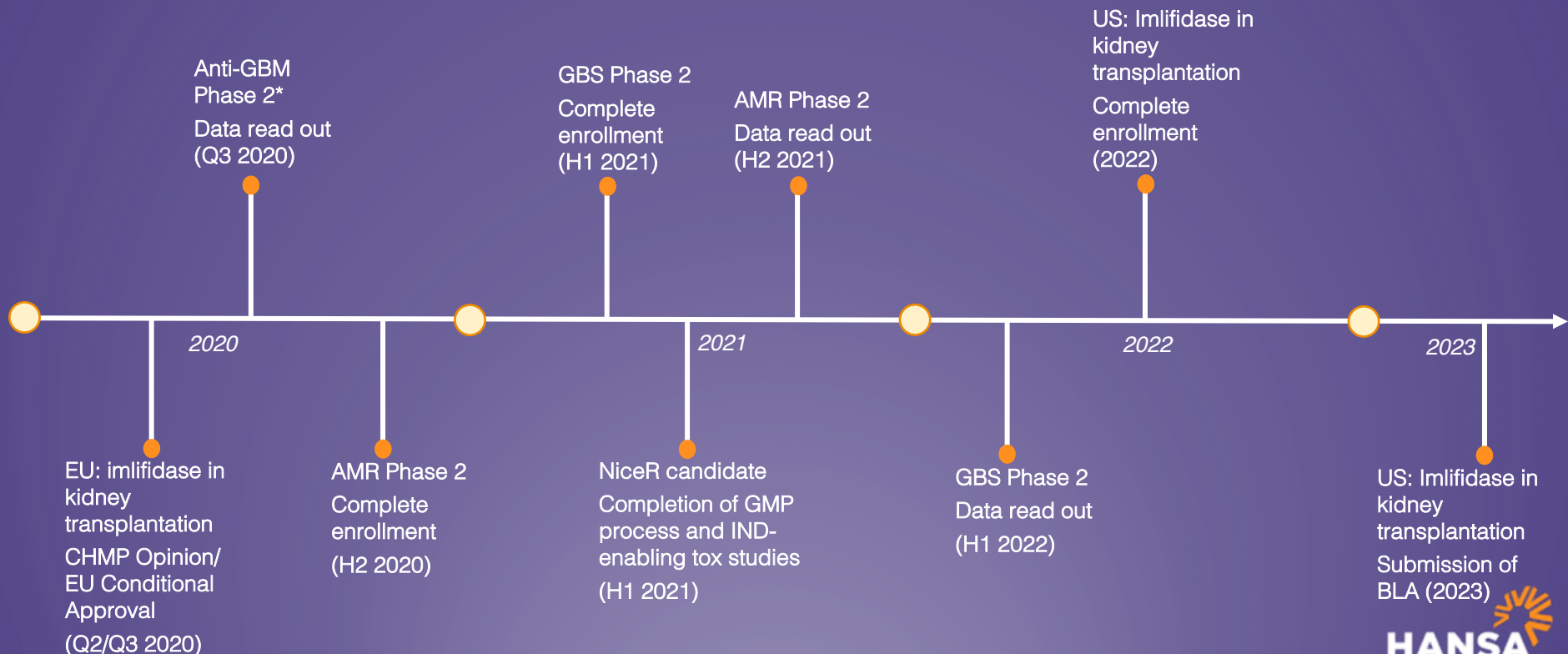
Operating cash flow (Y/Y)



Shareholders equity (Q/Q)



Upcoming milestones



*) Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

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

