



Conference Call
Presentation
Q2 2019

Lund, July 18, 2019



Forward-looking statement

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Hansa Biopharma's business, financial condition and results of operations. The terms "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 statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realized. Factors that could cause these differences include, but are not limited to, implementation of Hansa Biopharma's strategy and its ability to further grow, risks associated with the development and/or approval of Hansa Biopharma's products candidates, ongoing clinical trials and expected trial results, the ability to commercialize imlifidase, 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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Continued progress on strategic agenda; Imlifidase highlighted at ATC

Highlights for the second quarter 2019

- Good progress on strategic agenda
 - Guillain Barré Syndrome (GBS) study started - expansion outside transplantation and into auto-immune diseases continues
 - Divestment of equity holding in Genovis
 - Advancement across pipeline
 - Expanding our presence in Europe and the U.S
- High level of excitement at the 2019 American Transplant Congress, with imlifidase highlighted in three presentations. Plenary abstract by Dr. Huang won the “People’s Choice Award”
- Advancing imlifidase toward commercialization for kidney transplantation in highly sensitized patients. MAA under review by EMA; complementary analysis being conducted in the U.S.
- All resolutions were passed at the AGM 2019
- Cash position stood at SEK 763m (~USD 80m) end of June 2019



Imlifidase benefits highlighted in recent ATC presentations

Plenary abstract by Dr. Huang, Cedars-Sinai wins “People’s Choice Award”

Dr. Huang, Cedars-Sinai Medical Center

“Three-year outcomes of highly sensitized kidney transplant recipients”

- Demonstrated a significant reduction in time on the waitlist for transplantation among imlifidase treated patients compared to similarly sensitized matched controls in both the current and previous U.S. Kidney Allocation System
- The plenary abstract by Dr. Huang won the ATC’s People Choice Award as the most impactful to the transplant community

Dr. Montgomery, NYU Langone

“The safety and efficacy data of imlifidase in highly sensitized kidney transplant patients”

- Six months follow up results continue to show that imlifidase has enabled all patients to undergo transplantation resulting in good kidney function and graft survival

Dr. Everly, Terasaki Research Institute

“A Prognostic Drug Development Tool to Assess the Transplantability at the Time of Listing for Kidney Transplant Candidates.”

- Dr. Everly reported on the results of simulations done in highly sensitized patients, which demonstrated that transplant rates could be increased by 25% if there were a therapy to address the HLA antibody barrier



Continued advancement toward commercialization

Imlifidase in kidney transplantation

Europe (EMA)

- MAA for imlifidase accepted end of Feb'19; regulatory review progressing
- Opinion from EMA expected within 210 working days, plus clock stops

U.S. (FDA)

- Conducting complementary transplantability analyses comparing imlifidase-treated patients and matched controls from U.S. transplant registry
- Upon completion of analyses, Hansa to request FDA meeting to determine U.S. regulatory path forward. Meeting expected in H2'19
- U.S. administration announced initiatives to increase transplant rate and quality of life for dialysis patients and also reduce expenditure to treat chronic and end-stage renal disease



Anti-GBM enrolling; AMR & GBS receives CTA approval. NiceR lead candidate selected

Advancement across our pipeline in 1H 2019

Anti-Glomerular Basement Membrane Disease (Anti-GBM)

- 9 patients enrolled out of targeted 15. Adding more sites and expect the study to be fully enrolled by year-end

Antibody Mediated Rejection (AMR) in kidney transplant

- Phase 2 study with imlifidase in AMR received CTA approval in March'19. Recruitment of up to 30 patients initiated from eight sites in the U.S., Europe and Australia.
- Study is a randomized, open-label multi-center, active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in acute AMR

Guillain-Barré Syndrome (GBS)

- Phase 2 study with imlifidase in GBS received CTA in April'19

NiceR

- Lead candidate selected in next-generation program for repeat dosing
- Development of a GMP process initiated; preparations for toxicology studies are ongoing



New GBS study marks continued expansion outside transplantation

Initiation of GBS Phase 2 study in Europe

- Guillain Barré Syndrome (GBS) is a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system affecting 1-2 in 100,000 people annually
- CTA approval obtained for Phase 2 study in GBS in April
- Recruitment of up to 30 patients initiated at ten clinics in France, U.K. and the Netherlands.
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS
- In 2018, the FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS



Broad pipeline in transplantation and auto-immune diseases

Candidate / Projecting	Indication	Research/ Preclinical	Phase 1 ¹	Pivotal program/ Phase 2	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	Kidney transplantation in highly sensitized patients	<div></div>	<div></div>	<div></div>	<div>*)</div>		MAA review by EMA Follow-up meeting with FDA
	Anti-GBM antibody disease	<div></div>	<div></div>	<div></div>			Complete enrolment
	Antibody mediated kidney transplant rejection (AMR)	<div></div>	<div></div>	<div></div>			Complete enrolment
	Guillain-Barré syndrome	<div></div>	<div></div>	<div></div>			Complete enrolment
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	<div></div>					Development of CMC process / Tox studies
EnzE	Cancer immunotherapy	<div></div>					Research phase

Completed
 Ongoing

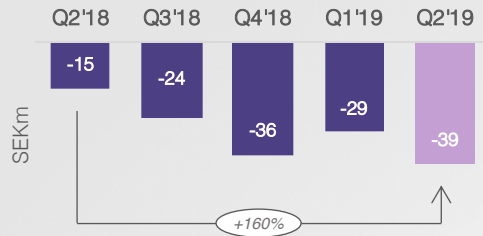
¹ Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7).

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

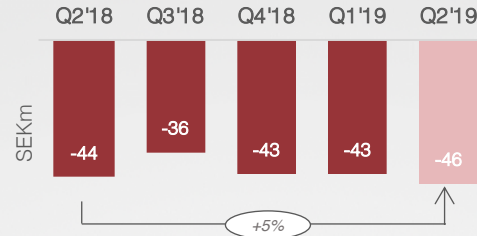
FDA: Discussion on path forward in the US is still ongoing.

SG&A and R&D spending increase with commercial preparation and pipeline advancement

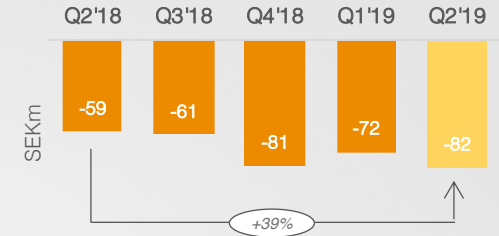
SG&A expenses (Q/Q)



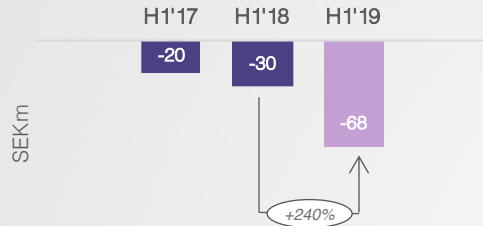
R&D expenses (Q/Q)



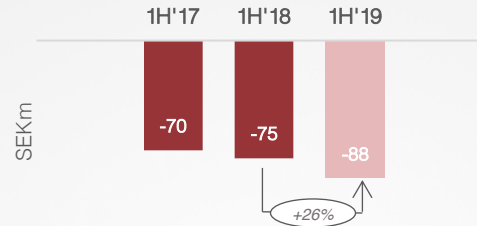
Net loss (Q/Q)



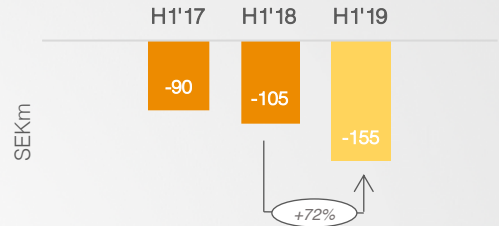
SG&A expenses (Y/Y)



R&D expenses (Y/Y)

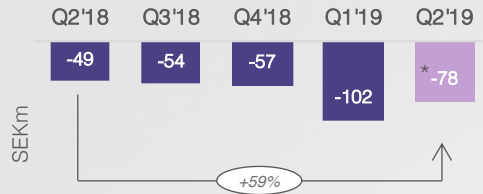


Net loss (Y/Y)

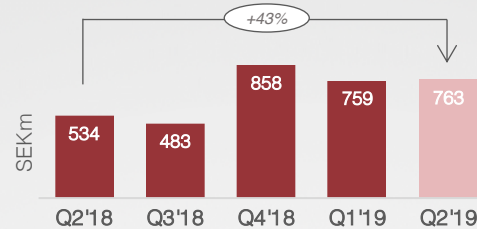


Cash flow follows increased activity level; positively impacted by the divestiture of equity stake in Genovis.

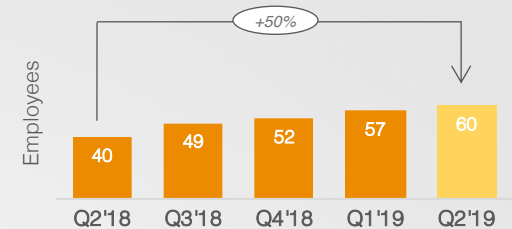
Operating cash flow (Q/Q)



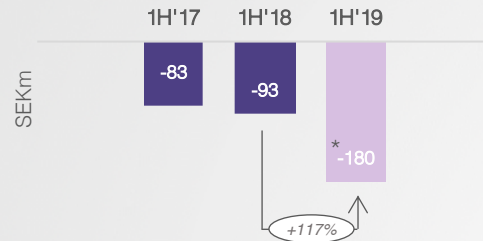
Cash & short term investments (Q/Q)



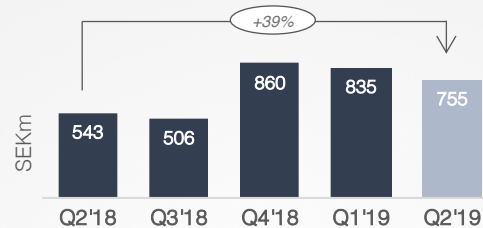
Number of employees (Q/Q)



Operating cash flow (Y/Y)



Shareholders equity (Q/Q)



Near-term milestones

- ✓ Complete complementary transplantability analysis and request FDA meeting in order to determine U.S. regulatory path forward. Meeting expected 2H 2019
- ✓ Imlifidase MAA review: EMA opinion expected 210 days post submission, plus clock stops
- ✓ Complete enrolment in Phase 2 in anti-GBM by year end
- ✓ Enrolment in AMR and GBS Phase 2 studies
- ✓ Development of GMP process and toxicology studies for lead NiceR candidate

Q&A

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

