HANSA BIOPHARMA

Conference Call Presentation Jan-Sep 2019

Lund, October 31, 2019

Forward-looking statement

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Positive results presented at ESOT; FDA meeting confirmed

Highlights for the third quarter 2019

- Solid progress across the organization
  - Expanding our global footprint
  - Building medical and commercial team to support potential launch of imlifidase in 2020
  - Increasing our engagements with the healthcare community
- Positive imlifidase data presented at the ESOT congress in Copenhagen. Pooled analysis of 46 highly sensitized patients
- EMA regulatory review process progressing as planned; CHMP opinion expected in the first half of 2020.
- Follow-up meeting with the FDA scheduled for Nov 20, 2019
- First patient dosed in AMR; Continued enrollment in Anti-GBM
- Explore potential to enable gene therapy in patients with Neutralizing Antibodies (NAbs)
- Cash position stood at SEK 680m (~USD 70m) end of Sep 2019

Imlifidase enabled transplantation in 46 highly sensitized patients

Pooled analysis of four Phase 2 trials presented

- Analysis included 46 patients
  - 50% had a cPRA of 100% (Average 99%)
  - 85% were crossmatch positive
  - 70% were retransplanted
- Donor Specific Antibody (DSA) levels rapidly decreased and all crossmatches were converted to negative, thus enabling transplantation in all patients
- No strong correlation between DSA levels and AMR. AMR episodes occurred in 33% of patients - all treated with standard of care
- At study completion, all patients alive and graft survival at 94%

ESOT CONGRESS 2019
INSPIRING MINDS, DRIVING PROGRESS
in COPENHAGEN

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Continued advancement toward potential commercialization

Imlifidase in kidney transplantation

Europe (EMA)

- MAA for imlifidase accepted end of Feb'19; regulatory review progressing as expected
- Opinion from Committee for Medicinal Products for Human Use (CHMP) expected during the first half of 2020

U.S. (FDA)

- Follow-up meeting with the U.S. Food and Drug Administration scheduled for November 20, 2019
- Discussions from Dec 2018 meeting to be continued to determine U.S. regulatory path forward
- U.S. Department of Health and Human Services set out three specific goals for end-stage renal disease (ESRD):
  1) Reduce number of patients who develop ESRD by 25% by 2030
  2) 80% of new ESRD patients in 2025 either receive a transplant or homecare dialysis
  3) Double the number of kidneys available for transplant by 2030

First patient treated in AMR; 11 patients enrolled in Anti-GBM

Solid progress in our pipeline over 9 months

Anti-Glomerular Basement Membrane Disease (Anti-GBM)

- 11 patients enrolled out of targeted 15. Additional sites have been added to complete the enrollment by year-end

Antibody Mediated Rejection (AMR) in kidney transplant

- First patient treated with imlifidase in our AMR Phase 2 study
- The study is designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in the treatment of episodes of acute AMR

Guillain-Barré Syndrome (GBS)

- Recruitment process initiated in our GBS Phase 2 study; enrolling up to 30 patients at ten clinics in the EU
- The study is designed to evaluate the safety, tolerability and efficacy of imlifidase in GBS patients in combination with standard-of-care intravenous immunoglobulin (IVIg)

NiceR

- Lead candidate selected. Development of a GMP process ongoing as well as preparations for toxicology studies

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				*)		MAA review by EMA Follow-up meeting with FDA Nov 20, 2019
	Anti-GBM antibody disease						Complete enrollment
	Antibody mediated kidney transplant rejection (AMR)						Complete enrollment
	Guillain-Barré syndrome						Complete enrollment
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology						Development of CMC process / Tox studies
EnzE	Cancer immunotherapy						Research phase

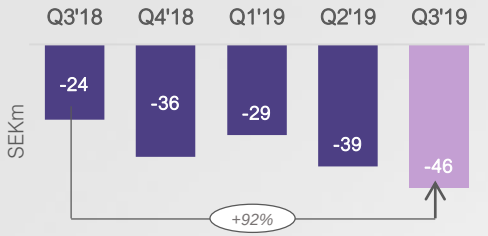
[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7).

*) 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.

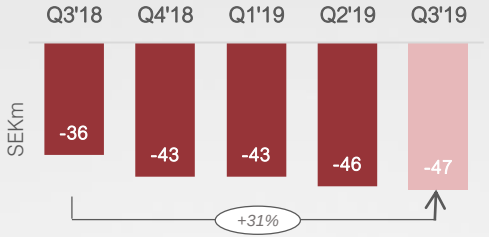
FDA: Discussion on path forward in the US is still ongoing.

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

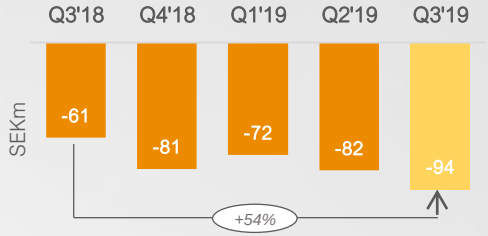
SG&A expenses (Q/Q)



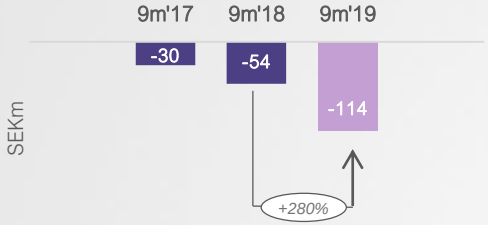
R&D expenses (Q/Q)



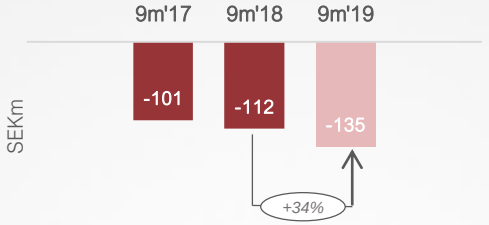
Net loss (Q/Q)



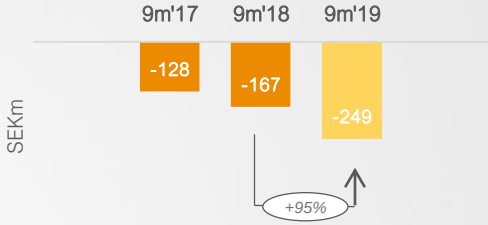
SG&A expenses (Y/Y)



R&D expenses (Y/Y)

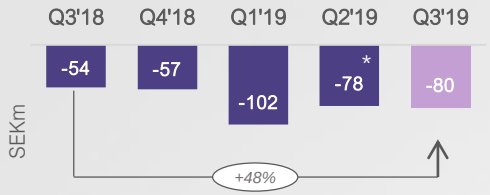


Net loss (Y/Y)

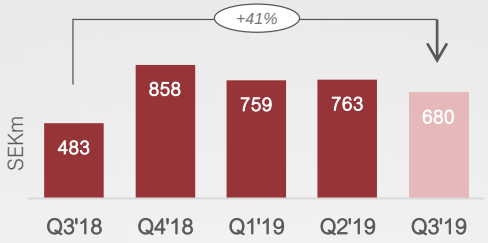


Cash flow follows increased activity level; Cash position stood at SEK 680m (~USD 70m) end of September 2019

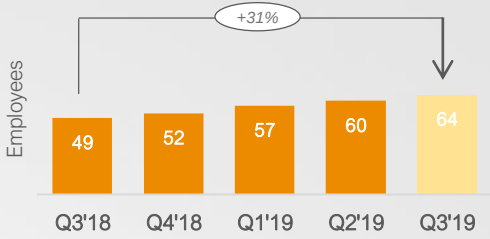
Operating cash flow (Q/Q)



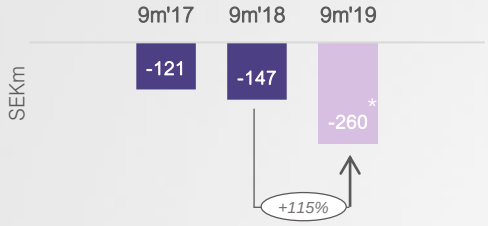
Cash & short term investments (Q/Q)



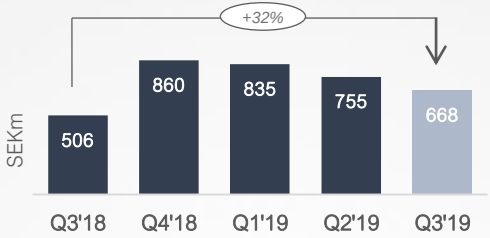
Number of employees (Q/Q)



Operating cash flow (Y/Y)

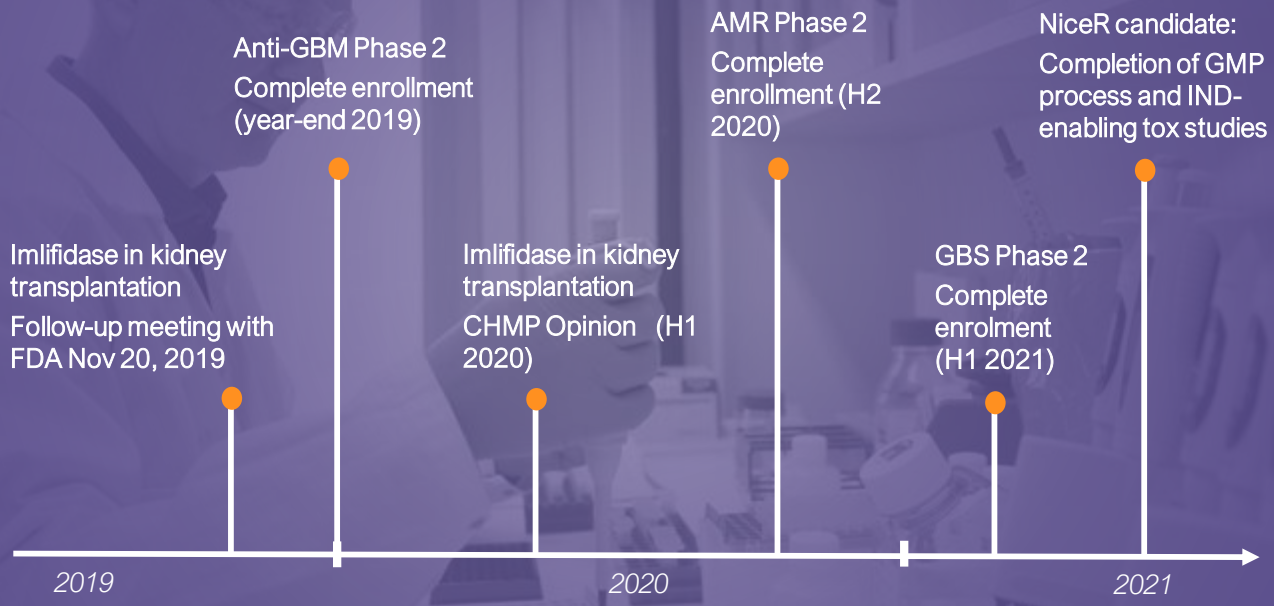


Shareholders equity (Q/Q)



* Excl. positive impact from sale of Genovis shares of SEK 89m in Q2'19

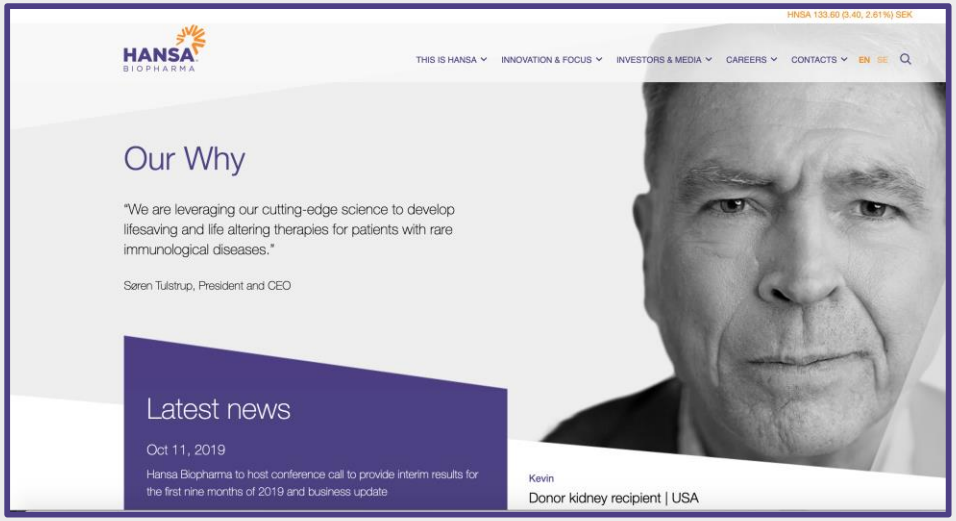
Upcoming milestones



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



EMA – The process towards approval