



Conference Call
Presentation
Jan-Mar 2020

Lund, April 28, 2020



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EMA process on track; CHMP opinion expected in the second quarter 2020

Highlights for the first quarter 2020

- Imlifidase in kidney transplantation
 - Formal adoption of outstanding questions expected in April; CHMP opinion expected in the second quarter 2020
 - Discussions with the FDA on the design of a new trial in kidney transplantation in the US is progressing according to plan
 - Long-term follow-up data demonstrate two-year graft survival of 89% after imlifidase treatment and transplantation
- Progress in our pipeline
 - Anti-GBM study fully enrolled; Completion marks an important milestone for the Company outside transplantation
 - Four patients have been treated in GBS and AMR respectively.
- COVID-19 pandemic may impact parts of the business
 - Recruitment in AMR and GBS expected to be delayed 3-6 months
 - Initiation of US imlifidase trial
 - Potential European launch of imlifidase in kidney transplantation
 - Financing strategy
- Cash position stood at SEK 477m (~USD 47m) end of March; Hansa Biopharma is financed through mid 2021



EMA: Formal adoption of outstanding questions expected at April meeting. CHMP Opinion expected in Q2 2020

EU: Imlifidase in kidney transplantation

Europe (EMA review)

- Regulatory review process progressing as expected. Day 180 responses submitted end of Q1 2020
- Good dialogue with EMA; expect formal adoption of list of outstanding questions at the April CHMP session
- CHMP Opinion expected at subsequent CHMP meeting in Q2
- Decision by European Commission expected in Q3 2020

Launch strategy

- Our launch strategy involves targeting of leading kidney transplantation centers with the potential to become early adopters and centers of reference
- COVID-19 impact: Our potential launch may be affected by the pandemic, incl. limited access to market access authorities, potentially delaying pricing and reimbursement
- It remains, however, our aim to launch imlifidase this year





**FDA: Discussions around new US trial design progressing as planned;
New study planned to be initiated in Q4**

US: Imlifidase in kidney transplantation

U.S. (FDA)

- Discussions with the FDA on the design of a new US trial in kidney transplantation is progressing according to plan. Submission of the study protocol is expected in Q2 2020
- The new trial is expected to include ~50 patients with a cPRA score of 99.9% or above. eGFR (kidney function) will be used as a surrogate endpoint to demonstrate a clinical benefit of imlifidase therapy vs. patients being waitlisted
- COVID-19 impact: Potential reprioritization of activities by the FDA may impact the timeline for the initiation of our new US trial
- It remains our aim to start recruitment in Q4 2020 following receipt of the necessary ethical approvals and setting up of trial centers in the US

Enrollment in Anti-GBM completed; Four patients recruited in each of the AMR and GBS studies

Ongoing Phase 2 studies

Enrollment status
end Q1'2020



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

- 4/30 patients enrolled in AMR study.
- COVID-19 expected to delay the recruitment of AMR patients by 3-6 months. Enrollment is now expected to be completed H1 2021



Guillain-Barré Syndrome

- 4/30 patients enrolled
- COVID-19 expected to delay the recruitment of GBS patients by 3-6 months. Enrollment is now expected to be completed in H2 2021

■ Patients enrolled
■ Patients left



Broad pipeline in transplantation and auto-immune diseases

Candidate / Project	Indication	Research/ Preclinical	Phase 1	Potentially Pivotal/ Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients ^{1,2}	<div></div>	<div></div>	<div></div>	<div></div>	<div>*)</div>		CHMP Opinion Q2 2020
	US: Kidney transplantation in highly sensitized patients ^{1,2}	<div></div>	<div></div>	<div></div>	<div>**)</div>			Finalization of study design Q2 2020 / first patient dosed Q4 2020
	Anti-GBM antibody disease	<div></div>	<div></div>	<div></div>				Data read-out Q3 2020
	Antibody mediated kidney transplant rejection (AMR)	<div></div>	<div></div>	<div></div>				Complete enrolment of 30 patients
	Guillain-Barré syndrome (GBS)	<div></div>	<div></div>	<div></div>				Complete enrolment of 30 patients
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).

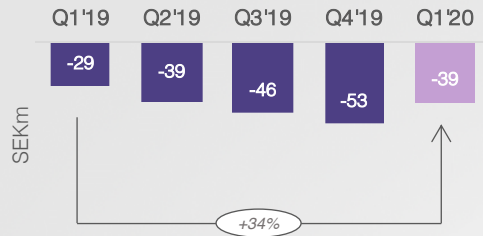
² Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine).

*) 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.

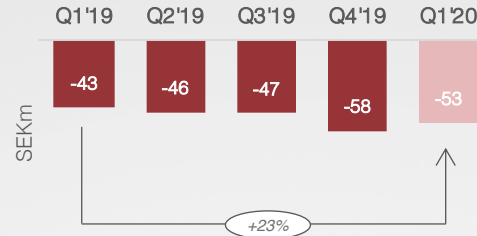
**) FDA: Agreement with the FDA on a regulatory path forward in the US. New clinical study could support BLA submission by 2023

Investments in SG&A and R&D increased in preparation for potential conditional approval in EU and due to pipeline advancement

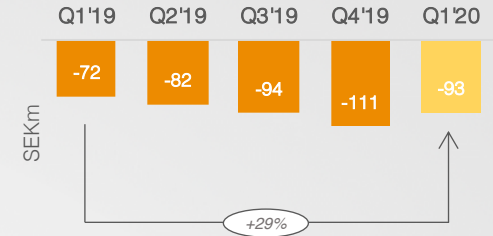
SG&A expenses (Q/Q)



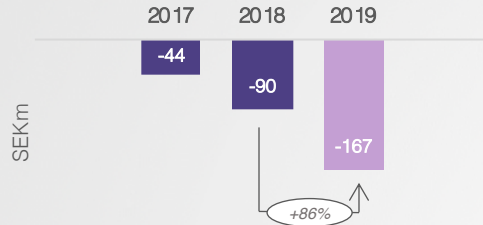
R&D expenses (Q/Q)



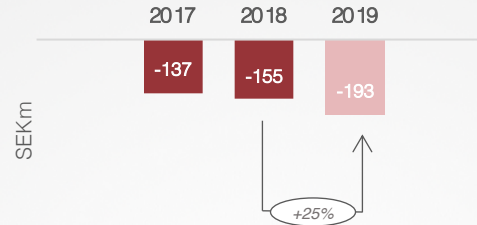
Net loss (Q/Q)



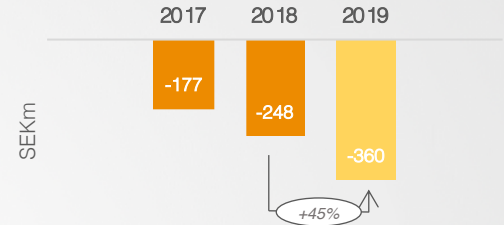
SG&A expenses (Y/Y)



R&D expenses (Y/Y)

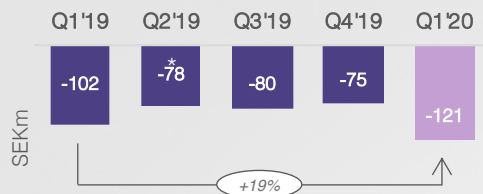


Net loss (Y/Y)

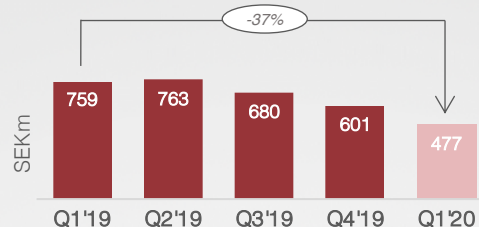


Cash position stood at SEK 477m (~USD 47m) end of Q1 2020; Hansa Biopharma is financed through mid 2021

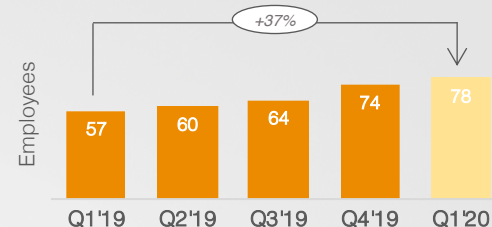
Operating cash flow (Q/Q)



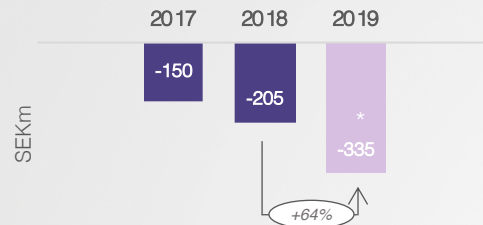
Cash & short term investments (Q/Q)



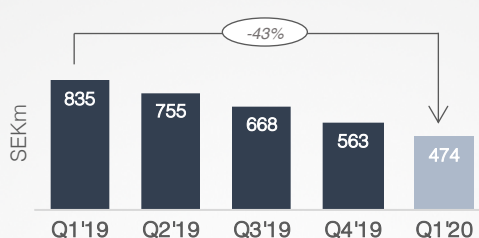
Number of employees (Q/Q)



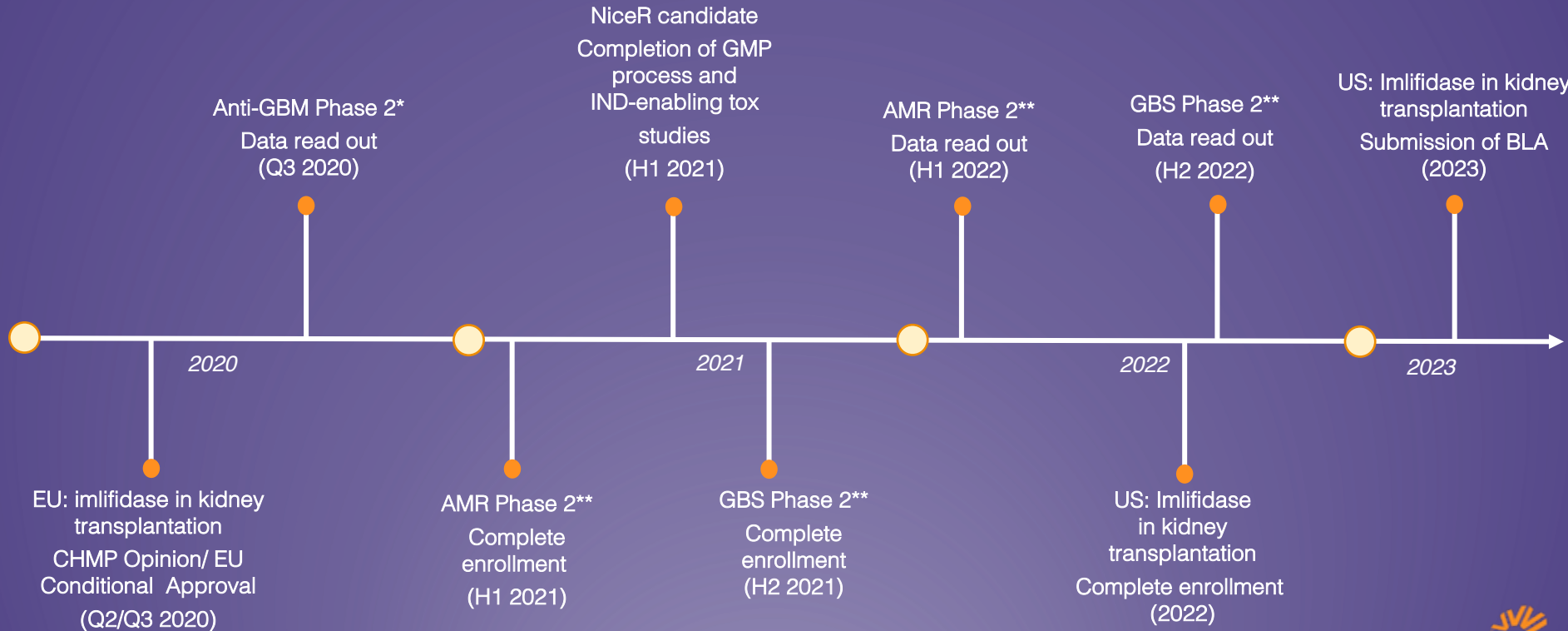
Operating cash flow (Y/Y)



Shareholders equity (Q/Q)



Upcoming milestones



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

** An expected delay in the recruitment of patients of 3-6 months in the AMR and GBS studies have been incorporated following COVID-19 (Corona)

Q&A

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

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