Interim Report Q1 2019
Business Update

April 29, 2019

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No assurance can be given that such expectations will prove to have been correct. Hansa Biopharma disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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Today’s presenters

Søren Tulstrup
President and CEO

Eva Maria Joed
VP, Chief Financial Officer

Lead product on cusp of potential commercialisation

Lead, late-stage clinical program: IDEFIRIX (imlifidase) in kidney transplantation

- MAA under review by the EMA
- Decision to conduct complementary analyses with respect to transplantability of the highly sensitized patients in our successfully completed Phase 2 studies and of matched controls of highly sensitized patients from the U.S. transplant registry with a view to further illustrate the value of IDEFIRIX in the U.S. healthcare system.
- Hansa to request FDA-meeting upon completion of analyses - expected 2H 2019. Meeting to determine U.S. regulatory path forward for filing and approval of IDEFIRIX in the U.S.
- Long-term, observational follow-up study in up to 46 highly sensitized patients is ongoing

Earlier clinical pipeline progresses: Imlifidase in other indications

- Acute AMR in kidney transplantation: received CTA and Ethics Committee approval for Phase 2 study
- Anti-GBM antibody disease: 8/15 patients treated in Phase 2 study.
- GBS: received CTA and Ethics Committee approval for Phase 2 study

Next generation immunomodulatory enzymes

- NiceR - lead candidate selected for clinical development

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Imlifidase in kidney transplantation

Phase 2 studies demonstrated potential to significantly improve transplantation outcomes for highly sensitized patients

Imlifidase enabled kidney transplantation for all 35 highly sensitized patients

- Following imlifidase treatment, patients had a rapid cross-match conversion and a clinically significant reduction in donor specific antibodies

Study patient population extremely unlikely to receive a compatible kidney transplant

- Median calculated Panel Reactive Antibody (cPRA) >99.5%, with more than half at 100%
- Mean time on dialysis prior to imlifidase-enabled transplantation >7 years
- Majority of patients had experienced previous failed kidney transplants

Graft survival at study completion, six months post-transplantation, was 91%

- 32 patients were off dialysis with good kidney function with estimated glomerular filtration rate (eGFR) within the expected range

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Completed and ongoing studies with imlifidase in kidney transplantation

Study	Subjects	Status	Publication
Phase 1 (Sweden)	29 healthy subjects	• Completed 2014	PLOS ONE (2015)[1]
Phase 2 (Sweden)	8 sensitized patients	• Completed 2015	American Journal of Transplantation (2018)[2]
Phase 2 (Sweden)	10 sensitized patients	• Completed 2016	The New England Journal of Medicine (2017)[3]
Phase 2 (US)	17 highly sensitized patients	• Completed 2018	
Highdes Phase 2 (US, France, Sweden)	18 highly sensitized patients	• Completed 2018	
Observational follow-up study (US, France, Sweden)	Up to 46 previously treated and transplanted patients	• Enrolling. Transplanted patients to be followed up to five years	

1 Winstedt et al. (2015) PLoS ONE 10(7): e0132011
2 Lorant et al. Am J Transplant. 2018;1–11
3 Jordan et al. N Engl J Med 2017;377:442-53

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Positive interaction with regulatory agencies regarding imlifidase in kidney transplantation

European Medicines Agency

- Submitted Marketing Authorisation Application for IDEFIRIX (INN: imlifidase) to EMA on February 5, 2019
- EMA accepted MAA submission on February 28, 2019
- An opinion of from the EMA Committee for Medicinal Products for Human Use (CMPH) is expected within 210 days plus potential clock stops for applicant responses

U.S. Food and Drug Administration

- Overall positive End of Phase 2 Meeting with the FDA
  - Agency acknowledged high unmet medical need
  - Dialogue to continue in subsequent meeting
- Hansa is currently conducting complementary analyses on transplantability
  - The analyses include data from matched controls of highly sensitized patients from the U.S. transplant registry and from the successfully completed Phase 2 studies of imlifidase.
- Once completed, Hansa will request next meeting with FDA to determine U.S. regulatory path forward

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Preparing for commercialization

Well positioned to bring IDEFIRIX to market

- Highly concentrated transplant market reachable by small commercial team
- In EU5, 70-80% of all kidney transplantations are performed at 15-20 centers in each EU5 country
- In the U.S., 50 transplant centers represent more than half of all kidney transplants
- Reimbursement Strategy based on cost of dialysis as benchmark
- Expanding commercial infrastructure: Medical Affairs, Market Access and Patient Advocacy

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Imlifidase in other indications

Imlifidase in other indications
Additional Phase 2 studies ongoing and planned

Candidate / Project	Indication	Research/ Preclinical	Phase 1 [1]	Phase 1/2	Phase 2	Reg. interact.	Registration	No. of patients	Next Anticipated Milestone
Imlifidase	Anti-GBM antibody disease							Approx. 15 patients	Finalize enrollment (2019) 8 patients enrolled as per March 30 2019
	Antibody mediated kidney transplant rejection (AMR)							Up to 30 patients	Phase 2 recruitment of patients over the coming 12 months
	Guillain-Barré syndrome							Up to 30 patients	Phase 2 recruitment of patients over the coming 18 months

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Novel IgG cleaving enzymes – lead candidate selected

Next generation enzyme technology: NiceR

NiceR: IgG cleaving enzymes candidates with lower immunogenicity and with the potential for repeat dosing

- Potential application for a broad array of indications, including relapsing autoimmune diseases and oncology
- Lead candidate selected
- Development of a GMP-manufacturing process and toxicology studies

Financials and shareholder base

SEK m (unless otherwise stated)	Q1 2019	Q1 2018	Year 2018	Year 2017
Net revenue	1.1	0.6	3.4	3.4
Sales, general and administration expenses	-29.5	-15.5	-90.4	-43.7
of which cost, LTIP 2016/2018	-0.6	-4.9	-10.9	-4.5
Research and development expenses	-42.6	-31.5	-154.6	-137.1
of which cost LTIP 2016/2018	-0.8	-0.4	-4.9	-5.4
Operating profit/loss	-72.7	-46.6	-246.5	-176.1
Cash flow from operating activities	-101,6	-44.1	-204.6	-150.1
Cash and cash equivalent*	759.2	575.0	858.2	616.1
FTE's end of period	57	35	49	33
of which R&D	45	28	41	27

* including short term investments

Financials

The SG&A expenses reflect the continued build-up of the organization to prepare for commercial launch.

Regulatory activities to prepare for filing.

15 largest shareholders

March 30, 2019

Name	Number of C Shares	Number of A shares	Share (%)
Nexttobe AB		5,755,379	14.1
Oppenheimer		2,310,614	5.7
Thomas Olausson (private and via company)		1,613,474	4.0
Handelsbanken Funds		1,546,766	3.8
Avanza Pension		1,226,685	3.0
Norron Funds		1,075,774	2.6
Third Swedish National Pension Fund		1,068,523	2.6
Polar Capital		1,030,321	2.5
Fourth Swedish National Pension Fund		958,044	2.4
AFA Insurance		958,044	2.3
Gladiator		902,000	2.2
Vanguard		768,928	1.9
Canaccord Genuity Wealth Management		666.000	1.6
BlackRock		639,463	1.6
BWG Invest Sàrl (William Gunnarsson)		600 370	1.5
Other		19 615 562	49.6
In total		40,731,654	100.0

Source: Monitor by Modular Finance AB. Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

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Near-term milestones

- ✓ **Hansa to request FDA-meeting upon completion of complementary analysis of transplantability data in order to determine regulatory path forward. Meeting expected 2H 2019**
- ✓ **IDEFIRIX (imlifidase) MAA review process 210 days plus potential clock stops**
- ✓ **Patient recruitment in AMR and GBS Phase 2 study over the next 12-18 months**
- ✓ **Finalize enrollment to Phase 2 in anti-GBM study; 8 of 15 patients enrolled**
- ✓ **Development of GMP process and toxicology studies for our lead NiceR candidate**

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Q&A

Søren Tulstrup
President and CEO

Eva Maria Joed
VP, Chief Financial Officer


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