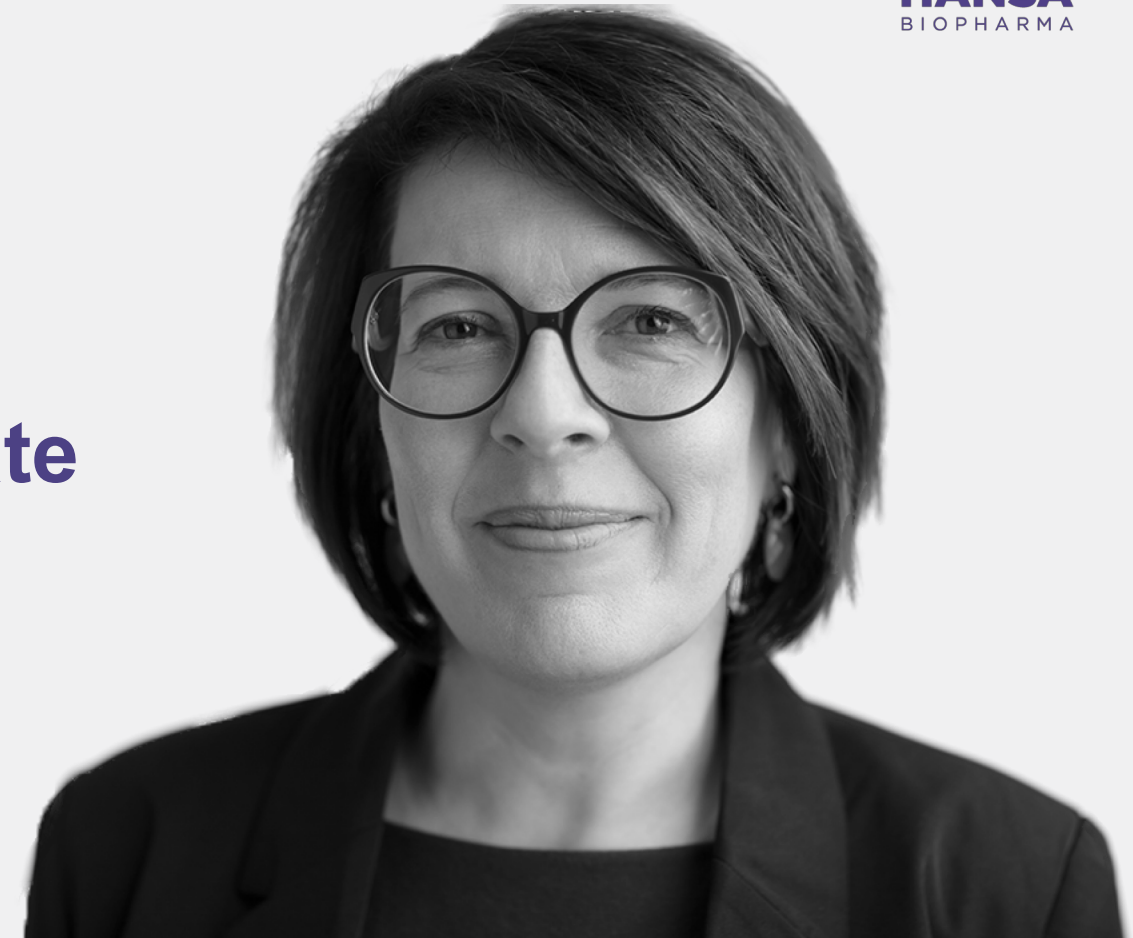

HANSA
BIOPHARMA

2018 Year End Report Business Update

February 8, 2019



Forward-looking statements

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 Medical'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 Medical's strategy and its ability to further grow, risks associated with the development and/or approval of Hansa Medical's products candidates, ongoing clinical trials and expected trial results, the ability to commercialize imlifidase, technology changes and new products in Hansa Medical'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.

No assurance can be given that such expectations will prove to have been correct. Hansa Medical 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

Emanuel Björne
VP, Business Development and IR

Advancing the potential of Hansa's immunomodulatory enzyme technology in 2018

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

Successful completion of two Phase 2 studies in highly sensitized patients
FDA Fast Track Designation
Peer review validation: Phase 2 study published in the American Journal of Transplantation
Initiated long-term observational prospective follow-up study

Imlifidase in other indications

Seven of 15 patients enrolled in Phase 2 study in anti-GBM antibody (Goodpasture's) disease
FDA and EMA granted Orphan Drug Designation for anti-GBM
FDA granted Orphan Drug Designation for Guillain-Barré syndrome

Next generation immunomodulatory enzymes

NiceR - R&D progressing to candidate selection for repeat dosing

Preparing for commercialization

Strengthened balance sheet with SEK 453 / $50 million raise
Established U.S. subsidiary; building commercial organization
Changed name to Hansa Biopharma

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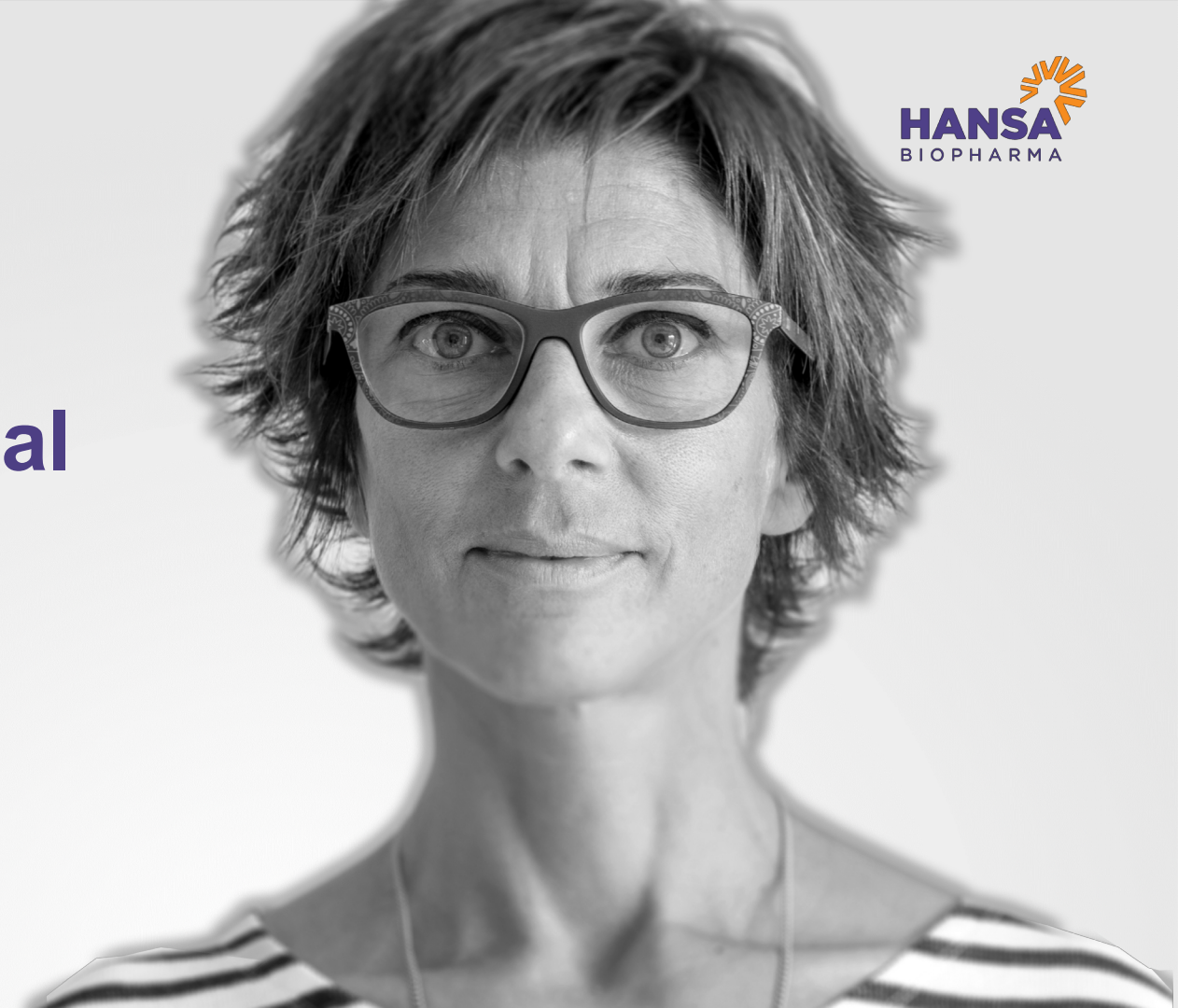
Hansa Medical has changed

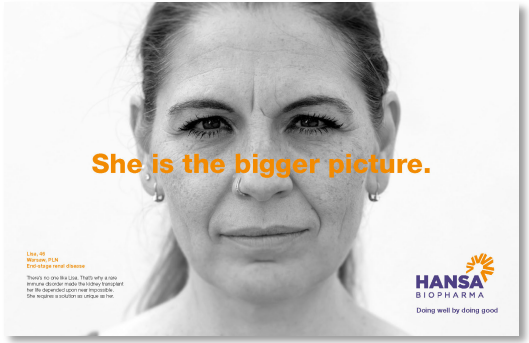


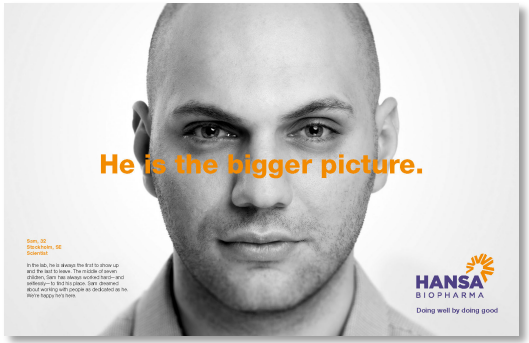
Hansa Medical is now Hansa Biopharma

It better reflects our ongoing evolution and long-term aspiration to deliver our proprietary enzyme technology platform for IgG-mediated rare, immunopathological conditions, transplant rejections and cancer.

Our new logo has been designed to convey the company's technological and scientific core, by linking our current strength and vision with our ambition to provide value to society at large.

Our coming new campaign presents our new patient-focused brand promise.





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Imlifidase in kidney transplantation

Addressing a significant unmet need

Human leukocyte antigen (HLA) sensitization is a major barrier to kidney transplantation and desensitization is a critical step in optimizing outcomes

HLA sensitization occurs in patients with anti-HLA antibodies to potential donors, resulting in significantly lower likelihood of donor matching

Highly sensitized patients are more likely to remain on long-term dialysis

- Debilitating disease state
- Poor QOL
- Increased mortality
- High cost

~ 9,000 patients die every year on kidney transplant waitlists in the U.S. and Europe

Notes 1) Jordan et al. British Medical Bulletin, 2015, 114:113–125; 2) Orandi et al. N Engl J Med 2016;374:940-50

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Addressable patients in kidney transplantation in the U.S. and Europe

Pre-transplant treatment

- 15% of kidney waitlist patients are highly sensitized (~ 30,000 patients)
- 15% of kidney waitlist patients are moderately sensitized (~ 30,000 patients)
- Adjusted for current rate of organ donation, ~ 12,000 sensitized patients annually could benefit from imlifidase
- More than 3,000 donated kidneys are discarded in the U.S. alone

Treatment of antibody mediated rejection (AMR)

- ~10% of all transplanted patients experience AMR
  - ~ 4,000 of the 40,000 patients transplanted annually
  - ~ 40,000 of the 400,000 patients currently living with a kidney transplant

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Phase 2 studies demonstrated good safety profile after six-month follow-up

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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Supportive data from five clinical studies

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	

Notes: 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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Regulatory progress

Positive interaction with regulatory agencies regarding imlifidase in kidney transplantation

Expect to file a Marketing Authorisation Application with the EMA in the first quarter of 2019

Dialogue with FDA ongoing – timeline for a potential Biologic License Application (BLA) to be determined in the coming months

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Imlifidase in other indications

Additional imlifidase Phase 2 studies ongoing and planned

Indication	Description	Number of patients	Status
Anti-GBM disease	Ultra rare kidney disease	Approx. 15	Ongoing. 7/15 patients treated as of Dec 31, 2018
AMR	Antibody mediated rejection post transplantation	Approx. 30	CTA filed. Initiate Phase 2 enrollment in Q1-19
Guillain-Barré syndrome	IgG attack on peripheral nerves	Approx. 30	CTA filed. Initiate Phase 2 enrollment in Q1-19

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Novel IgG cleaving enzymes – Development approach, timelines and potential

Next generation enzyme technology: NiceR

IgG cleaving enzymes candidates with lower immunogenicity with potential for repeat dosing

Potential application for a broad array of indications, including relapsing autoimmune diseases and oncology

Expect to select a candidate for clinical development in 2019

Financials and shareholder base

SEK m (unless otherwise stated)	Q4 2018	Q4 2017	Year 2018	Year 2017
Net revenue	1.4	1.0	3.4	3.4
Sales, general and administration expenses	-36.3	-13.6	-90.4	-43.7
of which cost, LTIP 2016	-0.6	-1.6	-10.9	-4.5
Research and development expenses	-42.6	-35.8	-154.6	-137.1
of which cost LTIP 2016	-0.5	-1.8	-4.9	-5.4
Operating profit/loss	-80. 6	-48.9	-246.5	-176.1
Cash flow from operating activities	-57.5	-29.1	-204.6	-150.1
Cash and cash equivalent*	858.2	616.1	858.2	616.1
FTE’s end of period	49	33	49	33
of which R&D	41	27	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

December 31, 2018

Name	Number of shares	Share (%)
Nexttobe AB	5,755,379	14.4
Oppenheimer	2,358,370	5.9
Thomas Olausson (private and via company)	1,613,474	4.0
Handelsbanken Funds	1,301,766	3.3
Gladiator	1,275,000	3.2
Avanza Pension	1,170,248	2.9
Polar Capital Funds PLC	1,140,691	2.9
Norron Funds	988,973	2.5
AFA Insurance	959,734	2.4
Fourth Swedish National Pension Fund	958,044	2.4
Third Swedish National Pension Fund	780,509	2.0
BWG Invest Sàrl	600,370	1.5
Sven Sandberg	494,000	1.2
C WorldWide Asset Management	482,291	1.2
Oberweis Funds	385,269	1.0
Other	19,695,772	49.2
In total	39,959,890	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 aims

Initiate patient enrollment to Phase 2 in AMR

Initiate patient enrollment to Phase 2 in GBS

Imlifidase MAA filing in transplantation by Q1 2019 with potential launch in 2020

Meeting with FDA in the coming months to discuss path to BLA-filing

Finalize enrollment to Phase 2 in anti-GBM

Lead selection in the NiceR-program

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Q&A

Søren Tulstrup
President and CEO

Eva Maria Joed
VP, Chief Financial Officer

Emanuel Björne
VP, Business Development and IR


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