



Hansa Medical AB  
Interim report January-  
March 2017

Conference Call Business  
Update Presentation

April 26, 2017

**Hansa Medical**

# 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 IdeS, 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.

# Key Highlights

## Continued progress of lead candidate IdeS in sensitized patients

- › To date, more than 30 patients treated with IdeS and subsequently transplanted in four separate studies in Sweden and the US
- › On April 30, encouraging top-line results from the US investigator initiated clinical study at Cedars Sinai Medical Center will be presented at 2017 American Transplant Congress (ATC) in Chicago
- › The top-line data demonstrate that treatment with IdeS completely eliminated donor specific antibodies (DSA) in all 15 treated patients and enabled kidney transplantation
- › Patient enrollment on track in the US and EU multicenter study Highdes

# Key Highlights

## Progress of lead candidate IdeS in other indications

- › Initiating Phase II study in anti-GBM antibody disease (Goodpastures syndrome) at several European nephrology clinics (investigator initiated)
- › Published preclinical data demonstrates the potential of IdeS in Guillain Barré syndrome

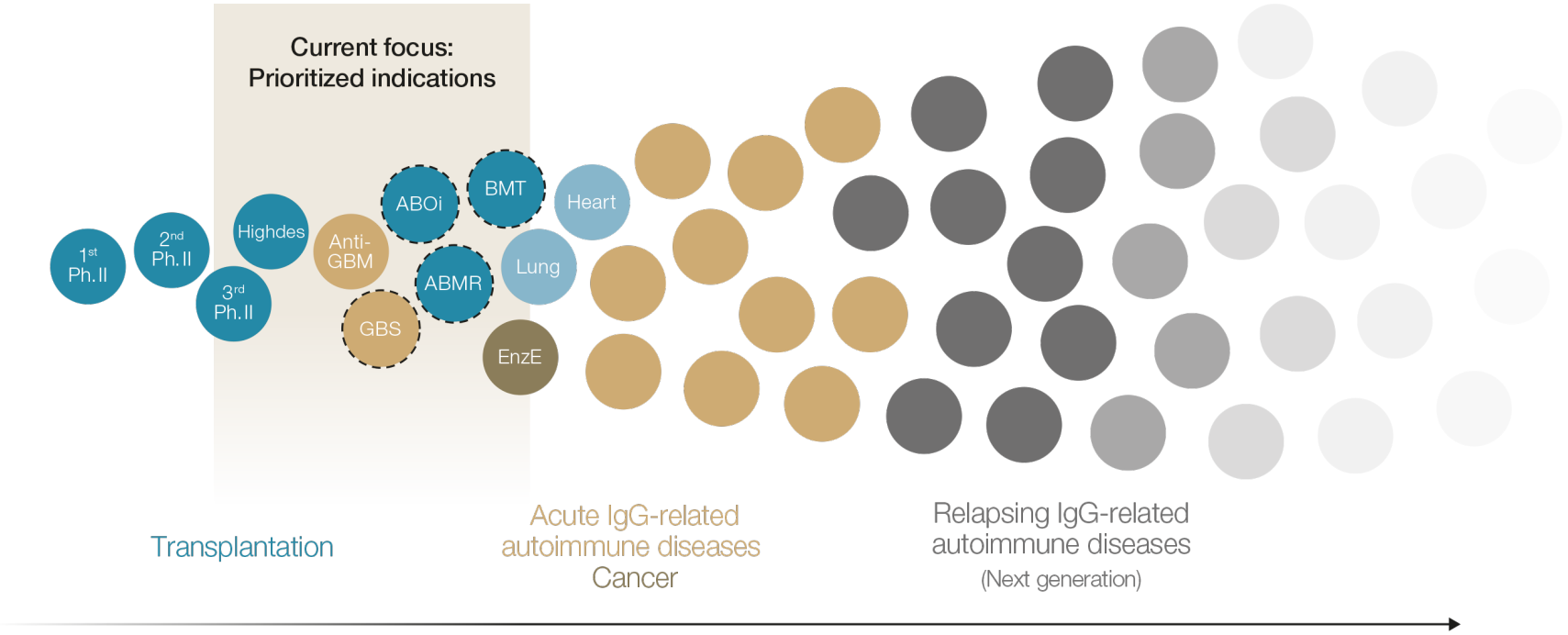
## Second wave of IgG-eliminating enzymes

- › Project NiceR – Novel IgG cleaving enzymes for Repeat dosing – is progressing nicely with the ambition to initiate clinical studies in 2018

## Organization

- › Appointment of Dr Sam Agus as new Chief Medical Officer as company prepare to enter the commercialization phase for IdeS in transplantation

# Development strategy for IdeS and novel IgG cleaving enzymes for repeat dosing (NiceR)



1<sup>st</sup> Ph. II

2<sup>nd</sup> Ph. II

3<sup>rd</sup> Ph. II

Highdes

Anti-GBM

ABOi

BMT

Heart

GBS

ABMR

Lung

EnzE

IdeS

NiceR

Planned studies

# The development of IdeS in transplantation is going according to plan

Study	Subjects	Status
Phase I (SWE)	29 healthy subjects	● Successfully completed 2014
Phase II (SWE)	8 sensitized patients	● Successfully completed 2015
Phase II (SWE)	10 sensitized patients	● Successfully completed 2016
Phase II (USA, investigator initiated)	20 sensitized patients	● Ongoing
Highdes - Multicenter Phase II (USA+EU)	20 refractory HLA sensitized patients	● Ongoing

# Abstract ahead of American Transplant Congress, April 30, 2017

## Top-line data from US Phase II with IdeS (investigator initiated)

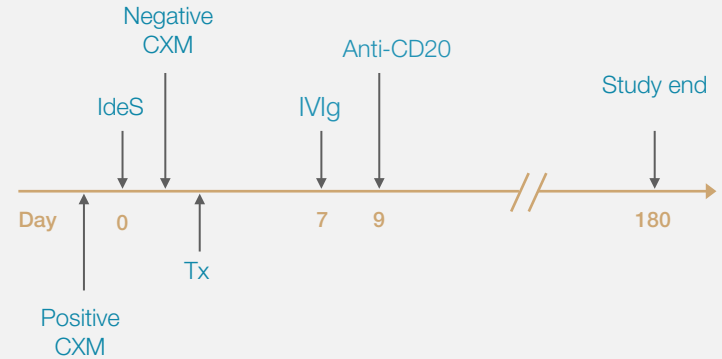
- › Principal investigator: Prof. Stanley Jordan, Cedars-Sinai Medical Center, Los Angeles
- › 15 highly sensitized patients with mean cPRA 95% treated with IdeS and subsequently transplanted

## Conclusions

- › IdeS completely eliminates donor specific antibodies in HLA incompatible patients
- › IdeS is generally well tolerated
- › IdeS may provide a more rapid and durable method to desensitize HLA sensitized patients, offering them life-saving transplantation

# The Highdes –study: A multicenter study in refractory HLA-sensitized patients – Ongoing

- › Primary objective: Transplantability
- › Secondary objectives, e.g. safety parameters and kidney function
- › Number of patients: 20
- › 6 months follow-up
- › 3 US sites, 2 European sites
- › **Aim: File BLA in 2018**





# Cost expansion according to plan as we are progressing our pipeline

SEK m (unless otherwise stated)	Q1 2017	Q1 2016	Year 2016	Year 2015
<b>Net revenue</b>	<b>1.1</b>	<b>0.6</b>	<b>2.6</b>	<b>6.7</b>
Sales, general and administration expenses	-9.8	-5.0	-29.7	-28.2
Research and development expenses	-36.2	-15.4	-82.9	-4.4
<b>Operating profit/loss</b>	<b>-44.8</b>	<b>-19.9</b>	<b>-111.1</b>	<b>-66.2</b>
<b>Cash flow from operating activities</b>	<b>-43.7</b>	<b>-17.6</b>	<b>-94.6</b>	<b>-57.8</b>
<b>Cash and cash equivalent*</b>	<b>209.4</b>	<b>158.1</b>	<b>253.6</b>	<b>175.7</b>

\* including short term investments

## > SG&A

- Strengthened the organization
- Increased pre-commercial activities
  - > VP Commercial joined in Q2 2016
  - > Market access research in the US and EU

## > R&D

- Continue to strengthen the organization, clinical and regulatory
- External project expenses tripled to SEK 24m vs 2016, mainly due to CMC
  - > CMC costs front loaded in H1 2017

# Near term goals 2017–2018

- › Publication of results from 2<sup>nd</sup> Phase II study in peer reviewed journal
- › Finalization of US Phase II (investigator initiated)
- › Complete recruitment to the Highdes study
- › Initiate Phase II in additional indications
- › IdeS BLA and MAA filing in transplantation in 2018

IgG-related  
autoimmune diseases

GBS

Anti-  
GBM

Oncology

EnzE

HSCT

Kidney  
HLA

ABOi

Kidney

Acute AMR

Desensitization

Transplantation

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# Upcoming events

- › 2017 American Transplant Congress (ATC) in Chicago, April 30
- › 18<sup>th</sup> Annual BioEquity Europe 2017, Paris, May 22
- › Jefferies 2017 Global Healthcare Conference, New York, June 6-9
- › Capital Markets Day – TBA