HANSA BIOPHARMA

Road Show Presentation Jan-Sep 2019

Forward-looking statement

This presentation may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future. Some of these forward-looking statements, by their nature, could have an impact on Hansa Biopharma's business, financial condition and results of operations [or that of its parent, affiliate, or subsidiary companies]. Terms such as "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 statements. There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to, changes in implementation of Hansa Biopharma's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Hansa Biopharma's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize imlifidase if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Hansa Biopharma'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.

The factors set forth above are not exhaustive and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment, and it is not possible to predict all factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

Hansa Biopharma expressly disclaims any obligation to update or revise any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or otherwise, and disclaims any express or implied representations or warranties that may arise from any forward-looking statements. You should not rely upon these forward-looking statements after the date of this presentation.

HANSA BIOPHARMA

Hansa Biopharma at a glance

Company background

- Founded 2007 with HQ in Lund, Sweden
- Sören Tulstrup, CEO – Ulf Wiinberg, Chairman
- 64 employees (~3/4 in R&D) at Sep 30, 2019
- Operations in Sweden, US & Europe
- Market cap: SEK ~6bn (USD ~600m) Oct, 2019
- Listed on Nasdaq OMX Stockholm (HSNA)

Leader in immunomodulatory enzymes for rare IgG-mediated diseases

- Imlifidase is a unique IgG antibody-cleaving enzyme
- Imlifidase has been studied in five clinical studies and published in peer-reviewed journals (e.g. New England Journal of Medicine and the American Journal of Transplantation)
- If approved, Imlifidase may have the potential to meet a large unmet need and transforming the lives of people with rare disease

Broad pipeline in transplantation and autoimmune diseases

- Lead indication in kidney transplantation in highly sensitized patients (MAA under review by EMA)
- Anti-GBM antibody disease (Phase 2)
- Antibody mediated kidney transplant rejection (AMR) (Phase 2)
- Guillain-Barré syndrome (Phase 2)
- NiceR - Recurring treatment in autoimmune disease, transplantation and oncology (Preclinical)
- EnzE – Cancer immunotherapy (Preclinical)

Key Financials

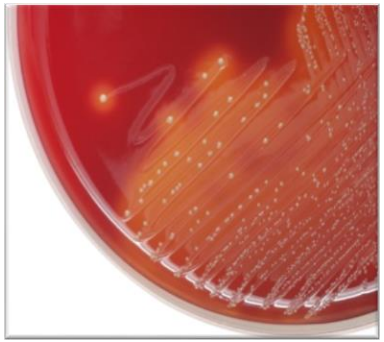
• Cash position	9m'19 SEK 680m
• Operating Cash Flow	9m'19 SEK -260m
• R&D cost	9m'19 SEK -135m
• Net Profit	9m'19 SEK -249m

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

Imlifidase – a novel approach to eliminate pathogenic IgG

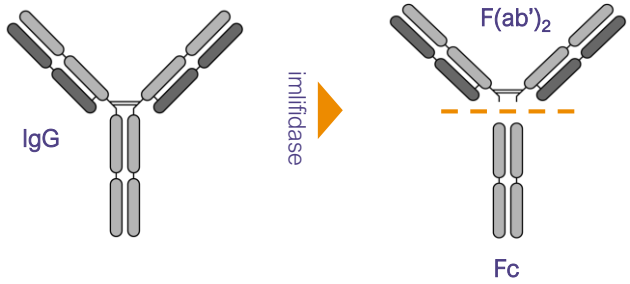
Origins from Streptococcus pyogenes

- Species of Gram-positive, spherical bacteria in the genus Streptococcus
- Usually known from causing a strep throat infection



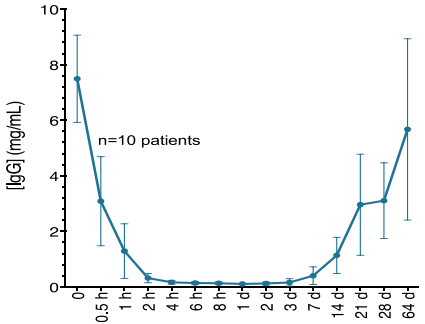
Imlifidase, a unique IgG antibody-cleaving enzyme

- Interacts with Fc-part of IgG with extremely high specificity
- Cleaves IgG at the hinge region, generating one $F(ab')_2$ fragment and one homo-dimeric Fc-fragment



Imlifidase inactivates IgG in 2 hours

- Rapid onset of action that inactivates IgG below detectable level in 2 hours
- IgG antibody-free window for approximately one week



Hansa Biopharma, a company well positioned for a commercial success

Imlifidase cleaves IgG antibodies

- Imlifidase is a unique IgG antibody-cleaving enzyme studied in five clinical studies.
- By removing the immunological barrier, imlifidase has the potential to enable kidney transplantation in highly sensitized patients

Potentially addressing a clear unmet need

- Patients may become sensitized after losing a first transplant or being exposed to foreign tissues through blood transfusion or pregnancy.
- Such sensitized patients account for roughly 30% of people on the kidney waiting lists.

A company well positioned for commercial success

- Hansa Biopharma is establishing its own commercial and medical organization in EU and the US. Outside these core markets we will seek commercial partnerships.
- Hansa Biopharma has a broad patent coverage throughout 2035 in key markets and orphan drug designation in EU and US for imlifidase in kidney transplantation.

Rich pipeline

- We are leveraging our proprietary immuno-modulatory enzyme platform in phase 2 clinical studies in rare autoimmune indications incl:
  - Anti-GBM (Goodpasture's)
  - Guillain-Barré syndrome
  - Acute AMR post transplantation

Broad pipeline in transplantation and auto-immune diseases

Candidate / Projecting	Indication	Research/ Preclinical	Phase 1[1,2]	Pivotal program/ Phase 2	Marketing Authorization Review	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

Completed Ongoing

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

[2] Kidney transplantation in highly sensitized patients" with reference to " Results from Phase 2 studies have been published in N Engl J Med 2017; 377:442-453 and in Am J Transplant. 2018 Nov;18(11):2752-2762.

*) 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.

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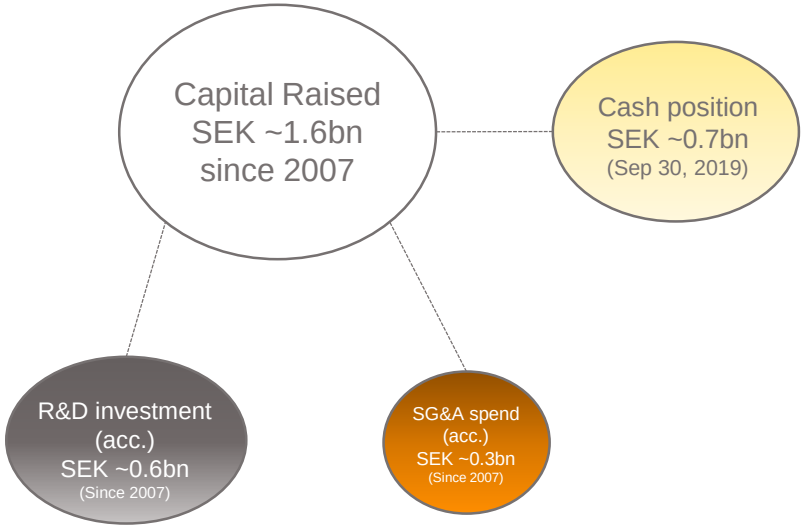
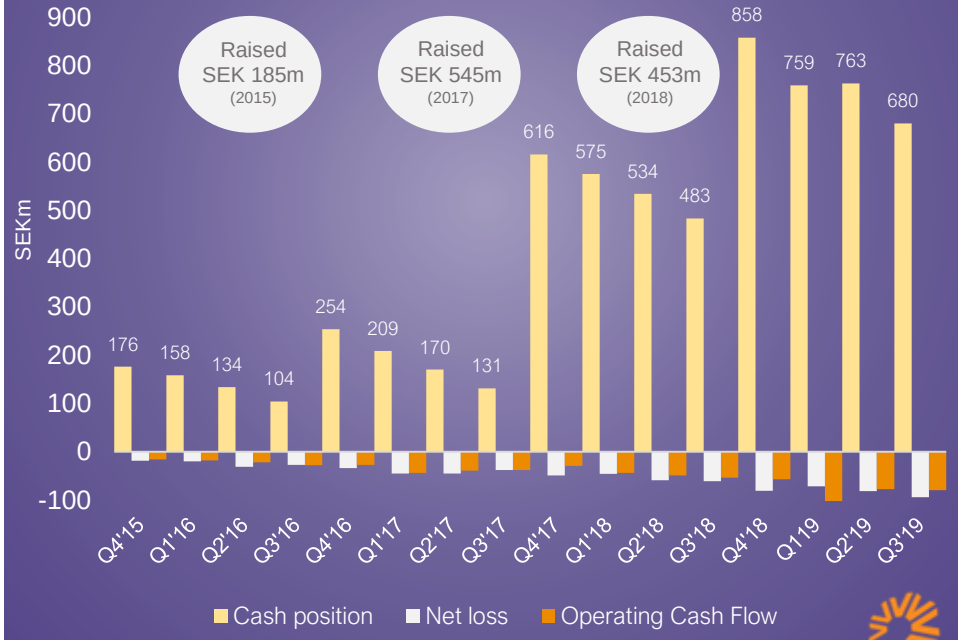
Hansa Biopharma is financed through 2020

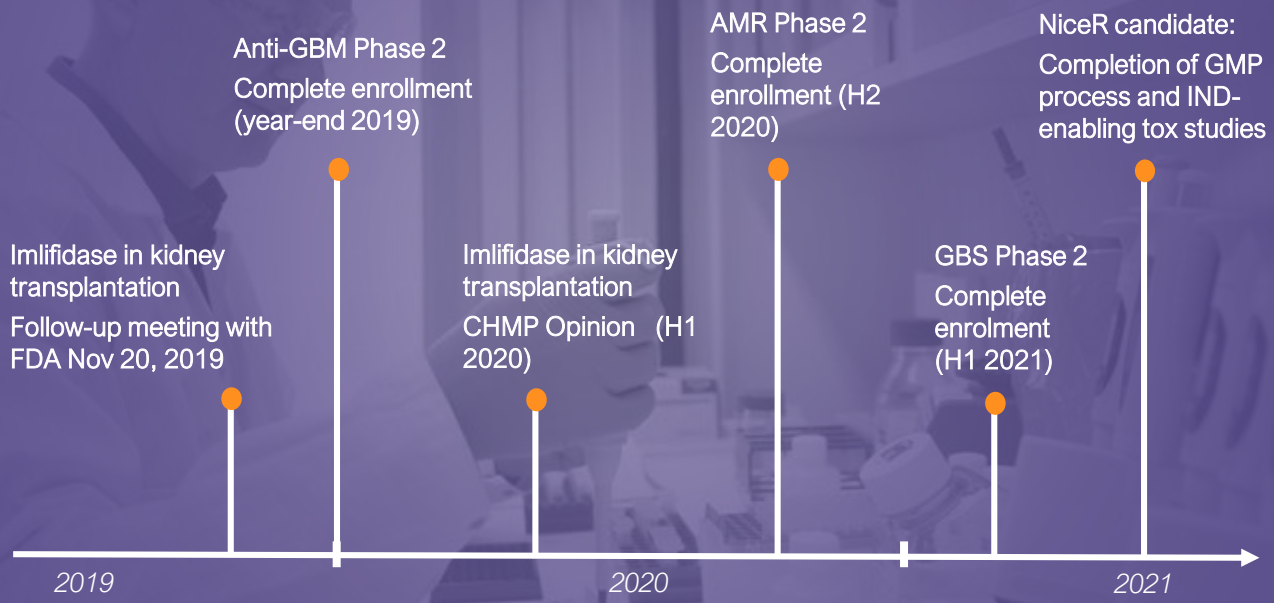
Significant capital raised since 2007



Solid cash position end of September 2019



Upcoming milestones



Q3 Business Update

Road Show Presentation
Jan-Sep 2019

Imlifidase enabled kidney transplantation in 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
- At study completion, all patients alive and graft survival at 94% six months post transplantation.

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in COPENHAGEN

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Regulatory review with EMA is progressing as expected

Imlifidase in kidney transplantation

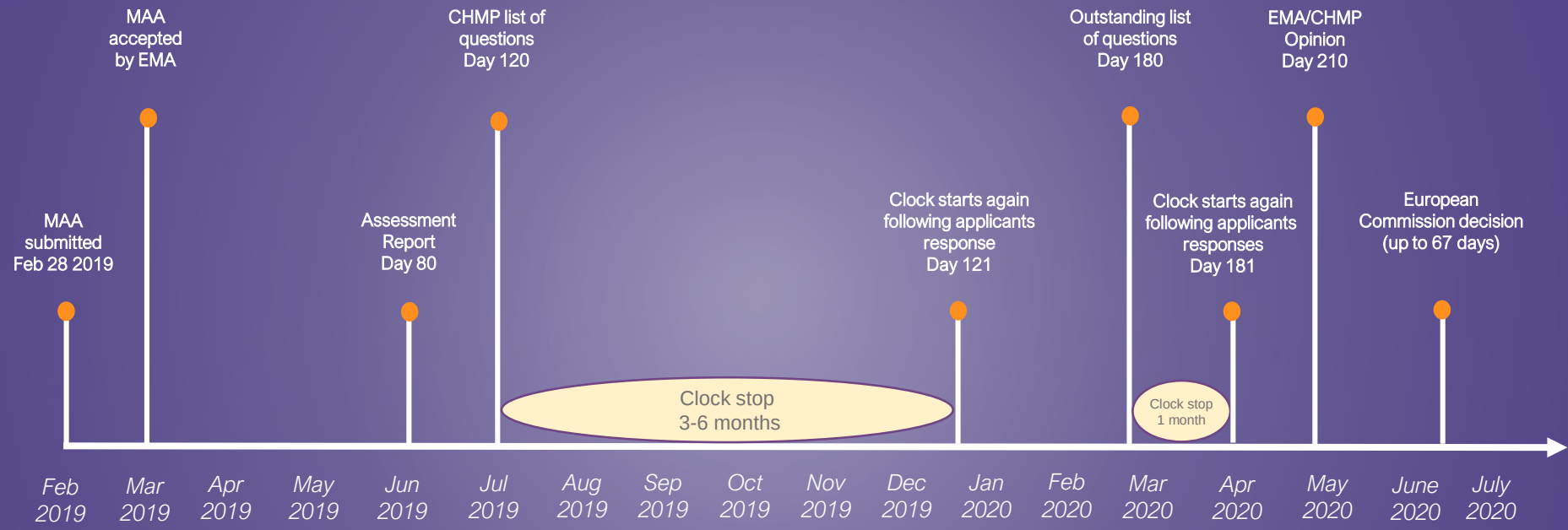
Europe (EMA)

- 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
- Decision by European Commission expected June/July 2020

U.S. (FDA)

- Follow-up meeting with the U.S. Food and Drug Administration scheduled for November 20, 2019 to discuss regulatory path forward in the U.S.
- Minutes from the meeting is expected by end of December

The EMA process towards marketing authorization



Focused launch strategy optimizes patient access to imlifidase

Strong outreach with limited footprint in EU

- Building awareness through MSL and Patient Advocacy
  - MSL organization established in key markets
  - MSLs educate KOLs and physicians at transplantation clinics
  - Reaching out to healthcare providers through Patient Advocacy
- A sequenced and focused launch strategy
  - In EU5, 70-80% of all kidney transplantations are performed at 15-20 centers in each EU5 country
  - Potential Initial launch in early launch countries in the second half of 2020 followed by second wave launch countries

High unmet medical need in spite of updated Kidney Allocation System

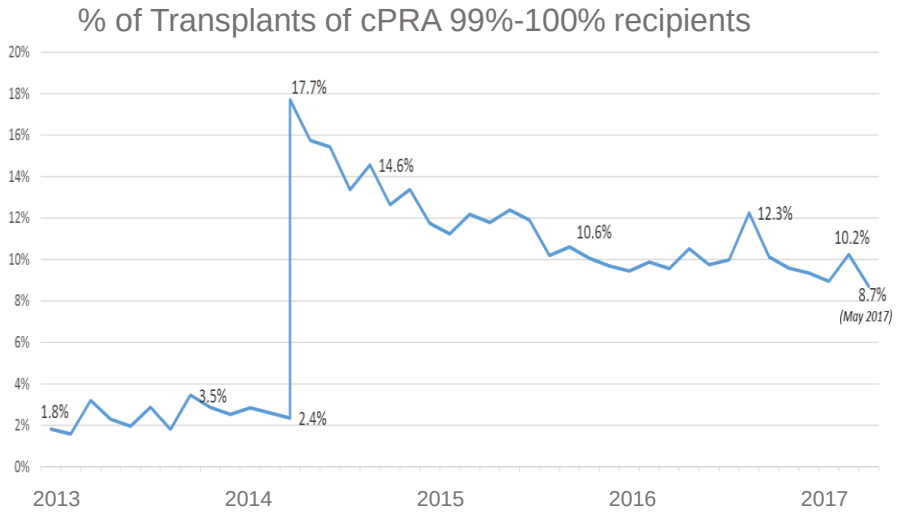
Imlifidase may potentially complement KAS

- The Kidney Allocation System (KAS) in U.S. was updated in 2014 to prioritize national allocation for highly sensitized patients
- Implementation initially resulted in a bolus effect; however a group of highly sensitized patients are still not helped due to lack of matched organs
- If approved, imlifidase may potentially complement allocation systems like KAS and Euro-transplant and reduce time to transplant in highly sensitized patients

"We thought the KAS would be very good, but the experience was different. I don't think you can have a bureaucratic solution for an immunologic problem, we have to face that we do need drugs to deal not only with acute antibodies but also with the rebound."

Stanley Jordan M.D., Director Kidney Transplantation and Transplant Immunology at the Cedars-Sinai Medical Center in LA.

Significant number of highly sensitized patients remains on the waiting list post KAS



Source:
OPTN/UNOS
Darren Stewart, MS,
UNOS Research Department

Completed and ongoing studies with imlifidase in kidney transplantation

STUDY	SUBJECTS/ COUNTRY	CLINICAL TRIALS.GOV ID	STUDY DESIGN	PRIMARY ENDPOINT	SECONDARY ENDPOINTS	STATUS	PUBLICATION
Study 01 Phase 1	29 subjects	NCT01802697 (2013/2014)	• Randomized placebo-controlled dose-escalation study with 29 (20 active plus 9 placebo) healthy subjects	• Safety and tolerability	• Efficacy in IgG cleavage, the pharmacokinetics (PK) and immunogenicity of imlifidase	Complete	PLOS ONE (2015)[1]
Study 02 Phase 2	8 subjects	NCT02224820	• Single-center, single-arm, open-label	• Dosing resulting in HLA-antibody reduction (MFI<1100)	• Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay)	Complete	Lorant et al (2018) American Journal of Transplantation[2]
Study 03 Phase 2	10 subjects	NCT02475551	• Single-center, single-arm, open-label • No prior desensitization	• Safety: AEs, clinical laboratory tests, vital signs, ECGs	• Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay)	Complete	The New England Journal of Medicine (2017)[3]
Study 04 Phase 2	17 subjects	NCT024226684	• Investigator initiated study, Single-center, single-arm, open-label • All patients had prior desensitization with IVIG and/or plasmapheresis	• Assessment of efficacy in eliminating DSAs in DSA and flow cytometry positive, highly sensitized patients • Assessment of safety • Assessment of efficacy and kidney function	• Serum creatinine (0-6 months) • Proteinuria (0-6 months) • DSA at multiple timepoints posttransplant (day 0, D30, D90, D180)	Complete	The New England Journal of Medicine (2017)[3]
Study 06 "Highdes" Phase 2	18 subjects	NCT02790437	• Multicenter, multinational, single-arm, open-label Included pts who may have had prior unsuccessful desensitization or pts in whom it was unlikely to be effective	• Crossmatch conversion in DSA+ patients who have a positive XM test to their available LD or DD	• DSA reduction at multiple timepoints (2, 6, 24, 48 h after imlifidase) • Time to create negative CDC XM test and/or flow cytometry (FACS) XM test • Safety	Complete	Annals of Surgery (Lonze et al, only New York patients) Montgomery et al ATC abstract (2019)[4]
Long-term follow-up study	Up to 46 subjects	NCT03611621	• A prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation	• Long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration	• Patient survival, kidney function, comorbidity, treatments and quality of life • Safety • DSA • Immunogenicity	Ongoing	

[1] Winstedt el al., "Complete Removal of Extracellular IgG Antibodies in a Randomized Dose Escalation Phase I Study with the Bacterial Enzyme IdeS – A Novel Therapeutic Opportunity", PLOS ONE 2015, 10(7)
[2] Lorant et al., "Safety, immunogenicity, pharmacokinetics and efficacy of degradation of anti-HLA antibodies by IdeS (imlifidase) in chronic kidney disease patients" Am J Transplant. 2018 Nov;18(11):2752-2762
[3] Jordan et al., "IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation", N Engl J Med 2017;377:442-53.
[4] Montgomery et al., "Safety And Efficacy Of Imlifidase In Highly-sensitized Kidney Transplant Patients: Results From A Phase 2 Study" ATC Abstract, 2019

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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

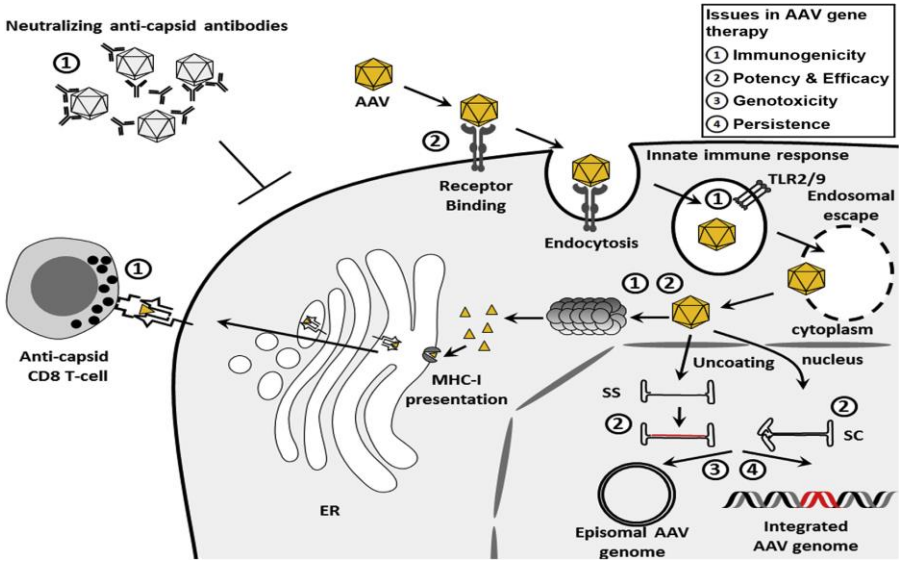
- Lead candidate selected. Development of a GMP process ongoing as well as preparations for toxicology studies

Exploring imlifidase in gene therapy as a potential pre-treatment to neutralize antibodies (Nabs)

Nabs are immunological barriers in gene therapy

- Gene therapy programs may exclude up to 40% of patients from clinical studies and approved treatments due to presence of neutralizing antibodies[1]
- Most gene programs use viral vectors originating from Adeno-Associated Viruses (AAV) for gene insertions *in vivo*; however in many cases the human immune system have developed preformed neutralizing anti-AAV that prevents effective and safe use
- Today experimental protocols are used based on plasma-pheresis, or with immunosuppressants; however these protocols protocols have not demonstrated sufficient efficacy and safety
- 187 in vivo programs are ongoing in gene therapy including 73 clinical stage programs, while two *in vivo* gene therapy products have been approved by FDA (Luxturna from Spark Therapeutics and Zolgensma from Novartis)

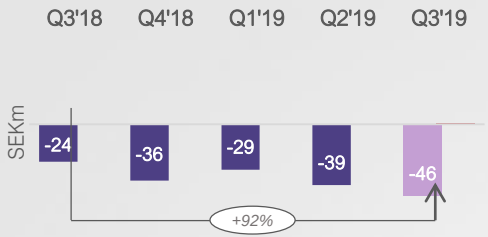
Idea is to enable gene therapy despite Nabs



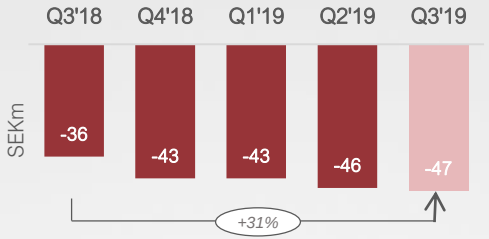
1 http://www.ijcem.com/files/ijcem0094241.pdf

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

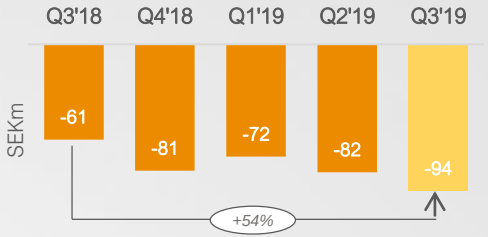
SG&A expenses (Q/Q)



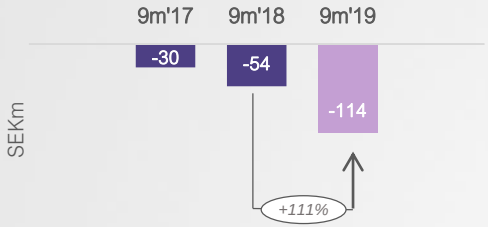
R&D expenses (Q/Q)



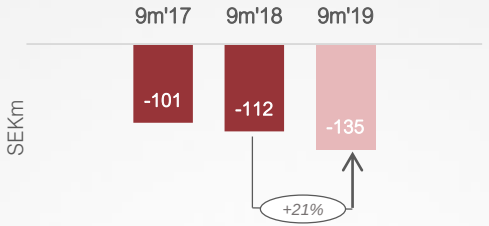
Net loss (Q/Q)



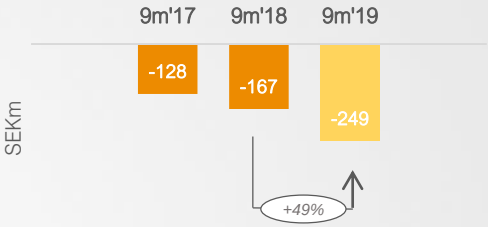
SG&A expenses (Y/Y)



R&D expenses (Y/Y)

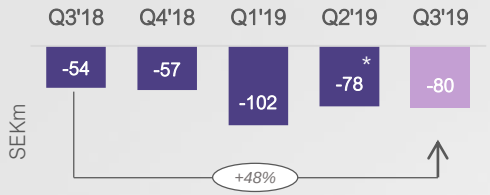


Net loss (Y/Y)

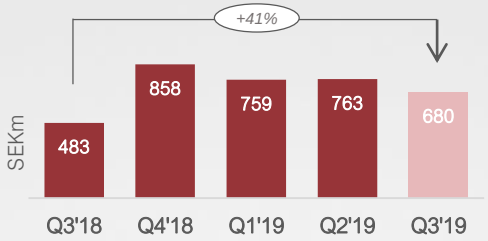


Cash flow follows increased activity level; Cash position stood at SEK 680m (~USD 70m) end of September 2019

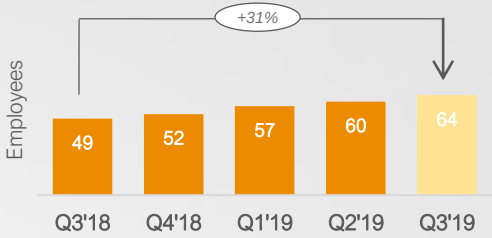
Operating cash flow (Q/Q)



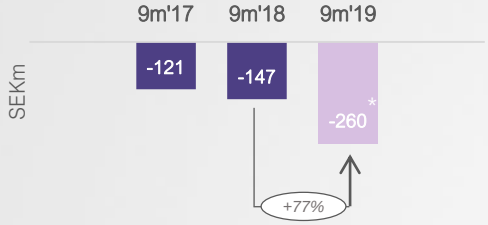
Cash & short term investments (Q/Q)



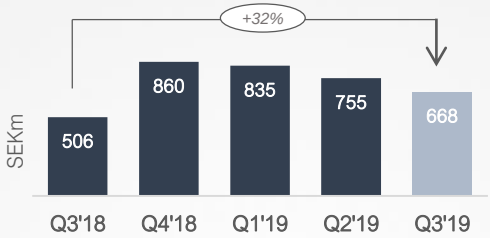
Number of employees (Q/Q)



Operating cash flow (Y/Y)



Shareholders equity (Q/Q)



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

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Appendix

Road Show Presentation
Jan-Sep 2019

Contact our Investor Relations and Corporate Communications team

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Visit our new web site
www.hansabiopharma.com

Calendar

Oct 31, 2019	Interim report Jan – Sep 2019
Nov 4-7, 2019	NDRS MorganStanley, US
Nov 12, 2019	Bryan Garnier Healthcare Conference, Paris
Nov 14-15, 2019	NDRS Kempen, Amsterdam and Zurich
Nov 15, 2019	NDRS Carnegie, Stockholm
Nov 19, 2019	Redeye Lifescience Conference, Stockholm
Nov 20, 2019	Jefferies Global Healthcare Conference, London
Dec 4, 2019	Evercore Annual Health CONx Conf, Boston
Dec 5, 2019	DNB Nordic-American Life Science Conf, NYC
Jan 8, 2020	SEB Nordic Seminar, Copenhagen
Jan 12-15, 2020	JPM Week, San Francisco
Feb 6, 2020	Interim Report Oct-Dec 2019
Mar 4, 2020	Carnegie Nordic Healthcare Seminar, Stockholm
Apr 2, 2020	Annual Report 2019
Apr 28, 2020	Interim Report Jan-Mar 2020

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