



## Investor Presentation

*Ökonomisk Ugebrev Life Science  
November 25, 2020  
Copenhagen*



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

# 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 at a glance



## Company background

- Founded 2007 with HQ in Lund, Sweden
- Søren Tøulstrup, CEO – Ulf Wiinberg, Chairman
- ~80 employees (~2/3 in R&D) end of Q3 2020
- Operations in Sweden, US & across Europe
- Market cap: SEK ~11bn (~1.25 bn USD) end of September 2020
- Listed on Nasdaq OMX Stockholm (HNSA)



## Leader in immunomodulatory enzymes for rare IgG-mediated diseases

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



## Broad pipeline in transplantation and autoimmune diseases

- Lead indication in kidney transplantation in highly sensitized patients
  - The European commission has granted conditional approval for Idefixir™ (imlifidase) in highly sensitized kidney transplant patients in the European Union
  - US: Study protocol for RCT submitted June 2020, discussions with FDA ongoing
- Anti-GBM antibody disease (Phase 2)
- Antibody mediated kidney transplant rejection (AMR) (Phase 2)
- Guillain-Barré syndrome (GBS) (Phase 2)
- NiceR - Recurring treatment in autoimmune disease, transplantation and oncology (Preclinical)
- EnzE – Cancer immunotherapy (Preclinical)



## Key financials\*

• Cash & short-term inv.	9M'20* SEK 1.5bn (9M'19 SEK 680m)	FY'19 SEK 601m
• Operating Profits/Loss	9M'20* SEK -317m (9M'19 SEK -250m)	FY'19 SEK -360m
• Operating cash flow	9M'20* SEK -194m (9M'19 SEK -260)	FY'19 SEK -335m

\* Unaudited

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

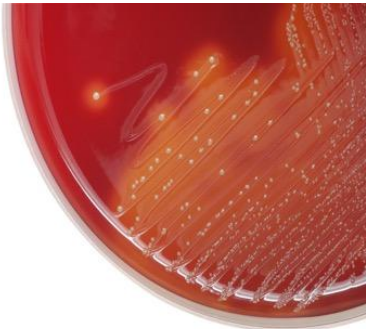


# Imlifidase – a novel approach to eliminate pathogenic IgG



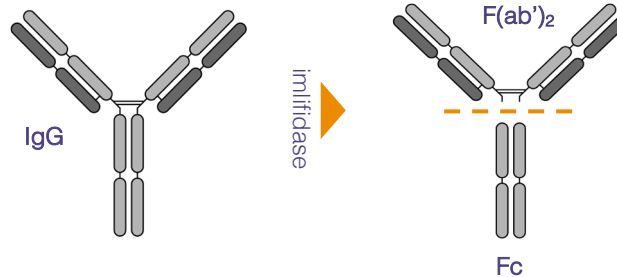
## Origins from *Streptococcus pyogenes*

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



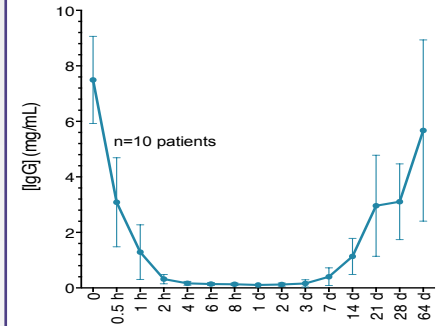
## Imlifidase, a unique IgG antibody-cleaving enzyme

- 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

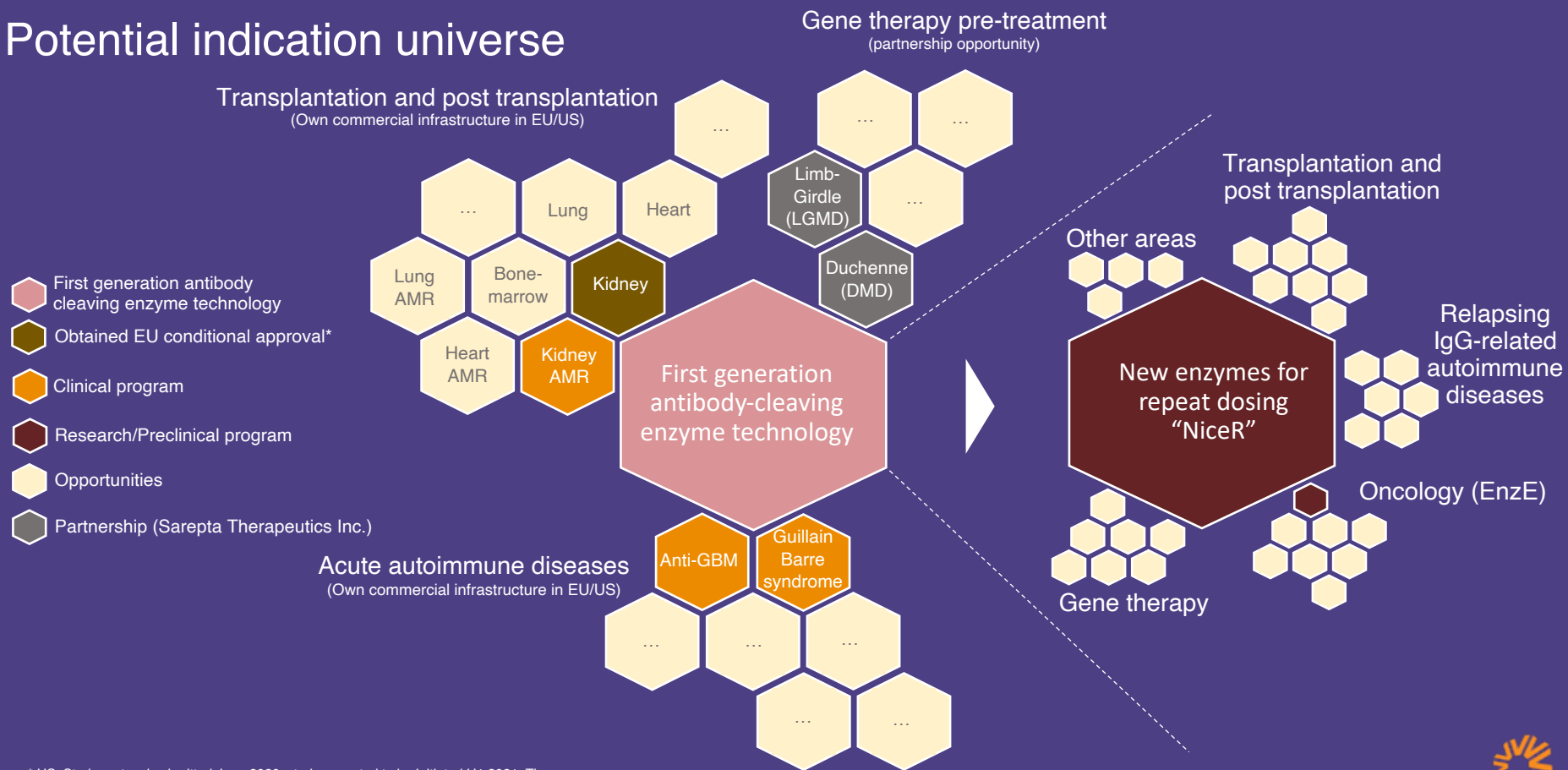


## Imlifidase inactivates IgG in 2 hours

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



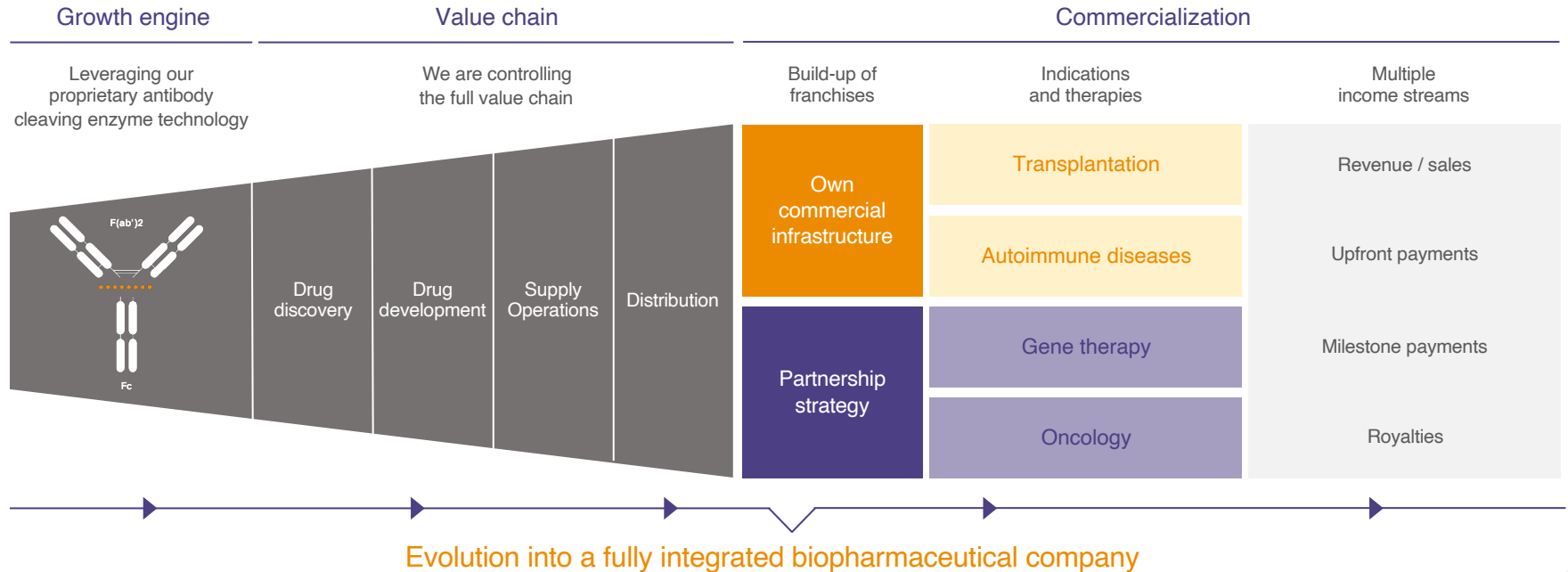
# Potential indication universe



\* US: Study protocol submitted June 2020, study expected to be initiated H1 2021. The new clinical study could support BLA submission by 2023

# Leveraging our technology platform

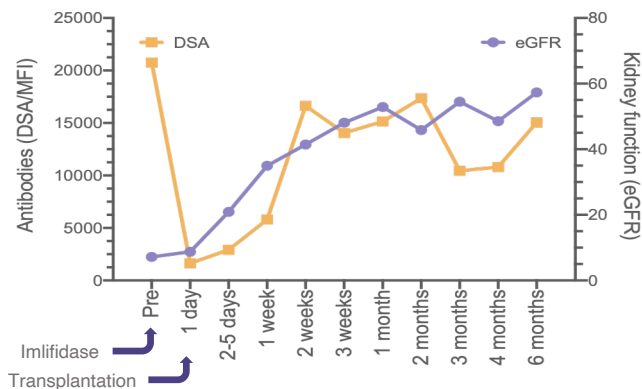
Developing new therapies targeting rare diseases with unmet medical need across a range of indications









# Imlifidase has enabled kidney transplantation in 46 highly sensitized patients

## Pooled analysis from four Phase 2 trials

- 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



## Study design of our four Phase 2 trials

Study 02 Phase 2	Subjects	8 patients 
	Design	Single-center, single-arm, open-label
	Main objective	Efficacy defined as Imlifidase dosing scheme resulting in HLA antibody levels acceptable for transplantation, within 24 hours
Study 03 Phase 2	Subjects	10 patients 
	Design	Single-center, single-arm, open-label, no prior desensitization
	Main objective	Safety in the transplantation setting and efficacy defined as HLA antibody levels acceptable for transplantation
Study 04 Phase 2	Subjects	17 patients 
	Design	Investigator initiated, single-center, single-arm, open-label. All patients had prior desensitization with IVIG and/or PLEX
	Main objective	Safety in combination with Cedars Sinai's "standard protocol" for desensitization of highly sensitized patient
Study 06 Phase 2	Subjects	18 patients   
	Design	Multicenter, multinational, single-arm, open-label
	Main objective	Efficacy in creating a negative crossmatch test

# Idefirix® (Imlifidase) has received conditional approval in the European Union



## Idefirix® is indicated for

*desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor.*

*The use of Idefirix® should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritization programs for highly sensitized patients*

Highly sensitized patients that are likely to be transplanted with a compatible donor

Highly sensitized patients unlikely to be transplanted under available KAS, including prioritization programs

Potential patients

**idefirix®**  
imlifidase

Actual patient have given consent to provide images

<sup>1</sup> EDQM. (2020). International figures on donation and Transplantation 2019  
<sup>2</sup> SRTR Database and individual assessments of allocation systems

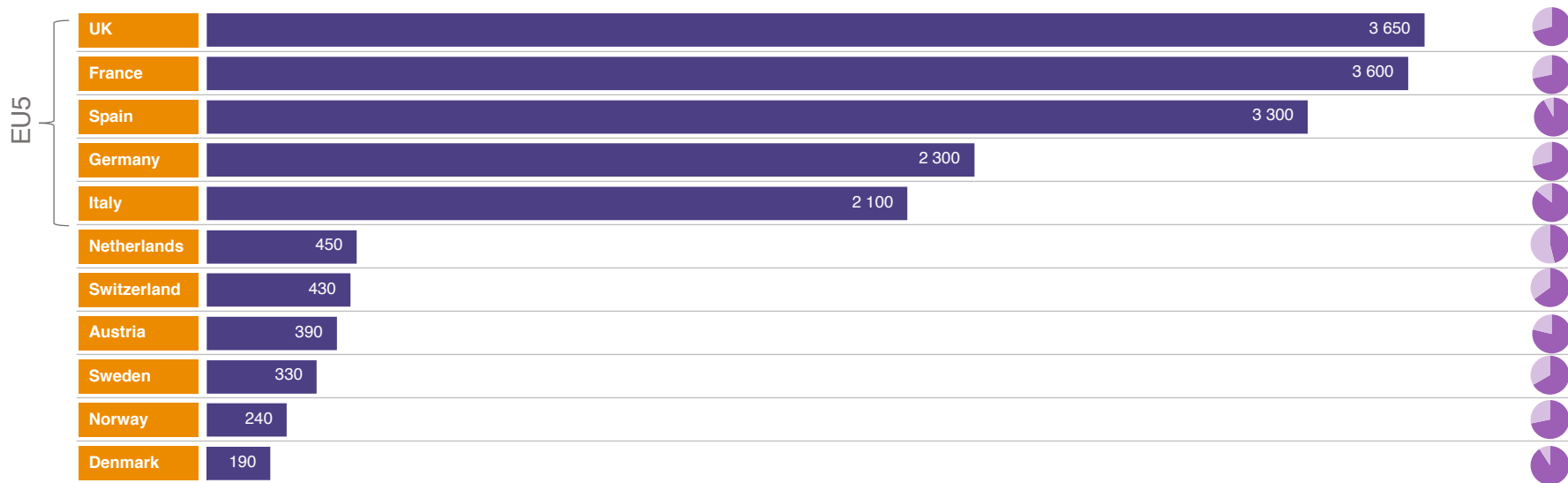


# European kidney transplantation landscape

Approximately 15,000 annual kidney transplants in EU5 +2,000 annual kidney transplants in Netherlands, Sweden, Norway, Denmark, Austria and Switzerland<sup>1</sup>

- Transplants annual
- Living donor transplants
- Deceased donor transplants

## Patients

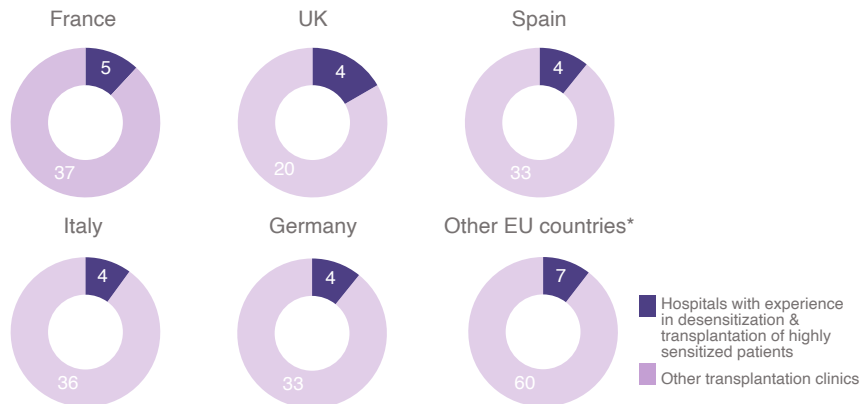


# Early launch in centres of excellence

## First launch wave defined

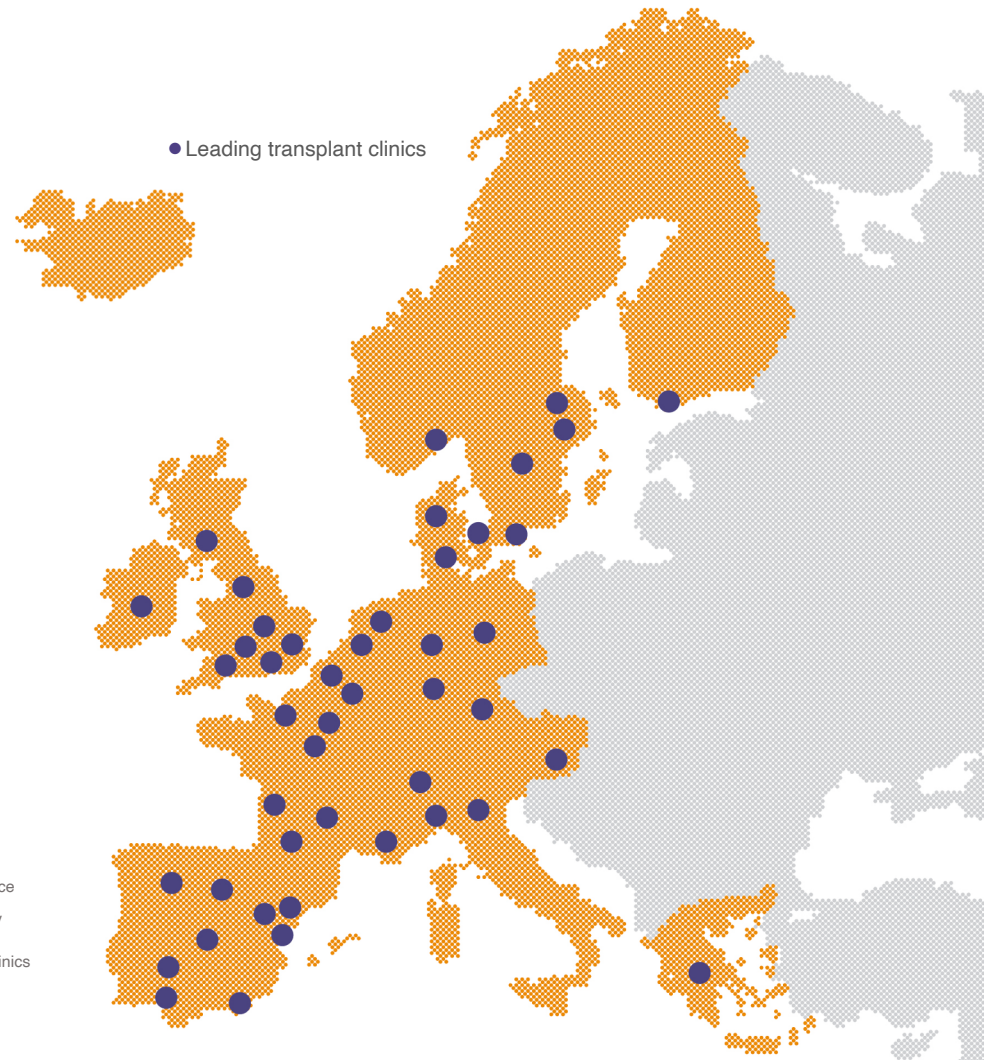
1. Launch Idefirix® with kidney transplant specialists who have experience in desensitization
2. Create positive momentum with Idefirix as the new Gold Standard in desensitization protocols
3. Prepare post approval study to confirm filing data

## Leading transplantation centres perform the majority of all transplantations in EU



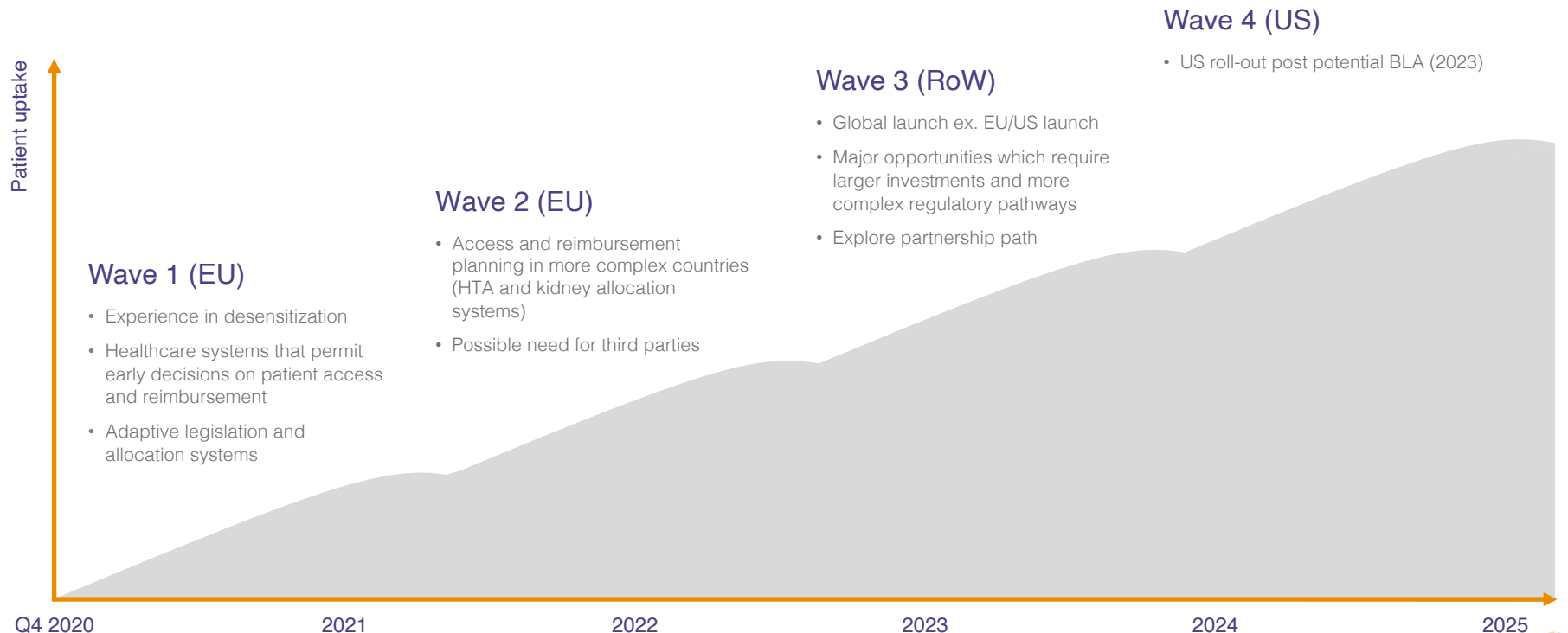
Idefirix approved in EU under conditional approval

\*Other EU countries incl. Sweden, Denmark, Norway, Austria, Switzerland, Netherlands, Belgium, Poland, Czech Rep. and Portugal



# Plans for global expansion

## Launching in parallel waves with centre-by-centre approach in Europe



# 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 <sup>1,2</sup>				→		*)	EU: Commercial launch Q4 2020
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>				**) )			First patient dosed H1 2021
	Anti-GBM antibody disease <sup>3</sup>							Next step is to engage with regulators and agree on a path forward toward BLA/MAA
	Antibody mediated kidney transplant rejection (AMR)							Complete enrolment of 30 patients H2'21
	Guillain-Barré syndrome (GBS)							Complete enrolment of 30 patients H2'21
	Limb-Girdle (LGMD) & Duchenne (DMD) (Pre-treatment ahead of gene therapy with Sarepta)							Research phase
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology							Development of CMC process / Tox studies
EnzE	Cancer immunotherapy							Research phase

Completed Ongoing

<sup>1</sup> Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)

<sup>2</sup> Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)

<sup>3</sup> Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

\*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch

\*\*) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients. Given the continued impact of the COVID-19 pandemic and the timeline for the finalization of the study protocol

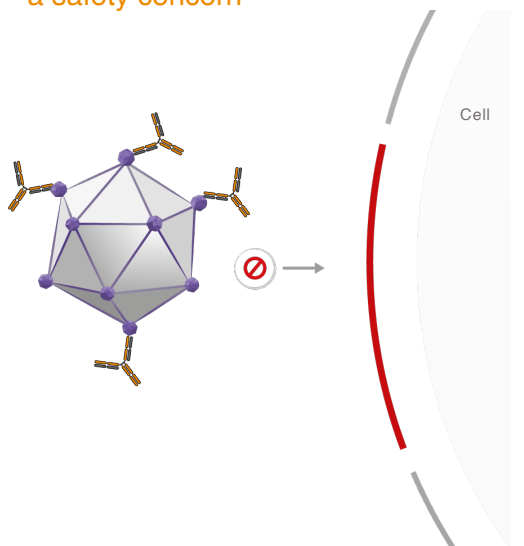
Hansa expect recruitment of the first patient to be in H1 2021

# Neutralizing antibodies (Nabs) are immunological barriers in gene therapy

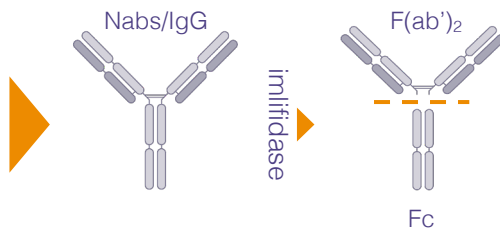
*Between approximately 5% and 70%<sup>1,2</sup> of patients considered for gene therapy treatment carry neutralizing anti-AAV antibodies forming a barrier for treatment eligibility*

*Our hypothesis is that imlifidase has the potential to eliminate neutralizing antibodies as a pre-treatment, prior to the introduction of gene therapy*

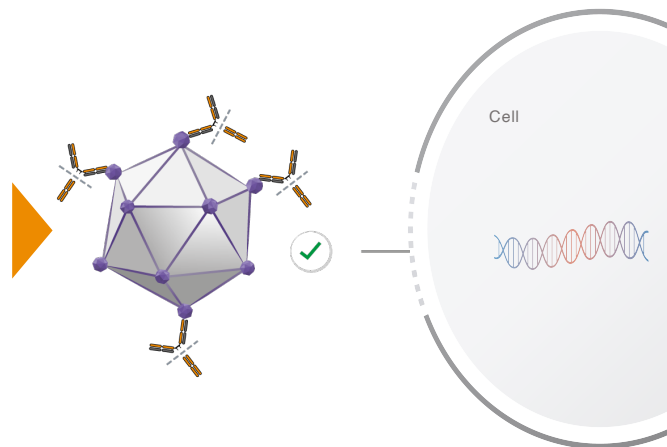
- 1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



- 2 Imlifidase is a unique IgG antibody-cleaving enzyme that cleaves IgG at the hinge region with extremely high specificity



- 3 The idea is to eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy



# Exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications

## A unique opportunity to combine efforts...

...and to use the unique features of imlifidase to potentially enable gene therapy treatment in patients who today aren't eligible for these breakthrough therapies due to pre-existing neutralizing antibodies in two indications with a very high unmet medical need

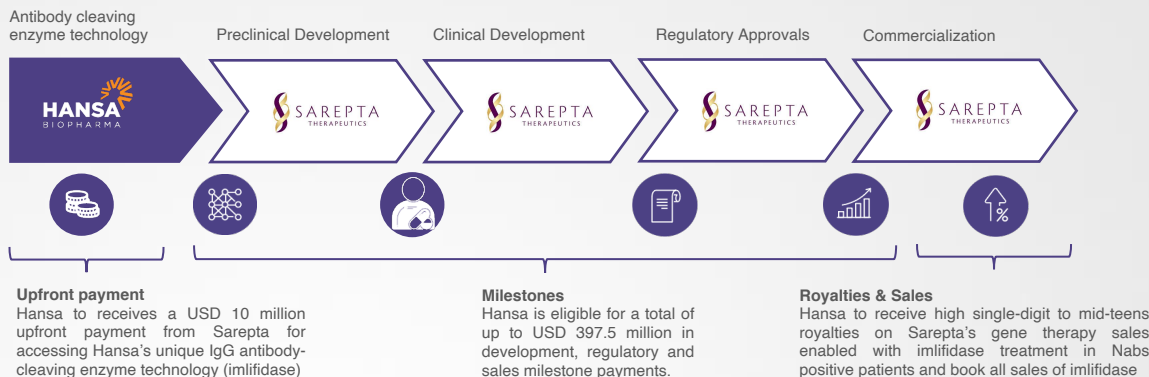
## Structure of the partnership

- Sarepta will be responsible for conducting
- Pre-clinical/clinical studies with imlifidase
  - Regulatory approvals
  - Promotion of imlifidase as a pre-treatment to Sarepta's gene therapies following potential approval

Hansa will supply product, support with know-how and involve in the regulatory approval process

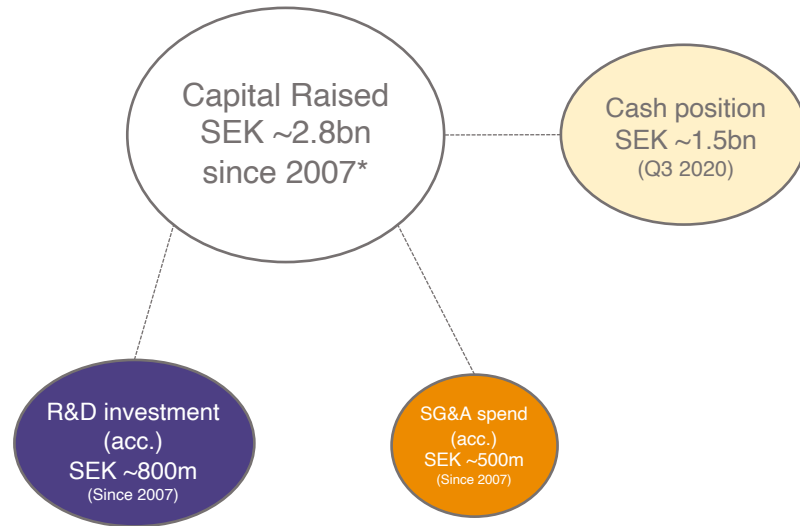
## Hansa's financial participation

Potential total deal value for Hansa amounts to up to USD ~400m plus royalties and incremental imlifidase sales

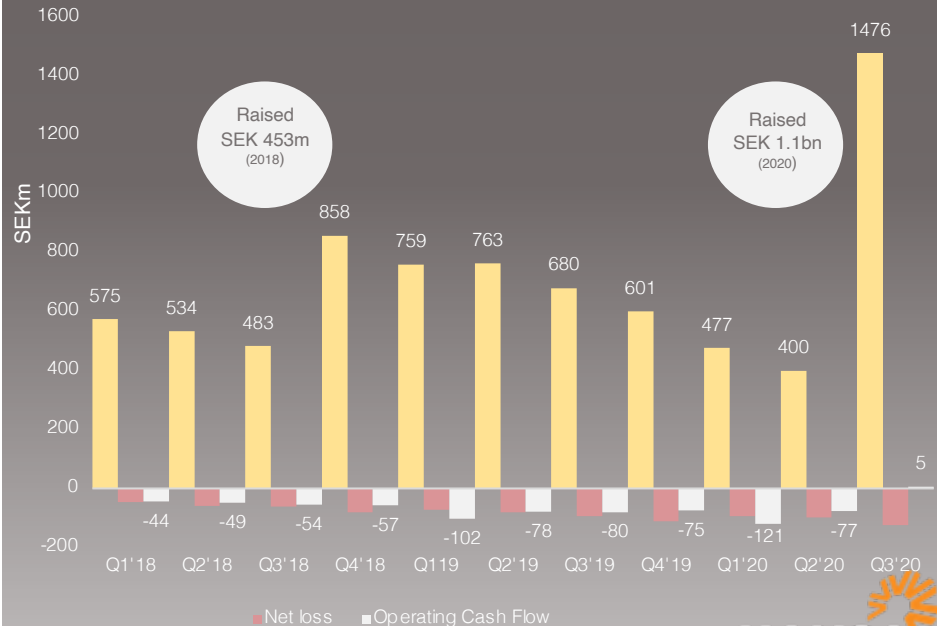


# With the recent capital injection Hansa Biopharma is financed into 2023

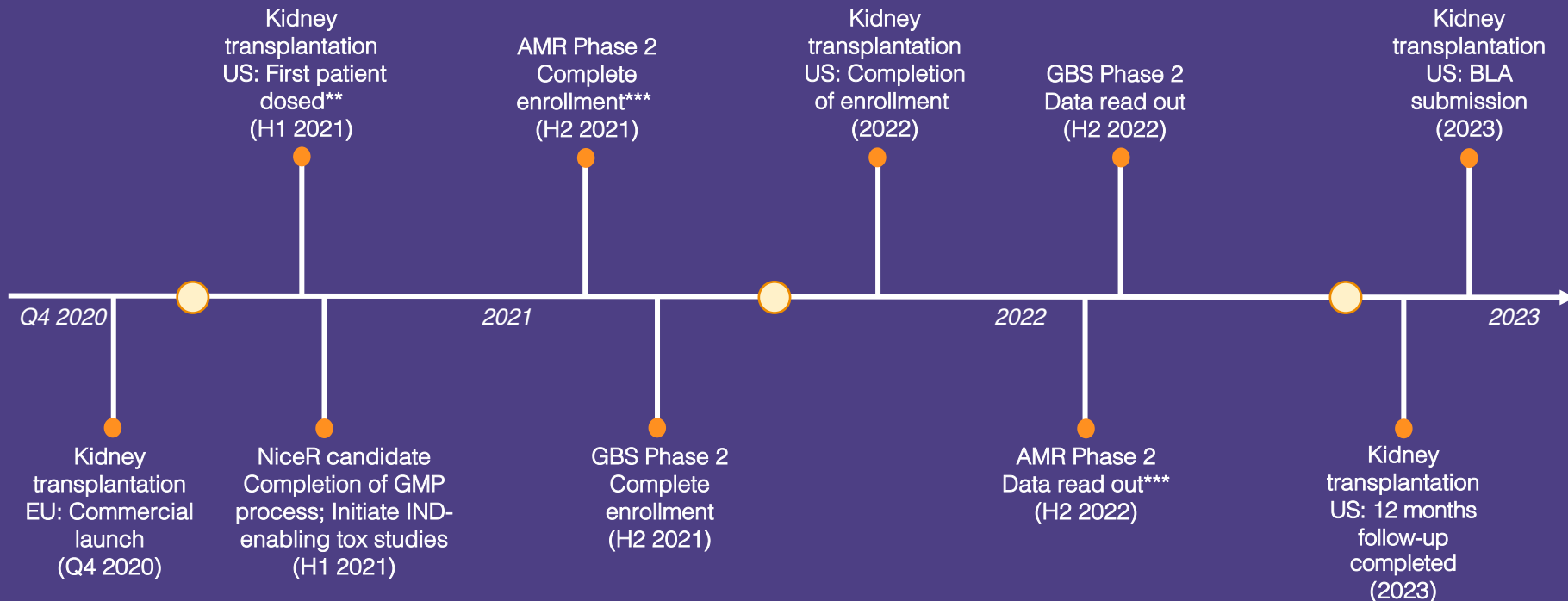
Since 2007 Hansa has mainly been backed by VCs funding the development of our enzyme platform



Capital injection from new shares (SEK 1.1bn) and Sarepta (SEK 100m) will finance Hansa into 2023



# Upcoming milestones



\*\*) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients. Given the continued impact of the COVID-19 pandemic and the timeline for the finalization of the study protocol Hansa expect recruitment of the first patient to be in H1 2021

\*\*\*) AMR/GBS Due to the impact from the COVID-19 pandemic, the enrollment in GBS and AMR were temporarily halted for the past six months. Hansa Biopharma expects to reinstate enrollment of these studies in Q4 2020 under a risk-based, site-by-site approach. Enrollment of patients in the AMR study is now expected to be completed in the second half of 2021, while completion of patient enrollment in the GBS study is still expected in the second half of 2021. High-level data readout for both studies are expected in the second half of 2022.



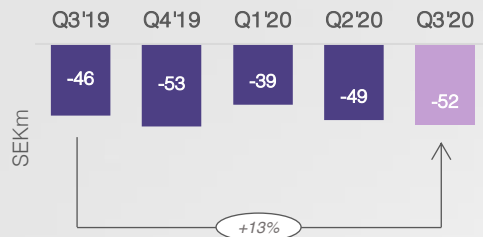


# Capital Markets



# Hansa Biopharma continues to invest in the R&D pipeline and the commercial preparation towards the expected launch in Q4 2020

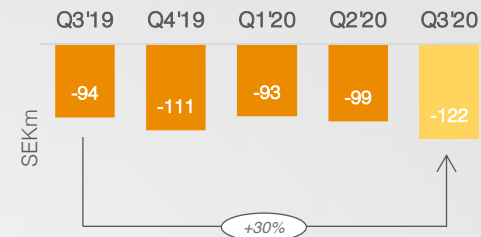
SG&A expenses (Q/Q)



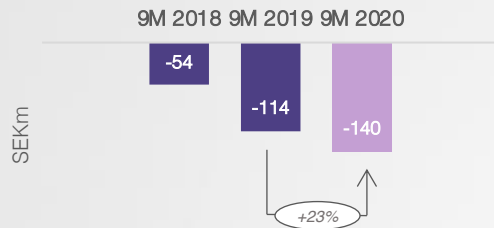
R&D expenses (Q/Q)



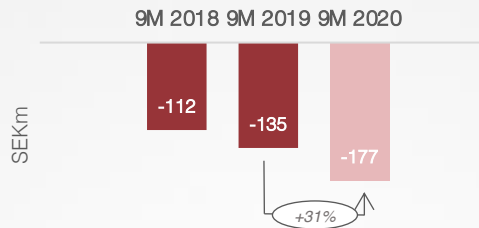
Net loss (Q/Q)



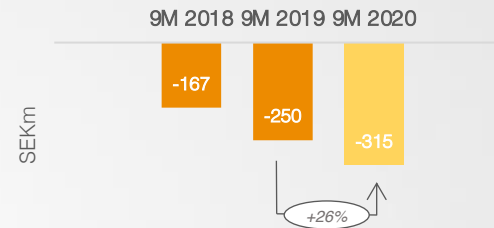
SG&A expenses (9M/9M)



R&D expenses (9M/9M)

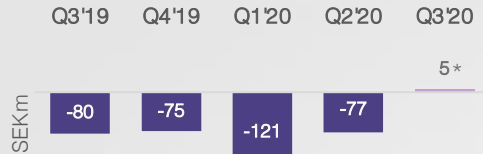


Net loss (9M/M)

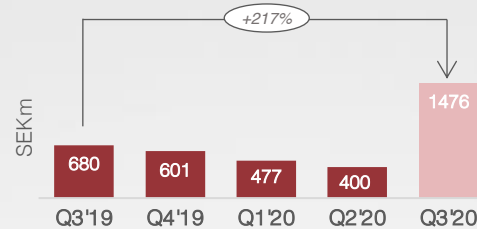


# Cash position stood at SEK 1.5bn (~USD 150m) end of Q3 2020; Hansa Biopharma is financed through 2023

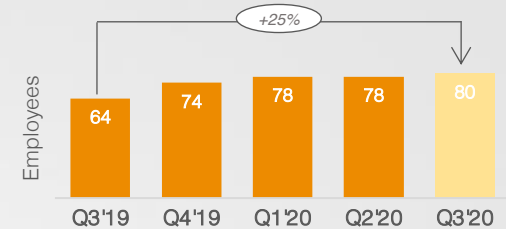
Operating cash flow (Q/Q)



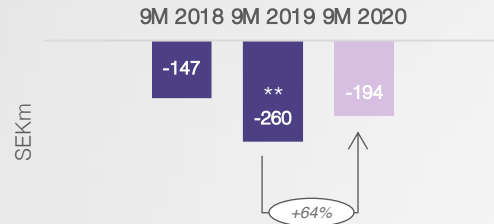
Cash & short term investments (Q/Q)



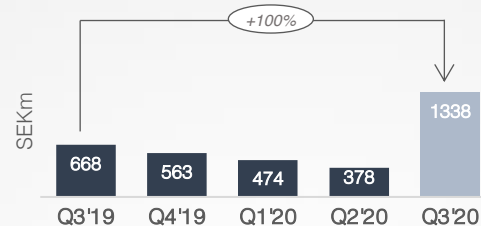
Number of employees (Q/Q)



Operating cash flow (9M/9M)



Shareholders equity (Q/Q)



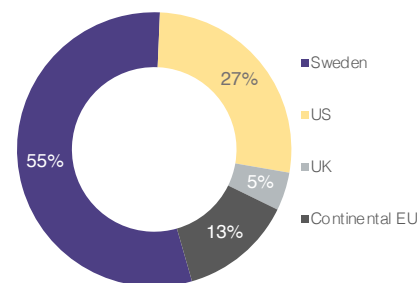
# Ownership in Hansa Biopharma

## Top 10 ownership as per September 30, 2020

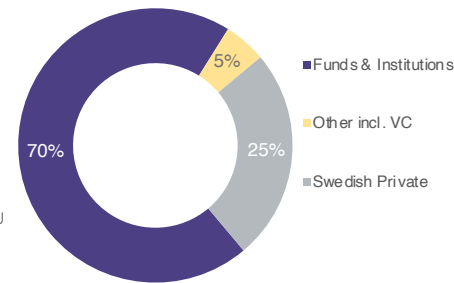
Name	No. of shares	Ownership in pct.
Consonance Capital Management	2 655 009	6.0
Redmile Group	2 323 708	5.2
NXT2B	2 155 379	4.8
Invesco	1 938 841	4.4
Thomas Olausson	1 750 474	3.9
Fourth Swedish National Pension Fund	1 536 624	3.5
Avanza Fonder AB	1 387 380	3.1
Handelsbanken Fonder AB	1 329 744	3.0
Gladiator	1 025 000	2.3
ClearBridge, LLC	1 012 786	2.3
Other	27 358 507	61.5
Outstanding A shares in total	44 473 452	100.0

## Classification of ownership

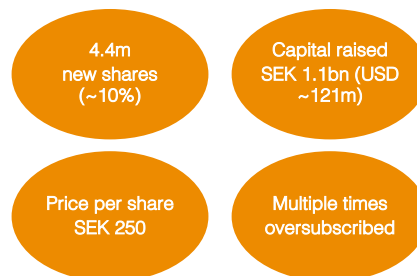
Ownership by country



Ownership by type



Capital Raise July 2020



No. of shareholders



# Hansa Biopharma - Market data and share price development

## Market data (Sep 2020)

**Stock Exchange:** Nasdaq, Stockholm since Nov 2015  
(First North Oct 2007- Nov 2015)

**Ticker** HNSA

**Market Cap:** SEK ~11bn (USD ~1.25 bn)

**52-week range:** SEK 59-288 per share

**Avg. Daily Turnover:** vol ~565k shares

**Shares outstanding:** 44 473 452

**Shareholders** ~18,000

**Top 5 Shareholders:** Consonance Capman 6.0%  
As per September 2020

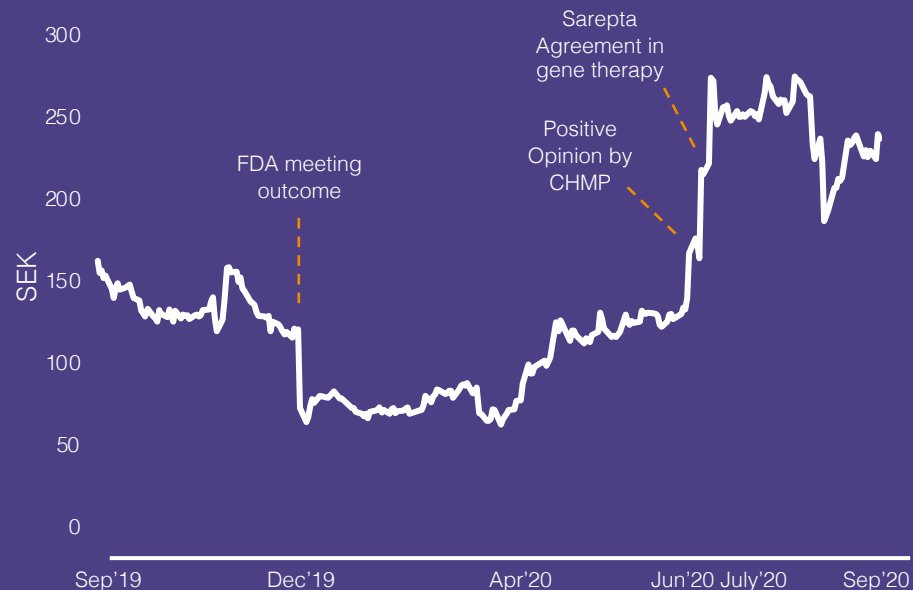
Redmile Group 5.2%

NXT2B 4.8%

Invesco 4.4%

Thomas Olausson 3.9%

## 12 months Share price development (Sep 2020)



# Analysts covering Hansa Biopharma (ticker: HNSA, NASDAQ Stockholm)

Analyst	Bank / Research institution (year of initiation)	Location	Email	Phone
Christopher Uhde	SEB (2016)	Stockholm	<a href="mailto:christopher.uhde@seb.se">christopher.uhde@seb.se</a>	+46 (0) 876-385 53
Viktor Sundberg	ABG Sundal Collier (2018)	Stockholm	<a href="mailto:viktor.sundberg@abgsc.se">viktor.sundberg@abgsc.se</a>	+46 (0) 856-628 641
Charles Weston	RBC (2017)	London	<a href="mailto:Charles.Weston@rbccm.com">Charles.Weston@rbccm.com</a>	+44 7935 202349
Ingrid Gafanhão	Kempen (2019)	Amsterdam	<a href="mailto:ingrid@gafanhao@kempen.com">ingrid@gafanhao@kempen.com</a>	+31 689 937 525
Naresh Chouhan	Intron Health Research (2020)	London	<a href="mailto:naresh@intronhealthresearch.com">naresh@intronhealthresearch.com</a>	+44 7939 224 322
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Erik Hultgård	Carnegie (2019)	Stockholm	<a href="mailto:erik.hultgard@carnegie.com">erik.hultgard@carnegie.com</a>	+46 (0) 858-869 237
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Visit our web site  
[www.hansabiopharma.com](http://www.hansabiopharma.com)



## Calendar

Nov 17, 2020	Bryan Garnier Healthcare Conference, Paris (virtual)
Nov 18, 2020	Jefferies Healthcare Conference, London (virtual)
Nov 25, 2020	Ökonomisk Ugebrev Life Science Conference, Copenhagen
Nov 26, 2020	Redeye Life Science Day, Stockholm (virtual)
Jan 11-14, 2021	JP Morgan Week (virtual)
Jan 11-14, 2021	H.C. Wainwright Bioconnect Conference (virtual)
Jan 18, 2021	SEB Nordic Healthcare seminar (virtual)
Feb 4, 2021	Interim report Jan-Dec 2020
Mar 9, 2021	Carnegie Nordic Healthcare seminar (virtual)
April 8, 2021	Annual Report 2020
April 22, 2021	Interim report for Jan-Mar 2021
May 5, 2021	Kempen Life Sciences Conference (virtual)
July 15, 2021	Interim report for Jan-Jun 2021
Oct 21, 2021	Interim report for Jan-Sep 2021



