# HANSA BIOPHARMA Investor Presentation

Redeye Life Science Conference November 26, 2020



## Forward-looking statement

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

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.



# Hansa Biopharma at a glance



#### Company background

- · Founded 2007 with HQ in Lund, Sweden
- · Søren Tulstrup, 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 Nasdag OMX Stockholm (HNSA)



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

- Imlifidase is a unique IgG antibody-cleaving enzyme that 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 Idefirix<sup>™</sup> (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

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



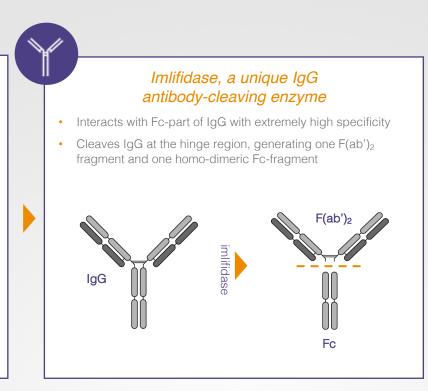
<sup>\*</sup> Unaudited

# Imlifidase – a novel approach to eliminate pathogenic IgG

# Origins from Streptococcus pyogenes

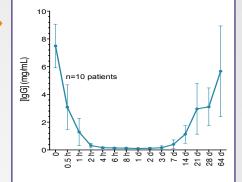
- Species of Gram-positive, spherical bacteria in the genus Streptococcus
- Usually known from causing a strep throat infection







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

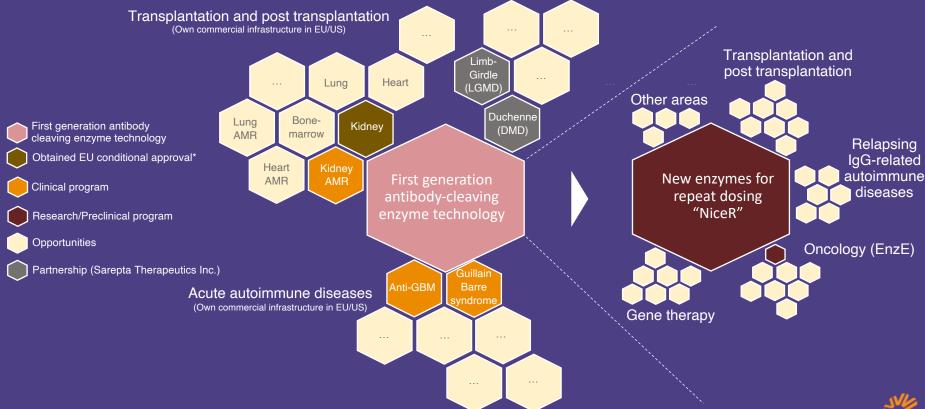




## Potential indication universe

#### Gene therapy pre-treatment

(partnership opportunity)

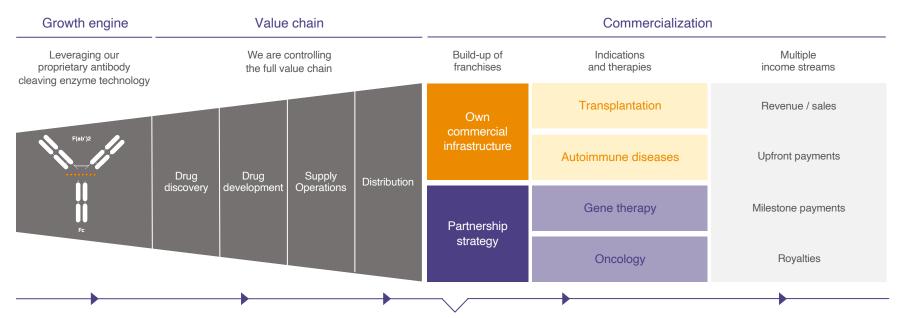


<sup>\*</sup> US: Study protocol submitted June 2020, study expected to be initiated H1 2021. The new clinical study could support BLA submission by 2023



# Leveraging our technology platform

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



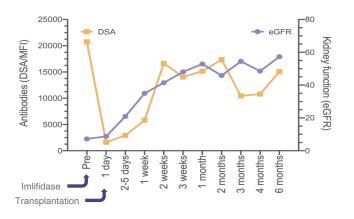
Evolution into a fully integrated biopharmaceutical company



## 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

Main objective

Single-center, single-arm, open-label, no prior desensitization 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



Actual patient have given consent to provide images



EDQM. (2020). International figures on donation and Transplantation 2

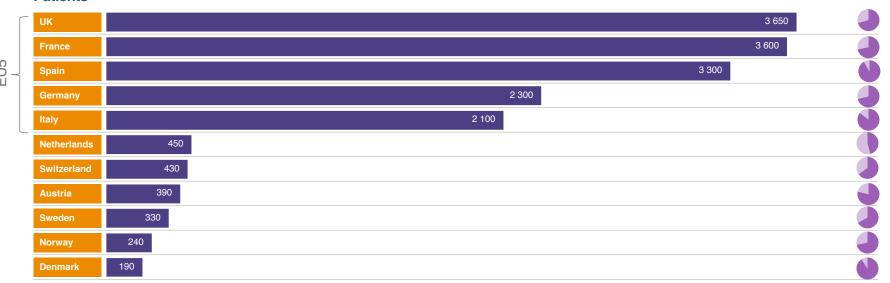
## European kidney transplantation landscape



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**



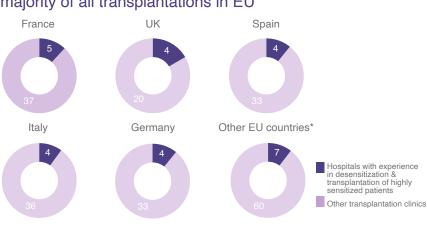


## Early launch in centres of excellence

#### 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





Belgium, Poland, Czech Rep. and Portugal

## Broad pipeline in transplantation and auto-immune diseases



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



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

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

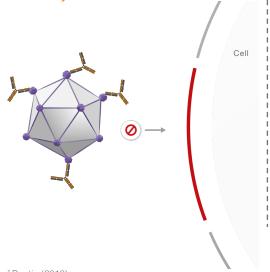
<sup>\*)</sup> The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch \*\*) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once 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

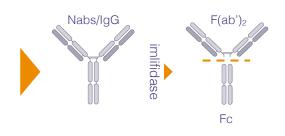
Between approximately 5% and 70%<sup>1,2</sup> of patients considered for gene therapy treatment carry neutralizing anti-AAV antibodies forming a barrier for treatment eligibility

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 antibodycleaving enzyme that cleaves IgG at the hinge region with extremely high specificity



The idea is to eliminate the neutralizing antibodies as a pretreatment to enable gene therapy Cell

# 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

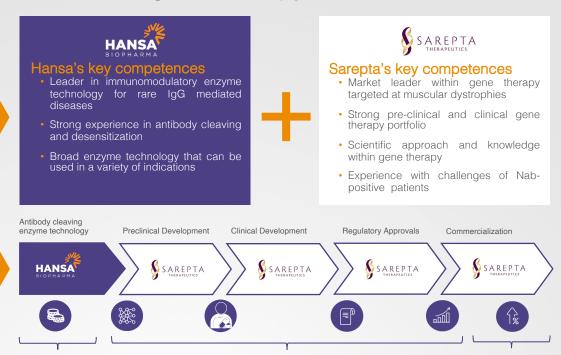
Sarepta will be responsible for conducting

- 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



#### **Upfront payment**

Hansa to receives a USD 10 million upfront payment from Sarepta for accessing Hansa's unique IgG antibodycleaving enzyme technology (imlifidase)

#### Milestones

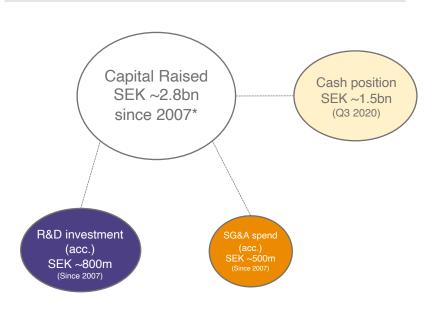
Hansa is eligible for a total of up to USD 397.5 million in development, regulatory and sales milestone payments.

#### **Royalties & Sales**

Hansa to receive high single-digit to mid-teens royalties on Sarepta's gene therapy sales enabled with imlifidase treatment in Nabs positive patients and book all sales of imlifidase

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

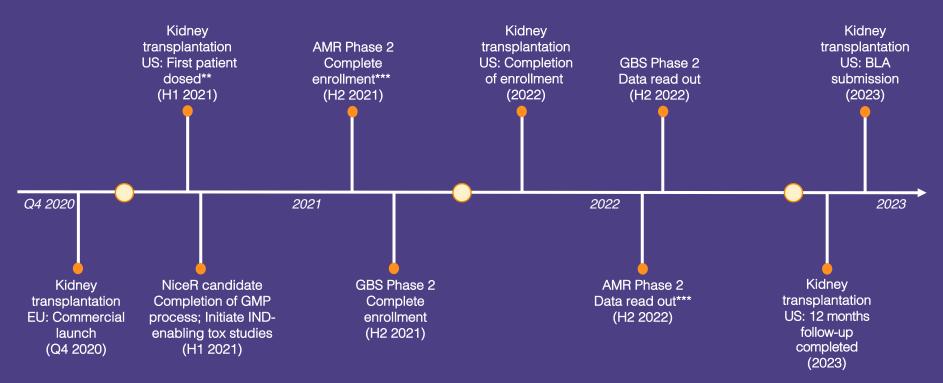
Since 2007 Hansa has mainly been backed by VCs funding the development of our enzyme platform



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



# Upcoming milestones



<sup>\*\*)</sup> 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



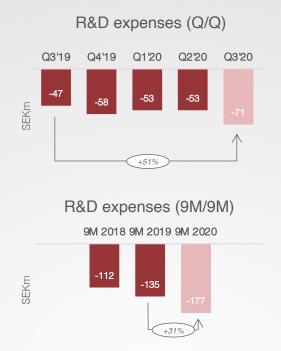
<sup>\*\*\*)</sup> AMR/GBS Due to the impact from the COVID-19 pandemic, the enrollment in GBS and AMR were temporarily halted for the past six months. Hansa Biopharma expects to reinitiate enrollment of these studies in Q4 2020 under a risk-based, site-by-site approach. Enrollment of patients in the 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.

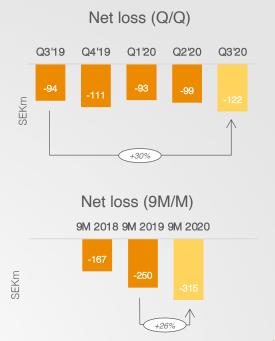




# Hansa Biopharma continues to invest in the R&D pipeline and the commercial preparation towards the expected launch in Q4 2020









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

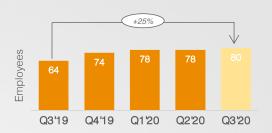
#### Operating cash flow (Q/Q)



#### Cash & short term investments (Q/Q)



#### Number of employees (Q/Q)



#### Operating cash flow (9M/9M)



#### Shareholders equity (Q/Q)





<sup>\*</sup> Including positive cash impact of SEK 90m from Sarepta upfront payment
\*\* Excl. positive impact from sale of Genovis shares of SEK 89m in Q2'19

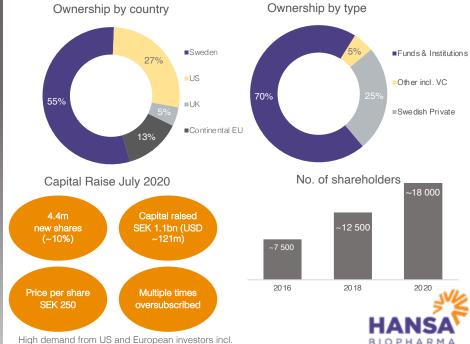
## Ownership in Hansa Biopharma

#### 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

Redmile, Consonance, HBM and Fonden TIN Ny Teknik



# 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%

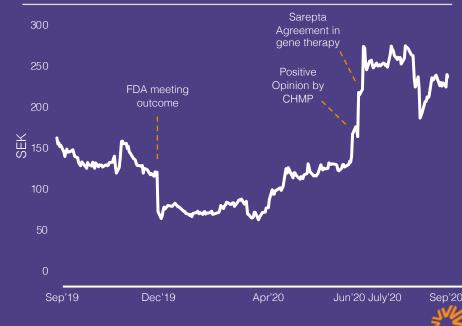
As per September 2020 Redmile Group 5.2%

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	christopher.uhde@seb.se	+46 (0) 876-385 53
Viktor Sundberg	ABG Sundal Collier (2018)	Stockholm	viktor.sundberg@abgsc.se	+46 (0) 856-628 641
Charles Weston	RBC (2017)	London	Charles.Weston@rbccm.com	+44 7935 202349
Ingrid Gafanhão	Kempen (2019)	Amsterdam	ingrid@gafanhao@kempen.com	+31 689 937 525
Naresh Chouhan	Intron Health Research (2020)	London	naresh@intronhealthresearch.com	+44 7939 224 322
Maneka Mirchandaney	Evercore (2018)	New York City	maneka.mirchandaney@evercoreisi.com	+1 646 740 1482
Erik Hultgård	Carnegie (2019)	Stockholm	erik.hultgard@carnegie.com	+46 (0) 858-869 237
Ludvig Svensson	Redeye (2008)	Stockholm	ludvig.svensson@redeye.se	+46 (0) 704-962 535
Joseph Hedden	RX Securities (2016)	London	joseph@rxsecurities.com	+44 773 061 8803
Lars Hatholt	Ökonomisk Ugebrev (2020)	Copenhagen	hatholt@outlook.com	+45 22 23 78 15



# Contact our Investor Relations and Corporate Communications

## Visit our web site www.hansabiopharma.com





Klaus Sindahl
Head of Investor Relations
Mobile: +46 (0) 709-298 269

Email: klaus.sindahl@hansabiopharma.com

Email: katja.margell@hansabiopharma.com



Katja Margell
Head of Corporate Communications
Mobile: +46 (0) 768-198 326

#### Calendar

Nov 25, 2020	Ökonomisk Ugebrev Life Science Conference, Copenhagen
Nov 26, 2020	Redeye Life Science Day, Stockholm (virtual)
Dec 8-9, 2020	Jefferies Road Show (virtual)
Dec 10, 2020	ABG Road Show (virtual)
Jan 11-14, 2021	J.P. Morgan Healthcare Conference (virtual)
Jan 14, 2021	H.C. Wainwright BioConnect Conference (virtual)
Jan 18, 2021	SEB Nordic Healthcare seminar (virtual)
Feb 2, 2021	Interim report Jan-Dec 2020
Mar 9, 2021	Carnegie Nordic Healthcare seminar (virtual)
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



