

# Addressing unmet need in rare diseases

Annual Report 2023





## Hansa Biopharma in brief

Hansa Biopharma (“Hansa”, “the Company”, “we”) is a commercial-stage biopharmaceutical company and pioneer in immunoglobulin G (IgG)-cleaving enzyme technology. We are dedicated to developing and commercializing innovative, lifesaving and life-altering treatments for patients with rare immunological conditions.

Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company’s proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available.

Hansa is based in Lund, Sweden with operations in Europe and the U.S.

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## Our vision

**We envision a world where all patients with rare immunologic diseases can lead long and healthy lives.**



# Overview

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## Chairman's letter

# Strong purpose driven culture



**Peter Nicklin**  
Chairman

### Dear shareholders,

2023 was another important year for Hansa Biopharma. We are a company whose purpose is rooted in scientific innovation, improving patient outcomes, and operating with the highest ethical standards.

As my second full year as Chairman of the Board of Directors of Hansa Biopharma approaches, I am even more enthusiastic about the road ahead for our company. Hansa continues to pursue exciting scientific advancements in the lab and in the clinic, based on its proprietary enzyme technology platform and increased access to Idefirix® through the efforts of our highly engaged and committed culture of talented individuals with deep expertise spanning early drug discovery, clinical development, global product launch and in-market commercialization.

**Hansa is developing science that will change lives.** In 2023, alone, the Company advanced seven clinical trials in either Phase 2 or Phase 3 in areas with high unmet medical

need, including autoimmunity, gene therapy enablement, and transplantation. Additionally, the R&D organization continued to progress the development of next generation enzymes to expand potential indications.

**Hansa is ensuring access to innovative, new medicines.** As evidenced by the efforts in Europe to ensure access to Idefirix®, the first approved desensitization therapy for highly sensitized patients, Hansa is paving the path for improving transplantation patient care. This work goes beyond the delivery of medicines and involves ongoing engagement and collaboration with stakeholders across the healthcare continuum. This level of commitment – to truly change the treatment paradigm for patients in need – represents a significant opportunity for Hansa.

**Hansa is operating as a responsible, ethical business.** Over the course of 2023, Hansa remained focused on delivering on its purpose while also taking accountability for its impact on society. Continued refinement and evolution of its Sustainability strategy and reporting reflects the change happening

at the Company and the industry. Guided by its values, and ethical decision-making, Hansa remains focused on three key areas related to Sustainability – Healthy People, Healthy Business and Healthy Planet – and has continued to embrace Sustainability in a way that is highly meaningful to its employees, shareholders, customers, and, most importantly, patients.

As we look ahead to many exciting new milestones, the Board is confident the strong and highly experienced team at Hansa will continue to deliver on its important drug development and commercial priorities.

On behalf of the Board of Directors,

**Peter Nicklin**  
Chairman, Hansa Biopharma AB  
Lund, Sweden, March 2024



# 2023 highlights





## CEO statement

# Hansa enters 2024 in a strong position to successfully execute on our key priorities



**Søren Tulstrup**  
President and CEO

Despite continued global economic and geopolitical challenges impacting the biotech sector, 2023 was another year marked by significant progress across Hansa Biopharma's commercial and R&D operations.

I joined Hansa Biopharma in 2018 (then known as Hansa Medical) with a strong belief in its exciting enzyme technology platform and pipeline. I recognized early on the potential to build a pioneering, immunology-focused commercial-stage biotech company. The Company was at the precipice of completing a successful Phase 2 development program of its lead molecule, imlifidase, in kidney transplantation and based on this, seeking early conditional marketing approval in Europe. Simultaneously, ongoing development of Hansa's unique and versatile enzyme technology platform

was advancing in areas of significant unmet medical need, including autoimmunity and other adjacent therapeutic areas.

### **A strategy to address unmet medical need**

My belief in Hansa remains strong. Together we have successfully transformed the organization into a multi-pronged, commercial-stage biotech company despite facing significant external headwinds – including the COVID-19 pandemic and a significant downturn in the “biotech” capital markets.

With a highly experienced, results-driven team we continue to execute towards our key strategic priorities, underpinned by our extensive scientific and commercial expertise. The Company remains focused on advancing cutting-edge science and delivering new treatments in areas of high unmet need, including autoimmune diseases, gene therapy enablement, and desensitization in kidney transplantation.

Autoimmune diseases are increasing in prevalence every year, with nearly 1 in 10 people worldwide diagnosed with at least one autoimmune disease. Hansa is firmly committed to advancing the role of its IgG cleaving enzyme, imlifidase, in stopping or slowing the progression of these conditions. We have generated very encouraging data from Phase 2 studies in anti-GBM and Guillain-Barré Syndrome and are supporting an investigator-initiated trial in ANCA-associated vasculitis.

Gene therapy represents a significant new growth opportunity for imlifidase as a pre-treatment to gene therapy in patients who have developed Neutralizing Antibodies

(NAb)s against some of the most common viral vectors used to transfer healthy genes into the cells of patients. Our partnership strategy enables us to collaborate with leading gene therapy innovators to potentially enable more patients suffering from serious genetic diseases to access life-altering gene therapies. Our partnership with US-based Sarepta Therapeutics – formed in 2020 – is focused on Duchenne Muscular Dystrophy (DMD) and Limb-Girdle Muscular Dystrophy. Strong proof of concept data has been generated in non-human primates in DMD, and imlifidase as a pre-treatment to Sarepta's Elevidys® is now being tested in the clinic. In 2023, we also formed a partnership with the leading French gene therapy company Genethon focused on the devastating disease Crigler-Najjar syndrome.

Finally, we continue to further establish imlifidase as the desensitization treatment for kidney transplantation in highly sensitized patients. Following the successful completion of the Phase 2 clinical trial programs, we secured conditional approval for Idefirix® (imlifidase) in Europe and we have aligned with the FDA on a pathway to potential accelerated approval in the United States where our pivotal Phase 3 trial, ConfldeS, is progressing towards completion in 2025.

To continue to advance our launch efforts with Idefirix® and prepare for an exciting future with additional indications, we have created medical and commercial teams with significant expertise. Excellent progress has been made to ensure Idefirix® is accessible to patients across the wider European region and at a price point that reflects the significant value it brings to clinicians and patients.



## CEO statement continued

We know a multi-stakeholder approach is needed to truly improve patient outcomes. Therefore, we closely collaborate with key professional societies and public health decision makers to advance national and local medical guidelines, treatment protocols, and organ allocation initiatives to support an improved and more equitable approach to kidney transplantation and increase appropriate clinical utilization of Idefirix®.

### Advancing innovative immunomodulating science

It's clear that imlifidase has significant potential as a pipeline-in-a-molecule in several acute diseases and conditions in a range of therapeutic areas. Further, building on the expertise and experience we have with imlifidase, our teams are developing the next generation of IgG-cleaving enzymes through the NiceR program. The lead candidate in the program, HNSA-5487, has moved into clinical development and we have seen encouraging results from the first in human trial. The results demonstrated that the molecule is safe and well tolerated, with fast and complete depletion of IgG antibodies.

HNSA-5487 could allow for two distinctly different re-dosing regimens – short interval redosing and long interval redosing – enabling innovative treatment approaches in a broad range of indications, including addressing both acute and chronic autoimmune diseases, as an enabler for redosing in gene therapy, and potentially extending treatment regimens in systemic oncolytic virus therapy.

### A thriving culture centered on people

For all that we have accomplished – significant pipeline advancement, solid commercialization achievements and the

successful transformation from a small project-focused R&D operation to a fully-integrated, international commercial-stage biotech – I am convinced that it is because of the highly skilled and dedicated team we have at Hansa. With more than 30 different nations represented in our organization and an average industry tenure of more than 20 years this is a results-driven team that remains highly engaged – as evidenced by the fact that we have qualified as a Great Place to Work in Sweden for the last four years based on employee feedback.

### An attainable ambition

I'm excited for what's to come at Hansa – we are poised to deliver on our bold ambition of providing life-altering and life-saving medicines to people with rare immunological diseases and conditions. I expect to see further acceleration in kidney transplantation as more and more leading clinics move to repeat usage of Idefirix® as a desensitization strategy in Europe. Additionally, we look forward to the completion of patient randomization in the pivotal Phase 3 US Confides trial.

In autoimmune diseases, we expect final read-outs from the Phase 2 trial of imlifidase in GBS and continued enrolment of patients in the pivotal Phase 3 trial in Anti-GBM. In gene therapy, we are working closely with our partners to advance clinical trial efforts, including initiation of the first clinical trial of imlifidase in Crigler-Najjar syndrome.

And finally, we expect 2024 to be the year where we determine the path forward with HNSA-5487, including a clinical development program and selection of a first indication. We see this as a significant future value driver for the Company.

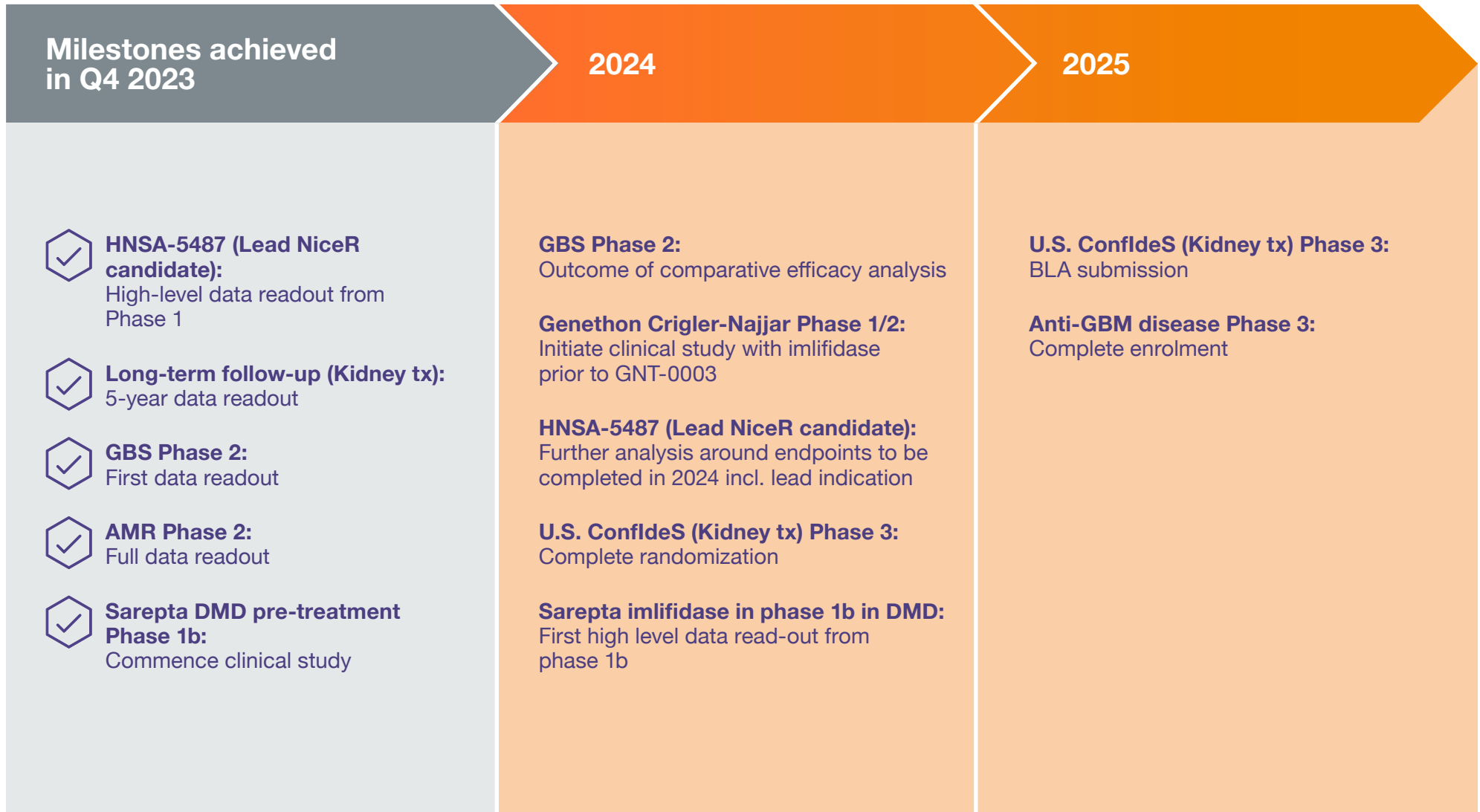
**We are poised to deliver on our bold ambition of providing life-altering and life-saving medicines to people with rare immunological diseases and conditions.**

I would like to sincerely thank everyone at Hansa for their extraordinary efforts and dedication, our Board of Directors for their strong oversight and excellent collaboration, the patients who participate in our trials and the investigators who help us run them, and not least our many shareholders for their continued support and belief in the importance of our mission.

**Søren Tulstrup**  
President and CEO, Hansa Biopharma  
Lund Sweden, March 2024



## Achieved and upcoming milestones







# Strategy

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## Our strategic priorities

**Hansa's mission is to become a global leader in rare diseases through the development of innovative, lifesaving and life altering treatments for patients with rare immunological conditions**

The Company's strategy is anchored on the proprietary enzyme technology platform and with a goal of developing and commercializing immunomodulatory first-in-class or best-in-class treatments for organ transplants, rare IgG-mediated autoimmune conditions, and gene therapy, as well as exploring the potential application of the technology platform in oncology. To deliver on the ambition we have three key priorities:



### 1. Commercialize Idefirix® in first indications and markets

- > Successfully launch Idefirix® in Europe
- > Secure FDA approval and launch Idefirix® in the U.S.
- > Geographical expansion



### 2. Advance ongoing imlifidase clinical programs

- > Achieve approval/usage of imlifidase in follow-on indications
- > Broaden the Idefirix® label beyond kidney transplantation



### 3. Expand IgG-cleaving enzyme technology

- > Expand IgG-cleaving enzyme technology platform into gene therapy
- > Develop our next generation IgG-cleaving enzymes for repeat usage

Build focused, integrated, agile and empowered international organization and seek partnerships to accelerate growth and reduce risk



## Our strategic priorities continued



### 1. Commercialize Idefirix® in first indication and markets

- > **Successfully launch Idefirix® in Europe<sup>1</sup>**
- > **Secure FDA approval and launch Idefirix® in the U.S.**
- > **Geographical expansion**

In August 2020, Hansa received conditional approval from the European Commission for Idefirix® (imlifidase) for the desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor.

We have launched Idefirix® in several major European countries driving reimbursement and partnering closely with leading clinical experts. Commercial access has been obtained in fourteen European countries, including Germany, UK, Spain, Italy and France (through a reimbursed Early Access Program). We continue to advance access and reimbursement in ten other countries including Portugal, and Switzerland. Following completion of our post-approval commitments, we will seek full approval from the European Commission.

In the U.S. we have an ongoing pivotal phase 3 study “ConfIdeS” to support the submission of a Biologics License Application (BLA). The ConfIdeS trial is currently enrolling and randomizing patients with the aim to complete

12 months follow-up data on eGFR and submit a BLA for accelerated approval in 2025. Given that 10-15% of patients waiting for a kidney transplant in the U.S. are considered highly sensitized, the approval and availability of Idefirix® would be an important option for these patients.

Beyond Europe and the U.S., the Company is exploring commercial opportunities for Idefirix® in markets where the EMA approval can be leveraged to gain approval and market access such as Switzerland (iQone), Israel, Australia (Medison Pharma) and in the beginning of 2024 Hansa also announced a new commercial partnership NewBridge covering the MENA region.



### 2. Advance ongoing imlifidase clinical programs in transplantation and autoimmune diseases

- > **Achieve approval/ usage of imlifidase in follow-on indications**
- > **Broaden the Idefirix® label beyond kidney transplantation**

We have ongoing clinical programs in follow-on indications such as anti-GBM (phase 3), GBS (phase 2) and in ANCA-associated vasculitis (IIT in phase 2). Our phase 2 program in AMR was completed in 2023 and the company is

now exploring the opportunity submit data for publication in a peer-reviewed journal.

In anti-GBM we initiated a pivotal global phase 3 study end of 2022 with the first patient treated in May 2023 out of a target of 50 patients. Anti-GBM is an acute autoimmune disease where antibodies are directed against an antigen intrinsic to the glomerular basement membrane (GBM), causing acute injury of kidney and/or lung function. Anti-GBM is an ultra-rare and very serious disease that annually affects approximately 1.6 people per million worldwide. We expect to complete enrollment in 2025 with a follow up on renal function evaluated by estimated glomerular filtration rate (eGFR) at six months.

In GBS we have announced positive high-level data of our phase 2 study (15-HMedIdeS-09) demonstrating that imlifidase was safe and well tolerated when administered prior to standard of care and that there was a rapid improvement in disease-related efficacy measures. The results from this phase 2 trial are very encouraging as Immunoglobulin G (IgG) antibodies are thought to play an important role in GBS disease. With its ability to rapidly cleave IgG, imlifidase could be a promising new option for halting this progressive and oftentimes highly debilitating disease. Additional analysis of efficacy data will be concluded this year to further contextualize efficacy data.

In AMR, in December 2023, we reported full results from our phase 2 trial in patients with antibody mediated rejection (AMR) following kidney transplant, showing that imlifidase

met the primary endpoint, demonstrating its ability to significantly reduce donor specific antibodies (DSAs) within the first five days of treatment. While we are encouraged to have met the primary endpoint, it is important to note that the secondary endpoints, which included a range of kidney function measures and graft and patient survival, were not met, as the trial was neither designed nor sufficiently powered to show a statistically significant difference between the two arms given the heterogeneity of patients, involving many patients with an additional cellular component of the immune rejection, and given the small number of patients enrolled. Patients with an acute AMR and without an additional cellular component of the immune rejection may be best positioned to benefit from a rapid and significant reduction in DSA, one of the main goals of any AMR treatment according to existing treatment guidelines. Based on this Hansa plans to publish results in a peer-reviewed journal later this year.

Lastly, an investigator-initiated phase 2 trial in ANCA-associated vasculitis has been initiated during 2023 to assess efficacy and safety of imlifidase together with standard of care in the treatment of patients with pulmonary haemorrhage due to severe ANCA-associated vasculitis. The new trial is a single center, single arm study in 10 patients led by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité – Universitätsmedizin Berlin.

<sup>1</sup> Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724



## Our strategic priorities continued



### 3. Expand our IgG-cleaving enzyme technology platform into new disease areas and indications

- > **Expand IgG-cleaving enzyme technology platform into gene therapy**
- > **Develop next gen IgG-cleaving enzymes for repeat usage**

As part of Hansa Biopharma's platform strategy and objective to broaden the application of imlifidase as a potential therapy to change the course of IgG-mediated immunological diseases, the Company has recently started to explore new therapeutic areas, where our IgG antibody-cleaving enzyme technology platform would have relevance to address indications with a high unmet medical need indications both through Investigator-Sponsored Trials (IST) programs and Hansa-Sponsored Trials.

In gene therapy, Hansa is working with three partners, Sarepta Therapeutics, AskBio (Bayer AG) and during 2023 a new partnership with Genethon was established. The three partnerships cover four gene therapy programs, namely DMD, LGMD (Sarepta), Pompe disease (Askbio) and Crigler-Najjar syndrome (Genethon), where imlifidase is being evaluated as a potential pre-treatment

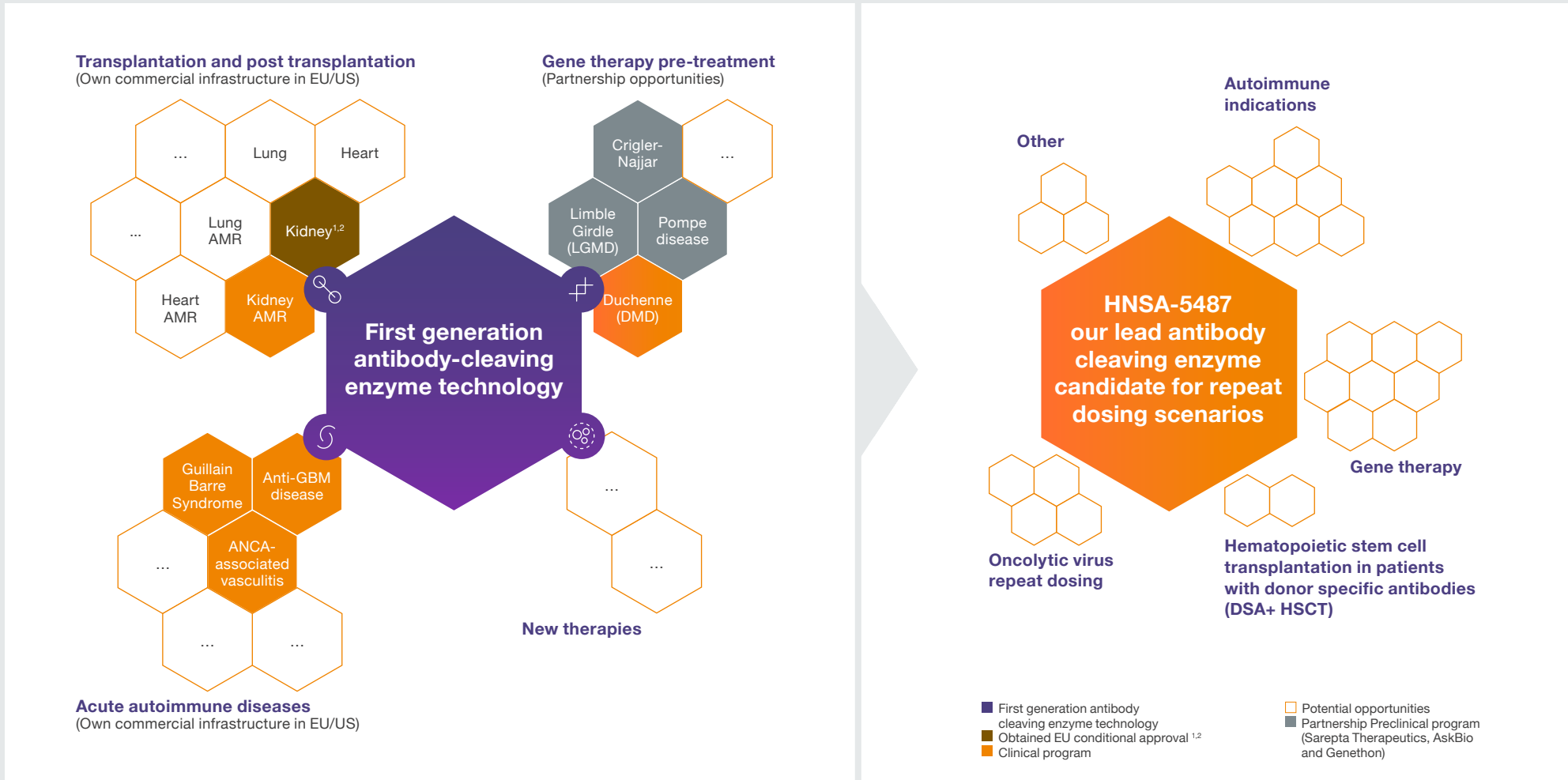
to gene therapy in patients with pre-existing neutralizing antibodies (NABs) against adeno-associated virus (AAV). Nabs against the AAV-based vector commonly used in gene therapies remain a major challenge and make these patients ineligible to receive gene therapy treatment. We see significant potential for our antibody-cleaving enzyme technology to help overcome this barrier.

Another exciting area the Company is currently looking into is our next generation IgG-cleaving enzymes under the NiceR program for repeat dosing. During the fall 2023, Hansa announced encouraging first results from the first-in-human trial of HNSA-5487, Hansa's lead candidate in the NiceR program. It is our aim with this new enzyme to enable repeated infusions and thereby target diseases and conditions where either a prolonged IgG-free window or intermittent therapy is desirable. If successful, this new approach could enable innovative treatment approaches in a broad range of indications, including chronic autoimmune diseases.





# Potential indication universe



<sup>1</sup> The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients

<sup>2</sup> In the U.S. a new study has commenced targeting a BLA filing in 2024



## Potential indication universe continued

Imlifidase is being developed for the treatment and prevention of diseases and conditions caused by IgG antibodies in the acute phase, including desensitization prior to kidney transplantation. The Company has received conditional approval for marketing in Europe for this indication.

We are also investigating the potential use of imlifidase as a treatment of active antibody mediated rejection (AMR) episodes in kidney transplantation.

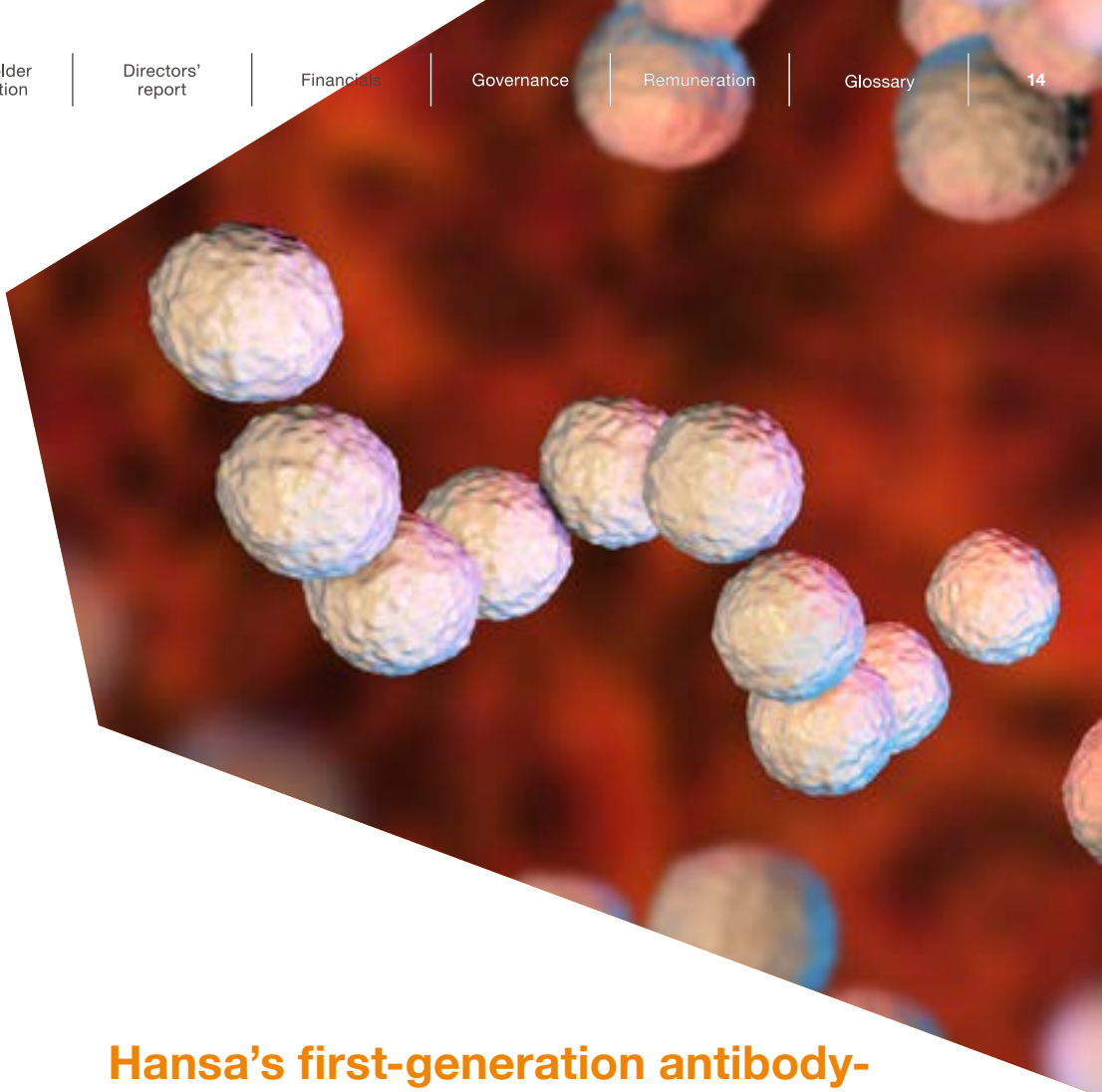
Looking beyond transplantation, there are several other growth vectors and areas where imlifidase may play a role, including acute autoimmune diseases, gene therapy and oncology. More specifically, we are investigating rare life-threatening conditions such as anti-GBM antibody disease (phase 3) and Guillain-Barré Syndrome (phase 2). A new investigator-initiated trial (IIT) in ANCA-associated vasculitis (phase 2) was commenced during the summer 2023. The IIT is sponsored by Charité Universitätsmedizin in Berlin.

In addition, Hansa, with its partners, is investigating imlifidase as a pre-treatment to potentially enable gene therapy in patients with pre-existing neutralizing antibodies (NAbs) against the viral vectors used by the gene therapy. End of 2023 Sarepta Therapeutics commenced the first clinical study in gene therapy aimed for using imlifidase as a pretreatment in Duchenne Muscular Dystrophy.

Further, we are also developing new IgG-cleaving enzymes under the program "NiceR"

(Novel Immunoglobulin Cleaving Enzymes for Repeat Dosing). The NiceR program aims to develop next-generation enzymes with lower immunogenicity that would potentially allow for repeat dosing in a range of indications including IgG-driven autoimmune diseases where patients experience flares, transplantation where repeat dosing would be beneficial, gene therapy and oncology.

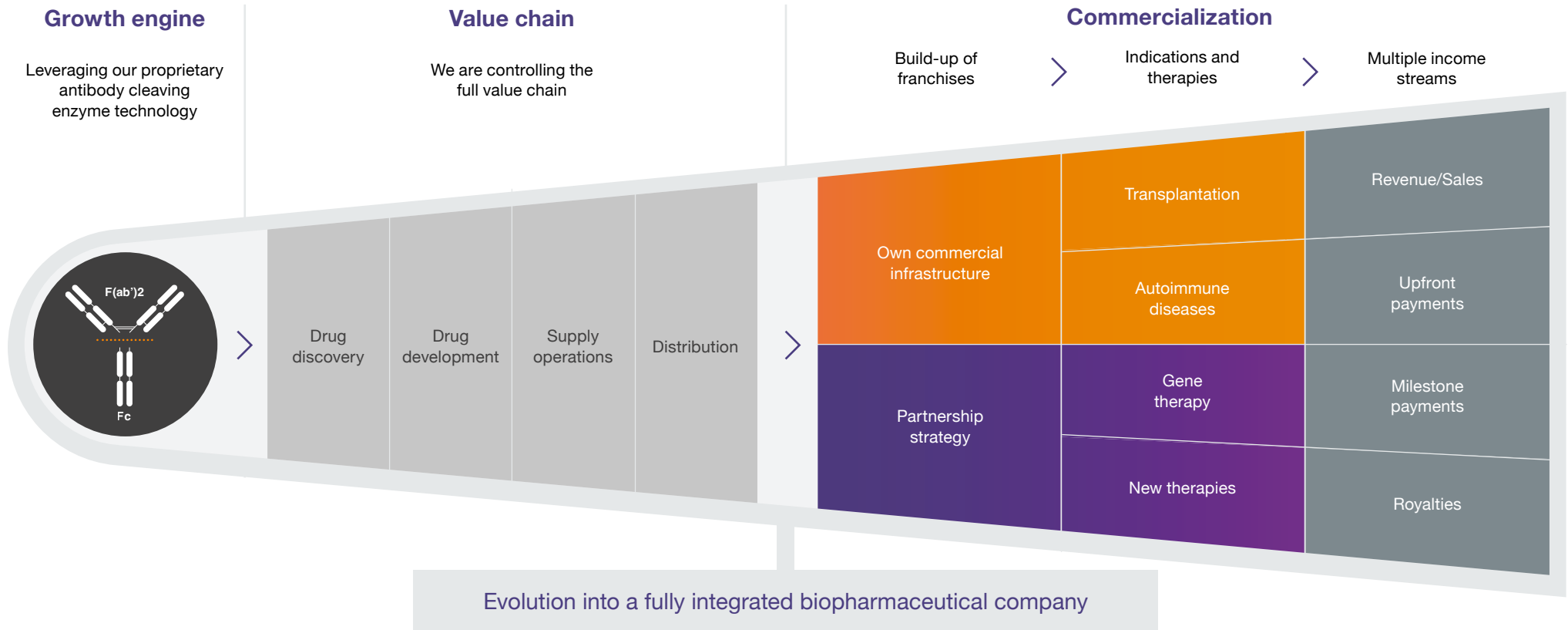
HNSA-5487 is Hansa's lead candidate in the NiceR development program and in October 2023 encouraging high-level results from NICE-01, the first-in-human trial for HNSA-5487 was announced demonstrating that administration of HNSA-5487 was safe and well tolerated. Hansa will continue to explore the potential for HNSA-5487 to better understand how this powerful, new enzyme could benefit patients and clinicians. An enzyme with lower immunogenicity would potentially enable repeat dosing, allowing a prolonged effect by flexibly extending the IgG-free window depending on the number of repeated infusions. This could enable innovative treatment approaches in a broad range of indications, and benefit patients with diseases where a prolonged IgG-free window is needed. Further analysis around endpoints and immunogenicity are to be completed in 2024 including the selection of a lead indication.



**Hansa's first-generation antibody-cleaving enzyme, imlifidase, is a protein with properties that enable it to inactivate IgG antibodies quickly and effectively. Imlifidase is derived from the human pathogen, *Streptococcus pyogenes*.**

## Business model

Leveraging a unique and proprietary technology platform to develop new therapies in areas of high unmet medical need in rare disease



Hansa's ambition is to become a leading player in rare diseases by expertly leveraging the Company's unique and proprietary antibody-cleaving enzyme technology platform and supporting scientific and commercial innovation. The evolution to a fully integrated biopharmaceutical company begins with the technology platform – the growth engine of the current and future pipeline. From discovery and

development to commercialization, the intention is to retain strategic control and capture much of the economic upside generated.

There are four priority franchises within Hansa – transplantation, autoimmune, gene therapy and new therapies. Given the diverse and complex nature of these four disease areas the Company has employed an agile approach to

commercialization. The Company will leverage its strong commercial and medical expertise in autoimmune and transplantation where we have existing experience and relationships, and the customer base is relatively concentrated. In complex disease areas or in certain markets, the Company will consider strategic partnerships and agreements. To date, we have a commercial partnership with Medison

Pharma in select countries in Central Eastern Europe and Israel as well as with NewBridge Pharmaceuticals covering the Middle East and North Africa to enable supply of Hansa's novel treatment Idefirix® to kidney transplant patients. In addition, Hansa has formed three development partnerships with AskBio, Genethon and Sarepta Therapeutics in gene therapy.



# Market

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## Idefirix<sup>®</sup> approved in Europe

### The first and only approved drug in Europe for desensitization of highly sensitized kidney transplant patients

According to the Global Observatory on Donation and Transplantation there are approximately 170,000 patients in the U.S. and Europe, alone, waiting for a new kidney. However, given that organ availability continues to be a limiting factor, only approximately 50,000 kidney transplants are performed in these markets, of which, roughly 73% are from deceased donors<sup>1</sup>.

A subgroup of kidney transplant patients, representing between 10-15% of those waiting for kidney transplantation<sup>1</sup>, are so-called highly sensitized. This means that these patients are highly sensitized against potential donor tissues due to prior exposure to foreign antigens during pregnancy, after blood transfusions, from previous organ transplantations, or, in rare cases, infections. The presence of donor specific antibodies is either an absolute or relative contraindication, depending on the breadth and strength of the antibody response. For this group of patients with a wide range of anti-HLA antibodies, it is extremely difficult to find a compatible donor.

In 2020, the European Commission granted a conditional approval in the European Union for Idefirix<sup>®</sup> (imlifidase), representing the first conditionally approved treatment for adult patients waiting for a kidney transplant who are highly sensitized against tissue from the donor and who have a positive crossmatch test against an available kidney from deceased donor.

<sup>1</sup> Source: The U.S. Department of Health and Human Services, [irodat.org](https://www.rodatt.org), Global Observatory on Donation and Transplantation (2023), and company estimates

Low complexity transplants

Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA-sensitization

High complexity transplants

**~70% of patients**

Non or less sensitized  
(cPRA < 20%)

**15-20% of patients**

Moderately sensitized  
(20% < cPRA < 80%)

**10-15% of patients**

Highly sensitized  
(cPRA > 80%)

#### Causes of sensitization include:

##### Pregnancy



##### Blood transfusion



##### Previous transplantations



Addressable market (annually)

**4,000-6,000**

split across Europe and the U.S.

Patients that are likely to be transplanted with a compatible donor

Patients unlikely to be transplanted under current prioritization programs

**idefirix<sup>®</sup>**  
imlifidase



## Idefirix<sup>®</sup> is changing the entire ecosystem in transplantation

At Hansa, we are committed to creating paradigm shifts in kidney transplant clinical care resulting in significantly better patient outcomes. With Idefirix<sup>®</sup>, we are paving the way forward in changing the desensitization treatment ecosystem in transplantation requiring significant changes in both transplant protocols and organ allocation systems.

For decades, the medical training and practice of transplantation has been predicated on compatibility, only in cross match negative patients as the modalities considered to enable transplantation each have some limitations. Plasma Exchange is known to remove antibodies from circulation, IVIg replaces pathogenic antibodies, while B-cells lowers antibody levels through B-cell depletion. However, none of these approaches eliminate IgG antibodies in both the blood circulation and tissue.

None of these approaches are known to have meaningful outcomes data in kidney transplantation, are considered standard of care, or have been regulatory approved. As a result, highly sensitized patients have suffered the inequity of going untreated.

Fortunately, with this novel treatment option we can address the limitations of these other modalities from a mechanistic, outcomes, and regulatory standpoint. Idefirix<sup>®</sup> provides a completely IgG free window of clinically suitable duration by cleaving the Fc region of IgG pre-and post-operatively and is part of an overall treatment approach that includes immunosuppression. Further Idefirix<sup>®</sup> has demonstrated critical outcomes such as engraftment, long-term and high-functional eGFR levels, and most importantly patient survival with good outcome out to year five. As a result of this, and our safety data, Idefirix<sup>®</sup> has regulatory approval in Europe, providing the opportunity for greater equity for the crossmatch positive patients.

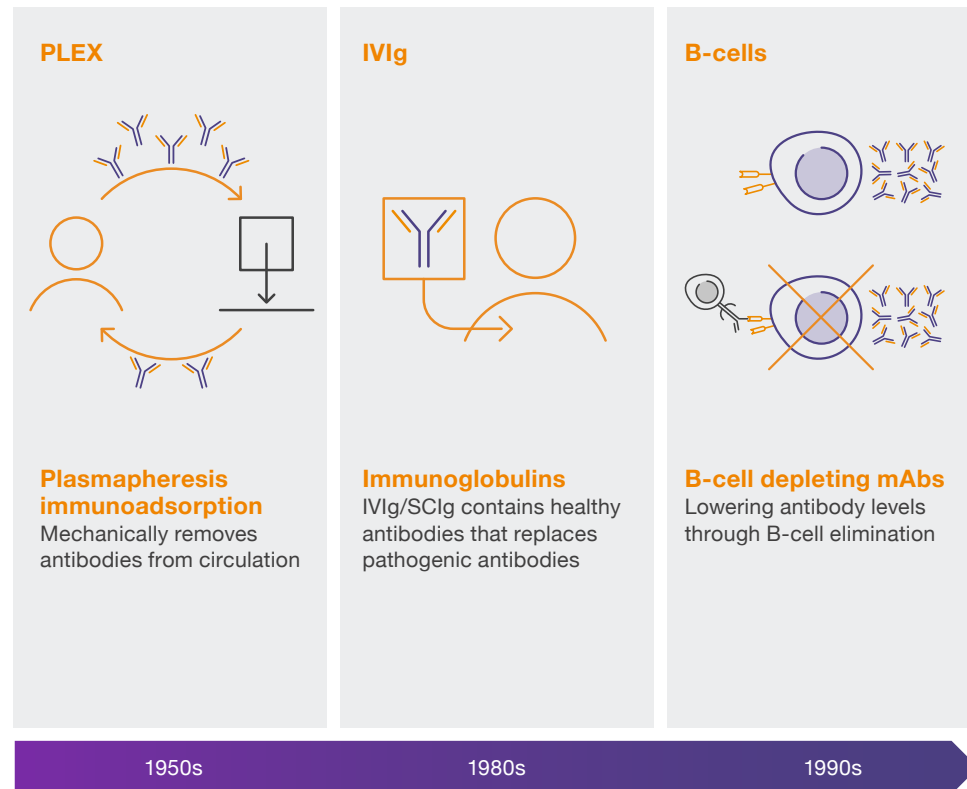
To be able to identify the right patient, and then manage the immunological complexity is considered a huge leap in modernizing transplantation care for highly sensitized patients. Generating successful early experiences in key early adopter clinics is highly critical for the long-term market uptake of Idefirix<sup>®</sup>.



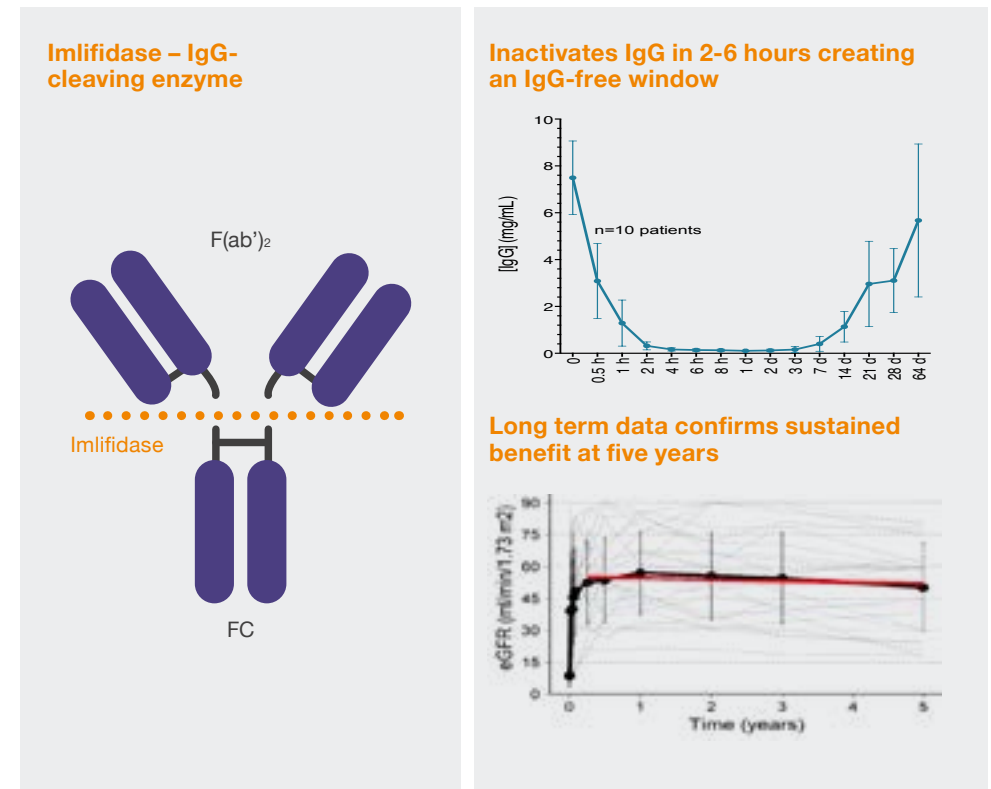
**The long-term market uptake of Idefirix<sup>®</sup> is highly dependent on successful early experiences in patients**

## Idefirix® addresses unmet needs in highly sensitized kidney transplantation

For decades, medical practice (SoC) in transplantation has been predicated on compatibility as modalities came with certain limitations



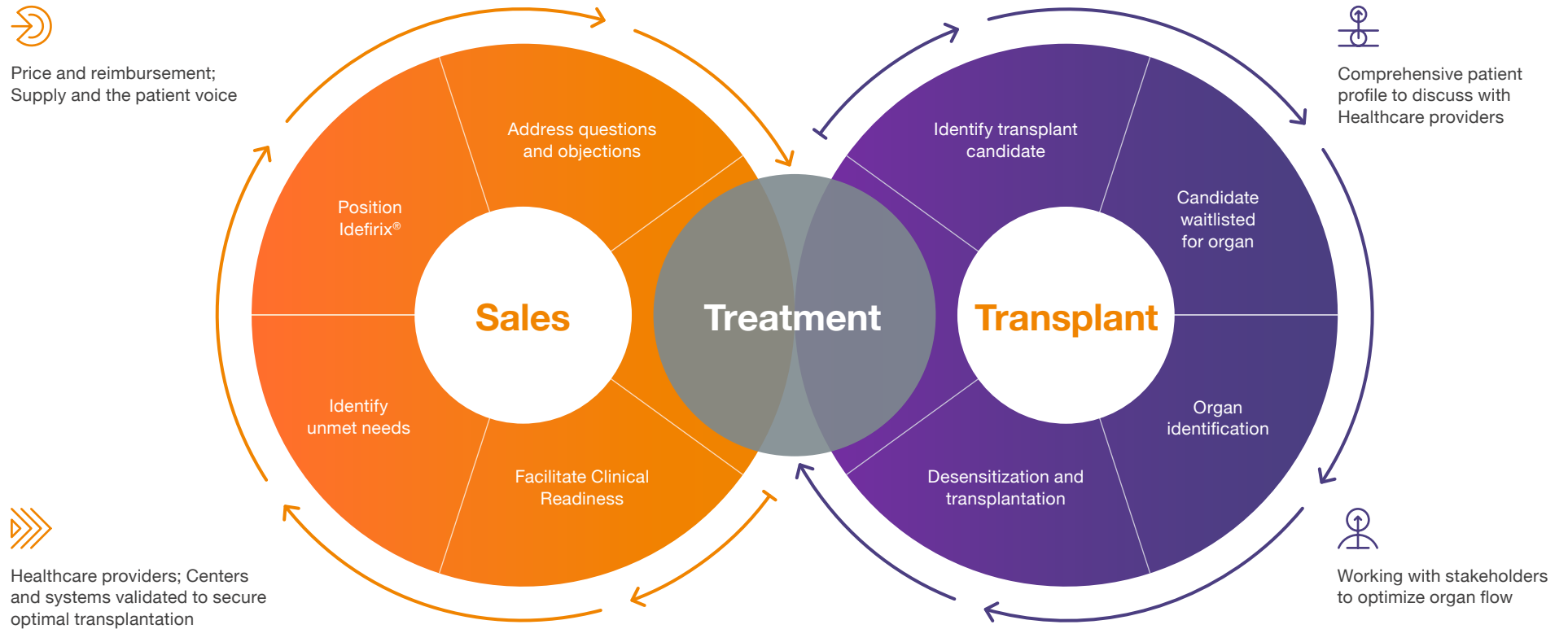
Idefirix® addresses the limitations of these other modalities and is the first and only approved drug to enable incompatible kidney transplants



## Commercial excellence

The unique market position of Idefirix® requires consideration of both the sales – and the transplant cycle

### Sales and transplant cycle adds complexity and time to patient treatment



### Excellence revolves around four strategic themes

Market Access

Clinical readiness

Organ allocation

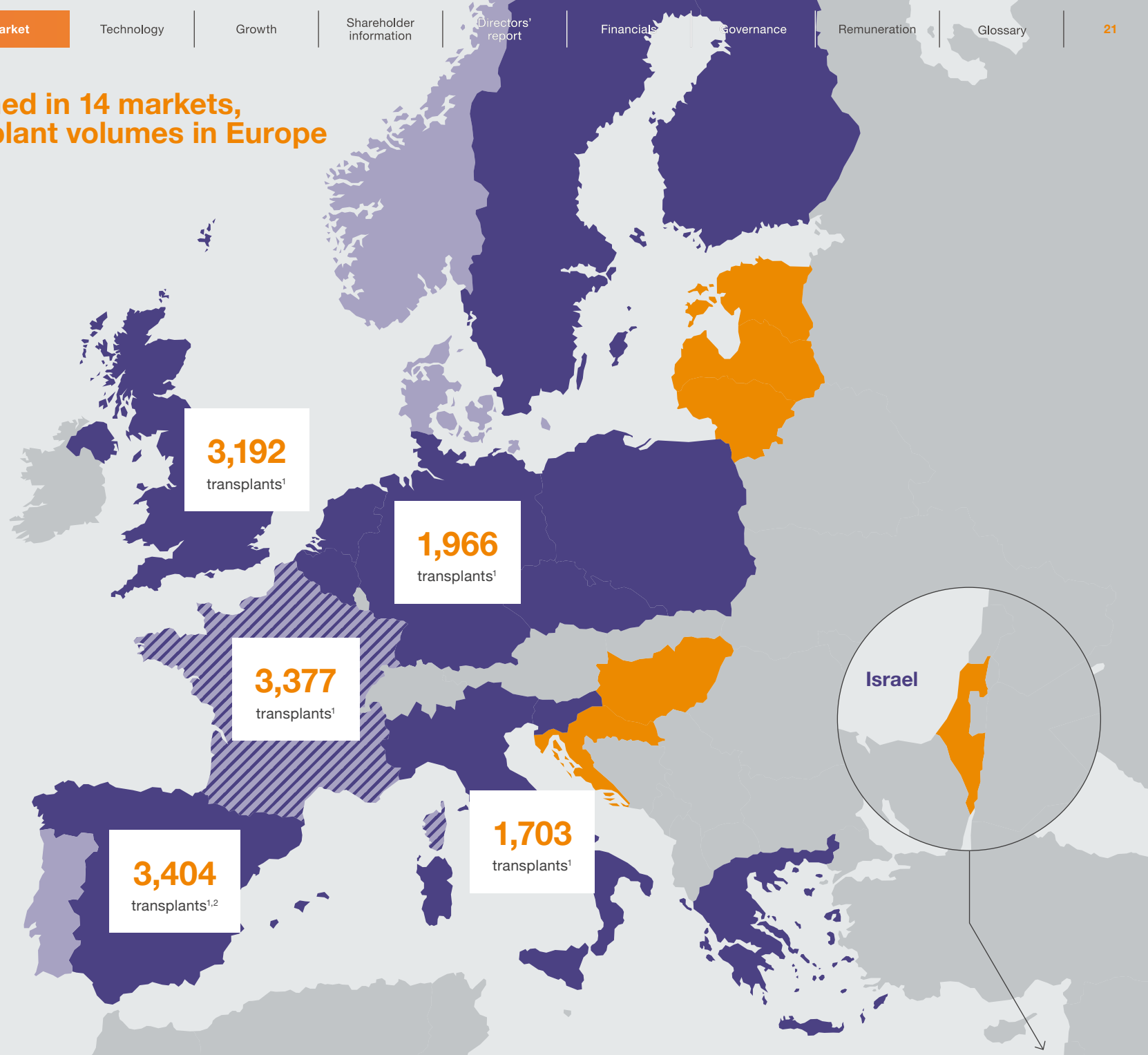
Patient selection and treatment



# Market access obtained in 14 markets, covering 3/4 of transplant volumes in Europe

## Legend

- Health Technology Assessments (HTA) dossiers filed
- Reimbursed Early Access Program
- Pricing & reimbursement obtained (country or clinic level)
- Territories covered commercially by Medison Pharma



<sup>1</sup> Annual kidney transplantations 2022. Transplantation data is from Global Observatory on Donation and Transplantation, <https://www.transplant-observatory.org/> [Accessed 2023-07-10]

<sup>2</sup> A positive recommendation for pricing and reimbursement of Idefirix® in Spain was published on February 6, 2023, [https://www.sanidad.gob.es/profesionales/farmacia/pdf/20230202\\_ACUERDOS\\_CIPM\\_230.pdf](https://www.sanidad.gob.es/profesionales/farmacia/pdf/20230202_ACUERDOS_CIPM_230.pdf)



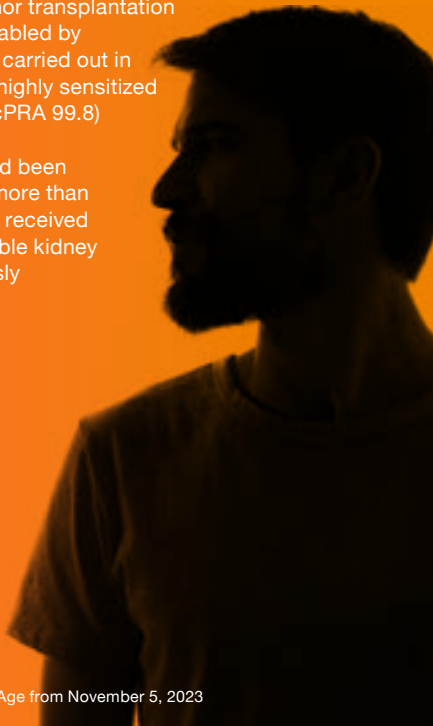
## Encouraging patient outcome in new markets following imlifidase-enabled kidney transplantations

### Austin Health

#### First living donor transplantation

First living donor transplantation in Australia enabled by imlifidase was carried out in a 64-year-old highly sensitized male patient (cPRA 99.8)

The patient had been waitlisted for more than four years and received two incompatible kidney offers previously



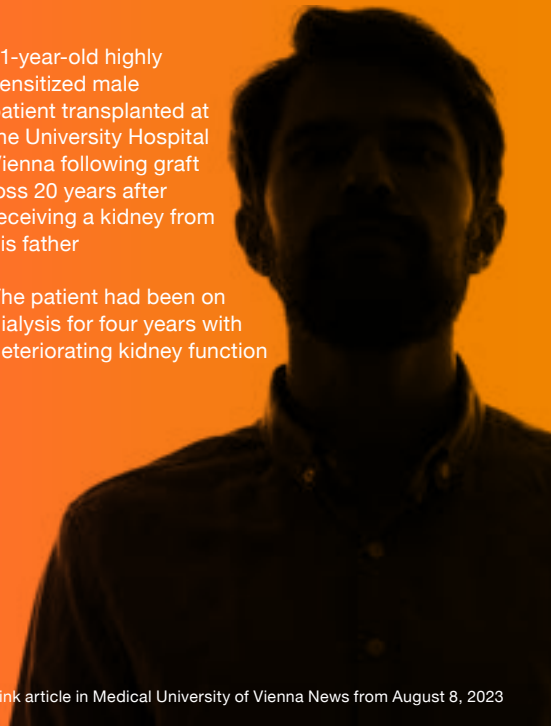
[Link article in The Age from November 5, 2023](#)

### Medizinische Universität Wien

#### Transplantation 20 years after first kidney transplant

51-year-old highly sensitized male patient transplanted at the University Hospital Vienna following graft loss 20 years after receiving a kidney from his father

The patient had been on dialysis for four years with deteriorating kidney function

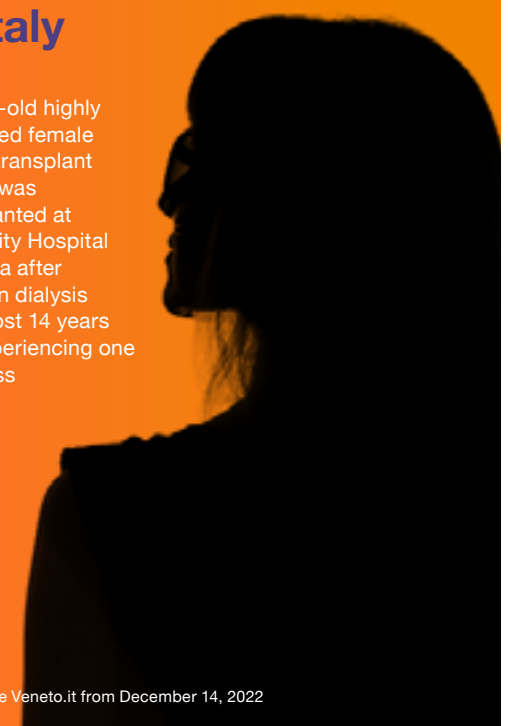


[Link article in Medical University of Vienna News from August 8, 2023](#)

### Università degli Studi di Padova

#### First imlifidase-enabled kidney transplantation in Italy

43-year-old highly sensitized female kidney transplant patient was transplanted at University Hospital of Padua after being on dialysis for almost 14 years and experiencing one graft loss



[Link article Veneto.it from December 14, 2022](#)

Stock photography, not actual patients



## Leveraging multi-stakeholder engagement to modernize kidney transplantation care

There are over 170,000 people in the U.S. and Europe waiting for a kidney transplant,<sup>1</sup> and those considered highly sensitized face extended and often indefinite time on the transplant waiting list. For too long, the burden of kidney disease has impacted the lives of these patients.

To create change and ensure positive patient outcomes, a constellation of stakeholders – including patient advocacy groups, clinicians, payers, caregivers, and policy makers – must work together to increase awareness of unmet needs of highly sensitized kidney transplant patients, improve treatment equity for patients, and ensure access to innovative therapeutic solutions that can address patients' unmet needs.

As a committed partner to the kidney transplant community, Hansa values and prioritizes its collaboration with these stakeholders to modernize the continuum of care for highly sensitized patients and improve overall outcomes.

### Understanding the unmet needs of highly sensitized kidney transplant patients

A person is considered highly sensitized when they have donor-specific antibodies (DSAs) with a broad reactivity against 'human leukocyte antigens' (HLAs), found in non-self tissues such as a donor organ.<sup>2</sup> The presence of these antibodies can increase the risk that a transplanted donor organ will trigger an immune response and be rejected.<sup>2,3</sup>

The complex immunological profile of highly sensitized patients means they will spend longer time than average on transplant waiting

lists, with evidence showing that this longer wait time leads to increased mortality risk.<sup>4</sup> To be considered for a transplant, patients must first be desensitized.

As healthcare systems worldwide grapple with the significant economic burden of kidney disease a recent report from Kidney research UK, supported by Hansa Biopharma, has shown kidney transplantation to be the only cost-effective solution for patients with end stage kidney disease.<sup>5</sup>

There remains an urgent need for action to ensure highly sensitized patients have access to high quality care and guideline directed desensitization strategies to enable them to receive a life-changing kidney transplant. Highly sensitized patients need information to understand what being highly sensitized means and how this impacts their treatment. Critically, highly sensitized patients need to be prioritized on organ allocation systems to enable equitable access to transplantation.

### Increasing fair and equitable access for highly sensitized kidney transplant patients

To identify opportunities to increase equitable access to transplantation, Hansa engages with organizations overseeing the allocation of organs, like Eurotransplant, to understand how highly sensitized patients are prioritized and how access to innovative treatments can increase the opportunities for these patients to receive a donor organ.

Eurotransplant is a non-profit organization dedicated to ensuring fair and equitable allocation of organs by serving as mediators between donor hospitals and transplant centers.

Eurotransplant helps facilitate the allocation and exchange of suitable organs for transplantation by connecting key stakeholders throughout its multi-country network.

In 2023, Hansa partnered with Eurotransplant for the initiation of its Desensitization Program – a first ever international allocation system utilizing imlifidase, Hansa's IgG-cleaving enzyme, to enable kidney transplantation in highly sensitized patients with a very low chance of transplantation.

The Desensitization Program is an additional component to the Acceptable Mismatch (AM) program that Eurotransplant implemented over the last 30 years to increase transplantation for highly sensitized patients. To date, the AM program has helped more than 1,700 highly sensitized patients receive a kidney transplant.<sup>6</sup>

In the first few months since its implementation the Desensitization Program identified in the first few months since its initiation over 170 highly sensitized patients that have been on the wait list for more than 5 years without being able to receive a successful transplant. Eurotransplant is spearheading access to innovation and making a tangible impact in ensuring highly sensitized patients have equitable access to transplantation.

To create change and ensure positive patient outcomes, stakeholders must work together to increase awareness of unmet needs of highly sensitized kidney transplant patients.

### Ensuring guideline directed desensitization for highly sensitized kidney patients

As science advances and new treatment options become available, updated guidelines play a critical role in the adoption of clinical approaches. In the case of desensitization in kidney transplantation, a common set of clinical guidelines or consensus have been missing. Over the last two years, however, the transplant clinical community has given voice to the importance of more consistent approaches to desensitization in kidney transplantation.

Hansa and the European Society for Organ Transplantation (ESOT) were able to convene key thought leaders in the transplant community to better articulate the challenges of desensitization, patient prioritization schemes, and opportunities to increase access



## Leveraging multi-stakeholder engagement continued

to transplantation for highly sensitized kidney transplant patients, including the appropriate use of innovative new desensitization strategies like imlifidase.

In 2022, ESOT published the first set of clinical guidelines which represent the first international consensus on a management pathway for highly sensitized patients.<sup>7</sup> The guidelines served as a foundation for country-specific guidelines and consensus across Europe.

### Advancing the science of incompatible kidney transplantation

As innovations in desensitization become more readily available and transplant centers gain experience navigating the complexities of transplanting highly sensitized patients, Hansa continues to advance the science around desensitization.

In 2023 we concluded an international long-term 5-year follow-up study, 17-HMedIdeS-14,<sup>8</sup> of patients who received a kidney transplant following desensitization with imlifidase. The study demonstrated sustained positive outcomes out to five years in most highly sensitized patients who received an imlifidase-enabled kidney transplant.

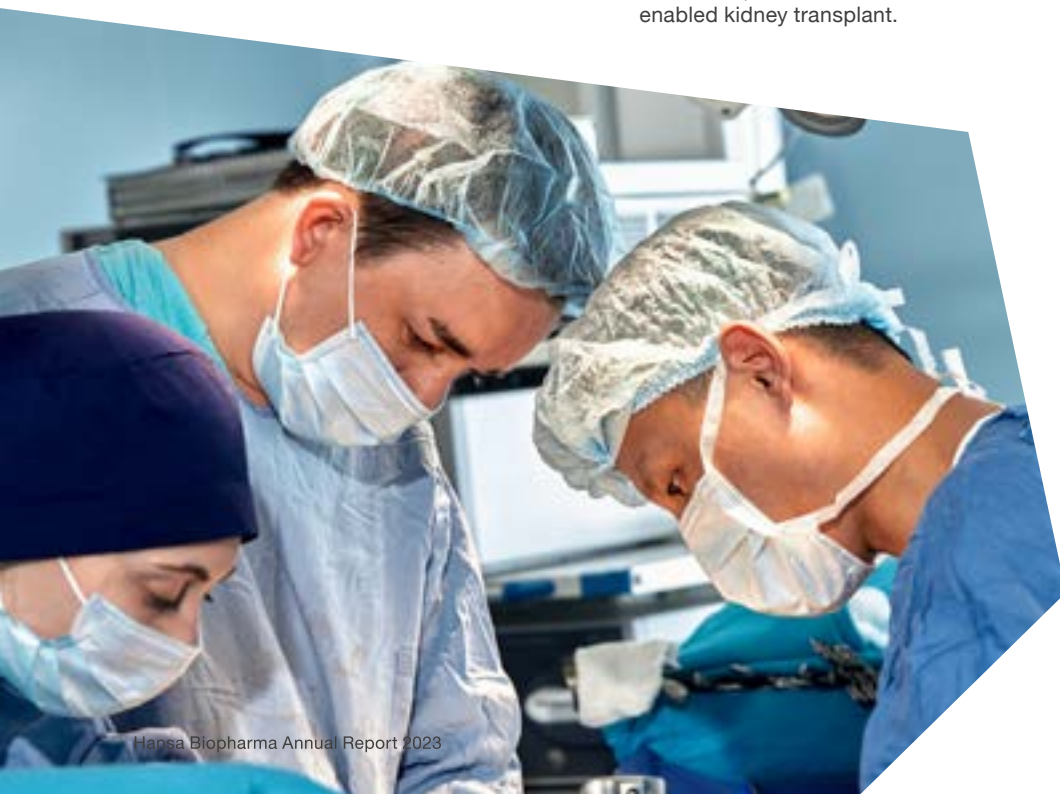
This study reinforces the clinical benefit of enabling HLA-incompatible kidney transplantation with imlifidase, with a stable long-term outcome both on graft survival and patient survival, not different from what commonly observed in compatible kidney transplantation.<sup>9</sup>

This study is the result of Hansa's scientific collaboration with a group of dedicated clinicians that pioneered the use of imlifidase in clinical trials and are still contributing to expanding the depth and breadth of data on desensitization.

As we advance the science around desensitization, we are beginning to see transformative and disruptive approaches to transplantation care for highly sensitized patients. While modernizing and standardizing clinical practice to reflect new approaches to care can take time, multi-stakeholder collaboration can speed innovative new approaches, drive increased awareness, and deliver positive patient outcomes.

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- <sup>1</sup> Newsletter Transplant 2015-2021. Available at: <https://freepub.edqm.eu/publications>.
- <sup>2</sup> Eurostam Report (A Europe-wide strategy to enhance transplantation of highly sensitized patients on the basis of acceptable HLA mismatches.) Available at <https://cordis.europa.eu/project/id/305385/reporting>.
- <sup>3</sup> Lonze BE, et al. IdeS (Imlifidase): A Novel Agent That Cleaves Human IgG and Permits Successful Kidney Transplantation Across High-strength Donor-specific Antibody. *Ann Surg.* 2018 Sep;268(3):488-496. doi: 10.1097/SLA.0000000000002924. PMID: 30004918.
- <sup>4</sup> Redfield RR, et al. The mode of sensitization and its influence on allograft outcomes in highly sensitized kidney transplant recipients. *Nephrol Dial Transplant.* 2016 Oct;31(10):1746-53. doi: 10.1093/ndt/gfw099. Epub 2016 Jul 6. PMID: 27387475.
- <sup>5</sup> 'Kidney disease: A UK public health emergency', Kidney research UK. Available at: [https://www.kidneyresearchuk.org/wp-content/uploads/2023/06/Economics-of-Kidney-Disease-full-report\\_accessible.pdf](https://www.kidneyresearchuk.org/wp-content/uploads/2023/06/Economics-of-Kidney-Disease-full-report_accessible.pdf). Accessed: 9 February 2024.
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- <sup>7</sup> European Guidelines for the Management of Kidney Transplant Patients with HLA antibodies. [https://esot.org/wp-content/uploads/2022/07/WS06\\_Full-doc\\_07202022.pdf](https://esot.org/wp-content/uploads/2022/07/WS06_Full-doc_07202022.pdf). Accessed on 7 February 2024
- <sup>8</sup> Trial NCT03611621. Available at <https://clinicaltrials.gov/study/NCT03611621>
- <sup>9</sup> Poggio ED, et al. Long-term kidney transplant graft survival-Making progress when most needed. *Am J Transplant.* 2021 Aug;21(8):2824-2832. doi: 10.1111/ajt.16463.







# Technology

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## Imlifidase

### A novel approach to eliminating pathogenic IgG

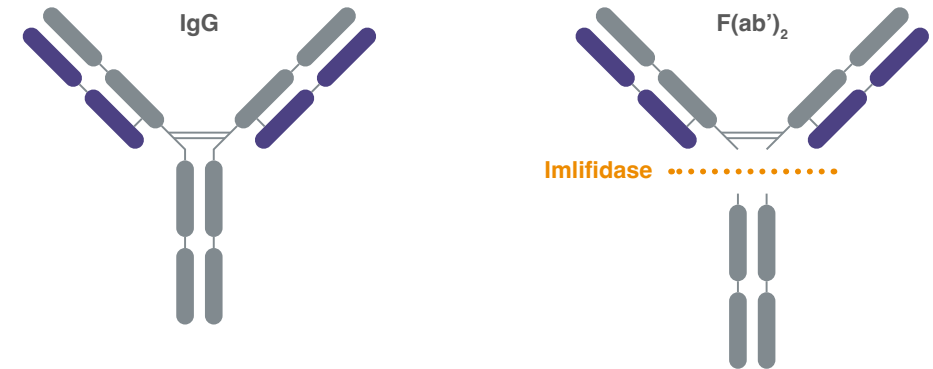
Imlifidase cleaves IgG below the so-called 'hinge region' separating it into a F(ab')<sub>2</sub> and an Fc component. As therapeutic this enzyme is highly specific and IgG antibodies are degraded and inactivated without affecting any other protein in the body. Remarkably, Imlifidase cleaves all four IgG subclasses in the human body efficiently and to date no other targets have been identified.

The rapid onset of action and the efficacy imlifidase brings to the table is impressive, with just a very small percentage of IgG remaining within 2-6 hours from administering a single dose.

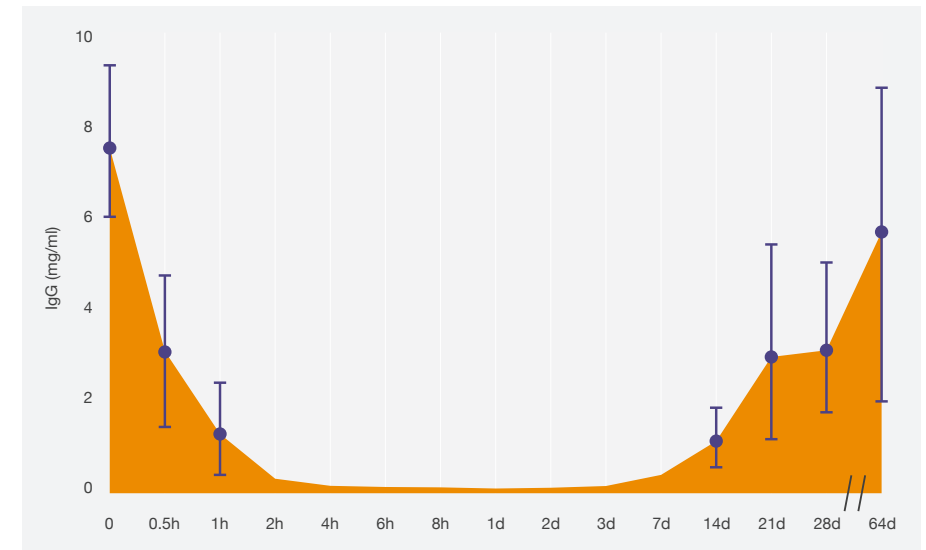
In addition, IgG antibodies are targeted efficiently intravascularly and extravascularly as well as bound to the surface of a cell. This means that in the case of autoimmune diseases, where pathogenic IgG is attached to target structures, autoantibodies can be inactivated instantly.

The effect is transient and IgG levels slowly start to rise again a few days from dosing reaching normal IgG levels within a few weeks.

#### Imlifidase inactivates IgG in 2-6 hours



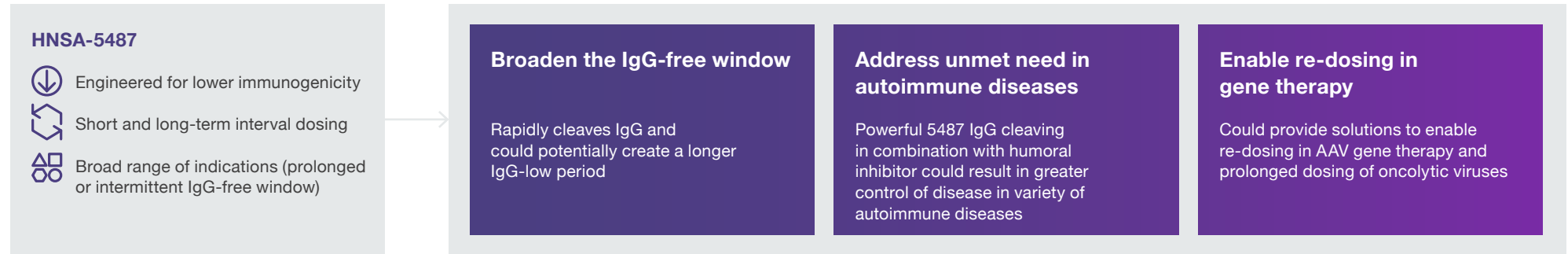
**Imlifidase is an enzyme originating from a human pathogen, a bacterium called *Streptococcus pyogenes***



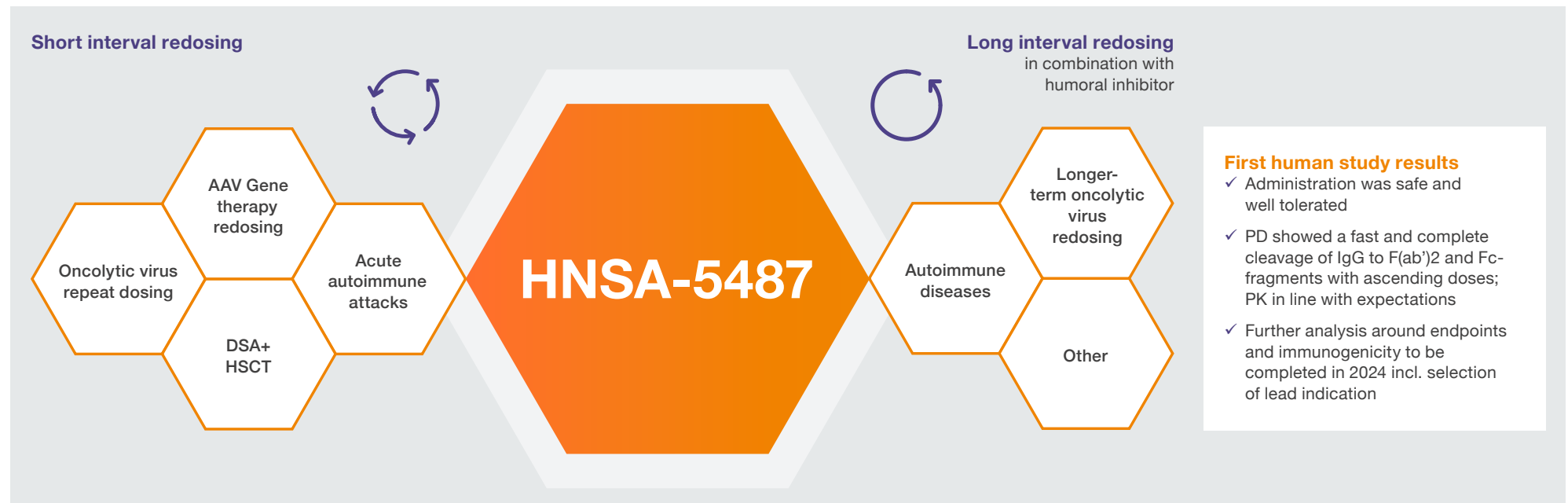
## Advancing HNSA 5487

### A high potential next-gen enzyme for repeat dosing

#### Advancing HNSA 5487 – A high potential next-gen enzyme for repeat dosing



#### Potential indication landscape for HNSA 5487 and reasons to believe





## Encouraging data from the first in human trial of HNSA 5487

Beyond imlifidase, our Novel Immunoglobulin Cleaving Enzymes for Repeat Dosing, or NiceR, program has yielded lead candidates that were engineered for lower pre-existing immunity compared to imlifidase and at the same time full activity across all IgG subclasses.

The most advanced drug candidate from this program, HNSA-5487 has entered clinical development with the aim to establish and assess two distinctly different re-dosing regimens – short interval re-dosing and long interval re-dosing. This would potentially enable use across a broad range of indications including acute clinical phases of several autoimmune diseases. In addition, we see potential for HNSA-5487 to address unmet need in autoimmune diseases by improving long term disease control in combination with humoral inhibitors targeting B-cells or plasma cells. Furthermore, this novel drug candidate could play a key role in enabling AAV based gene therapy re-dosing and in extending treatment regimes in systemic oncolytic virus therapy.

The potential for short- and long-term interval dosing is something we continue to explore so that we can better understand the role of HNSA-5487 in several indications and how this powerful new drug candidate, and the broader NiceR program, could benefit patients with diseases where a prolonged IgG-free window is needed and where repeat dosing would be beneficial.

In early 2023, HNSA-5487 moved into the clinic, and, in October 2023, we announced encouraging results from our first-in-human trial for HNSA-5487 (NICE 01), which was designed as a double blind, randomized, placebo-controlled trial evaluating safety, PK and PD of single ascending doses of HNSA-5487 in 36 healthy volunteers. Data from the NICE 01 study showed that the molecule is safe and well tolerated, with fast and complete depletion of IgG antibodies observed at increasing doses in all subjects. Pharmacokinetics (PK) were in line with expectations and pharmacodynamics (PD), expressed through efficacy on IgG cleavage, showed a fast and complete cleavage of IgG to F(ab')<sub>2</sub>- and Fc-fragments with increasing doses.

The trial also included exploratory endpoints focused on achieving a deeper understanding of the immunogenicity profile, with follow up on all subjects for 12 months, and this part is currently ongoing. In addition, we are evaluating different dosing levels that potentially can increase and extend efficacy. This analysis will give us key input which will be helpful in determining the further clinical development program, including selection of first indication in 2024.

**We see potential for HNSA-5487 to address unmet need in autoimmune diseases by improving long-term disease control in combination with humoral inhibitors targeting B-cells or plasma cells.**

## Targeting rare IgG mediated diseases

Our unique antibody cleaving enzyme technology may have relevance across a range of indications



### Autoimmune diseases

Anti-GBM paves the way for development in other autoimmune diseases

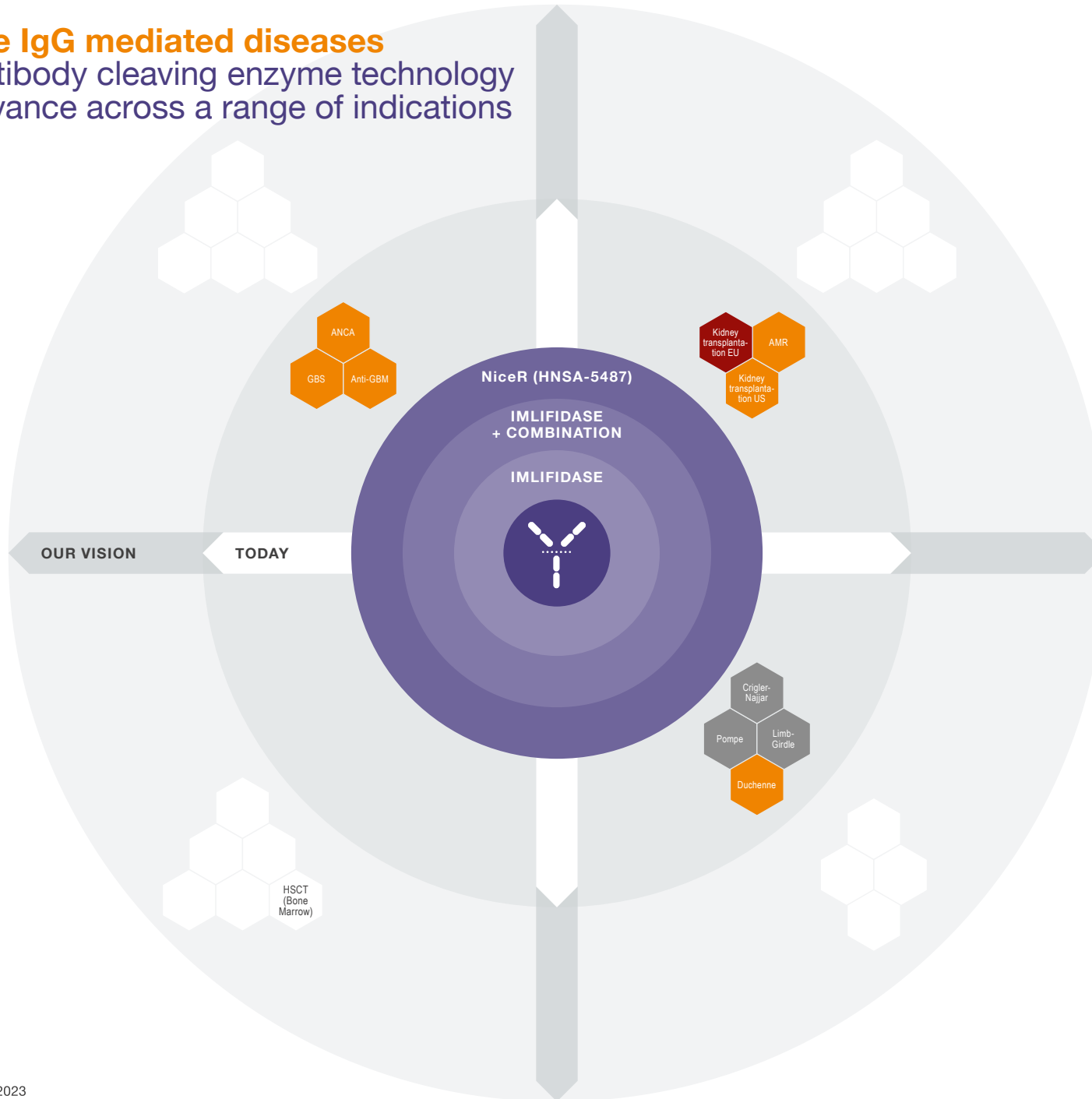
- > Rapidly progressive glomerulonephritis
- > Neurological disorders
- > Skin and blood disorders



### New therapies

IgG-cleaving enzymes to enable cancer therapy

- > Allogenic stem cell (bone marrow) transplantation (HSCT)



- Expanding our commercial franchises**
- Regulatory approval (conditional)
  - Clinical development
  - Planned clinical trial
  - Partnership (preclinical development)
  - Potential indications (currently not pursued)



### Transplantation

Shaping a new standard for desensitization will help enable new indications in transplantations

- > Antibody mediated rejection (AMR) in kidney transplantation
- > Other transplantation types



### Gene therapy

Exploring opportunities in gene therapy

- > Encouraging preclinical data published in Nature
- > Validation through collaborations with Sarepta, AskBio, and Genethon
- > Wide indication landscape beyond



## Intellectual property rights, data exclusivity, and orphan drug designation

Hansa aims at securing broad patent and related IP protection for our current and future products and treatments developed within our technology platform.

The Company's patent and related IP position is global, and covers markets deemed to be of critical clinical, manufacturing and commercial relevance for the product pipeline. As our technology platform further develops, we will pursue new patent and related IP filings.

Our IP portfolio currently includes patent families related to imlifidase and its use, with coverage up to 2035, in key markets. Geographically, these patent families cover a large number of jurisdictions, including the U.S., Europe and Japan.

Our lead product, imlifidase, is protected by six patent families including both granted patents and pending applications and cover the use of imlifidase. The most significant patent families protecting imlifidase and its use provides basis for extended patent terms, which are available in certain major markets, including the U.S. (as patent term extension (PTE)) and the EU (as supplementary protection certificate, SPC). The term of the PTE/SPC can vary from zero to maximum five years, depending on the time taken to obtain marketing approval. Patents with expirations up to 2035 can be extended up to five years via available extensions of patent term.

Our next-generation enzyme, HNSA-5487, is protected by currently three patent families including both granted patents and pending patent applications. Patent coverage is pursued in key markets, i.e. US, EU and more. Based on the standard twenty-year term, without any extended patent terms, HNSA-5487 has patent protection until 2041 in those markets.

In addition to patent and IP related protection, the Company continuously reviews its exclusivity strategy for drug candidates through data exclusivity and orphan drug designations.

Orphan drug designation is granted to therapies aimed at treating life-threatening or chronically debilitating rare diseases where no therapeutic options are either authorized, or where the drugs will be of significant benefit to those affected by the condition. Rare diseases are those defined as having a prevalence of no more than five in 10,000 persons in Europe or affecting less than 200,000 patients in the U.S. The designation provides development and commercial incentives, including ten years of market exclusivity in the EU and seven years in the U.S., protocol assistance on the development of the drug, including clinical studies and certain exemptions from or reductions in regulatory fees.

Since 2017, Hansa has been granted five orphans drug designations by EMA/EC and the FDA across transplantation, anti-GBM antibody disease and GBS (only FDA).

### EMA Orphan drug designation

Imlifidase for the prevention of graft rejection following solid organ transplantation (2017)

Imlifidase for the treatment of the rare and acute anti-GBM disease (2018)

### FDA Orphan drug designation

Imlifidase for the prevention of antibody-mediated organ rejection in solid organ transplantation (2015)

Imlifidase for the treatment of Guillain-Barre Syndrome (2018)

Imlifidase for the treatment of the rare and acute anti-GBM disease (2018)



# Growth

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## Our development programs

### Broad clinical pipeline in transplantation and autoimmune diseases

	Research/ preclinical	Phase 1	Phase 2	Phase 3	Marketing authorization	Marketed	Partner	Next anticipated milestone
<b>Imlifidase</b>								
EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Planned	Completed	Completed		EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Ongoing				Completion of randomization (64 patients) mid 2024
Anti-GBM antibody disease	Completed	Completed	Completed	Ongoing				Complete enrollment (50 patients)
Antibody mediated rejection in kidney transplantation (AMR)	Completed	Completed	Completed					Publication in peer-reviewed journal
Guillain-Barré syndrome (GBS)	Completed	Completed	Ongoing					Comparative efficacy analysis 2024
ANCA-associated vasculitis <sup>3</sup>	Completed	Completed	Ongoing					Complete enrollment (10 patients)
Pre-treatment ahead of gene therapy in Duchenne (DMD)	Completed	Ongoing					Sarepta Therapeutics	Completion of enrollment
Pre-treatment ahead of gene therapy in Limb-Girdle (LGMD)	Ongoing						Sarepta Therapeutics	Preclinical research
Pre-treatment ahead of gene therapy in Pompe disease	Ongoing						AskBio	Preclinical research
Pre-treatment ahead of gene therapy in Crigler-Najjar Syndrome	Ongoing						Genethon	Preclinical research
<b>HNSA-5487</b>								
Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR)	Completed	Ongoing						Further analysis around endpoints from Phase 1 to be completed in 2024 incl. selection of lead indication

<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 Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

Completed

Ongoing

Planned

Post approval study running in parallel with commercial launch







# Strong momentum across the pipeline

## In areas of high unmet need

### Phase 1


 **HNSA-5487 (Lead from NiceR)**

- > Encouraging first read-out
- > Ongoing collection of immunogenicity data in 2024


 **Pre-treatment Gene Therapy Duchenne**

- > Study site activated in Dec '23
- > Dosing of first patient in due course


### Phase 2

 **Antibody Mediated Rejection (AMR)**

- > Primary endpoint met
- > Plans to publish in peer-reviewed journal


 **Guillain-Barré syndrome (GBS)**

- > Positive high-level data
- > Further analysis in 2024 to contextualize efficacy data


 **ANCA-associated vasculitis**

- > 10 to be enrolled
- > 1/3 into completion (Feb 2, 2024)


### Phase 3

 **US ConfIdaS Study in kidney**





- > 104 patients enrolled
- > 2/3 into completion (Feb 2, 2024)
- > Randomization to complete mid '24





 **Post Approval Study in kidney**

- > 50 patients to be enrolled
- > 56% into completion (Feb 2, 2024)
- > Study to complete by 2025

 **Anti-GBM disease**

- > 50 patients to be enrolled
- > 36% into completion (Feb 2, 2024)
- > Complete enrollment in 2025

-  Next generation enzymes
-  Gene Therapy
-  Autoimmune / Allograft
-  Transplantation

-  Started
-  Ongoing
-  Over enrolled
-  Completed

## U.S. randomized controlled trial “ConfIdeS”

The ConfIdeS trial is evaluating imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a deceased donor kidney through the U.S. kidney allocation system.

The trial is expected to randomize 64 highly sensitized kidney transplant patients with a cPRA of  $\geq 99.9\%$ , representing a subset of very highly sensitized patients that continue to be disadvantaged despite prioritization under the U.S. kidney allocation system. When a donor organ becomes available and a positive crossmatch with the intended recipient indicates that the organ is not compatible, the patient will be randomized to either imlifidase desensitization treatment or to a control arm that will receive standard of care (i.e. waiting for a more compatible kidney offer or receiving an experimental desensitization treatment). The study’s primary endpoint for imlifidase to evaluate benefit in transplanting highly sensitized patients is kidney graft function at 12 months, measured by eGFR (estimated Glomerular Filtration Rate).

Robert A. Montgomery, M.D., Professor of Surgery and Director, NYU Langone Transplant Institute in New York City, has been appointed National Coordinating Investigator for the ConfIdeS trial. The trial will enroll patients at up to 25 leading transplantation centers in the U.S.

During 2023 it was decided to implement measures to accelerate ConfIdeS enrollment and randomization as identifying and screening of patients for this trial can take anywhere from weeks to several months. Unlike other trials that can progress once patients meet certain criteria, the ConfIdeS trial is dependent on allocation of suitable organs to consented patients, a process

that in the U.S. is managed by an independent third party. Additionally, there is variability in the acceptance of those organs that are allocated based on the immunologic profile of both the donor and recipient.

As consequence of these learnings Hansa is increasing the number of study sites to up to 25 geographically dispersed transplant centers across the U.S. Secondly, protocol amendments have been implemented to allow a greater portion of waiting recipients to be allocated an organ and thirdly, the study will be overenrolled to increase the likelihood for patients to be randomized.

Completion of randomization is expected by mid-2024, while a BLA submission is expected under the accelerated approval path in 2025.

In addition to the ongoing ConfIdeS trial in kidney transplantation, Hansa is also carrying out a post approval efficacy study (PAES) in parallel with the commercial launch in Europe. The PAES was initiated in July 2022 and is an obligation under the European conditional marketing authorization and will be used to investigate the long-term graft survival in 50 highly sensitized kidney transplant patients treated with Idefirix<sup>®</sup>. The PAES is expected to be completed by end of 2025.

Beyond the four completed phase 2 studies in kidney transplantation, Hansa has conducted a prospective, observational, long-term follow-up study of patients treated with imlifidase prior to kidney transplantation to measure long-term graft survival. In October 2023, Hansa announced results from an extended pooled analysis of data from the long-term follow-up study of patients who have received

a kidney transplant following desensitization with imlifidase, showing sustained positive outcomes out to 5 years in the majority of highly sensitized patients who received an imlifidase-enabled kidney transplant. Patient survival was 90% (death censored) and graft survival was 82%, in line with outcomes seen

at 3-years post-transplant and in line with compatible kidney transplants. The 5-year extended pooled analysis is a continuation of the analysis at 3-years of crossmatch positive only patients, published in the *American Journal of Transplantation*.

### Highly sensitized patients are less likely to find a matching organ from a deceased donor through KAS



Degree of sensitization	cPRA%	Est. no. of organs to find match <sup>2</sup>	Estimated number of patients on waitlist (U.S.) <sup>3</sup>
Less and moderately sensitized	0-20	1-2	~66,000
	20-80	2-14	~16,000
Highly sensitized	80-98	14-300	~5,000
	98-99.9	300-3,000	~3,500
	>99.9	3,000-300,000	~2,500



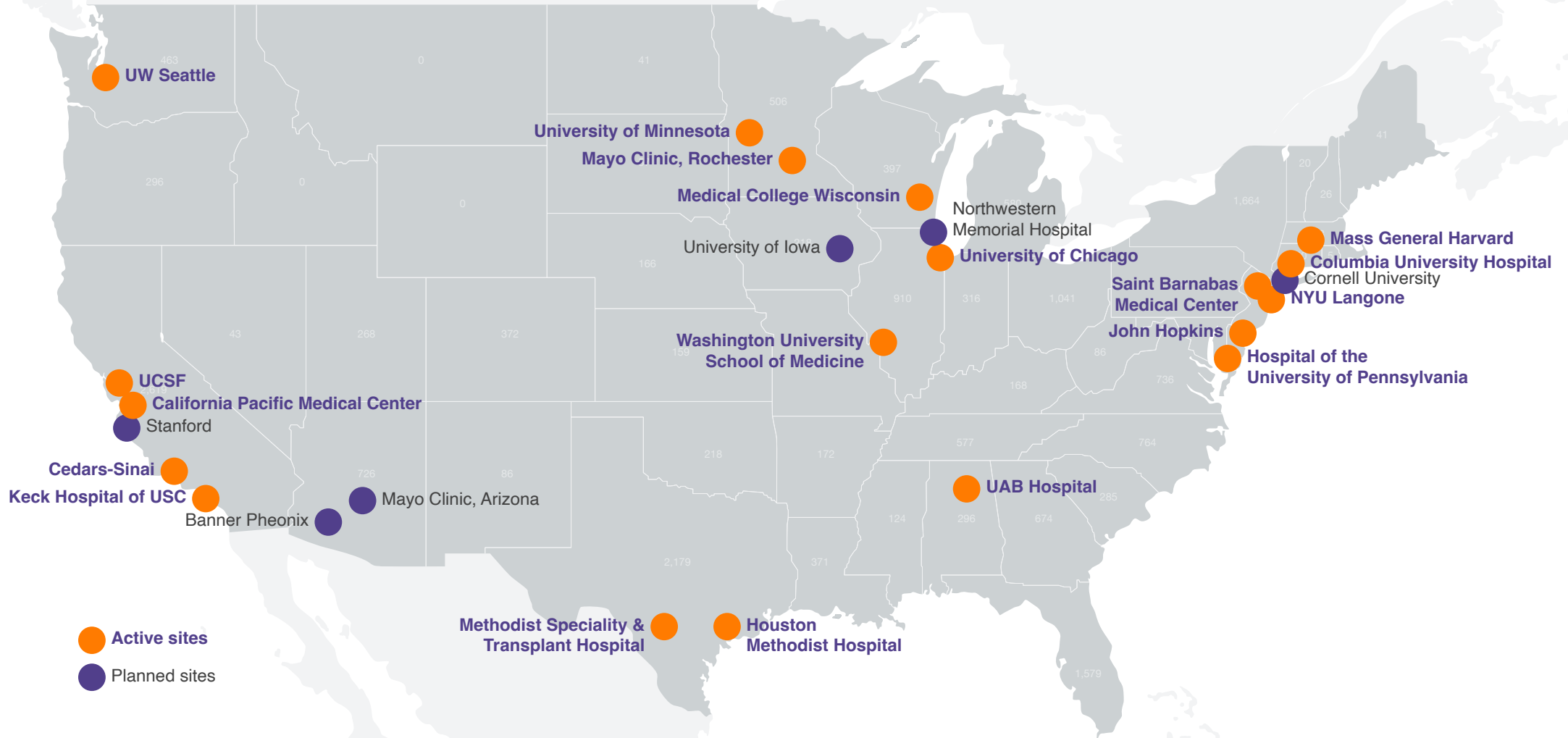
If approved, Idefirix<sup>®</sup> may address highly sensitized kidney transplant patients, who are incompatible to a deceased donor in the U.S. Kidney Allocation System

<sup>1</sup> OPTN, [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf)

<sup>2</sup> p=95%, Clinical Journal of the American Society of Nephrology, 2016

<sup>3</sup> Company estimates, OPTN and Global Observatory on Donation and Transplantation

## Involved ConfideS sites cover more than 20% of total transplantation volumes in the U.S.



## Opportunities beyond kidney transplantation

Hansa is exploring autoimmune diseases where our unique antibody-cleaving platform may have relevance

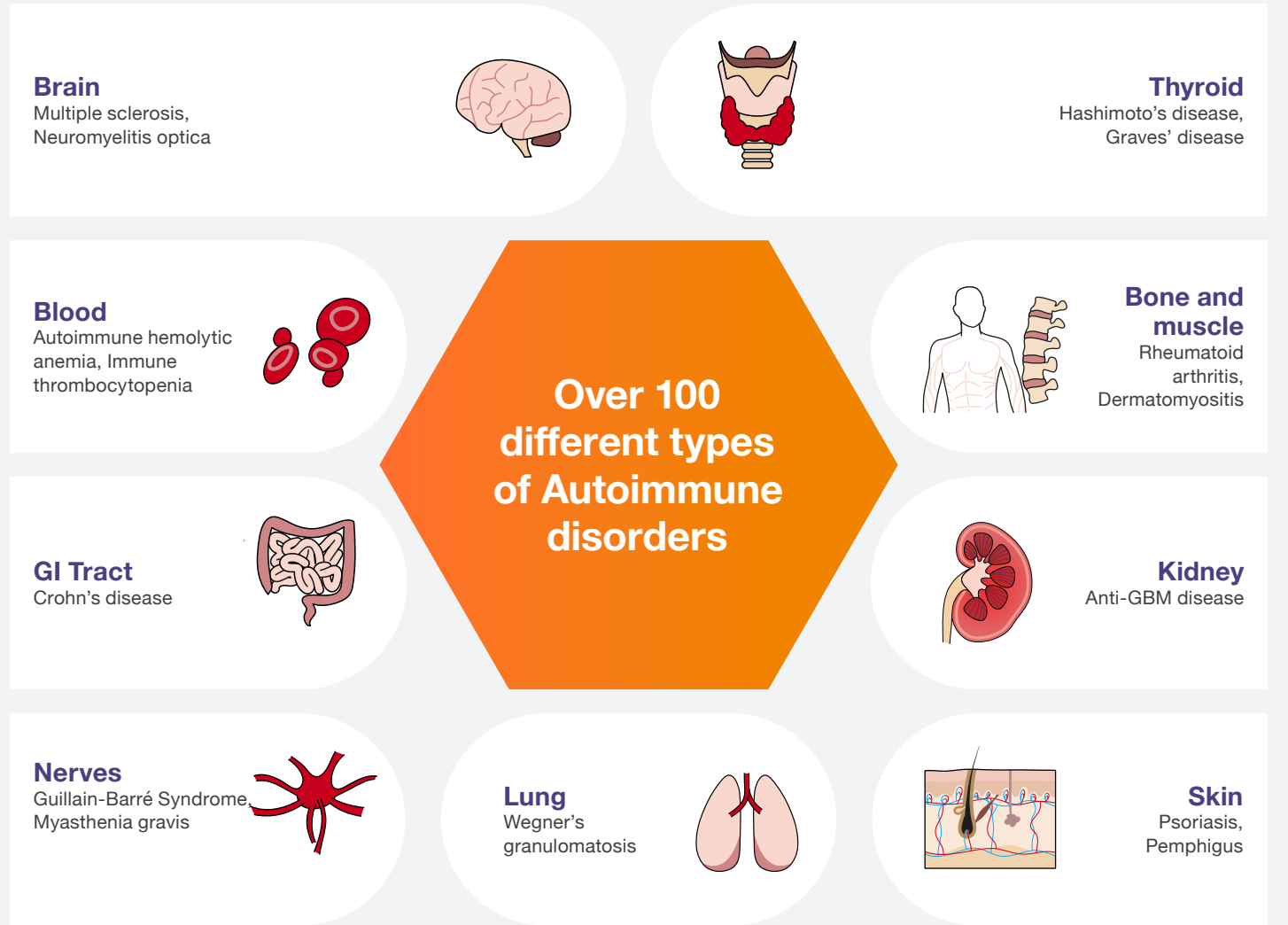
**A result of when the body's immune system by mistake damages its own tissue. Autoimmune disease remains a big challenge and requires immediate treatment.**

### What is an autoimmune disease?

- > Humoral or cell-mediated immune responses to self-antigens (breaking of tolerance)
- > Requires genetic predisposition, and often triggered by viral, bacterial and/or other environmental factors
- > 3-5%<sup>1</sup> of populations affected; mainly women (75%)<sup>2</sup>

<sup>1</sup> Wang et al., J. Intern. Med., 2015

<sup>2</sup> Desai et al., Front. Endocrinol., 2019





## The potential of IgG Modulation

### Bringing immunomodulating therapeutic options to areas of high unmet need

Antibodies, including Immunoglobulin G, or IgG, are an important part of the immune response. In some situations, IgG can become harmful, like in autoimmune conditions. In other instances, antibodies interfere with and undermine the success of biological therapies such as gene therapies. There remains a high unmet need to provide patients and clinicians with effective immunomodulating therapies that can prevent and counteract the unwanted antibody-driven immune response.

#### From friend to foe

Autoimmune diseases are caused by the immune system mistakenly mounting an immune attack against the body's own cells and tissues often through the action of autoantibodies – antibodies that participate in the autoimmune attack.<sup>1,3</sup> They can affect any organ, at any age, with a greater prevalence among women.<sup>1,4</sup> There are approximately 80 recognized autoimmune diseases, with evidence of more than 100 existing.<sup>5</sup>

Autoimmune diseases are generally distinguished between acute indications, where an autoimmune attack can suddenly and swiftly cause life-threatening organ failure and long-term damage,<sup>4</sup> and chronic indications, where the damage develops over extended time from the ongoing damage caused by the autoimmune agents.<sup>4</sup>

Hansa's proprietary IgG-cleaving technology with its rapid and selective mode of action can play a pivotal role in counteracting the action of IgG autoantibodies and help effectively halting the autoimmune attack.

#### Running against time: acute autoimmune diseases

There is an urgent need for rapid and specific therapies to treat acute autoimmune diseases, as many are still without a dedicated therapy, with patients forced to rely on generic immunosuppressive treatments not tailored to halt the acute autoimmune attacks.

Hansa is currently pursuing clinical development of new immunomodulating therapies in two acute autoimmune diseases with a pivotal phase 3 trial (GOOD-IDES-02) in anti-glomerular basement membrane disease (anti-GBM), and a phase 2 trial (15-HMedIdeS-09) in Guillain-Barré syndrome (GBS). 2023 also saw the start of a new investigator-initiated phase 2 study (ImlifidARDSe.01) in ANCA-associated vasculitis disease at Charité Universitätsmedizin, Berlin, Germany.

Anti-GBM, also known as Goodpasture's syndrome, is an acute and very severe inflammatory disease in which IgG-antibodies attack structures in the membrane of the kidneys and often of the lungs.<sup>6</sup> The acute autoimmune attacks can become fatal in up to one in eight patients in the first year,<sup>7</sup> while the majority of patients lose their kidney function and end up on dialysis.<sup>8,9</sup> In anti-GBM, it is estimated that only one in three patients will have a preserved renal function after six months with current standard of care.<sup>10</sup>

“Given the severity of Anti-GBM's acute phase, the autoimmune reaction needs to be counteracted and stopped as quickly as possible if we want to limit the damage to the organs. Only if treatment is instituted early, there is a chance of salvaging the organ's

function” explained Mårten Segelmark, Professor of Nephrology at Lund University in Sweden.

Similar outcomes are observed in a group of conditions known as anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis, where anti-neutrophil IgG autoantibodies trigger an immune reaction that causes blood vessel inflammation and damage<sup>11,12</sup> affecting multiple organs, most frequently lungs and kidneys. The progress of the disease results in end stage kidney disease in one in four patients and respiratory failure in worst cases.<sup>13,14</sup>

GBS, is another severe acute disease that manifests suddenly following an infection and is characterized by an autoimmune response targeting peripheral nerves and their spinal roots. The acute autoimmune attack can lead to severe paralysis of the arms and legs with approximately 25% of patients requiring mechanical ventilation for days to months and 20% unable to walk after six months.<sup>15,16</sup>

“In my career, I have seen cases where patients had to make three visits to the emergency room before the diagnosis of GBS was made. This complicates things, as a timely diagnosis and treatment is crucial to reduce

the severity of the symptoms and minimize long term damage”, explained Professor Shahram Attarian, Head of Department of Neuromuscular Diseases and ALS, Hopitaux Universitaires de Marseille (APHM), and International Coordinating Principal Investigator in the 15-HMedIdeS-09 trial.

**Given the severity of Anti-GBM's acute phase, the autoimmune reaction needs to be counteracted and stopped as quickly as possible if we want to limit the damage to the organs.**



## The potential of IgG Modulation continued

“We are seeing great potential and interest in the use of our IgG-cleaving technology in the treatment of acute autoimmune conditions” said Achim Kaufhold, Chief Medical Officer. “Used in combination with standard of care, our enzyme could improve the management of acute autoimmune attacks providing a rapid and selective response against IgG autoantibodies, ultimately allowing better outcomes for patients”.

### Chronic indications: keeping autoantibodies at bay over time

In chronic indications, the need is focused on helping patients keep the autoimmune response under control over time to prevent constant damage to cells and tissues. Sometime patients can experience a resurgence in autoantibody activity in conditions like refractory or relapsing autoimmune disease and chronic antibody-mediated organ rejection (AMR).

We believe our next-generation IgG-cleaving enzyme HNSA-5487 could have the potential to improve long term-disease control of autoimmune conditions in combination with humoral inhibitors.

### Bridging the access to gene therapies for more patients

Sometimes, a perfectly functional immune system can have detrimental effects for a patient in need of treatment, like in the case of gene therapies. As for the majority of biopharmaceuticals, gene therapies are known to cause the production of anti-drug antibodies, also known as neutralizing antibodies or NABs. The presence of NABs is a challenge for AAV-based gene therapies, preventing up to 1 in 3 people from benefiting from these treatments.<sup>17-20</sup>

Most gene therapies utilize modified viral vectors from Adeno Associated Viruses (AAV),<sup>17-20</sup> common in nature and the cause of many common infections. In their lifetime, many people develop NABs following exposure to an Adeno Associated Virus, to protect the body against it. NABs recognize the AAV vectors used in gene therapy and trigger an immune response against them, preventing their success.

We see the potential for both our enzymes – imlifidase and HNSA-5487 – to help overcome the immunological barrier created by pre-existing neutralizing antibodies (NABs) by leveraging the same mode of action that could help treat autoimmune diseases. By working with gene therapy companies at the forefront of innovation, we are evaluating the use of our technology to enable access to these lifesaving treatments.

Through their partnership, Hansa and Sarepta have initiated study SRP-9001-104, whereby patients who have Duchenne Muscular Dystrophy (DMD) with pre-existing NABs will receive imlifidase as a pretreatment ahead of Sarepta’s Elevidys. Similarly, in the spring of 2023, Hansa formed a partnership with Genethon, a leading gene therapy research not for profit organization, to enable gene therapy treatment in patients with Crigler-Najjar syndrome, a genetic disease-causing bilirubin accumulation, with plan to start a clinical trial in 2024. Finally, Hansa is advancing pre-clinical work with AskBio to assess the use of imlifidase ahead of their gene therapy in Pompe disease.

Understanding how to overcome the action of anti-AAV antibodies is crucial to ensure

all patients in need can receive gene therapy treatments. In fact, it is estimated that 14% of patients with DMD have NABs against the vector used in Sarepta’s Elevidys,<sup>21</sup> while about 30% of patients with Crigler-Najjar have pre-formed NABs against Genethon’s therapy. “Our primary focus is patients”, concluded Achim, “and our priority is ensuring we can enable all patients, including those with both preformed and acquired NABs, to receive innovative treatments”.

At Hansa we remain committed to helping patients who live with debilitating conditions like autoimmune diseases, by advancing our technology platform as quickly as possible ensuring they have access to innovative new treatment options.

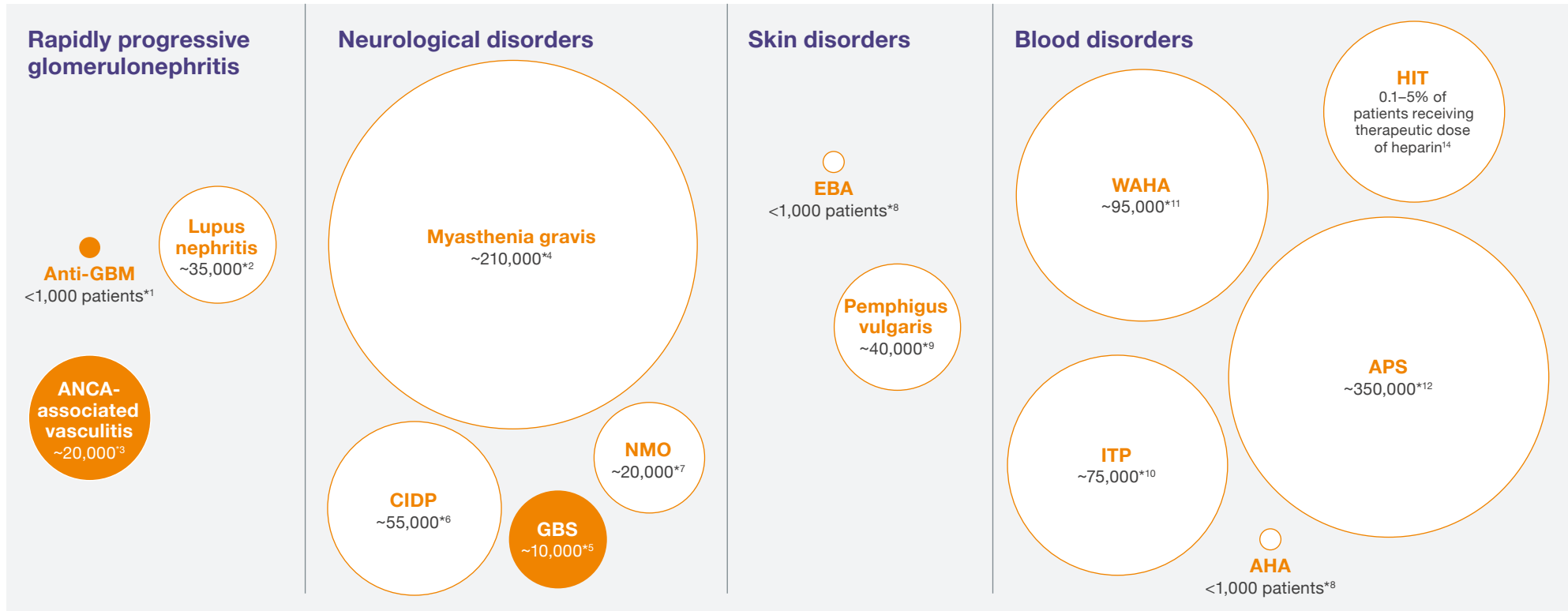
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# Hansa's antibody cleaving enzyme technology may have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis



**CIDP:** Chronic inflammatory demyelinating polyradiculoneuropathy  
**NMO:** Neuromyelitis optica  
**EBA:** Epidermolysis bullosa acquisita  
**ITP:** Immune thrombocytopenia  
**WAHA:** Warm antibody hemolytic anemia  
**APS:** Antiphospholipid syndrome  
**AHA:** Acquired hemophilia A  
**HIT:** Heparin-induced thrombocytopenia

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<sup>4</sup> Myasthenia Gravis. National Organization for Rare Disorders, <https://rarediseases.org/rare-diseases/myasthenia-gravis/> [accessed 2021-03-29]  
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■ Clinical programs  
□ Potential autoimmune indications (currently not pursued)  
\* Total disease populations in EU & US, based on prevalence and population data



## Indications

### Acute Anti-GBM antibody disease (Goodpasture's disease)

#### A rare acute autoimmune disease affecting kidneys and lungs

Anti-GBM (anti-glomerular basement membrane) disease, also known as “Goodpasture’s disease”, is an acute and very severe inflammatory disease impacting the kidneys. For largely unknown reasons, the immune system develops IgG-antibodies that recognize a membrane associated antigen in the kidney and sometimes, in the lungs. Anti-GBM disease is one form of glomerulonephritis (GNN), which comprises a number of inflammatory diseases in the kidney. In glomerulonephritis, the inflammation starts in the glomeruli (filtering unit of the kidneys) and the small blood vessels. The result is an acute immune attack on these organs. In most cases, anti-GBM antibody disease leads to significant loss of kidney function, requiring chronic dialysis or results in death.

Anti-GBM is an ultra-rare disease that affects approximately 1.6 per million people globally, every year<sup>1,2</sup> (e.g. 1,000 cases across EU and the U.S. annually). For one out of six patients, anti-GBM can become fatal during the acute phase of the disease, while the majority of patients will end up on chronic dialysis<sup>3</sup>. Only one in three anti-GBM patients

will have a preserved renal function after six months with current treatment<sup>4</sup>.

In March 2022, Hansa announced that key data from an investigator-initiated phase 2 trial (GoodIdeS) of imlifidase to treat anti-GBM disease were published in Journal of American Society of Nephrology (JASN)<sup>5</sup>. The study, led by Principal Investigator, Mårten Segelmark, Professor of Nephrology at Lund University, previously Linköping University, showed that two-thirds of patients achieved dialysis independence six months after treatment as compared to typically two-thirds of patients losing their kidney function and ending up on dialysis after six months.

Following the successful data in the phase 2 trial we have commenced a pivotal phase 3 with the first patient enrolled in May 2023. This study is an open label, controlled, randomized, multi-center phase 3 trial evaluating kidney function measured by eGFR at 6 months from randomization in patients with severe anti-GBM disease receiving imlifidase plus SoC versus SoC. Completion of enrollment is expected in 2025.

### Active antibody mediated rejection (AMR)

#### Long term graft survival is challenged by AMR episodes post transplantation

Active antibody mediated rejection, or AMR, is a serious condition after transplantation that occurs in roughly 5-7<sup>1</sup>% of kidney transplants and is a significant challenge to long-term graft survival. AMR is the main cause for graft dysfunction and loss after kidney transplantation. Today’s standard of care for AMR treatment includes plasma exchange and treatment with steroids and IVIg. AMR patients not treated successfully risk graft failure, dialysis and return to the waitlist.<sup>2</sup>

Hansa has run a randomized, open-label, multi-center, controlled phase 2 study in AMR. 30 patients with acute or chronic acute AMR were enrolled across centers in France, Germany, Austria, Australia and the U.S. The study is designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in acute AMR patients, post transplantation. Twenty patients were randomized to receive imlifidase treatment comprised of one intravenous dose of 0.25mg/kg, while 10 patients in the active control arm received 5-10 sessions of plasma exchange. Efficacy and safety were monitored

over a 6-month period, post treatment. More information about the trial is available at ClinicalTrials.gov under NCT03897205 (2019).

In December 2023, Hansa announced full data from the imlifidase phase 2 study in AMR, demonstrating a statistically significantly superior capacity of imlifidase to rapidly reduce levels of DSAs compared to plasma exchange in the five days following the start of the treatment. The secondary endpoint investigated overall kidney function following treatment. The imlifidase arm demonstrated a 74% six-month graft survival and eGFR of 30mL/min/1.73m<sup>2</sup>. A 100% six-month graft survival and eGFR of 33mL/min/1.73m<sup>2</sup> was observed in the plasma exchange arm.

Given the heterogeneity of the patient population, the trial was not designed nor sufficiently powered to be able to show a statistically significant difference in the secondary outcome measures. Patients with an acute AMR and without an additional cellular component of the immune rejection may be best placed to benefit from a rapid and significant reduction in DSA, one of the main goals of any AMR treatment according to existing treatment guidance. Hansa plans to submit the data for publication in a peer-reviewed journal during 2024.

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<sup>2</sup> Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12

<sup>3</sup> Cohort of 13 studies (661 patients in anti-GBM 1993-2017) Treating anti-GBM disease with imlifidase Mårten Segelmark, Professor OF Nephrology

<sup>4</sup> Kluth et al. J Am Soc Nephrol. 1999 Nov;10(11):2446-53 and Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12

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<sup>2</sup> Puttarajappa et al., 2012; Jordan et al., 2015





## Indications continued

### Guillain-Barré syndrome (GBS) An acute autoimmune attack on the peripheral nervous system

GBS is an aggressive neurological disease of the peripheral nervous system that affects 1-2 in 100,000 people, annually, representing an addressable population of ~11,000 per year in the seven major markets.<sup>1</sup> GBS is the most frequent cause of acute neuromuscular weakness in the western world and can affect anyone at any age and many patients deteriorate, despite standard of care treatment.

Two thirds of GBS patients have severe symptoms, resulting in an inability to walk unaided, and 20-30% require mechanical ventilation for weeks or months<sup>2</sup>. While patients are typically treated with either IVIg or plasmapheresis, a significant unmet medical need remains, as not all patients fully recover from GBS. Up to 40% of patients will lose strength and have ongoing pain. Mortality is estimated at between 3-5%.<sup>3,4</sup>

Hansa is investigating imlifidase in an open-label, single arm, multicenter phase 2 study evaluating the safety, tolerability and efficacy of imlifidase in GBS patients, in combination with standard of care intravenous immunoglobulin (IVIg). We are targeting 30 GBS patients to be enrolled across clinics in France, the UK and

the Netherlands. GBS patients enrolled in the study will receive a single dose of 0.25 mg/kg of imlifidase and will be compared with a matched control group of GBS patients treated with IVIg, from the International GBS Outcome Study (IGOS) database.

In December 2023 high level data was announced demonstrating that imlifidase was safe and well tolerated when administered prior to standard of care, including rapid improvement in disease-related efficacy measures. Further analysis of efficacy data will be conducted this year.

### Investigator-initiated phase 2 study in ANCA-associated vasculitis

As part of the Company's platform strategy and objective to broaden the application of our antibody-cleaving enzymes as a potential therapy to change the course of IgG-mediated immunological diseases and conditions, we are exploring new indications with high unmet need both through Investigator-Sponsored Trials (IST) programs and Hansa-Sponsored Trials.

One of such indication is anti-neutrophil cytoplasmic antibody ("ANCA")-associated vasculitis, where imlifidase, in an investigator-initiated phase 2 study sponsored by Charité Universitätsmedizin, Berlin, Germany, is investigated as a potential new treatment for ANCA-associated vasculitis in patients with severely active disease.

ANCA-associated vasculitis is a group of conditions that affect approximately 30 people in a million annually in the EU and U.S.<sup>1,2</sup> It is characterized by the presence of IgG anti-neutrophil cytoplasmic antibodies<sup>3</sup> directed against antigens expressed by the neutrophils, a type of white blood cell part of the body's immune system response. The consequent activation of neutrophils by the

ANCA antibodies causes blood vessel damage<sup>4</sup> that can affect multiple organs, most frequently lungs and kidneys, where it leads to rapidly deteriorating organ function. The progress of the disease results in end stage kidney disease in 25 percent of patients<sup>5</sup>. The most severe cases involving lungs lead to pulmonary hemorrhage with consequent respiratory failure

The new study is a single center, single arm, phase 2 trial led by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany. The primary objective of the study is to assess efficacy and safety of imlifidase together with standard of care in the treatment of patients with pulmonary hemorrhage due to severe ANCA-associated vasculitis.

A total of 10 patients with severe ANCA-associated vasculitis and Acute Respiratory Distress Syndrome ("ARDS") due to pulmonary hemorrhage will be treated with imlifidase on top of standard of care (consisting of standard immunosuppression as per center protocol and intensive support care). Efficacy and safety of imlifidase will be assessed by evaluating ANCA antibody seroconversion and titers, adverse events, mortality, as well as amelioration of lung and renal function over a 6-month observation period.

<sup>1</sup> Seven Major Markets Seven major markets include US, Germany, UK, France, Spain, Italy, and Japan

<sup>2</sup> Fletcher DD, Lawn ND, Wolter TD, et al. Long-term outcome in patients with Guillain-Barré syndrome requiring mechanical ventilation. *Neurology* 2000;54:2311-5

<sup>3</sup> McGrogan et al. "The Epidemiology of Guillain-Barré Syndrome Worldwide", *Neuroepidemiology*;2009, 32(2):150-63

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<sup>1</sup> Uhlin F, et al. *J Am Soc Nephrol*. 2022 Apr;33(4):829-838

<sup>2</sup> Berti A, et al. *Arthritis Rheum* atol. 2017;69.

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<sup>4</sup> Falk RJ, Jennette JC. *The New England journal of medicine*. 1988;318(25):1651-7.

<sup>5</sup> Booth AD, et al. *American journal of kidney diseases*. 2003;41(4):776-84.

## Imlifidase in gene therapy an emerging opportunity

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

Genetic disorders are caused by defective genes which fail to produce a functioning protein. Gene therapy treatments are designed to introduce genetic material into cells to compensate for these non-functioning genes. Thus, if a mutated gene causes an essential protein to be faulty or missing, gene therapy may be able to introduce a normal copy of the gene to restore the gene function to produce the desired protein.

In order to transfer a healthy and functioning gene into a cell, non-replicating and non-disease causing viruses, usually

adeno-associated virus vectors (AAVs), are utilized. The transfer and insertion of the healthy gene and its vector into a cell is called transduction.

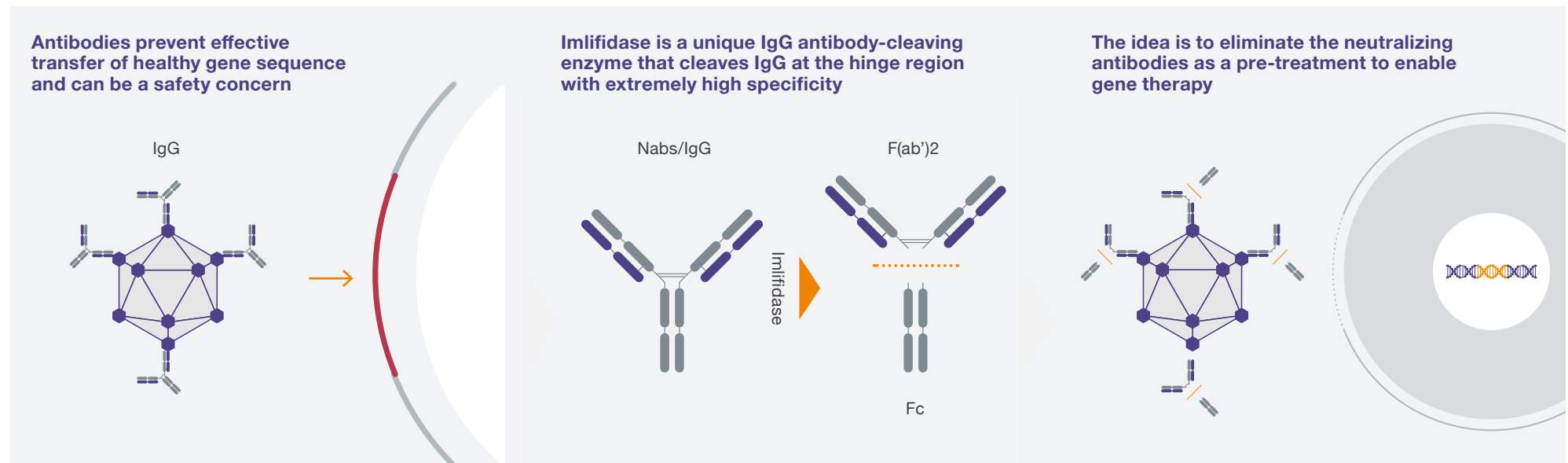
There are vectors that can be administered locally to selected target tissues including specific cells in the eye and the brain. There are also vectors that can be distributed systemically, targeting liver or muscle cells. Since most people have been exposed to adenoviruses at some point in their lives, there is a relatively high prevalence of preformed antibodies against AAVs. The prevalence of those antibodies varies significantly between the different type of vectors and can be as high as up to 70% in the general population (e.g. AAV 1)<sup>1</sup>. The presence of

antibodies against AAV blocks the transduction, thus preventing successful gene therapy treatment in those patients. This means that a substantial proportion of patients are excluded from the possibility of having a potentially disease-curing gene therapy treatment.

Imlifidase has the potential to eliminate antibodies which can bind and inhibit gene therapy, thereby enabling effective transfer of a healthy gene sequence into these patients. The concept of using IgG cleaving enzymes as a potential pre-treatment to overcome pre-existing antibodies to AAV-based gene therapy was highlighted in "Nature Medicine," in 2020<sup>2</sup>. In addition, highly encouraging results from preclinical studies with imlifidase have

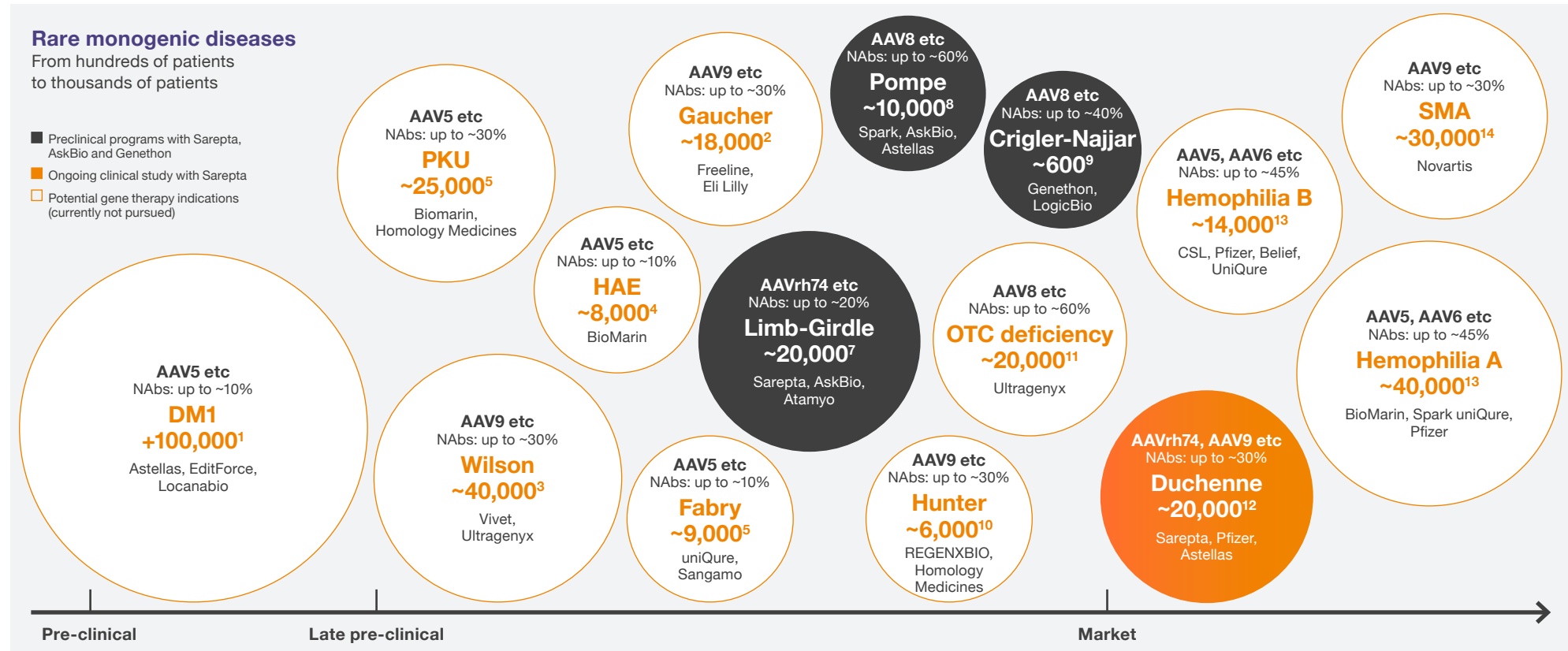
demonstrated that imlifidase can eliminate the blocking effect of NABs towards AAVs in a mouse model, in non-human primates, as well as in human plasma samples from patients with antibodies against AAVs<sup>3</sup>.

- <sup>1</sup> Boutin et al (2010), Griffin et al (2019), Wang et al (2018), Calcedo & Wilson (2013), Falese et al (2017), Haiyan et al (2017), Ellsworth et al (2018), Greig et al (2017)
- <sup>2</sup> Leborgne, C., Barbon, E., Alexander, J.M. et al. IgG-cleaving endopeptidase enables in vivo gene therapy in the presence of anti-AAV neutralizing antibodies. Nat Med 26, 1096–1101 (2020). <https://doi.org/10.1038/s41591-020-0911-7>
- <sup>3</sup> The Safety and Efficacy of Pre-Treatment with Imlifidase Prior to Adeno Associated Virus (AAV)-Based Gene Therapy in Non-Human Primates with Pre-Existing Anti-AAVrh74 Antibodies. R. Potter et al, ASGCT Abstracts, Molecular Therapy Vol 31 No 4S1, April 2023



## Systemic gene therapy is an emerging opportunity

With a focus on the potential to correct diseases causing genes in rare monogenic diseases



<sup>1</sup> Rarediseases.org, <https://rarediseases.org/rare-diseases/dystrophy-myotonic/> [Accessed 2023-06-28]

<sup>2</sup> Medlineplus.gov, <https://medlineplus.gov/genetics/condition/gaucher-disease/#frequency> Accessed 2023-06-20

<sup>3</sup> Sandahl TD, Laursen TL, Munk DE, Vilstrup H, Weiss KH, Ott P. The Prevalence of Wilson's Disease: An Update. *Hepatology*. 2020 Feb;71(2):722-732. doi: 10.1002/hep.30911. Epub 2020 Jan 31. PMID: 31449670.

<sup>4</sup> Ghazi A, Grant JA. Hereditary angioedema: epidemiology, management, and role of icatibant. *Biologics*. 2013;7:103-113. doi: 10.2147/BTT.S27566. Epub 2013 May 3. PMID: 23662043; PMCID: PMC3647445.

<sup>5</sup> Hillert A, et al. The Genetic Landscape and Epidemiology of Phenylketonuria. *Am J Hum Genet*. 2020 Aug 6;107(2):234-250. doi: 10.1016/j.ajhg.2020.06.006. Epub 2020 Jul 14. PMID: 32668217; PMCID: PMC7413859.

<sup>6</sup> Medlineplus.gov, <https://medlineplus.gov/genetics/condition/fabry-disease/#frequency> [Accessed: 2023-07-12]

<sup>7</sup> Liang, WC., Jong, YJ., Wang, CH. et al. Clinical, pathological, imaging, and genetic characterization in a Taiwanese cohort with limb-girdle muscular dystrophy. *Orphanet J Rare Dis* 15, 160 (2020). <https://doi.org/10.1186/s13023-020-01445-1>

<sup>8</sup> Rarediseases.org, <https://rarediseases.org/rare-diseases/pompe-disease/> [Accessed 2023-07-12]

<sup>9</sup> Genethon.com, <https://www.genethon.com/our-pipeline/crigler-najjar-syndrome/> [Accessed 2023-06-15]

<sup>10</sup> Gajula P, Ramalingam K, Bhadrashetty D. A rare case of mucopolysaccharidosis: Hunter syndrome. *J Nat Sci Biol Med*. 2012 Jan;3(1):97-100. doi: 10.4103/0976-9668.95984

<sup>11</sup> Rarediseases.org, <https://rarediseases.org/rare-diseases/ornithine-transcarbamylase-deficiency/> [Accessed 2023-07-12]

<sup>12</sup> Crisafulli S. et al. Global epidemiology of Duchenne muscular dystrophy: an updated systematic review and meta-analysis. *Orphanet J Rare Dis*. 2020 Jun 5;15(1):141. doi: 10.1186/s13023-020-01430-8. PMID: 32503598; PMCID: PMC7275323.

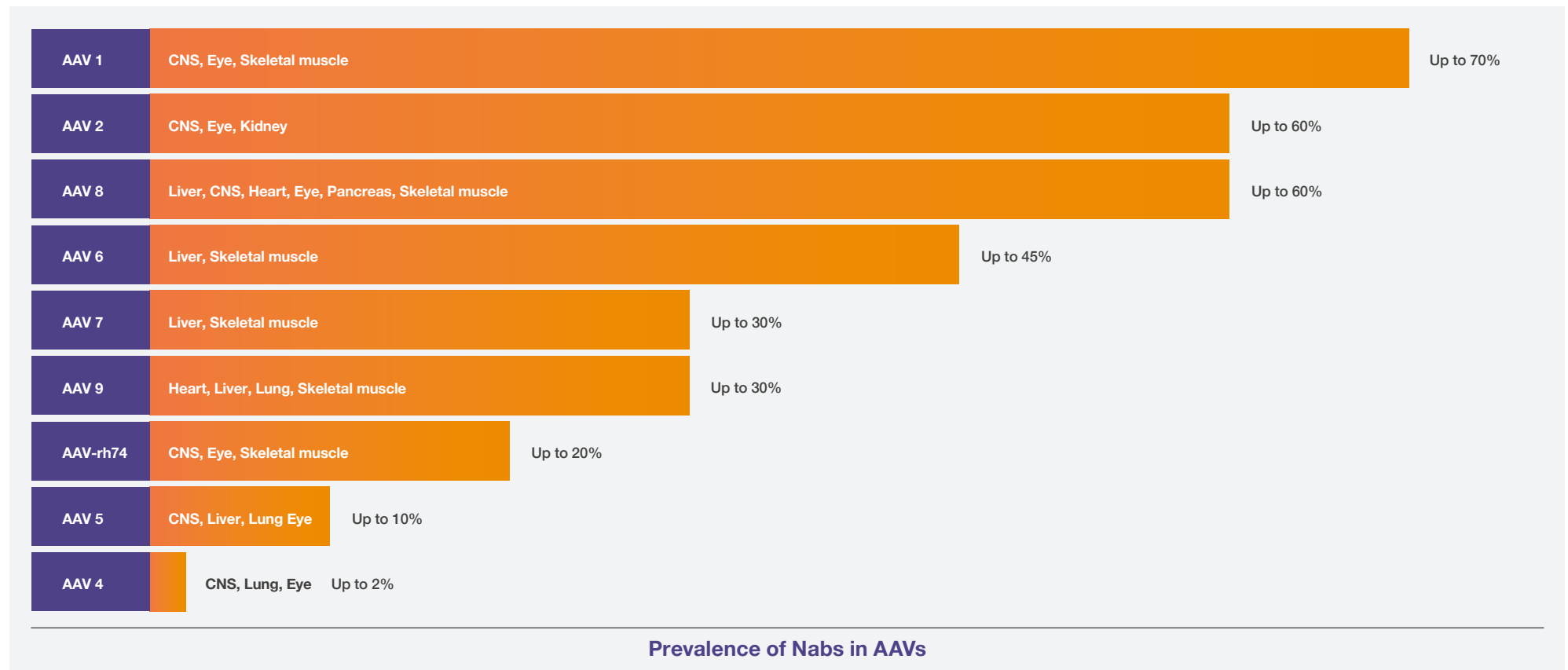
<sup>13</sup> GlobalData [Accessed 2023-12-15]

<sup>14</sup> Verhaart, I.E.C., Robertson, A., Wilson, I.J. et al. Prevalence, incidence and carrier frequency of 5q-linked spinal muscular atrophy – a literature review. *Orphanet J Rare Dis* 12, 124 (2017). <https://doi.org/10.1186/s13023-017-0671-8>



## Neutralizing antibodies – a barrier that precludes gene therapies

The prevalence of Nabs varies significantly across the different vectors








Source:  
Boutin et al (2010), Griffin et al (2019), Wang et al (2018), Calcedo & Wilson (2013),  
Falese et al (2017), Haiyan et al (2017), Ellsworth et al (2018), Greig et al (2017)



## Collaborations in gene therapy

To evaluate the feasibility of imlifidase as pre-treatment ahead of gene therapy for patients with pre-existing neutralizing antibodies (NAbs) to adeno-associated virus (AAV)

Partner	Key resources	Indication exclusivity	Collaborative research, development and commercialization				
	<ul style="list-style-type: none"> <li>&gt; World leader within gene therapy targeted at muscular dystrophies</li> <li>&gt; Pre-clinical and clinical plan</li> <li>&gt; Regulatory</li> <li>&gt; Promotion</li> <li>&gt; FDA approval in 4–5-year-old kids suffering with DMD</li> </ul>	<b>Duchenne Muscular Dystrophy (DMD)</b> 1/3,500 to 5,000 male births worldwide	 Antibody cleaving enzyme technology	 Preclinical Development	Initiated Clinical Development	Regulatory Approvals	Commercialization
		<b>Limb-Girdle Muscular Dystrophy (LGMD)</b> Global prevalence of ~1.6 per 100k individuals	 Antibody cleaving enzyme technology	Preclinical Development	Clinical Development	Regulatory Approvals	Commercialization
	<ul style="list-style-type: none"> <li>&gt; Early innovator in gene therapy</li> <li>&gt; Conducts pre-clinical and clinical trials (Phase 1/2)</li> </ul>	<b>Pompe disease</b> Approximate incidence is 1 per 40,000 births, or ~200 per year in the U.S. + EU	 Antibody cleaving enzyme technology	Preclinical Development	Clinical Development Phase 1/2 study (feasibility)	Exclusive option for AskBio to negotiate a potential full development and commercialization agreement	
	<ul style="list-style-type: none"> <li>&gt; A pioneer in the discovery and development of gene therapies</li> <li>&gt; Conducts pre-clinical and clinical trials (Phase 1/2)</li> </ul>	<b>Crigler-Najjar syndrome</b> Approximately incidence is 0.6-1 case per one million people or 600 patients in Europe and the U.S.	 Antibody cleaving enzyme technology	Preclinical Development	Clinical Development Phase 1/2 study (feasibility)	The initial agreement is focused on research and development  The companies will consider a subsequent agreement for commercialization at a later stage	



## Collaborations



### Sarepta Therapeutics

Since 2020 we have collaborated exclusively with Sarepta Therapeutics to develop and promote imlifidase as a potential pre-treatment prior to the administration of gene therapy in Duchenne Muscular Dystrophy (DMD) and Limb-Girdle Muscular Dystrophy (LGMD) in patients with pre-existing NABs to adeno-associated virus.

Under the terms of the agreement, Hansa received USD 10 million as an upfront payment and is eligible for up to USD 397.5 million in development, regulatory and sales milestones, as well as royalties on any Sarepta gene therapy sales enabled through pre-treatment with imlifidase in NAB-positive patients. In addition, Hansa will book all future sales of imlifidase when used as a pre-treatment.

On June 22, 2023, Sarepta's gene therapy product Elevidys (SRP-9001), received U.S. FDA approval as a one-time treatment in ambulatory paediatric patients aged 4 through 5 years, suffering from Duchenne Muscular Dystrophy. In combination with imlifidase, additional treatment may potentially be enabled in up to 14% of patients who are currently suffering from too high titres of neutralizing antibodies against AAVrh74. The first clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD was initiated mid-December 2023.

In LGMD the collaboration is progressing as planned, currently at a preclinical stage. For further information about Sarepta's programs please refer to [www.sarepta.com](http://www.sarepta.com).

### About Duchenne Muscular Dystrophy (DMD)

Duchenne muscular dystrophy is a rare genetic disease. It predominantly affects males, but, in rare cases, can also affect females. Duchenne causes the muscles in the body to become weak and damaged over time and is eventually fatal. The genetic change that causes Duchenne—a mutation in the DMD gene—happens before birth and can be inherited, or new mutations in the gene can occur spontaneously. Muscle weakness becomes increasingly noticeable between the ages of 3 and 5, and most patients use a wheelchair by the time they are 12. During adolescence, heart and breathing muscles weaken, leading to serious, life-threatening complications. Duchenne affects approximately 1 in 3,500 to 5,000 males born worldwide. Approximately 15% of patients have pre-existing IgG antibodies to AAVrh74.

### About Limb-girdle muscular dystrophy (LGMD)

Limb-Girdle muscular dystrophy is a group of distinct diseases that cause weakness and wasting of the muscles, generally starting with the muscles around the hips and shoulders and eventually progressing to the arms and legs. However, some subtypes start distally at the leg or arm muscles and then progress to the hip and shoulder muscles. LGMD can be caused by a single gene defect that

affects specific proteins within the muscle cell, including those responsible for keeping the muscle membrane intact. Taking into account the various subtypes, limb-girdle muscular dystrophy has a global prevalence of approximately 1.63 per 100,000 individuals worldwide. Over 30 subtypes exist, and both genders are affected equally.

**On June 22, 2023, Sarepta's gene therapy product Elevidys (SRP-9001), received U.S. FDA approval as a one-time treatment in ambulatory paediatric patients aged 4 through 5 years, suffering from Duchenne Muscular Dystrophy.**



## Collaborations continued



### AskBio

Since January 2022 we have collaborated with AskBio (subsidiary of Bayer AG), a fully integrated AAV gene therapy Company dedicated to developing medicines that improve the quality of life for patients with genetic diseases.

The collaboration is designed to evaluate the potential use of imlifidase as a pre-treatment prior to the administration of AskBio's gene therapy in Pompe disease in a preclinical and clinical feasibility program for patients with pre-existing NABs to the adeno-associated viral vector used in AskBio's gene therapy. Under terms of the agreement, Hansa received a USD 5 million payment upon execution of the agreement and AskBio has the exclusive option to negotiate a full development and commercialization agreement following evaluation of the results from an initial phase 1/2 study.

Additional pre-clinical data evaluating the potential use of imlifidase as a pre-treatment prior to the administration of gene therapy have been generated under the Hansa-AskBio Option Product Collaboration Agreement and will be presented at an upcoming scientific congress.

For further information regarding AskBio's gene therapy program in Pompe disease, please refer to [www.askbio.com](http://www.askbio.com).

### About Pompe disease

Pompe disease is a rare genetic, often fatal, disorder caused by a defect in a gene making an enzyme called acid alpha- glucosidase (GAA). GAA is used to break down glycogen (a sugar used to store energy in cells) and a defect GAA enzyme leads to accumulation of glycogen in the body's cells. The glycogen accumulation in certain organs and tissues, especially muscles, liver and heart, severely impact normal organ function. While enzyme replacement therapy (ERT) has shown promise in patients with Pompe disease, no curative therapy is available.

Pompe disease is estimated to affect 1 in 40,000 births in the U.S.<sup>1</sup>, and equates to an incidence of ~200 per year in the U.S. and Europe. Additionally, data indicates that the prevalence of Pompe disease in the U.S. and Europe, combined, is approximately 10,000<sup>2</sup>. The percentage of patients that are expected to have NABs against the AAV8-vector components used in AskBio's gene therapy is 40-60%<sup>3</sup>.

<sup>1</sup> Pompe disease, <https://rarediseases.org/rare-diseases/pompe-disease/>

<sup>2</sup> Calculated by Hansa on the basis of incidence numbers from <https://rarediseases.org/rare-diseases/pompe-disease/> and life expectancy estimates from <https://pompediseasenews.com/late-onset-pompe-disease/>, as well as population statistics for the United States and European Union/Europe

<sup>3</sup> ESGCT 27th Annual Congress Abstracts, Sensitivity of different AAV serotypes to pre-existing NABs, [https://www.esgct.eu/home/Barcelona%202019/NEW\\_All%20Barcelona%20Abstracts.pdf](https://www.esgct.eu/home/Barcelona%202019/NEW_All%20Barcelona%20Abstracts.pdf) & Boutin et al. Prevalence of serum IgG and neutralizing factors against adeno-associated virus (AAV) types 1, 2, 5, 6, 8, and 9 in the healthy population: implications for gene therapy using AAV vectors. Hum Gene Ther. 2010. <https://pubmed.ncbi.nlm.nih.gov/20095819/>



### Genethon

On April 27, 2023 we announced a research and development collaboration with Genethon, a pioneer and a leader in gene therapy research and development for rare genetic diseases. The collaboration will, in a clinical study, evaluate the safety and efficacy of Hansa's antibody cleaving enzyme imlifidase as a pre-treatment prior to the administration of Genethon's gene therapy product candidate GNT-0003 in Crigler-Najjar syndrome in patients with pre-existing neutralizing antibodies (NABs) to adeno-associated virus serotype 8 (AAV8).

GNT-0003 is currently being evaluated in a pivotal clinical study in France, Italy, and the Netherlands and has received PRIME (PRiority Medicines) status from the EMA.

Through the collaboration announced, patients with Crigler-Najjar and pre-formed antibodies to AAV8 will be enrolled in a study with similar design where imlifidase is evaluated as a pre-treatment to enable gene therapy treatment with GNT-0003. The outcome of the ongoing clinical study of GNT-0003 could potentially form the basis for a MAA or BLA application in Europe or the U.S.

### About Crigler-Najjar syndrome

Crigler-Najjar syndrome is a rare genetic liver disease characterized by abnormally high levels of bilirubin in the blood (hyperbilirubinemia). This accumulation of bilirubin is caused by a deficiency of the UGT1A1 enzyme, responsible for transforming bilirubin into a substance that can be eliminated by the body and can result in significant neurological damage and death if not treated quickly. At present, patients must undergo phototherapy for up to 12 hours a day to keep their bilirubin levels below the toxicity threshold.

**The outcome of the ongoing clinical study of GNT-0003 could potentially form the basis for a MAA or BLA application in Europe or the U.S.**



# Shareholder information

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## Shareholder information

Hansa Biopharma's shares are listed on Nasdaq OMX Stockholm, under the ticker HNSA

They are included in several indexes including, but not limited to:

- > OMX Nordic Mid Cap
- > OMX Stockholm Health Care
- > OMX Stockholm Mid Cap
- > OMX Stockholm Pharmaceuticals & Biotechnology

### Brief facts, the Hansa Biopharma-share

According to the shareholder register maintained by Euroclear Sweden AB, as of 31 December 2023, Hansa Biopharma had approximately 20,000 shareholders, compared to approximately 19,000 shareholders as of 31 December 2022. Information regarding shareholders and shareholdings is updated each quarter on the Company's website, [hansabiopharma.com](https://hansabiopharma.com).

### Share capital

Total shares issued as of 31 December 2023 amounted to 52,443,962 ordinary shares outstanding and 2,590,279 C-shares. At year end 2023, the share capital amounted to SEK 55,034,241. At the general meeting, each ordinary share entitles the holder to one vote and each shareholder may vote the full number of shares held by him or her. All outstanding shares are fully paid up. The Company's share capital is denominated in Swedish kronor (SEK) and divided among the Company's shares with a quotient value of SEK 1 per share.

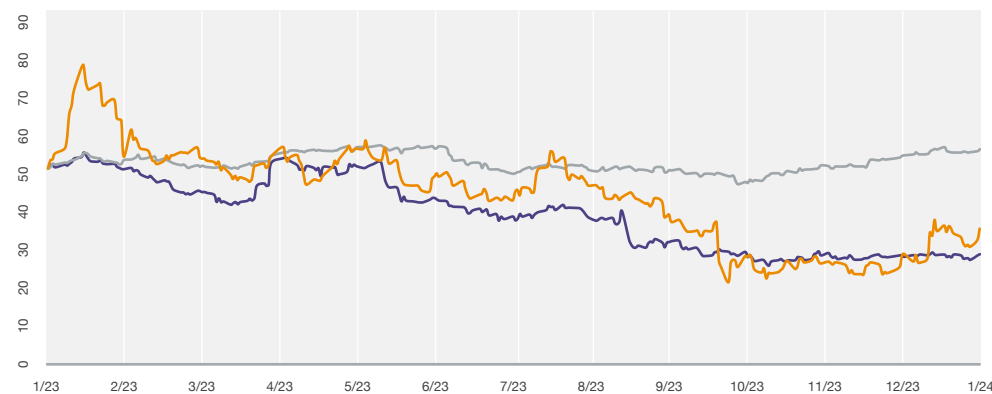
### Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	55,034,241 (52,671,796 A-shares and 2,362,445 C-shares)
Market Cap December 31, 2023	SEK ~1.45bn (USD ~140m)
Ticker	HNSA
ISIN	SE0002148817

### Price development for the HNSA share in 2022 and 2023

SEK	2023		2022	
	High	Low	High	Low
1st quarter	76.9	46.0	97.8	50.8
2nd quarter	58.1	41.02	70.5	47.5
3rd quarter	55.3	33.52	105.8	47.2
4th quarter	36.54	20.14	66.9	47.7

### Hansa share price development versus peer group<sup>1</sup> during 2023



■ OMXS Health Care ■ Peer group ■ HNSA

<sup>1</sup> Peer group consist of Scandinavian biotech and pharmaceutical companies with negative EBIT and 1-year average market cap of SEK 1bn to SEK 5bn



## Ownership and analyst coverage

### Top 10 shareholders as per December 31, 2023

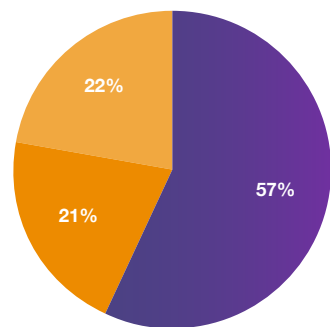
Owners	Number of shares HNSA	Capital (%)
Redmile Group, LLC	9,653,214	18.3%
Nexttobe AB	2,155,379	4.1%
Jeansson, Theodor	2,100,000	3.7%
Olausson, Thomas	1,917,000	3.6%
Försäkrings AB Avanza Pension	1,765,506	3.4%
Fjärde AP-Fonden (AP 4)	1,700,000	3.2%
Tredje AP-Fonden (AP 3)	1,389,650	2.6%
Max Mitteregger Kapitalförvaltning AB	725,000	1.4%
VOB & T Trading AB	644,800	1.2%
BWG Invest SARL	600,000	1.1%
Other	30,021,247	57.0%
<b>Total</b>	<b>52,671,796</b>	<b>100.0%</b>

### Analyst coverage 2023 and 2024

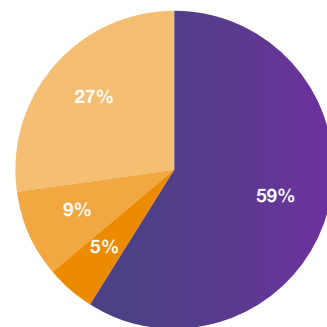
Analyst	Bank / Research institution (year of initiation)	Location	Email	Phone
Christopher Uhde	SEB (2016)	Stockholm	christopher.uhde@seb.se	+46 (0) 876 385 53
Gonzalo Artiach Castañón	ABG Sundal Collier (2018)	Stockholm	gonzalo.artiach@abgsc.se	+46 (0) 733 217 396
Johan Unnerus	Redeye (2008)	Stockholm	johan.unnerus@redeye.se	+46 (0) 724 023 385
Suzanne van Voorthuizen	Van Lanschot Kempen (2019)	Amsterdam	s.vanvoorthuizen@vanlanschotkempen.com	+31 629 713 490
Erik Hultgård	Carnegie (2019)	Stockholm	erik.hultgard@carnegie.com	+46 (0) 858 869 237
Naresh Chouhan	Intron Health Research (2020)	London	naresh@intronhealthresearch.com	+44 7939 224 322
Lars Hatholt	Ökonomisk Ugebrev (2020)	Copenhagen	hatholt@outlook.com	+45 22 23 78 15
Douglas Tsao	H.C. Wainwright & Co. (2021)	New York City	dtsao@hwcwresearch.com	+1 212 916 3968
Ludvig Svensson	Erik Penser Bank (2021)	Stockholm	ludvig.svensson@penser.com	+46 (0) 704 962 535
Matt Phipps	William Blair (2023)	Chicago	mhipps@williamblair.com	+1 312 364 8602
Alex Cogut	Bryan, Garnier & Co. (2023)	Paris	acogut@bryangarnier.com	+31 651 310 426

### Ownership by type and location, June 2023

Ownership by country



Ownership by type



#### Split by region

■ Sweden  
■ United States

■ Europe & UK

#### Investor type

■ Institutions & funds

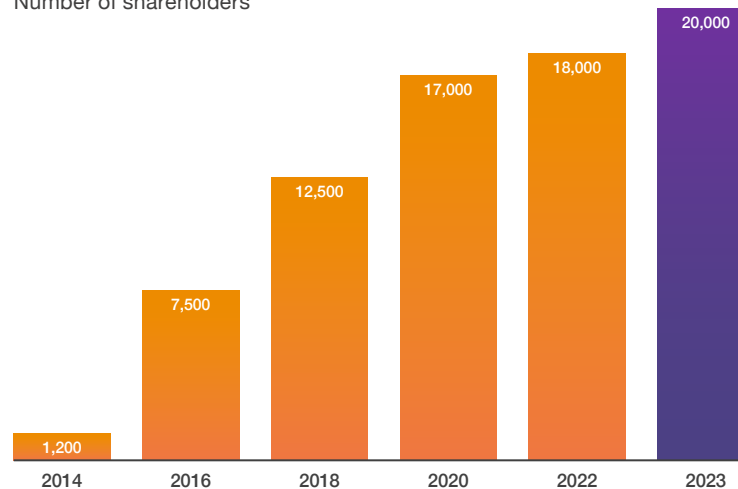
■ Other incl. VC

■ High net-worth

■ Retail

Source: S&P Global compiled and processed data from various sources, including Euroclear, Morningstar, Factset and the Swedish Financial Supervisory Authority (Finansinspektionen)

Number of shareholders





# Directors' report

2023 Directors' report

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## 2023 Directors' report

### Operations

Hansa is a commercial-stage biopharmaceutical company pioneering the development and commercialization of innovative, life-saving and life-altering treatments for patients with rare immunological conditions.

The Company has developed a proprietary antibody-cleaving enzyme technology platform to target pathogenic or disease-causing antibodies. Its broad therapeutic pipeline has potential applications across transplantation, autoimmune diseases, gene therapy and oncology indications addressing significant unmet medical needs. Hansa's first-generation IgG-cleaving enzyme, imlifidase, is designed to inactivate IgG antibodies in the plasma and tissue through a single intravenous treatment. In 2020, Idefirix® (imlifidase) received conditional approval from the European Commission for desensitization treatment of highly sensitized adult kidney transplant patients, who may not otherwise be able to receive a new kidney. Additionally, the Company is running a phase 3 study to support the approval of imlifidase in the U.S. for the same indication.

Hansa is also currently evaluating imlifidase across a wide spectrum of both potential disease areas and indications in an effort to address significant unmet medical needs. Its broad pipeline spans pre-kidney transplantation desensitization and post-transplantation antibody-mediated organ rejection, or AMR, and rare, mono-phasic IgG-mediated autoimmune conditions such as anti-glomerular basement membrane, or anti-GBM, antibody disease and Guillain-Barre Syndrome, or GBS.

Through collaborations with Sarepta Therapeutics, Inc., Asklepios BioPharmaceutical, Inc. (AskBio) and Genethon, Hansa is also evaluating imlifidase as a pre-treatment prior to gene therapy to potentially allow the treatment of patients with pre-existing neutralizing antibodies against gene therapy vectors.

Beyond imlifidase, the Company is also pursuing a second-generation IgG-cleaving enzyme program, NiceR. It is designed to enable expansion into a large spectrum of potential indications, including relapsing autoimmune diseases and gene therapy, as well as oncology indications. In 2023, Hansa started the clinical development phase with its second generation lead molecule HNSA-5487 and reported positive results from its first in-human trial with HNSA-5487. Analysis of additional exploratory endpoints on IgG recovery and immunogenicity is currently being conducted with results expected to become available during 2024. During 2024, Hansa also aims at selecting the lead indication for the further clinical development of HNSA-5487.

Hansa Biopharma is headquartered in Lund, Sweden, is listed on Nasdaq Stockholm, and also has operations in other European countries and in the U.S.

### 2023 Business review

2023 was year marked by significant progress across Hansa Biopharma's commercial and R&D operations. The Company remains focused on advancing cutting-edge science and delivering new treatments in areas of high unmet need, including autoimmune diseases, gene therapy enablement, and desensitization in kidney transplantation.

The Company progressed the launch of and market access efforts for Idefirix® in Europe, securing reimbursement in a number of additional markets, including Spain which completed access to the key 5 European markets. Market access is now secured in 14 European countries, representing 75% of transplant volumes in Europe. In Australia, Idefirix (imlifidase) received provisional approval as desensitization treatment for highly sensitized patients prior to kidney transplantation from both living and deceased donors.

Product sales of Idefirix increased to SEK 104 million with a strong Q4-2023 performance contributing SEK 43 million in sales. In addition, medical guidelines and recommendations including the use of Idefirix® were implemented on a national level in U.K., Finland, France, Belgium and the Netherlands. And Eurotransplant launched a desensitization program as a pilot in June 2023 initially targeting 20 imlifidase-eligible patients under the Acceptable Mismatch Program.

Also, Hansa announced 5-year data from the long-term follow-up study of imlifidase in kidney transplantation confirming sustained benefit through year 5, demonstrating 90% patient survival and 82% graft survival in extended pooled analysis with data from the 17-HMedldeS-14 study.

With regard to its development programs, Hansa continued to make progress across its pipeline.

In March, Hansa completed enrolment to its phase 2 trial with imlifidase in Guillain-Barré Syndrome, and in December we reported positive safety, tolerability, and early efficacy results from the trial. In May, Hansa dosed the first patient in its phase 3 trial in anti-GBM disease with imlifidase and by February 2, 2024, 18 out of 50 targeted patients have been enrolled.

The Company also continued to progress enrolment and randomization related to its ConfideS study, the ongoing pivotal, phase 3 trial in kidney transplantation in the US. As of February 2, 2024, 104 patients have been enrolled and 40 have been randomized.

Full data of the phase 2 trial in AMR was published in December. Imlifidase met the primary endpoint; explorative secondary outcome measures were not designed nor sufficiently powered to show statistical significance versus the control arm.

In the first quarter, Hansa initiated the clinical program for HNSA-5487, the Company's lead candidate in the Novel Immunoglobulin Cleaving Enzymes for Repeat Dosing (NiceR) program. In October, Hansa announced encouraging high-level results from its first-in-human trial with HNSA-5487 showing the molecule was safe and well tolerated with fast and complete depletion of immunoglobulin G (IgG) antibodies at increasing doses in all 36 male and female participants.

Hansa also further strengthened its gene therapy franchise by entering into its third gene therapy collaboration. The collaboration with Genethon will evaluate imlifidase as a pre-treatment to gene therapy GNT-0003 in Crigler-Najjar syndrome. In addition, Sarepta initiated the first clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in Duchenne Muscular Dystrophy (DMD).



## 2023 Directors' report continued

During 2023, Hansa also strengthened its senior leadership team – in March, Matthew Shaulis joined Hansa as Chief Commercial Officer and president of the U.S. operations. In December, Dr. Hitto Kaufmann joined Hansa as Chief Scientific Officer assuming responsibility for all research, early development, translational and manufacturing activities.

Further, in December, Hansa announced its plans to restructure the organisation to better align and focus on key clinical development and commercial priorities, including a reduction in workforce of approximately 20 – 25%. The restructuring was initiated in December and is expected to complete during the first half of 2024.

### Risk management

Hansa is committed to effective risk management. Risk management is recognized as an integral part of good management practice and is a basis for the Company to achieve its objectives and strategies. Hansa's risk management policy was launched in 2015 and substantially revised in 2020. The policy forms part of Hansa's quality management system and is reviewed on a regular basis. It provides management with a facilitating framework of guidance when dealing with risks inherent in achieving the organization's objectives and, specifically, to:

- > Establish a common organizational approach to risk management to ensure consistent and efficient risk identification, assessment, and control
- > Raise awareness of the need for risk management
- > Integrate risk management into the Company culture and processes
- > Establish defined roles, responsibilities, and reporting structures for risk management

Hansa's executive management and the Board of Directors regularly discuss the Company's key risks and respective risk management.

### Risk factors

Hansa's business is influenced by several factors, the effects of which on the Company's earnings and financial position, in certain respects, cannot be controlled by the Company at all or in part. In an assessment of the Company's future development and business prospects, it is important, alongside the possibilities for growth in earnings, to also consider these risks.

Set forth below is a description, without any internal order of priority, of the risks which are considered to have the highest level of significance on the Company's future development. For natural reasons, not all the risk factors can be described. Instead, the risks which are specific to the Company, or the industry are set forth here. It is important to also note that the significance of risks may change over time – risks which are not considered significant may become significant over time despite not being listed below. An overall assessment must also include other information contained in the annual report as well as an overall assessment of extraneous factors in general.

### Financial risks

Hansa carries out capital-intensive and value generating pharmaceutical development and

commercialization. Future financing of its operations is expected to take place either through new issues of shares, loans, structured financing, convertible bonds, licensing revenue, cooperation with other parties, the sales of rights and/or patents or a combination of any the above. The Company has, since the start of its operations, incurred net losses and cash flow is expected to remain negative for the foreseeable future until the Company generates substantial revenues from any marketed product. The Company has historically financed its operations primarily through equity financings, and in addition, in 2022, took up a long-term loan with NovaQuest to help financing future operations.

Under the NovaQuest loan agreement Hansa is obliged to repay a total amount of USD 140 million in the form of milestone or catch-up and royalty-based payments over an approximately 3-year period, starting no later than early 2026. In connection with the loan agreement, Hansa has also entered into a security agreement under which it pledges and provides a broad security interest to NovaQuest in and to certain assets, proceeds and IP rights related to imlifidase in kidney transplantation in highly sensitized patients and anti-GBM disease (the "Pledged Assets"). Please refer to Note 21 to the Consolidated Financial Statements for further information on the NovaQuest loan.

If the Company is not able to repay the loan as per the foreseen royalty, milestone or catch-up payments amounts and dates, or any other defaulting event occurs, NovaQuest may take ownership of all or a portion of the Pledged Assets, which may substantially limit or make it impossible for Hansa to continue to research, develop or commercialize imlifidase. This will significantly harm the Company's business, financial position and earnings.

The Company has devoted substantially all of its resources on, inter alia, raising capital, organizing and staffing the company, business planning, development, regulatory approval and commercialization of imlifidase and other candidates and protecting the Company's intellectual property portfolio. The Company expects that it will be several years, if ever, before the Company has commercialized imlifidase in any major jurisdictions other than Europe or any other product candidates. The Company expects to continue to incur significant expenses and increasing operating losses for the foreseeable future.

If the Company is not able to continue to finance its operations this may result in the Company being unable to continue operations and as a result significantly harm the value of the Company and thus the share price of the Company. For further description of the Company's financial risks, see Note 20 to the Consolidated Financial Statements.

### Risks related to public health crisis, geopolitical factors and cyberattacks

The global outbreak of COVID-19 did have, and partly still has, certain negative impact on economies and businesses globally. A continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on the Company's business, financial condition, and operating results. To the extent any potential future public health crisis adversely affects the Company's business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk factors" section, such as those relating to the Company's clinical development, the supply chain for the Company's commercial and clinical supply, the availability of



## 2023 Directors' report continued

governmental and regulatory authorities, and the success of the Company's commercial operations in Europe and potential other territories.

In February 2022, Russia invaded Ukraine. Hansa does not have any operations in nor collaborations with any third-party service providers from either Ukraine or Russia. Therefore, Hansa's operational activities are not directly affected by the conflict. However, the conflict did, and may continue to have general negative impacts on the global economy, stock markets, exchange rates, energy prices, global supply, and free trade, and, as such, may indirectly negatively impact Hansa's business.

In October 2023, Israel was attacked by Hamas. Hansa has entered into a partnership with Israel-based Medison Pharma to commercialize Idefirix (imlifidase) in kidney transplantation in Israel and certain eastern European countries. The partnership and Hansa's operational activities have, as of the date of this report, not been directly negatively affected. However, the conflict may in future, either directly or indirectly, have significant negative impact on Hansa's partnership with Medison Pharma potentially resulting in a significant negative impact on Hansa's business, its financial results and conditions.

Any potential future geopolitical crises may have significant negative impact on Hansa's business and business partners.

Threats in the form of cyberattacks can exploit the Group's systems and processes and give rise to security incidents that may affect the Company's information assets, technology, products or services. These cybersecurity incidents can include ransomware or other malicious attacks, intrusions, exploitation of system vulnerabilities, leakage of confidential or sensitive data, and unauthorized use or modification of data. The Group's systems and applications can be expected to be subject to cybersecurity incidents that could cause serious harm to the Group and could adversely affect the Group's operations, financial results, relationships with business partners, creditworthiness and reputation and could result in litigations or regulatory investigations or actions as well as increased costs of remediation and compliance.

### Product development, regulatory approval, and commercialization

The Company operates procedures to secure the integrity and protection of its R&D and commercial activities and data, and to optimize allocation of budgets and resources.

Nevertheless, due to limited resources and access to capital, the Company must and have in the past decided to prioritize development of certain product candidates; these decisions may prove to have been wrong and may adversely affect Hansa's business. The Company is heavily dependent on the success of its product candidate imlifidase. Hansa is also dependent on the success of its other product candidates, for example in the NiceR program.

The Company cannot give any assurance that any product candidate will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized. Hansa's business and

future success is substantially dependent on its ability to develop successfully, obtain regulatory approval for, and then successfully commercialize its product candidate imlifidase and its other product candidates. Hansa is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA, the EMA or any other comparable regulatory authority, and Hansa may never receive such regulatory approval for any of its product candidates, or, if approved, such approval may be revoked if an approved product is later found to be unsafe or lack efficacy.

The Company cannot give any assurances that its clinical trials for imlifidase or its other product candidates will be completed in a timely manner, or at all. If imlifidase or any other product candidate is not approved and/or commercialized, Hansa will not be able to generate any revenues for that product candidate.

The regulatory approval processes of the FDA, the EMA and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if the Company is ultimately unable to obtain (full) regulatory approval for its product candidates, Hansa's business will be substantially harmed.

Clinical testing is expensive and does take many years to complete, and its outcome is inherently uncertain. Results of earlier studies and trials as well as data from any interim analysis of ongoing clinical trials may not be predictive of future trial results and failure can occur at any time during the clinical trial process. If Hansa experiences delays in the completion of any clinical trial of its product candidates, the commercial prospects of the product candidates may be significantly harmed, and Hansa's ability to generate revenues from any of these product candidates will be delayed and/or significantly reduced. If imlifidase or any other product candidate is found to be unsafe or lack efficacy, Hansa will not be able to obtain regulatory approval for it and its business will be materially harmed.

The rates at which Hansa completes its scientific studies and clinical trials depend on many factors, including, but not limited to, patient enrolment. Patient enrolment is a significant factor in the timing of clinical trials and is affected by many factors including competing clinical trials, clinicians', and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies and the relatively limited number of patients. Any of these factors may harm Hansa's clinical trials and by extension, Hansa's business, financial condition, and prospects.

The Company's product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following potential marketing approval. Undesirable side effects caused by our product candidates could cause Hansa or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval, or if approved, market withdrawals, by the FDA, the EMA, or other comparable regulatory authorities. The drug-related side effects could negatively affect patient recruitment or the ability of enrolled patients to complete a trial, the commercial prospects or result in potential product liability claims. Any of these occurrences may harm Hansa's business, financial condition, and prospects significantly. Box warnings, labelling restrictions, dose limitations and similar restrictions on use could



## 2023 Directors' report continued

have a material adverse effect on Hansa's ability to commercialize imlifidase or any other product candidate, if approved, in those jurisdictions where such restrictions apply.

If the Company is not able to maintain orphan product exclusivity for imlifidase or obtain such status for other or for future product candidates for which it seeks this status, or if the Company's competitors are able to obtain orphan product exclusivity before the Company does, it may not be able to obtain approval for its competing products for a significant period of time.

Hansa's commercial success depends upon attaining significant market acceptance of its product candidates, if approved, among physicians, healthcare payers, patients, and the medical community. Coverage and reimbursement decisions by third-party payers may have an adverse effect on pricing and market acceptance. Legislative and regulatory activity may exert downward pressure on potential pricing and reimbursement for any of Hansa's commercial products and/or product candidates, if approved, that could materially affect the commercial opportunity.

### Collaboration and partnerships

The Company has entered and may in future enter into agreements with 3rd party partners related to the research, development and/or commercialization of Hansa's product candidates and/or commercial products, such as with Genethon, Sarepta Therapeutics, Inc., Medison Pharma, IQone Healthcare Switzerland and Asklepios BioPharmaceutical, Inc. Such partnerships and agreements may be terminated, unsuccessful, not achieve the intended results and outcomes, not meet Hansa's objectives or expectations, and therefore materially negatively impact Hansa's business, its financial position, and earnings prospects.

### Reliance on Contract Manufacturing Organisations (CMOs)

The manufacturing and packaging process for imlifidase is made in collaboration with several contract manufacturers/packagers in Europe.

Hansa is dependent on the quality of the manufacturing and packaging processes, as well as the availability and maintenance of the production facilities. Regulatory authorities require that all manufacturing processes and methods, as well as all equipment, comply with current requirements of Good Manufacturing Practice (GMP). Respective consequences for the Company in the event of deficiencies in GMP requirements, and potential withdrawal of approval from the regulatory authorities for those facilities providing the services, may lead to delays in or the inability to supply the product for clinical trials or commercialization which will significantly negatively affect the Company's earnings and future prospects. In addition to the compliance risk of our collaborators, the Company is exposed to business continuity risk as our collaborator's facilities might be damaged, destroyed or not have sufficient capacity for other reasons. This may lead to the Company not being able to continue clinical trials or sell its products which will significantly negatively affect the Company's earnings and future prospects.

### Reliance on Contract Research Organisations (CROs)

The Company has relied upon and will continue to rely upon third-party contract research

organizations, or CROs, to conduct, monitor and manage its preclinical and clinical programs. The Company relies on these parties for execution of its preclinical studies, analytical and laboratory work, data management and analysis, and clinical trials and controls only certain, limited aspects of the CRO's activities. Nevertheless, the Company is responsible for ensuring that each of its trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and its reliance on a CRO or any other vendor does not relieve Hansa of its regulatory responsibilities. If Hansa or any of its CROs or vendors fail to comply with applicable regulations, the data generated in Hansa's preclinical studies, analytical and laboratory work and/or clinical trials may be deemed incomplete or unreliable, and the EMA, FDA or other regulatory authorities may require Hansa to repeat or perform additional preclinical studies, analytical and laboratory work and/or clinical trials before potentially approving Hansa's marketing applications.

If any of the relationships with these third-party CROs terminates, the Company may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms, which may result in any preclinical studies, analytical and laboratory work and/or clinical trials having to be stopped prematurely rendering such studies, trials and work unusable for any purposes and the Company may not be able to obtain regulatory approval for or successfully commercialize its product candidates.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data, they obtain is compromised due to the failure to adhere to Hansa's protocols, regulatory requirements or for other reasons, Hansa's pre-clinical and/or clinical trials may be extended, delayed, or terminated, and the Company may not be able to obtain regulatory approval for or successfully commercialize its product candidates. CROs may also generate higher costs than anticipated. As a result, the Company's results of operations and the commercial prospects for its product candidates would be harmed, Hansa's costs could significantly increase, and the Company's ability to generate revenue could be delayed, reduced or destroyed.

### Intellectual property

The value of Hansa Biopharma is largely dependent on its ability to obtain and defend patents and its ability to protect specific know-how. Patent protection for biomedical and biotech companies may be uncertain and involve complicated legal and technical questions. There is significant risk that a patent sought will not be granted for an invention, that the patent granted will not provide sufficient protection, or that the patent granted will be circumvented or revoked.

If the Company fails to obtain and/or maintain patent protection and trade secret protection for its product candidates and/or commercial products, it could lose its competitive advantage and the competition the Company faces would increase, reducing or eliminating any potential revenues and adversely affecting its ability to attain or maintain profitability, impacting the Company's future prospects and valuation significantly.

In connection with the NovaQuest loan agreement, Hansa has also entered into a security agreement under which it pledges and provides a broad security interest to NovaQuest in and to certain assets,



## 2023 Directors' report continued

proceeds and IP rights related to imlifidase in kidney transplantation in highly sensitized patients and anti-GBM disease (the "Pledged Assets"). Please refer to the "Financial Risks" sub-section further above and Note 21 to the Consolidated Financial Statements for further information on the NovaQuest loan.

If the Company is not able to repay the loan as per the foreseen royalty, milestone or catch-up payments amounts and dates, or any other defaulting event occurs, NovaQuest may take ownership of all or a portion of the Pledged Assets, which may substantially limit or make it impossible for Hansa to continue to research, develop or commercialize imlifidase. This will significantly harm the Company's business, financial position and earnings.

### Dependence on key product

The Company has a concentrated pipeline in transplantation and autoimmune diseases. The value of the Company is primarily dependent on success in the Company's first-generation molecule imlifidase and the second-generation molecule, HNSA-5487. The market value of the Company, and thus the Company's share price, might be significantly negatively impacted or entirely lost by setbacks related to imlifidase and/or HNSA-5487.

### Market and competition

The product candidates Hansa has under development, and any commercial product, risk being exposed to competition from new pharmaceuticals and/or diagnostic methods. Developing a new pharmaceutical from invention to an approved product requires a long time. Not the least for this reason, when development is underway it is uncertain whether there will be any market for the product when it is finally developed and, in such case, how large this market will be, as well as which competing products the Company's products will encounter when they reach the market. To the extent competition consists of existing preparations or methods, Hansa's success is dependent on its ability to induce potential customers to replace known products or methods with those of Hansa.

Another risk is that competitors, who in many cases have greater resources than the Company, will develop alternative preparations that are more effective, more secure, or cheaper than those offered by Hansa. This may lead to the Company facing limited sales or not being able to sell its products at all which may negatively affect the Company's earnings.

### Pricing and reimbursement

On many markets, purchases of pharmaceuticals of the type being developed or commercialized by the Company are financed, in whole or in part, by a party other than the patient, for example, caregivers, insurance companies or governmental authorities subsidizing pharmaceuticals. If the Company does not achieve acceptance for its commercial products and pricing and reimbursement of the products by such financiers, it may make it more difficult or impossible for the products to reach the market and may prejudice their commercial potential, which may negatively affect the Company's earnings and financial position.

### Dependence on key persons

Hansa is, to a high degree, dependent on key persons, both employees as well as directors. The

Company's future earnings are affected by its ability to attract and retain qualified key persons. In cases where one or more key persons leave the Company and the Company is not successful in replacing such person(s), this might harm the Company's business, financial position and earnings.

### Sustainability and social responsibility

Hansa Biopharma (Hansa) believes that all patients with rare immunologic diseases deserve to lead a long and healthy life. To make this a reality, our efforts to advance innovative science and deliver new medicines must be done within the context of sustainability. To that end, we have identified key priorities that reflect both external requirements and standards as well as where our business is today. Hansa's Sustainability reporting aligns with the Global Reporting Initiative standards (GRI), the world's most widely used sustainability reporting standards and continually review changes and updates to the reporting legislation.

In 2022, Hansa conducted a stakeholder engagement and material assessment and developed a strategic approach to align with the United Nations (UN) Sustainable Development Goals - action for people, the planet, and prosperity. Hansa also took into consideration the Global Reporting Initiative's (GRI) reporting standard. No changes have been made to our material topics since the 2022 Sustainability Report. In 2024 we plan to conduct a double materiality analysis to align with upcoming EU regulations and requirements.

### Employees – Personal development – Equality & Inclusion – Work environment

Talent remains the most important asset at Hansa – our employee base of highly skilled individuals are based around the globe who cultivate a culture of inclusivity and diversity, dedicated to enabling all employees to develop and grow while offering a healthy and safe work environment. Our company values provide a framework for how we work and interact with one another and our external stakeholders. As a culture grounded in authentic, transparent communications and with a shared purpose in mind, Hansa is able to advance innovative science and deliver new medicines in areas of highest unmet need. Please refer to Hansa's Sustainability Report at [www.hansabiopharma.com](http://www.hansabiopharma.com)

### Revenue and financial result for the Group

The Group consists of the parent company, Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc., Hansa Biopharma Australia PTY LTD and Hansa Biopharma Italy S.r.l. Hansa Biopharma Italy S.r.l. was registered in July 2023 to support commercialization in Italy. The subsidiary had no employees as of December 31, 2023. Hansa Biopharma Inc had ten employees at the end of December 2023. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had seven employees at the end of December 2023.

Revenue for 2023 amounted to SEK 134.1 million (2022: SEK 154.5m) and comprises of product sales in the amount of SEK 103.7 million (2022: 86.7m), revenue recognition from the upfront payment the Company received under the Sarepta and AskBio agreements in the amount of SEK 27.4 million (2022: 64.3m), and royalty income and cost reimbursements from Axis-Shield Diagnostics (Abbott group) in the amount of SEK 3.0 million (2022: 3.5m).





## 2023 Directors' report continued

The loss from operations for 2023 amounted to SEK 788.5 million (2022: SEK 588.6m). Compared to 2022, 2023 expenses have increased primarily in line with the progress in and expansion of Hansa's R&D activities; more specifically, the ongoing phase 3 clinical trial in anti-GBM disease, the post-approval commitments in Europe and investments in Hansa's lead molecule HNSA-5487 of its second-generation enzyme program which was taken into the clinic during 2023. The result for 2023 includes non-cash expenses related to the Company's long-term incentive programs (LTIP) amounting to SEK 60.6 million (2022: SEK 58.2m).

Finance income for 2023 amounted to SEK 63.2 million (2022: SEK 27.2m) and is mainly resulting from interest income and positive currency effects on financial assets and liabilities. Finance expenses amount to SEK 105.5 million (2022: SEK 48.6m) and mainly relate to interest expenses on the long-term loan taken-up in July 2022.

The loss for 2023 amounted to SEK 831.7 million (2022: SEK 611.1m).

### Cash flow and financial position

Net cash used in operating activities amounted to SEK 755.7 million in 2023 (2022: 502.7m). The increase in cash consumption is in line with the growth in Hansa's commercial spend and R&D investments, partly offset by increased product sales.

Cash and cash equivalents amounted to SEK 732.1 million as of December 31, 2023 (SEK 1,496.2m as of December 31, 2022), which is expected to finance Hansa's operations into 2025.

In July 2022, Hansa completed a non-dilutive debt-financing of USD 70 million and in December 2022 it raised USD ~40 million by the placement of 7.8 million ordinary shares in a directed share issue. Together, the two financing events contributed SEK 1,124.6 million in proceeds net of transaction cost.

### Capital expenditures

Capital expenditures during 2023 amounted to SEK 0.3 million (2022: SEK 3.3m).

### Shareholders' equity, consolidated for the Group

On December 31, 2023, shareholders equity amounted to SEK -167.9 million compared to SEK 602.9 million at the end of the financial year 2022.

### Parent Company

The Parent Company's revenue for 2023 amounted to SEK 134.1 million (2022: SEK 154.5m). The loss for the period for the Parent Company amounted to SEK 595.5 million for 2023 (2022: SEK 596.7m). On December 31, 2023, cash and cash equivalents amounted to SEK 715.5 million compared to SEK 1,486.5 million at the end of the year 2022.

The Parent Company's shareholders equity amounted to SEK 1,216.9 million as per December 31, 2023, compared to SEK 615.8 million at the end of 2022.

### Five-year summary, consolidated for the Group

KSEK, unless other stated	2023	2022	2021	2020	2019
Revenue	134,094	154,525	33,878	6,098	3,364
Sales, general and administration expenses	(450,492)	(337,861)	(327,269)	(202,987)	(167,310)
Research and development expenses	(411,332)	(346,244)	(230,764)	(227,191)	(192,949)
Other operating income (expenses)	2,377	(20,532)	(7,398)	2,270	(1,907)
Loss from operations	(788,496)	(588,588)	(546,978)	(422,807)	(359,668)
Loss for the period	(831,720)	(611,134)	(548,282)	(420,853)	(360,009)
Net cash used in operating activities	(755,654)	(502,733)	(481,168)	(290,274)	(334,775)
Cash and cash equivalents, including short-term investments	732,060	1,496,179	888,961	1,377,506	601,094
Earnings per share before and after dilution (SEK)	(15.83)	(13.60)	(12.33)	(9.98)	(9.00)
Number of outstanding shares at the end of the period	52,671,796	52,443,962	44,473,452	44,473,452	40,026,107
Weighted average number of shares before and after dilution	52,540,089	44,923,998	44,473,452	42,176,872	40,020,429
Number of FTE's end of the period	168	150	131	87	74

### Share capital and ownership

The Company is authorized to issue 80,000,000 shares. Two classes of shares may be issued, ordinary shares (Class A) and Class C shares and together they may not exceed 80,000,000.

Total shares issued as of 31 December 2023 comprised of 52,671,796 ordinary shares and 2,362,445 C-shares held by the Company as treasury shares. During 2023 the Company issued 227,834 of new ordinary shares to deliver shares under its long-term incentive plan LTIP 2020 by conversion of the respective amount from C-shares the Company holds as treasury shares. Each share has a nominal value of SEK 1 resulting in SEK 55,034,241 share capital and SEK 52,671,796 in outstanding share capital as of 31 December 2023.

At the general meeting, each ordinary share entitles the holder to one vote and C-shares to one tenth of a vote each. C shares are not entitled to dividends. Each shareholder may vote the full number of shares held by him or her. The Company's share capital is denominated in Swedish kronor (SEK) and divided amongst the Company's outstanding shares with a quotient value of SEK 1 per share. As per December 31, 2023, the single largest shareholder in Hansa was Redmile Group LLC, with a total of 9,653,214 shares, representing 18.3 percent of the voting rights and the outstanding share capital.

### Share-based compensation programs

Hansa uses share-based long-term compensation programs to create conditions for motivating and retaining



## 2023 Directors' report continued

key employees and to align interests and long-term objectives between the shareholders and the Company, as well as to incentivise meeting and exceeding the Company's business and financial targets.

As in certain previous years, and upon the proposal of Hansa's Board of Directors, the AGM resolved to adopt a long-term, share-based compensation program in 2023.

### 2023 Long-term incentive program

Hansa's Annual General Meeting (the "AGM") on June 29, 2023 resolved to adopt a long-term incentive program, LTIP 2023, based on (a) performance-based share rights and (b) employee stock options.

#### LTIP 2023 based on performance-based share rights

Under the terms of LTIP 2023 key employees may participate in the program and may receive so-called performance-based share awards free-of charge (a "Share Right") which, provided certain pre-defined Performance Conditions (as briefly summarized below) and other criteria are met, give the participants the right to acquire ordinary shares in Hansa Biopharma AB at no cost. Each Share Right represents the right to acquire one share in Hansa Biopharma AB and carries a vesting period of three years commencing on the day of its allotment to a participant (the "Vesting Period").

The final number of ordinary shares a participant is entitled to receive is, amongst other terms, conditional upon meeting the following performance conditions during the Vesting Period:

- > 30 per cent of the Performance Shares in the event the U.S. FDA has approved imlifidase in the U.S. in any indication ("Performance Condition 1"),
- > 25 per cent of the Performance Shares in the event of completion of a phase 2 trial with HNSA5487 in any indication or a pivotal anti-GBM trial with imlifidase ("Performance Condition 2"),
- > 25 per cent of the Performance Shares in the event that more than 50 per cent of the targeted transplantation centers in Europe had repeat business, i.e. used Idefirix more than once ("Performance Condition 3"), and
- > 20 per cent of the Performance Shares related to the total shareholder return (the return to shareholders through an increased share price and reinvestments of any dividends during the Vesting Period) on the company's ordinary shares ("Performance Condition 4"). This entails that participants will under Performance Condition 4 be entitled to 20 per cent of the Performance Shares if the total shareholder return out-performs the Benchmark Index (as defined below) by 10 per cent or more. If the total shareholder return during the Vesting Period is less than the performance of the Benchmark Index, no allotment of Performance Shares will be made under Performance Condition 4. If the total shareholder return, as compared to the Benchmark Index, is either equal or out-performing by up to 10 per cent, allotment will be made linearly. The benchmark for assessing the total shareholder return under Performance Condition 4 should be the EURO STOXX Total Market Biotechnology Index (EUR) (the "Benchmark Index") at constant EUR/SEK exchange rate.

A maximum of 800,000 Share Rights may be allotted to participants under LTIP 2023 from the day following the 2023 AGM up and until the day prior to the AGM in 2024.

As of December 31, 2023, 643,000 Share Rights are allotted to plan participants under LTIP 2023.

#### LTIP 2023 based on stock options

The 2023 AGM also resolved to adopt an employee stock option program under the terms of LTIP 2023. Senior executives may participate in the program and receive employee stock options free-of-charge.

Each employee stock option entitles the holder to receive one new ordinary share in Hansa Biopharma AB at an exercise price of SEK 28.50 corresponding to 110 per cent of the volume weighted average share price during the 30 trading days immediately prior to the offer to subscribe for the employee stock options, and provided that the participant, with certain exceptions, from the date of the start of participation in LTIP 2023 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

A maximum of 600,000 employee stock options may be allotted to participants under LTIP 2023 from the day following the 2023 AGM up and until the day prior to the AGM in 2024.

As of December 31, 2023, 480,000 employee stock options are allotted to plan participants under LTIP 2023.

Expenses related to share rights and employee stock options are reported in accordance with IFRS 2. The total expenses including social security contributions for the share rights and options under LTIP 2023 allotted as of December 31, 2023, is expected to amount to approximately SEK 24.4 million, of which SEK 1.0 million is included in the results for the Group for the year 2023.

Please refer to Notes 2 and 14 to the Consolidated Financial Statements for further information and previously adopted share-based compensation programs.

#### 2023 Guidelines for remuneration to senior executives

A prerequisite for the successful implementation of the Company's business strategy and safeguarding of its long-term interests, including its sustainability, is that the Company is able to recruit and retain qualified personnel, consequently, it is necessary that the Company offers market competitive remuneration.

The 2023 guidelines are unchanged compared to the guidelines adopted by the 2022 annual general meeting and entail that senior executives, i.e. the CEO and members of the executive committee, will be offered remuneration which is competitive and on market terms. The level of the remuneration for the individual senior executive shall be based on factors such as complexity and responsibility of the position, expertise, experience, and performance. The remuneration consists of a fixed base salary and pension



## 2023 Directors' report continued

benefits and, in addition, may consist of a variable cash remuneration, performance-based short-term incentive (STI), share based long-term incentive programs (LTIP) as resolved by a general meeting, severance remuneration, and other benefits. The STI shall be based on the achievement of quantitative and qualitative performance targets and shall not exceed 75 percent of the annual fixed base salary. The variable cash remuneration is intended to support recruitment or retention of key personnel or to reward extraordinary performance beyond the individual's ordinary responsibilities and shall not exceed 30% of the annual fixed base salary. Contributions to pension plans shall not exceed 30% of the annual fixed base salary. Salary during the notice of termination period and severance remuneration shall be possible in a total maximum amount of 18 monthly base salaries.

Ultimate responsibility for the remuneration to senior executives as well as setting the respective performance targets lies with the Board of Directors which is supported by the Remuneration Committee and the CEO.

Please see the Remuneration Report on page 132 in this Annual Report for additional information on remuneration to senior executives.

### 2024 proposed changes to remuneration guidelines for senior executives

No changes to the guidelines are proposed for 2024.

### Dividend

The Board proposes that no dividend will be paid for the financial year 2023. For more information about Hansa Biopharma's dividend policy, please refer to the Hansa Biopharma Corporate Governance Report available on the Company's website at <https://hansabiopharma.com/this-is-hansa/corporate-governance/>

### Other information

For additional information, please see the Corporate governance report and the Remuneration report on page 118 and page 132 or on the Company's website.

### Annual general meeting 2024

The annual general meeting of Hansa Biopharma AB (publ) is planned to take place on June 27, 2024. Notice to attend the annual general meeting will be published on Hansa Biopharma's website at: [www.hansabiopharma.com](http://www.hansabiopharma.com).

### Financial calendar 2024

March 21, 2024	Annual Report 2023
April 18, 2024	Interim report for January - March 2024
June 27, 2024	Annual General Meeting 2024
July 18, 2024	Half year 2024 report
October 24, 2024	Interim Report for January - September 2024

### Appropriation of loss carried forward

#### Unrestricted shareholders' equity in the Parent Company

SEK	
Share premium reserve	3,082,574,199
Treasury shares	(2,362,445)
Loss carried forward	(2,530,481,990)
Result for the year	(595,535,899)
<b>Total</b>	<b>(45,806,315)</b>

The Board of Directors proposes the loss carried forward and unrestricted reserves to be allocated as follows

SEK	
Share premium reserve	3,082,574,199
Treasury shares	(2,362,445)
Profit/loss carried forward	(3,126,017,889)
<b>Total</b>	<b>(45,806,315)</b>

The Group's and the Parent Company's results and financial position are shown in the following section "Financials" further below in this Annual Report, which includes the accompanying notes and supplementary information, which are an integral part of the financial statements.



# Financials

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# The Group Financial Statements

## Consolidated statement of financial position

(in thousands of SEK)	Note	As of December 31,	
		2023	2022
<b>ASSETS</b>			
<b>Non-current assets:</b>			
Intangible assets	4	135,817	46,866
Property and equipment	5	6,343	8,113
Right-of-use assets	6	20,730	27,723
<b>Total non-current assets</b>		<b>162,890</b>	<b>82,702</b>
<b>Current assets:</b>			
Inventories	7	1,513	973
Trade receivables and unbilled revenues	8	78,025	42,959
Prepaid expenses and accrued income	9	21,543	33,278
Other receivables	10	22,010	31,315
Cash and cash equivalents	20	732,060	1,496,179
<b>Total current assets</b>		<b>855,151</b>	<b>1,604,704</b>
<b>TOTAL ASSETS</b>		<b>1,018,041</b>	<b>1,687,406</b>
<b>EQUITY</b>			
Share capital	23	55,034	55,034
Share premium	24	3,082,667	3,021,541
Treasury share reserve	25,26	(2,362)	(2,590)
Translation reserves	26	(408)	13
Accumulated deficit		(3,302,807)	(2,471,087)
<b>Total equity attributable to owners of the parent company</b>		<b>(167,876)</b>	<b>602,912</b>

(in thousands of SEK)	Note	As of December 31,	
		2023	2022
<b>LIABILITIES</b>			
<b>Non-current liabilities:</b>			
Long-term loan	21	844,903	762,601
Lease liabilities	6	14,362	21,326
Deferred revenue	13	—	29,500
Contingent consideration	18	843	757
Provisions	15	4,454	5,192
Deferred tax liabilities	16	367	405
<b>Total non-current liabilities</b>		<b>864,929</b>	<b>819,781</b>
<b>Current liabilities:</b>			
Current tax liabilities		1,599	604
Lease liabilities	6	7,503	7,165
Trade payables	20	86,966	62,476
Other liabilities	12	21,782	18,278
Deferred revenue	13	41,473	40,430
Refund liabilities	8	49,266	27,013
Accrued expenses	11	112,399	108,747
<b>Total current liabilities</b>		<b>320,988</b>	<b>264,713</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>1,018,041</b>	<b>1,687,406</b>

The accompanying notes are an integral part of these Consolidated Financial Statements.



## The Group Financial Statements continued

### Consolidated statement of profit or loss and other comprehensive income (loss)

(in thousands of SEK, except for shares and per share data)	Note	Years Ended December 31,	
		2023	2022
Revenue	13	134,094	154,525
Cost of revenue		(63,143)	(38,477)
Sales, general and administrative expenses	29	(450,492)	(337,861)
Research and development expenses	29	(411,332)	(346,244)
Other operating income/(expenses)	28	2,377	(20,532)
<b>Loss from operations</b>		<b>(788,496)</b>	<b>(588,588)</b>
Finance income	22	63,204	27,248
Finance expenses	22	(105,520)	(48,639)
<b>Loss before tax</b>		<b>(830,812)</b>	<b>(609,979)</b>
Income tax expense	16	(908)	(1,155)
<b>Loss for the year</b>		<b>(831,720)</b>	<b>(611,134)</b>
Loss for the year attributable to owners of the parent		(831,720)	(611,134)
Loss per share, basic and diluted (SEK)	17	(15,83)	(13,60)
<b>Weighted-average number of ordinary shares outstanding, basic, and diluted</b>		<b>52,540,089</b>	<b>44,923,998</b>

(in thousands of SEK)	Note	Years Ended December 31,	
		2023	2022
<b>Loss for the year</b>		<b>(831,720)</b>	<b>(611,134)</b>
<b>Other comprehensive income (loss):</b>			
<b>Items that are or may be reclassified subsequently to profit or loss, net of tax:</b>			
Exchange differences on translating foreign operations		(422)	(114)
<b>Other comprehensive loss for the year</b>		<b>(422)</b>	<b>(114)</b>
<b>Total comprehensive loss for the year</b>		<b>(832,142)</b>	<b>(611,248)</b>
<b>Total comprehensive loss for the year attributable to owners of the parent</b>		<b>(832,142)</b>	<b>(611,248)</b>

The accompanying notes are an integral part of these Consolidated Financial Statements.



## The Group Financial Statements continued

### Consolidated statement of cash flow

(in thousands of SEK)	Note	Years Ended December 31,	
		2023	2022
<b>Cash Flows from Operating Activities</b>			
Loss for the year		(831,720)	(611,134)
<b>Adjustments to reconcile net loss to net cash flows:</b>			
Depreciation and amortization expenses		19,792	12,054
Capitalized development cost	4	(87,205)	(18,291)
Expenses related to incentive programs		60,636	58,226
Accrued interest and unrealized currency differences		44,570	31,444
<b>Total adjustments to net cash flows</b>		<b>(793,927)</b>	<b>(527,701)</b>
<b>Changes in working capital:</b>			
(Increase)/decrease of trade receivables & unbilled revenues	8	(35,065)	(33,247)
(Increase)/decrease of other operating assets		20,558	(21,897)
Increase/(decrease) trade payables	20	24,488	9,116
Increase/(decrease) of other operating liabilities		1,455	67,460
<b>Total changes in working capital</b>		<b>11,436</b>	<b>21,432</b>
Interest received		27,993	6,267
Interest paid		(1,023)	(1,166)
Income taxes paid		(133)	(1,565)
<b>Net cash used in operating activities</b>		<b>(755,654)</b>	<b>(502,733)</b>
<b>Cash Flows from Investing Activities</b>			
Proceeds from sale of short-term investments		—	232,644
Acquisition of property and equipment	5	(284)	(3,331)
<b>Net cash (used in) from investing activities</b>		<b>(284)</b>	<b>229,313</b>

(in thousands of SEK)	Note	Years Ended December 31,	
		2023	2022
<b>Cash Flows from Financing Activities</b>			
Proceeds from long-term loan, net of transaction costs <sup>(1)</sup>		—	728,373
Proceeds from issue of ordinary shares, net of transaction costs <sup>(2)</sup>		—	396,196
Payment of lease liabilities	6,30	(7,545)	(6,888)
<b>Net cash (used in) from financing activities</b>		<b>(7,545)</b>	<b>1,117,681</b>
Net change in cash and cash equivalents		(763,483)	844,261
Cash and cash equivalents at beginning of year		1,496,179	651,342
Effects of movements in exchange rate on cash held		(636)	576
<b>Cash and cash equivalents at end of year</b>		<b>732,060</b>	<b>1,496,179</b>

<sup>(1)</sup> Total long-term loan transaction cost amounted to SEK 8,027k.

<sup>(2)</sup> Total share issue cost amounted to SEK 19,754k.

The accompanying notes are an integral part of these Consolidated Financial Statements.



## The Group Financial Statements continued

### Consolidated statement of changes in equity

(in thousands of SEK)	Note	Share Capital	Share Premium	Treasury Share Reserve	Translation Reserve	Accumulated deficit	Total equity attributable to owners of the parent company
<b>Balance at January 1, 2022</b>		46,335	2,572,925	(1,862)	127	(1,859,953)	757,573
<b>Consolidated statement of profit or loss and other comprehensive income (loss):</b>							
Loss for the year		–	–	–	–	(611,134)	(611,134)
Translation reserve		–	–	–	(114)	–	(114)
<b>Total comprehensive loss for the year</b>		–	–	–	(114)	(611,134)	(611,248)
Issue of ordinary shares <sup>(1)</sup>		7,848	388,348	–	–	–	396,196
Issue of Class C shares <sup>(2)</sup>		851	–	(851)	–	–	–
Exercise of share rights		–	(122)	122	–	–	–
Long term incentive program		–	60,391	–	–	–	60,391
<b>Balance at December 31, 2022</b>	23,24,25,26	55,034	3,021,541	(2,590)	13	(2,471,087)	602,912
<b>Balance at January 1, 2023</b>		55,034	3,021,541	(2,590)	13	(2,471,087)	602,912
<b>Consolidated statement of profit or loss and other comprehensive income (loss):</b>							
Loss for the year		–	–	–	–	(831,720)	(831,720)
Translation reserve		–	–	–	(422)	–	(422)
<b>Total comprehensive loss for the year</b>		–	–	–	(422)	(831,720)	(832,142)
Exercise of share rights		–	(228)	228	–	–	–
Long term incentive program		–	61,354	–	–	–	61,354
<b>Balance at December 31, 2023</b>	23,24,25,26	55,034	3,082,667	(2,362)	(408)	(3,302,807)	(167,876)

<sup>(1)</sup> Total share issue cost amounted to SEK 19,754k.

<sup>(2)</sup> The year 2022 additions of Class C shares refer to the new issue and subsequent repurchase of Class C shares that have taken place in accordance with the respective long term incentive plan (LTIP) program.

The accompanying notes are an integral part of these Consolidated Financial Statements.





# Notes to the Group Financial Statements

## Note 1 General Information

Hansa Biopharma AB (Hansa, the Company; and together with its subsidiaries, the Group) is a commercial-stage biopharmaceutical company pioneering the development and commercialization of innovative, lifesaving and life-altering treatments for patients with rare immunological conditions. The Company has developed a proprietary antibody-cleaving enzyme technology platform to target pathogenic or disease-causing antibodies. Its broad therapeutic pipeline has potential applications across transplantation, autoimmune diseases, gene therapy and oncology indications addressing significant unmet medical needs. Hansa has received conditional approval of Idefirix (imlifidase) by the European Commission for desensitization treatment of highly sensitized kidney transplant patients. Hansa is a public limited liability company under the laws of Sweden, based in Lund, Sweden, and has operations in Europe and the United States. The Group consists of the parent company, Hansa Biopharma AB, and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc, Hansa Biopharma Australia PTY LTD and Hansa Biopharma Italy s.r.l. Hansa Biopharma Italy S.r.l. was registered in July 2023 to support commercialization in Italy.

## Note 2 Basis of Presentation and Summary of Significant Accounting Policies Basis of Accounting

The consolidated financial statements are reported in Swedish Krona, Hansa Biopharma AB's functional currency, and prepared in accordance with International Financial Reporting Standards (IFRS), issued by the International Accounting Standards Board (IASB) and the interpretations issued by the IASB's International Financial Reporting Interpretation Committee. The consolidated financial statements provide a general overview of the Group's activities and the results achieved. They present fairly the entity's financial position, its financial performance, and cash flows, on a going concern basis. The accounting policies described in Note 2 and 3 of the Group's consolidated financial statements have been applied in preparing the consolidated financial statements as of and for the year ended December 31, 2023, and for the comparative information as of and for the year ended December 31, 2022. The significant accounting policies applied in the preparation of the above consolidated financial statements are set out below.

The preparation of consolidated financial statements requires management to exercise its judgment in the process of applying the Group's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates that are significant to the consolidated financial statements are disclosed in Note 3.

These consolidated financial statements of the Group as of December 31, 2023, and for the year then ended were approved by the Board of Directors of the Group and authorized for issue on March 20, 2024.

## Changes in Accounting Policies and Disclosures

Several amendments to and interpretations of IFRS applied for the first time in 2023, which has not had an impact on the accounting policies applied by the Group. Thus, the accounting policies applied when preparing these consolidated financial statements have been applied consistently to all the periods presented, unless otherwise stated.

## Basis of Consolidation

The consolidated financial statements include Hansa Biopharma AB, Lund Sweden, and subsidiaries over which the Group has control. Control is achieved when the Group:

- > has power over the investee;
- > is exposed, or has rights, to variable returns from its involvement with the investee; and
- > has the ability to use its power to affect its returns.

The Group reassesses whether it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above. If the Group does not have a majority of the voting rights of an investee, it has power over the investee when the voting rights are sufficient to give it the practical ability to direct the relevant activities of the investee unilaterally.

The Group considers all relevant facts and circumstances in assessing whether the Group's voting rights in an investee are sufficient to give it power, including:

- > the size of the Group's holding of voting rights relative to the size and dispersion of holdings of the other vote holders;
- > potential voting rights held by the Group;
- > rights arising from other contractual arrangements; and
- > any additional facts and circumstances that indicate that the Group has, or does not have, the current ability to direct the relevant activities at the time that decisions need to be made, including voting patterns at previous shareholders' meetings.

Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statement of profit or loss and other comprehensive income (loss) from the date the Group gains control until the date when the Group ceases to control the subsidiary.



## Notes to the Group Financial Statements continued

Adjustments are made to the financial statements of subsidiaries to bring their accounting policies in line with the Group's accounting policies. All intra group transactions, balances, income, and expenses are eliminated in full in the consolidation. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.

The Group holds investments either directly or indirectly in the following subsidiaries:

Subsidiaries	Functional currency	Registered office/Country	Share ownership percentage (%)	
			2023	2022
Cartela R&D AB	SEK	Lund, Sweden	100	100
Hansa Biopharma Ltd	GBP	Cheltenham, UK	100	100
Hansa Biopharma Inc	USD	Delaware, USA	100	100
Hansa Biopharma Australia Pty Ltd <sup>(1)</sup>	AUD	Australia	100	100
Hansa Biopharma Italy s.r.l.	EUR	Rome, Italy	100	—

<sup>(1)</sup> Dormant company

The functional currency for the Group's subsidiaries are GBP, USD and EUR, thus the Group has foreign currency exposure. See "Functional and Presentation Currency" section that follows and Note 20, "Financial Risk and Financial Instruments."

### Functional and Presentation Currency

The presentation currency of the consolidated financial statements is Swedish Kronor (SEK). The functional currency, which is the currency that best reflects the economic environment in which the subsidiaries of the Group operate and conduct their transactions, is separately determined for the Group's subsidiaries, and is used to measure their financial position and operating results.

Transactions in currencies other than the functional currency of a subsidiary are recorded at the rates of exchange prevailing at the date of the transaction. Monetary assets and liabilities in currencies other than the functional currency are remeasured at the rates of exchange prevailing on the date of the consolidated statements of financial position and the related translation gains and losses are recognized in the Consolidated statement of profit or loss and other comprehensive income. Non-monetary items that are carried at cost are translated using the rate of exchange prevailing at the date of the transaction. Non-monetary items that are carried at fair value are translated using the exchange rate prevailing when the fair value was determined, and the related translation gains and losses are reported in the Consolidated statement of profit or loss and other comprehensive income.

Upon consolidation, the results of operations of subsidiaries whose functional currency is other than SEK are translated into SEK at the average yearly exchange rates and assets and liabilities are translated at the year-end exchange rates. Translation adjustments are recognized directly in other comprehensive income.

### Measurement of Fair Values

The Group's accounting policies and disclosures require the measurement of fair values, for both financial and non-financial assets and liabilities. The Group has an established control framework with respect to the measurement of fair values. This includes the use of valuation specialists that have responsibility for overseeing certain significant fair value measurements, including Level 3 fair values, and reports directly to the chief financial officer. If third party information, such as broker quotes or pricing services, is used to measure fair values, then the Group assesses the evidence obtained from the valuation specialists to support the conclusion that these valuations meet the requirements of the Standards, including the level in the fair value hierarchy in which the valuations should be classified. Significant valuation issues are reported to the Group's audit committee.

When measuring the fair value of an asset or a liability, the Group uses observable market data as far as possible. Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques as follows:

- > Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.
- > Level 2: inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e., as prices) or indirectly (i.e., derived from prices).
- > Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

If the inputs used to measure the fair value of an asset or a liability fall into different levels of the fair value hierarchy, then the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire measurement. The Group recognizes transfers between levels of the fair value hierarchy at the end of the reporting period during which the change has occurred.

### Revenue

Revenue is recognized when control of the promised goods or services is transferred to the customer, and in an amount that reflects the consideration the Group received or expects to receive in exchange for those goods or services.

The Group derives its revenues primarily from products and contractual arrangements. The Group determines revenue recognition through the following steps:



## Notes to the Group Financial Statements continued

- > (1) Identification of the contract, or contracts, with a customer.
- > (2) Identification of the performance obligation(s) in the contract.
- > (3) Determination of the transaction price.
- > (4) Allocation of the transaction price to the performance obligations in the contract.
- > (5) Recognition of revenue when, or as, the Group satisfies a performance obligation.

### Product revenue

Product revenue is recognized net of any sales and value added taxes and sales deductions based on contractually agreed payment terms. The control passes according to contractual terms. The amount of consideration the Group receives and revenue the Group recognizes varies based on actual or estimated rebates, discounts, returns and charge backs. The Group adjusts its estimate of revenue at the earlier of when the most likely amount of consideration the Group expects to receive changes or when the consideration becomes fixed.

Sales returns are generally estimated and recorded based on historical sales and returns information. Sales returns allowances represent a reserve for products that may be returned due to expiration, damage or potential other reasons typically calculated as a percent of gross revenues.

### Contract revenue

The Group accounts for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable.

In determining the proper revenue recognition method, the performance obligation(s) under an agreement is reviewed and evaluated if such obligation(s) be accounted for as more than one performance obligation.

For certain contracts, a service of combining a license and related tasks into a single performance obligation may be provided. In such a case, the entire contract is accounted for as one performance obligation. Certain contracts may promise to provide a distinct license with distinct services within a contract, in which case the contract is separated into more than one performance obligation. If a contract is separated into more than one performance obligation, the total transaction price is allocated to each performance obligation in an amount based on the estimated relative standalone selling price of the promised goods or services underlying each performance obligation. Non-refundable upfront payments and substantive development and sales milestone payments are typically recognized over the remaining performance period based on the progress towards satisfying its identified performance obligation.

### Grant revenue

Because the Group carry out extensive research and development activities, the Group may benefit from various grants, research and development incentives and payroll tax rebates from certain governmental agencies. These grants, research and development incentives and payroll tax rebates generally aim to partly reimburse approved expenditures incurred in research and development efforts of the Group and are credited to the consolidated statement of profit or loss and other comprehensive income, under the line other operating income, when the relevant expenditure has been incurred and there is reasonable assurance that the grants or research and development incentives are receivable.

### Research and Development Expenses

Research costs are expensed as incurred. Development costs are typically expensed as incurred, unless capitalized. Costs of research and development equipment with alternative future uses are capitalized and depreciated over the equipment's useful life.

Research and development expenses primarily include costs for third-party services in connection with clinical studies and research projects, costs for producing substance to be used in such studies and projects, personnel expenses for the Group's research and development groups, and depreciation of equipment used for research and development activities. In addition, research and development expenses contain expenses for producing pharmaceutical material which may be used for commercialization subject to regulatory approval, and which was produced prior to obtaining regulatory approval or evidence being available that regulatory approval can reasonably be expected.

Expenditures on research activities are recognized in the consolidated statement of profit or loss and other comprehensive income (loss) as incurred. Development expenditures are capitalized only if the expenditure can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Group intends to and has sufficient resources to complete development and to use or sell the asset. Otherwise, it is recognized in the consolidated statement of profit or loss and other comprehensive income (loss) as incurred. Subsequent to initial recognition, development expenditure is measured at cost less accumulated amortization and any accumulated impairment losses.

Generally, expenditures are not capitalized before the pharmaceutical authorities have given approval due to the level of uncertainty associated with the approval process. In 2022, Hansa started to capitalize certain development cost related to fulfilment of the EMA post-approval commitments related to its conditional approval of imlifidase in the EU as it met all requirements under IAS 38. Please refer to Note 4 for further information.



## Notes to the Group Financial Statements continued

### Sales, General and Administrative Expenses

Sales, general and administrative expenses consist primarily of (i) personnel expenses relating to salaries and related costs for personnel, including share-based compensation, of our employees in executive, commercial, finance, business development and support functions, (ii) fees relating to professional services for commercialization, marketing, selling, medical affairs, corporate management, legal, finance, human resources, business development, licensing and investor relations, (iii) board expenses consisting of directors' fees and travel expenses for board members, and (iv) other general and administrative expenses, including leasing costs, office expenses and travel costs. General and administrative expenses are recognized in the consolidated statement of profit or loss and other comprehensive income (loss) in the period to which they relate.

### Pensions

Hansa only have pension plans where the Group's obligations are limited to the contribution the Group has undertaken to pay. These plans are classified as "defined contribution pension plans. In such cases, the size of the employee's pension is dependent upon the contribution which the Group pays into the plan, or to an insurance company, and the return on capital which the contribution generates. Consequently, it is the employee who bears the actuarial risk (that the benefits will be lower than anticipated) and the investment risk (that the invested assets will be insufficient to generate the anticipated benefits). The Group's obligations regarding fees paid to defined contribution plans are reported as an expense in the consolidated statement of profit or loss and other comprehensive income (loss) when they are earned by the employees performing their services on behalf of the Group during a given period of time.

### Employee Benefits

#### Short-term employee benefits

Short-term employee benefits are expensed as the related service is provided. A liability is recognized for the amount expected to be paid if the Group has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee and the obligation can be estimated reliably.

#### Long-term employee benefits

The Group's net obligation in respect of long-term employee benefits is the amount of future benefit that employees have earned in return for their service in the current and prior periods. That benefit is discounted to determine its present value. Remeasurements are recognized in profit or loss in the period in which they arise.

#### Termination benefits

Termination benefits are expensed at the earlier of when the Group can no longer withdraw the offer of those benefits and when the Group recognizes costs for a restructuring. If benefits are not expected to be settled wholly within 12 months of the reporting date, then they are discounted.

### Share-based Payments

The Company has provided share-based payment awards through long-term incentive programs for certain employees whereby participants are provided ordinary shares of the Company after the vesting period, either through share rights or employee stock options, if certain performance conditions are met. Vesting is based on market or non-market performance conditions. For awards that vest upon achieving a market condition, the Company's share price must achieve certain thresholds. For awards that vest upon achieving non-market conditions, the Company must achieve certain pre-defined business objectives related to financial, portfolio and/or commercial targets.

The awards are classified as equity-settled share-based payments since the only settlement alternative is in shares of the Company. For equity-settled programs, the fair value of the instruments is determined at the grant date and is subsequently not remeasured. The share-based payment expense is recognized over the vesting period with a corresponding entry recognized directly in equity. Social security costs relating to share-based compensation are recognized as expense in profit or loss over the same vesting period, based on the fair value of the equity instruments at each reporting date. An amount corresponding to the recognized expense is recognized as a liability.

The fair value of the options is calculated based on the Black-Scholes model and expensed over the vesting period. During the vesting period, the expense is adjusted to account for the number of options that are expected to vest.

For share rights that vest upon achieving market conditions, the Company determines the value of the awards using the Monte Carlo model at the grant date because different share price realizations result in different values for the award. The effect of a market condition is reflected in the grant-date fair value of an award. The share-based payment expense is recognized over the three-year vesting period provided that the service is rendered, regardless of when, if ever, the market condition is satisfied.

For share rights with a non-market performance condition, the Company valued the awards using Black-Scholes model. The exercise price of the share rights has been set using a volume weighted average of the Company's share price over a certain period before grant date. For the estimation of expected future volatility, the average 90-day historical volatility was estimated for the Company and, as a benchmark, for several peers over periods between one and seven years. The yield curve for Swedish government bonds is used to determine the risk-free interest rate. After the value of the awards were determined, the Company estimated the probability of achieving the non-market conditions and adjusted the number of awards that would expense over the amortization period. The Company re-evaluates the probability of achieving the nonmarket conditions each reporting period.



## Notes to the Group Financial Statements continued

### Other Operating Income and Expenses

#### Other income

Other operating income includes foreign currency gain on receivables from operating activities and gain from disposal of assets.

#### Other expenses

Other operating expenses include foreign currency loss on receivables from operating activities and loss from disposals of assets.

### Financial Income and Expenses

Financial income and expenses comprise of interest income and expenses, and realized and unrealized exchange rate gains and losses on transactions denominated in foreign currencies.

Interest income or expense is recognized using the effective interest method. The effective interest rate is the rate that exactly discounts estimated future cash payments or receipts through the expected life of the financial instrument to the gross carrying amount of the financial asset or the amortized cost of the financial liability. In calculating interest income and expense, the effective interest rate is applied to the gross carrying amount of the asset (when the asset is not credit-impaired) or to the amortized cost of the liability. However, for financial assets that have become credit-impaired subsequent to initial recognition, interest income is calculated by applying the effective interest rate to the amortized cost of the financial asset. If the asset is no longer credit-impaired, then the calculation of interest income reverts to the gross basis.

### Income Taxes

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in the Consolidated statement of profit or loss and other comprehensive income (loss) by the portion attributable to the profit or loss for the year and recognized directly in equity or other comprehensive income by the portion attributable to entries directly in equity and in other comprehensive income. The current tax payable or receivable is recognized in the consolidated statement of financial position, stated as tax computed on this year's taxable income, adjusted for prepaid tax.

When computing the current tax for the year, the tax rates and tax rules enacted or substantially enacted at the reporting date are used. Current tax payable is based on taxable profit or loss for the year. Taxable profit or loss differs from net profit or loss as reported in the consolidated statement of profit or loss and other comprehensive income (loss) because it excludes items of income or expense that are taxable or deductible in prior or future years. In addition, taxable profit or loss excludes items that are never taxable or deductible.

Deferred tax is recognized according to the balance sheet liability method of all temporary differences between carrying amounts and tax-based values of assets and liabilities, apart from deferred tax on all temporary differences occurring on initial recognition of goodwill or on initial recognition of a transaction which is not a business combination, and for which the temporary difference found at the time of initial recognition neither affects profit or loss nor taxable income.

Deferred tax liabilities are recognized on all temporary differences related to investments in subsidiaries and/or associates, unless the Group is able to control when the deferred tax is realized, and it is probable that the deferred tax will not become due and payable as current tax in the foreseeable future.

Deferred tax assets, including the tax base of tax loss carry forwards, are recognized in the statement of financial position at their estimated realizable value, either as a set-off against deferred tax liabilities or as net tax assets for offset against future positive taxable income. Deferred tax assets are only offset against deferred tax liabilities if the entity has a legally enforceable right to set off, and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same tax jurisdiction. Deferred tax is calculated based on the planned use of each asset and the settlement of each liability, respectively.

Deferred tax is measured using the tax rates and tax rules in the relevant countries that, based on acts in force or acts in reality in force at the reporting date are expected to apply when the deferred tax is expected to crystallize as current tax. Changes in deferred tax resulting from changed tax rates or tax rules are recognized in the consolidated statement of profit or loss and other comprehensive income (loss) unless the deferred tax is attributable to transactions previously recognized directly in equity or other comprehensive income. In the latter case, such changes are also recognized in equity or other comprehensive income. On every reporting date, it is assessed whether sufficient taxable income is likely to arise in the future for the deferred tax asset to be utilized.

### Property and Equipment

Property and equipment are measured at cost less accumulated depreciation and any accumulated impairment losses. Cost comprises the acquisition price, costs directly attributable to the acquisition and preparation costs of the asset until the time when it is ready to be used in operation. Subsequent costs are included in the carrying amount of the asset or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the assets will flow to the Group and the costs of the items can be measured reliably. All repair and maintenance costs are charged to the consolidated statement of profit or loss and other comprehensive income (loss) during the financial periods in which they are incurred.



## Notes to the Group Financial Statements continued

Equipment acquired for research and development activities with alternative use, which is expected to be used for more than one year, is capitalized and depreciated over the estimated useful life as research and development costs. Equipment acquired for research and development activities, which has no alternative use, is recognized as research and development costs when incurred.

If the acquisition or use of the asset involves an obligation to incur costs of decommissioning or restoration of the asset, the estimated related costs are recognized as a provision and as part of the relevant asset's cost, respectively.

The basis for depreciation is cost less estimated residual value. The residual value of an asset is the estimated amount that an entity would currently obtain from disposal of the asset, after deducting the estimated costs of disposal, if the asset were already of the age and in the condition expected at the end of its useful life. If significant parts of an item of property and equipment have different useful lives, then they are accounted for as separate items (major components) of property and equipment. Depreciation commences when the asset is available for use, which is when it is in the location and condition necessary for it to be capable of operating in the manner intended.

Depreciation is calculated on a straight-line basis, based on an asset's expected useful life, being within the following ranges:

Property and equipment	3–10 years
Right-of-use assets	3–6 years, in accordance with the respective lease agreement

Depreciation methods, useful lives and residual values are reviewed at each reporting date and adjusted if appropriate.

Depreciation and impairment losses of property and equipment is recognized in the Consolidated statement of profit or loss and other comprehensive income (loss) as research and development costs or as selling, general and administrative expenses, as appropriate.

Gains and losses on disposal of property and equipment are recognized in the Consolidated statement of profit or loss and other comprehensive income (loss) at its net proceeds, as either other income or other expenses, as appropriate.

### Intangible Assets

#### Internally generated intangible assets

Development expenditure is capitalized only if all respective requirements under IAS 38 are fully met, particularly, the expenditure can be measured reliably, the product or process is technically and

commercially feasible, future economic benefits are probable, and the Group intends to and has sufficient resources to complete the development and to use or sell the asset. Otherwise, it is recognized in profit or loss as incurred. Subsequent to initial recognition, capitalized development expenditure is measured at cost less accumulated amortization and any accumulated impairment losses.

Subsequent expenditure is capitalized only when it increases the future economic benefits embodied in the specific asset to which it relates. All other expenditure, including expenditure on internally generated goodwill and brands, is recognized in profit or loss as incurred.

In 2022, Hansa started to capitalize certain development cost related to fulfilment of the EMA post-approval commitments related to its conditional approval of imlifidase in the EU as it met all requirements under IAS 38. Please refer to Note 4 for further information.

Amortization is calculated to write off the cost of intangible assets less their estimated residual value using the straight-line method over their estimated useful life and is generally recognized in consolidated statement of profit or loss and other comprehensive income (loss). The capitalized development expenditure is subject to regular amortization over its useful life which is estimated to be up until end of 2032.

The estimated useful lives for current and comparative periods are as follows:

Development costs:	10 years
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Amortization methods, useful lives and residual values are reviewed at each reporting date and adjusted if appropriate.

#### Acquired intangible assets

Acquired intangible assets held by the Group consists of patents and in-process development projects acquired in a business combination. The intangible assets were originally recognized at the acquisition date fair value. Subsequently, they are measured at cost less accumulated amortization and any impairment. Amortization is calculated to write off the cost of development projects, less their estimated residual values, using the straight-line method over their estimated useful lives and commence when the projects start to generate revenue, being within the following range:

Patents:	Until expiry date
In-process development projects:	10–15 years



## Notes to the Group Financial Statements continued

### Impairment

If circumstances or changes in the Group's operations indicate that the carrying amount of noncurrent assets in a cash-generating unit may not be recoverable, management reviews the asset for impairment. An annual impairment test is also performed for assets yet to be brought into use, i.e. per December 31, 2023, in-process development projects and capitalized development cost relating to imlifidase. The basis for the review is the recoverable amount of the assets, determined as the greater of the fair value less costs of disposal or its value in use. Such review uses an analysis of current market value (market cap of the Company) as the fair value less cost of disposal. If the carrying amount of an asset is greater than the recoverable amount, the asset is written down to the recoverable amount. An impairment loss is recognized in the consolidated statement of profit or loss and other comprehensive income (loss) when the impairment is identified. The Group assesses at the end of each reporting period whether there is any indication that an asset may be impaired. If any such indication exists, the Group will estimate the recoverable amount of the asset.

### Inventories

Inventories are assets:

- (a) held for sale in the ordinary course of business;
- (b) in the process of production for such sale; or
- (c) in the form of materials or supplies to be consumed in the production process or in the rendering of services.

Costs related to the manufacturing of inventories which occurred after the receipt of regulatory approval for the respective product are capitalized, otherwise, they are expensed as research and development expenses when incurred.

The cost of inventories includes all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition. Inventories are valued at the lower of cost and net realizable value. Cost is determined based on the first-in first-out ("FIFO") costing method. The Company regularly reviews the net realizable value and adjusts the carrying inventory amounts for any excess, obsolete or slow-moving inventory.

### Unbilled Revenues & Refund Liabilities

Unbilled revenues primarily relate to the Group's right to consider product sold but not billed at the reporting date. The unbilled revenues are transferred to trade receivables when the rights become unconditional. This usually occurs when the Group issues an invoice to the customer.

Refund liabilities primarily relate to the Group's actual or estimated rebates, discounts, return and charge back obligations. The refund liabilities are transferred to trade payables when the obligation becomes unconditional. This usually occurs when the Group receives an invoice from third party, typically the healthcare sponsor in the country where the sale occurred.

### Trade Receivables

Trade receivables are recorded at net realizable value after consideration of an allowance for expected credit losses. The Company generally maintains allowances for estimated uncollectible receivables based on historical experience and, where such historical experience does not exist, on country-specific default rates. The adequacy of the allowance is evaluated on an ongoing and periodic basis and adjustments are made in the period in which a change in condition occurs.

Please refer to section "Financial instruments" below for further information.

### Cash and Cash Equivalents

Cash and cash equivalents comprise of on-demand deposits with financial institutions. Cash and cash equivalents are measured at amortized cost.

### Shareholders' Equity

The share premium reserve is comprised of the amount received, attributable to shareholders' equity, in excess of the nominal amount of the shares issued, reduced by any amount allocated external expenses directly attributable to the offerings. The share premium reserve can be distributed.

Shareholders are entitled to dividends which are determined after they become shareholders. Shareholdings entitle a shareholder to one vote per share at general meetings.

The year 2022 additions of Class C shares refer to the new issue and subsequent repurchase of Class C shares related to the funding of the long-term incentive plan (LTIP) 2022, as approved by the 2022 AGM. During 2023 no new share issue of Class C shares was done.

The treasury shares reserves comprise own shares repurchased by the Group. The total amount paid to acquire treasury shares including directly attributable costs and the proceeds from the sale of treasury shares are recognized in treasury share reserve.

The translation reserve comprises all foreign exchange differences arising on translation of financial statements from foreign business prepared in currency other than the reporting currency for the financial statements of the Group.

Retained earnings/accumulated deficit, including profit/loss for the year, includes profits earned/losses incurred by the Group and its subsidiaries. Previous allocations to statutory reserves, excluding transferred share premium reserves, are included in this shareholders' equity item.

No dividend was paid for the periods ended December 31, 2023, or 2022.



## Notes to the Group Financial Statements continued

### Leases

The Group leases various offices, laboratory facilities, equipment, and vehicles. Rental contracts are typically made for fixed periods of three to four years, but certain contracts may have extension options.

Contracts may contain both lease and non-lease components. The Group allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices. For leases of real estate, it has elected not to separate lease and non-lease components and instead accounts for these as a single lease component. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leases are recognized as right-of-use assets and corresponding liabilities at the date at which the underlying assets are available for use by the Group. Leased assets and lease liabilities arising from a lease are initially measured at present value. Lease liabilities include the net present value of the lease payments, and they are discounted using the lessee's incremental borrowing rate.

Subsequent to initial recognition, the right-of-use is measured at amortized cost using the effective interest method.

Leased assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use assets are depreciated over the underlying asset's useful life. Payments associated with short-term leases of equipment and all leases of low-value assets are recognized on a straight-line basis as an expense in the consolidated statement of profit or loss and other comprehensive income. Short-term leases are leases with a lease term of twelve months or less. Low-value assets comprise mainly of IT equipment and small items of office furniture.

Extension and termination options are included in a number of property and equipment leases across the Group. These are used to maximize operational flexibility in terms of managing the assets used in the Group's operations.

### Trade Payables

Trade payables are measured in the consolidated statement of financial position at amortized cost.

### Other Liabilities

Other liabilities comprise payables to public authorities, and short-term employee benefits. Other liabilities are measured at their either amortized cost or historical cost which is reasonable approximation of their fair value.

### Financial Instruments

Financial instruments which are recognized in the consolidated statement of financial position include, on the assets side, cash and equivalents, short term investments, other receivables, trade receivables and listed shares. On the liability side, long-term loan, trade payables and contingent consideration.

Trade receivables are initially recognized when they are originated. Regular-way purchases and sales of financial assets are recognized on the settlement date. Other financial assets and financial liabilities are recognized when the Group becomes party to the instrument's contractual terms.

Financial instruments are initially recognized at fair value with the addition/deduction for transaction expenses, except for instruments that are continuously measured at fair value through the consolidated statement of profit or loss and other comprehensive income (loss) for which transaction expenses are instead expensed when they arise. Trade receivables (without a significant financing component) are initially valued at the transaction price as determined in accordance with IFRS 15.

On initial recognition, a financial asset is classified as measured at: amortized cost, fair value through other comprehensive income (debt instrument investment), fair value through other comprehensive income (equity investment), or fair value through the consolidated statement of profit or loss and other comprehensive income (loss).

Holdings of units in interest funds are reported at fair value through the consolidated statement of profit or loss and other comprehensive income (loss). The shares (seen from the fund's perspective) constitute financial liabilities and as such do not give rise to solely payments of principal and interest and do therefore not fulfil the amortized cost requirements.

Other financial assets that are held within the framework of a business model with a goal to obtain the contractual cash flows at the same time as the cash flows from the assets and consist solely of payments of principal and interest (SPPI) are recognized at amortized cost.

Financial liabilities are classified as valued at amortized cost or valued at fair value through the consolidated statement of profit or loss and other comprehensive income (loss). Financial liabilities that are measured at fair value through the consolidated statement of profit or loss and other comprehensive income (loss) consist of contingent consideration, not yet paid. Other financial liabilities are valued at amortized cost.

Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.





## Notes to the Group Financial Statements continued

The Group derecognizes a financial liability from the consolidated statement of financial position when, and only when, it is extinguished. That is, when the obligations specified in the contract is either discharged or cancelled or has expired. The Group also removes a financial liability from the statement of financial position when the contractual terms are modified and the cash flows from the modified debt are significantly different. In that case, a new financial liability is reported at fair value based on the modified terms.

### Impairment of Financial Assets

For financial assets valued at amortized cost, a reserve must be booked for expected credit losses according to IFRS 9. The loss reserve for trade receivable is valued at an amount corresponding to the expected losses for the remaining term. In addition, the loss reserve for deposits in banks is insignificant since the Group's deposits are held with Swedish banks with good credit rating and the deposits may be withdrawn upon request.

### Statement of Cash Flow

The cash flow statement is presented using the indirect method with basis in the net result. Cash flow from operating activities is stated as the net result adjusted for net financial items, non-cash operating items such as depreciation, amortization, impairment losses, share-based compensation expenses, provisions, and for changes in working capital, interest paid and received, and corporate taxes paid. Working capital mainly comprises changes in receivables, deferred revenue, provisions paid and other payables excluding the items included in cash and cash equivalents. Changes in non-current assets and liabilities are included in working capital, if related to the main revenue-producing activities of the Group.

Cash flow from investing activities is comprised of cash flow from the purchase and sale of intangible assets and property and equipment and financial assets as well as purchase and sale of marketable securities.

Cash flow from financing activities is comprised of cash flow from the issuance of shares, if any, and payment of long-term loans including instalments on lease liabilities.

Cash and cash equivalents, consist of bank deposits. The cash flow statement cannot be derived solely from the financial statements.

### Segment Reporting

The Group is managed and operated as one operating and reportable segment. No separate operating segments or reportable segments have been identified in relation to product candidates or geographical markets. Accordingly, except for entity wide disclosures, no segment information on business segments or geographical markets is disclosed.

### Earnings per Share

Basic Earnings per Share (EPS) is calculated by dividing profit or loss attributable to ordinary equity holders of the parent entity by the weighted average number of ordinary shares outstanding during the period. Diluted earnings per share is calculated as profit or loss attributable to ordinary equity holders of the parent entity divided by the weighted average number of ordinary shares outstanding during the period, both adjusted for the effects of all dilutive potential ordinary shares. If the result is a net loss, no adjustment is made for the dilutive effect, as such effect would be anti-dilutive.

### New Accounting Policies and Disclosures effective 2023

In the year ended December 31, 2023, the following new standards, and amendments to IFRS and interpretations issued by the Board became effective. The Group has applied the new standard and amendments as applicable. Their adoption has not had any material impact on the disclosure or on the amounts reported in these consolidated financial statements.

- > **IFRS 17 Insurance contracts** - establishes principles for the recognition, measurements, presentation, and disclosure of insurance contracts.
- > **Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2** – Disclosure of Accounting policies.
- > **Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors** – Definition of Accounting Estimates.
- > **Amendments to IAS 12 Income Taxes** – Deferred Tax related to Assets and Liabilities arising from a Single Transaction.

### Standards, Amendments, and Interpretations in issue

The adoption of the following mentioned standards, amendments and interpretations in future years are not expected to have a material impact on the Group's financial statements:

	Effective date periods beginning on or after
Amendment to IFRS 16 – Leases on sale and leaseback	January 1, 2024
Amendment to IAS 1 – classification of liabilities	January 1, 2024
Amendment to IAS 7 and IFRS 7 – Supplier finance	January 1, 2024
Amendments to IAS 21 – Lack of Exchangeability	January 1, 2025

The Group has not elected to early adopt any of the above standards, amendments and interpretations in the years ended December 31, 2023, and 2022. The Group plans to adopt these standards on the effective dates.



## Notes to the Group Financial Statements continued

### Note 3 Use of Judgements and Estimates

In the application of the Group's accounting policies, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. Judgements and estimates applied are based on historical experience and other factors that are relevant, and which are available at the reporting date. Uncertainty concerning judgements and estimates could result in outcomes, that require a material adjustment to assets and liabilities in future periods.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods. While the application of critical accounting estimates is subject to material estimation uncertainties, management's ongoing revisions of critical accounting estimates have not revealed any material impact in any of the years ended December 31, 2023, and 2022.

### Significant Judgements made in the Application of the Group's Accounting Policies

Significant judgements that management has made in the process of applying the Group's accounting principles are described below.

#### Revenue

Revenue is primarily generated from product sales and license agreements, which typically involve multiple promises, and thus require significant judgements by the Group on certain areas including:

- > Determining whether the promises in the agreements are distinct performance obligations;
- > Identifying and constraining variable consideration in the transaction price including milestone payments;
- > Allocating transaction price to identified performance obligations based on their relative stand-alone selling prices;
- > Determining whether performance obligations are satisfied over time, or at a point in time; and
- > Classification of licenses as "Right-to-Use" or "Right-to-Access".

Regarding the classification of licenses as "Right-to-Use" or "Right-to-Access", the Group considers whether it is obligated or expected to perform research and development activities that significantly affect the licensee's ability to benefit from product candidates. If the Group is contractually obligated or is expected to perform research and development activities affecting the stand-alone functionality of the product candidate, the license is classified as "right-to-access". The licensed products have been considered "rights-to-access" since the Group is required to perform activities that significantly affect the licensee's ability to benefit from the products.

### Share-Based Payment

IFRS 2, "Share-Based Payment" requires an entity to reflect in its consolidated statement of profit or loss and other comprehensive income (loss) and consolidated statement of financial position, the effects of share-based payment transactions. Share-based compensation costs are recognized as research and development expenses or selling, general and administrative expenses, as appropriate, over the vesting period, based on management's best estimate of the number of awards that will ultimately vest, which is subject to uncertainty. In addition, share-based compensation costs are measured according to the grant date fair values of the instruments granted. Estimating fair values requires the Group to apply generally accepted valuation models and apply these models consistently according to the terms and conditions of the specific share-based compensation programs. Depending on the instrument, the Group applies the Black Scholes or the Monte Carlo model to determine the fair value of the awards granted. Subjective judgements and assumptions, which are subject to estimation uncertainties, need to be exercised in determining the appropriate input to the valuation model.

### Note 4 Intangible Assets

#### Internally Generated Intangible Assets

Expenditure on research activities is recognized as an expense in the period in which it is incurred. An internally-generated intangible asset arising from development (or from the development phase of an internal project) is recognized if, and only if, all of the following have been demonstrated in accordance with IAS 38:

- > the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- > the intention to complete the intangible asset and use or sell it;
- > the ability to use or sell the intangible asset;
- > how the intangible asset will generate probable future economic benefits;
- > the availability of adequate technical, financial, and other resources to complete the development and to use or sell the intangible asset; and
- > the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets all the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditures are recognized in the statement of profit and loss and other comprehensive income in the period in which they are incurred.

The Company assessed that with respect to Idefirix® (imlifidase) and its conditional approval by EMA in enabling kidney transplantation in highly sensitized patients it does meet all the above criteria as of Q4-2022. Going forward, the Company will on a quarterly basis re-assess whether or not it continues to meet all above criteria and continue to capitalize respective cost for as long as all criteria are met.



## Notes to the Group Financial Statements continued

At the year ending December 31, 2023, the total net value for the Company's capitalized development cost amounts to SEK 112.6 million related to performing its Idefix® (imlifidase) EMA post-approval commitments. Capitalized development cost mainly includes fees paid to third party service providers, personnel expenses of Hansa staff and appropriate finance cost. The capitalized development cost is subject to regular amortization over its useful life which is estimated to be up until end of 2032.

Due to uncertainties inherent to the development and registration with the relevant healthcare authorities of imlifidase in any other indications, the Company estimates that the conditions for capitalization are not yet met and thus does not capitalize any development cost related to such other indications.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses, on the same basis as intangible assets that are acquired separately.

Capitalized internal development expenditures for imlifidase's previous production process were completely amortized during the year 2018 and written-off in 2022.

### Acquired Intangible Assets

#### Patents

The patents are amortized over the finite useful life of the underlying patents in the amount of SEK 772k for the year 2023 (2022: SEK 758k). The patent cost is amortized over sales, general and administration line item in the consolidated statement of profit or loss and other comprehensive income.

The patent for the HBP-assay is a method of analysis used to predict severe sepsis in emergency clinics. A first version has been launched, primarily intended for research purposes, and interested specialists. The HBP-assay has been licensed to a cooperating partner, Axis-Shield Diagnostics Ltd. (Axis-Shield), which is currently developing a fully commercial product. The Company receives milestone compensation and additional royalty revenue upon the sale of the sublicensed technology.

### In-process Development Projects

Certain projects pending in the Group are a combination of acquired development projects and continued activities in these projects. Of the total acquisition cost for acquired in-process development projects, approximately 75% relates to imlifidase and 25% relates to HBP-assay.

The acquired intangible asset relating to imlifidase presented as in-process development projects will be amortized over the estimated useful life of the underlying asset. Following the first commercial sale of imlifidase in Q1-2021 the Group started to amortize the SEK 25,136k from the period of first sale in Q1-2021. The estimated useful life is 12 years.

Acquired in-process development projects are assessed for possible impairment at least on an annual basis and the impairment assessment on December 31, 2023, and 2022 demonstrated that there was no need for impairment. The estimated recoverable amount supported by external and internal valuation reports by far exceeds the assets' carrying amount, resulting in no impairment charges for the year 2023 and 2022.

(in thousands of SEK)	Internally generated	Acquired intangible assets		Total Intangible Assets
	Capitalized development costs	Patents	In-process development projects	
<b>Cost:</b>				
Opening balance January 1, 2023	20,853	12,501	25,136	58,490
Internally developed	98,753	—	—	98,753
Effects of movements in exchange rates	—	28	—	28
<b>Closing balance December 31, 2023</b>	<b>119,606</b>	<b>12,529</b>	<b>25,136</b>	<b>157,271</b>
<b>Accumulated amortization and impairment losses:</b>				
Opening balance January 1, 2023	—	(7,435)	(4,188)	(11,624)
Amortization for the year	(6,958)	(772)	(2,095)	(9,825)
Effects of movements in exchange rates	—	(5)	—	(5)
<b>Closing balance December 31, 2023</b>	<b>(6,958)</b>	<b>(8,211)</b>	<b>(6,283)</b>	<b>(21,453)</b>
<b>Carrying amounts:</b>				
At January 1, 2023	20,853	5,066	20,948	46,866
<b>At December 31, 2023</b>	<b>112,648</b>	<b>4,317</b>	<b>18,853</b>	<b>135,817</b>



## Notes to the Group Financial Statements continued

(in thousands of SEK)	Internally generated	Acquired intangible assets		Total Intangible Assets
	Capitalized development expenditures	Patents	In-process development projects	
<b>Cost:</b>				
Opening balance January 1, 2022	4,485	12,339	25,136	41,960
Write-off	(4,485)	—	—	(4,485)
Internally developed	20,853	—	—	20,853
Effects of movements in exchange rates	—	162	—	162
<b>Closing balance December 31, 2022</b>	<b>20,853</b>	<b>12,501</b>	<b>25,136</b>	<b>58,490</b>
<b>Accumulated amortization and impairment losses:</b>				
Opening balance January 1, 2022	(4,485)	(6,619)	(2,094)	(13,199)
Write-off	4,485	—	—	4,485
Amortization for the year	—	(758)	(2,094)	(2,852)
Effects of movements in exchange rates	—	(58)	—	(58)
<b>Closing balance December 31, 2022</b>	<b>—</b>	<b>(7,435)</b>	<b>(4,188)</b>	<b>(11,624)</b>
<b>Carrying amounts:</b>				
At January 1, 2022	—	5,720	23,042	28,761
<b>At December 31, 2022</b>	<b>20,853</b>	<b>5,066</b>	<b>20,948</b>	<b>46,866</b>

### Note 5 Property and Equipment

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Cost:</b>		
Opening balance January 1	15,380	14,451
Reclassification	—	(2,403)
Additions during the year	284	3,332
<b>Closing balance December 31</b>	<b>15,664</b>	<b>15,380</b>
<b>Accumulated depreciation and impairment losses:</b>		
Opening balance January 1,	(7,267)	(8,019)
Reclassification	—	2,403
Depreciation during the period	(2,054)	(1,651)
<b>Closing balance December 31</b>	<b>(9,321)</b>	<b>(7,267)</b>
<b>Carrying amounts:</b>		
At January 1	8,113	6,432
<b>At December 31</b>	<b>6,343</b>	<b>8,113</b>

### Note 6 Right-of-Use Assets and Lease Liabilities

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Leased assets:</b>		
Buildings	20,576	27,250
Equipment	—	135
Vehicles	154	338
<b>Total</b>	<b>20,730</b>	<b>27,723</b>
<b>Lease liabilities:</b>		
Non-current	14,362	21,326
Current	7,503	7,165
<b>Total</b>	<b>21,865</b>	<b>28,491</b>



## Notes to the Group Financial Statements continued

For the years ended December 31, 2023, and 2022, there were SEK 0k and SEK 0k respectively, in additions of right-of-use assets. In 2023, leased assets and lease liabilities have both increased with SEK 919k due to a conditional term in the existing lease agreement.

### Depreciation charge of leased assets for the period

(in thousands of SEK)	As of December 31,	
	2023	2022
Buildings	(7,593)	(7,195)
Equipment	(135)	(135)
Vehicles	(184)	(220)
<b>Total</b>	<b>(7,912)</b>	<b>(7,550)</b>

Interest expense (included in finance cost) amounted to SEK 932k (2022: SEK 1,123k). Expenses related to low-value leases and short-term leases amounted to SEK 3,351k (2022: SEK1,918k). Total cash outflow of leases amounted to SEK 10,896k (2022: SEK 9,904k).

Most of the Group's operational leasing agreements involve leases of real property and premises on which the business operations are conducted. The current lease for the premises in Lund, Sweden, headquarters offices is five years from November 1, 2021. The agreement is automatically extended with three years at a time unless cancellation is made no later than twelve months before the end of the contract period. There are no variable fees included in the leases. The Group has entered into lease agreements with respect to office space, IT, and office equipment. The leases are non-cancellable for various periods up to October 2026. For further information see Note 20. The lease term covered by the extension option was not included in the lease term when the lease was originally recognized as the Group did not consider that the exercise of the option would be reasonably certain.

### Note 7 Inventories

Inventories include material, labour and overhead and consisted of the following:

(in thousands of SEK)	As of December 31,	
	2023	2022
Raw materials and supplies	9,295	3,783
Work in process	7,227	13,455
Packaging material	758	502
Finished goods	13,294	3,814
<b>Total inventories, gross</b>	<b>30,574</b>	<b>21,555</b>
Less: provision for excess & obsolete inventories	(29,061)	(20,582)
<b>Total inventories, net</b>	<b>1,513</b>	<b>973</b>

The Company has recorded a provision for excess and obsolete inventories in the amount of SEK 29,061k (2022: SEK 20,582k) to account for the potential expiry of inventories ahead of their commercial use.

### Note 8 Trade Receivables, Unbilled Revenues and Refund Liabilities

#### Trade receivables and unbilled revenues

(in thousands of SEK)	As of December 31,	
	2023	2022
Trade receivables, net of provisions	76,266	8,360
Unbilled revenue, net of provisions	1,759	34,600
<b>Total</b>	<b>78,025</b>	<b>42,959</b>

Trade receivables primarily consist of receivables from product sales to healthcare organisations in European countries. During the periods ended December 31, 2023, and December 31, 2022, respectively, the Company did not incur any losses from defaults related to its trade receivables.

Unbilled revenues primarily relate to product sales to healthcare organisations in European countries with the Group's right to consider product sold despite not billed at the reporting date. During the periods ended December 31, 2023, and December 31, 2022, respectively, the Company did not incur any losses from defaults related to its unbilled revenues.



## Notes to the Group Financial Statements continued

Provisions for expected credit losses amounted to SEK 539k (2022: SEK 78k), for further information see credit risk in Note 20.

### Refund liabilities

(in thousands of SEK)	As of December 31,	
	2023	2022
Volume discounts	27,795	14,039
Other discounts	18,352	9,855
Other refund liabilities	3,119	3,119
<b>Total</b>	<b>49,266</b>	<b>27,013</b>

Refund liabilities primarily consist of the Group's actual or estimated rebates, discounts, return and charge back obligations to its customers.

### Note 9 Prepaid Expenses and Accrued Income

(in thousands of SEK)	As of December 31,	
	2023	2022
R&D expenses	11,398	7,587
License fees	2,484	3,857
Rent	2,001	2,385
Pension	1,925	1,770
Insurances	1,059	1,137
Healthcare conference	204	2,604
Software	470	1,777
Legal expenses	–	9,989
Other	2,002	2,171
<b>Total</b>	<b>21,543</b>	<b>33,278</b>

### Note 10 Other Receivables

(in thousands of SEK)	As of December 31,	
	2023	2022
Tax and VAT receivables	12,994	21,179
Advance payments to suppliers	8,279	9,262
Other receivables	737	874
<b>Total</b>	<b>22,010</b>	<b>31,315</b>

### Note 11 Accrued Expenses

(in thousands of SEK)	As of December 31,	
	2023	2022
Accrued short term incentives, incl. related social security contributions	41,204	33,138
Annual leave accrual	23,238	18,267
R&D project costs	17,641	26,701
Consulting fees and services	12,602	15,295
Accrued social security contribution on salaries	6,431	5,243
License fees	3,257	5,500
Audit costs	1,180	1,550
Other expenses	6,846	3,053
<b>Total</b>	<b>112,399</b>	<b>108,747</b>

### Note 12 Other Current Liabilities

(in thousands of SEK)	As of December 31,	
	2023	2022
Personnel related liabilities	21,782	18,121
VAT liabilities	–	158
<b>Total</b>	<b>21,782</b>	<b>18,278</b>



## Notes to the Group Financial Statements continued

### Note 13 Revenue

The Group's revenue from its contracts with customers is primarily generated from product sales and three license agreements, as further described below. Revenue has been recognized in the consolidated statement of profit or loss and other comprehensive income (loss) with the following amounts:

#### Revenue from contracts with customers:

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
Product sales	103,712	86,735
Contract revenue, Axis-Shield agreement	2,575	2,892
Cost reimbursement, Axis-Shield agreement	388	624
Contract revenue, Sarepta, AskBio agreements	27,419	64,273
<b>Total</b>	<b>134,094</b>	<b>154,525</b>

#### The revenue with external customers is split as follows by geography:

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
Sweden	—	4,678
North America	27,419	64,273
Europe (excl. Sweden)	106,675	85,573
<b>Total</b>	<b>134,094</b>	<b>154,525</b>

### Performance Obligations Satisfied Over Time

The transaction price is allocated to each performance obligation according to their stand-alone selling prices and is recognized when control of the goods or services are transferred to the customer, either over time or at a point in time, depending on the specific terms and conditions in the contracts.

For the Group's current licensing arrangements, our professionals are required to be committed throughout the development period. Therefore, promises such as the license, materials or professional support are one performance obligation. Accordingly, upfront payments are recognized over time.

### Variable Consideration

In the transaction price, variable consideration, including milestone payments, is only included to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is

subsequently resolved. Therefore, royalties and milestone payments from licensing arrangements are constrained for the periods ended December 31, 2023, and 2022, with the exception of the Axis-Shield minimum royalty payment.

### Product Sales

For the period ended December 31, 2023, the Group recorded product sales of SEK 103.7 million (2022: SEK 86.7 million). Product sales are recognized net of any sales and value-added taxes and sales deductions based on contractually agreed payment terms.

### License Agreement with Sarepta

On July 1, 2020, the Company executed an agreement with Sarepta. Sarepta was granted an exclusive, worldwide license to develop and promote imlifidase, in addition to access to the Group's materials and professional support as a pre-treatment to enable Sarepta's gene therapy treatment in Duchenne muscular dystrophy (DMD) and Limb-girdle muscular dystrophy (LGMD). The pre-treatment is intended for patients with pre-existing neutralizing antibodies (NAb-positive patients) to adeno-associated virus (AAV), the technology that is the basis for Sarepta's gene therapy products.

Sarepta is responsible for conducting preclinical and clinical studies with imlifidase and any subsequent potential filings for regulatory approvals. Sarepta will also be responsible for the promotion of imlifidase as a pre-treatment to Sarepta's gene therapies following potential approval.

Under the terms of the agreement, the Company received a \$10.0 million (SEK 81.9 million) non-refundable upfront payment in July 2020 and is eligible for a total of up to \$397.5 million in development, regulatory and sales milestone payments. The Company will record all sales of imlifidase and earn high single-digit to mid-teens royalties on Sarepta's incremental gene therapy sales when treating NAb-positive patients enabled by pre-treatment with imlifidase.

The exclusive worldwide license to develop and promote imlifidase was determined to be not distinct as Sarepta cannot benefit from the license without the Group's materials and professional support and therefore the license and related support that includes the requirements to provide the Group's materials and professional support are one performance obligation.

The upfront payment will be recognized over the development period, currently estimated at 51 months, as the Group fulfils its performance obligation under the Agreement. The Company concluded that labour hours expended by the Group's professionals was the appropriate measure of the transfer of control of the combined promises of the license, Hansa materials and professional services as it is the measure that is most indicative of the performance obligation satisfied.



## Notes to the Group Financial Statements continued

For the milestone payments associated with the development and regulatory milestones, the Group concluded that the successful completion of the development and regulatory activities are not probable at this time since the project is still in preclinical stage and therefore will not recognize any of these milestones for the Group's December 31, 2023, financial reporting period. Revenue from performance-based and sales-based milestones and sales-based royalties will be constraint because it is probable that a reversal of revenue will occur if these were recognized.

For the period ended December 31, 2023, the Group recorded contract revenue in the amount of SEK 27.4 million (2022: SEK 26.8 million) related to its agreement with Sarepta in connection with the upfront payment received in July 2020.

### License Agreement with AskBio

On January 3, 2022, Hansa announced a collaboration agreement with AskBio (subsidiary of Bayer AG), a fully integrated AAV gene therapy company dedicated to developing medicines that improve the quality of life for patients with genetic diseases.

The collaboration was initiated during the first quarter of 2022. It is designed to evaluate the potential use of imlifidase as a pre-treatment, prior to the administration of AskBio's gene therapy in Pompe disease, in a preclinical and clinical feasibility program for patients with preexisting NAb to the adeno-associated viral vector used in AskBio's gene therapy.

Under terms of the agreement, Hansa received a USD 5 million payment upon execution of the agreement and AskBio has the exclusive option to negotiate a full development and commercialization agreement following evaluation of the results from an initial phase 1/2 study.

The upfront payment will be recognized over the development period, currently estimated at 24 months from start of the collaboration, as the Group fulfils its performance obligation under the Agreement. The Company concluded that delivery of Hansa materials was the appropriate measure of the transfer of control of the combined promises of the Hansa materials and professional services as it is the measure that is most indicative of the performance obligation satisfied.

For the period ended December 31, 2023, the Group recorded contract revenue in the amount of SEK 0 million (2022: SEK 37.5 million) related to its agreement with AskBio in connection with the upfront payment received in January 2022.

### License Agreement with Axis-Shield

In 2023, the Group recorded contract revenue in the amount of SEK 2.6 million (2022: SEK 2.9 million) under its agreement with Axis-Shield related to a minimum royalty payment of \$250,000. The agreement entails a license to access the Group's intellectual property regarding HBP analysis during

the license period. The agreement requires the Group to conduct activities that substantially affect the intellectual property rights during the license period, which in turn affects Axis-Shield as a license holder. Royalty payments are accrued and recognized as income during the period to which the royalty refers.

In addition, the Group recorded revenue related to reimbursable costs upon rendering services related to maintaining licensed patents in an amount of SEK 0.4 million (2022: SEK 0.6 million).

### Deferred revenue

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Opening balance January 1,</b>	<b>69,930</b>	<b>71,981</b>
Addition under existing contracts	—	90,251
Addition under new contracts	—	45,750
Revenue recognized	(27,420)	(154,525)
Adjustments, foreign exchange	(1,037)	16,473
<b>Closing balance December 31,</b>	<b>41,473</b>	<b>69,930</b>

Revenue may vary from period to period as revenue comprises product sales, royalties, milestone payments, deferred revenue, and reimbursement of certain expenses.





## Notes to the Group Financial Statements continued

### Note 14 Staff Costs

Total personnel expenses recorded in the Group broken down to senior management, which includes the Board of Directors and executive management, and other employees:

Year Ended December 31, 2023			
(in thousands of SEK)	Senior Management	Other Employees	Total
Salaries, bonuses, and other benefits	45,007	205,083	250,090
Social security contribution	12,074	33,978	46,052
Pension cost, contribution plan	2,223	26,574	28,797
Share-based compensation	28,133	32,504	60,637
<b>Total</b>	<b>87,437</b>	<b>298,139</b>	<b>385,576</b>

Year Ended December 31, 2022			
(in thousands of SEK)	Senior Management	Other Employees	Total
Salaries, bonuses, and other benefits	36,927	153,642	190,569
Social security contribution	11,423	24,636	36,059
Pension cost, contribution plan	2,812	21,307	24,118
Share-based compensation	32,844	25,382	58,226
<b>Total</b>	<b>84,005</b>	<b>224,967</b>	<b>308,972</b>

### Share-based payments

#### Long-term incentive program 2019 (LTIP 2019)

At Hansa's AGM on May 22, 2019, shareholders resolved to adopt a long-term incentive program, LTIP 2019. Under the terms of LTIP 2019, participants in the program could receive performance-based share rights (share rights) free of charge and/or share options, as further described below.

#### Share rights under LTIP 2019

Each share right provides a participant the right to acquire one ordinary share in the Company free-of-charge provided certain pre-defined performance conditions are met and provided that the participant, with certain exceptions, from the date of the start of participation in LTIP 2019 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

The final number of ordinary shares a participant is entitled to receive is, amongst other terms, conditional upon meeting the following performance conditions during the Vesting Period:

- > Condition 1 (accounting for 22%): Obtain market approval in the EU by the EMA;
- > Condition 2 (accounting for 22%): At least 10 patients enrolled in US RCT (Confldes); and
- > Condition 3 (accounting for 56%): TSR of at least 25% against the baseline share price at the date of allotment.

In December 2021, Hansa's Board of Directors in line with the terms and conditions of the LTIP 2019 resolved to adjust Condition 2 from the previous condition "Imlifidase U.S. approval" to the new condition "At least 10 patients enrolled in US RCT (Confldes)".

A total of 306,303 share rights were allotted to participants, of which 288,727 were allotted in June 2019, and 17,576 were allotted in October 2019.

The Group used the following inputs when valuing the share rights under LTIP 2019 based on Monte Carlo simulation:

	Allotment Jun 17, 2019	Allotment Oct 24, 2019
Starting value (baseline share price) for TSR calculation, SEK	178.38	129.28
Risk-free interest rate, (%)	(0.59)	(0.41)
Expected volatility, (%)	43.0	43.0
Expected dividend, SEK	—	—
Calculated weighted average fair value per share right, SEK	122.12	89.00

As of December 31, 2023, no share rights were outstanding under LTIP 2019:

	Years Ended December 31,	
	2023	2022
Share rights, Opening balance January 1	—	278,181
Share rights lapsed or forfeited	—	(155,781)
Share rights vested	—	(122,400)
<b>Share rights, Closing balance December 31</b>	<b>—</b>	<b>—</b>
Recorded share-based compensation expenses, thousands of SEK	—	3,509

#### Share options under LTIP 2019

The share option program consists of two option series: Series 1—Warrants, and Series 2—Employee stock options.



## Notes to the Group Financial Statements continued

Each warrant or employee stock option entitles the holder to receive one new ordinary share in the Company at an exercise price corresponding to 110% of the volume weighted average share price during the 10 trading days immediately prior to the offer to subscribe for the instruments, and provided that the participant, with certain exceptions, from the date of the start of participation in LTIP 2019 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

### LTIP 2019, Warrants

A total of 11,000 warrants were sold to participants in June 2019. In connection with the warrants program participants (except the CEO) received a subsidy of up to 100% of the purchase price.

The Group used the following inputs when valuing the warrants under LTIP 2019 based on Black Scholes model:

	Issuance Jun 17, 2019
Underlying volume-weighted average share price, SEK	178.38
Exercise price, SEK	196.20
Risk-free interest rate, (%)	(0.59)
Warrant term, years	3.0
Expected volatility, (%)	43.0
Expected dividend, SEK	—
Calculated fair value per warrant, SEK	45.54

As of December 31, 2023, no warrants were outstanding under LTIP 2019:

	Years Ended December 31,	
	2023	2022
Warrants, Opening balance January 1	—	11,000
Warrants expired or redeemed in advance	—	(11,000)
<b>Warrants, Closing balance December 31</b>	—	—
Recorded share-based compensation expenses, thousands of SEK	—	28

### LTIP 2019, Employee Stock Options (ESOs)

A total of 149,148 ESOs were issued to participants in June 2019.

The Group used the following inputs when valuing the ESOs under LTIP 2019 based on Black Scholes model:

	Issuance Jun 17, 2019
Underlying volume-weighted average share price, SEK	178.38
Exercise price, SEK	196.20
Risk-free interest rate, (%)	(0.59)
ESO term, years	3.0
Expected volatility, (%)	43.0
Expected dividend, SEK	—
Calculated fair value per ESO, SEK	45.19

As of December 31, 2023, 149,148 ESOs had vested and were outstanding under LTIP 2019:

	Years Ended December 31,	
	2023	2022
ESO, Opening balance January 1	149,148	149,148
ESO forfeited or expired during the period	—	—
<b>ESO, Closing balance December 31</b>	<b>149,148</b>	<b>149,148</b>
Recorded share-based compensation expenses, thousands of SEK	—	930

### Long-term incentive program 2020 (LTIP 2020)

At Hansa's AGM on June 23, 2020, shareholders resolved to adopt a long-term incentive program, LTIP 2020. Under the terms of LTIP 2020 participants in the program may receive share rights free of charge and/or ESOs as further described below.

#### Share rights under LTIP 2020

Each share right entitles a participant to acquire one ordinary share in the Company at no cost provided certain pre-defined performance conditions are met and the employment is maintained within the Group during the vesting period. Each share right carries a vesting period of three years commencing on the day of its allotment to a participant (the Vesting Period).



## Notes to the Group Financial Statements continued

The final number of ordinary shares a participant is entitled to receive is, amongst other terms, conditional upon meeting the following performance conditions during the Vesting Period:

- > Condition 1 (accounting for 22%): The U.S. randomized controlled trial (ConfIdeS) has enrolled 64 patients;
- > Condition 2 (accounting for 11%): Top-line data read out of the ongoing Phase 2 study in either AMR or GBS is completed with data providing a solid scientific rationale for a path forward;
- > Condition 3 (accounting for 11%): At least 70% of the targeted transplantation centers in Europe have been initiated; and
- > Condition 4 (accounting for 56%): TSR of at least 25% against the baseline share price at the date of allotment.

In December 2021, Hansa's Board of Directors in line with the terms and conditions of the LTIP 2020 resolved to adjust Condition 1 from the previous condition "The U.S. randomized controlled trial is completed during the Vesting Period" to the new condition "US RCT study (ConfIdeS) fully enrolled". In December 2022, Hansa's Board of Directors in line with the terms and conditions of the LTIP 2020 resolved to adjust (a) Condition 1 from the previous condition "US RCT study (ConfIdeS) fully enrolled" to the new condition "The U.S. randomized controlled trial (ConfIdeS) has enrolled 64 patients", and (b) Condition 2 from the previous condition "Top-line data read out of the ongoing Phase 2 study in either AMR or GBS is completed with data providing a solid scientific rationale to continue either of the two programs" to the new condition "Top-line data read out of the ongoing Phase 2 study in either AMR or GBS is completed with data providing a solid scientific rationale for a path forward".

A total of 417,556 share rights were allotted to participants, of which 401,556 were allotted in July 2020 and 16,000 were allotted in February 2021.

The Group used the following inputs when valuing the share rights under LTIP 2020 based on Monte Carlo simulation:

	Allotment Jul 23, 2020	Allotment Feb 12, 2021
Starting value (baseline share price) for TSR calculation, SEK	252.60	252.60
Risk-free interest rate, (%)	(0.33)	(0.25)
Expected volatility, (%)	43.0	43.0
Expected dividend, SEK	—	—
Calculated weighted average fair value per share right, SEK	173.26	120.07

As of December 31, 2023, 16,000 share rights were outstanding under LTIP 2020:

	Years Ended December 31,	
	2023	2022
Share rights, Opening balance January 1	398,311	400,556
Share rights forfeited	(214,094)	(2,245)
Share rights vested	(168,217)	—
<b>Share Rights, Closing balance December 31</b>	<b>16,000</b>	<b>398,311</b>
Recorded share-based compensation expenses, thousands of SEK	15,758	21,607

### Employee Stock Options under LTIP 2020

Each ESO entitles the holder to receive one new ordinary share in the Company at an exercise price corresponding to 125% of the volume weighted average share price during the 10 trading days immediately prior to the offer to subscribe for the instruments, and provided that the participant, with certain exceptions, from the date of the start of participation in LTIP 2020 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

A total of 507,520 ESOs were issued to participants of which 487,520 were issued in July 2020 and 20,000 were issued in February 2021.

The Group used the following inputs when valuing the ESOs under LTIP 2020 based on Black Scholes model:

	Issuance Jul 23, 2020	Issuance Feb 12, 2021
Underlying volume-weighted average share price, SEK	252.60	185.13
Exercise price, SEK	315.75	315.75
Risk-free interest rate, (%)	(0.33)	(0.25)
ESO term, years	3.0	3.0
Expected volatility, (%)	43.0	43.0
Expected dividend, SEK	—	—
Calculated fair value per ESO, SEK	53.05	27.25



## Notes to the Group Financial Statements continued

As of December 31, 2023, 487,520 ESOs were outstanding under LTIP 2020 of which 467,520 had vested:

	Years Ended December 31,	
	2023	2022
ESO, Opening balance January 1	487,520	497,520
ESO forfeited	—	(10,000)
<b>ESO, Closing balance December 31</b>	<b>487,520</b>	<b>487,520</b>
Recorded share-based compensation expenses, thousands of SEK	5,721	7,808

### Long-term incentive program 2021 (LTIP 2021)

At Hansa's AGM on May 12, 2021, shareholders resolved to adopt a long-term incentive program, LTIP 2021. Under the terms of LTIP 2021 participants in the program may receive share rights free of charge and/or ESOs as further described below.

#### Share rights under LTIP 2021

Each share right entitles a participant to acquire one ordinary share in the Company at no cost provided certain pre-defined performance conditions are met and the employment is maintained within the Group during the vesting period. Each share right carries a vesting period of three years commencing on the day of its allotment to a participant (the Vesting Period).

The final number of ordinary shares a participant is entitled to receive is, amongst other terms, conditional upon meeting the following performance conditions during the Vesting Period:

- > Condition 1 (accounting for 22%): U.S. FDA has accepted a BLA filing for approval of imlifidase in the U.S.;
- > Condition 2 (accounting for 11%): A phase 3 study in either AMR or GBS is initiated or a filing for regulatory approval is accepted by either the FDA or EMA for one of these indications or anti-GBM;
- > Condition 3 (accounting for 11%): At least 80% of the targeted transplantation centers in Europe have been initiated; and
- > Condition 4 (accounting for 56%): TSR of at least 25% against the baseline share price at the date of allotment.

In December 2023, Hansa's Board of Directors in line with the terms and conditions of the LTIP 2021 resolved to adjust (a) Condition 1 from the previous condition "U.S. FDA has accepted a BLA filing for approval of imlifidase in the U.S." to the new condition "At least 56 patients randomized in the US ConfideS study", and (b) Condition 2 from "A phase 3 study in either AMR or GBS is initiated or a filing for regulatory approval is accepted by either the FDA or EMA for one of these indications or anti-GBM"

to the new condition "GBS phase 3 development strategy aligned with FDA or EMA, and 30% of patients enrolled into anti-GBM phase 3 study".

A total of 557,000 share rights were allotted to participants in June 2021.

The Group used the following inputs when valuing the share rights under LTIP 2021 based on Monte Carlo simulation:

	Allotment Jun 7, 2021
Starting value (baseline share price) for TSR calculation, SEK	153.75
Risk-free interest rate, (%)	(0.18)
Expected volatility, (%)	46.9
Expected dividend, SEK	—
Calculated weighted average fair value per share right, SEK	98.94

As of December 31, 2023, 481,263 share rights were outstanding under LTIP 2021:

	Years Ended December 31,	
	2023	2022
Share rights, Opening balance January 1	551,263	557,000
Share rights forfeited	(70,000)	(5,737)
<b>Share Rights, Closing balance December 31</b>	<b>481,263</b>	<b>551,263</b>
Recorded share-based compensation expenses, thousands of SEK	20,542	7,948

#### Employee Stock Options under LTIP 2021

Each ESO entitles the holder to receive one new ordinary share in the Company at an exercise price corresponding to 125% of the volume weighted average share price during the 30 trading days immediately prior to the offer to subscribe for the instruments, and provided that the participant, with certain exceptions, from the date of the start of participation in LTIP 2021 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

A total of 430,000 ESOs were issued to participants in June 2021.



## Notes to the Group Financial Statements continued

The Group used the following inputs when valuing the ESOs under LTIP 2021 based on Black Scholes model:

	Issuance Jun 7, 2021
Underlying volume-weighted average share price, SEK	153.70
Exercise price, SEK	192.20
Risk-free interest rate, (%)	(0.04)
ESO term, years	4.5
Expected volatility, (%)	46.9
Expected dividend, SEK	—
Calculated fair value per ESO, SEK	42.98

As of December 31, 2023, 360,000 ESOs were outstanding under LTIP 2021:

	Years Ended December 31,	
	2023	2022
ESO, Opening balance January 1	430,000	430,000
ESO forfeited	(70,000)	—
<b>ESO, Closing balance December 31</b>	<b>360,000</b>	<b>430,000</b>
Recorded share-based compensation expenses, thousands of SEK	3,047	5,892

### Long-term incentive program 2022 (LTIP 2022)

At Hansa's AGM on June 30, 2022, shareholders resolved to adopt a long-term incentive program, LTIP 2022. Under the terms of LTIP 2022 participants in the program may receive share rights free of charge and/or ESOs as further described below.

#### Share rights under LTIP 2022

Each share right entitles a participant to acquire one ordinary share in the Company at no cost provided certain pre-defined performance conditions are met and the employment is maintained within the Group during the vesting period. Each share right carries a vesting period of three years commencing on the day of its allotment to a participant (the Vesting Period).

The final number of ordinary shares a participant is entitled to receive is, amongst other terms, conditional upon meeting the following performance conditions during the Vesting Period:

- > Condition 1 (accounting for 22%): U.S. FDA has approved imlifidase in the U.S.;
- > Condition 2 (accounting for 11%): Imlifidase has been approved, or a Marketing Authorization Application/Biologics License Application has been submitted, in any jurisdiction in an indication outside kidney transplant;
- > Condition 3 (accounting for 11%): At least 80% of the targeted transplantation centers in Europe have had repeat business; and
- > Condition 4 (accounting for 56%): TSR of at least 25% against the baseline share price at the date of allotment.

In December 2023, Hansa's Board of Directors in line with the terms and conditions of the LTIP 2022 resolved to adjust (a) Condition 1 from the previous condition "U.S. FDA has approved imlifidase in the U.S." to the new condition "At least 60 patients have completed the 12-months follow-up visit in the U.S. ConfdeS study", and (b) Condition 2 from "Imlifidase has been approved, or a Marketing Authorization Application/Biologics License Application has been submitted, in any jurisdiction in an indication outside kidney transplant" to the new conditions 2a. "A pivotal study outside of kidney Tx fully enrolled (accounting for 5%)" and, 2b. "70% of patients enrolled into anti-GBM phase 3 study (accounting for 6%)".

A total of 588,000 share rights were allotted to participants, of which 543,000 were allotted in July 2022 and 45,000 were allotted in April 2023.

The Group used the following inputs when valuing the share rights under LTIP 2022 based on Monte Carlo simulation:

	Allotment Jul 20, 2022	Allotment Apr 1, 2023
Starting value (baseline share price) for TSR calculation, SEK	56.00	50.86
Risk-free interest rate, (%)	(1.87)	2.84
Expected volatility, (%)	58.6	61.3
Expected dividend, SEK	—	—
Calculated weighted average fair value per share right, SEK	80.29	38.03



## Notes to the Group Financial Statements continued

As of December 31, 2023, 515,000 share rights were outstanding under LTIP 2022:

	Years Ended December 31,	
	2023	2022
Share rights, Opening balance January 1	543,000	—
Allotted to participants July 20, 2022	—	543,000
Allotted to participants April 1, 2023	45,000	—
Share rights forfeited	(73,000)	—
<b>Share Rights, Closing balance December 31</b>	<b>515,000</b>	<b>543,000</b>
Recorded share-based compensation expenses, thousands of SEK	11,411	7,277

### Employee Stock Options under LTIP 2022

Each ESO entitles the holder to receive one new ordinary share in the Company at an exercise price corresponding to 125% of the volume weighted average share price during the 30 trading days immediately prior to the offer to subscribe for the instruments, and provided that the participant, with certain exceptions, from the date of the start of participation in LTIP 2022 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

A total of 442,300 ESOs were issued to participants of which 384,000 were issued in July 2022 and 58,300 were issued in April 2023.

The Group used the following inputs when valuing the ESOs under LTIP 2022 based on Black Scholes model:

	Issuance	Issuance
	Jul 20, 2022	Apr 1, 2023
Underlying volume-weighted average share price, SEK	56.01	51.02
Exercise price, SEK	70.00	63.58
Risk-free interest rate, (%)	(1.86)	(2.48)
ESO term, years	4.5	4.5
Expected volatility, (%)	58.6	61.3
Expected dividend, SEK	—	—
Calculated fair value per ESO, SEK	52.45	23.26

As of December 31, 2023, 312,300 ESOs were outstanding under LTIP 2022:

	Years Ended December 31,	
	2023	2022
ESO, Opening balance January 1	384,000	—
ESO allotted to participants July 20, 2022	—	384,000
ESO allotted to participants April 1, 2023	58,300	—
ESO forfeited	(130,000)	—
<b>ESO, Closing balance December 31</b>	<b>312,300</b>	<b>384,000</b>
Recorded share-based compensation expenses, thousands of SEK	3,139	2,934

### Long-term incentive program 2023 (LTIP 2023)

At Hansa's AGM on June 29, 2023, shareholders resolved to adopt a long-term incentive program, LTIP 2023. Under the terms of LTIP 2023 participants in the program may receive share rights free of charge and/or ESOs as further described below.

### Share rights under LTIP 2023

Each share right entitles a participant to acquire one ordinary share in the Company at no cost provided certain pre-defined performance conditions are met and the employment is maintained within the Group during the vesting period. Each share right carries a vesting period of three years commencing on the day of its allotment to a participant (the Vesting Period).

The final number of ordinary shares a participant is entitled to receive is, amongst other terms, conditional upon meeting the following performance conditions during the Vesting Period:

- > Condition 1 (accounting for 30%): U.S. FDA has approved imlifidase in the U.S.;
- > Condition 2 (accounting for 25%): Completion of a phase 2 trial with HNSA5487 in any indication or a pivotal anti-GBM trial with imlifidase;
- > Condition 3 (accounting for 25%): More than 50% of the targeted transplantation centers in Europe had repeat business, i.e. used Idefirix more than once; and
- > Condition 4 (accounting for 20%): Relates to the total shareholder return (the return to shareholders through an increased share price and reinvestments of any dividends during the Vesting Period) on the company's ordinary shares.

Condition 4 entails that participants will be entitled to 20% of the Performance Shares if the total shareholder return out-performs the Benchmark Index (as defined below) by 10% or more. If the total shareholder return during the Vesting Period is less than the performance of the Benchmark Index, no allotment of Performance Shares will be made under Condition 4. If the total shareholder return, as



## Notes to the Group Financial Statements continued

compared to the Benchmark Index, is either equal or out-performing by up to 10%, allotment will be made linearly. The benchmark for assessing the total shareholder return under Performance Condition 4 should be the EURO STOXX Total Market Biotechnology Index (EUR) (the "Benchmark Index") at constant EUR/SEK exchange rate.

A maximum of 800,000 share rights can be allotted under LTIP 2023. As of December 31, 2023, a total of 716,000 share rights have initially been allotted to participants.

The Group used the following inputs when valuing the share rights under LTIP 2023 based on Monte Carlo simulation:

	Allotment Nov 6, 2023
Starting value (baseline share price) for TSR calculation, SEK	25.90
Risk-free interest rate, (%)	3.26
Expected volatility, (%)	63.2
Expected dividend, SEK	—
Calculated weighted average fair value per share right, SEK	21.95

As of December 31, 2023, 643,000 share rights were outstanding under LTIP 2023:

	Years Ended December 31,	
	2023	2022
Share rights, Opening balance January 1	—	—
Allotted to participants November 6, 2023	716,000	—
Share rights forfeited	(73,000)	—
<b>Share Rights, Closing balance December 31</b>	<b>643,000</b>	—
Recorded share-based compensation expenses, thousands of SEK	714	—

### Employee Stock Options under LTIP 2023

Each ESO entitles the holder to receive one new ordinary share in the Company at an exercise price corresponding to 110% of the volume weighted average share price during the 30 trading days immediately prior to the offer to subscribe for the instruments, and provided that the participant, with certain exceptions, from the date of the start of participation in LTIP 2023 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

A maximum of 600,000 ESOs can be issued to participants under LTIP 2023. As of December 31, 2023, a total of 550,000 ESOs have initially been issued to participants.

The Group used the following inputs when valuing the ESOs under LTIP 2023 based on Black Scholes model:

	Issuance Nov 6, 2023
Underlying volume-weighted average share price, SEK	23.58
Exercise price, SEK	28.50
Risk-free interest rate, (%)	2.87
ESO term, years	5.5
Expected volatility, (%)	63.2
Expected dividend, SEK	—
Calculated fair value per ESO, SEK	12.59

As of December 31, 2023, 480,000 ESOs were outstanding under LTIP 2023:

	Years Ended December 31,	
	2023	2022
ESO, Opening balance January 1	—	—
ESO allotted to participants November 6, 2023	550,000	—
ESO forfeited	(70,000)	—
<b>ESO, Closing balance December 31</b>	<b>480,000</b>	—
Recorded share-based compensation expenses, thousands of SEK	305	—

### Note 15 Provisions

Provisions relate to social security contributions linked to outstanding share or option rights in the Group's ongoing incentive programs. The social security contributions are expected to be incurred after vesting if and when plan participants realize value under their specific rights under the LTIP programs. Please refer to Note 14 related to the Group's LTIP programs and respective vesting dates.



## Notes to the Group Financial Statements continued

The decrease in provisions for 2023 was mainly driven by impact of the decrease in the Company's share price that resulted in lower provision for social security contributions under the LTIP programs.

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Opening balance January 1</b>	<b>5,192</b>	<b>7,357</b>
Change in provision related to LTIP 2019	(34)	(2,910)
Change in provision related to LTIP 2020	332	(216)
Change in provision related to LTIP 2021	(505)	(357)
Change in provision related to LTIP 2022	(705)	1,318
Change in provision related to LTIP 2023	174	—
<b>Closing balance December 31</b>	<b>4,454</b>	<b>5,192</b>

### Note 16 Income Taxes

#### Deferred taxes

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Opening balance January 1</b>	<b>405</b>	<b>426</b>
Tax income in the consolidated statement of profit or loss and other comprehensive income	(42)	(41)
Currency differences for the year	4	20
<b>Closing balance December 31</b>	<b>367</b>	<b>405</b>

#### Accumulated losses carried forward

Deferred tax assets have not been recognized regarding temporary differences and losses carried forward since it is not probable that it can be used in a foreseeable future.

The Group's accumulated losses carried forward at the end of 2023 amounted to SEK 3,031,482k (2022: SEK 2,361,926k). The losses carried forward is, in all material respects, attributable to Swedish companies and therefore has no due date.

A reconciliation of Hansa's effective tax rate relative to the Swedish statutory tax rate is as follows:

	2023		2022	
	%	(in thousands of SEK)	%	(in thousands of SEK)
Result before tax	—	(830,812)	—	(609,979)
Tax according to current tax rate in parent company	20.6	171,147	20.6	125,656
<b>Tax effect of:</b>				
Other tax rates for foreign subsidiaries	—	(66)	—	(21)
Non-deductible expenses	4.1	(34,353)	3.6	(21,920)
Deductible part of foreign income tax	0.0	167	—	—
Tax losses for which no deferred tax asset has been reported	16.5	(136,994)	17.2	(104,869)
Reported foreign income tax	0.1	(809)	—	—
<b>Reported effective tax</b>	<b>0.1</b>	<b>(908)</b>	<b>0.2</b>	<b>(1,155)</b>

The corporate tax rate in Sweden is 20.6%, from January 1, 2021

### Note 17 Earnings per Share

(in SEK)	Years Ended December 31,	
	2023	2022
Loss per share, basic and diluted	(15.83)	(13.60)

Diluted net loss per share is computed using the weighted-average number of ordinary shares outstanding during the period, plus the dilutive effect of potential ordinary shares. Diluted net loss per share does not differ from basic net loss per share since potential ordinary shares from the conversion of share rights, stock options and warrants are antidilutive for all periods presented and are, therefore, excluded from the calculation. For the year ended December 31, 2023, and 2022, share rights to receive 1,655,263 and 1,492,574 ordinary shares, respectively, options to purchase 1,788,968 and 1,450,668 ordinary shares, respectively, were not included in the computation of diluted loss per share since their inclusion would be antidilutive.

The calculation of the numerator and denominator used in the above stated calculations of loss per share are stated below.





## Notes to the Group Financial Statements continued

### Loss attributable to ordinary shareholders, basic and diluted

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
Loss for the year attributable to owners of the parent	(831,720)	(611,134)
Loss attributable to ordinary shareholders, basic and diluted	(831,720)	(611,134)

### Weighted average number of ordinary shares, basic and diluted

	Years Ended December 31,	
	2023	2022
Outstanding ordinary shares January 1	52,443,962	44,473,452
Effect of conversion of C to A shares in June 2022	—	62,202
Effect of conversion of C to A shares in October 2022	—	1,314
Effect of issue of ordinary shares in December 2022	—	387,030
Effect of conversion of C to A shares in July 2023	96,127	—
Weighted average number of ordinary shares, basic and diluted	52,540,089	44,923,998

### Note 18 Contingent Consideration

The Group acquired Immago Ltd (today Hansa Biopharma Ltd) on July 19, 2016. The agreed upon purchase price was GBP 170,000. An additional GBP 70,000 milestone payment is to be paid if a clinical study based on the acquired technology is initiated in Europe or the U.S. The payment of the contingent liability, which is estimated to take place in 2025, has a fair value of SEK 843k (2022: SEK 757k).

The estimated future cash flow is discounted using a 10% risk adjusted interest rate, for further information see Note 20.

### Note 19 Capital Management

The Board of Directors' policy is to maintain a strong capital base to maintain investor, creditor and market confidence, and a continuous advancement of Hansa's product pipeline and business in general. Hansa has financed its operations mostly from shareholders equity through the issuance of shares. As of December 31, 2023, The Group's cash position (including short-term investments) amounted to SEK 732.1 million.

The adequacy of available funds will depend on many factors, including growth of ldefirix sales, progress in research and development programs, the magnitude of those programs, commitments to existing and new collaborators, the ability to establish commercial and licensing arrangements, capital

expenditures, market developments, and any potential future acquisitions. Accordingly, Hansa may require additional funds and may attempt to raise additional funds through equity or debt financings, collaborative agreements with partners, or from other sources.

The Board of Directors monitors the share and capital structure to ensure that Hansa's capital resources support the strategic goals. Neither the Company nor any of its subsidiaries are subject to externally imposed capital requirements. Managed capital is all reported equity.

### Note 20 Financial Risk and Financial Instruments

The Group has exposure to the following risks arising from financial instruments:

- A. Liquidity risk
- B. Market risk
- C. Credit risk

### Risk management framework

The Group's board of directors has overall responsibility for the establishment and oversight of the Group's risk management framework. The Group's risk management policies are established to identify and analyze the risks faced by the Group, to set appropriate risk limits and controls and to monitor risks and adherence to limits. Risk management policies and systems are reviewed to reflect changes in market conditions and the Group's activities. The Group, through its training and management standards and procedures, aims to maintain a disciplined and constructive control environment in which all employees understand their roles and obligations. The Group's audit committee oversees how management monitors compliance with the Group's risk management policies and procedures and reviews the adequacy of the risk management framework in relation to the risks faced by the Group. The Group's audit committee is assisted in its oversight role by corporate finance function. Corporate finance function undertakes both regular and ad hoc reviews of risk management controls and procedures, the results of which are reported to the audit committee.

### Liquidity Risk

Liquidity risk is the risk that the Group will encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivering cash or another financial asset. The Group's approach to managing liquidity is to ensure, as far as possible, that it will have sufficient liquidity to meet its liabilities when they are due, under both normal and stressed conditions, without incurring unacceptable losses or risking damage to the Group's reputation. The Board of Directors is responsible for the long-term financing strategy and for the acquisition of capital. The management of financial risks in the day-to-day operations is managed by the CFO and the corporate finance function.



## Notes to the Group Financial Statements continued

To secure short-term liquidity, Hansa's treasury policy prescribes that an appropriate level of liquidity in the form of cash and cash equivalents shall be held in an amount sufficient to cover the expected Group financial obligations over at least the next nine-month period. This principle shall be checked and assured every time a new investment decision is taken. On the reporting date, this goal was fulfilled.

Cash and cash equivalents on December 31, 2023, amounted to SEK 732.1 million. Cash and cash equivalents on the reporting date consisted of bank deposits.

Set forth below is a term-based analysis of the Group's remaining contractual financial liabilities:

As of December 31, 2023					
(in thousands of SEK)	Nominal Amount	0–3 months	3–12 months	1–5 years	5–7 years
Long-term loan	1,405,600	—	—	790,650	614,950
Contingent consideration	894	—	—	894	—
Non-current leasing liabilities	14,848	—	—	14,848	—
Current leasing liabilities	8,145	2,044	6,101	—	—
Trade payables	86,966	86,966	—	—	—
Accrued expenses (see Note 11)	41,526	41,526	—	—	—
<b>Total</b>	<b>1,557,979</b>	<b>130,536</b>	<b>6,101</b>	<b>806,392</b>	<b>614,950</b>

As of December 31, 2022					
(in thousands of SEK)	Nominal Amount	0–3 months	3–12 months	1–5 years	5–7 years
Long-term loan	1,458,800	—	—	820,575	638,225
Contingent consideration	887	—	—	887	—
Non-current leasing liabilities	22,744	—	—	22,744	—
Current leasing liabilities	8,154	2,038	6,116	—	—
Trade payables	62,476	62,476	—	—	—
Accrued expenses (see Note 11)	52,099	52,099	—	—	—
<b>Total</b>	<b>1,605,160</b>	<b>116,613</b>	<b>6,116</b>	<b>844,206</b>	<b>638,225</b>

### Market Risk

Market risk is the risk that changes in market prices, e.g. foreign exchange rates, interest rates and equity prices will affect the Group's income or the value of its holdings of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimizing the return.

### Currency risk

The Group is exposed to transactional foreign currency risk to the extent that there is a mismatch between the currencies in which sales, purchases, receivables, and borrowings are denominated and the respective functional currencies of Group companies. The functional currencies of Group companies are primarily the SEK, GBP, and USD. The currencies in which transactions are primarily denominated are SEK, EUR, GBP, and USD. In 2022, the Company took up a long-term loan in the amount of USD 70 million. The Company is exposed to USD currency risk related to such loan as per the contractual repayment dates. Refer to Note 21 for further information on the loan.

To manage the currency risk exposure, the Group may in its normal course of business, hold funds in foreign currency or enter into currency forward contracts or similar instruments to benefit from trends in exchange rates on the basis of a sophisticated analysis considering exchange rate forecasts published by banks or other analysts as well as short and mid-term currency needs of the Group.

All cash and investments shall only be made and held in Swedish Krona. In case of investments in funds or the like, an investment can only be made if the currency fluctuation risk is fully hedged by the fund.

As an exception to the above, the Group may hold cash in foreign currency in the normal course of business to pay any trade payables in foreign currencies. Subsidiaries will hold cash in their local currency within their normal course of business.

The Group is exposed to translation risk that arise from consolidation of foreign subsidiaries. The Group net assets on December 31, 2023, relating to Hansa Biopharma Inc. amounted to USD 920k (2022: USD 574k) and the Group net assets relating to Hansa Biopharma Ltd. amounted to GBP 196k (2022: GBP 102k).

### Sensitivity analysis

The Company purchases services mainly in USD, EUR, and GBP. A weakening of the Swedish krona in relation to these currencies therefore leads to increased costs for the Group, all else remaining the same. In addition, the Group have revenues from product sales and licensing revenue which are mainly paid in USD, EUR, and GBP. A strengthening of the Swedish krona in relation to USD, EUR and GBP therefore leads to reduced revenue for the Group expressed in SEK, all else remaining the same.

A weakening of the SEK in relation to USD, EUR, or GBP by an average of 10% would have negatively affected the Group's earnings before tax by approximately SEK 17.3 million, SEK 31.6 million and SEK 2.2 million, respectively. This analysis assumes that all other variables, in particular interest rates, remain constant and ignores any impact of forecast sales and purchases.



## Notes to the Group Financial Statements continued

The Company has taken up a long-term loan in the amount of USD 70 million in 2022. As of December 31, 2023, the carrying amount of such loan is USD 84.2 million, corresponding SEK 844.9 million. A strengthening of the USD by 10% would have resulted in an increase in long-term liabilities in the amount of approximately SEK 84.5 million.

The sensitivity analysis is based on approximated cash flows in foreign currencies. Income and expenses of foreign operations are translated into Swedish kronor at an average exchange rate that approximates the exchange rates presented at each transaction date.

### Interest rate risk

The interest rate risk consists of the risk that a change in market interest rates will have a negative effect on earnings. The Group's exposure to interest rate risks is considered to be low as the Group only has very limited interest-bearing liabilities. There is certain exposure to interest rate risks in cash and cash equivalents in the form of bank deposits.

During 2022 the Group sold all its investments in interest funds – see further information in the Cash Flow Statement.

In 2022, the Company took up a long-term loan in the amount of USD 70 million. The Company is not exposed to any material interest rate risk with regard to such loan as the repayment amount is fixed at twice the principal loan amount.

### Credit risk

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Group's receivables from customers and investments in debt securities. The carrying amounts of financial assets and unbilled revenues represent the maximum credit exposure.

The Group's credit risk is primarily related to bank deposits. However, this risk is considered to be low since the bank deposits are held with four Swedish banks with good credit ratings. See further discussions in Note 2. According to the Group's treasury policy, The Company may only hold bank deposits with, or initiate payments through, Swedish and foreign banks under the supervision of the Swedish Financial Supervisory Authority or similar foreign agency.

The Group has risk related to its trade receivables. The Company determined that the country risk premium was the appropriate factor to use as the default rate as this factor represents the expected losses from default on the sovereign debt. The Company concluded these factors could be generalized to its receivables from the Product sold in these geographies due to direct or indirect involvement of the respective governments.

### Provision for bad debt

(KSEK)	As of December 31,	
	2023	2022
Opening balance January 1	78	—
Change in provision	461	78
Closing balance December 31	539	78

The Group has also risk related to other receivables that consist mainly of advance payments to suppliers. The credit risk is considered to be low as the Group uses trading history as an evaluation factor.

The maximum credit exposure of financial assets amounted to SEK 809.1 million and SEK 1,505.4 million for the periods ended December 31, 2023, and 2022, respectively.

### Investment policy

The Group may invest a portion of its funds in bank deposits, bonds, investment funds and the like with maturity of more than 35 days, while managing the interest rate risk exposure, credit risk exposure as well as the cluster risk. As a general principle, the Group may only invest in investment grade issuers, measured at the day of the investment.

Therefore, the following applies:

1) Minimum credit rating of one of the following rating agencies (or comparable):

	S&P Rating	Moody's rating
Up to one year	A-2	P2
More than one year	A	A

2) The maximum amount invested with one counterparty or issuer is limited to 30% of total funds at the time a new investment decision is taken. This limit might be increased to up to 50% upon prior approval by the Audit Committee.

3) The duration management within the portfolio of investments is the responsibility of the CFO. The maximum maturity of an individual investment shall not exceed two years.



## Notes to the Group Financial Statements continued

### Carrying amounts of financial assets and financial liabilities

The table below shows the carrying amounts for financial assets and financial liabilities broken down by measurement categories under IFRS 9:

(in thousands of SEK)	Financial assets valued at amortized cost		Financial assets valued at fair value through the income statement	
	2023	2022	2023	2022
<b>Financial assets:</b>				
Trade receivables and unbilled revenue	78,025	42,959	—	—
Other receivables	737	874	—	—
Cash and cash equivalents	732,060	1,496,179	—	—
<b>Total</b>	<b>810,822</b>	<b>1,540,011</b>	<b>—</b>	<b>—</b>

(in thousands of SEK)	Financial liabilities valued at amortized cost		Financial liabilities valued at fair value through the consolidated statement of profit or loss and other comprehensive income	
	2023	2022	2023	2022
<b>Financial liabilities:</b>				
Long-term loan	844,903	762,601	—	—
Contingent consideration	—	—	843	757
Trade payables	86,966	62,476	—	—
Accrued expenses (see Note 11)	41,526	52,099	—	—
<b>Total</b>	<b>974,227</b>	<b>877,176</b>	<b>843</b>	<b>757</b>

### Levels of financial assets and financial liabilities per valuation hierarchy

Management considers the carrying amounts for all financial assets and financial liabilities to be a reasonable approximation of their fair value.

The table below presents the carrying amount of financial assets and financial liabilities per valuation hierarchy in IFRS 13:

(in thousands of SEK)	Valuation Hierarchy	As of December 31,	
		2023	2022
<b>Financial liability:</b>			
Contingent consideration	Level 3	843	757
<b>Total</b>		<b>843</b>	<b>757</b>

The table below presents a reconciliation between the opening and closing balances for the contingent consideration valued in accordance with Level 3:

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Contingent liabilities:</b>		
Opening balance January 1	757	722
Currency differences	(30)	89
Interest (expense) / income	116	(54)
<b>Closing balance December 31</b>	<b>843</b>	<b>757</b>

The contingent consideration will be at minimum GBP 0 and at maximum GBP 70,000.

The Group's best estimate on December 31, 2023, is that the contingent consideration will be paid in 2025. The fair value of the contingent consideration is estimated based on management assessment when a clinical study utilizing the relevant technology is initiated in Europe or the U.S resulting in a milestone payment under the share purchase agreement. The estimated future cash flow is discounted using a 10% risk adjusted interest rate.

### Note 21 Long-term Loan

On July 18, 2022, the Company entered into a \$70.0 million funding agreement with NovaQuest. The funding was accounted for as liability classified debt as the Company has an unavoidable obligation to settle the funding in cash. The debt is accounted for at amortized cost.

The net proceeds from the funding were \$69.2 million after the deduction of transaction costs. The transaction costs were capitalized and offset against the carrying value of the debt and will be amortized over the term of the debt.

The debt is secured by certain of the Company's intellectual property and assets.

Under the terms of the debt, the Company will make quarterly mid-single-digit royalty percentage payments to NovaQuest on future worldwide annual net sales of imlifidase, commencing upon approval of imlifidase in the U.S. in kidney transplantation or anti-GBM. In addition, Hansa will make certain milestone payments to NovaQuest upon U.S. approval of imlifidase in kidney transplantation or anti-GBM. The agreement also provides for time-based catch-up payments within the payment cap if specified payment amounts have not been received by NovaQuest by specified dates. The repayment must start latest January 2026, irrespectively whether the above mentioned approvals were achieved, with the last potential catch-up payment due on December 31, 2028. The company is obligated to

## Notes to the Group Financial Statements continued

repay a total amount of USD 140 million in the form of milestone- or catch-up and royalty payments. Hansa has also entered into a security agreement under which it pledges and provides a broad security interest to NovaQuest in and to certain assets, proceeds and IP rights related to imlifidase in kidney transplantation in highly sensitized patients and anti-GBM disease (the "Pledged Assets").

The Company will record the difference between the principal and the total estimated future payments as interest expense over the forecasted term of the debt by applying the effective-interest-rate method. Based on the actual repayment pattern, the Company will recalculate the effective interest each reporting period until the debt is satisfied.

On 31 December 2023, the loan amounted to SEK 844.9 million (2022: SEK 762.6 million), thereof SEK 149.8 million (2022: SEK 41.2 million) in accrued interest.

### Note 22 Financial Income and Expenses

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
<b>Financial income</b>		
Interest income on bank deposits measured at amortized cost	27,992	8,833
Interest income, other	70	—
Net exchange rate variances	35,142	18,415
<b>Total</b>	<b>63,204</b>	<b>27,248</b>
<b>Financial costs</b>		
Interest expense on long-term loan at amortized cost	(104,381)	(42,470)
Interest expenses, other	(1,139)	(1,196)
Changes in the fair value of interest funds during the year	—	(4,973)
<b>Total</b>	<b>(105,520)</b>	<b>(48,639)</b>
<b>Financial income / (expense), net</b>	<b>(42,316)</b>	<b>(21,391)</b>

### Note 23 Share Capital and Number of Shares

Number of shares	Years Ended December 31,	
	2023	2022
<b>Outstanding as of January 1</b>	<b>52,443,962</b>	<b>44,473,452</b>
Effect of conversion of C to A in June 2022	—	114,666
Effect of conversion of C to A shares in October 2022	—	7,733
Effect of new share issue in December 2022	—	7,848,111
Effect of conversion of C to A shares in July 2023	227,834	—
<b>Outstanding as of December 31</b>	<b>52,671,796</b>	<b>52,443,962</b>

The Parent Company's share has a par value of SEK 1. Per December 31, 2023, the total number of registered shares of Hansa amounts to 55,034,241, whereof 52,671,796 are ordinary shares and 2,362,445 are class C shares, held by the Company. The total registered share capital amounts to SEK 55,034,241.

Holders of ordinary shares are entitled to dividends which are determined after they become shareholders. Each ordinary share entitles the holder to one vote per share.

### Note 24 Share Premium

The share premium reserve is comprised of the amount received, attributable to shareholders' equity, in excess of the nominal amount of the shares issued, reduced by any amount allocated to external expenses directly attributable to the offerings. The share premium reserve can be distributed.

### Note 25 Treasury Shares Included in Equity

	Number of Shares		Amount, In thousands of SEK	
	2023	2022	2023	2022
<b>Opening balance January 1</b>	<b>2,590,279</b>	<b>1,861,909</b>	<b>2,590</b>	<b>1,862</b>
Additions	—	850,769	—	851
Exercise of share rights	(227,834)	(122,399)	(228)	(122)
<b>Closing balance December 31</b>	<b>2,362,445</b>	<b>2,590,279</b>	<b>2,362</b>	<b>2,590</b>

Treasury shares have a par value of SEK 1.

The year 2022 additions of Class C shares result from the new issue and subsequent repurchase of Class C shares related to the funding of the long-term incentive plan (LTIP) 2022, as approved at the 2022 AGM. Class C shares correspond to treasury shares held by the Company and are reserved to fund the respective LTIP programs. Each Class C share entitles the holder to 0.1 vote per share.



## Notes to the Group Financial Statements continued

### Note 26 Reserves

#### Treasury share reserve

The treasury share reserve comprises own shares repurchased by the Group. Please refer to Note 14 related to the Group's LTIP programs and respective vesting dates.

#### Translation reserve

The translation reserve comprises all foreign exchange differences arising on translation of financial statements from foreign business prepared in currency other than the reporting currency for the financial statements of the Group. The Group presents their financial statements in Swedish Kronor.

### Note 27 Royalty Agreements

#### Royalty agreement with researchers

The Company is a party to two separate royalty agreements (the "Royalty Agreements") with certain researchers and an affiliated entity (collectively, the "Counterparties") of certain patents related to methods of use of imlifidase. Under each agreement, in consideration of the assignment of these patents, the Counterparties are entitled to receive a low single-digit royalty percentage of the Company's net income related to the utilization of the patents, in each case as defined in the applicable agreement, and a low-teens percentage of any once-only considerations, milestones, royalties, license income, consideration for transfer of patents, patent applications and other intellectual property rights and other payments received by the Company related to the exploitation of rights related to these patents, in each case subject to certain specified reductions. As the Company has received conditional regulatory approval for Idefirix® (imlifidase) in the EU, commercially launched Idefirix®, above-mentioned compensation obligations under the Royalty Agreements have become effective during 2022.

On April 20, 2021, the Company received a request for arbitration from the Counterparties claiming they were entitled to 10% of the upfront payment the Company received under its 2020 collaboration agreement with Sarepta as well as entitlement to participate in payments the Company may receive under the Sarepta agreement in the future.

In the third quarter 2022, the Company and the Counterparties settled the dispute by entering into an amendment and settlement agreement (the "Agreement"), which covers all compensation obligations under the Royalty Agreements. Under the Agreement, the Royalty Agreements will be treated as one agreement with respect to the Researchers' right to consideration entitling the Counterparties to low single-digit royalties on net sales as well as mid-single-digit participation in any once-only consideration received by Hansa in respect of imlifidase. The settlement also includes a one-off settlement payment.

### Note 28 Other Operating Income and Expenses

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
<b>Other operating income</b>		
Net foreign currency gains on receivables/liabilities from operating activities	2,663	—
Other operating income	177	—
<b>Total</b>	<b>2,840</b>	<b>—</b>
<b>Other operating expenses</b>		
Foreign currency losses on receivables/liabilities from operating activities	—	(12,469)
Other operating expenses	(463)	(8,063)
<b>Total</b>	<b>(463)</b>	<b>(20,532)</b>
<b>Total other operating income/(expenses)</b>	<b>2,377</b>	<b>(20,532)</b>

### Note 29 Operating Expenses by Nature

The table below presents an analysis of operating expenses presented in profit or loss in classification based on the nature of the expenses:

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
Personnel expenses	(373,850)	(313,516)
Third party expenses	(477,236)	(360,630)
Depreciation and amortization expenses	(10,738)	(9,959)
Other operating expenses	2,377	(20,532)
<b>Total</b>	<b>(859,447)</b>	<b>(704,637)</b>



## Notes to the Group Financial Statements continued

Following table summarizes amortization and depreciation expenses from note 4, 5 and 6 above presented by function in profit or loss and other comprehensive income (loss):

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
Research and development expenses	(9,060)	(7,027)
Sales, general and administrative expenses	(1,678)	(2,932)
<b>Total</b>	<b>(10,738)</b>	<b>(9,959)</b>

Amortization of capitalized development cost and in-process development projects are reported as cost of revenue in the profit or loss and amounts to SEK 9,053k (2022: SEK 2,094k).

### Note 30 Supporting Information to the Cash Flows

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Cash and cash equivalents consist of:</b>		
Cash and bank deposits	732,060	1,496,179
Total according to statement of financial position	732,060	1,496,179
Total according to cash flow analysis	732,060	1,496,179

Reconciliation of liabilities arising from financing activities:

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Opening balance January 1,</b>	<b>791,092</b>	<b>35,379</b>
Termination of lease agreement	—	(25)
Changes in current lease agreement	919	—
Payment of lease liabilities	(7,545)	(6,863)
Net present value of long-term loan	—	687,221
Accrued interest on long-term loan	115,928	41,152
Unrealized currency differences on long-term loan	(33,626)	34,228
<b>Closing balance December 31,</b>	<b>866,768</b>	<b>791,092</b>

### Note 31 Subsequent Events

On March 1, 2024, Evan Ballantyne joined Hansa Biopharma AB as new CFO. There are no other subsequent events to report.



## Parent Company Financial Statements

### Statement of financial position

(in thousands of SEK)	Note	As of December 31,	
		2023	2022
<b>ASSETS</b>			
<b>Non-current assets:</b>			
Intangible assets	2	1,504,277	44,718
Property and equipment	3	6,343	8,113
Right-of-use assets	4	20,730	27,723
Financial assets:			
Investment in subsidiaries	5	30,044	24,264
Receivables, group companies	6	—	—
<b>Total non-current assets</b>		<b>1,561,394</b>	<b>104,818</b>
<b>Current assets:</b>			
Inventories	7	1,513	973
Trade receivables & unbilled revenues	8,13	78,025	42,959
Prepaid expenses and accrued income	9	21,472	33,226
Other receivables	10	21,733	31,142
Cash and cash equivalents	19,29	715,538	1,486,502
<b>Total current assets</b>		<b>838,281</b>	<b>1,594,802</b>
<b>TOTAL ASSETS</b>		<b>2,399,675</b>	<b>1,699,620</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>			
Restricted shareholders' equity:			
Share capital	22	55,034	55,034
Development cost reserve	25	119,606	20,853
Revaluation reserve	25	1,088,111	—
Unrestricted shareholders' equity:			
Share premium reserve	23	3,082,574	3,021,541
Treasury share reserve	24,25	(2,362)	(2,590)
Accumulated deficit		(2,530,482)	(1,882,304)
Loss for the year	16	(595,536)	(596,735)
<b>Total shareholders' equity</b>		<b>1,216,945</b>	<b>615,799</b>

(in thousands of SEK)	Note	As of December 31,	
		2023	2022
<b>LIABILITIES</b>			
<b>Non-current liabilities:</b>			
Long-term loan	20	844,903	762,601
Lease liabilities	4	14,362	21,326
Deferred revenue	13	—	29,500
Contingent consideration	17	843	757
Provisions	15	4,454	5,192
<b>Total non-current liabilities</b>		<b>864,562</b>	<b>819,376</b>
<b>Current liabilities:</b>			
Current tax liabilities		1,409	604
Liabilities, group companies	6	7,089	5,738
Lease liabilities	4	7,503	7,165
Trade payables	19	86,966	62,357
Other liabilities	12	21,079	17,868
Deferred revenue	13	41,473	40,430
Refund liabilities	8	49,266	27,013
Accrued expenses	11	103,383	103,270
<b>Total current liabilities</b>		<b>318,168</b>	<b>264,445</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>2,399,675</b>	<b>1,699,620</b>

The accompanying notes are an integral part of these Consolidated Financial Statements.





## Parent Company Financial Statements continued

### Statement of profit or loss and other comprehensive income (loss)

(in thousands of SEK)	Note	Years Ended December 31,	
		2023	2022
Revenue	13	134,094	154,525
Cost of revenue		(122,726)	(38,477)
Sales, general and administrative expenses	28	(448,133)	(330,071)
Research and development expenses	28	(412,404)	(340,192)
Other operating income/(expenses)	27	2,200	(20,532)
<b>Loss from operations</b>		<b>(846,969)</b>	<b>(574,747)</b>
Financial net			
Financial income	21	63,181	27,245
Financial expenses	21	(105,519)	(48,629)
<b>Financial net</b>		<b>(42,338)</b>	<b>(21,384)</b>
<b>Loss before tax</b>		<b>(889,307)</b>	<b>(596,131)</b>
Income tax expense	16	293,771	(604)
<b>Loss for the year</b>		<b>(595,536)</b>	<b>(596,735)</b>
Other comprehensive income/(loss) for the year		—	—
<b>Total comprehensive loss for the year</b>		<b>(595,536)</b>	<b>(596,735)</b>

The accompanying notes are an integral part of these Consolidated Financial Statements.



## Parent Company Financial Statements continued

### Statement of cash flows

(in thousands of SEK)	Note	Years Ended December 31,	
		2023	2022
<b>Cash Flows from Operating Activities</b>			
Loss for the year		(830,532)	(596,735)
<b>Adjustments to reconcile net loss to net cash flows:</b>			
Depreciation and amortization expenses		19,578	11,854
Capitalized development cost	2	(87,205)	(18,291)
Expenses related to incentive programs		54,877	41,566
Accrued interest and unrealized currency differences		44,609	31,361
<b>Total adjustments to net cash flows</b>		<b>(798,673)</b>	<b>(530,245)</b>
<b>Changes in working capital:</b>			
(Increase)/decrease of trade receivables & unbilled revenue	8	(35,065)	(33,247)
(Increase)/decrease of other operating assets		20,692	(21,897)
Increase/(decrease) trade payables	19	24,610	9,117
Increase/(decrease) of other operating liabilities		(1,529)	65,705
<b>Total changes in working capital</b>		<b>8,708</b>	<b>19,678</b>
Interest received		27,969	6,267
Interest paid		(1,021)	(1,166)
Income taxes paid		(4)	—
<b>Net cash used in operating activities</b>		<b>(763,021)</b>	<b>(505,467)</b>
<b>Cash Flows from Investing Activities</b>			
Proceeds from sale of short-term investments		—	232,644
Investment in subsidiaries		(113)	—
Acquisition of property and equipment	3	(284)	(3,331)
<b>Net cash (used in) from investing activities</b>		<b>(398)</b>	<b>229,313</b>

(in thousands of SEK)	Note	Years Ended December 31,	
		2023	2022
<b>Cash Flows from Financing Activities</b>			
Proceeds from long-term loan, net of transaction costs <sup>(1)</sup>		—	728,373
Proceeds from issue of ordinary shares, net of transaction costs <sup>(2)</sup>		—	396,196
Payment of lease liabilities	4,29	(7,545)	(6,888)
<b>Net cash (used in) from financing activities</b>		<b>(7,545)</b>	<b>1,117,681</b>
Net change in cash and cash equivalents		(770,964)	841,527
Cash and cash equivalents at beginning of year		1,486,502	644,975
<b>Cash and cash equivalents at end of year</b>	29	<b>715,538</b>	<b>1,486,502</b>

<sup>(1)</sup> Total long-term loan transaction cost amounted to SEK 8,027k.

<sup>(2)</sup> Total share issue cost amounted to SEK 19,754k.

The accompanying notes are an integral part of these Consolidated Financial Statements.



## Parent Company Financial Statements continued

### Statement of changes in shareholders' equity

(in thousands of SEK)	Note	Restricted shareholders' Equity				Unrestricted shareholders' Equity			Total shareholders' Equity
		Share Capital	Development Cost reserve	Revaluation reserve	Share Premium reserve	Treasury Share reserve	Accumulated deficit	Loss for the year	
<b>Balance at January 1, 2022</b>		46,335	—	—	2,572,925	(1,862)	(1,312,353)	(549,098)	755,948
<b>Statement of profit or loss and other comprehensive income/(loss):</b>									
Loss for the year		—	—	—	—	—	—	(596,735)	(596,735)
Other comprehensive income/(loss) for the year		—	—	—	—	—	—	—	—
<b>Total comprehensive loss for the year</b>		—	—	—	—	—	—	(596,735)	(596,735)
Appropriation of loss of the year 2021 carried forward		—	—	—	—	—	(549,098)	549,098	—
Capitalization of development cost		—	20,853	—	—	—	(20,853)	—	—
Issue of ordinary shares <sup>(1)</sup>		7,848	—	—	388,348	—	—	—	396,196
Issue of Class C shares <sup>(2)</sup>		851	—	—	—	(851)	—	—	—
Exercise of share rights		—	—	—	(122)	122	—	—	—
Long term incentive program		—	—	—	60,391	—	—	—	60,391
<b>Balance at December 31, 2022</b>	22,23,24,25	55,034	20,853	—	3,021,541	(2,590)	(1,882,304)	(596,735)	615,799
<b>Balance at January 1, 2023</b>		55,034	20,853	—	3,021,541	(2,590)	(1,882,304)	(596,735)	615,799
<b>Statement of profit or loss and other comprehensive income/(loss):</b>									
Loss for the year		—	—	—	—	—	—	(595,536)	(595,536)
Other comprehensive income/(loss) for the year		—	—	—	—	—	—	—	—
<b>Total comprehensive loss for the year</b>		—	—	—	—	—	—	(595,536)	(595,536)
Appropriation of loss of the year 2022 carried forward		—	—	—	—	—	(596,735)	596,735	—
Capitalization of development cost		—	98,753	—	—	—	(98,753)	—	—
Effect from IP Write-up		—	—	1,088,111	—	—	47,310	—	1,135,421
Exercise of share rights		—	—	—	(228)	228	—	—	—
Long term incentive program		—	—	—	61,261	—	—	—	61,261
<b>Balance at December 31, 2023</b>	22,23,24,25	55,034	119,606	1,088,111	3,082,574	(2,362)	(2,530,482)	(595,536)	1,216,945

<sup>(1)</sup> Total share issue cost amounted to SEK 19,754k.

<sup>(2)</sup> The year 2022 additions of Class C shares refer to the new issue and subsequent repurchase of Class C shares that have taken place in accordance with the respective long term incentive plan (LTIP) program.

The accompanying notes are an integral part of these Consolidated Financial Statements.



# Notes to the Parent Company Financial Statements

## Note 1 Accounting Policies

Hansa Biopharma AB (the Parent Company) has prepared its annual report in accordance with the Swedish Annual Accounts Act (SFS 1995:1554) and Recommendation RFR 2 issued by the Swedish Financial Reporting Board, Reporting for legal entities. The statements issued by the Swedish Financial Reporting Board applicable to listed companies have also been applied. RFR 2 entails that in the annual report for the legal entity the Parent Company must apply all of IFRS and the statements adopted by the EU to the extent possible within the scope of the Swedish Annual Accounts Act, the Securing of Pension Obligations Act, and taking into consideration the connection between reporting and taxation. The Recommendation sets forth which exceptions from, and additions to, IFRS are to be made.

## Differences between the Group's and the Parent Company's Accounting Principles

The differences between the Group's and the Parent Company's accounting principles are set forth below. The accounting principles set forth below for the Parent Company have been applied consistently to all periods presented in the Parent Company's financial statements.

## Subsidiaries

Investment in subsidiaries is recognized at cost after deducting for potential impairment. Cost includes acquisition-related expenses and potential additional purchase considerations. When there is an indication that investment in subsidiaries is impaired, recoverable amount is measured. If the recoverable amount is lower than the carrying amount, an impairment is recognized. Impairment is recognized in the statement of profit or loss.

## Presentation and Classification

The differences in the Parent Company's income statement and statement of financial position as compared with the Group's statements consist primarily of the reporting of cost of revenue, financial income and expenses, non-current assets, and shareholders' equity. Cost of revenue and non-current assets for the Parent Company include the effect from the IP write-up in 2023 and the amortization made on that write-up.

Note 14 "Employees and accrued personnel cost" and Note 30 "Audit fees" includes information for the Group and the Parent Company as required by the Swedish Annual Accounts Act.

## Note 2 Intangible Assets

### Internally generated intangible assets

Expenditure on research activities is recognized as an expense in the period in which it is incurred. An internally-generated intangible asset arising from development (or from the development phase of an internal project) is recognized if, and only if, all of the following have been demonstrated in accordance with IAS 38:

- > the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- > the intention to complete the intangible asset and use or sell it;
- > the ability to use or sell the intangible asset;
- > how the intangible asset will generate probable future economic benefits;
- > the availability of adequate technical, financial, and other resources to complete the development and to use or sell the intangible asset; and
- > the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets all the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditures are recognized in the statement of profit and loss and other comprehensive income in the period in which they are incurred.

The Company assessed that with respect to Idefirix® (imlifidase) and its conditional approval by EMA in enabling kidney transplantation in highly sensitized patients it does meet all the above criteria as of Q4-2022. Therefore, as of Q4-2022, the Company has on a quarterly basis re-assess whether or not it continues to meet all above criteria and continue to capitalize respective cost for as long as all criteria are met.

At the year ending December 31, 2023, the total net value for the Company's capitalized development cost amounts to SEK 112.6 million related to performing its Idefirix® (imlifidase) EMA post-approval commitments. Capitalized development cost mainly includes fees paid to third party service providers, personnel expenses of Hansa staff and proportionate finance cost. The capitalized development cost is subject to regular amortization over its useful life which is estimated to be up until end of 2032.

Due to uncertainties inherent to the development and registration with the relevant healthcare authorities of imlifidase in any other indications, the Company estimates that the conditions for capitalization are not yet met and thus does not capitalize any development cost related to such other indications.

Subsequent to initial recognition, internally generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses, on the same basis as intangible assets that are acquired separately. If circumstances or changes in the Group's operations indicate that the carrying amount of non-current assets in a cash-generating unit may not be recoverable, management reviews the asset for impairment. An annual impairment test is also performed for assets yet to be brought into use, i.e. per December 31, 2023, in-process development projects (see below) and capitalized development cost relating to imlifidase.



## Notes to the Parent Company Financial Statements continued

Capitalized internal development expenditures for imlifidase's previous production process were completely amortized during the year 2018 and written-off in 2022.

### Acquired intangible assets

#### Patents

The HBP-assay patent cost is amortized over the finite useful life of the underlying patent in the amount of SEK 559 k for the year 2023 (2022: SEK 559 k). The patent cost is amortized over sales, general and administration line item in the consolidated statement of profit or loss and other comprehensive income.

HBP-assay is a method of analysis used to predict severe sepsis in emergency clinics. A first version has been launched, primarily intended for research purposes, and interested specialists. The HBP-assay has been licensed to a cooperating partner, Axis-Shield Diagnostics Ltd. (Axis-Shield), which is currently developing a fully commercial product. The Company receives milestone compensation and additional royalty revenue upon the sale of the sublicensed technology.

### In-process development projects

Certain projects pending in the Group are a combination of acquired development projects and continued activities in these projects. Of the total acquisition cost for acquired in-process development projects, approximately 75% relates to imlifidase and 25% relates to HBP-assay.

The acquired intangible asset relating to imlifidase presented as in-process development projects will be amortized over the estimated useful life of the underlying asset. Following the first commercial sale of imlifidase in Q1-2021 the Group started to amortize the SEK 25,136k from the period of first sale in Q1-2021. The estimated useful life is 12 years.

Acquired in-process development projects are assessed for possible impairment at least on an annual basis and the impairment assessment on December 31, 2023, and 2022 demonstrated that there was no need for impairment. The estimated recoverable amount supported by external and internal valuation reports by far exceeds the assets' carrying amount, resulting in no impairment charges for the year 2023 and 2022.

### Recognition of IP write-up

As of June 30, 2023, Hansa recognized a write-up of SEK 1,430.0 million in intangible assets in the statutory financial statements of the parent company Hansa Biopharma AB, in accordance with chapter 4, 6§ of the Swedish Annual Accounts Act (1995:1554) and RFR 2.

The write-up relates to Idefirix®, that has received a conditional market authorization in the European Union (EU)/EEA and United Kingdom (UK) for the desensitization treatment of highly sensitized adult

kidney transplant patients with a positive crossmatch against an available deceased donor. After the write-up, the asset will have a gross value of 1,500.0 million SEK in the financial statements of Hansa Biopharma AB. The write-up increased the restricted shareholder equity in Hansa Biopharma AB by SEK 1,430.0 million. The write-up resulted in a taxable temporary difference for which a deferred tax liability of SEK 294.6 million was recognized, with a corresponding decrease in restricted shareholder equity. As a result of recognizing the deferred tax liability Hansa recognized a deferred tax asset of SEK 294.6 million through profit or loss, increasing unrestricted shareholder equity, related to previously unrecognized tax losses.

The intangible asset will be subject to regular amortization over its useful life of estimated 12 years.

As of December 31, 2023, the Company in its statutory financial statements recorded an amortisation expense of SEK 59.6 million in cost of revenue thereby reducing the previously recorded intangible asset by the same amount. In addition, the Company recorded an adjustment of SEK 12.3 million to its previously recorded deferred tax assets and tax liabilities in connection with the amortization charge.

The write-up and subsequent amortization of the intangible asset does not impact the consolidated IFRS financial statements of the Hansa Group.

(in thousands of SEK)	Internally generated	Acquired intangible assets		Total intangible assets
	Capitalized development expenditures	Patents	In-process development projects	
<b>Cost:</b>				
Opening balance January 1, 2023	20,853	8,504	25,136	54,493
Write-up	—	1,430,000	—	1,430,000
Internally developed	98,753	—	—	98,753
<b>Closing balance December 31, 2023</b>	<b>119,606</b>	<b>1,438,504</b>	<b>25,136</b>	<b>1,583,246</b>
<b>Accumulated amortization and impairment losses:</b>				
Opening balance January 1, 2023	—	(5,587)	(4,188)	(9,775)
Amortization for the year	(6,958)	(60,141)	(2,095)	(69,194)
<b>Closing balance December 31, 2023</b>	<b>(6,958)</b>	<b>(65,728)</b>	<b>(6,283)</b>	<b>(78,969)</b>
<b>Carrying amounts:</b>				
At January 1, 2023	20,853	2,917	20,948	44,718
<b>At December 31, 2023</b>	<b>112,648</b>	<b>1,372,776</b>	<b>18,853</b>	<b>1,504,277</b>



## Notes to the Parent Company Financial Statements continued

(in thousands of SEK)	Internally generated	Acquired intangible assets		Total intangible assets
	Capitalized development expenditures	Patents	In-process development projects	
<b>Cost:</b>				
Opening balance January 1, 2022	4,485	8,504	25,136	38,125
Write-off	(4,485)	—	—	(4,485)
Internally developed	20,853	—	—	20,853
<b>Closing balance December 31, 2022</b>	<b>20,853</b>	<b>8,504</b>	<b>25,136</b>	<b>54,493</b>
<b>Accumulated amortization and impairment losses:</b>				
Opening balance January 1, 2022	(4,485)	(5,028)	(2,094)	(11,607)
Write-off	4,485	—	—	4,485
Amortization for the year	—	(559)	(2,094)	(2,653)
<b>Closing balance December 31, 2022</b>	<b>—</b>	<b>(5,587)</b>	<b>(4,188)</b>	<b>(9,775)</b>
<b>Carrying amounts:</b>				
At January 1, 2022	—	3,476	23,042	26,518
<b>At December 31, 2022</b>	<b>20,853</b>	<b>2,917</b>	<b>20,948</b>	<b>44,718</b>

### Note 3 Property and Equipment

The property and equipment held by the Parent Company is the same as for the Group, see Note 5 for the Group.

### Note 4 Right-of-Use Assets and Lease Liabilities

The right-of-use assets held by the Parent Company is the same as for the Group, see Note 6 for the Group.

### Note 5 Investment in Subsidiaries

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Opening balance January 1,</b>	<b>24,264</b>	<b>5,095</b>
Shareholder contribution to Hansa Biopharma Inc. <sup>(1)</sup>	4,018	12,882
Shareholders contribution to Hansa Biopharma Ltd. <sup>(1)</sup>	1,649	6,286
Paid in capital of Hansa Biopharma Pty Ltd (1 AUD)	—	—
Paid in capital of Hansa Biopharma Italy S.R.L (10,000 EUR)	113	—
<b>Closing balance December 31,</b>	<b>30,044</b>	<b>24,264</b>

<sup>(1)</sup> The shareholders contribution relates to push down of the LTIP expenses for the year 2018 to 2023 from the parent company to the subsidiaries and the subsequent conversion to equity.

(in thousands of SEK, except for number of shares and share percentage)	Number of shares	Share %	As of December 31,	
			2023	2022
Cartela R & D AB (556746-0083), Lund, Sweden	1,000	100	2,630	2,630
Hansa Biopharma Ltd, (08361712), Cheltenham, UK	100,000	100	10,391	8,742
Hansa Biopharma Inc, (6846164), Delaware, USA	1,000	100	16,910	12,891
Hansa Biopharma Australia Pty Ltd, Melbourne, Australia <sup>(1)</sup>	1	100	—	—
Hansa Biopharma Italy S.R.L, Rome, Italy	1	100	113	—
<b>Total</b>	<b>—</b>	<b>—</b>	<b>30,044</b>	<b>24,264</b>

<sup>(1)</sup> Dormant Company



## Notes to the Parent Company Financial Statements continued

### Note 6 Intercompany Balances

#### Receivables, group companies

Non-current assets (in thousands of SEK)	As of December 31,	
	2023	2022
Opening balance January 1,	–	2,203
Change in receivables, net <sup>(1)</sup>	–	(2,203)
Closing balance December 31,	–	–

<sup>(1)</sup> Converted to equity.

#### Liabilities, group companies

Current liabilities (in thousands of SEK)	As of December 31,	
	2023	2022
Opening balance January 1,	5,738	3,901
Change in liabilities, net <sup>(1)</sup>	1,351	1,837
Closing balance December 31,	7,089	5,738

<sup>(1)</sup> Increase due to increased intercompany services received.

### Note 7 Inventories

The Inventories held by the Parent Company is the same as for the Group, see Note 7 for the Group.

### Note 8 Trade Receivables, Unbilled Revenue and Refund Liabilities

The Trade receivables, unbilled revenue and refund liabilities held by the Parent Company are the same as for the Group, see Note 8 for the Group.

### Note 9 Prepaid Expenses and Accrued Income

(in thousands of SEK)	As of December 31,	
	2023	2022
R&D expenses	11,398	7,587
Licence fees	2,484	3,857
Rent	2,001	2,385
Pension	1,925	1,770
Insurances	1,059	1,137
Software	470	1,777
Healthcare conferences	204	2,604
Legal expenses	–	9,989
Other	1,931	2,120
<b>Total</b>	<b>21,472</b>	<b>33,226</b>

### Note 10 Other Receivables

(in thousands of SEK)	As of December 31,	
	2023	2022
Tax and VAT receivables	12,938	21,006
Advance payments to suppliers	8,279	9,262
Other receivables	516	874
<b>Total</b>	<b>21,733</b>	<b>31,142</b>



## Notes to the Parent Company Financial Statements continued

### Note 11 Accrued Expenses

(in thousands of SEK)	As of December 31,	
	2023	2022
Accrued short term incentives, incl. related social security contributions	35,347	28,652
Annual leave accrual	22,405	17,459
R&D project costs	17,641	26,701
Consulting fees	12,602	15,114
Accrued social security contribution on salaries	6,431	5,243
License fees	3,257	5,500
Audit fees	1,180	1,550
Other	4,520	3,050
<b>Total</b>	<b>103,383</b>	<b>103,270</b>

### Note 12 Other Current Liabilities

(in thousands of SEK)	As of December 31,	
	2023	2022
Personnel related liabilities	21,079	17,868
<b>Total</b>	<b>21,079</b>	<b>17,868</b>

### Note 13 Revenue

The revenue generated by the Parent Company is the same as for the Group, see Note 13 for the Group.

### Note 14 Employees and Accrued Personnel Cost

#### 2023 Guidelines for remuneration to senior executives

The 2023 guidelines proposed by the Board of Directors entail that executive management is offered a remuneration which is competitive and on market terms. The level of the remuneration for the individual manager shall be based on factors such as position, expertise, experience, and performance. The remuneration consists of a fixed salary and pension benefits and, in addition, may consist of variable salary, share based long-term incentive programs, severance remuneration and non-monetary benefits. The variable salary is based on the achievement of quantitative and qualitative targets and should not exceed 75 percent of the annual fixed salary. Salary during the notice of termination period and severance remuneration can be a maximum amount of 18 months salaries.

Please refer to the Governance section in this Annual Report 2023 or visit the Company's website at [www.hansabiopharma.com](http://www.hansabiopharma.com) for information on the 2023 guidelines for remuneration to senior executives.

Total personnel expenses recorded in the Parent Company are presented below in different breakdowns:

#### Parent Company 2023

#### Total personnel expenses recorded in the Parent Company broken down to senior management and other employees

(in thousands of SEK)	Senior management	Other employees	Total Parent Company
Salaries, bonuses, and other benefits	39,404	159,826	199,230
Social security contribution	12,074	30,962	43,036
Pension cost, contribution plan	2,223	25,094	27,317
Share-based compensation	27,436	27,441	54,877
<b>Total</b>	<b>81,137</b>	<b>243,323</b>	<b>324,460</b>





## Notes to the Parent Company Financial Statements continued

### Personnel expenses recorded in the Parent Company related to Senior management

(in thousands of SEK)	Base salary / Directors fee	Variable compensation	Total salaries, bonuses, and other benefits	Social security contributions	Pension cost	Share-based compensation	Total
Chair of the Board of Directors Peter Nicklin	1,038	–	1,038	99	–	–	1,137
Director Anders Gersel Pedersen	375	–	375	38	–	–	413
Director Andreas Eggert	453	–	453	142	–	–	595
Director Eva Nilsagård	450	–	450	141	–	–	591
Director Hilary Malone	552	–	552	173	–	–	725
Director Mats Blom	375	–	375	118	–	–	493
CEO Søren Tulstrup <sup>(1)</sup>	8,431	3,839	12,270	3,855	–	11,380	27,505
Other senior executives (5 persons)	16,793	7,098	23,891	7,508	2,223	16,056	49,678
<b>Total</b>	<b>28,467</b>	<b>10,937</b>	<b>39,404</b>	<b>12,074</b>	<b>2,223</b>	<b>27,436</b>	<b>81,137</b>

<sup>(1)</sup> Base salary includes 1,828 KSEK, representing 30% of base salary, intended for own pension contribution

### Personnel expenses recorded in the Parent Company related to Senior management

(in thousands of SEK)	Base salary / Directors fee	Variable compensation	Total salaries, bonuses, and other benefits	Social security contributions	Pension cost	Share-based compensation	Total
Chair of the Board of Directors Ulf Wiinberg <sup>(1)</sup>	471	–	471	148	–	–	619
Chair of the Board of Directors Peter Nicklin <sup>(2)</sup>	479	–	479	46	–	–	525
Director Anders Gersel Pedersen	350	–	350	36	–	–	386
Director Andreas Eggert	440	–	440	138	–	–	578
Director Eva Nilsagård	450	–	450	141	–	–	591
Director Hilary Malone	531	–	531	167	–	–	698
Director Mats Blom	375	–	375	118	–	–	493
CEO Søren Tulstrup <sup>(3)</sup>	7,586	4,024	11,610	3,648	–	11,223	26,481
Other senior executives (5 persons)	15,435	6,786	22,221	6,982	2,812	21,622	53,635
<b>Total</b>	<b>26,117</b>	<b>10,810</b>	<b>36,927</b>	<b>11,423</b>	<b>2,812</b>	<b>32,844</b>	<b>84,005</b>

<sup>(1)</sup> Board member until AGM 2021.

<sup>(2)</sup> Board member from AGM 2021.

<sup>(3)</sup> Base salary includes 1,694 KSEK, representing 30% of base salary, intended for own pension contribution

### Parent Company 2022

#### Total personnel expenses recorded in Parent Company broken down to senior management and other employees

(in thousands of SEK)	Senior management	Other employees	Total Parent Company
Salaries, bonuses, and other benefits	36,927	129,428	166,354
Social security contribution	11,423	23,008	34,431
Pension cost, contribution plan	2,812	20,550	23,362
Share-based compensation	32,844	20,121	52,965
<b>Total</b>	<b>84,005</b>	<b>193,107</b>	<b>277,113</b>



## Notes to the Parent Company Financial Statements continued

### Average number of employees

	2023		2022	
	Number	Of which are men	Number	Of which are men
<b>Total Group</b>	<b>159</b>	<b>35%</b>	<b>144</b>	<b>37%</b>
Parent Company				
Sweden	143	35%	135	37%
<b>Subsidiaries</b>				
UK	6	62%	4	75%
US	10	19%	5	25%
<b>Total subsidiaries</b>	<b>16</b>		<b>9</b>	

### Breakdown of senior management according to gender

	Share of women	
	2023	2022
<b>Total Group</b>		
Board of Directors	33%	33%
Other senior management	17%	17%
<b>Parent Company</b>		
Board of Directors	33%	33%
Other senior management	17%	17%

### Benefits to senior executives

Senior management of the Company includes the Board of Directors, the CEO, and the other members of the executive management.

### Remuneration to Board of Directors

Fees are payable to the chair of the Board of Directors and other directors pursuant to a resolution adopted by the annual general meeting ("AGM"). The 2023 AGM resolved that fees paid to directors from AGM 2023 to AGM 2024 will be SEK 900,000 to the chair of the Board of Directors and SEK 300,000 to each of the other directors, SEK 150,000 to the chair and SEK 75,000 each to the other directors who are members of the Audit Committee, SEK 40,000 to the chair and SEK 25,000 each to other directors who are members of the Remuneration Committee, USD 20,000 to the chair of the U.S. committee and SEK 50,000 each to the other director who is a member of the U.S. committee, SEK 75,000 to the chair

of the Scientific Committee and SEK 50,000 each to directors who are members of the Scientific Committee. In addition, the other director who is a member of the U.S. committee shall retroactively receive SEK 50,000 for the work performed during 2022. There are no contracts regarding severance compensation or other benefits for the chair of the Board of Directors or other directors.

### Salaries and other remuneration to the CEO

#### Salaries, bonuses, and other benefits

Please refer to the Company's Remuneration Report elsewhere in this 2023 Annual Report for further information on the CEOs compensation.

#### Notice of termination periods and severance compensation

If notice of termination of employment is made by the Company, the notice period may not exceed six months. Fixed cash salary during the period of notice and any severance pay may together not exceed an amount equivalent to the fixed cash salary for 18 months for the CEO, i.e., 6 plus 12 months.

#### Pension contributions

The CEO is responsible for his pension provision, thus the Company has no direct pension cost for the CEO.

### Salaries and other remuneration to other members of executive management

Salaries and other remuneration to the other members of the executive management is determined by the CEO and approved by the chair of the Board of Directors. In 2023, executive management comprised of six people including the CEO.

#### Notice period of termination and severance payments

Fixed cash salary during the period of notice and any severance pay may together not exceed an amount equivalent to the fixed cash salary for 6 months, and in exceptional cases, 12 months for the other members of the executive management. When termination is made by the executive officer the period of notice may not exceed six months.

During their notice period, other members of executive management are entitled to full salary and other employment benefits.

#### Pension contributions

Hansa provides pension contributions and benefits in accordance with local statutory requirements and in accordance with the Company's insurance and pension policy.



## Notes to the Parent Company Financial Statements continued

### Share-based compensation

The share-based compensation recorded and presented by the Parent Company amounted to SEK 54,877k and SEK 52,965k for the years ended on December 31, 2023, and 2022, respectively. The total amount of LTIP expenses pushed down from the parent company to the subsidiaries at year end 2022, that relates to the years 2018 to 2021, amounted to SEK 11,399k, resulting in net amount of SEK 41,566k as presented in the Parent Company's Cash Flow Statement for the year ended December 31, 2022. Please refer to Note 14 for the Group for further information on Hansa's LTIP programs.

### Note 15 Provisions

The provisions recorded by the Parent Company is the same as for the Group, see Note 15 for the Group.

### Note 16 Income Taxes

#### Unrecognized deferred tax assets

Deferred tax assets have not been recognized regarding temporary differences and losses carried forward since it is not probable that such can be set off against taxable profits in the foreseeable future.

The Parent Company's losses carried forward in 2023 amounted to SEK 3,031,197k (2022: SEK 2,361,668k). The losses carried forward are, in all material respects, attributable to Swedish companies and therefore have no due date. A reconciliation of Hansa's effective tax rate relative to the Swedish statutory tax rate is as follows:

	2023		2022	
	%	(in thousands of SEK)	%	(in thousands of SEK)
Result before tax	—	(889,307)	—	(596,131)
Tax at applicable rate, parent company	20.6	183,197	20.6	122,803
<b>Tax effect of:</b>				
Non-deductible expenses	(5.1)	(45,441)	(3.1)	(18,488)
Deductible part of foreign income tax	0.0	167	0.0	124
Tax losses for which no deferred tax asset has been reported	(15.5)	(137,923)	(17.6)	(104,439)
Deferred tax on previous year's losses <sup>(1)</sup>	31.7	282,306	—	—
Deferred tax IP write-up	1.4	12,274	—	—
Reported foreign income tax	(0.1)	(809)	(0.1)	(604)
<b>Reported effective tax</b>	<b>33.0</b>	<b>293,771</b>	<b>(0.1)</b>	<b>(604)</b>

(1) The recognized deferred tax on previous year's losses refers to the deferred tax liability which, as a result of the intangible asset write-up in 2023 of totally SEK 1,430.0 million, has decreased the unrestricted shareholder equity with the corresponding amount. For additional information see Note 2. The write-up and its tax effects does not impact the consolidated IFRS financial statements of the Hansa Group.

The corporate tax rate in Sweden is 20.6%, from January 1, 2021.

### Note 17 Contingent Consideration

The Contingent consideration recorded by the Parent Company is the same as for the Group, see Note 18 for the Group.

### Note 18 Capital Management

The Capital management of the Parent Company is the same as for the Group, see Note 19 for the Group.



## Notes to the Parent Company Financial Statements continued

### Note 19 Financial Risk and Financial Instruments

The Parent Company has exposure to the same financial risks arising from financial instruments as the Group, see Note 20 for the Group.

#### Carrying amounts of financial assets and financial liabilities

The table below shows the carrying amounts for financial assets and financial liabilities broken down by measurement categories under IFRS 9 in the Parent Company.

	Financial assets valued at amortized cost		Financial assets valued at fair value through the income statement	
	2023	2022	2023	2022
<b>Financial assets:</b>				
Trade receivables and unbilled revenue	78 025	42 959	—	—
Other receivables	516	874	—	—
Cash and cash equivalents	715,538	1,486,502	—	—
<b>Total</b>	<b>794 079</b>	<b>1 530 335</b>	<b>—</b>	<b>—</b>

(in thousands of SEK)	Financial liabilities valued at amortized cost		Financial liabilities valued at fair value through the consolidated statement of profit or loss and other comprehensive income	
	2023	2022	2023	2022
<b>Financial liabilities:</b>				
Long-term loan	844,903	762,601	—	—
Contingent consideration	—	—	843	757
Liabilities, group companies	7,089	5,738	—	—
Trade payables	86,966	62,357	—	—
Accrued expenses (see Note 11)	39,200	51,915	—	—
<b>Total</b>	<b>978,158</b>	<b>882,611</b>	<b>843</b>	<b>757</b>

### Note 20 Long-term Loan

The long-term loan stated by the Parent Company is the same as for the Group, see Note 21 for the Group.

### Note 21 Financial Income and Expenses

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
<b>Financial income</b>		
Interest income	27,969	8,829
Interest income, other	70	—
Net exchange rate variances	35,142	18,416
<b>Total</b>	<b>63,181</b>	<b>27,245</b>
<b>Financial expenses</b>		
Interest expense on long-term loan at amortized cost	(104,381)	(42,470)
Interest expenses, other	(1,138)	(1,186)
Changes in the fair value of interest funds during the year	—	(4,973)
<b>Total</b>	<b>(105,519)</b>	<b>(48,629)</b>
<b>Total Financial income / (expense), net</b>	<b>(42,338)</b>	<b>(21,384)</b>

### Note 22 Share Capital and Number of Shares

The Share Capital stated and number of shares for the Parent Company is the same as for the Group, see Note 23 for the Group.

### Note 23 Share Premium

The Share Premium stated by the Parent Company is the same as for the Group, see Note 24 for the Group.

### Note 24 Treasury Shares Included in Equity

The Treasury shares included in equity stated by the Parent Company is the same as for the Group, see Note 25 for the Group.

### Note 25 Reserves

#### Treasury Share Reserve

The treasury share reserve represents own shares repurchased by the Group. Please refer to Note 14 related to the Group's LTIP programs and respective vesting dates.

#### Development Cost Reserve

The development cost reserve represents the capitalized development cost. Amounts capitalized in respect of internally generated development expenditure are transferred from unrestricted equity to

## Notes to the Parent Company Financial Statements continued

development cost reserve in restricted equity. The capitalized amounts are amortized over their useful lives, reducing the reserve accordingly. Please refer to Note 2 for further information on the capitalized development cost.

### Revaluation Reserve

The revaluation reserve represents the net value of the write-up of intangible assets done in June 2023 and the deferred tax liability connected to that write-up. Please refer to Note 2 for further information regarding the write-up of intangible assets.

### Note 26 Royalty Agreements

The Parent Company is party to the same royalty agreements as the Group, see Note 27 for the Group.

### Note 27 Other Operating Income and Expenses

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
<b>Other operating income</b>		
Foreign currency gains on receivables/liabilities from operating activities	2,663	—
<b>Total</b>	<b>2,663</b>	<b>—</b>
<b>Other operating expenses</b>		
Foreign currency losses on receivables/liabilities from operating activities	—	(12,469)
Other operating expenses	(463)	(8,063)
<b>Total</b>	<b>(463)</b>	<b>(20,532)</b>
<b>Total other operating income/(expenses)</b>	<b>2,200</b>	<b>(20,532)</b>

### Note 28 Operating Expenses by Nature

The table below presents an analysis of operating expenses presented in profit or loss in classification based on the nature of the expenses:

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
Personnel expenses	(309,038)	(269,437)
Third party expenses	(540,974)	(391,066)
Depreciation and amortization expenses	(10,525)	(9,760)
Other operating expenses	2,200	(20,532)
<b>Total</b>	<b>(858,337)</b>	<b>(690,795)</b>

Following table summarizes amortization and depreciation expenses from Note 2, 3 and 4 above presented by function in profit or loss and other comprehensive income/(loss).

(in thousands of SEK)	As of December 31,	
	2023	2022
Research and development expenses	(8,847)	(7,027)
Sales, general and administrative expenses	(1,678)	(2,733)
<b>Total</b>	<b>(10,525)</b>	<b>(9,760)</b>

Amortization of capitalized development cost, in-process development projects and amortization of the patent write-up in 2023, are reported as cost of revenue in the profit or loss and amounts to SEK 68,635k (2022: SEK 2,094k).

### Note 29 Supporting Information to the Cash Flows

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Cash and cash equivalents consist of:</b>		
Cash and bank deposits	715,538	1,486,502
<b>Total according to the statement of financial position</b>	<b>715,538</b>	<b>1,486,502</b>
<b>Total according to the cash flow</b>	<b>715,538</b>	<b>1,486,502</b>



## Notes to the Parent Company Financial Statements continued

Reconciliation of liabilities arising from financing activities:

(in thousands of SEK)	As of December 31,	
	2023	2022
<b>Opening balance January 1,</b>	<b>791,092</b>	<b>35,379</b>
Termination of lease agreement	—	(25)
Changes in current lease agreement	919	—
Payment of lease liabilities	(7,545)	(6,863)
Net present value of long-term loan	—	687,221
Accrued interest on long-term loan	115,928	41,152
Unrealized currency differences on long-term loan	(33,626)	34,228
<b>Closing balance December 31,</b>	<b>866,768</b>	<b>791,092</b>

### Note 30 Audit fees – Group and Parent Company

(in thousands of SEK)	Years Ended December 31,	
	2023	2022
<b>Group</b>		
KPMG AB:		
Auditing services	2,650	2,565
Other services closely related to audit services	300	385
Azets Holdings Ltd (Wilkins Kennedy Audit Services):		
Auditing services	130	110
<b>Total</b>	<b>3,080</b>	<b>3,060</b>
<b>Parent Company</b>		
KPMG AB:		
Auditing services	2,650	2,565
Other services closely related to audit services	300	385
<b>Total</b>	<b>2,950</b>	<b>2,950</b>

The auditing services involves review of the Annual Report and financial accounting and the administration by the Board and the CEO. Other services closely related to audit services mean quality assurance services required by enactment, articles of association, regulations or agreement. The amount includes a fee for reviewing the nine month interim report.

### Note 31 Collateral Provided, Contingent Liabilities and Contingent Assets

Nothing to report related to the financial year 2023 and 2022.

### Note 32 Related Party Transactions

#### Subsidiaries

Interest in subsidiaries and intercompany receivables and liabilities are set out in Note 6.

#### Transactions with key persons in a senior management position

Transactions with key persons in a senior management position are set forth in Note 14.

### Note 33 Information Regarding the Parent Company

Hansa Biopharma AB (publ) is a Swedish registered public company (Company reg. no. 556734-5359).

The registered office is located in Lund. The Parent Company's shares are registered on NASDAQ Stockholm. The address of the headquarters is Scheelevägen 22, 223 63 Lund.

The consolidated accounts for 2023 and 2022 cover the Parent Company and its subsidiaries, jointly referred to as the Group.

### Note 34 Appropriation of Loss Carried Forward

#### Unrestricted shareholders' equity in the Parent Company:

(in SEK)	As of December 31,	
	2023	2022
Share premium reserve	3,082,574,199	3,021,541,484
Treasury shares	(2,362,445)	(2,590,279)
Loss carried forward	(2,530,481,990)	(1,882,303,903)
Loss for the year	(595,535,899)	(596,735,718)
<b>Total</b>	<b>(45,806,315)</b>	<b>539,911,584</b>



## Notes to the Parent Company Financial Statements continued

The Board of Directors proposes that the loss carried forward and unrestricted reserves to be allocated as follows:

(in SEK)	As of December 31,	
	2023	2022
Share premium reserve	3,082,574,199	3,021,541,484
Treasury shares	(2,362,445)	(2,590,279)
Loss carried forward	(3,126,017,889)	(2,479,039,621)
<b>Total</b>	<b>(45,806,315)</b>	<b>539,911,584</b>

### Note 35 Subsequent events

The subsequent events for the Parent Company are the same as for the Group, see Note 31 for the Group.



## Definitions

### Equity ratio

Shareholders' equity as percentage of total statement of financial position assets at the end of the period.

### Shareholders' equity per share

Shareholders' equity in relation to number of outstanding shares at the end of the period.

### Legal disclaimer

This financial report includes statements that are forward looking, and actual future results may differ materially from those stated. In addition to the factors discussed, among other factors that may affect results are development within research programs, including development in preclinical and clinical trials, the impact of competing research programs, the effect of economic conditions, the effectiveness of the Company's intellectual property rights and preclusions of potential second party's intellectual property rights, technological development, exchange rate and interest rate fluctuations and political risks.





## Signatures

The Board of Directors and the CEO affirm that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and give a fair view of the Group's financial position and results. The annual report has been prepared in accordance with generally accepted accounting principles for the Group and the Parent Company and gives a fair overview of the development of the Group's and the Parent Company's operations, financial positions and results, and describes material risks and uncertainties facing the Parent Company and the companies included in the Group.

Lund 20 March 2024

**Peter Nicklin**  
Chairman of the Board

**Hilary Malone**  
Director

**Mats Blom**  
Director

**Andreas Eggert**  
Director

**Eva Nilsagård**  
Director

**Anders Gersel Pedersen**  
Director

**Søren Tulstrup**  
CEO and Executive President

The Board of Directors and CEO approved the annual report for publication on 20 March 2024. The consolidated income statement, report on comprehensive income and statement of financial position as well as the Parent Company's income statement, report on comprehensive income and statement of financial position will be subject to adoption at the annual general meeting to be held on 27 June 2024.

Our auditors' report was submitted on 20 March 2024.

KPMG AB

**Stefan Lundberg**  
Authorized Public Accountant



## Auditor's Report

### To the general meeting of the shareholders of Hansa Biopharma AB, corp. id 556734-5359

#### Report on the annual accounts and consolidated accounts Opinions

We have audited the annual accounts and consolidated accounts of Hansa Biopharma AB for the year 2023. The annual accounts and consolidated accounts of the company are included on pages 51-113 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of Sunday, 31 December 2023 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of Sunday, 31 December 2023 and their financial performance and cash flow for the year then ended in accordance with IFRS Accounting Standards, as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 118-131. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the statement of comprehensive income and statement of financial position for the group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional

report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

#### Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

#### Revenue

See disclosure 13 and accounting principles on pages 66-67 in the annual account and consolidated accounts for detailed information and description of the matter.

#### Description of key audit matter

During 2023, the Company recognize contract revenue in the amount of SEK 27.4 million related to its agreement with Sarepta Therapeutics Ltd. This relates to an upfront payment of USD 10 million received in July 2020. The revenue from the upfront payment is recognized over the period when the Company fulfils its performance obligation under the agreement.

The assessment of performance obligations and allocation of the upfront payment requires significant knowledge and detailed review of the contract terms and accounting standards.

The Company has prepared a budget of total estimated hours expected to be used for the fulfillment of the obligation. The hours spent up to each reporting date is then used to measure progress. The estimation of the hours needed to fulfil the obligation requires management's judgment.

#### Response in the audit

We have reviewed the agreement as to the terms and the performance obligation identified by management.

The revenues from Sarepta Therapeutics Ltd. have also been verified against upfront payment.

We have performed a retrospective review and compared management's estimated hours,

with the actual hours spent up until reporting date. Furthermore we have by sample traced such hours to underlying records.

We have also assessed accounting principles and the disclosures related to revenue included in the annual accounts and consolidated accounts.

#### Other Information than the annual accounts and consolidated accounts

The other information comprises also of the remuneration report and directors' report, which we obtained prior to the date of this auditor's report. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.



## Auditor's Report continued

### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS Accounting Standards as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

### Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are

free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- > Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- > Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.

- > Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- > Conclude on the appropriateness of the Board of Directors' and the Managing Director's, use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- > Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.

- > Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, measures that have been taken to eliminate the threats or related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.



## Auditor's Report continued

### Report on other legal and regulatory requirements

#### Auditor's audit of the administration and the proposed appropriations of profit or loss

##### Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Hansa Biopharma AB for the year 2023 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the loss be dealt with in accordance with the proposal in the statutory administration report and that the member of the Board of Directors and the Managing Director be discharged from liability for the financial year.

##### Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner.

The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether the member of the Board of Directors or the Managing Director in any material respect:

- > has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- > in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation.

We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

### The auditor's examination of the Esef report Opinion

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for Hansa Biopharma AB for year 2023.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report has been prepared in a format that, in all material respects, enables uniform electronic reporting.

### Basis for opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the Esef report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of Hansa Biopharma AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical



## Auditor's Report continued

responsibilities in accordance with these requirements.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the Esef report in accordance with the Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

### Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in

aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies International Standard on Quality Management 1, which requires the firm to design, implement and operate a system of quality management including policies or procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Managing Director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of the assumptions made by the Board of Directors and the Managing Director.

The procedures mainly include a validation that the Esef report has been prepared in a valid XHTML format and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the consolidated statement of financial performance, financial position, changes in equity, cash flow and disclosures in the Esef report have been marked with iXBRL in accordance with what follows from the Esef regulation.

### The auditor's examination of the corporate governance statement

The Board of Directors is responsible for that the corporate governance statement on pages 118-131 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's standard RevR 16. The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

KPMG AB, Box 382, 101 27, Stockholm, was appointed auditor of Hansa Biopharma AB by the general meeting of the shareholders on the 29 June 2023. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2014.

Stockholm Wednesday, 20 March 2024  
KPMG AB

**Stefan Lundberg**  
Authorized Public Accountant



# Governance

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# Governance

## General principles

### Introduction

The Board of Directors of Hansa Biopharma AB (publ) (the “Board”), Company reg. no. 556734-5359 (“Hansa” or the “Company”) hereby submits the 2023 Corporate Governance Report in accordance with the requirements of the Swedish Annual Accounts Act (1995:1554) (Sw. årsredovisningslagen) and the Swedish Corporate Governance Code (the “Code”).

The Company’s corporate governance is mainly regulated by the provisions of the Company’s articles of association, the Swedish Companies Act (2005:551) (Sw. aktiebolagslagen) and other Swedish legislation, the Nordic Main Market Rulebook for Issuers of Shares and the Code next to all applicable laws and regulations.

This Corporate Governance Report has been reviewed by the Company’s auditors in accordance with the Swedish Annual Accounts Act. It does not constitute a part of the formal annual report documents.

No infringements of Nasdaq’s rules and no breach of good practice on the securities market were reported by the stock exchange’s disciplinary committee or the Swedish Securities Council during the financial year 2023.

The Group comprises the Parent Company, Hansa Biopharma AB, and its wholly owned subsidiaries Cartela R & D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc, Hansa Biopharma Australia Pty Ltd, and Hansa Biopharma Italy S.R.L.

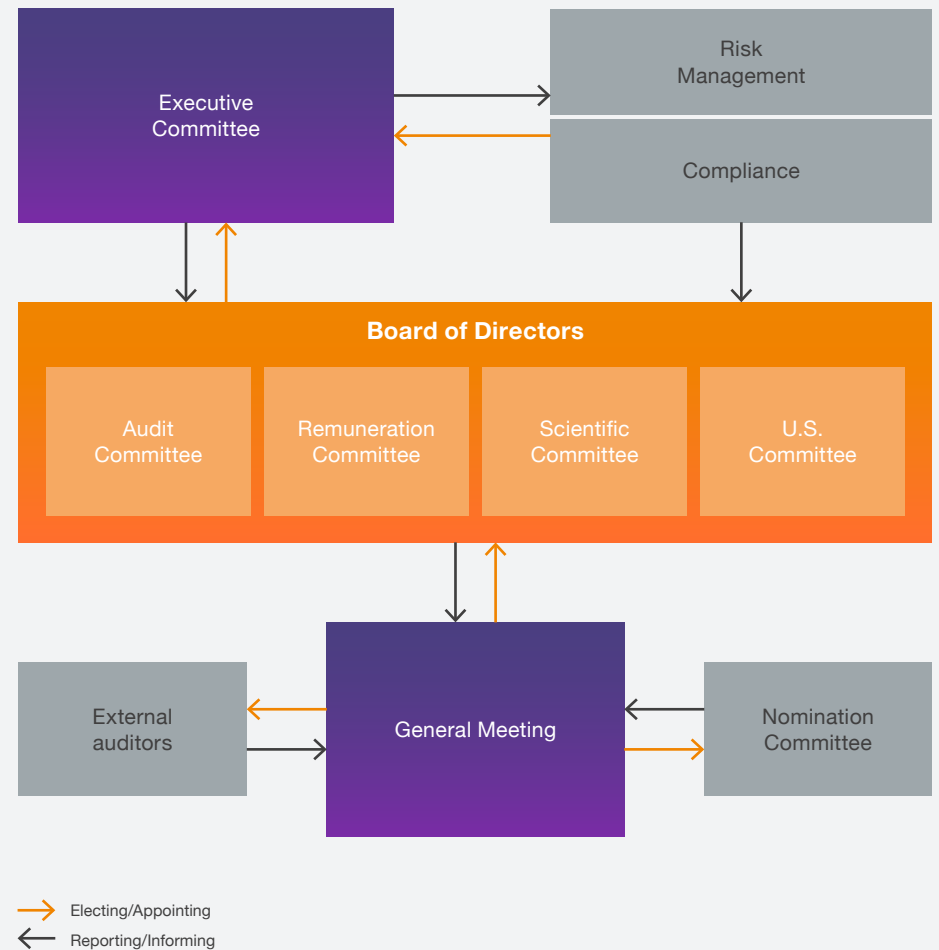
### Shareholders

There are no limitations on the transferability of Hansa’s shares due to legal restrictions or provisions of the articles of association. To Hansa Biopharma’s knowledge, no agreement has been entered into between any shareholders which might limit the transferability of the shares. As of 31 December 2023, Redmile Group LLC is the only shareholder owning more than 10 percent of the Company’s shares, in its shareholdings of 18.3 percent.

### Significant external and internal regulations and policies which affect corporate governance: Significant internal regulations and policies:

- > Articles of association
- > Instruction for the CEO, including the financial reporting instruction
- > Work procedures for the Board
- > Disclosure policy
- > Insider policy
- > Procurement and expenditure policy
- > Treasury policy
- > Finance policy
- > Risk management policy
- > Staff handbook
- > Executive remuneration policy
- > Code of Conduct
- > Supplier Code
- > Global Data Privacy policy
- > Compliance Concerns Reporting and Investigations policy
- > Corporate Giving policy (Grants, Donations, Contributions, and Sponsorships)

### Governance Structure





## Governance General principles continued

### Significant external regulations:

- > Market Abuse Regulation
- > Swedish Companies Act
- > Swedish Accounting Act
- > Swedish Annual Accounts Act
- > International standards for audits and financial reporting (IFRS)
- > Nordic Main Market Rulebook for Issuers of Shares
- > Swedish Corporate Governance Code

### Information regarding Hansa Biopharma AB shares

The Company's shares were admitted for trading on Nasdaq Stockholm, Small Cap, in November 2015. The Company's shares were previously, since 2007, listed on Nasdaq First North.

The Company's shares are divided into ordinary shares and C-shares. On 31 December 2023, the total number of shares issued was 55,034,241 with 52,671,796 ordinary shares outstanding and 2,362,445 C-shares, with a quotient value of SEK 1. Each ordinary share carries one vote, and each C-share carries one tenth. All C-shares are owned by the Company. Each person entitled to vote may vote for his or her full number of shares. The number of votes in the Company amounts to 52,908,040.5.

Each ordinary share confers the right to an equally large percentage of the Company's distributable profits. The C-shares are not entitled to dividends and are subject to a redemption and reclassification clause.

### General meeting

The Company's highest decision-making body is the general meeting, where the shareholders' influence over the Company is

exercised. In addition to what follows from applicable law regarding shareholders' right to participate at general meetings, shareholders who wish to participate at a general meeting, personally or through a proxy, must give notice of their attendance.

Notices to attend general meetings are given through advertisement as well as on the Company's website ([www.hansabiopharma.com](http://www.hansabiopharma.com)). The Annual General Meeting ("AGM") must be held within six months from the close of the financial year. At the AGM, the shareholders adopt resolutions regarding, among other things: the Board and auditors; the procedure for appointing the Nomination Committee; and discharge from liability for the Board and the CEO in respect of the preceding year. Resolutions are also adopted regarding adoption of the annual report; disposition of profits or treatment of losses; fees for the directors and auditors; and, if applicable, guidelines for remuneration for Senior Executives.

### 2023 Annual General Meeting

The 2023 AGM was held on June 29, 2023 in Lund, with participation through advance voting according to sections 20 and 22 in the Act on temporary exemptions in order to facilitate the conduction of general meetings (Sw. lag (2020:198) om tillfälliga undantag för att underlätta genomförandet av bolags- och föreningsstämmor). In total, 16,427,831 of the shares in the Company were represented, meaning that 36.7 percent of the total number of votes and 35.45 percent of the total number of shares in the Company were represented.

It was decided, in accordance with the Board of Directors' proposal and supported

by the auditor, that there shall be no dividend and that the result of the company shall be carried forward.

It was resolved, in accordance with the Nomination Committee's proposal, to re-elect Mats Blom, Andreas Eggert, Anders Gersel Pedersen, Hilary Malone, Peter Nicklin and Eva Nilsagård, as members of the Board of Directors, all for the period until the end of the next Annual General Meeting. The AGM further resolved to re-elect Peter Nicklin as chair of the Board for the period until the end of the next AGM. It was resolved, in accordance with the Nomination Committee's proposal and the audit committee's recommendation, to re-elect KPMG AB as auditor of the company for the period until the end of the next Annual General Meeting. It was noted that KPMG AB had informed the company that Stefan Lundberg will be appointed as auditor-in-charge. It was resolved, in accordance with the Nomination Committee's proposal, that the number of auditors shall be one registered accounting firm without deputy auditors.

### Remuneration to Senior Executives

The 2023 guidelines are unchanged compared to the guidelines adopted by the 2022 annual general meeting and entail that Senior Executives, i.e. the CEO and members of the Executive Committee, will be offered remuneration which is competitive and on market terms. The level of the remuneration for the individual Senior Executive shall be based on factors such as complexity and responsibility of the position, expertise, experience, and performance. The remuneration consists of a fixed base salary and pension benefits and, in addition, may consist of a variable cash remuneration,

performance-based short-term incentive (STI), share based long-term incentive programs (LTIP) as resolved by a general meeting, severance remuneration, and other benefits. The STI shall be based on the achievement of quantitative and qualitative performance targets and shall not exceed 75 percent of the annual fixed base salary. The variable cash remuneration is intended to support recruitment or retention of key personnel or to reward extraordinary performance beyond the individual's ordinary responsibilities and shall not exceed 30% of the annual fixed base salary. Contributions to pension plans shall not exceed 30% of the annual fixed base salary. Salary during the notice of termination period and severance remuneration shall be possible in a total maximum amount of 18 monthly base salaries.

Ultimate responsibility for the remuneration to Senior Executives as well as setting the respective performance targets lies with the Board of Directors which is supported by the Remuneration Committee and the CEO.

It was resolved, in accordance with the Nomination Committee's proposal, that the fees to the Board of Directors, for the period until the end of the next Annual General Meeting, shall remain unchanged from the previous year and be SEK 900,000 to the chair of the Board and SEK 300,000 each to the other Board members. It was further resolved that the remuneration to the chair of the Audit Committee shall be SEK 150,000 and SEK 75,000 to each other member of the Audit Committee, SEK 40,000 to the chair of the Remuneration Committee and SEK 25,000 to each other member of the Remuneration Committee, SEK 75,000 to the chair of the





## Governance General principles continued

Scientific Committee and SEK 50,000 to each member of the Scientific Committee and USD 20,000 to the chair of the U.S. Committee and SEK 50,000 to the other member of the U.S. Committee. Each member in the U.S. Committee “based in North America” shall also receive SEK 100,000 for travel expenses. Further, the member of the U.S. Committee shall retroactively receive remuneration of SEK 50,000 for his work during 2022. It was further resolved that the remuneration to the auditor shall be paid as per approved current account.

Minutes from the 2023 AGM are available at Hansa Biopharma’s website ([www.hansabiopharma.com](http://www.hansabiopharma.com)). The 2024 AGM will take place on 27 June 2024 in Lund, Sweden.

### Remuneration to employees

The Board of Directors’ proposal including a resolution to adopt a long-term incentive program, based on performance-based share rights (the “Share Rights Program 2023”) was presented in accordance with paragraph 16(a) in the notice, Appendix 3. It was established that the Board of Directors’ proposal on a resolution on hedging measures in accordance with paragraphs 16(b)(i)-(iii) in the notice did not acquire the required majority. The proposal to enter into equity swap arrangements with third parties in accordance with paragraph 16(c) in the notice was therefore presented. The shareholders were given the opportunity to ask questions.

It was thereafter resolved, in accordance with the Board of Directors’ proposal, to adopt the long-term incentive program according to paragraphs 16(a) and 16(c) in the notice. It was established that the resolution was adopted with the required majority.

During 2023, neither the Remuneration Committee nor the Board of Directors received any comments or questions from shareholders on the remuneration guidelines adopted at the 2023 AGM.

The Board of Directors’ proposal including a resolution to adopt a long-term incentive program, based on employee stock options (the “Option Program 2023”) was presented in accordance with paragraph 17(a) in the notice, Appendix 3. It was established that the Board of Directors’ proposal on a resolution on hedging measures in accordance with paragraphs 17(b)(i)-(iii) in the notice did not acquire the required majority. The proposal to enter into equity swap arrangements with third parties in accordance with paragraph 17(c) in the notice was therefore presented. The shareholders were given the opportunity to ask questions.

It was thereafter resolved, in accordance with the Board of Directors’ proposal, to adopt the long-term incentive program according to paragraphs 17(a) and 17(c) in the notice. It was established that the resolution was adopted with the required majority.

### Issue of ordinary shares and warrants and/or convertibles

The Board of Directors’ proposal, regarding authorisation for the Board of Directors to resolve on new issue of ordinary shares and warrants and/or convertibles was presented in accordance with item 18(a) in the notice convening the Annual General Meeting, Appendix 3. The shareholders were given the opportunity to ask questions.

It was resolved in accordance with the Board of Directors’ proposal. It was established

that the resolution was supported by shareholders representing at least two thirds of both the votes cast and the shares represented at the Annual General Meeting.

### Nomination Committee

Prior to the 2024 AGM, Hansa’s Nomination Committee comprises of Florian Reinaud (representing Redmile Group Nomination Committee), Jonas Wikström (representing Theodor Jeansson), and Sven Sandberg (representing Thomas Olausson). Peter Nicklin (Chair of the Board) is the convener of the Nomination Committee.

During the 2023 AGM, it was resolved, in accordance with the Nomination Committee’s proposal, to approve the principles for the establishment of the Nomination Committee for the Annual General Meeting 2024, pursuant to the proposal in the convening notice.

Procedures for appointing members of the Nomination Committee were adopted by the 2023 AGM. The Nomination Committee shall, pursuant to the Code, consist of at least three members of which a majority shall be independent in relation to Hansa Biopharma and its management. In addition, at least one member of the Nomination Committee shall be independent in relation to the largest shareholder in terms of voting rights or group of shareholders who cooperates in terms of Hansa’s management.

The Nomination Committee shall prepare proposals for the 2024 AGM for the chair of the AGM, board members, chair of the Board

Minutes from the 2023 AGM are available on our website at [hansabiopharma.com](http://hansabiopharma.com).

of Directors, remuneration to the Board, auditors, remuneration to the auditors, and the principles for the Nomination Committee before the 2024 AGM.

### External auditors

The external audit of the accounts of the Parent Company and the Group, as well as of the management by the Board and the CEO, is carried out in accordance with generally accepted accounting standards in Sweden. The auditor participates in at least one Board meeting per year, going through the accounts for the year and leading a discussion with the directors without the CEO or any other Senior Executive present.

Pursuant to the articles of association, Hansa must have a registered accounting firm as its external auditor. The accounting firm KPMG AB has been the auditor of the Company since the 2014 AGM. As from the 2023 AGM, certified public accountant Stefan Lundberg is auditor in charge. Stefan Lundberg is a member of the Swedish Institute of Authorized Public Accountants. For information regarding fees paid to the auditors, please refer to Note 30 to the 2023 Financial Statements.



## The Board

### The Board is the highest management body under the AGM

The overall task of the Board is to manage the affairs of the Company in the best possible manner on behalf of the shareholders. The Board must continuously evaluate the Group's operations, development and financial situation, as well as the operative management including identifying how sustainability issues impact risks to and business opportunities for the Group. The Board decides upon, among other things: issues concerning the Group's strategic focus and organization; business plans; financial plans and budget; significant agreements; major investments and commitments; and finance, disclosure, and risk management policies. The Board must also ensure that the Company prepares insider instructions. The Board works according to written rules of procedure which are adopted annually, and which regulate the framework for the Board meetings, including the frequency and agenda of meetings, distribution of materials for meetings, and matters to be presented to the Board for information or for a decision. The rules of procedure also govern how the board work is allocated among the Board and its committees. The Board has also adopted CEO instructions which govern the allocation of work among the Board, the chair of the Board, and the CEO, and which defines the CEO's authority.

The Board is elected by the shareholders at the AGM up until the end of the next AGM, with the possibility of re-election. In addition, the Company's employees may, pursuant to statutory rules regarding the representation of employees on the Board, elect employee representatives to the Board. Currently, the Board has no employee representatives. All current board members are considered independent under the corporate governance standards of the Code and Nasdaq Stockholm.

The chair of the Board is responsible for contacts with the shareholders regarding ownership issues and for communicating the shareholders' views to the Board of Directors. The chair is further responsible for the day-to-day contact with the CEO and Senior Executives and must keep her/himself well informed about, and monitor, the Company's business. The chair is responsible for ensuring that the Board's work is carried out efficiently and that the Board fulfils its obligations in accordance with applicable laws and regulations, the Code, the articles of association, resolutions of the general meeting, and the Board's own rules of procedure, and that the Board carries out the decisions that are made and that their work is evaluated. Further, the chair is responsible for ensuring that the directors regularly update their knowledge about the Company and that new directors receive necessary introductory training. The chair must also approve remuneration and other employment terms and conditions for Senior Executives, and is responsible for the Company's archives, in which minutes from all Directors' meetings and general meetings must be saved.

The chair prepares Board meetings together with the CEO and Corporate Secretary. The notice of the meeting and the agenda are sent to the directors together with sufficient decision-making documentation. A Board meeting includes a review of the business, including development and advances within research and development, business development, consolidated earnings and financial position, financial reports, and forecasts.

Pursuant to the Company's articles of association, the Board must comprise of not less than three and not more than ten directors elected by the AGM. The Board is quorate when more than half of the directors are present. The articles of association do not contain any provisions regarding appointment or dismissal of directors or regarding amendment of the articles of association.

#### Directors

The Board currently comprises six individuals, including the chairman.

The 2023 AGM re-elected Mats Blom, Andreas Eggert, Anders Gersel Pedersen, Hilary Malone, Peter Nicklin and Eva Nilsagård, as members of the Board of Directors, all for the period until the end of the next Annual General Meeting in 2024.

Prior to the 2023 AGM, the Nomination Committee announced that it had applied the provisions of rule 4.1 of the Swedish Corporate Governance Code as the Board diversity policy. The aim is that the Board as a collective should possess the required mix in terms of background and knowledge, whereby an even gender distribution is considered. The result of the Nomination Committee's application of the diversity policy is a Board that represents a mix of both professional experience and knowledge as well as geographical and cultural backgrounds. One third (1/3) of the current Board members elected by the AGM are female.



## The Board continued

### Information about Board members as of 31 December 2023

Holdings in the Company include one's own holdings as well as those of closely related persons.



#### Peter Nicklin

Born 1963

Member and chair of the Board since 2022, member of the Remuneration Committee, the Scientific Committee and the U.S. Committee.

**Shareholding: 14,500 shares**

Peter Nicklin has more than 30 years of extensive experience and background in the pharmaceutical and healthcare sector in both developed, as well as emerging markets and significant experience in leading global teams. Chair of the Board at Tunstall Healthcare and Sciensus. Previously, CEO and member of the Board of Amann Girrbach AG, Corporate Vice President and EMEA President of Baxter International (NYSE: BAX), as well as senior executive roles at Bayer Healthcare (XETRA: BAYN), Novartis (SWX: NOVN) and Bristol-Myers Squibb (NYSE: BMY). Peter holds a Bachelor of Arts with Honours in Finance from Lancaster University. He is also a Chartered Accountant having qualified at PriceWaterhouseCoopers in London.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



#### Eva Nilsagård

Born 1964

Member of the Board since 2019 and chair of the Audit Committee.

**Shareholding: 3,000 shares**

Eva Nilsagård is the founder and Chief Executive Officer of Nilsagård Consulting AB. Previous interim Chief Financial Officer of various companies, including OptiGroup AB, Plastal, and CFO of Vitrolife AB (STO: VITR). She has also served in various senior positions at the Volvo Group, or Volvo (STO: VOLV), including Senior Vice President Strategy & Business Development. Earlier in her career, Eva also held senior positions in finance and business development at AstraZeneca plc (LSE: AZN) and AB SKF (STO: SKF). Board member and chair of the audit committee of SEK (Swedish Export Credit Company), AddLife (STO: ALIF), Bufab Group (STO: BUFAB), Nimbus Group AB (STO: BOAT), Nanexa (STO: NANEXA), Ernströmgruppen and Xbrane Biopharma (STO: XBRANE), the chair of Spermosens AB (Spotlight: SPERM) and board member of eEducation Albert AB (STO: ALBERT). Eva has more than ten years of experience as a mentor for young female managers with high potential. She holds an Executive M.B.A. in Economics and a B.Sc. in accounting and finance from School of Business, Economics and Law in Gothenburg.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



#### Mats Blom

Born 1965

Member of the Board since 2019 and member of the Audit Committee.

**Shareholding: 1,000 shares**

Mats Blom serves as Chief Financial Officer of NorthSea Therapeutics B.V. Previous Chief Financial Officer of Modus Therapeutics AB (STO: MODTX), Zealand Pharma A/S (CSE: ZELA), Swedish Orphan International AB (acquired by BioVitrum, now Swedish Orphan Biovitrum AB (publ) (STO:SOBI)), Active Biotech AB (publ) (STO:ACTI), and Anoto Group AB (STO: ANOT). Previously also management consultant at Gemini Consulting and Ernst & Young. Board member of Egetis Therapeutics AB (STO: EGTX), Altamira Therapeutics Ltd. (NASDAQ: CYTO), and Pephexia Therapeutics ApS. Mats holds a B.A. in Business Administration and Economics from Lund University and an M.B.A. from the IESE University of Navarra, Barcelona.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



## The Board continued



### Andreas Eggert

Born 1967

Member of the Board since 2018, chair of the Remuneration Committee, and member of the Audit Committee and the Scientific Committee.

Shareholding: 5,500 shares

Andreas Eggert has over 25 years of cross-functional leadership experience in P&L management, commercial operations, successful product launches, market access, and strategic consulting. Previously, Chief Operating Officer at X-Vax Technology Inc. in the U.S. Served as Senior Group Vice President, Global Product Strategy & Portfolio Development, and member of the Corporate Management Committee at H. Lundbeck A/S (CSE: LUN) in Denmark. Prior to that, served in various senior commercial roles at Wyeth, LLC (acquired by Pfizer Inc. (NYSE: PFE)) in the U.S., Japan and in Germany, including as Vice President & Global Business Manager. Earlier in his career, Andreas also was a Management Consultant at A.T. Kearney. He holds an M.B.A. from Azusa Pacific University.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



### Anders Gersel Pedersen

Born 1951

Member of the Board since 2018, chair of the Scientific Committee, and member of the Remuneration Committee.

Shareholding: 2,500 shares

Anders Gersel Pedersen has over 33 years of experience in the international pharmaceutical industry. Served in various roles at H. Lundbeck A/S in Denmark (CSE: LUN), including most recently as Executive Vice President of Research & Development, as responsible for the discovery and development of the product pipeline from preclinical activities to post-launch marketing studies. Prior to that, served in various roles at Eli Lilly and Company (NYSE: LLY), including most recently as a director overseeing worldwide clinical research in oncology. Anders is Chairman at Aelis and Deputy Chair at Bavarian. Serves on the supervisory boards of Avillion LLP, Bavarian Nordic A/S (CSE: BAVA), AELIS Farma SA, and Genmab A/S (CSE: GMAB). He received his medical degree and a doctoral degree in neuro-oncology from the University of Copenhagen and a B.Sc. in Business Administration from Copenhagen Business School.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



### Hilary M Malone

Born 1965

Member of the Board since 2021, Chair of the US Committee and member of the Scientific Committee.

Shareholding: 0

Hilary Malone has over 25 years of experience in global drug development, regulatory and government affairs, manufacturing and commercialization within the biopharma industry. Hilary is currently Chief Executive Officer of Stylus Medicine, a private genetic medicine biotech company. Previously she served as Chief Executive Officer of a private neuroscience company in start-up phase. Prior to these roles, Hilary served as Chief Operating Officer and Executive Vice President at Valo Health Inc., and as the Chief Regulatory Officer and Senior Vice President & Head of Global Regulatory Affairs at Sanofi Inc. (subsidiary of Sanofi SA (Euronext: SAN)). Previous experience also includes senior regulatory and drug development roles at Reata Pharmaceuticals, Inc. (recently acquired by Biogen Inc.), Pfizer Inc. (NYSE:PFE), Wyeth, LLC (acquired by Pfizer Inc.), AstraZeneca plc (LSE:AZN) and GlaxoSmithKline plc (LSE: GSK). Hilary also serves on the board of Adthera Bio. She holds a Ph.D. in Molecular Neuropharmacology and a B.Sc. in Physiology from the University of Dundee, Scotland.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



## The Board continued

### The Board of Directors' work in 2023

During 2023, the Board has held 10 meetings. The Board has also made resolutions per capsulam at five occasions.

At the Board meetings held during the 2023 financial year, the directors were present as set forth below. The number of meetings and the maximum number of meetings each director could have been present at during the financial year are stated in parentheses.

### Evaluation of the Board of Directors' work

Pursuant to the Code, the Board is to evaluate its work annually, using a systematic and structured process, with the aim of developing the Board's working methods and efficiency. The evaluation has been carried out by the chair of the Board and an independent evaluation company, in the beginning of 2023, interviewing the directors with questions about the work of the Board. The result of the responses has been declared to the directors and the members of the Nomination Committee.

### Board members and meeting presence for the reporting period

1 January – 31 December 2023

Board member	Elected	Present at meetings of the Board	Present at meetings of the Remuneration Committee	Present at meetings of the Audit Committee	Present at meetings of the Scientific Committee	Present at meetings of the US Committee	Independent in relation to the Company and Executive management	Independent in relation to the Company's largest shareholders
Peter Nicklin	2022	10(10)	6(6)	–	2(2)	2(2)	Yes	Yes
Hilary Malone	2021	10(10)	–	–	2(2)	2(2)	Yes	Yes
Anders Gersel Pedersen	2018	9(10)	6(6)	–	2(2)	–	Yes	Yes
Andreas Eggert	2018	10(10)	6(6)	6(6)	2(2)	–	Yes	Yes
Eva Nilsagård	2019	10(10)	–	6(6)	–	–	Yes	Yes
Mats Blom	2019	10(10)	–	6(6)	–	–	Yes	Yes



## The Board continued Board Committees

### Audit Committee

After the 2023 AGM, the Audit Committee consisted of Eva Nilsagård, chair, Mats Blom and Andreas Eggert. The Audit Committee is obligated to keep the minutes of its meetings and make the minutes available to the Board. The Audit Committee shall perform the duties incumbent upon audit committees as required by law and the Code.

The Audit Committee assists the Board in overseeing the Company's accounting and financial reporting processes. The Audit Committee consists exclusively of members of the Board who are financially literate and are each considered an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. The Board has determined that all of the members of the Audit Committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act. The Audit Committee is governed by a charter that complies with Nasdaq rules.

#### The primary duties of the Audit Committee are to:

- > Assist the Board in overseeing the Company's financial position, performance, and reporting;
- > With respect to the financial reporting, monitor the effectiveness of the Company's internal control system, internal audit and risk management;
- > Keep itself informed of the audit of the annual accounts and consolidated accounts;
- > Review and monitor the auditor's impartiality and independence, and, in this context, particularly monitor whether the auditor is

providing the Company with services other than auditing services; and

- > Take decisions regarding guidelines for services other than the auditing services which the external auditor can provide.

### Remuneration Committee

After the 2023 AGM, the Remuneration Committee consists of Andreas Eggert, chair, Peter Nicklin and Anders Gersel Pedersen. The Remuneration Committee is charged with performing the duties set forth in the Swedish Corporate Governance Code. The Remuneration Committee is obligated to keep minutes of its meetings and make the minutes available to the Board.

#### The primary duties of the Remuneration Committee are to:

- Propose guidelines and principles for remuneration and other terms of employment of the Chief Executive Officer and senior executives;
- Monitor and evaluate any programs pending or adopted during the year for variable remuneration for Senior Executives;
- Monitor and evaluate the implementation of the guidelines for remuneration of Senior Executives adopted by the AGM, as well as applicable remuneration structures and levels for the Company;
- Oversee and administer the Company's employee share option scheme or equity incentive plans in operation from time to time.

### Scientific Committee

After the 2023 AGM, the Scientific Committee consists of Anders Gersel Pedersen, chair,

Andreas Eggert, Peter Nicklin and Hilary Malone. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board.

#### The primary duties of the Scientific Committee are to:

- > Assist the Board with recommendations regarding the Company's research and development strategies and possibilities;
- > Perform such other duties as are considered necessary and appropriate in conjunction with the work set forth above and perform such other duties as instructed by the Board from time to time.

### U.S. Committee

The rules of procedure for the U.S. Committee were adopted by the Board at a meeting held on July 14, 2021. After the 2023 AGM, the U.S. Committee consists of Hilary Malone, chair, and Peter Nicklin. The U.S. Committee is obligated to keep minutes of its meetings and make the minutes available to the Board.

#### The primary duties of the U.S. Committee are to:

- > Discuss and provide input to significant issues and aspects related to the Company's U.S. operations and environment, including R&D, regulatory and commercial aspects; and
- > Provide advice and proposals for resolutions, subject to final approval by the Board or the CEO, as the case may be, regarding matters related to the Company's and the group's U.S. operations and development.



## Executive management

The Board appoints a CEO to manage the Company. In addition to the CEO, there are five roles who together make up Company executive management:

- > President and Chief Executive Officer
- > Senior Vice President, Chief Financial Officer
- > Senior Vice President, Chief Commercial Officer and President, US
- > Senior Vice President, Chief Scientific Officer
- > Senior Vice President, Chief Human Resources Officer
- > Senior Vice President, Chief Medical Officer

The executive management holds meetings every month to discuss the Group's earnings and financial position, the status of research and development projects, operational and strategic issues, and follow-up on budgets and forecasts.

### The CEO's responsibility

The CEO is responsible for managing the Company's day-to-day operations pursuant to the Board's guidelines and instructions. The CEO is also responsible, in accordance with the Board's written instructions, for preparing and presenting to the Board issues which fall beyond the scope of day-to-day management, and he must act in accordance with the instructions to the CEO adopted by the Board, the decisions of the Board and the general meeting, and in the best interests of all shareholders.

He must also respect the fiduciary duty and duty of confidentiality which apply to affairs and circumstances which might cause damage to the Company if disclosed, as well as the

duty to report matters and circumstances which are material to the Company.

In accordance with the Board's instructions, the CEO must take any and all measures which are necessary to ensure that the Company's book keeping is legally compliant and to ensure that funds are managed in a satisfactory manner. Accordingly, it is the CEO's responsibility to ensure that the Company has good internal management and routines to ensure application of the adopted principles for financial reporting and internal control.

Further, the CEO shall each month (with the exception of January and July) compile a report regarding the Company's financial situation. He is responsible for ensuring that the Company complies with applicable laws and guidelines, including Swedish law, the Nordic Main Market Rulebook for Issuers of Shares and the Code. The CEO must ensure, at a minimum, that the six-month report or the nine-month report is reviewed by an auditor. The CEO also has specific responsibility to ensure the competitive supply of all purchases of goods or services exceeding SEK 1 m. The CEO must provide the Board with all necessary background information and documentation, both before and between Board meetings. The CEO must attend Board meetings unless the chairman informs him that he need not to attend.

The CEO must also attend all general meetings of the Company, including both AGM's and extraordinary general meetings. The CEO may not have any engagements outside of the Company without the Board's approval.

The CEO is also responsible for implementing the strategy approved by the Board and to propose such other strategies and operational measures to the Board which he deems appropriate. The CEO is responsible for the Company's internal organization, but must obtain the Board's approval prior to major organizational changes. The CEO is responsible for issuing and maintaining instructions for delegation to Senior Executives of the Company. He is also responsible for entering into or terminating employment agreements and for other employment terms and conditions; how ever the chairman of the Board's approval is necessary for such issues in respect of Senior Executives.

In a crisis situation, it is the CEO's responsibility to inform the Board immediately and, if necessary, to form and instruct a crisis committee and to prepare a contingency plan for the business. The CEO must immediately report any event or procedure which he suspects may be significantly adverse to the business or the Company's financial position, e.g. a liquidity crisis, to the chairman of the Board.

Information regarding the CEO's age, primary education, work experience, significant engagements outside of Hansa Biopharma, and his holdings of shares in the Company and those of closely related persons are set forth overleaf.

## Executive management continued

### Senior Executives

Hansa Biopharma's Senior Executives currently comprise six individuals:

- > President and CEO Søren Tulstrup
- > Senior Vice President, Chief Scientific Officer Hitto Kaufmann (effective from 1 Dec 2023)
- > Senior Vice President, Chief Financial Officer Donato Spota (until 29 Feb 2024)
- > Senior Vice President, Chief Commercial Officer and President, U.S. Matthew Shaulis
- > Senior Vice President, Chief Human Resources Officer Anne Säfström Lanner
- > Senior Vice President, Chief Medical Officer Achim Kaufhold and Chief Science Officer ad interim from 1 Feb to 1 Dec 2023
- > Senior Vice President, Chief Scientific Officer and Chief Operating Officer Christian Kjellman (until 1 February 2023)

Hansa Biopharma's current Senior Executives, the years when they assumed their positions, their years of birth, education, work experience, significant engagements outside the Company and holdings in Hansa Biopharma as of 31 December 2023 are listed further below in this Corporate Governance report.

Holdings in the Company includes both one's own holdings and/or those of closely related persons.

A detailed description of each incentive program can be found in Note 14 to the 2023 Consolidated Financial Statements.



#### Søren Tulstrup

Born 1965  
President and CEO

Shareholding: 50,347  
Share rights: 260,000  
ESOP's: 575,107

Søren Tulstrup has served as President and Chief Executive Officer since March 2018. He has extensive experience as a senior executive in the global biopharma industry. Prior to joining Hansa, Søren served as Chief Executive Officer of Vifor Pharma AG (SIX: VIFN), (now part of CSL Behring), and he has also served as President & Chief Executive Officer of Santaris Pharma A/S (now part of F. Hoffmann-La Roche AG (SIX: ROG)). Furthermore, Søren has served in several senior general management and commercial roles within Shire Pharmaceuticals (now The Takeda Pharmaceutical Company Limited (TSE: 4502)), Merck & Co., Inc. (NYSE: MRK) and Sandoz Pharma AG (now Novartis AG, or Novartis (NYSE: NVS)) in both Europe and the United States. He holds a Master of Science, Economics and Business Administration from Copenhagen Business School.



#### Hitto Kaufmann

Born 1970  
Chief Scientific Officer

Shareholding: 0  
Share rights: 60,000  
ESOP's: 70,000

Hitto Kaufmann has served as Chief Scientific Officer since December 2023. Hitto has over 20 years' experience as biopharma leader in the development of innovative medicines, advancement of strategic R&D partnerships, and building of next generation therapeutic platforms. His track record includes the development of approximately 100 biological therapeutic entities, many of them advanced by him actively steering strategic partnerships. Prior to joining Hansa, Hitto served as Chief Scientific Officer at Pieris Pharmaceuticals, directing discovery, technical development, CMC, data sciences, project management and alliance management departments. He furthermore was appointed site head of the R&D site of Pieris in Munich.

Before his tenure at Pieris he spent 5 years at Sanofi where he held several executive positions in Industrial Affairs and Sanofi R&D. He led efforts to build a strong cross-divisional end-to-end technology platform for biologics including several strategic deals before becoming the Global Head of Biopharmaceuticals Development. During more than a decade at Boehringer Ingelheim he held several leadership positions including Vice President, Process Sciences. He began his career as a Research Scientist at the Walter and Eliza Hall Institute in Melbourne. Hitto currently serves as a member of the Scientific Advisory Board of Instituto de Biologia Experimental e Tecnologica (iBET). He holds a Ph.D. in Natural Science, from the Swiss Federal Institute of Technology in Zurich.



#### Donato Spota<sup>1</sup>

Born 1971  
Senior Vice President, Chief Financial Officer

Shareholding: 15,076  
Share rights: 0  
ESOP's: 106,842

Donato Spota has served as Chief Financial Officer since May 2019. He has more than 25 years of pharmaceutical industry experience in international environments, including strategic finance, business development, investor relations and international capital markets transactions. Prior to joining Hansa, he served in various roles at Basilea Pharmaceutica AG (SIX: BSLN), including as Chief Financial Officer. Prior to that, he held different finance roles at F. Hoffmann-La Roche AG (SIX: ROG). He holds a B.A. in Information Technology from the Swiss BBT (Bundesamt für Berufsbildung und Technologie) and an M.B.A. from the Hochschule für Wirtschaft und Umwelt Nürtingen-Geislingen.

<sup>1</sup> On 27 November 2023, Hansa announced that Donato Spota decided to leave the company. His last day was 28 February 2024.





## Executive management continued



### Anne Säfström Lanner

Born 1969

Senior Vice President, Chief Human Resources Officer

Shareholding: 7,273  
Share rights: 125,000  
ESOP's: 160,000

Anne Säfström Lanner has served as Chief Human Resources Officer since June 2020, and served as Vice President Global Human Resources from 2019 to June 2020. Prior to joining Hansa, she served in various senior roles at the European Spallation Source, a European multi-disciplinary research facility, including Head of Resourcing. Prior to that, Head of Human Resources at Cellavision AB (STO:CEVI). Anne has held positions as Head of HR, Head of Resourcing, HR Manager & Deputy Head of HR and has extensive experience from fast growing start-up international companies. Holds a Bachelor of Social Science in Human Resource Management, focusing on strategic organizational development & leadership, from Lund University.



### Achim Kaufhold<sup>2</sup>

Born 1957

Senior Vice President, Chief Medical Officer (also Chief Scientific Officer ad interim 01 February until 01 December 2023)

Shareholding: 8,800  
Share rights: 111,000  
ESOPs: 144,000

Achim Kaufhold has served as Chief Medical Officer since June 2020. He is a highly experienced senior leader in immunology, infectious diseases and oncology. Achim has over 25 years of international experience within the biotechnology and pharmaceutical industry. Prior to joining Hansa, Achim served in various senior executive positions in general management, product and business development. Has served as Chief Executive Officer of Affitech AS and Pharmexa A/S (both companies merged), Chief Medical Officer of Basilea Pharmaceutica AG (SIX: BSLN), Pharmexa A/S, Chiron (acquired by Novartis (NYSE: NVS)) and Berna Biotech AG (now Johnson & Johnson (LSE: JNJ)). Prior to that, he headed the worldwide clinical development of the paediatric vaccine portfolio of GlaxoSmithKline plc (LSE: GSK). Currently also serves on the board of directors of Biosergen AB (STO: BIOSGN). Graduated as a Doctor of Medicine from the University of Cologne and holds a professorship in Medical Microbiology and Infectious Diseases at the University of Aachen, Germany.

<sup>2</sup> As of 1 February 2023, until 1 December 2023, Achim also served as ad-interim Chief Scientific Officer.



### Matthew Shaulis<sup>3</sup>

Born 1973

Chief Commercial Officer and President, US since 16 March 2023

Shareholding: 0  
Share rights: 105,000  
ESOs: 128,300

Matthew Shaulis has served as Chief Commercial Officer and President of the U.S. affiliate, Hansa Biopharma Inc since March 2023. Prior to his role at Hansa Biopharma, Matthew gained over 20 years of U.S. and international experience in the pharmaceutical industry in general management, global strategic and in-line marketing, sales management, business development, and product and indication launches. He held several senior executive roles at Pfizer Inc. (NYSE: PFE), including President of Inflammation & Immunology for International markets in Europe and Asia, President of Oncology for North America, and more recently as the Senior Vice President responsible for leading the company's global commercial and medical go-to-market model transformation. Prior to that, Matthew served in various leadership roles at Teva Pharmaceutical Industries (NYSE: TEVA), Cephalon, Johnson & Johnson (LSE: JNJ), and Schering-Plough (now part of Merck & Co., Inc. (NYSE: MRK)). He holds a B.S. in Accounting from Pennsylvania State University and an M.B.A. from The Fuqua School of Business, Duke University, North Carolina.

<sup>3</sup> As of 16 March 2023, Matthew Shaulis joined Hansa as Chief Commercial Officer and President, U.S.



### Christian Kjellman<sup>4</sup>

Born 1967

Senior Vice President, Chief Scientific Officer and Chief Operating Officer (until 01 February 2023)

Shareholding: 8,222  
Share rights: 95,000  
ESOPs: 134,380

Christian Kjellman has served as Chief Scientific Officer since 2008 and Chief Operating Officer since 2020. Prior to joining Hansa, he served as Principal Scientist at Biolnvent AB (STO: BINV), where he focused on novel target evaluation and antibody technology. Prior to that, Christian served as Head of Research at the biopharmaceutical

development company Cartela AB. He has extensive research experience in cell and molecular biology and as an Assistant Professor in Molecular Genetics at Lund University. Christian holds a M.Sc. in Chemical Biology and a Ph.D. in Tumour Immunology from Lund University.

<sup>4</sup> On 30 January 2023 Hansa announced the planned departure of Christian Kjellman by 2024. As of 01 February 2023 Christian Kjellman no longer serves as Chief Scientific Officer nor Chief Operating Officer.



## Internal Controls and Risk Management In respect of the Financial Reporting

### Introduction

The following description is based on guidelines issued in 2008 by the Confederation of Swedish Enterprise and FAR.

The Company's internal control procedures in respect of financial reporting have been formulated to ensure, with reasonable certainty, quality, and accuracy in the reporting. The procedures are designed to ensure that the reporting is prepared in accordance with applicable laws and regulations as well as the requirements which are imposed on companies with shares admitted for trading on a regulated market in Sweden. The important prerequisites for achieving this are: (i) the existence of a satisfactory control environment; (ii) the execution of reliable risk assessments; (iii) the existence of established control structures and control activities; and (iv) satisfactory information, communications, and follow-up.

### Internal Audit

The Board has evaluated the need for an internal audit function and has concluded that it is not warranted for Hansa due to the scope and size of the operations and because the Board's follow-up of the internal control is deemed sufficient to ensure that the internal control is effective. The Board will review the need in the event of changes which may give rise to re-evaluation and at least once annually.

### Control Environment

Internal control is based on Hansa's control environment, which comprises the values and ethics from which the Board, the Audit Committee, the CEO, the Executive Committee, and other employees communicate and operate. The control environment also includes the

Company's organizational structure, leadership, decisional structure, decision-making authority, responsibility, and employee proficiency.

### Risk Assessment

Risk identification and evaluation are carried out in a manner to also include risks regarding financial reporting. As part of this procedure, items in the income statement and statement of financial position entailing a great risk of significant error are identified. For Hansa, accrued project costs in the Company's clinical projects have, at various times, involved significant amounts. The size of these is based, to a great extent, on management's assessment of the degree of completion. More recently, product sales, contract revenue and inventory valuation became items which could include an elevated risk of significant error as they may involve a significant amount of judgement and estimates. Further, cash and equivalents, as well as current investments, comprise a significant percentage of the Company's total assets and are therefore deemed to give rise to a risk in the financial reporting. Moreover, the fact that Hansa's administration is handled by a relatively small number of individuals is listed as a risk since the dependency on a small number of key individuals becomes great and the possibility to allocate tasks and responsibility becomes limited. The Company's risk management policy and further policies include controls to prevent and detect shortcomings in these and other areas.

### Control Structure and Control Activities

The Board's rules of procedure and the instructions for the CEO and Board committees ensure a clear allocation of roles

and responsibility. The Board has overall responsibility for internal controls. The CEO is responsible for the development of the system of routines, procedures, and controls for the day-to-day operations. This includes, among other things, guidelines, and role descriptions for the various decision-makers as well as regular reporting to the Board based on established routines. Procedures, routines, instructions and templates for the financial reporting and the day-to-day administrative financial operations and financial issues are documented in Hansa's policies. Routines and activities have been designed to manage and rectify significant risks which are related to financial reporting, and which are identified in the risk analysis. The most significant, overall, group-wide corporate governance documents are the work procedures for the Board, instructions for the CEO, disclosure policy, insider policy, risk management policy, and Code of Conduct.

The primary purpose of control activities is the prevention and early-stage detection of errors in the financial reporting so that they can be addressed and corrected. The Group has implemented entity level controls as well as process controls. Access to IT systems is limited and controlled in accordance with powers and authorization. Manual and automated control steps are incorporated throughout

the accounting, financial closing and financial reporting process. The CFO compiles monthly financial reports which, among other things, are to report earnings and cash flow for the preceding period and state budget deviations. These reports, and above all the budget deviations, are analysed and commented upon by Company management. Follow-up takes place through regular meetings for review of these reports and analyses with the various managers and project managers. The work involved with annual accounts and annual reports are processes which pose additional risks for errors in the financial reports.

**The Board has overall responsibility for internal controls. The CEO is responsible for the development of the system of routines, procedures, and controls for the day-to-day operations.**



## Internal Controls and Risk Management continued

This work is of a less repetitive nature and contains more evaluative elements. Important control activities include, among other things, external confirmations (e.g. bank statements or third party vendor confirmations) as well as ensuring that there is a properly functioning reporting structure in which the various managers and project managers report pursuant to standardized templates, and that important income statement and statement of financial position items are analysed and commented upon.

### Information and Communication

The informational activities are governed by a disclosure policy. There are guidelines for external communications which ensure that the Company meets high standards for providing correct information to the shareholders and the financial market. Hansa's communications must be characterized by transparency and must be correct, relevant, reliable and clear; they may not be misleading. All communications must take place in accordance with Nordic Main Market Rulebook for Issuers of Shares, the Swedish Corporate Governance Code, and the laws and requirements imposed on Swedish companies whose shares are admitted for trading on a regulated market. The policy applies to all employees and directors of Hansa Biopharma and applies to both oral and written information.

The Board releases annual reports, financial statements and interim reports. All financial reports are published on the website ([www.hansabiopharma.com](http://www.hansabiopharma.com)) simultaneously as being published pursuant to Nasdaq Stockholm's rules and regulations. The annual report is made available on the website and is provided as a hard copy to those shareholders who so wish.

### Follow-up

The Board's follow-up on internal controls in respect of the financial reporting takes place, among other things, through follow-up by and through the Audit Committee, on the work and reports of the CFO and the external auditors. The work includes ensuring that measures are taken in respect of the shortcomings and proposed measures generated in conjunction with the external audit. The focus of the follow-up is Hansa compliance with policies, rules and guidelines; and the existence of efficient and suitable processes for risk management, operational management, and internal control. Each year, the external auditor follows up on the selected elements of the internal control within the scope of the statutory audit.

The auditor reports the results of the examination to the Audit Committee and Company management. Significant observations are reported, where applicable, directly to the Board.

The CEO is responsible for compiling all experience from the Company's risk management work and, following discussions with Company management, proposing any changes which the CEO deems necessary or applicable. The Board will decide on any changes.

### Compliance

Hansa has adopted a Code of Conduct for all of its directors, officers, and associates which sets forth the standards for business behaviours that apply throughout the Company and describes the expectations Hansa has for its business partners, and those acting on behalf of the Company.

The Code of Conduct contains guidance in the areas of personal and corporate integrity, responsibility toward the Company, its associates and the community as well as responsible and comprehensive compliance management.

Aligned with the Code of Conduct, Hansa has established a global compliance framework. This compliance framework includes, but is not limited to, compliance and business unit policies and procedure documents, compliance risk mitigation and violation reporting processes, data privacy precautions as well as internal auditing and monitoring activities. Hansa has also brought on a dedicated compliance specialist as a consultant to promote ethical conduct and a culture of compliance throughout the organization.



# Remuneration

Remuneration report 2023

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# Remuneration report 2023

## Introduction

This remuneration report provides an outline of how Hansa's guidelines for remuneration (the "Remuneration guidelines"), adopted by the annual general meeting 2023, were implemented in 2023. The report also provides information on remuneration to the CEO and a summary of Hansa's outstanding share-based long-term incentive programs. The report has been prepared in accordance with the Swedish Companies Act and the Remuneration Rules issued by the Swedish Corporate Governance Board.

Further information on senior executive remuneration is available in Note 14 to the Consolidated Financial Statements in the Annual Report 2023. Information on the work of the remuneration committee in 2023 is set out in the corporate governance report included in the Annual Report 2023.

Remuneration of the Board of Directors is not covered by this report. Such remuneration is resolved annually by the annual general meeting and disclosed in Note 14 to the Financial Statements of the Parent Company in the Annual Report 2023.

## Key Developments 2023

### Company performance in 2023

The CEO summarizes the Company's overall performance in his statement in the Annual Report 2023. In addition, the directors report included in the Annual Report 2023 summarizes the Company's 2023 business and operations.

## The Company's remuneration guidelines: scope, purpose and deviations

A prerequisite for the successful implementation of the Company's business strategy and safeguarding of its long-term interests, including its sustainability, is that the Company is able to recruit and retain highly qualified personnel, consequently, it is necessary that the Company offers market competitive remuneration. This has been becoming of paramount importance as the Company is required to attract talent from and in Sweden, other European countries and the US. Under Hansa's remuneration guidelines, remuneration of senior executives shall be on market terms and may consist of the following components: fixed base salary, variable cash remuneration (including STI), pension benefits and other benefits.

The Remuneration guidelines, adopted by the annual general meeting 2023, can be found in the Governance section in the Annual Report 2023. During 2023, the Company has complied with the applicable Remuneration guidelines adopted by the general meeting. No deviations from the guidelines have been decided and no derogations from the procedure for implementation of the guidelines have been made. The auditor's report regarding the Company's compliance with the guidelines is available on the Company's website, [www.hansabiopharma.com](http://www.hansabiopharma.com). No remuneration has been reclaimed.

In addition to remuneration covered by the Remuneration guidelines, the annual general meetings of Hansa have also resolved to implement long-term share-based incentive plans for certain groups of Hansa employees and on remuneration guidelines for the Board of Directors.

## Table 1 – Total remuneration of the CEO (kSEK)<sup>1</sup>

Table 1 below sets out the total remuneration related to Hansa's CEO for 2023.

Name of Director, position	Financial year	1 Fixed remuneration		2 Variable remuneration			3 Extraordinary items	4 Pension expense	5 Total remuneration	6 Proportion of fixed and variable remuneration in %
		Salary	Other benefits	One-year variable	Financial year variable					
Søren Tulstrup (CEO)	2023	8,431 <sup>2</sup>	-	3,839	1,099 <sup>3</sup>	—	—	13,369	63% / 37%	

<sup>1</sup> Except for Multi-year variable remuneration, the table reports remuneration earned in 2023. Multi-year variable remuneration is reported if vested in 2023, as set out in column 8 of Table 2 and column 10 of Table 3 below (as applicable). Disbursement of any payments may or may not have been made the same year.

<sup>2</sup> Includes KSEK 1,828, representing 30% of base salary, intended for own pension contribution.

<sup>3</sup> Corresponds to 25,202 ordinary Hansa shares at a value of SEK 43.60 each received under the LTIP 2020 and 128,760 stock options at no value vested and earned under the LTIP 2020. The stock options do not carry value as of the date of vesting since share price was below the exercise price.



## Remuneration report 2023 continued

### Share based remuneration

#### Outstanding share-based long-term incentive programs

As of December 31, 2023, the Company has five long-term incentive programs outstanding in which amongst others also the CEO participates: long-term incentive program ("LTIP") 2019, 2020, 2021, 2022 and 2023. LTIP 2019 partly vested and partly lapsed during 2022. LTIP 2020 partly vested and partly lapsed during 2023.

As a general condition to all programs, any rights may only vest provided that the participant, with certain exceptions, from the start of the incentive program and during the three (3) years vesting period thereafter maintains his or her employment within the Group.

#### Long-term incentive program 2019

On May 22, 2019, the annual general meeting in Hansa Biopharma resolved to adopt a long-term incentive program for certain employees of the Group. The long-term incentive program 2019 includes two elements; one performance-based share rights program, and one option program comprising two series, a warrant and an employee stock option ("ESO") series. The CEO was granted 35,151 share rights and 66,347 employee stock options but chose not to acquire any warrants under incentive program 2019.

Under the performance-based share rights program, each share right entitled the holder to receive one ordinary share in Hansa Biopharma AB free-of-charge provided that the below performance conditions were met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of ordinary shares that each participant was entitled to receive was conditional upon the following performance conditions being met during the vesting period:

- (a) 22 percent of the shares in the event that market approval is obtained by EMEA within the EU,
- (b) 22 percent of the shares in the event that at least 10 patients enrolled in US RCT (ConfIdaS), and
- (c) up to 56 percent of the shares related to the total shareholder return on the Company's ordinary shares (if the total shareholder return for the Company's ordinary share during the vesting period reaches or exceeds 75 percent, the participant will be awarded 56 percent of the performance shares and if the total shareholder return for the Company's ordinary share falls below 25 percent, no allotment of performance shares will be made under this performance condition. In between the percentages, allotment will be made linearly).

The option program comprises two series; Series 1 – Warrants, and Series 2 – Employee stock options. Series 1 consists of warrants which could be exercised for subscription of ordinary shares during the period from 15 June 2022 up to and including 15 July 2022. The transfer of the warrants to participants was made at a price corresponding to the market value of the warrants at the time of transfer.

The Company subsidized up to 100 percent of the price for the transfer of the warrants. Series 2 consists of ESOs allotted free-of-charge. The ESOs have a vesting period of three years and an exercise period of three years. Each warrant or ESO entitles the holder to acquire one new ordinary share in Hansa Biopharma AB at a strike price of SEK 196.20, which corresponds to 110 percent of the volume weighted average share price during the ten (10) trading days immediately prior to the offer to subscribe for the options and/or warrants.

In total, 278,181 share rights, 149,148 ESOs and 11,000 warrants were outstanding under the LTIP 2019 as of 1 January 2022. During 2022, 122,400 share rights and 149,148 ESOs vested, while 155,781 share rights and 11,000 warrants lapsed. By December 31, 2022 and 2023, a total of 149,148 vested ESOs were outstanding.

#### Long-term incentive program 2020

On June 23, 2020, the annual general meeting in Hansa Biopharma resolved to adopt a long-term incentive program for certain employees of the Group. The long-term incentive program 2020 includes two elements: one performance-based share rights program, and one employee stock option program. The CEO has been granted 57,278 share rights and 128,760 employee stock options ("ESO") under the long-term incentive program 2020.

Under the performance-based share rights program, each share right entitles the holder to receive one ordinary share in Hansa Biopharma AB free-of-charge provided that the below performance conditions are met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of shares that each participant is entitled to receive is also conditional upon the following performance conditions being met during the vesting period: (a) 22 percent of the shares in the event the U.S. randomized controlled trial (ConfIdaS) has enrolled 64 patients, (b) 11 percent of the shares in the event that top-line data read out of the ongoing Phase 2 study in either AMR or GBS is completed with data providing a solid scientific rationale for a path forward, (c) 11 percent of the shares in the event that at least 70 percent of the targeted transplantation centres in Europe have been initiated, and (d) up to 56 percent of the shares related to the total shareholder return on the Company's ordinary shares (if the total shareholder return for the Company's ordinary share during the vesting period reaches or exceeds 75 percent, the participant will be awarded 56 percent of the performance shares and if the total shareholder return for the Company's ordinary share falls below 25 percent, no allotment of performance shares will be made under this performance condition. In between the percentages, allotment will be made linearly).

The option program 2020 consists of ESOs allotted free-of-charge. The ESOs have a vesting period of three years, and an exercise period of three years. Each ESO entitles the holder to acquire one ordinary share in Hansa Biopharma AB, provided that the participant, with certain exceptions, remains employed within the Group, at an exercise price of SEK 315.75 which corresponds to 125 percent of



## Remuneration report 2023 continued

the volume weighted average share price during the 10 trading days immediately preceding the respective allotment of the ESOs.

In total, 398,311 share rights and 487,520 ESOs were outstanding under the long-term incentive program 2020 as of 31 December 2022. During 2023, 168,217 share rights and 467,520 ESOs vested, while 214,094 share rights lapsed or forfeited. As of December 31, 2023, a total of 467,520 vested ESOs and 16,000 unvested share rights and 20,000 unvested ESOs were outstanding.

### Long-term incentive program 2021

On May 12, 2021, the annual general meeting in Hansa Biopharma resolved to adopt a long-term incentive program for certain employees of the Group. The long-term incentive program 2021 includes two elements: one performance-based share rights program, and one employee stock option program. The CEO has been granted 80,000 share rights and 120,000 employee stock options ("ESO") under the long-term incentive program 2021.

Under the performance-based share rights program, each share right entitles the holder to receive one ordinary share in Hansa Biopharma AB free-of-charge provided that the below performance conditions are met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of shares that each participant is entitled to receive is also conditional upon the following performance conditions being met during the vesting period: (a) 22 percent of the shares in the event that at least 56 patients were randomized in the US ConfldeS study, (b) 11 percent of the shares in the event that the GBS phase 3 development strategy aligned with FDA or EMA, and 30% of patients were enrolled into anti-GBM phase 3 study, (c) 11 percent of the shares in the event that at least 80% of the targeted transplantation centers in Europe have been initiated, and (d) up to 56 percent of the shares related to the total shareholder return on the Company's ordinary shares (if the total shareholder return for the Company's ordinary share during the vesting period reaches or exceeds 75 percent, the participant will be awarded 56 percent of the performance shares and if the total shareholder return for the Company's ordinary share falls below 25 percent, no allotment of performance shares will be made under this performance condition. In between the percentages, allotment will be made linearly).

The option program 2021 consists of ESOs allotted free-of-charge. The ESOs have a vesting period of three years, and an exercise period of three years. Each ESO entitles the holder to acquire one ordinary share in Hansa Biopharma AB, provided that the participant, with certain exceptions, remains employed within the Group, at an exercise price of SEK 192.20 which corresponds to 125 percent of the volume weighted average share price during the 30 trading days immediately preceding the respective allotment of the ESOs.

In total, 481,263 share rights and 360,000 employee stock options were outstanding under the long-term incentive program 2021 as of 31 December 2023.

### Long-term incentive program 2022

On June 30, 2022, the annual general meeting in Hansa Biopharma resolved to adopt a long-term incentive program for certain employees of the Group. The long-term incentive program 2022 includes two elements: one performance-based share rights program, and one employee stock option program. The CEO has been granted 80,000 share rights and 120,000 employee stock options ("ESO") under the long-term incentive program 2022.

Under the performance-based share rights program, each share right entitles the holder to receive one ordinary share in Hansa Biopharma AB free-of-charge provided that the below performance conditions are met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of shares that each participant is entitled to receive is also conditional upon the following performance conditions being met during the vesting period: (a) 22 percent of the shares in the event at least 60 patients have completed the 12-months follow-up visit in the US ConfldeS study (b) 11 percent of the shares in the event that a pivotal study outside of kidney Tx is fully enrolled (accounting for 5%) and, 70% of patients were enrolled into anti-GBM phase 3 study (accounting for 6%), (c) 11 percent of the shares in the event that at least 80% of the targeted transplantation centers in Europe have had repeat business, and (d) up to 56 percent of the shares related to the total shareholder return on the Company's ordinary shares (if the total shareholder return for the Company's ordinary share during the vesting period reaches or exceeds 75 percent, the participant will be awarded 56 percent of the performance shares and if the total shareholder return for the Company's ordinary share falls below 25 percent, no allotment of performance shares will be made under this performance condition. In between the percentages, allotment will be made linearly).

The option program 2022 consists of ESOs allotted free-of-charge. The ESOs have a vesting period of three years, and an exercise period of three years. Each ESO entitles the holder to acquire one ordinary share in Hansa Biopharma AB, provided that the participant, with certain exceptions, remains employed within the Group, at an exercise price of SEK 70.00 which corresponds to 125 percent of the volume weighted average share price during the 30 trading days immediately preceding the respective allotment of the ESOs.

In total, 515,000 share rights and 312,300 employee stock options were outstanding under the long-term incentive program 2022 as of 31 December 2023.

### Long-term incentive program 2023

On June 29, 2023, the annual general meeting in Hansa Biopharma resolved to adopt a long-term incentive program for certain employees of the Group. The long-term incentive program 2023 includes two elements: one performance-based share rights program, and one employee stock option program. The CEO has been granted 100,000 share rights and 140,000 employee stock options ("ESO") under the long-term incentive program 2023.



## Remuneration report 2023 continued

Under the performance-based share rights program, each share right entitles the holder to receive one ordinary share in Hansa Biopharma AB free-of-charge provided that the below performance conditions are met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of shares that each participant is entitled to receive is also conditional upon the following performance conditions being met during the vesting period: (a) 30 per cent of the shares in the event the U.S. FDA has approved imlifidase in the U.S. in any indication ("Performance Condition 1"), (b) 25 per cent of the shares in the event of completion of a phase 2 trial with HNSA5487 in any indication or a pivotal anti-GBM trial with imlifidase, (c) 25 per cent of the shares in the event that more than 50 per cent of the targeted transplantation centers in Europe had repeat business, i.e. used Idefirix more than once, and (d) 20 per cent of the shares related to the total shareholder return (the return to shareholders through an increased share price and reinvestments of any dividends during the Vesting Period) on the company's ordinary shares. This entails that participants will be entitled to 20 per cent of the shares if the total shareholder return out-performs the Benchmark Index (as defined below) by 10 per cent or more. If the total shareholder return during the vesting period is less than the performance of the Benchmark Index, no allotment of shares will be made under this condition. If the total shareholder return, as compared to the Benchmark Index, is either equal or out-performing by up to 10 per cent, allotment will be made linearly. The benchmark for assessing the total shareholder return under Performance Condition 4 should be the EURO STOXX Total Market Biotechnology Index (EUR) (the "Benchmark Index") at constant EUR/SEK exchange rate.

The option program 2023 consists of ESOs allotted free-of-charge. The ESOs have a vesting period of three years, and an exercise period of five years. Each ESO entitles the holder to acquire one ordinary share in Hansa Biopharma AB, provided that the participant, with certain exceptions, remains employed within the Group, at an exercise price of SEK 28.50 which corresponds to 110 percent of the volume weighted average share price during the 30 trading days immediately preceding the respective allotment of the ESOs.

In total, 643,000 share rights and 480,000 employee stock options were outstanding under the long-term incentive program 2023 as of 31 December 2023.





## Remuneration report 2023 continued

### Remuneration of the CEO in share rights and employee stock options

Table 2 – Remuneration of the CEO in share rights

Name, position	The main conditions of share rights					Information regarding the reported financial year						
	1 Name of plan	2 Performance period	3 Award date	4 Vesting date	5 End of retention period	6 Opening balance	7 During the year 2023			8 Closing balance 31 Dec 2023		
						6 Share rights held at the beginning of the year	7 Awarded	8 Vested	9 Expired	10 Subject to a performance condition(s)	11 Awarded and unvested	12 Rights subject to a retention period
Søren Tulstrup (CEO)	LTIP2020	2020-2023	2020-07-23	2023-07-23	2023-07-23	57,278	—	25,202	32,076	—	—	—
	LTIP2021	2021-2024	2021-06-07	2024-06-07	2024-06-07	80,000	—	—	—	80,000	80,000	80,000
	LTIP2022	2022-2025	2022-07-20	2025-07-20	2025-07-20	80,000	—	—	—	80,000	80,000	80,000
	LTIP2023	2023-2026	2023-11-06	2026-11-06	2026-11-06	—	100,000 <sup>1</sup>	—	—	100,000	100,000	100,000
						<b>217,278</b>	<b>100,000</b>	<b>25,202</b>	<b>32,076</b>	<b>260,000</b>	<b>260,000</b>	<b>260,000</b>

<sup>1</sup> Each of the 100,000 Share rights represents a computed fair value of SEK 21.95 per share right calculated based on a Monte Carlo simulation. For further information please refer to Note14 to the Consolidated Financial Statements in Hansa Biopharma's Annual Report 2023.

Table 3 – Remuneration of the CEO in stock options

Name, position	The main conditions of stock options					Information regarding the reported financial year								
	1 Name of plan	2 Performance period	3 Award date	4 Vesting date	5 End of retention period	6 Exercise Period	7 Exercise Price (SEK)	8 Opening balance	9 During the year 2023			10 Closing balance 31 Dec 2023		
								8 Stock options held at the beginning of the year	9 Awarded	10 Vested	11 Expired	12 Subject to a performance condition(s)	13 Awarded and unvested	14 Rights subject to a retention period
Søren Tulstrup (CEO)	LTIP2019	2019-2022	2019-06-17	2022-06-17	2022-06-17	2022-06-17 2025-06-17	196.20	66,347	—	—	—	66,347	—	—
	LTIP2020	2020-2023	2020-07-23	2023-07-23	2023-07-23	2023-07-23 2026-07-23	315.75	128,760	—	128,760	—	128,760	—	—
	LTIP2021	2021-2024	2021-06-07	2024-06-07	2024-06-07	2024-06-07 2027-06-07	192.20	120,000	—	—	—	120,000	120,000	120,000
	LTIP2022	2022-2025	2022-07-20	2025-07-20	2025-07-20	2025-07-20 2028-07-20	70.00	120,000	—	—	—	120,000	120,000	120,000
	LTIP2023	2023-2026	2023-11-06	2026-11-06	2026-11-06	2026-11-06 2031-11-06	28.50	—	140,000 <sup>1</sup>	—	—	140,000	140,000	140,000
							<b>435,107</b>	<b>140,000</b>	<b>128,760</b>	<b>—</b>	<b>575,107</b>	<b>380,000</b>	<b>380,000</b>	

<sup>1</sup> Each of the 140,000 Stock options represents a computed weighted average fair value of SEK 12.59 per stock option calculated based on a Black-Scholes valuation. For further information please refer to Note14 to the Consolidated Financial Statements in Hansa Biopharma's Annual Report 2023.



## Remuneration report 2023 continued

### Application of performance criteria related to the 2023 CEO compensation

Both, long-term and short-term performance measures have been selected to reflect key milestones in delivering the Company's strategy and to encourage behaviour which is in the long-term interest of the Company. This is reflected in the performance criteria related to the Company's long-term incentive programs as well as the corporate objectives applied to performance measurement related to the short-term incentive program of Hansa. In selecting performance measures, the strategic objectives as well as short-term and long-term business priorities have been considered.

In 2023, the share rights program under the LTIP 2020, in which the CEO held 57,278 performance share rights, hit the vesting date. Since the pre-defined performance criteria were only partly met, plan participants received 44% of the maximum potential share allocations. In total, 168,216 shares were allocated under the plan of which the CEO received 25,202 shares. Further, in 2023, the employee stock option ("ESO") program under the LTIP 2020, in which the CEO holds 128,760 ESOs, vested. In accordance with the terms of the LTIP 2020, plan participants may exercise the vested ESOs over a 3-year period from vesting through 23 July 2026 at an exercise price of SEK 315.75.

Set out in Table 4 below is a description of how the criteria for payment of variable short-term compensation have been applied for the financial year 2023. Such criteria are based on the annual corporate objectives and form the basis for the short-term performance measurement of the CEO and, together with pre-defined individual objectives, accounting for up to 80% of the performance targets for all other members of the executive management.



## Remuneration report 2023 continued

**Table 4 – Criteria for payment of variable short-term compensation**

Name, Position	Description of the criteria related to the corporate goals	2023 corporate goals	Overall weight	a) Measured goal achievement and	
				b) Actual weighted outcome	
Soren Tulstrup, CEO	Imlifidase commercial launch – Sales, market access, EMA post-approval commitments	3 sub-goals	22.5%	a) 68%	b) 15%
	Progressing pipeline activities in transplantation, autoimmune indications, gene therapy and NiceR	6 sub-goals	52.5%	a) 93%	b) 50%
	Business development and financial strength	2 sub-goals	20%	a) 75%	b) 15%
	Corporate Social Responsibility	1 sub-goal	5%	a) 100%	b) 5%
				<b>Total: 85%</b>	

### Comparative information on remuneration and Company performance

	2023	2022
<b>CEO remuneration</b>		
Soren Tulstrup, CEO	<b>KSEK 13,369</b>	KSEK 12,451
<b>Company's performance</b>		
Achievement of the annual corporate objectives	<b>85%</b>	95%
Operating loss	<b>KSEK (788,496)</b>	KSEK (611,134)



# Glossary

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## Glossary

### Adeno-associated virus (AAV)

AAV is a versatile viral vector technology that can be engineered for very specific functionality in gene therapy applications.

### Allogeneic hematopoietic stem cell transplantation (HSCT)

Allogeneic HSCT, also known as “bonemarrow” transplantation, involves transferring stem cells from a healthy person (the donor) to the patient’s body after high-intensity chemotherapy or radiation. The donated stem cells can come from either a related or an unrelated donor.

### AMR

Antibody mediated transplant rejection.

### Antibody

One type of protein produced by the body’s immune system with the ability to recognize foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM.

### Anti-Glomerular Basement Membrane (anti-GBM) disease (Goodpasture syndrome)

Anti-GBM antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

### Autoimmune disease

Diseases that occur when the body’s immune system reacts against the body’s own structures.

### B-cells

B-cells, also known as B-lymphocytes, are a type of white blood cell of the lymphocyte subtype. They are an important part of the adaptive immune system and secrete antibodies.

### Biologics License Application (BLA)

A Biologics License Application (BLA) is submitted to the Food and Drug Administration (FDA) to obtain permission for distribution of a biologic product across the United States.

### CD20

B-lymphocyte antigen CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

### Clinical studies

Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

### Clinical Phase 1

The first time a drug under development is administered to humans. Phase I studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

### Clinical Phase 2

Refers to the first time a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

### Clinical Phase 3

Trials that involve many patients and often continue for a longer time; they are intended

to identify the drug’s effects and side effects during ordinary but still carefully controlled conditions.

### DSA

Donor specific antibodies. Donor specific antibodies are antibodies in a transplant patient which bind to HLA and/or non-HLA molecules on the endothelium of a transplanted organ, or a potential donor organ. The presence of pre-formed and de novo (newly formed) DSA, specific to donor/recipient mismatches are major risk factors for antibody-mediated rejection.

### EMA

The European Medicines Agency (EMA) is a European Union agency for the evaluation of medicinal products.

### Enzyme

A protein that accelerates or starts a chemical reaction without itself being consumed.

### ESOT

The European Society for Organ Transplantation (ESOT) is an umbrella organization which oversees how transplantations are structured and streamlined.

### FDA

U.S. Food and Drug Administration.

### Guillain-Barré syndrome

GBS, Guillain-Barré syndrome, is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies.

### HBP

Heparin Binding Protein is a naturally occurring protein that is produced by certain immune cells, i.e. neutrophilic granulocytes, to direct immune cells from the bloodstream into the tissues.

### HLA

Human Leukocyte Antigen is a protein complex found on the surface of all cells in a human. The immune system uses HLA to distinguish between endogenous and foreign.

### IgG

IgG, Immunoglobulin G, is the predominant type of antibody in serum.

### Imlifidase

Imlifidase, is the immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

### IND

An Investigational New Drug (IND) application is required to get approval from the FDA to administer an investigational drug or biological product to humans.

### INN

International Nonproprietary Name (INN) is a generic and non-proprietary name to facilitate the identification of a pharmaceutical substances or active pharmaceutical ingredient. Each INN is a unique name that is globally recognized and is public property. The INN system has been coordinated by the World Health Organization (WHO) since 1953.



## Glossary continued

### In vitro

Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

### In vivo

Term within biomedical science to indicate that experiments or observations are made in living organisms.

### IVD

IVD, In vitro diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

### Marketing Authorization Application (MAA)

A Marketing Authorization Application (MAA) is an application submitted to the European Medicines Agency (EMA) to market a medicinal product in the EU member states.

### Neutralizing Antibodies (NABs)

NAB is an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically.

### Pivotal trial

A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase 2 studies can be used as pivotal studies if the drug is intended to treat lifethreatening or severely debilitating conditions.

### PRA

Panel Reactive Antibody (PRA) is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as a percentage between 0% and 99%. It represents the proportion of the population to which the person being tested will react via pre-existing antibodies.

### Preclinical development

Testing and documentation of a pharmaceutical candidate's properties (e.g. safety and feasibility) before initiation of clinical trials.

### Randomized Control Trial (RCT)

(RCT) is a study design where the trial subject is randomly allocated to one of two or more study cohorts to test a specific intervention against other alternatives, such as placebo or standard of care. The study participants are followed up to compare outcomes of different cohorts.

### Streptococcus pyogenes

A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

### Standard of Care (SOC)

Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals.



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### Calendar and events

<b>Mar 21, 2024</b>	Annual Report 2023
<b>Apr 18, 2024</b>	Interim Report for January-March 2024
<b>Jul 18, 2024</b>	Half-year Report January-June 2024
<b>Oct 24, 2024</b>	Interim Report for January-September 2024

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