

# Changing society with science

Annual Report 2021



# Contents

1 **Overview**

5 **Growth**

9 **Financials**

2 **Strategy**

6 **The share**

10 **Governance**

3 **Market**

7 **Director's  
report**

11 **Remuneration**

4 **Technology**

8 **ESG**

12 **Glossary**





# Hansa Biopharma in brief

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, life-saving and life-altering treatments for patients with rare immunological conditions.

We have developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy, which can enable kidney transplantation in highly sensitized patients. We have a rich and expanding research and development pipeline, based on our proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer.

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

## Our vision

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



# Overview

Chairman's letter	5
2021 highlights	6
CEO statement	7
Impact from the COVID-19 pandemic	10



# Chairman's letter



## Dear Shareholders,

**Hansa's long-term goal is to become a recognized global leader in rare diseases across multiple therapeutic areas through the development of new, transformative drugs that could be both lifesaving and life altering for patients suffering from rare immunologic diseases and conditions. Given the versatility and flexibility of the scientific technology platform, its valuable pipeline of drug candidates, and its talented and dedicated team of employees, we believe Hansa has what it takes to become a leading player in rare immunologic diseases.**

During 2021, we took another major step in this direction, advancing to become a fully integrated commercial stage biopharmaceutical company through the European launch of Idefirix® in kidney transplantation. This product launch is not

only a landmark milestone for Hansa Biopharma, but, more importantly, great news for highly sensitized patients in need of a kidney transplant.

From a strategic point of view, the Board and I have been very encouraged by our team's ability to secure a number of important partnerships across both research and development and commercial operations. During the last 12 months alone, Hansa has entered into three new collaborations with argenx, Medison Pharma and AskBio. These agreements and the continued level of interest we are experiencing serve as further validation of the potential of the Company's unique IgG-cleaving enzyme technology platform.

The year ahead promises to be as exciting as 2021 as we plan to expand activities across our business and R&D activities. Notably, I am very encouraged by the additional progress in our clinical development projects, with further advances in the important U.S. pivotal ConfideS study in kidney transplantation, which could lead to submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) under the accelerated approval pathway in 2024. Also, I am equally excited about the progress we have seen in anti-GBM, a serious disease with high unmet medical need. Anti-GBM is the first indication outside of transplantation, where imlifidase has shown proof-of-concept and I am pleased that we have been able to align on the design of a pivotal trial of imlifidase in anti-GBM disease with both the U.S. FDA and EMA.

Lastly, we also look forward to following the Company's efforts to explore the potential development of imlifidase as a drug candidate in allogeneic hematopoietic stem cell transplantation (HSCT), also known as "bone-marrow" transplantation. Stem cell transplantation is a large indication, similar to kidney transplantation, where there is a high unmet medical need for patients with high levels of donor specific antibodies, as current desensitization methods remain inadequate.



We are building Hansa into a global leader in rare diseases.

While Hansa saw solid progress during 2021, with further validation of its business model and technology platform and solid execution on its strategic priorities, the operating environment and capital market have both been challenging. From a capital market perspective, the biotechnology industry as a whole has had its worst period in more than a decade. The direct and indirect impacts from the COVID-19 pandemic, increasing interest rates, sector rotation and geopolitical uncertainties are just some of the dynamics that have caused and continue to cause weakness to the valuations in the sector.

The fundamental drivers behind the success of the biotech industry as a very significant value creator over the past decades are, however, intact, and we firmly believe that Hansa Biopharma, as a commercial stage company with a validated technology platform, an exciting pipeline of late-stage valuable drug candidates, and a strong organization is well-positioned to succeed in delivering on its strategic priorities even in such a volatile and challenging environment.

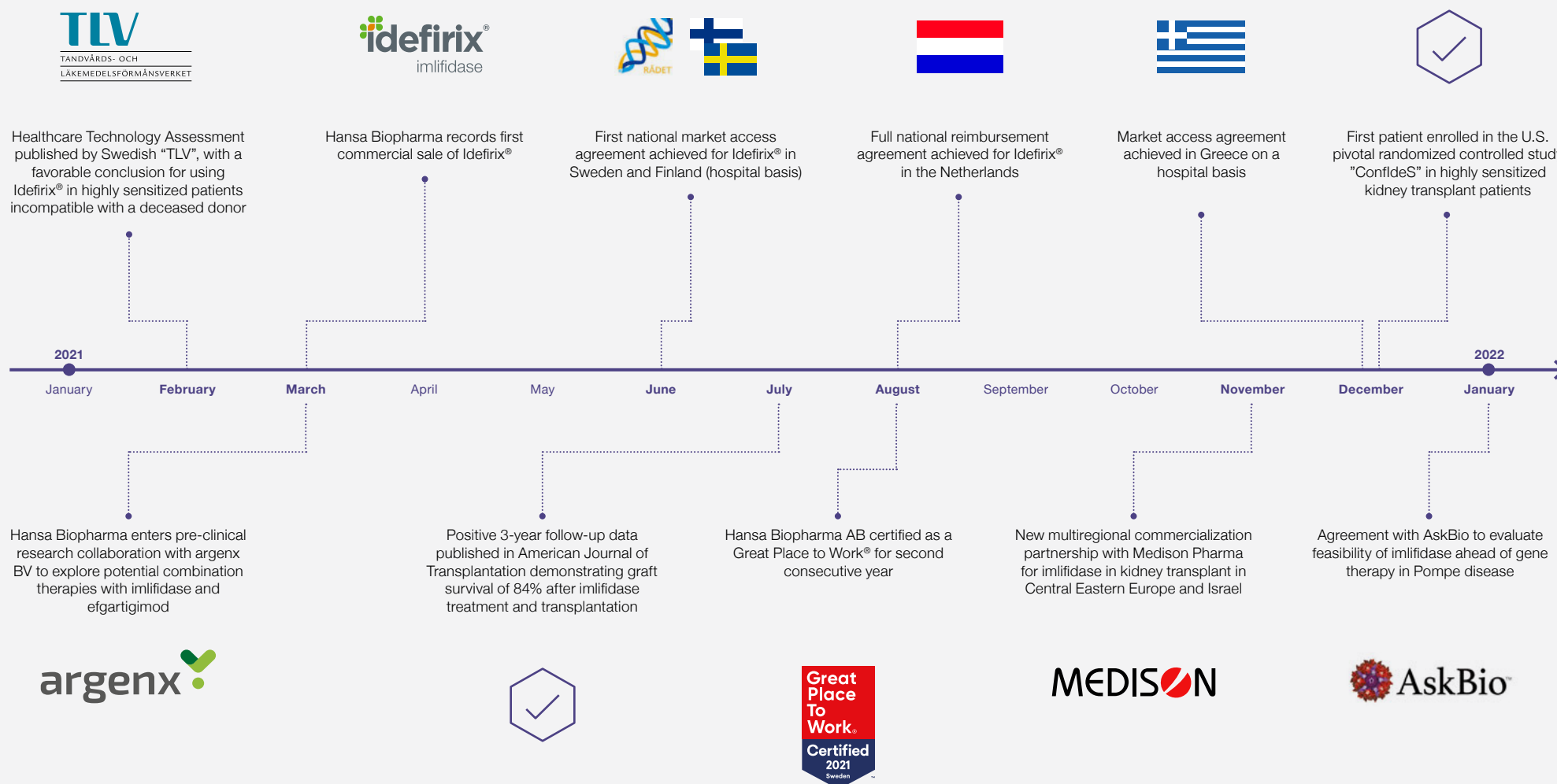
On behalf of the Board of Directors,

**Ulf Wiinberg**

*Chairman, Hansa Biopharma  
Lund Sweden, April 2022*



# 2021 highlights







# CEO statement

**2021 was, overall, a transformative and successful year for Hansa as we advanced into a fully integrated, commercial-stage biopharmaceutical company following the commercial launch in Europe of Idefirix® (imlifidase), for desensitization of highly sensitized kidney transplant patients incompatible to a deceased donor.**

Despite a challenging operating environment, we were able to solidly execute on our key priorities for the year, which were to:

1. Ensure a successful launch of Idefirix® in leading transplantation centres in select European markets;
2. Initiate a pivotal study in the U.S. to support a future BLA for imlifidase in highly sensitized patients waiting for a kidney transplant; and
3. Continue to build on the strong momentum behind our efforts to advance our pipeline of drug candidates within autoimmune diseases and gene therapy.

As far as the European launch of Idefirix® is concerned, we saw solid execution in expanding our market access footprint. During 2021, pricing and reimbursement were secured in Sweden and the Netherlands as well as on an individual hospital basis in Finland and Greece, while Germany and France (early access program) were added to the list of countries with commercial access on negotiated terms during the first quarter of 2022. Notably, a health-economic assessment conducted by

the Swedish Dental and Pharmaceutical Benefits Agency (TLV) concluded that Idefirix® treatment in appropriate highly sensitized patients on dialysis waiting for a kidney transplant would be cost effective and potentially even lead to cost savings, which is rarely seen for orphan drugs.

Market access procedures are now ongoing in 10 countries incl. HTA dossiers submitted in the UK, Italy and Spain. This is a great achievement by our experienced market access team and an important milestone as we build the foundation for Idefirix® as a potentially transformative therapy that is bringing hope to the thousands of highly sensitized patients across the continent who are currently waiting for a compatible kidney transplant.

Looking beyond the early launch hospitals and countries, I am also pleased with our new multiregional commercialization partnership with Medison Pharma for Idefirix® in Central Eastern Europe and Israel. Medison is a recognized international pharmaceutical company focused on providing access to highly innovative therapies to patients in international markets. This commercial partnership represents an important milestone for Hansa as we expand access to Idefirix® beyond initial markets for highly sensitized patients awaiting kidney transplants.

In the U.S., we initiated our pivotal ConfldeS trial in kidney transplantation. The ConfldeS study 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. We expect to enroll<sup>1</sup> patients at 12-15 leading transplantation centers across the U.S. and aim to complete enrollment by the end of this year. In addition to generating important new data, the ConfldeS trial will also enable the participating key transplant centers to gain important experience with the use of imlifidase as a desensitization treatment ahead of a potential commercial launch in the U.S.



Despite a challenging operating environment, we were able to solidly execute on our key priorities for the year.

**Søren Tulstrup**  
President and CEO,  
Hansa Biopharma

<sup>1</sup> Enrollment in the U.S. ConfldeS trial is defined by patient consent and waiting for a suitable organ offer



## CEO statement continued

On the research side, Hansa has entered into two new collaborations during the last 12 months. The first, announced at the end of March 2021, is a pre-clinical research collaboration with argenx BV, a leader in the field of FcRn-inhibition, to evaluate the therapeutic potential of combining Hansa's IgG antibody-cleaving enzyme, and efgartigimod, argenx's FcRn antagonist. A combination of imlifidase and efgartigimod could potentially be used in both the acute and chronic setting of autoimmune diseases and transplantation.

In the area of gene therapy, we were also excited to announce an agreement in early 2022 with AskBio, a subsidiary of Bayer AG, to evaluate imlifidase in a pre-clinical and clinical feasibility program as pre-treatment ahead of gene therapy in Pompe disease in patients with pre-existing neutralizing antibodies (NABs). NABs against adeno-associated virus used in gene therapies remain a major challenge and we see significant potential for our antibody-cleaving enzyme technology to enable gene therapy also in NABs positive patients. The new collaboration with AskBio marks another key step in the implementation of our partnership strategy in the gene therapy space.

In anti-GBM disease, following a successful pre-IND meeting with the U.S. FDA, we recently announced plans to initiate a phase 3 study of imlifidase. This pivotal study, our first phase 3 study in the area of autoimmune diseases, marks an important milestone for Hansa Biopharma's expansion beyond transplantation. The study aims at enrolling approximately 50 patients with anti-GBM disease across the U.S. and Europe, with the first patient expected to be enrolled in 2022.

As part of Hansa's platform strategy and objective to broaden the use of imlifidase as a potential therapy to change the course of IgG-mediated immunological diseases and conditions, the Company is exploring new indications with a high unmet need. One such indication is allogeneic hematopoietic stem cell transplantation (HSCT), also known as "bone-marrow" transplantation is a challenge and there are currently no approved drugs available to facilitate transplantation in these patients. We believe that imlifidase may have the potential to transform this field by enabling clinicians to inactivate DSAs prior to transplantation, thereby creating the basis for enabling engraftment.

Hansa's mission is to leverage our unique IgG-cleaving enzyme technology platform to develop innovative, lifesaving and life-altering immunomodulating therapies, bring these to the patients with rare diseases and conditions who need them, and generate value to society at large. To help deliver on this mission, we are building a high-performance team by attracting and integrating the most talented and experienced candidates while creating a rewarding, productive and stimulating workplace for our employees. The progress we are making in this effort was illustrated again in 2021 as we received certification as a "Great Place to Work" for the second consecutive year by the GPTW Institute.

At Hansa, sustainability is at the core of all we do, and we have during 2021 formalized our ESG approach. Embarking on this journey, we have identified key environmental, social and governance priorities, which need to be addressed and used to develop the Company's first sustainability strategy.



In 2021 we received certification as a "Great Place to Work" for the second consecutive year by the GPTW Institute.







## CEO statement continued

We have another exciting year ahead of us with several important milestones to be achieved across our platform and franchises. Our key priorities for the year are to:

1. Continue the successful execution of our commercial launch strategy for Idefirix® through obtaining pricing and reimbursement agreements in new key markets in Europe, making additional prioritized transplant centers clinically ready for initiation, and generating growing commercial sales.

2. Complete enrollment in the U.S. ConfldeS trial.

3. Further advance our pipeline of drug candidates for autoimmune diseases and post transplant management by initiating a pivotal trial of imlifidase in anti-GBM disease and advancing our ongoing phase 2 trials in Antibody-Mediated Rejection (AMR) and Guillian-Barré syndrome (GBS) toward first data read-outs.

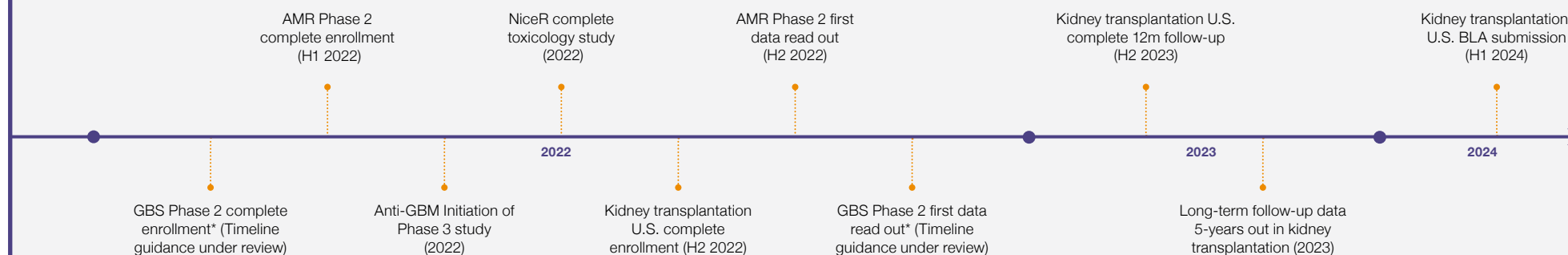
I am profoundly grateful to our employees for their commitment, passion and hard work in the past year and I look forward to making further progress in the year ahead towards the vision that we are pursuing with single-minded focus: A world where patients with rare immunologic diseases can lead long and healthy lives.

**Søren Tulstrup**

*President and CEO, Hansa Biopharma  
Lund Sweden, April 2022*

### Upcoming milestones

Milestones subject to potential COVID-19 impact



Guidance assumes no persistent impact or further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again

\* GBS: Given the current difficulty of predicting enrollment due to the direct and indirect effects of the persistent and even escalating pandemic, Hansa expects to update its guidance for completion of enrollment in GBS in April 2022



# Impact from the COVID-19 pandemic

**The COVID-19 pandemic is the defining global health crisis of our time. With the emergence of new variants, the Company continues to take measures to protect employees and to be socially responsible, while working to limit the potential negative effects of the pandemic on its business.**

There are still uncertainties with regard to the continued spread of COVID-19 and its implications, and we will continue to assess the situation and seek to put in place relevant mitigating measures where necessary.

Although we believe we have implemented strategies designed to manage the impact of the COVID-19 pandemic to our business, we have experienced, are experiencing and may continue to experience, adverse effects to our business, including delays with respect to enrolling patients, the initiation of certain additional studies and receipt of any governmental or regulatory approvals. For example, recruitment of patients in our phase 2 clinical studies in GBS and AMR was temporarily halted during 2020.

Again in the fourth quarter of 2021, we experienced how the direct and indirect effects of the continued pandemic and the emergence of the Omicron variant affected a number of our trial centers in our GBS phase 2 program including the shortage of IVlg and available trial staff. This, in turn, affected the enrollment rate in the GBS program at a subset of participating hospitals. To mitigate these hurdles, Hansa has initiated measures to simplify the study protocol, actively

support the hiring of additional staff at the clinics and added two new sites for the recruitment of patients in the U.K. and the Netherlands.

We may experience additional delays to our ongoing studies, as well as delays to the planned initiation of our post-approval study of imlifidase in kidney transplantation in Europe and our planned phase 3 study of imlifidase in anti-GBM. Also, our commercial launch activities in Europe were, are and may continue to be, negatively impacted due to limited access to, and reduced decision-making ability of, market access authorities, potentially causing delays in the granting of reimbursement status to Idefix® by authorities in traditional early launch countries.

Further, our new phase 3 study in anti-GBM antibody disease in approximately 50 patients which is expected to commence in 2022 in the EU and U.S. may be delayed due to reduced decision-making or reprioritizations by regulators. The extent to which the COVID-19 pandemic impacts the timing of these matters will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the identification of new variants of the virus, the duration of the pandemic, any restrictions on the ability of hospitals and study sites to conduct studies that are not designed to address the COVID-19 pandemic or procedures such as transplantations that are elective in nature, including restrictions due to shortages in supplies and staff, and the perceived effectiveness of actions taken in the U.S., Europe and other countries to contain and treat the disease. We will continue to evaluate the impact of the COVID-19 pandemic on our business.



# Strategy

Potential indication universe	12
Business model	14
Our strategic priorities	15
Mid-term financial priorities	17
Our Environmental, Social and Governance (ESG) strategy	18



# Potential indication universe



\* The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients

\*\* In the U.S. a new study has commenced targeting a BLA filing by H1 2024

■ First generation antibody cleaving enzyme technology

■ Opportunities

■ Obtained EU conditional approval

■ Partnership Preclinical program (Sarepta Therapeutics Inc. and AskBio)

■ Clinical program

■ Research/Preclinical program





## Potential indication universe continued

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

It is being developed for the treatment and prevention of diseases and conditions caused by IgG antibodies in the acute phase, such as to enable transplantation for highly sensitized patients. There are a large number of relevant indications and specific disease areas that can be targeted within this universe.

In addition to desensitization prior to kidney transplantation, which has received conditional approval for marketing in Europe, we are also investigating imlifidase as a potential drug candidate for treatment of active AMR episodes in kidney transplantation. In addition, there are other solid organ transplants which may be relevant for imlifidase, both pre- and post-transplantation (e.g. heart and lung).

Looking beyond transplantation, there are a number of other growth vectors and areas, where imlifidase may play a role, such as in acute autoimmune diseases, gene therapy as well as oncology. More specifically, we are currently investigating rare life-threatening conditions such as anti-GBM antibody disease and Guillain-Barré Syndrome (GBS), which are both two ongoing clinical programs.

In addition, Hansa, with its partners, is investigating imlifidase as a pre-treatment to potentially enable gene therapy in patients with pre-existing NABs. Through the partnership with Sarepta Therapeutics, imlifidase is currently being investigated in Limb-Girdle Muscular Dystrophy (LGMD) and Duchenne Muscular Dystrophy (DMD); and through the partnership with AskBio, a subsidiary of Bayer AG, in Pompe Disease.

Further, Hansa has started to explore potential indications within oncology. Initially the Company will look into exploring the potential development of imlifidase in allogeneic HSCT. Stem cell transplantation is a significant indication, where there is a high unmet medical need for patients with high levels of donor specific antibodies, as current desensitization methods remain inadequate.

Beyond imlifidase for the acute treatment in IgG mediated conditions and diseases, we are also developing new IgG-cleaving enzymes under the program “NiceR” (Novel Immunoglobulin Cleaving Enzymes for Repeat Dosing). These “next-generation” enzymes from the NiceR program will be designed to have a lower propensity to induce immunity, in order to increase the therapeutic window. The new enzymes are being developed to be utilized in a number of IgG-driven autoimmune diseases where patients experience flares or in transplantation, where repeat dosing would be beneficial and add further value, particularly post-transplant.

Lastly, Hansa and argenx BV are evaluating the therapeutic potential of combining imlifidase, and efgartigimod, argenx's FcRn antagonist. A combination of imlifidase and efgartigimod could potentially be used in both the acute and chronic setting of autoimmune diseases and transplantation.



# Business model

## Leveraging our technology platform to develop new therapies targeting rare diseases with unmet medical need across a range of indications

As Hansa advances the development of new therapies targeting rare diseases with a high unmet medical need and transforms into a fully integrated biopharmaceutical company, a well-defined business model supports the Company's plans to leverage its technology platform across the entire value chain.

At the core of the business model is our "growth engine" – our proprietary antibody-cleaving enzyme technology platform. As new drug candidates advance from discovery through development to regulatory approval and commercialization,

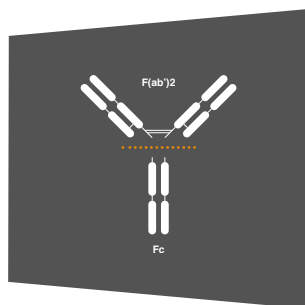
it is our intention to retain strategic control at the different stages to capture the majority of the economic upside generated.

As new products approach commercialization, we have the flexibility to pursue market entry via two different pathways. In transplantation and autoimmune diseases, where target audiences are relatively concentrated, we intend to primarily utilize our own commercial and medical infrastructure, including an experienced and skilled customer facing team, to secure successful launches in these markets.

In other areas, where the target audiences and markets are more complex and fragmented, or where access to gene therapies or oncology compounds is required, we will consider different approaches. Among them, Hansa may employ a partnering strategy similar to the agreements the Company has with Sarepta Therapeutics and AskBio in gene therapy or the commercial partnership with Medison Pharma covering select countries in Central Eastern Europe and Israel in kidney transplantation.

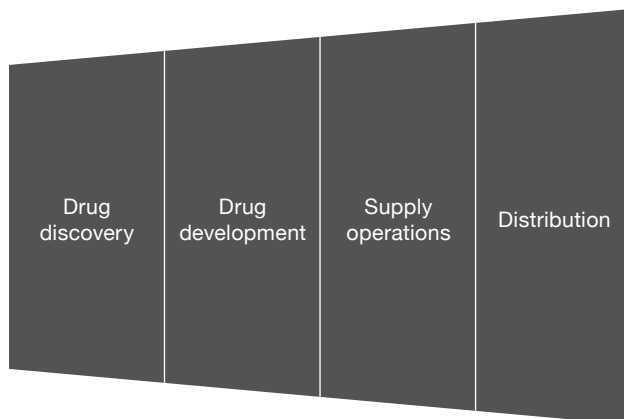
### Growth engine

Leveraging proprietary antibody cleaving enzyme technology



### Value chain

Controlling the full value chain



### Commercialization

Build-up of franchises

Indications and therapies

Multiple income streams

Own commercial infrastructure	Transplantation	Revenue / sales
	Autoimmune diseases	Upfront payments
Partnership strategy	Gene therapy	Milestone payments
	New therapies and oncology	Royalties

**Evolution into a fully integrated biopharmaceutical Company**



# Our strategic priorities

Hansa is embarking on a mission to become a global leader in rare diseases through the development of innovative, life-saving and life-altering treatments for patients with rare immunological conditions.

Our strategy builds upon our proprietary enzyme technology platform with the 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 for our technology in oncology. In executing upon our strategy, we intend to pursue the following near and mid-term goals:

## 1.

**Successfully commercialize Idefix® in kidney transplantation in Europe, the U.S. and selected international markets**

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

We are pursuing the launch of Idefix® in several major European countries by seeking pricing and reimbursement approval, raising awareness and working closely with leading clinical experts. Following completion of our post-approval commitments, we plan to seek full approval for this indication from the European Commission.

In the U.S., we also plan to seek FDA approval. To support the submission of a BLA in the U.S., Hansa has initiated a phase 3 clinical study (the ConfideS study). If successful, we aim to submit a BLA seeking accelerated approval in the first half of 2024.

By the time of this annual report, we have obtained pricing and reimbursement for Idefix® in kidney transplantation in Germany, France (early access), Sweden, the Netherlands as well as in Finland and Greece on a hospital basis; we have market access procedures ongoing in 10 countries, with Health Technology Assessment (HTA) dossiers filed in all of the five largest markets in Europe.

Our U.S. ConfideS study has enrolled<sup>2</sup> 13 of the targeted 64 patients at 9 centers across the U.S. by the time of the annual report.

## 2.

**Advance our ongoing clinical programs in AMR and rare autoimmune diseases to regulatory approval**

We have an ongoing clinical program in AMR, for which we are currently conducting a clinical phase 2 study. We expect to complete enrollment in the first half of 2022 and to report initial data by the end of 2022. By the time of this annual report, 28 of the targeted 30 patients have been enrolled at 14 centers across the U.S., Europe and Australia.

We also have two ongoing clinical-stage programs in rare acute autoimmune diseases – anti-GBM antibody disease and GBS.

In anti-GBM, a phase 2 investigator-initiated study was completed in September 2020 in which 10 out of 15 patients had a functioning kidney at six months, five of whom required dialysis at study entry. We believe this outcome demonstrated proof-of-concept by showing that the use of imlifidase was associated with a substantially better renal outcome, as compared with historical controls. In November 2021, Hansa announced plans to initiate a phase 3 study of imlifidase following a successful pre-IND meeting with the U.S. FDA. In addition Hansa completed a scientific advice process with EMA and received their positive feedback on the planned phase 3 study. The new pivotal phase 3 study aims to enroll approximately 50 patients with anti-GBM disease across the U.S. and Europe, with the first patient expected to be enrolled in 2022.

We are also developing imlifidase for the treatment of GBS for which we have an ongoing clinical program, and for which we are currently conducting a clinical phase 2 study. By the time of this annual report, 16 of targeted 30 patients have been enrolled at 10 centers across the U.K., Netherlands and France.

<sup>2</sup> Enrollment in the U.S. ConfideS trial is defined by patient consent and waiting for a suitable organ offer



## Our strategic priorities continued

### 3.

#### Develop imlifidase as pre-treatment to gene therapy, starting with our collaborations with Sarepta and AskBio

In July 2020, Hansa announced a partnership with Sarepta to develop imlifidase as a potential pre-treatment to gene therapy in DMD and LGMD for patients that carry neutralizing anti-AAV antibodies which would otherwise make them ineligible to receive treatment. The program is being led by Sarepta, which initiated pre-clinical studies in 2020. We expect Sarepta to advance the program into the clinic and, if successful, to establish imlifidase as a pre-treatment in DMD and LGMD.

In January 2022, Hansa announced a collaboration with AskBio to evaluate imlifidase in a pre-clinical and clinical feasibility program as pre-treatment ahead of gene therapy in Pompe disease in patients with pre-existing Nabs. Nabs against adeno-associated virus used in gene therapies remain a major challenge and we see significant potential for our antibody-cleaving enzyme technology to help overcome this barrier.

### 4.

#### Develop our next generation IgG-cleaving enzymes to allow for recurring treatment

We are pursuing our NiceR program, aimed at developing a next generation IgG-cleaving enzyme that could allow for repeat dosing and, thus, recurring treatment in autoimmune diseases, transplantation and oncology. We have now identified a lead molecule and toxicology studies in nonclinical models are currently ongoing in preparation for a clinical phase 1 study. We expect the toxicology studies to be completed in 2022.

### 5.

#### Successfully market our products by pursuing a hybrid commercialization model

In transplantation and autoimmune disease indications, we aim to maximize value by commercializing our assets through our own commercial team for major markets in Europe and the U.S. During 2021 we continued to successfully progress the launch of Idefix® in Europe.

In other markets, our goal is to leverage the market potential through commercial partnerships in the form of distribution or license agreements, depending on the partner, the territory and the specific indication. For that purpose, in 2021 we entered into our first commercial distribution agreement with Medison Pharma.

In other disease areas such as gene therapy or oncology, we may rely on our partners for commercialization, while aiming to secure certain rights to co-promote or co-market, depending on the partner, the territory and the indication.





# Mid-term financial priorities

As of December 31, 2021 Hansa had cash, cash equivalents and short-term investments of SEK 889m, corresponding to approximately USD 98m, which is expected to fund Hansa's operations into 2023.

Our key financial priorities over the coming years will be focused on ensuring a successful European launch of Idefirix®, while targeting mid-term product profitability. In tandem, we expect to maintain investments to further strengthen our position in kidney transplantation through the completion of enrollment in our U.S. ConfldeS study. In addition, Hansa will continue to maintain its focus on advancing its ongoing clinical programs in AMR and rare autoimmune diseases through to regulatory approval.

Lastly, the Company will continue to support promising partnership structures, such as those already established with Sarepta, Medison, argenx and AskBio, in areas such as gene therapy, transplantation, oncology, and other strategic therapeutic areas.

Building upon the financing mandate approved by the last AGM in May 2021, we have also started to evaluate options to secure financing Hansa's operations beyond 2023.

## We expect to use our current cash position to:

Fund the launch and commercial expansion of Idefirix® in kidney transplantation in Europe

Initiate our EU post-approval commitments and complete the five-year data read-out in our long-term follow-up study and advance patient enrollment in our ConfldeS study in kidney transplantation in the U.S.

Complete enrollment of our ongoing phase 2 programs in AMR and GBS and initiate a phase 3 clinical program in anti-GBM

Complete the preclinical program for our lead molecule from our next generation enzymes for repeat dosing ("NiceR") and advance our initiatives in our other indications such as gene therapy and oncology

Fund working capital and general corporate purposes



# Our Environmental, Social and Governance (ESG) strategy

## Our approach to sustainability

By developing and delivering life-altering treatments for those with rare immunological conditions, Hansa positions sustainability at the core of its business and strives to create value to society at large. Stakeholders such as employees, healthcare professionals, patient advocacy groups and investors have high and ever-rising expectations for how pharmaceutical companies should integrate and work with environmental, social and governance issues. Therefore, we believe it is essential to formalize our approach to sustainability and communicate our work and progress to our stakeholders.

During 2021, we have embarked on this journey. We have identified the areas most crucial to our stakeholders and aligned with the UN Sustainable Development Goals to identify which actions are needed to address today's challenges, and

those we will face in the future. Our patient-centric approach aims to make new, lifesaving and life-altering medicines available to those who need them most, while we minimize our impact on the environment as we grow. Based on our materiality analysis, sustainability strategy, and now our first sustainability report, we will continue to evolve, monitor, and report on our progress.

## Material aspects and stakeholder dialogue

### Material aspects

Hansa carried out a materiality analysis in 2021 to identify the key sustainability priorities which need to be addressed.

In-depth interviews with key representatives from Hansa's stakeholders were carried out, addressing sustainability within the pharmaceutical industry, potential opportunities and

challenges for Hansa and our impact on this area.

Our stakeholders clarified their expectations for Hansa's sustainability initiatives, including which areas are the most materially relevant.

By analyzing this feedback and sustainability trends and issues within our industry, we identified the most important areas for Hansa's focus, going forward.

## Hansa's high-priority areas within sustainability





## Our Environmental, Social and Governance (ESG) strategy continued

### Hansa's stakeholders and stakeholder dialogue

Among Hansa's stakeholders are our employees, investors, patients and patient advocacy groups, government agencies, experts in pharmaceutical sustainability and the industry, as well as healthcare professionals at specialised transplantation clinics and the scientific community at large.

In addition to the stakeholder dialogue undertaken in conjunction with the materiality analysis and this reporting cycle, Hansa engages with its stakeholders throughout the year through formal and informal meetings and contact points. This includes in-depth dialogues with the leading ~40-60 transplant centers in Europe, and globally, through

collaborations with patient organizations and advocacy groups in key European countries, and by serving our investor community in approximately 150 meetings and investor events.

Additionally, we conduct a yearly survey among our employees to measure workplace experience and satisfaction.

### Sustainability strategy

In 2021, Hansa formalized its sustainability approach by developing a strategy based on a materiality analysis. The strategy is designed to contribute to Hansa's vision – a world where all patients with rare immunologic diseases can lead long and healthy lives. This does also underpin Hansa's business

strategy, guide priorities and initiatives, further strengthen our commitment to patients and meet stakeholder expectations.

The strategy is comprised of three pillars encompassing our main priorities: patient centricity – we call it **Healthy patients**, responsible business – we call it **Healthy business**, and environmental protection – we call it **Healthy planet**.

Going forward, Hansa plans to further solidify this strategy by setting targets and continuously providing progress updates in each annual report.

### Company vision



### ESG priorities

#### Healthy patients

We want to make new, life changing treatments available to those who need them most

#### Healthy business

We conduct our business responsibly throughout our entire value chain

#### Healthy planet

We minimize our impact on the environment

### Focus areas

- > Unmet medical needs
- > Patient safety
- > Patient access
- > Health equity

- > Ethical business
- > Happy and skilled people

- > Impact on the environment



## Our Environmental, Social and Governance (ESG) strategy continued

### Contribution to the UN Sustainable Development Goals (SDGs)

Hansa supports the SDGs, which call for concrete actions to achieve a better and more sustainable future for all. Our strategy is aligned with the SDGs, and includes key goals and targets to which Hansa is able to contribute.

### Sustainability Governance

The governance structure surrounding Hansa's sustainability work ensures that sustainability is fully integrated into its business model and operations. The Board of Directors approves the overall business strategy and Company policies – such as the Code of Conduct – and identifies how sustainability issues impact Hansa's business. In 2021, the Board also approved Hansa's sustainability strategy. The executive management team, led by the Chief Executive Officer, is ultimately responsible for its implementation including target-setting and investment in the initiatives and activities associated with achieving this strategy.







# Market

Helping highly sensitized patients who cannot access a kidney	22
Conditional approval in Europe for Idefirix® in highly sensitized kidney transplant patients	25
Highly focused and sequenced launch strategy	26
Our center focused and sequenced launch process	27
Ongoing market access processes	28
European guidelines for the management of kidney transplant patients with HLA antibodies	29
Medison Pharma-partnership expands access to Idefirix®	31



# Helping highly sensitized patients who cannot access a kidney

## An introduction to chronic kidney disease (CKD)

Chronic kidney disease is a progressive disorder characterized by the gradual loss of kidney function over time. As CKD worsens, it can progress to kidney failure, also referred to as end stage renal disease, or ESRD, which is the final and most critical stage of CKD, where the kidneys can no longer function without support. ESRD is a significant global health burden, with almost 2.5 million patients treated for the disease globally, including 710,000 patients in the U.S., 570,000 patients in Europe, 328,000 patients in Japan and 180,000 patients in Brazil<sup>4</sup>.

People who progress to ESRD will require renal replacement therapy, which involves either dialysis or kidney transplantation. Patients dependent on dialysis need four to six hours of treatment three to four times per week, which, for most patients, results in significantly impaired quality of life. Long-term dialysis is also associated with cardiovascular complications and premature death. According to the United States Renal Data System, in 2016, the adjusted mortality rates per 1,000 patient-years were 164 for dialysis patients, and 29 for transplant patients<sup>5</sup>. Kidney transplantation represents a life-saving treatment for patients with ESRD which, in most cases, enables patients to return to a normal life at a significantly lower cost.

<sup>4</sup> <https://www.kidney.org/>

<sup>5</sup> United States Renal Data System, 2018 USRDS Annual Data Report, Volume 2: ESRD in the United States (p. 411). Available at: [https://www.usrds.org/media/1730/v2\\_c05\\_mortality\\_18\\_usrds.pdf](https://www.usrds.org/media/1730/v2_c05_mortality_18_usrds.pdf)

## The 5 stages of CKD

Based on an individual's eGFR [mL/min/1.73m<sup>2</sup>]



**≥90%**

Kidney damage with **normal** kidney function



**89% to 60%**

Kidney damage with **mild** loss of kidney function



**59% to 45%**

Mild to **moderate** loss of kidney function



**44% to 30%**

**Moderate to severe** loss of kidney function



**29% to 15%**

**Severe** loss of kidney function



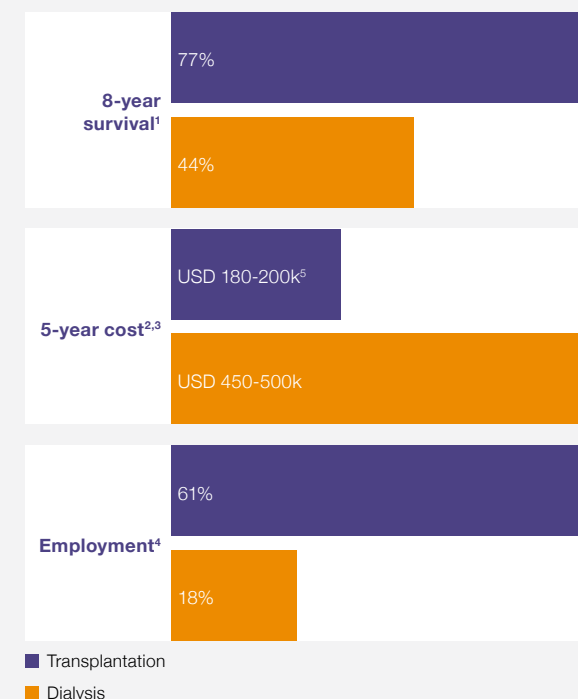
**<15%**

**Kidney failure**

## End Stage Renal Disease

ESRD occurs when the kidneys have reached the last stages of CKD, where they lose ≥85% of their normal function and are unable to function on their own.

## Better outcomes for transplantation patients



<sup>1</sup> Orandi et al. N Engl J Med 2016;374:940-50

<sup>2</sup> [www.usrds.org](http://www.usrds.org)

<sup>3</sup> Shehata et al, Transfus Med Rev 201, 24 Suppl 1: S7-S27

<sup>4</sup> Jarl et al. Transplantation, 2018, 102:1375-1381

<sup>5</sup> Cost of Kidney transplantation and 5 years of immuno-suppression treatment



## Helping highly sensitized patients who cannot access a kidney continued

### The kidney transplantation landscape

According to the United Network for Organ Sharing, there are approximately 107,000 patients waiting for an organ transplant in the U.S., approximately 90,000 of which are waiting for a kidney transplant<sup>6</sup>. Within the EU, approximately 80,000 patients are waiting for a kidney transplant<sup>7</sup>. Between 10% and 15% of patients waiting for kidney transplants are highly sensitized against potential donor tissues<sup>8</sup>. Yearly, 3% to 4% of patients waiting for a transplant die before they are able to receive a transplant<sup>9</sup>.

Globally, approximately 100,000 kidney transplants were performed in 2019, with 63% of kidneys received from deceased donors<sup>10</sup>. In 2020, transplantation and organ donation rates experienced a sharp drop due to the Covid-19 pandemic. In Europe, the number of kidney transplantations fell from 28,000 in 2019 to approximately 22,000. Transplantations from deceased donors were down by 19% from the previous year, while living donor transplantations fell by 25% versus the year before<sup>11</sup>.

In the U.S., deceased donor transplantations rose to an all-time record in 2020, with 18,410 kidney transplantations carried out, despite an initial dip in organ donation when the pandemic broke out<sup>12</sup>. Much of the increase in deceased donor transplantations in the U.S. was made possible as donors representing less traditional medical criteria were accepted for donation, including those from a higher age group than previously included and individuals who died of cardiorespiratory failure.

That said, living donor transplantations still dropped by 24% in 2020 compared to 2019, predominantly due to more restrictive protocols among recipients and donors, as well as priorities and resources at the hospitals treating Covid-19 related patients<sup>13</sup>.

Sensitized patients represent more than one-third of those waiting for kidney transplantation<sup>14</sup>. This group of patients are 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 DSA is either an absolute or relative contraindication, depending on the breadth and strength of the antibody response. For patients with a wide range of anti-HLA antibodies, it is extremely difficult to find a compatible donor.

While recent modifications to the Kidney Allocation System in the U.S. have increased the number of organs available for highly sensitized patients, there remains a large pool of highly sensitized patients unlikely to ever receive an organ offer and who, therefore, remain at risk, not only for waitlist removal, but also death on dialysis. For these patients, access to transplantation is a significant unmet medical need and imlifidase has the potential to meet this need via a standardized, effective, and predictable inactivation of HLA antibodies within the time constraints inherent in organ allocation and deceased donor transplantation.

### Total number of patients waitlisted

170,000

ACROSS U.S./EU

### Transplants performed globally in 2019

~100,000

63% OF KIDNEYS FROM DECEASED DONORS

### Highly sensitized patients awaiting kidney transplant

10-15%

<sup>6</sup> United Network for Organ Sharing

<sup>7</sup> Newsletter Transplant 2021. pg 62-64. Available at: <https://www.edqm.eu/en/news/newsletter-transplant-2021-now-available>

<sup>8</sup> EDQM. (2020). International figures on donation and Transplantation 2019 and SRTD Database and individual assessments of allocation systems

<sup>9</sup> <https://www.kidney.org/>

<sup>10</sup> <https://www.kidney.org/>

<sup>11</sup> Global Obeservatory on Donation and Transplantation. Available at: <http://www.transplant-observatory.org/data-charts-and-tables/>

<sup>12</sup> Global Obeservatory on Donation and Transplantation. Available at: <http://www.transplant-observatory.org/data-charts-and-tables/>

<sup>13</sup> Global Obeservatory on Donation and Transplantation. Available at: <http://www.transplant-observatory.org/data-charts-and-tables/>

<sup>14</sup> EDQM. (2020). International figures on donation and Transplantation 2019

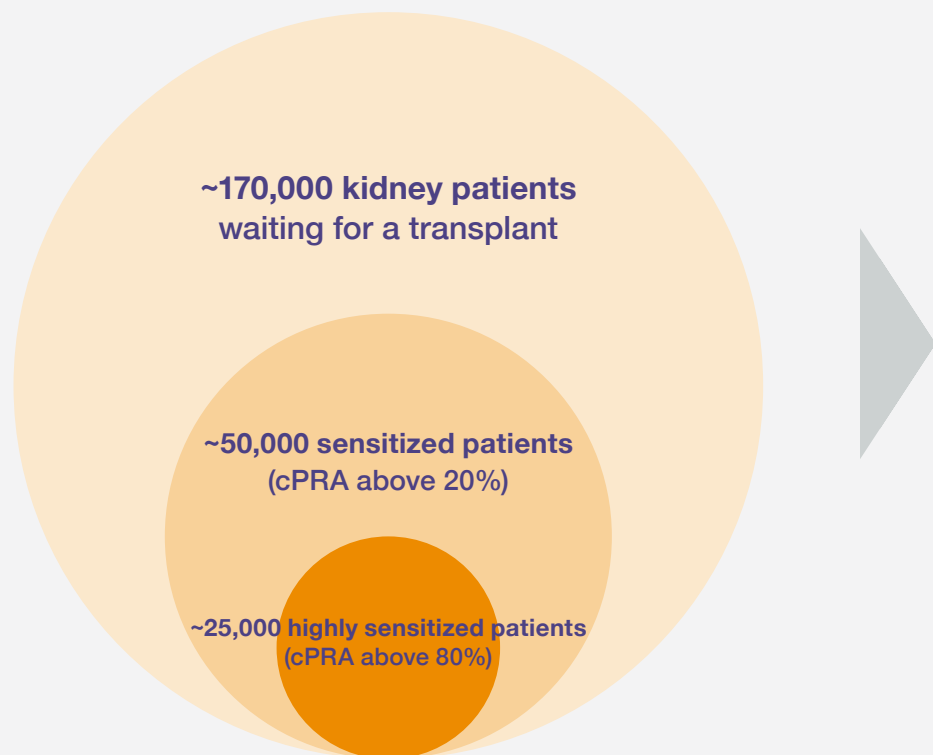


## Helping highly sensitized patients who cannot access a kidney continued

### The kidney transplantation landscape in Europe and the U.S.

Up to 15% of the patients waiting for a new kidney are highly sensitized

#### Breakdown of the kidney transplant waitlist in U.S. and EU



~50,000 transplants are done annually across the U.S. and Europe

#### U.S. annual kidney transplants

		5Y avg 22,083	Total	YoY
2020	18,410	5,234	23,644	▼ 3%*
2019	17,406	6,867	24,273	▲ 10%
2018	15,561	6,442	22,003	▲ 7%
2017	14,827	5,811	20,638	▲ 4%
2016	14,229	5,629	19,858	▲ 7%

#### Europe annual kidney transplants

		5Y avg 26,275	Total	YoY
2020	15,999	5,824	21,826	▼ 22%*
2019	20,287	7,766	28,053	▲ 1%
2018	20,097	7,820	27,917	▲ 3%
2017	19,510	7,565	27,075	▲ 2%
2016	18,979	7,524	26,503	▲ 3%

■ Deceased Donor Transplants ■ Living Donor Transplants

\* Reported to be impacted by the COVID-19 pandemic

Source: Global Observatory on Donation and Transplantation, <http://www.transplant-observatory.org/>

Source: The U.S. Department of Health and Human Services and .irodat.org





# Conditional approval in Europe\* for Idefirix® in highly sensitized kidney transplant patients

## Idefirix® label

The development of imlifidase for kidney transplantation is supported by two completed phase 1 studies in healthy subjects, three completed phase 2 studies in kidney patients and one investigator-initiated study also in kidney transplant patients. In total, 35 healthy subjects have been exposed to imlifidase and 46 patients have been transplanted after imlifidase treatment. Post-hoc analyses of the data pooled from all studies showed that 43 out of a total of 46 patients had a functioning kidney six months after transplantation.

On the basis of these studies, in August 2020, the European Commission granted a conditional approval in the European Union for Idefirix® (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 a deceased donor.

A post approval study in approximately 50 highly sensitized patients in Europe is expected to be initiated in 2022 in parallel with the commercial launch and will be key in integrating the commercial and scientific approach and to broadening the clinical experience with imlifidase.

Low complexity transplants

~70%<sup>1,2</sup>

Non or less  
sensitized  
(cPRA < 20%)

15-20%<sup>1,2</sup>

Moderately  
sensitized  
(20% < cPRA < 80%)

High complexity transplants

10-15%<sup>1,2</sup>

Highly  
sensitized  
(cPRA > 80%)

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

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

### Idefirix® label

Desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of Idefirix® should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritization programs for highly sensitized patients.

### Potential Patients

**idefirix®**  
imlifidase

Stock image

<sup>1</sup> EDQM. (2020). International figures on donation and Transplantation 2019

<sup>2</sup> SRTR Database and individual assessments of allocation systems



# Highly focused and sequenced launch strategy

## Our European launch strategy

Hansa's goal in kidney transplantation is to have a positive impact on patients as we work closely with the transplant community to reshape the area of desensitization and integrate Idefix<sup>®</sup> into clinical practice as a new standard-of-care.

Idefix<sup>®</sup> is the first and only treatment approved in Europe for desensitization treatment of highly sensitized patients. The introduction of this potential transformative drug is viewed by many leading experts, clinicians and those in the payer community as enabling a paradigm shift towards equity of access for highly sensitized patients to potentially lifesaving and life altering kidney transplants.

At transplantation centers, procedures are managed by a highly specialized team of clinicians including nephrologists, transplant surgeons, immunologists, tissue typists, transplant coordinators and nurse practitioners, as well as possibly other specialty physicians such as psychologists, cardiologists and neurologists, who all work tightly together before, during and after a transplantation.

As part of its launch strategy, Hansa will initially be focused on targeting leading centers with the potential to become early adopters and centers of excellence. The long-term market uptake of this innovation is highly dependent on successful early experiences in key early adopter centers. It is critical for a successful launch of Idefix<sup>®</sup>, that positive outcomes are generated in the first patients and for clinical centers to build the foundation necessary for expanded use of Idefix<sup>®</sup> as a potential new Gold Standard in desensitization protocols.

Our anticipated "S"-shaped launch curve reflects this careful approach in the initial years of commercialization, until more exponential growth occurs, which is anticipated mid-term, as Hansa expands beyond the first wave of early-launch countries, leverage the full potential in the five largest European markets as well as anticipate launching in the U.S. following

FDA approval. Longer term it is the Company's intention to potentially expand the label into new areas such as AMR post kidney transplantation, living donor transplantation, as well as heart and lung pre- and post-transplantation.

Operationally, we measure our launch progress using a set of key commercialization metrics, which directly impact future adoption and sales of Idefix<sup>®</sup> as a new transformative therapy. Those metrics include:

- > Pricing and reimbursement agreements
- > Market access procedures (HTA processes)
- > Clinical and commercial readiness
- > Increasing awareness

During 2021, Hansa secured positive pricing and reimbursement decisions in Sweden and the Netherlands, as well as on a hospital basis in Finland and Greece. In addition pricing and reimbursement was obtained in France (early access) and Germany during the first quarter 2022. Market Access procedures are ongoing in 10 countries including HTA dossiers in U.K., Italy and Spain. The five largest markets represent a total of 15,000 kidney transplantations, annually<sup>15</sup>.

In December 2021, Hansa announced a new, multiregional commercialization partnership with Medison Pharma for Idefix<sup>®</sup> in Israel and select Central Eastern European countries including Croatia, Hungary, Poland and Slovenia. Medison is a recognized international pharmaceutical company focused on providing access to highly innovative therapies to patients in international markets. This commercial partnership represents an important milestone for Hansa and will provide access to Idefix<sup>®</sup> in new markets beyond the early launch countries. Hansa and Medison will be working together to obtain pricing and reimbursement as required, depending on the country.

On the clinical side, Hansa continues to work with a number of priority centers to ensure and optimize clinical readiness, as

incompatible patients are being identified and prioritized for kidney transplants. End of December, 2021, 10 clinical centers have qualified as clinically ready to take on highly sensitized patients for incompatible kidney transplant and we continue to work closely with additional centers across Europe on their preparedness through training, Key Opinion Leader (KOL) engagement and logistics.

As far as awareness is concerned, Hansa has experienced extensive interest and engagement, with more than 30 experts in kidney transplantation who are committed to operationalizing HLA-incompatible kidney transplants in highly sensitized patients. The growing level of interest from KOLs was also exemplified at the Idefix<sup>®</sup> launch symposium sponsored in June 2021 with attendance from more than 120 transplant physicians representing 80 clinical centers in Europe from 13 countries.

In addition to the launch event, Hansa also sponsored a well-attended symposium titled, "A Roadmap to Transplant for the Highly Sensitized Patients" at the European Society for Organ Transplantation Congress (ESOT), which was held in Milan, Italy in August 2021. Beyond the symposium Hansa hosted more than 30 KOL meetings with our combined commercial and medical teams; and had two oral presentations in support of Idefix<sup>®</sup>.

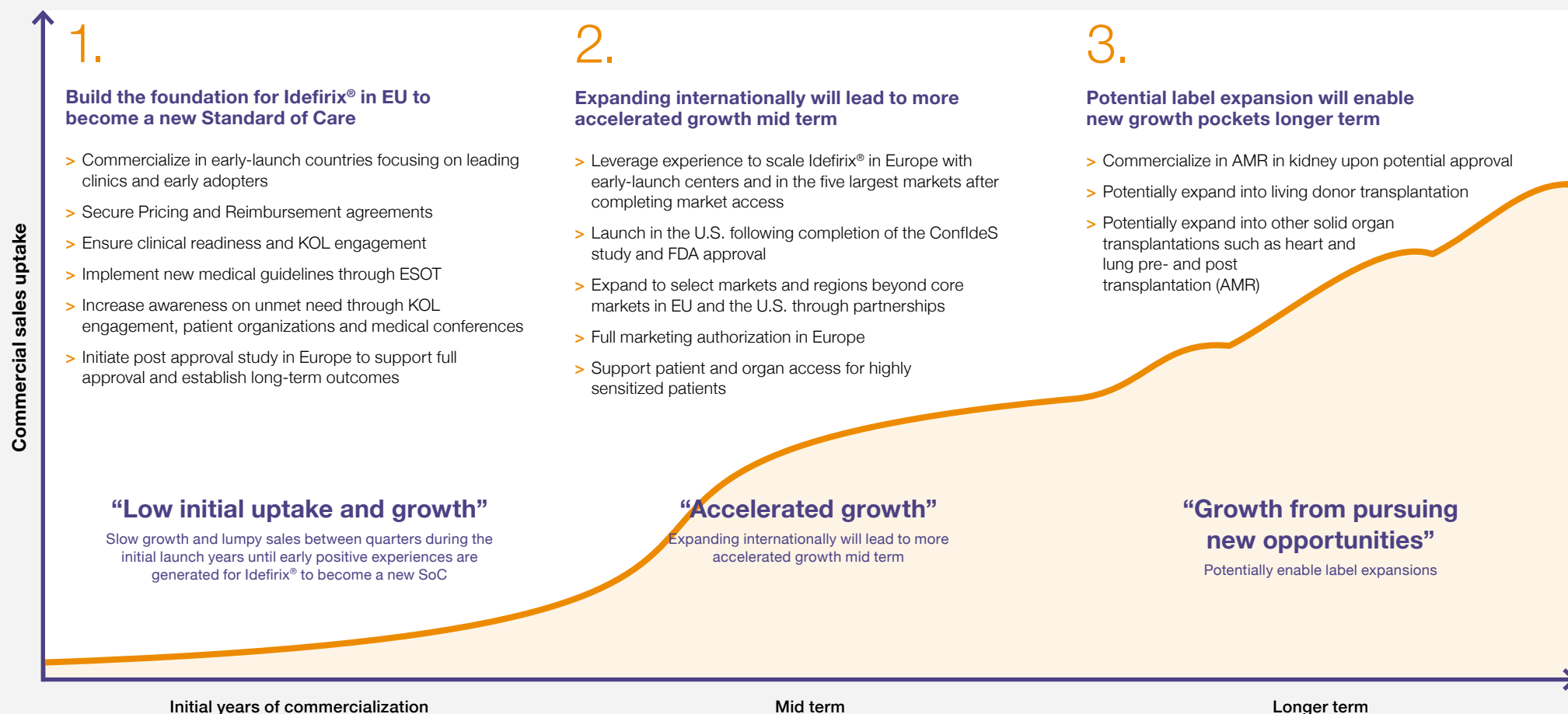
One of the key outcomes from ESOT was the formation of a new workstream with leading transplantation KOLs to advance clinical guidelines to include incompatible kidney transplant patients. The new ESOT guideline is expected to be a key driver for harmonization in the approach to transplanting highly sensitized patients. The first phase of the guideline is aimed at providing an evidence review of the literature, with clearly articulated recommendations and statements of the issues for incompatible kidney transplant patients. The second phase will focus on use and patient outcomes, as the experience with ilmilifase grows within the transplant community.



# Our center-focused and sequenced launch process will help build the foundation for Idefirix® to become a new Standard of Care in transplantation

Idefirix® is the first and only approved treatment in Europe for desensitization treatment of highly sensitized kidney transplant patients. The long-term market uptake is highly dependent on successful early experiences in key early adopter centers

Illustrative





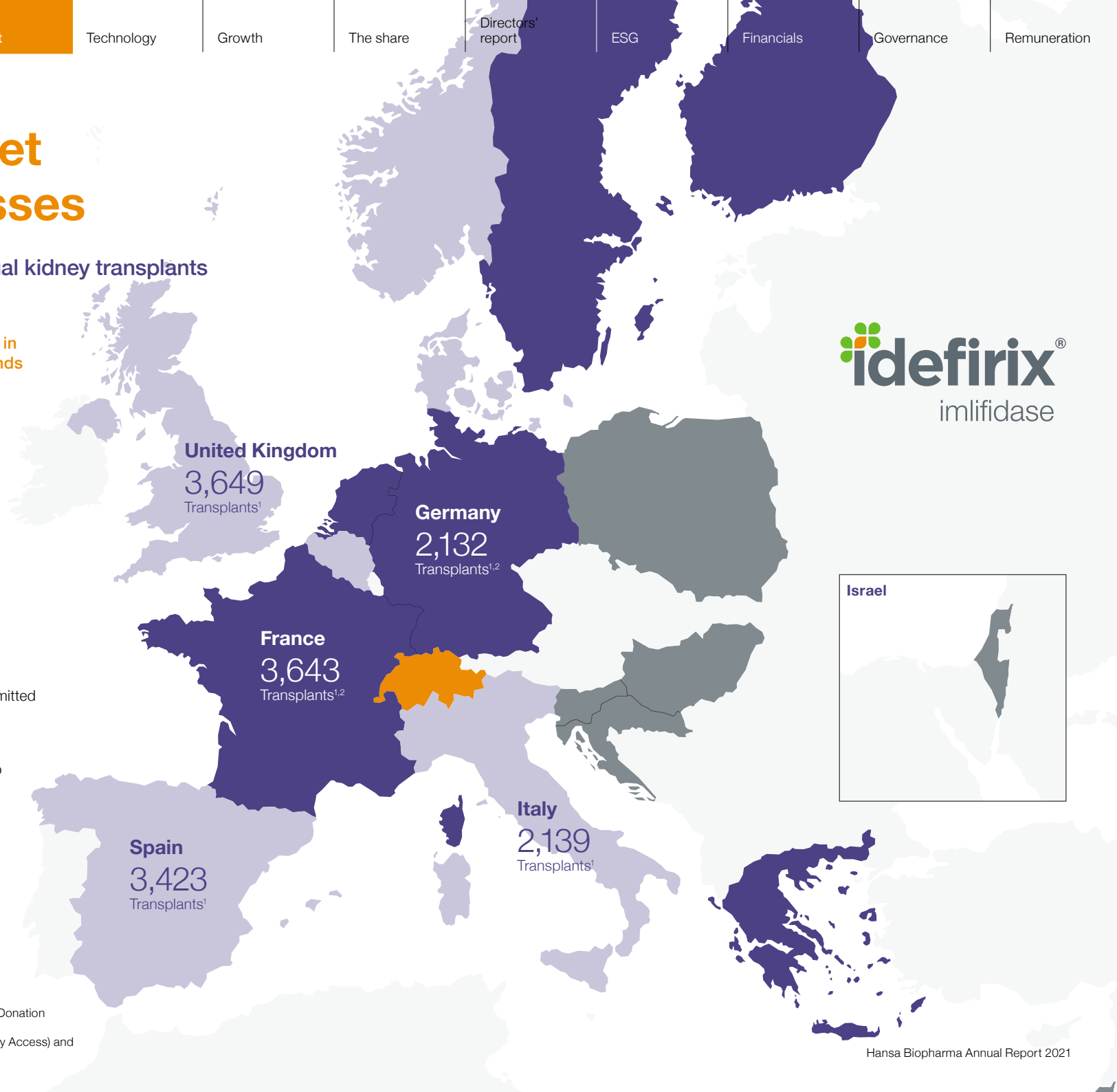
# Ongoing market access processes

EU4+UK represent ~15,000 annual kidney transplants



Pricing and reimbursement obtained in Germany, France, Sweden, Netherlands as well as Finland and Greece on a hospital basis.

- Health Technology Assessments (HTA) dossiers filed
- Marketing Authorization Application submitted
- Pricing & reimbursement obtained
- Medison Pharma distribution partnership



<sup>1</sup> Annual kidney transplantations 2019 (pre COVID-19)  
Transplantation data is from Global Observatory on Donation and Transplantation, 2019

<sup>2</sup> Pricing and Reimbursement obtained in France (Early Access) and Germany in February and March 2022



# European guidelines for the management of kidney transplant patients with HLA antibodies:

by the European Society for Organ Transplantation (ESOT) working group

## Interview

### Vincenza Nigro

*VP, Global Franchise Lead,  
Kidney transplantation and Head of Medical Affairs*

**Q. This year, Hansa sponsored a new workstream by ESOT on desensitization – why is this workstream so important?**

**A.** Hansa was delighted to be asked to support the human leukocyte antigen (HLA) Desensitization workstream as part of ESOT's educational Transplant Learning Journey (TLJ) 2.0 series, led by Transplant Surgeon, Professor Nizam Mamode, and supported by other leading experts. This working group focused on strategies for the management of those potential kidney transplant recipients with HLA sensitization who have antibodies directed against potential donor organs – termed donor-specific antibodies (HLA DSAs). Although kidney transplantation rates have increased in many countries in recent years, highly sensitized patients typically spend longer waiting for a transplant or may never receive one.

ESOT has a track record in creating extensive educational and training programmes, promoting changes in European policy, and is committed to improving transplant patient outcomes. At Hansa, we are focused on the bigger picture and want to be part of the solution at many levels for highly sensitized patients.

**Q. What have been the insights and results of the ESOT workstream, so far?**

**A.** This guideline represents the first international consensus on a management pathway for highly sensitized patients and articulates the variability in definitions, approaches, outcomes as well as the perceived success of HLAi Tx. The guideline is aimed at healthcare professionals who are faced with a patient with HLA DSA, to provide a roadmap regarding the most appropriate path to achieve a successful transplant. As the numbers of imlifidase-enabled transplant recipients remain low, this guideline is an important milestone on that journey to achieving equitable access for these disadvantaged patients.

**Q. Regarding the group of highly sensitized kidney transplant patients – why have they ended up as highly-sensitized and how many are there?**

**A.** Highly sensitized patients can be described as the most immunologically complex on the transplant waiting lists. Due to the patient's preformed HLA antibodies (HLA sensitization) through pregnancy, transfusions or previous transplants, these patients are difficult to match with a compatible deceased donor and, consequently, end up waiting indefinitely on the transplant list without access to a kidney transplantation.



We are focused on the bigger picture and want to be part of the solution at many levels for highly sensitized patients.

### Vincenza Nigro

*VP, Global Franchise Lead,  
Kidney transplantation and Head of Medical Affairs*





## European guidelines for the management of kidney transplant patients with HLA antibodies: continued

Highly sensitized patients are given priority within kidney allocation systems, but despite a rise in transplant rates, as many as 35% of the most highly sensitized patients ( $\geq 98\%$  cPRA) in the EU and those within the within the U.S. Kidney Allocation Systems, with cPRA  $\geq 99.9\%$ , a compatible donor is rarely found<sup>16</sup>. Although allocation systems and prioritization programs have improved access to transplantation for highly sensitized kidney patients, there is still a population of patients that remains underserved and in urgent need of more options.

### Q. What is Hansa's role in advancing the science for highly sensitized patients in kidney transplantation?

**A.** As an ambitious global company, we are focused on the bigger picture and want to be part of the solution at many levels. This means helping patients along their journey and engaging with healthcare communities in Europe, the U.S. and globally. We use this opportunity to, not only raise awareness about the unmet needs of the patients we aim to help but, also to advance the understanding of these complex fields. Every patient is unique, and this is even more true in rare conditions. We have an opportunity to set new Standards of Care deemed impossible until now. This means we are able to provide impactful collaborations with the scientific and medical community, patient organizations and research groups, and use the science to shape a better future, have a positive impact and create value across the entire system. We want to do this one patient at a time.

Hansa's role is to provide the tools to support specialist transplant teams and centers in ensuring that Idefix® (imlifidase) is available and used in a safe and appropriate way for those patients who need it. By leveraging our scientific expertise and, as experience with imlifidase grows in the market, we expect it to become the trusted gold standard therapy for highly sensitized patients whose only transplant option is an HLA-incompatible kidney. What we do here at Hansa is impactful for patients and the transplant community and I am very proud to be part of that.

### Vincenza Nigro

*VP, Global Franchise Lead,  
Kidney transplantation and Head of Medical Affairs*

<sup>16</sup>Kjellman et al. 2021, AJT



# Medison Pharma-partnership expands access to Idefirix®

## Interview

**Pierre-Henri Patin**

*Vice President Commercial Operations*

**Q. In December 2021, Hansa and Medison Pharma announced a partnership – what is the purpose of this agreement?**

**A.** We are extremely pleased and excited about this new commercial partnership with Medison Pharma. The partnership covers Israel and the following countries within Central Eastern Europe: Poland, Croatia, Hungary and Slovenia. The main objective is to expand access to imlifidase and accelerate its reach for highly sensitized patients awaiting kidney transplants in these countries.

**Q. What is the situation for highly sensitized kidney transplant patients in Central Eastern Europe and Israel?**

**A.** There is an unmet medical need identified in all countries covered by the Medison Pharma agreement. Patients suffering from this rare condition currently face very long wait times or are unable to find a suitable donor match due to high levels of preformed antibodies, elevating the risk of organ rejection. Thankfully, many countries have recognized the unmet needs of patients with rare diseases. The Polish Health Authority, for example, has listed imlifidase within its new advanced therapies program, which offers a potentially accelerated access pathway for highly innovative medicines. As Poland is the largest market in the region, we are thrilled to work towards expanding access to Polish patients through this pathway for highly innovative therapies.

**Q. How do Hansa and Medison Pharma work together?**

**A.** One of the great elements of the partnership is the true collaboration between our two companies and teams. The medical and commercial organizations of both companies are working hand in hand to better serve patients eligible for this much needed therapy. While Hansa brings its unique expertise in a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy, Medison Pharma brings its deep knowledge and experience in launching highly innovative medicines in these countries, well demonstrated through various successful partnerships with leading biopharmaceutical companies in Central Eastern Europe and Israel.

**Q. Israel is the first country outside Europe to gain marketing authorization for Idefirix® – why is this important to Hansa?**

**A.** Given that highly sensitized kidney patients are unserved in the health care system today, Hansa is striving to gain patient access in key markets throughout the world. With marketing authorization in the EU and UK, Israel is the first market outside of Europe to give hope to those previously unserved patients.



This new commercial partnership with Medison Pharma is an important milestone for Hansa as it expands access to imlifidase for highly sensitized patients awaiting kidney transplants.

**Pierre-Henri Patin**

*Vice President Commercial Operations*





# Technology

The role of immunoglobulin antibodies	33
Imlifidase – a novel approach to eliminating pathogenic IgG	34
Our unique antibody cleaving enzyme technology may have relevance across a range of indications	35
Intellectual property rights and orphan drug designations	37



# The role of immunoglobulin antibodies

An immune response begins with the recognition of a pathogen or foreign molecule, followed by a reaction to eliminate it

A wide variety of immune cells and molecules are involved in the development of immune responses. Antibodies, also known as immunoglobulins (Ig), are proteins produced and used by the immune system to recognize and eliminate pathogens or other foreign material. Each antibody binds to one of many molecules on the microorganism's surface and hence, there may be several different antibodies for a given pathogen.

Through this binding mechanism, one or more antibodies can tag a pathogen or infected cell. This tagging then results in one or several different so-called "effector functions," in which other parts of the immune system are activated in order to inhibit and/or eliminate the pathogen or foreign material. The human immune system uses different classes of antibodies called isotypes, known as IgA, IgD, IgE, IgG, and IgM. The isotypes have slightly different structures and they play different roles in the immune system. Immunoglobulin G (IgG), is the most common type found in the blood and tissue and provides the majority of antibody-based immunity against invading pathogens.

In various autoimmune diseases, the immune system mistakenly mounts a response toward the body's own cells and tissues. This misguided attack results in various clinical symptoms depending on which cells or tissues are subject to the attack. In several autoimmune diseases, antibodies capable of binding to self-antigens play an important role in the attack. These are called autoantibodies.

In transplantation, by design, foreign material is introduced to an individual's immune system. In order to prevent the body's immune system from rejecting the transplanted organ, all transplanted patients are treated with immunosuppressant drugs. Donors and potential recipients also need to be matched with respect to blood type and tissue type prior to transplantation to minimize the risk of transplant rejection.






As part of a natural immune response against the transplanted organ, the immune system can develop antibodies, which then contribute to a rejection. This process is referred to as AMR and these patients usually have developed antibodies to the donors HLA (Human Leukocyte Antigen).

Patients in need of a new organ, such as kidney, lung or heart, may also have developed anti-HLA (Human Leukocyte Antigen) antibodies prior to the transplantation. Typically, these pre-formed anti-HLA antibodies were developed earlier in life, when patients were exposed to foreign HLA due to pregnancies, blood transfusions or previous transplantations. These individuals are referred to as HLA-sensitized or HLA-immunized patients. In general, it is more difficult to find a compatible donor organ for HLA-sensitized patients.

Patients on transplant waitlists are screened with respect to their anti-HLA antibody profiles and are carefully tested with respect to donor-specific antibodies (DSA) prior to an actual transplantation. Highly sensitized patients have a wide

spectrum and often high levels of anti-HLA antibodies and are, therefore, likely to have DSAs. Since DSAs are likely to target and significantly compromise a transplanted organ, these patients are often prevented from receiving a transplant.

The broader reactivity of the antibodies, the lower the likelihood of finding a donor organ that will be a match. As a result, many of these highly sensitized patients remain, for an indefinite period, in a debilitating disease state on long-term dialysis treatment, which is associated with high cost, a poor quality of life and an increased mortality rate.

	 <b>IgM</b>	 <b>IgG</b>	 <b>IgA</b>	 <b>IgE</b>	 <b>IgD</b>
% of total antibody in serum	6%	80%	13%	0.002%	1%
Function	Primary response, fixes complement. Monomer serves as B-cell receptor	Main blood antibody, neutralizes toxins, opsonization	Secreted into mucus, tears, saliva	Antibody of allergy and anti-parasitic activity	B Cell Receptor



# Imlifidase – a novel approach to eliminating pathogenic IgG

Hansa's first generation enzyme, imlifidase, originates from a human pathogen – a bacteria called *Streptococcus pyogenes* – which is a species of Gram-positive, spherical bacteria in the genus *Streptococcus* and is usually known for causing a strep throat infection.

Imlifidase's *Mode of Action* is that it very quickly and effectively cleaves *Immunoglobulin G* (IgG) within 2-6 hours from a 15- to 30-minute infusion. The IgG is cleaved below the so-called 'hinge region,' creating an F(ab')<sub>2</sub> and an Fc component.

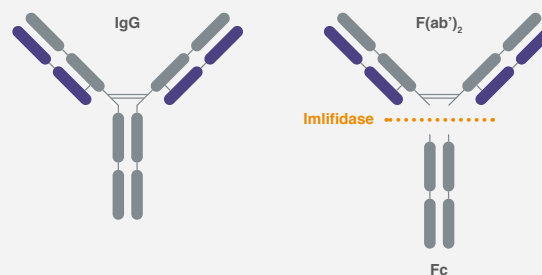
After treatment, intact IgG levels will drop to below detectable levels and stay suppressed for approximately 5-7 days, creating a window for transplantation before it gradually returns back to normal levels during the weeks following treatment. The imlifidase enzyme is highly specific to IgG and all subclasses of IgG, and has been demonstrated to not affect other Ig-isotypes.

## Origins from a bacteria *Streptococcus pyogenes*

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

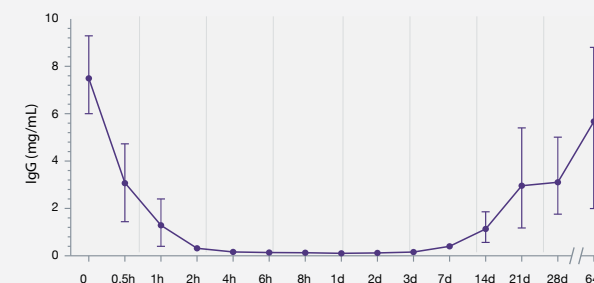
## Imlifidase, a unique IgG antibody-cleaving enzyme to eliminate pathogenic IgG

- > Interacts with Fc-part of IgG with extremely high specificity
- > Cleaves IgG at the hinge region, generating one F(ab')<sub>2</sub> fragment and one homo-dimeric Fc-fragment



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

- > Rapid onset of action that inactivates IgG below detectable level in 2-6 hours from a 15-minute infusion
- > IgG antibody-free window for approximately one week







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

## Targeting rare IgG mediated diseases

### Expanding our commercial franchises

- Regulatory approval (conditional)
- Clinical development
- Partnership (preclinical development)
- Preclinical development
- Opportunities currently not pursued

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

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

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

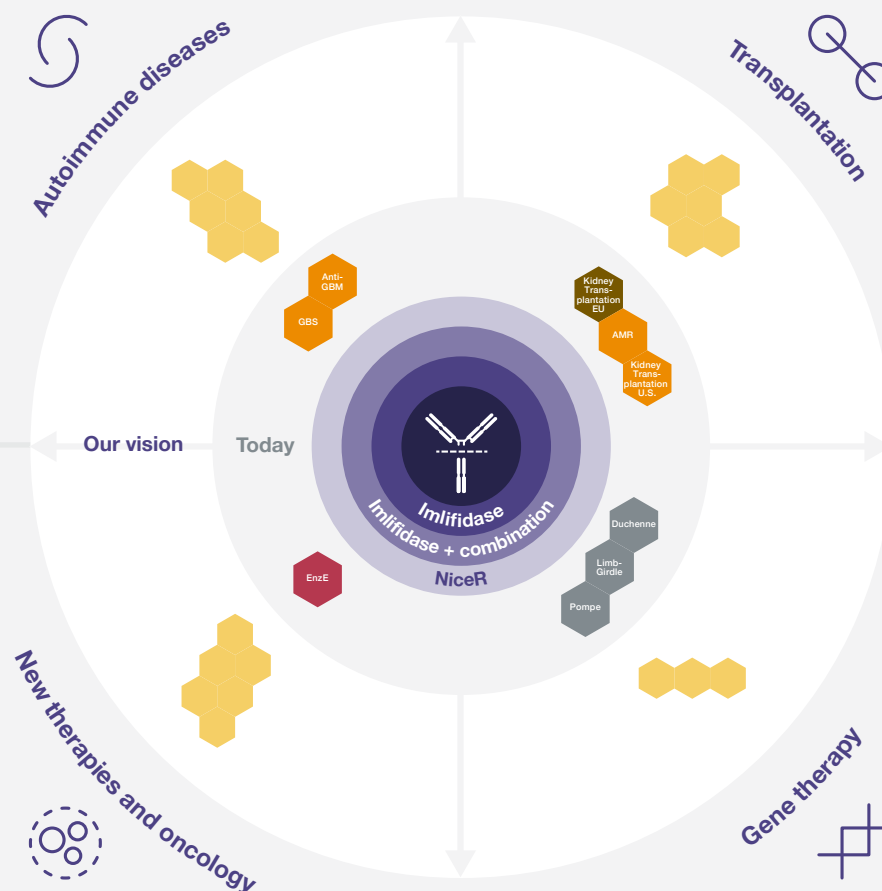
- > Antibody mediated rejection (AMR) in kidney transplantation
- > Other transplantation types

### IgG-cleaving enzymes to enable or even potentiate cancer therapy

- > Allogeneic stem cell (bone marrow) transplantation (HSCT)
- > Enzyme-based antibody Enhancement (EnzE)

### Exploring opportunities in gene therapy

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





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

Our proprietary antibody-cleaving enzyme technology platform to target pathogenic antibodies is at the core of our business. To sharpen our focus and commitment toward advancing Hansa's platform beyond kidney transplantation, we have established four distinct franchises in transplantation, autoimmune diseases, gene therapy and oncology/new therapies.

Hansa's first-generation IgG-cleaving enzyme, imlifidase, is designed to inactivate IgG antibodies in both plasma and tissue, with a single intravenous treatment. Through the NiceR program, we are also developing a second generation of IgG-cleaving enzymes designed to have lower immunogenicity, thereby enabling multiple administrations. Specifically, with NiceR, we are working on genetically modifying our enzymes to reduce the immunogenicity and the immune response, so that we can use them for repeated dosing. This could potentially open a new treatment paradigm in a broad range of indications.

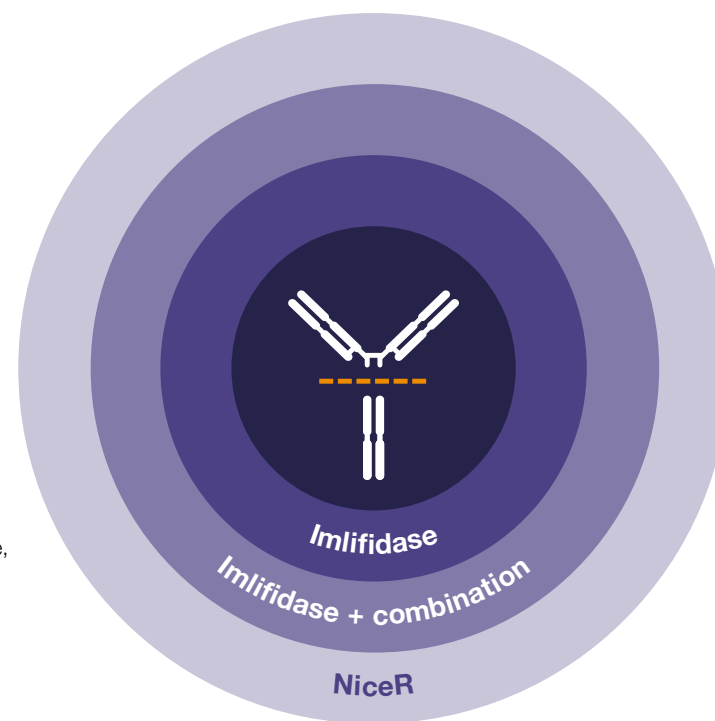
In addition to identifying the most relevant indications for our enzymes, we are also looking at how our unique antibody-cleaving enzyme technology can be used in potential combination with other technologies targeting IgG antibodies. For example, FcRn inhibitors, which do not give the same rapid and effective response as imlifidase, but can be useful for long-term management in indications known to be driven by disease-causing IgGs. In line with this idea, we entered into a pre-clinical research collaboration with argenx BV in March 2021 to explore the potential of combining imlifidase and efgartigimod, argenx's FcRn antagonist. If the data bears out, a combination of imlifidase and efgartigimod could potentially be used in both the acute and chronic setting of autoimmune diseases and transplantation.

### The technology platform is the primary basis for achieving our vision

#### Targeting rare IgG mediated diseases and conditions

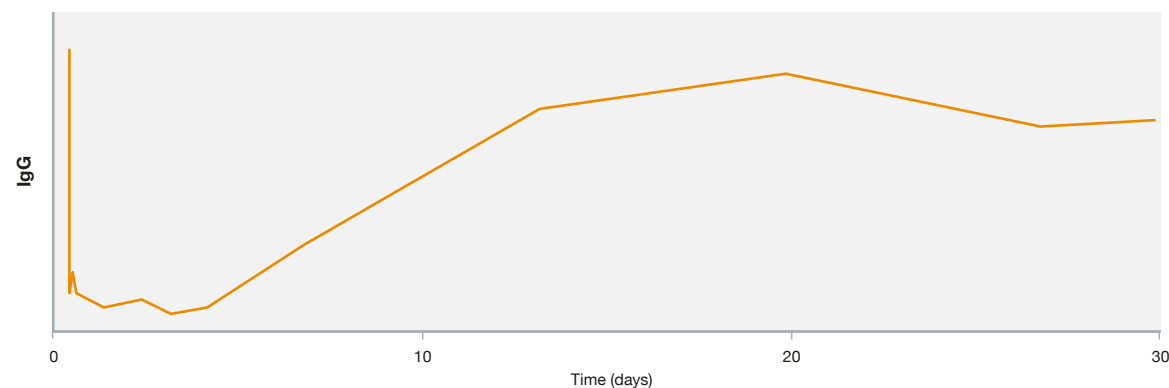
##### Key opportunities:

- > Expanding into **new indications**
- > Reduce immune response to IgG-cleaving enzyme, i.e. allow **repeated treatment**
- > **Combination therapy**, i.e. induction and maintenance therapy



#### IgG levels after imlifidase treatment in humans

First 30 days





# Intellectual property rights and orphan drug designations

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

In addition to this, exclusivity for our products and treatments is sought via orphan drug designations.

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 out 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 isolated imlifidase. The most significant patent families protecting imlifidase and its use provides basis for extended patent term extensions (PTEs), which are available in certain major markets, including the U.S. 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 patent term extensions.

In addition to patent and IP related protection, the Company continuously evaluates the opportunities for market exclusivity for drug candidates through orphan drug designations and data exclusivity.

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 orphan drug designations by EMA 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 disease anti-GBM (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 disease anti-GBM (2018)



# Growth

Our development programs	39	Active kidney transplant AMR	45
Ongoing clinical programs	40	Guillain-Barré syndrome (GBS)	46
U.S. randomized control trial “ConfideS”	41	Imlifidase in gene therapy – an emerging opportunity	47
Opportunities beyond kidney transplantation	42	Exploration of HSCT as an opportunity for imlifidase	52
Acute Anti-GBM antibody disease (Goodpasture’s disease)	43	Research and preclinical development projects	54
Advancing imlifidase in anti-GBM diseases	44		



# Our development programs

## Broad clinical pipeline in transplantation and auto-immune diseases

Candidate/ Project	Indication	Research/ Preclinical	Phase 1	Potentially Pivotal/Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Conditional approval based on Phase 2 data	Completed	*)	EU: Additional agreements around reimbursement from H2'21
	U.S.: Kidney transplantation in highly sensitized patients <sup>1,2</sup>	Completed	Completed	Completed	Ongoing			Completion of enrollment (64 patients) H2'22
	Anti-GBM antibody disease <sup>3</sup>	Completed	Completed	Completed	Planned			Pivotal Phase 3 study expected to commence in 2022 (50 patients)
	Antibody mediated kidney transplant rejection (AMR)	Completed	Completed	Ongoing				Completion of enrollment (30 patients) H1'22
	Gullain-Barre syndrome (GBS)	Completed	Completed	Ongoing				Timeline guidance under review
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)	Ongoing						Preclinical phase
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)	Ongoing						Preclinical phase
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)	Planned						Preclinical phase
NiceR	Recurring treatment in autoimmune diseases, transplantation and oncology	Ongoing						Completion of GLP toxicology studies in 2022
EnzE	Cancer immunotherapy	Ongoing						Research phase

<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 Märten Segelmark, Professor at the universities in Linköping and Lund

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

Completed

Ongoing

Planned

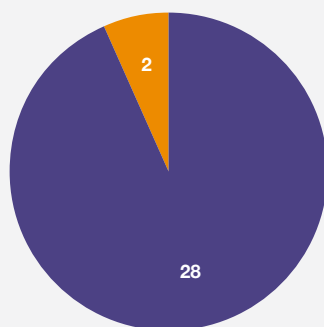
Conditional approval based on Phase 2 data



# Ongoing clinical programs

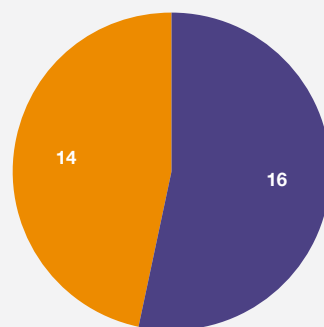
## Enrollment status Apr 6, 2022

### Antibody Mediated Rejection phase 2



- > 28/30 patients enrolled in the AMR phase 2 study
- > Completion of enrollment expected H1 2022\* as previously guided
- > First data read out expected in H2 2022\*

### Guillain-Barré Syndrome phase 2



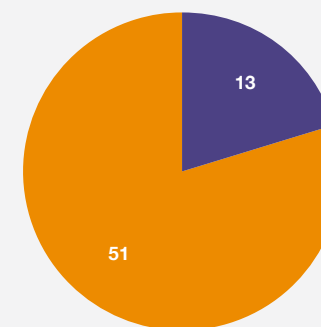
- > 16/30 patients enrolled in the GBS phase 2 study
- > GBS enrollment timeline under review given the difficulty of predicting enrollment due to the direct and indirect effects of the escalating pandemic
- > Hansa expects to update its guidance for completion of enrollment in GBS in April 2022

### Anti-GBM phase 3



- > Alignment with FDA on a pivotal Phase 3 study of imlifidase in anti-GBM patients
- > The planned study will target approximately 50 patients with anti-GBM disease across the U.S. and Europe
- > The first patient is expected to be enrolled in 2022\*

### U.S. ConfideS trial phase 3



- > 13/64 patients enrolled in the phase 3 "ConfideS" study
- > First patients enrolled at Columbia University (NY) at the end of Dec 2021
- > Nine centers are active and open for enrollment
- > Completion of enrollment expected H2 2022\*
- > Completion of 12 months follow-up expected H2 2023\*

■ Patients enrolled  
■ Patients remaining

\* Guidance assumes no further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again





# U.S. randomized control trial “ConfldeS”

In December 2021 Hansa announced that the first patient in its U.S. open-label, randomized, controlled pivotal trial (“ConfldeS”) had been enrolled at the Columbia University Medical Center, New York.

The ConfldeS 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 ConfldeS trial. The trial will enroll patients at 12 to 15 leading transplantation centers in the U.S.

End of December, 2021, 2 of the targeted 64 patients have been enrolled<sup>17</sup> at 5 centers across the U.S. (13 of the targeted 64 patients were enrolled by April 6, 2022). Completion of enrollment in the trial is expected in the second half of 2022, with a 12-month follow-up study period expected to be completed in the second half of 2023. Results from this pivotal trial are expected to support a potential BLA submission to the FDA under the accelerated approval pathway in the first half of 2024. The guidance assumes no further escalation or sustained negative impact of the COVID-19 pandemic potentially forcing trial centers to halt or delay patient recruitment or even shut down again.

Imlifidase has already received conditional marketing approval in Europe for the desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor.

## Timeline

First patient enrolled  
(H2 2021)

2021

2022

Complete enrolment  
(H2 2022)

12m follow-up eGFR  
(H2 2023)

2023

BLA submission  
(H1 2024)

2024

<sup>17</sup> Guidance assumes no further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again



# Opportunities beyond kidney transplantation

Hansa's unique antibody-cleaving platform may have relevance in numerous autoimmune diseases, where IgG autoantibodies play an important role

## Rapidly progressive glomerulonephritis

**Anti-GBM**

~1,000 patients<sup>\*1</sup>

**Lupus nephritis**  
~35,000<sup>\*2</sup>

**ANCA-associated vasculitis**  
~90,000<sup>\*3</sup>

## Neurological disorders

**Myasthenia gravis**  
~210,000<sup>\*4</sup>

**GBS**

~10,000 patients<sup>\*5</sup>

**CIDP**  
~55,000<sup>\*6</sup>

**NMO**  
~20,000<sup>\*7</sup>

## Skin disorders

**EBA**

<1,000 patients<sup>\*8</sup>

**Pemphigus vulgaris**  
~40,000<sup>\*9</sup>

## Blood disorders

**ITP**  
~75,000<sup>\*10</sup>

**WAHA**  
~95,000<sup>\*11</sup>

**APS**  
~350,000<sup>\*12</sup>

■ Clinical programs

■ Potential indications (currently not pursued)

\*Total disease populations in EU & US, based on prevalence and population data

**CIDP:** Chronic inflammatory demyelinating polyradiculoneuropathy

**NMO:** Neuromyelitis optica

**EBA:** Epidermolysis bullosa acquisita

**ITP:** Immune thrombocytopenia

**WAHA:** Warm antibody hemolytic anemia

**APS:** Antiphospholipid syndrome

<sup>1</sup> DeVrieze, B.W. and Hurley, J.A. Goodpasture Syndrome. StatPearls Publishing, Jan 2021. <https://www.ncbi.nlm.nih.gov/books/NBK459291/> [accessed 2021-03-29]

<sup>2</sup> Patel, M et al. The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK. Arthritis & Rheumatism, 2006

<sup>3</sup> Berti A, Cornec D, Crowson CS, Specks U, Matteson EL. The Epidemiology of ANCA Associated Vasculitis in the U.S.: A 20 Year Population Based Study. Arthritis Rheumatol. 2017;69

<sup>4</sup> Myasthenia Gravis. National Organization for Rare Disorders, <https://rarediseases.org/>

rare-diseases/myasthenia-gravis/ [accessed 2021-03-29]

<sup>5</sup> Guillain-Barré syndrome. Orpha.net, [https://www.orpha.net/consor/cgi-bin/OC\\_Exp.php?Lng=GB&Expert=2103](https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Lng=GB&Expert=2103) [accessed 2021-03-29]

<sup>6</sup> Chronic Inflammatory Demyelinating Polyneuropathy: Considerations for Diagnosis, Management, and Population Health. The American Journal of Managed Care, <https://www.ajmc.com/view/chronic-inflammatory-demyelinating-polyneuropathy-considerations-for-diagnosis-management-and-population-health> [accessed 2021-03-29]

<sup>7</sup> Marrie, R.A. The Incidence and Prevalence of Neuromyelitis Optica. International Journal of MS Care, 2013 Fall: 113-118

<sup>8</sup> Mehren, C.R. and Gniadecki, R. Epidermolysis bullosa acquisita: current diagnosis and therapy. Dermatol Reports, 2011-10-05

<sup>9</sup> Wertenteil, S. et al. Prevalence Estimates for Pemphigus in the United States. JAMA Dermatol, May 2019: 627-629

<sup>10</sup> Immune Thrombocytopenia. National Organization for Rare Disorders, <https://rarediseases.org/rare-diseases/immune-thrombocytopenia/> [accessed 2021-03-29]

<sup>11</sup> Warm Autoimmune Hemolytic Anemia. National Organization for Rare Disorders, <https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/> [accessed 2021-03-29]

<sup>12</sup> Litvinova, E. et al. Prevalence and Significance of Non-conventional Antiphospholipid Antibodies in Patients With Clinical APS Criteria. Frontiers in Immunology, 2018-12-14



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

## Anti-GBM, 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 is one form of glomerulonephritis (GNN), which comprises a number of inflammatory diseases in the kidney and is a leading cause of kidney disease. 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.

Patients with glomerulonephritis, including those diagnosed with anti-GBM disease, usually experience very few symptoms initially, which is why many patients are diagnosed late in disease progression. Today, diagnostic tests can determine if a patient has anti-GBM autoantibodies but, since this disease is rare, knowledge of the disease and when to use the diagnostic test is not widespread throughout the healthcare system.

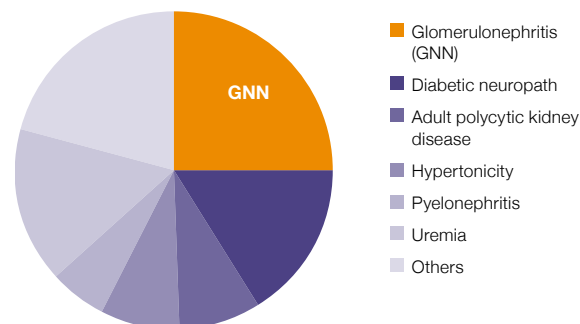
Early diagnosis and treatment is, however, crucial for these patients, as deterioration of kidney function progresses rapidly into the acute stage. The only way to halt an immunologic attack is through elimination of the antibodies as early as possible. Today's standard of care in anti-GBM disease involves medications such as cytotoxic drugs (e.g. corticosteroids and cyclophosphamide) and plasma exchange, but these treatments are seen as inadequate as

it can take several months for the autoantibody production to halt and typically only a fraction of the total IgG antibodies are removed through plasma exchange.

Anti-GBM is an ultra rare disease that affects approximately 1.6 per million people globally, every year<sup>18,19</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>20</sup>. Only one in three anti-GBM patients will have a preserved renal function after six months with current treatment<sup>21</sup>.

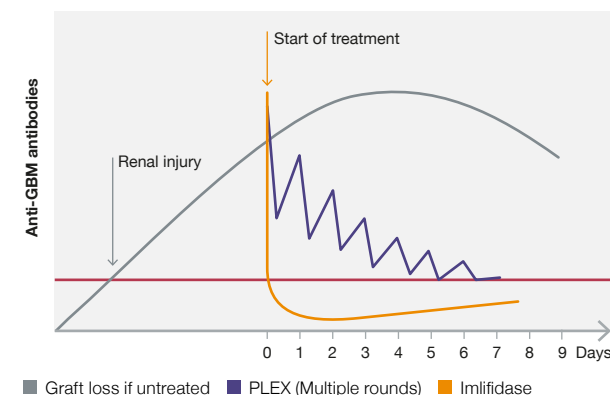
With imlifidase, the anti-GBM antibodies in circulation, as well as the IgG bound to the GBM, are cleaved by the enzyme within a few hours and may prevent further renal damage.

### Glomerulonephritis is a leading cause for kidney disease



### Potential of using imlifidase vs PLEX in anti-GBM

Illustrative



Source The Immunoglobulin G Degrading Enzyme imlifidase for the Treatment of Anti-GBM Disease – the Good-IDES 01 Trial Mårten Segelmark 1,2, Fredrik Uhlin 2, Elisabeth Sonesson 3 on behalf of the Good-IDES – 1.0 study team

In September 2020, positive high-level data were presented from an investigator-initiated phase 2 trial of imlifidase to treat anti-GBM disease. The study, led by Principal Investigator Mårten Segelmark, Professor at the Universities in Linköping and Lund, 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.

The positive outcome from the phase 2 trial marked an important milestone for the expansion of imlifidase outside transplantation and into auto-immune diseases. Hansa plans to initiate a Phase 3 study of imlifidase to treat anti-GBM disease following a successful pre-IND meeting with the U.S. FDA. The planned pivotal phase 3 clinical study will enroll approximately 50 patients with anti-GBM disease across the U.S. and Europe with the first patient expected to be enrolled in 2022.

<sup>18</sup> Kluth et al. J Am Soc Nephrol. 1999 Nov;10(11):2446-53

<sup>19</sup> Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12

<sup>20</sup> Cohort of 13 studies (661 patients in anti-GBM 1993-2017) Treating anti-GBM disease with imlifidase Mårten Segelmark, Professor OF Nephrology

<sup>21</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



# Advancing imlifidase in anti-GBM disease

## Interview

**Elisabeth Sonesson**

*Global Franchise Lead Autoimmunity*

### Q. What is anti-GBM disease and who is affected?

**A.** Anti-GBM disease, also known as Goodpasture's disease, is an ultra-rare, severe kidney disease which causes inflammation of the glomeruli. It affects approximately 1.6 in a million people annually<sup>23</sup>. The condition causes the immune system to mistakenly attack a specific part of the kidneys called the glomerular basement membrane (GBM) with IgG-antibodies, severely damaging the kidneys and, in some cases, the lungs. Many patients with anti-GBM disease lose kidney function and require chronic dialysis and kidney transplantation<sup>24</sup>. In severe cases, anti-GBM disease may lead to death.

### Q. What are the recent developments in Hansa's anti-GBM product program?

**A.** I am excited to see that our efforts in anti-GBM disease is progressing toward late stage development. We aim to have a global protocol for our phase 3 study, and have recently completed a series of successful interactions with various regulatory authorities, including the FDA and EMA. The goal is to have the trial up and running during 2022, with patient recruitment in the U.S. and EU.

### Q. What have trials shown so far?

**A.** The recently completed investigator-initiated phase 2 study<sup>26</sup>, being led by Professor Mårten Segelmark, showed that two thirds (67%) of patients (10 out of 15) achieved dialysis independence at six months after imlifidase treatment. As a comparison, the overall renal survival over 12 trials has been reported to be 26% with current Standard of Care (SoC)<sup>22</sup>. This positive outcome served as Proof of Concept (PoC) for the potential of imlifidase to treat IgG-mediated serious autoimmune diseases.

### Q. How is Hansa advancing the science for anti-GBM disease?

**A.** There have been no randomized controlled trials performed within anti-GBM since 1985<sup>25</sup>. Hansa plans to initiate a randomised controlled trial comparing imlifidase on top of SOC, or to SOC, alone, in 50 patients. The results of this trial may lead to a new, life saving treatment for patients diagnosed with this very serious disease.

Hansa wants to bring hope to patients with anti-GBM disease, which is a devastating autoimmune condition, severely damaging the kidney's and in some cases the lungs.

**Elisabeth Sonesson**

*Global Franchise lead Autoimmunity*

<sup>22</sup> Segelmark M et al. Anti-glomerular basement membrane disease: an update on subgroups, pathogenesis and therapies. *Nephrol Dial Transplant*. 2019;34:1826-32

<sup>23</sup> Canney, M., O'Hara, P. V., McEvoy, C. M., Medani, S., Connaughton, D. M., Abdalla, A. A., . . . Little, M. A. (2016). Spatial and Temporal Clustering of Anti-Glomerular Basement Membrane Disease Clin J Am Soc Nephrol, 11(8), 1392-1399. doi:10.2215/CJN.13591215

<sup>24</sup> McAdoo S et al. Anti-GBM disease. *Clin J Am Soc Nephrol* 2017. 12: 1162–11725

<sup>25</sup> Johnson et al. *Medicine (Baltimore)* 1985 Jul; 64(4):219-27

<sup>26</sup> GOOD-IDES-01 ClinicalTrials.gov Identifier: NCT03157037



# Active kidney transplant AMR

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

Active antibody mediated rejection, or AMR, is a serious condition after transplantation that occurs in roughly 10% 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. In the U.S. and Europe, there are approximately 45,000 patients who receive kidney transplants, annually, and approximately 400,000, who currently live with a kidney transplant<sup>27</sup>. AMR is one of the most challenging adverse events after kidney transplantation, occurring in approximately 10% of patients<sup>28</sup>, and there is no approved therapy.

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>29</sup>

Given that there are no approved therapies for AMR, the ability of imlifidase to directly intervene with the pathophysiology of AMR is potentially a significant new advancement in the treatment of AMR.

### Hansa's phase 2 program in AMR

Imlifidase is currently being investigated in a phase 2, randomized, open-label, multi-center, controlled trial, which is expected to enroll 30 AMR patients 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 subjects will be randomized to receive imlifidase treatment comprised of one intravenous dose of 0.25mg/kg, while 10 subjects in the active control arm will receive 5-10 sessions of plasma exchange. Efficacy and safety will be monitored over a 6-month period, post treatment.

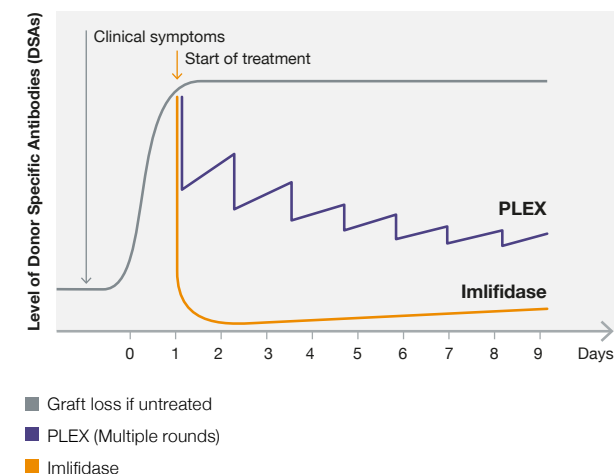
End of December, 2021, 23 of the targeted 30 patients have been enrolled at 14 centers across the U.S., Europe and Australia. 28 of the targeted 30 patients were enrolled by April 6, 2022) Enrollment is expected to be completed in the first half of 2022 with the first data read out expected in the second half of 2022, as previously guided. This guidance assumes no further escalation or sustained negative impact of the COVID-19 pandemic, potentially forcing trial centers to reprioritize patient recruitment or even shut down again.

A long-term, 3 year follow-up study with patients from the completed AMR phase 2 trial, has been initiated. The primary endpoint is graft survival. Five patients have completed the one-year visit.

More information about the trial is available at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03897205) under NCT03897205 (2019).

### Potential of using imlifidase vs. PLEX in AMR

Illustrative



<sup>27</sup> Global Observatory on donation & transplant

<sup>28</sup> Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724

<sup>29</sup> Puttarajappa et al., 2012; Jordan et al., 2015



# Guillain-Barré syndrome (GBS)

Guillain-Barré syndrome is 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>30</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>31</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>32,33</sup>

## Hansa's phase 2 program in GBS

Imlifidase is currently being investigated in a phase 2 trial targeted to enroll 30 GBS patients across clinics in France, the UK and the Netherlands. It is an open-label, single arm, multicenter study evaluating the safety, tolerability and efficacy of imlifidase in GBS patients, in combination with standard of care intravenous immunoglobulin (IVIg). GBS patients enrolled in the study will receive a single dose of 0.25 mg/kg of imlifidase. The patients will be compared with a matched control group of GBS patients treated with IVIg, from the International GBS Outcome Study (IGOS) database.

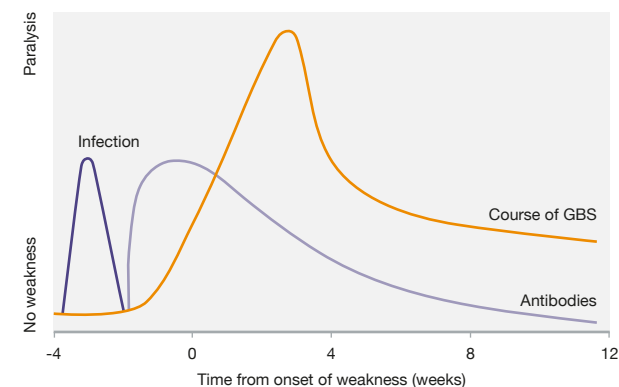
End of December, 2022, 15 of the targeted 30 patients have been enrolled across centers in France, the U.K. and the Netherlands. (16 of the targeted 30 patients were enrolled by April 6, 2022).

The widespread impact of the COVID-19 pandemic including the emergence of new variants have impacted the availability of staff across a number of trial centers. Additionally, a shortage of IVIg has affected the enrollment rate at a subset of participating hospitals in our GBS program. Given the current difficulty of predicting enrollment due to the direct and indirect effects of the continued pandemic and increased infection rates due to omicron, Hansa Biopharma expects to update its guidance related to the GBS study timelines on April 21, 2022, in connection with the publication of its Q1 report. In the meantime, in order to help mitigate these hurdles, the Company has simplified the study protocol and is actively supporting the hiring of additional staff at the affected clinics. In addition, two sites were added during January and February 2022, for the recruitment of patients in the U.K. and the Netherlands.

In 2018, the U.S. FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS. More information about the study is available at ClinicalTrials.gov under NCT03943589 (2019).

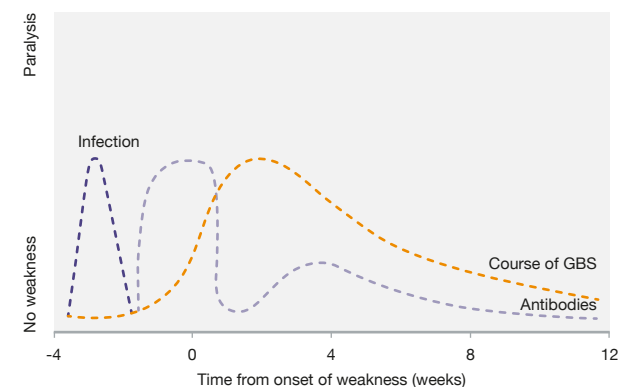
## Today's Standard of Care IVIg or PLEX

Illustrative



## Potential with imlifidase

Illustrative



<sup>30</sup>Seven Major Markets Seven major markets include US, Germany, UK, France, Spain, Italy, and Japan

<sup>31</sup>Fletcher DD, Lawn ND, Wolter TD, et al. Long-term outcome in patients with GuillainBarré syndrome requiring mechanical ventilation. *Neurology* 2000;54:2311-5

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

<sup>33</sup>van den Berg et al., 2014





# 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>34</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.

We believe that our antibody cleaving enzyme, 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 imlifidase as a potential pre-treatment to overcome pre-existing antibodies to AAV based gene therapy was highlighted in “*Nature Medicine*,” in 2020<sup>35</sup>. In particular, highly encouraging results from preclinical studies were published, illustrating that imlifidase could 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.

Our collaborations with Sarepta Therapeutics in LGMD and DMD, announced in 2020, and the collaboration with AskBio in Pompe disease, announced in the beginning of this year, are evidence of an interest amongst gene therapy companies to use imlifidase to potentially pre-treat gene therapy patients with pre-existing anti-AAV antibodies.

<sup>34</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>35</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>



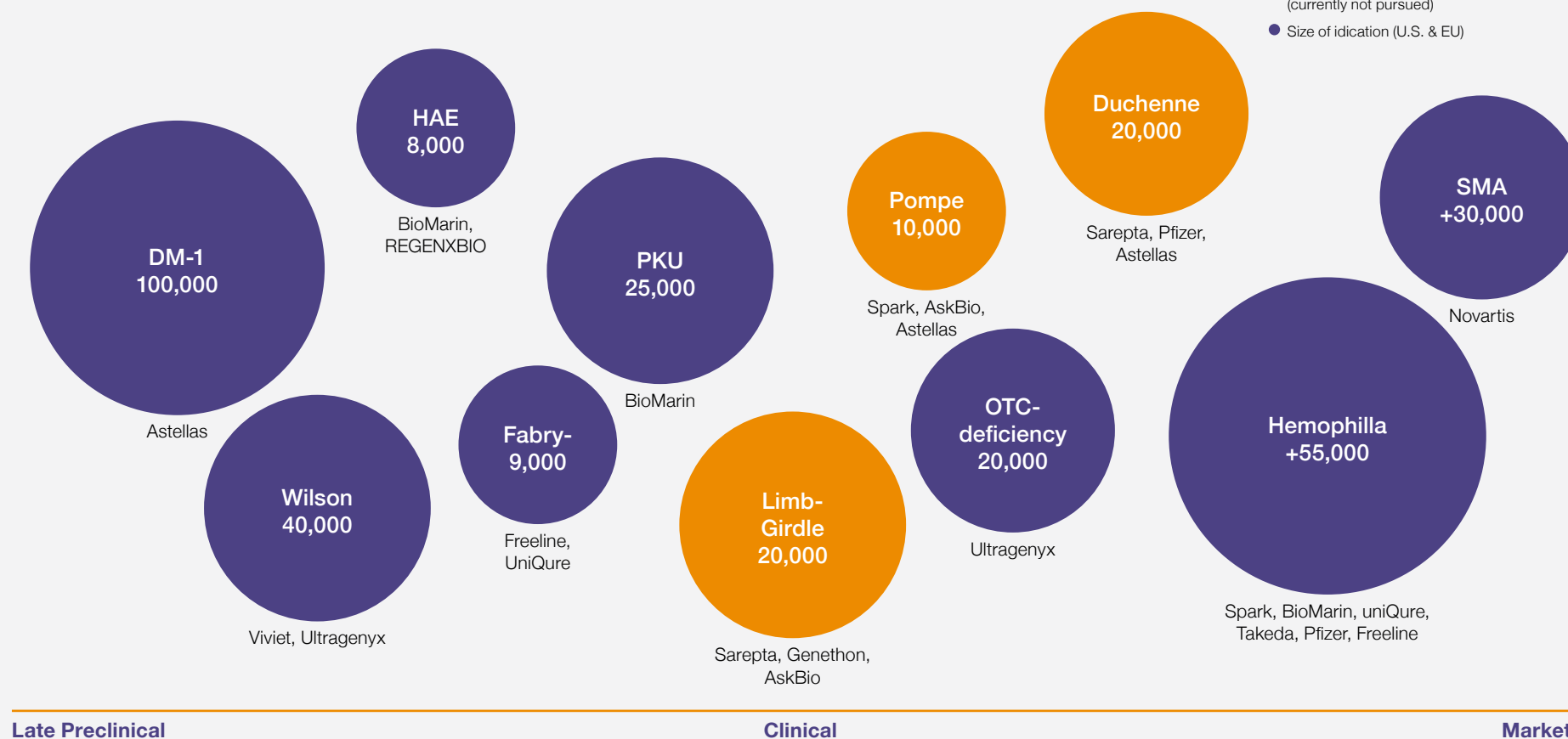
# Systemic gene therapy is an emerging opportunity

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

## Rare monogenic diseases

From hundreds of patients to thousands of patients

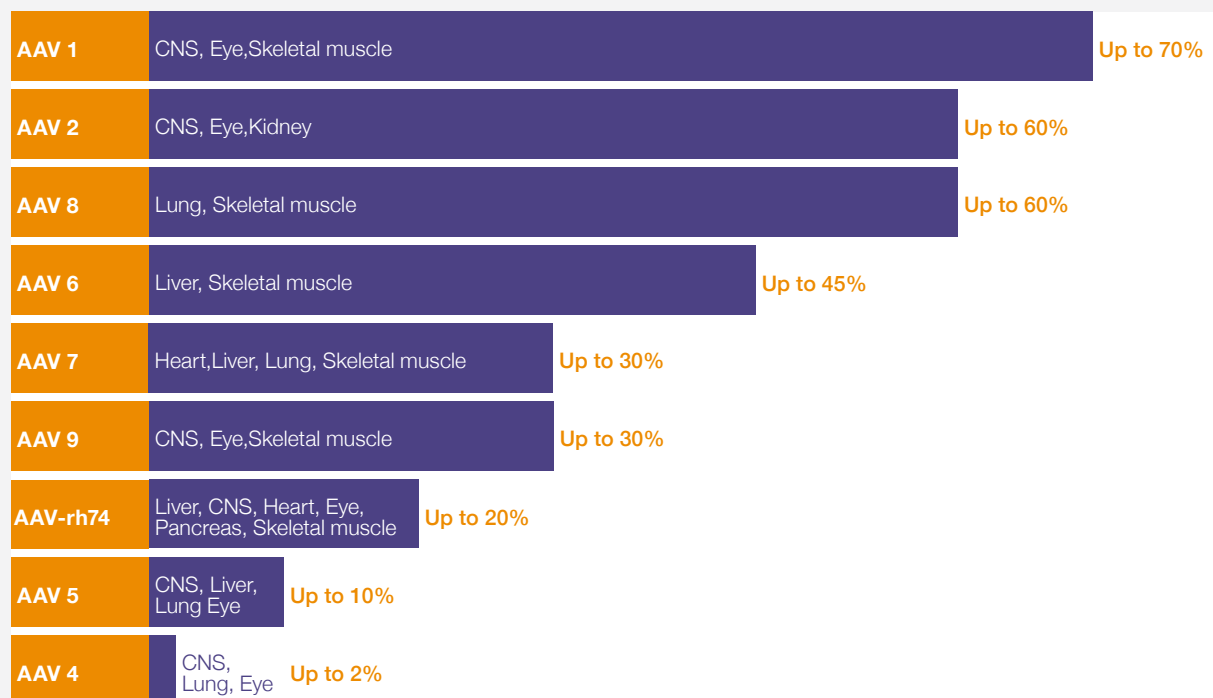
- Preclinical programs with Sarepta and AskBio
- Potential gene therapy indications (currently not pursued)
- Size of indication (U.S. & EU)





## Systemic gene therapy is an emerging opportunity continued

The prevalence of Nabs varies significantly and is a barrier that precludes gene therapies from working in a large group of patients



Prevalence of Nabs in AAVs

Tropism and target tissue

**Eye (local target)**

$\sim 1 \times 10^{11}$  vg



AAV 1, 2 & 5

**Brain (local target)**

$\sim 1 \times 10^{12}$  vg



AAV 4 & 8

**Liver (systemic)**

$\sim 1 \times 10^{14}$  vg



AAV 3, 7 & 8

**Muscle (systemic)**

$\sim 1 \times 10^{15}$  vg



AAV 6, 7, rh74

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)



# Collaboration with AskBio to evaluate feasibility of imlifidase as pre-treatment ahead of gene therapy in Pompe disease

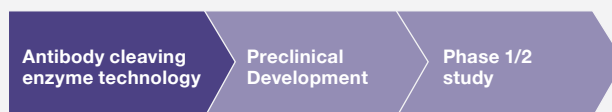
**Feasibility program to evaluate imlifidase as pre-treatment ahead of gene therapy in Pompe disease for patients with pre-existing neutralizing antibodies (NABs) to adeno-associated virus (AAV)**



#### Hansa's key resources and deliverables

- > Imlifidase validated with positive clinical efficacy and safety data as well as European approval
- > Significant know-how around antibody cleaving enzymes
- > Clear path to U.S. approval (kidney transplant)
- > Hansa supplies material and provides additional support

**Current agreement scoped around a feasibility program which covers preclinical work and a Phase 1/2 study**



**Upfront fee of USD 5m**

#### AskBio's key resources and deliverables

- > Early innovator in the Gene Therapy space with AAV platform and ongoing clinical stage Pompe disease program
- > Conducts pre-clinical and clinical trials according to agreed plan

**Exclusive option for AskBio to negotiate a potential full development and commercialization agreement**

#### Potential structure



**Potential milestone payments**

**Potential royalties and sales**



## Collaboration with AskBio to evaluate feasibility of imlifidase as pre-treatment ahead of gene therapy in Pompe disease continued

### Collaboration Agreement

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 will evaluate the potential use of imlifidase as a pre-treatment prior to the administration of AskBio's gene therapy in Pompe disease in a pre-clinical and clinical feasibility program for patients with pre-existing NABs to the adeno-associated viral vector used in AskBio's gene therapy.

Under the 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.

AskBio's gene therapy candidate, AAV2/8-LSPHGA, is being investigated for the treatment of Pompe Disease. This gene therapy candidate combines AAV2 and AAV8 capsids, to deliver a liver-specific promoter to express the GAA enzyme. It is currently being investigated by AskBio in an open-label, phase 1/2 study (ClinicalTrials.gov: NCT03533673), in which 8 patients with Late-Onset Pompe Disease will be enrolled. For further information regarding AskBio's gene therapy program in Pompe disease, please refer to [www.askbio.com](http://www.askbio.com).

### 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.

Up to 300 different mutations resulting in Pompe disease have been identified and the severity and age of onset is related to the specific mutations. The most severe forms (early onset or infantile form) result in, for example, an enlarged heart, muscle weakness and respiratory difficulties and most patients with the infantile form die from cardiac or respiratory failure before their first birthday. The late onset or juvenile/adult form initially presents as muscle weakness, progressing to respiratory weakness and death from respiratory failure after several years. 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>36</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>37</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>38</sup>.

<sup>36</sup> Pompe Disease, <https://rarediseases.org/rare-diseases/pompe-disease/>

<sup>37</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>38</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/>



# Exploration of HSCT as an opportunity for imlifidase

**As part of the Company's platform strategy and objective to broaden the application of imlifidase as a potential therapy to change the course of IgG-mediated immunological diseases and conditions, we are exploring new indications with high unmet need.**

One such indication is allogeneic HSCT, also known as "bonemarrow" transplantation. Desensitization treatment of patients with elevated levels of donor specific antibodies (DSA) prior to allogeneic HSCT transplant is a challenge, and currently there are no approved drugs to manage these patients. It is Hansa Biopharma's belief that imlifidase may have the potential to transform the standard of care by enabling clinicians to inactivate DSAs prior to transplantation so as to create the basis for successful transplantation.

Allogeneic HSCT is a key, potentially curative treatment intervention for patients with high-risk hematologic malignancies, with over 50,000 HSCT transplants performed annually, worldwide with approximately half being allogeneic<sup>39</sup>. The preferred donor for patients is a human leukocyte antigen, or HLA, matched individual. In the absence of HLA-matched donors, or when an urgent transplant is needed, haploidentical donors (siblings, parents, children) are now increasingly considered for transplantation. Overall, in haploidentical HSCT, the prevalence of donor-specific anti-HLA antibodies varies according to published data and may range between 10% and 21%<sup>40</sup>. This proportion is highly dependent on the recipient's

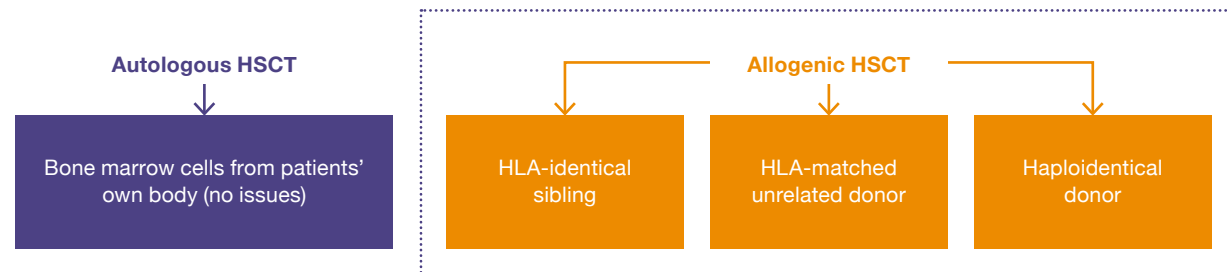
gender, with low prevalence in male recipients compared to female recipients, as a result of sensitization during pregnancies.

DSA have been recognized as an important barrier against successful engraftment of donor cells. Pre-existing DSA increase the risk of primary failure of engraftment of donor hematopoietic progenitor cells, leaving the patient in a state of marrow aplasia after transplantation and exposing the patient to a high risk of non-relapse mortality.

According to consensus guidelines from the European Society for Blood and Marrow Transplantation, if DSA levels have a Mean Fluorescence Intensity (MFI) above 1000, desensitization therapy is recommended, especially in patients with high DSA levels (>5000 MFI), which poses a very high risk of neutrophil engraftment failure. It is, therefore, also recommended that efforts be made to screen all patients before transplant, and desensitize patients with DSA prior to transplant to avoid the negative outcomes on neutrophil engraftment and patient survival.

Desensitization treatment of patients with high levels of DSA prior to allogeneic HSCT transplant remains a challenge, and currently there are no approved drugs to manage these patients. Different strategies, mostly adopted from solid organ transplantation approaches, have been explored to reduce the antibody titer or desensitize such patients, including antibody removal (plasmapheresis), inhibition of antibody production (rituximab, bortezomib), and increasing antibody turnover (e.g. IVIg), among others. Data for the effectiveness of these desensitization methods are derived from case reports and small case series. These approaches yield mixed results, whereby a significant proportion of patients will complete the transplant protocol with continued presence of DSA and risk to the allograft. Imlifidase may have the potential to transform the standard of care by enabling clinicians to inactivate DSA with a single administration prior to transplantation. Imlifidase can be readily integrated and operationalized within current practice at the time of transplant.

## Pre-existing DSAs may result in primary graft failure and poor survival after allogeneic hematopoietic stem cell transplantation



<sup>39</sup>[https://ashpublications.org/blood/article/134/Supplement\\_1/2035/427903/One-and-Half-Million-Hematopoietic-Stem-Cell](https://ashpublications.org/blood/article/134/Supplement_1/2035/427903/One-and-Half-Million-Hematopoietic-Stem-Cell)

<sup>40</sup>Ciurea et al. The European Society for Blood and Marrow Transplantation (EBMT) Consensus Guidelines for the Detection and Treatment of Donor-specific Anti-HLA Antibodies (DSA) in Haploidentical Hematopoietic Cell Transplantation. Bone Marrow Transplant. 2018;53(5):521-534. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7232774/>





## Exploration of HSCT as an opportunity for imlifidase continued

### Interview

**Sofia Järnum**

*Global Franchise lead New Therapies*

#### **Q. Hansa wants to broaden into a new disease area – why is that?**

**A.** The technology we have developed has great potential in many disease areas; oncology is just one we are now exploring. We are specifically focused on numerous indications within the rare disease space, where our technology appears to be most applicable, so expanding the number of indications we explore is a natural step for us.

#### **Q. Why is the therapeutic area of allogeneic HSCT so interesting?**

**A.** Matching of recipient and donor is a complex activity and as the average family size continues to decline, the likelihood of finding a matched, related donor, continues to decrease. Even though there are programs and registers in place to increase the chance of finding a perfect match for everyone, this sometimes fails and is a much longer process than when there is a related donor available. This is particularly troublesome for patients with more advanced disease in rapid need of a transplant. Donor specific antibodies are a major concern in allogeneic HSCT and are linked to primary graft failure and poor survival after HSCT. Our technology has the potential to remove donor specific antibodies, providing an opportunity to increase both the pool of available donors and number of patients who have access to a potentially life-saving therapy.

#### **Q. Who are affected, and why?**

**A.** Allogeneic HSCT is used as a treatment for many non-malignant and malignant diseases and is a treatment with a curative potential for many indications. Acute myeloid leukaemia (AML), acute lymphoid leukaemia (ALL) and myelodysplastic syndrome (MDS) are the main indications for which allogeneic HSCT is used. The major cause of sensitization to HLA antigens and development of donor specific antibodies are transfusions, previous transplant and pregnancies. Patients in need of allogeneic HSCT have often received transfusion support and are multiparous women, so the risk of being sensitized is higher among patients in need of an allogeneic HSCT compared to the average population.

#### **Q. How is Hansa advancing the science for allogeneic HSCT?**

**A.** Desensitization within allogeneic HSCT is building on the experience from desensitization strategies used within the kidney transplant field. However, the field is young, and no standard of care has been developed to manage patients with high levels of donor specific antibodies. We have the potential to impact standard of care for desensitization prior to allogeneic HSCT and our goal is to make our technology a game-changer for access to a potentially life-saving treatment.



Allogeneic HSCT is the only curative treatment intervention for most patients with high-risk hematologic malignancies, and presence of donor-specific antibodies is a contraindication to successful treatment.

**Sofia Järnum**

*Global Franchise lead New Therapies*

# Research and preclinical development projects

## NiceR – New set of enzymes for repeat dosing; potentially enabling treatment of relapsing diseases

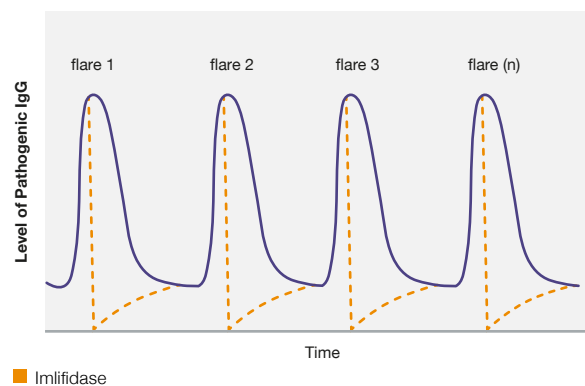
Hansa is developing novel IgG-degrading enzymes under the program name, “NiceR” (Novel Immunoglobulin Cleaving Enzymes for Repeat dosing). The objective of the enzymes developed from the NiceR program is to enable repeat dosing in a broad array of indications with significant unmet medical need including reoccurring transplantation, relapsing autoimmune diseases and oncology, where patients may benefit from more than one dose of an IgG-modulating enzyme.

A broad repertoire of novel immunoglobulin cysteine endopeptidases has been developed and patented within the program and a lead candidate was selected in 2019 for clinical development. The selected candidate is an IgG-cleaving enzyme (cysteine peptidase) with characteristics based on a homolog to imlifidase, but with potential for lowered immunogenicity.

Development of a GMP-manufacturing process is ongoing and IND-enabling toxicology studies for the lead NiceR candidate were initiated during the second quarter of 2021 in preparation for a clinical phase 1 study. Toxicology studies are expected to be completed in 2022 and, upon completion of these studies, Hansa expects to advance the NiceR program into the clinic.

## NiceR can potentially inactivate flares

Illustrative



■ Imlifidase

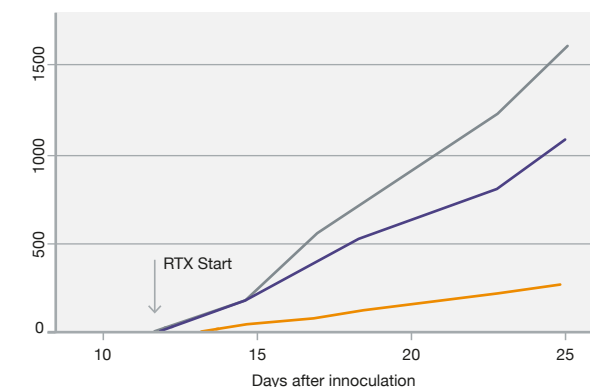
## EnzE – Enzyme-based antibody Enhancement

Hansa is currently investigating EnzE as a potential therapeutic intervention in oncology, in which imlifidase administration prior to therapeutic antibody treatment may lead to a more efficient anti-tumor therapy through cleaving the abundance of normal IgG in blood.

EnzE is currently a project in the research phase, while the proof-of-mechanism is being investigated. The concept is being evaluated in a B-cell lymphoma mouse model to demonstrate how pre-treatment with imlifidase in tumor patients may potentially increase the efficacy of currently available antibody-based cancer therapies.

High levels of plasma IgG in cancer patients have been shown to limit the efficacy of therapeutic antibodies, as plasma IgG can saturate the antibody receptors of the patient's immune cells, preventing them from efficiently killing the tumor cells. Removing plasma IgG with imlifidase or novel IgG-clearing enzymes from the NiceR program prior to dosing the patient with a therapeutic antibody may potentially increase the efficacy of a given cancer therapy.

## Mice with human IgG (~9mg/mL)



■ No treatment ■ Rituximab ■ Imlifidase + Rituximab

Source: 1 Järnum et al. Mol Cancer Ther 2017;16:1887-1897



# The share

Shareholder information	56
Ownership and analyst coverage	57



# Shareholder information

Hansa Biopharma's shares are listed on Nasdaq OMX Stockholm, under the ticker HNSA and are included in several indexes including, but not limited to:

- > OMX Nordic Mid Cap
- > OMX Nordic Health Care Index
- > OMX Stockholm Benchmark Index
- > OMX Stockholm Health Care
- > OMX Stockholm Mid Cap
- > OMX Stockholm Pharmaceuticals & Biotechnology
- > MSCI Global Small Cap
- > STOXX Europe Total Market Small Index

## Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	46,335,361 (44,473,452 ordinary shares and 1,861,909 C-shares)
Market Cap December 31, 2021	SEK ~4bn (USD ~440m)
Ticker	HNSA
ISIN	SE0002148817

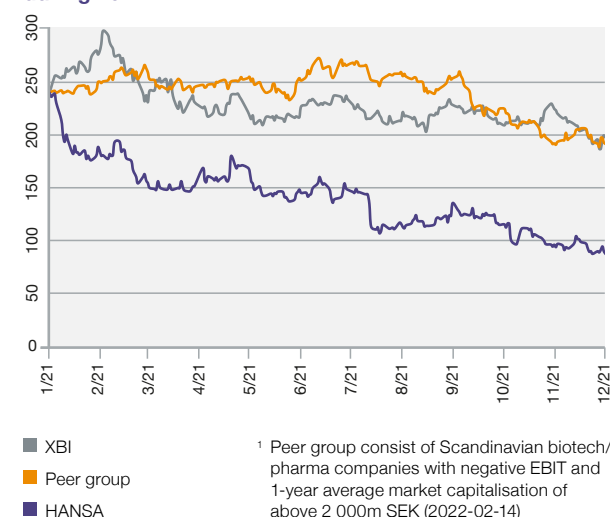
## Brief facts, the Hansa Biopharma-share

According to the shareholder register maintained by Euroclear Sweden AB, as of 31 December 2021, Hansa Biopharma had approximately 18,000 shareholders, compared to approximately 17,000 shareholders as of 31 December 2020. Information regarding shareholders and shareholdings is updated each quarter on the Company's website, [www.hansabiopharma.com](http://www.hansabiopharma.com).

## Share capital

Total shares issued as of 31 December 2021 amounted to 44,473,452 ordinary shares outstanding and 1,861,909 C-shares. At year end 2021, the share capital amounted to SEK 46,335,361. 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.

## Hansa share price development versus peer group<sup>1</sup> during 2021



## Price development for the HNSA share in 2020 and 2021

SEK	2021		2020	
	High	Low	High	Low
1st quarter	245.6	144.5	89.0	63.6
2nd quarter	180.9	132.2	177.2	78.2
3rd quarter	151.6	105.9	276.0	164.9
4th quarter	120.5	80.6	272.0	220.0



# Ownership and analyst coverage

## Top 10 largest shareholders, 31 December 2021

Owners	Number of shares HNSA	Capital (%)
Redmile Group	5,768,619	13
Handelsbanken Asset Management <sup>1</sup>	2,266,350	5.1
Fourth Swedish National Pension Fund	2,207,397	4.9
NXT2B	2,155,379	4.8
Invesco Advisers, Inc.	1,973,200	4.4
Thomas Olausson	1,820,500	4.1
Third Swedish National Pension Fund	1,389,650	3.1
Försäkrings AB Avanza Pension	1,232,081	2.8
Schroder Investment Management, LTD	1,160,900	2.6
The Vanguard Group, Inc.	1,158,200	2.6
Other	23,341,176	52.6
Outstanding ordinary shares in total	44,473,452	100

<sup>1</sup> Handelsbanken Asset Management decreased their ownership to under 5% during January 2022

## Hansa Biopharma shareholders

~18,000

AS OF 31 DECEMBER 2021

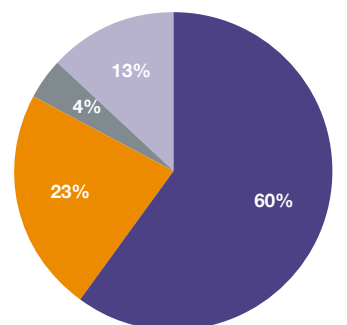
Source: IHS Markit/IPREO compiled and processed data from various sources, including Euroclear, Morningstar, Factset and the Swedish Financial Supervisory Authority (Finansinspektionen)

## Analyst coverage 2021 and 2022

Analyst	Bank / Research institution (year of initiation)	Location	Email	Phone
Christopher Uhde	SEB (2016)	Stockholm	christopher.uhde@seb.se	+46 (0) 876-385 53
Adam Karlsson	ABG Sundal Collier (2018)	Stockholm	adam.karlsson@abgsc.se	+46 (0) 8 566 286 91
Zoe Karamanoli	RBC (2017)	London	zoe.karamanoli@rbccm.com	+44 7834 765119
Naresh Chouhan	Intron Health Research (2020)	London	naresh@intronhealthresearch.com	+44 7939 224 322
Douglas Tsao	H.C. Wainwright (2021)	New York City	dtsao@hwcwresearch.com	+1 212-916-3968
Erik Hultgård	Carnegie (2019)	Stockholm	erik.hultgard@carnegie.com	+46 (0) 858-869 237
Johan Unnerus	Redeye (2008)	Stockholm	johan.unnerus@redeye.se	+46 (0) 724 023 385
Ludvig Svensson	Erik Penser Bank (2021)	Stockholm	ludvig.svensson@penser.com	+46 (0) 704 962 535
Lars Hatholt	Ökonomisk Ugebrev (2020)	Copenhagen	hatholt@outlook.com	+45 22 23 78 15
Ingrid Gafanhão	Kempen (2019)	Amsterdam	Ingrid.Gafanhao@kempen.com	+31 689 937 525
Caroline Banér	Danske Bank (2021)	Stockholm	caroline.baner@danskebank.se	+46 76 721 66 94

## Ownership by type and location, 31 December 2021

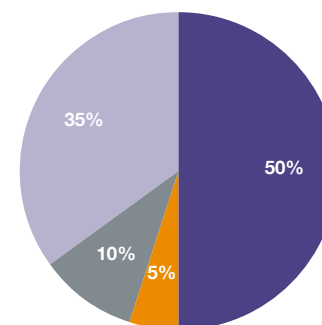
Ownership by country



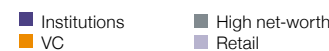
Split by region



Ownership by type



Investor type





# Directors' report

Directors' Report

59





# 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. Hansa's first-generation IgG-cleaving enzyme, imlifidase, is designed to inactivate IgG antibodies in the plasma and tissue through a single intravenous treatment. Idefirix (imlifidase) recently 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 has initiated 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 IgG-mediated autoimmune conditions such as anti-glomerular basement membrane, or anti-GBM, antibody disease and Guillain-Barre Syndrome, or GBS, as well as cancer.

Through collaborations with Sarepta Therapeutics, Inc. and Asklepios BioPharmaceutical, Inc. (AskBio) 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. In addition, Hansa entered a preclinical research collaboration with argenx BV to evaluate the therapeutic potential of combining the two companies' IgG-modulating technologies.

Beyond imlifidase, the Company's second-generation IgG-cleaving enzyme program, NiceR, is in preclinical development and is designed to enable expansion into a large spectrum of potential indications, including relapsing autoimmune diseases and gene therapy, as well as oncology indications. Through its preclinical EnzE program, Hansa is exploring the combined use of approved antibody-based cancer treatments with IgG-modulating enzymes. Hansa Biopharma is headquartered in Lund, Sweden and also has operations in other European countries and in the U.S.

## 2021 Business review

2021 was, overall, a transformative and successful year for Hansa as the Company advanced into a fully integrated, commercial-stage biopharmaceutical company following the commercial launch in Europe of Idefirix® (imlifidase). Hansa executed throughout the year on key priorities, including R&D, commercial and organizational objectives:

The Company progressed the launch of and market access efforts for Idefirix® in Europe, securing reimbursement in Sweden and the Netherlands as well as on a hospital basis in Finland and Greece while having market access procedures ongoing in 13 European countries, including key 5 markets. Also, Hansa recorded its first commercial sales in 2021.

Further, in December 2021, Hansa and Medison Pharma announced a multiregional commercialization partnership for Idefirix® covering Israel and key countries in the Central Eastern European region, i.e. Croatia, Hungary, Poland and Slovenia.

Hansa also progressed its pipeline activities by initiating the pivotal U.S. ConfideS phase 3 study in kidney transplantation and enrolled the first patients during December 2021 into the study. Also, the Company reported three-year follow-up data in crossmatch positive patients who received imlifidase prior to kidney transplantation demonstrating 3-year graft survival of 84%, confirming that imlifidase is a potent option to enable transplantation among patients who have a significant immunologic barrier to successful kidney transplantation.

Following the positive results from the completed investigator-initiated Phase 2 study and a successful pre-IND meeting with the U.S. FDA in fourth quarter 2021, the Company announced its intend to commence a Phase 3 study in 2022 marking an important milestone in the expansion of imlifidase into autoimmune diseases.

Recruitment into the ongoing phase 2 studies in AMR and GBS was continued progressing enrolment to 23 out of targeted 30 patients in the AMR trial and 15 out of targeted 30 patients in the GBS study as of December 31, 2021.

Beyond the collaboration with Medison on the commercial front, Hansa also entered a preclinical research collaboration with argenx BV (Argenx) to evaluate the therapeutic potential of combining the two companies' IgG-modulating technologies, imlifidase and efgartigimod, as well as an agreement with AskBio, a subsidiary of Bayer AG, to evaluate imlifidase in a pre-clinical and clinical feasibility program as pre-treatment ahead of gene therapy in Pompe disease in patients with pre-existing neutralizing antibodies (Nabs).

And finally, Hansa continued to build a high-performance team by attracting and integrating the most talented and experienced candidates, while creating a rewarding, productive and stimulating workplace for its employees. The progress the Company is making was again evidenced in 2021 as it received certification as a "Great Place to Work" for the second consecutive year by the GPTW Institute.

However, beyond the significant achievements during 2021, the Company has also seen its commercialization and pipeline activities, specifically related to the recruitment of patients in the ongoing GBS phase 2 study, significantly impacted by the COVID-19 pandemic and the emergence of the Omicron variant.



## Directors' Report continued

Given the current status and uncertainties around the COVID-19 pandemic, the Company may continue to see negative impact on its operational business and clinical trial activities, including potentially related to recruitment timelines for ongoing and planned clinical studies as well as the commercial launch of imlifidase in Europe.

Hansa will continue to monitor the situation very closely and diligently and implement further measures as required and keep the markets informed should the assessment of any potential impact change substantially.

### 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 reviewed and revised in 2020. It provides management with a facilitating framework providing guidance when dealing with risks inherent in achieving the organization's objectives and 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.

### Risks related to COVID-19 and public health crisis

The global outbreak of COVID-19 continues to rapidly evolve. While the extent of the impact of the current COVID-19 pandemic on the Company's business and financial results is uncertain, 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 the COVID-19 pandemic or any other 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 operations, the supply chain for the Company's ongoing and planned clinical studies, the availability of governmental and regulatory authorities to conduct inspections of the Company's clinical study sites, review materials submitted in support of the Company's applications for regulatory approval and grant approval for product candidates, and the success of the Company's commercial launch in Europe and potential other territories.

Due to the continued evolution and uncertain global impact of the COVID-19 pandemic, Hansa cannot precisely determine or quantify the impact this pandemic (or any potential future public health crisis) will have on the Company's business, results of operations and financial condition. The potential impact on the Company will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, scope and severity of the pandemic and the effectiveness of actions taken to contain and treat COVID-19, including global vaccination efforts.

The Company has experienced and may continue to experience delays in the initiation and completion of clinical studies, patient selection and enrollment or in the progression of the Company's activities related to its clinical studies and commercial launch activities, and the Company may encounter other negative impacts to its business due to the effects of the COVID-19 pandemic or any potential future public health crisis.

### 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,



## Directors' Report continued

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 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 the 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 argenix BV, Sarepta Therapeutics, Inc., Medison Pharma and Asklepios BioPharmaceutical, Inc. Such partnerships and agreements may be terminated, unsuccessful, not achieve the intended results and outcomes, not met 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 contract manufacturers/packagegers 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) and consequences for the Company in the event of deficiencies in GMP requirements, and potential withdrawal of approval from the regulatory authorities, in the respective territories, 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 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 negatively affect the Company's earnings and future prospects.



## Directors' Report continued

### 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 unreliable, and the EMA, FDA or other regulatory authorities may require Hansa to perform additional preclinical studies, analytical and laboratory work and/or clinical trials before 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.

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 increase, and the Company's ability to generate revenue could be delayed.

### Intellectual property

The value of Hansa 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 of 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.

### Dependence on key product

The Company has a thin and concentrated pipeline. The value of the Company is primarily dependent on success in the Company's leading development product candidate, imlifidase. The market value of the Company, and thus the Company's share price, would be significantly impacted or entirely lost by setbacks related to imlifidase.

### 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 finished 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, this 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.

### Financial risks

Hansa carries out capital-intensive and value generating pharmaceuticals 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 until the Company generates substantial revenues from any marketed product. The Company has historically financed its operations primarily through equity financings. 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 jurisdictions other than Europe



## Directors' Report continued

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.

### Sustainability and social responsibility

Hansa leverages its unique enzyme technology platform to develop innovative, lifesaving and life altering immunomodulating therapies, bring these to the patients with rare diseases who need them, and generate value to society at large.

By developing therapies that seek to prolong and significantly enhance the lives of people around the world, sustainability is why Hansa exists and works tirelessly to bring pioneering and life changing treatments to those who need them most. Hansa's vision is simple yet compelling, and whilst not easy to achieve is something that unites everybody associated with Hansa: *A world where patients with rare immunologic diseases can lead long and healthy lives.*

To read more on Hansa's approach to sustainability, please refer to our ESG strategy on page 18-20 and the "ESG" section on page 68-75 of this annual report for more details.

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

At Hansa, employees are the most valuable asset. They play a key role in reaching the Company's vision. Hansa strives to attract and keep the best talent. It values and promotes equality and inclusion in its workforce and across its global leadership. Hansa offers a range of personal and professional development opportunities such as, for example, career changes within Hansa, new project management roles, trainings and Hansa Academy. Hansa takes responsibility by ensuring good working conditions in a healthy and sustainable work environment.

Please refer to the section "Sustainability – our employees" on page 71 of this annual report for more details.

### Revenue and financial result

Revenue for 2021 amounted to SEK 33.9 million (2020: SEK 6.1m) and comprises of product sales in the amount of SEK 15.0 million, revenue recognition from the upfront payment the Company received under the Sarepta agreement in the amount of SEK 15.7 million, and royalty income and cost reimbursements from Axis-Shield Diagnostics (Abbott group) in an amount of SEK 3.2 million.

The loss from operation for the year 2021 amounted to SEK 547.0 million (2020: SEK 422.8m). Compared to the year 2020, 2021 expenses have increased primarily in line with the strategic objective to grow Hansa into a fully integrated commercial stage biopharmaceutical company and, as such, the increase reflects Hansa's expanding commercial footprint and increased activities including investments in key European markets, marketing, market access and supply chain

activities related to the launch of Idefix®. The result for 2021 includes non-cash expenses related to the Company's long-term incentive programs (LTIP) amounting to SEK 56.6 million (2020: SEK 43.3m).

Loss for the year 2021 amounted to SEK 548.3 million (2020: SEK 420.9m).

### Cash flow and financial position

Net cash used in operating activities amounted to SEK 481.2 million in 2021 (2020: SEK 290.3m). The increase in cash consumption is in line with the continued growth of the commercial footprint in Europe and the non-recurring 10 million U.S. dollar (SEK 81.9m) Sarepta upfront payment received in July of 2020.

### Five-year summary

KSEK, unless other stated	2021	2020	2019	2018	2017
Revenue	33,878	6,098	3,364	3,358	3,442
Sales, general and administration expenses	(327,269)	(202,987)	(167,310)	(90,387)	(43,723)
Research and development expenses	(230,764)	(227,191)	(192,949)	(154,558)	(137,060)
Other operating (expense)/income	(7,398)	2,270	(1,907)	(3,995)	1,479
Loss from operations	(546,978)	(422,807)	(359,668)	(246,498)	(176,083)
Loss for the year	(548,282)	(420,853)	(360,009)	(247,974)	(176,660)
Net cash used in operating activities	(481,168)	(290,274)	(334,775)	(204,560)	(150,105)
Cash and cash equivalents, including short-term investments	888,961	1,377,506	601,094	858,187	616,061
Shareholder's equity	757,573	1,242,124	562,815	859,876	630,661
Loss per share before and after the dilution (SEK)	(12.33)	(9.98)	(9.00)	(6.47)	(4.97)
Number of outstanding shares at the end of the year	44,473,452	44,473,452	40,026,107	39,959,890	37,087,386
Weighted average number of shares before and after dilution	44,473,452	42,176,872	40,020,429	38,326,098	35,519,029
Number of FTE's at the end of the year	131	87	74	52	33

In July 2020, Hansa successfully completed the placement of 4.4 million ordinary shares raising net proceeds of SEK 1,071 million.





## Directors' Report continued

Cash and cash equivalents including short term investments amounted to SEK 889.0 million as of December 31, 2021 (SEK 1,377.5m as of December 31, 2020), which is expected to finance Hansa's operations into 2023.

Building upon the financing mandate approved by the last AGM in June 2021, the Company has also started to evaluate options to secure financing Hansa's operations beyond 2023.

### Capital expenditures

Capital expenditures during 2021 amounted to SEK 2.6 million (2020: SEK 0.3m).

### Shareholders' equity

On December 31, 2021, shareholders equity amounted to SEK 757.6 million compared to SEK 1,242.1 million at the end of the financial year 2020.

### Parent Company

The Parent Company's revenue for 2021 amounted to SEK 33.9 million (2020: SEK 6.1m). The net loss for the Parent Company amounted to SEK 549.1 million for 2021 (2020: SEK 421.6m). On December 31, 2021, cash and cash equivalents including short-term investments amounted to SEK 882.6 million compared to SEK 1,371.8 million at the end of the year 2020.

The Parent Company's shareholders equity amounted to SEK 755.9 million as per December 31, 2021, compared to SEK 1,241.6 million at the end of 2020.

The Group consists of the parent company, Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc. and Hansa Biopharma Australia PTY LTD. Hansa Biopharma Inc. had four employees at the end of December 2021. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had four employees at the end of December 2021.

### 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 2021 comprised of 44,473,452 ordinary shares and 1,861,457 C-shares held by the Company as treasury shares. Each share has a nominal value of SEK 1 resulting in SEK 46,334,909 share capital and SEK 44,473,452 in outstanding share capital as of 31 December 2021.

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, 2021, the single largest shareholder in Hansa was Redmile Group LLC, with a total of 5,768,619 shares, representing 13.0 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 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 Biopharma's Board of Directors, the AGM resolved to adopt a long-term, share-based compensation program in 2021.

In 2021 the Board of Directors have decided to make certain amendments to LTIP2019 and LTIP2020 in order to account for the impact of the COVID-19 pandemic and changes to its operating environment as further outlined in Note 14 to the Group Financial Statements elsewhere in this Annual Report.

### 2021 Long-term incentive program

Hansa Annual General Meeting (the "AGM") on May 12, 2021 resolved to adopt a long-term incentive program, LTIP2021, based on (a) performance-based share rights and (b) employee stock options.

### LTIP2021 based on performance-based share rights

Under the terms of LTIP2021 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 shall carry a vesting period of three years commencing on the day of its allotment to a participant (the "Vesting Period").

The final number of shares a participant is entitled to receive is, amongst other terms, conditional upon if or to what extent the following performance conditions are met during the Vesting Period (the "Performance Conditions"):

- > Condition 1: U.S. FDA has accepted a BLA filing for approval of imlifidase in the U.S.
- > Condition 2: 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: At least 80 per cent of the targeted transplantation centers in Europe have been initiated
- > Condition 4: Total shareholder return of at least 25%

A maximum of 624,615 Share Rights may be allotted to participants under the LTIP 2021 from the day following the 2021 AGM up and until the day prior to the AGM in 2022.

As of December 31, 2021, 557,000 Share Rights have been allotted to plan participants.

### LTIP2021 based on stock options

The 2021 AGM also resolved to adopt an employee stock option program under the terms of LTIP2021. Senior executives may participate in the program and receive employee stock options free-of-charge.





## Directors' Report continued

Each employee stock option entitles the holder to receive one new ordinary share in Hansa Biopharma AB at an exercise price of SEK 192.20 corresponding to 125 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.

A maximum of 452,307 employee stock options may be allotted to participants under the LTIP2021 from the day following the 2021 AGM up and until the day prior to the AGM in 2022.

As of December 31, 2021, 430,000 employee stock options have been allotted to the plan participants under the LTIP2021.

Expenses related to share rights and employee stock options are reported in accordance with IFRS 2. The total expenses including social security contributions (based on social security tax of 31.4 percent) for the share rights and options under LTIP2021 allotted as of December 31, 2021, is expected to amount to approximately SEK 79.5 million, of which SEK 15.5m is included in the results for the Parent Company and the Group for the year 2021.

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

### 2021 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 guidelines adopted by the 2021 annual general meeting 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 who is supported by the Remuneration Committee and the CEO.

Please refer to the Remuneration Report elsewhere in this Annual Report for further information on remuneration to senior executives.

### 2022 proposed changes to remuneration guidelines for senior executives

The changes to the guidelines proposed by the Board of Directors stipulate that in order to drive the business outcomes through a tailored employee incentive program that balances individual achievement and organisational contribution it is proposed that the performance criteria for the "Annual Short-Term Incentive ("STI") shall include both corporate and individual objectives. Furthermore, it is proposed that the performance criteria, weighting and targets for the individual objectives under the STI are to be proposed, evaluated and approved annually CEO as manager for members of the executive committee or, if it is not the CEO, then the respective manager for such members of the executive committee, and for the CEO the Remuneration Committee. The proposed adjustments have been reflected in these guidelines which will be subject to the shareholders' approval at the annual general meeting 2022 and are appended to this document as an appendix to the Corporate Governance Section.

During 2021, neither the Remuneration Committee nor the Board of Directors received any comments or questions from the shareholders on the remuneration guidelines adopted at the 2021 AGM.

### Dividend

The Board proposes that no dividend will be paid for the financial year 2021. For more information about Hansa dividend policy, please refer to the Hansa 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.

### Annual general meeting 2022

The annual general meeting of Hansa Biopharma AB (publ) will take place on June 16, 2022. Notice to attend the annual general meeting will be published on Hansa website at: [www.hansabiopharma.com](http://www.hansabiopharma.com).

### Financial calendar 2022

April 7, 2022	Annual Report 2021
April 21, 2022	Interim report for January - March 2022
June 16, 2022	Annual General Meeting 2022
July 21, 2022	Half year 2022 report
October 20, 2022	Interim Report for January-September 2022



## Directors' Report continued

### Appropriation of loss carried forward

Unrestricted shareholders' equity in the Parent Company

#### SEK

Share premium reserve	2,572,925,209
Treasury shares	(1,861,909)
Loss carried forward	(1,312,352,987)
Result for the year	(549,097,916)
<b>Total</b>	<b>709,612,397</b>

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

#### SEK

Share premium reserve	2,572,925,209
Treasury shares	(1,861,909)
Loss carried forward	(1,861,450,903)
<b>Total</b>	<b>709,612,397</b>

The Group's and the Parent Company's results and financial position are shown in the section "Financials": further below in this Annual Report, which includes the statement of financial position, statement of profit or loss, statement of cash flow and statement of changes in equity as well as accompanying notes and supplementary information, which are an integral part of the financial statements.

### Address

Hansa Biopharma AB (publ)  
Scheelevägen 22, SE-223 63 Lund, Sweden

### Postal address

P.O. Box 785, SE-220 07 Lund, Sweden

### Registration number

556734-5359



# ESG

Sustainability

68

GRI

73



# Sustainability

## At Hansa, we have put sustainability at the core of our business, aiming to create value to society at large.

Therefore, in 2021 we began to formalize our approach to sustainability, both by advancing our ambitions and ensuring transparency in our activities. The first step in this process was a materiality analysis, which identified the most important aspects of sustainability for our stakeholders.

We aligned those material aspects with the UN Sustainable Development Goals, and used them to form the basis of our sustainability strategy, outlined in the strategy section of this report, pages 18-20. Our core focus is to promote Healthy patients, a Healthy planet and Healthy business, and have these lead us forward.

### Patient centricity



At Hansa, we want everyone to be able to live their life to the fullest and we are dedicated to helping patients in need, setting patient centricity at the core of our business.

One such group are highly sensitized patients in need of a kidney transplant, who currently are around 10 to 15% of patients on transplant waiting lists. Finding a donor match is particularly difficult for this patient group, and we work to find solutions to meet these unmet needs, as well as raising awareness of the condition to improve treatment options and management.

### Patient access

We are fully committed to bringing new, life-changing treatments to those who need them most. We believe access to medicines is a key part of patient centricity and recognize the challenges this can pose. As such, we support sustainable access to our treatments for all patients who need them.

To enhance access, we engage with health authorities, payers and patient organizations. We strive to ensure pricing and reimbursement on a per-patient price, making access to treatment as cost-effective as possible for hospitals. Additionally, we conduct advisory boards with key experts in the transplant field to identify any inequities in access or funding. We also support early access and have a bridging-access solution in place on a case-by-case basis.

### Collaborations with transplantation centers

In order to have a patient focus throughout our value chain, we collaborate with transplantation centers. During 2021, we collaborated with ~60 specialist transplantation centres in Europe as part of our imlifidase launch activities.

### Advancing the science

As an ambitious global company, we are focused on the bigger picture and want to be part of the solution at many levels. This means helping patients along their journey and engaging with the healthcare communities both in Europe and the U.S. We use this opportunity to not only raise awareness about the unmet needs of the patients we aim to help but also advance the understanding in these complex fields.

Our technology platform has a unique mechanism of action that makes it potentially suitable for many different applications. By rapidly inactivating potentially pathogenic antibodies, we may be able to impact a number of autoimmune conditions as well as pre-treatment in gene therapy. Every patient is unique, and this is



We are fully committed to bringing new life-changing treatments to those who need them most.

even more true in rare conditions. We have an opportunity to set new standards of care deemed impossible until now. This means we are in a position to provide impactful collaborations with the scientific and medical community, patient organizations, and research groups and use the science to shape a better future, have positive impact and create value across the entire system. And we want to do it one patient at a time.

### Expanding access to new markets

Imlifidase is approved in the EU and the U.K. and expansion is planned to the U.S. and to international markets. Each market represents its own challenges with regards to access to medicines, sometimes meaning new approaches will be required to support the expansion of a novel medicine. Thus, we strive to provide patients with early access to imlifidase with compassionate use and bridge-financing approaches on a case-by-case basis.

### Health equity

Our ambition is to increase equity in healthcare for patients with rare immunological conditions and to support and amplify the patient's voice. By working closely with healthcare professionals and patient organizations we hope to facilitate better treatment outcomes for our patients. One focal point for us in this regard is raising awareness of care disparities by gender and ethnicity experienced by highly sensitized kidney patients. We have also used our social media channels to amplify and raise awareness of the health inequities faced by highly sensitized patients.

### Training programs

As the decision to treat a patient with imlifidase is a complex one, made by many members in a specialist team of transplantation physicians and nurses, we have developed an onboarding program for health care personnel and transplant centers, which has been rolled out during 2020 and 2021.



## Sustainability continued

### Collaborations with patient advocacy groups and healthcare professional

Hansa works closely with patient organizations and supports several initiatives targeting health inequities. We support the European Society for Organ Transplantation (ESOT) to keep evolving their recommendations on standard of care for desensitization of highly sensitized kidney transplant patients, which seeks to keep guidelines up to date with the latest innovative treatments. This year, Hansa sponsored a new workstream by ESOT on desensitization through an unrestricted educational grant. Their workstream, involving leading transplantation specialists, aims to update European clinical guidelines for desensitization practices in highly sensitized kidney transplant patients.

As part of our ambitions to increase health equity and awareness of highly sensitized patients, we are also interacting with Europe- and U.S.-wide patient advocacy groups, such as the European Kidney Patient Federation, European Kidney Health Alliance, American Association of Kidney Patients, American Kidney Fund, American Society of Transplantations, the American Society of Transplantation and The Dutch Kidney Foundation which have a world-wide reach. In-country patient advocacy groups include Njurförbundet in Sweden, Kidney Care in U.K. and Renaloo in France. Through collaboration with several patient organizations, we aim to further strengthen the voice of the patient.

### Unmet medical needs

The patients we help are our key focus, and give us the motivation to continue developing life-altering therapies to address the unmet needs that remain amongst those living with rare conditions. We are therefore pleased that in late 2020, imlifidase received conditional approval in the EU for highly sensitized adult kidney transplant patients. We are also in dialogue with the FDA concerning future market authorization

in the U.S. Additionally, we have initiated two Phase 2 clinical studies in additional autoimmune indications, and we are planning to conduct a further phase 3 study, to further expand our portfolio and address unmet needs.

We are partnering with Sarepta to potentially expand the use of imlifidase in the field of gene therapy as a pre-treatment in clinical studies. The partnership with Sarepta is progressing as planned with pre-clinical investigations using imlifidase being currently ongoing. First few days in 2022, Hansa also reached an agreement with AskBio to further partner in the field of gene therapy, to evaluate feasibility of imlifidase as pre-treatment ahead of gene therapy for Pompe Disease.

Another key partnership Hansa embarked on in 2021 was with argenx. Our pre-clinical research collaboration agreement will explore the potential of combining imlifidase, Hansa's IgG antibody-cleaving enzyme, and efgartigimod, argenx's FcRn antagonist, to potentially unlock additional therapeutic value in both the acute and chronic setting of autoimmune diseases and transplantation.

Second week of 2022, Hansa also announced its intention to explore the possibility of expanding its pipeline into allogeneic hematopoietic stem cell transplantation (HSCT), also known as "bone-marrow transplantation". Anti-HLA antibodies against the donor may prevent the successful engraftment of donor cells in a patient requiring allogeneic HSCT. Allogeneic HSCT is the only curative treatment intervention for most patients with high-risk hematologic malignancies, with over 50,000 transplants performed annually worldwide.

Desensitization treatment of patients with high levels of donor specific antibodies (DSA) prior to allogeneic HSCT transplant is a challenge, and currently there are no approved drugs for managing these patients. Imlifidase may have the potential to

transform the standard of care by enabling clinicians to inactivate DSAs prior to transplantation and has thus the potential to enable successful transplantation. Treatment with imlifidase would potentially be a major advancement to currently available treatments.

### Patient safety

In our endeavor to provide life-altering therapies for people with rare immunological conditions, the safety of our patients is at the center of all of our work. We value both the safety and care of our patients and have systems in place to guarantee patient safety.

We aim to go beyond just compliance with applicable laws and regulations in our pre-clinical and clinical studies to ensure our therapies meet the highest pharmaceutical standards. All studies during the development phase of a treatment assess the efficacy and safety of the treatment. We always conduct our research with the upmost scientific integrity and educate our employees continuously on patient safety.

Hansa maintains a close dialogue with relevant authorities to ensure the safety of our products. In 2021, Hansa worked with EU authorities on the conditional marketing approval for imlifidase and post-efficacy study, and with the FDA in the United States on the regulatory path forward for imlifidase in kidney transplantation (Phase 3 study design) and anti-GBM (Phase 3 study design). The regulatory authorities carry out regular inspections of our facilities. Besides that, Hansa performs due diligence of our suppliers.

To ensure product quality, Hansa has a quality management system in place, which continuously perform pharmacovigilance activities and have a firmly integrated system for adverse events reporting, which ensures timely and transparent analysis.



## Sustainability continued

Hansa is also committed to support optimal patient care. Therefore, we onboard health care professionals and work closely with patient organizations to understand patients unique perspectives, aiming to achieve better treatment outcomes for all.

### Ethical business practices



#### Code of conduct and supplier code

The pharmaceutical industry is a strongly regulated sector with global supply chains and many organizations working together. All new employees take part in Company legal and compliance onboarding meetings, which introduce the company's most relevant legal and compliance policies, including the code of conduct. During 2021, six Company legal and compliance onboardings have taken place throughout the year. Our code of conduct reflects our values, providing our employees with guidance on how to do the right thing in their everyday role. The code of conduct covers topics such as anti-corruption, medical ethics, diversity and inclusion, supplier selection and sustainability.

Our responsible business practices concern our entire value chain. Just as Hansa holds itself to the highest ethical standards, we expect the same level of integrity from our suppliers. Therefore, Hansa selects its suppliers and enters new partnerships carefully. We ensure that our direct suppliers and partners maintain the high standards in regards to social, financial and environmental issues that we set ourselves through our supplier code. The supplier code is

therefore implemented into Hansas contract templates. Suppliers are also risk assessed and audited in accordance with our quality procedures.

#### Anti-corruption

Hansa has a zero tolerance to corruption, and our anti-corruption and anti-bribery commitment is manifested in our code of conduct. Since the risk for corruption is largest in relation to healthcare professionals, our policies are carefully considered to provide guidance on all key risk areas, including contractual arrangements with healthcare professionals; grants, sponsorships, and donations; as well as a compliant communications with healthcare professionals.

Hansa encourages the reporting of any suspected unethical behavior and have ensured appropriate channels to make this easy to do. If employees feel unable to discuss concerns with their direct manager, the Compliance Officer or Human Resources, a third-party whistleblowing service is also available to them, to remove any barriers that may prevent reporting. Information on the whistleblowing process is available in the code of conduct and on Hansa's intranet. During 2021, no reports were made and investigated.

#### Data privacy

Data privacy and protection plays a pivotal role in Hansa's way of working, so that data from our patients, clinical studies, employees and other business partners are protected. Data privacy is part of Hansa's code of conduct to ensure that all employees are educated on how to handle personal data. During 2021, we have worked to expand the resources available to employees on data privacy, including internal presentations and three online courses on data privacy for all

employees. These resources are designed to enable employees to uphold Hansa's stringent policies on data privacy and data subject rights. The guidelines and policies are instrumental for Hansa to comply with all applicable laws and regulations that protect the privacy of personally identifiable information and protected health information such as the General Data Protection Regulation (GDPR) in the European Union. With our IT Incident Handling Policy, we have a process in place to detect, report and manage data breaches of both data privacy and cyber security. During 2021, no reports of suspected personal data breaches were issued.



Just as Hansa holds itself to the highest ethical standards, we expect the same level of integrity from our suppliers.





## Sustainability continued

### Our employees

At Hansa, our employees are our most valuable asset. They play a key role in reaching our vision. We strive to attract and keep the best talent and want to encourage a diverse and inclusive workplace.

Hansa has systematic and preventive work environment safety processes in place, to safeguard employees, especially in our laboratories. We also place great importance on the psychological safety and wellbeing of our teams, many of whom work remotely.

By providing a range of personal and professional development opportunities such as career changes within Hansa, new project management roles, trainings and Hansa Academy, we aim to strengthen the skill sets of all our employees, enabling them to excel in their roles. These career development opportunities are individually planned during each employee's continuous performance reviews. Hansa also conducts an annual employee satisfaction survey, to get feedback on how Hansa can further improve. The results of our 2021 survey led to Hansa being certified a Great Place to Work® for the second consecutive year.

We have also implemented a living donor policy in line with the living Donor Circle of Excellence, ensuring no employee at the company would face negative financial consequences should they wish to become a living organ donor. No employee had the need to use this policy, but we believe it reflects who we are and what we do.

We value and promote equality and inclusion in our workforce and across our global leadership. To ensure our Company is inclusive, we have implemented a diversity and inclusion policy,

which promotes a fantastic blend of gender, age, ethnicity, cultural background and sexual orientation – whether we have a disability, gender identity and gender expression, level of education, family situation, values, and so forth. In 2021, we were proud to count people from more than 30 different nationalities among our workforce, and to onboard 46 new colleagues from many new territories. Having identified standout candidates in these locations, Hansa is attracting leading talent from across the world. This equated to a global growth for Hansa of 56%, all while maintaining a low employee turnover of 8.7%.

To specifically ensure gender equality at Hansa, we conduct yearly salary surveys to ensure that men and women receive equal pay for equivalent work. It serves as a tool for Hansa to avoid salary drift and to discover any unconscious discrimination. In 2021, no differences due to gender were found.

We continue to monitor the diversity at different levels of our company, with the goal of identifying areas for improvement and addressing them over time. In 2021, the board composition is 33% (2020: 33%) women and 67% (2020: 67%) men. On management level, the gender distribution was 45% (2020: 50%) women and 55% (2020: 50%) men. This compares to the company as a whole of 61% (2020: 57%) women and 39% (2020: 43%) men.

#### 56% employee growth

46

NEW COLLEAGUES FROM  
MANY NEW TERRITORIES

30

DIFFERENT NATIONALITIES

8.7%

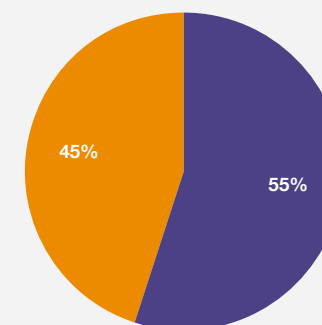
LOW EMPLOYEE  
TURNOVER RATE



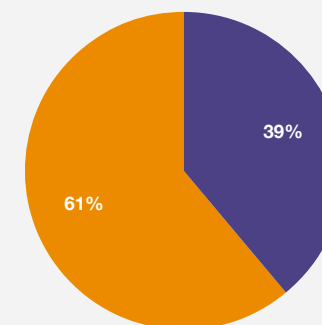
Hansa has been certified a Great Place to Work for the second consecutive year.

### Diversity levels of Hansa (F2021)

#### Management level



#### Company as a whole



#### Split by gender

■ Men  
■ Women



## Sustainability continued

### Environmental protection



While Hansa's production operations are small in scope, we are nevertheless committed to monitoring our environmental impact so we can reduce it where we can. Environmental impacts can be both direct and indirect, stemming not only from internal operations but the entire value chain. During 2021, we began to conduct comprehensive measurements of our footprint to better understand and minimize our impact.

During 2021, 63% of the energy (including 75% of the electricity) used in our operations was renewable, a proportion we hope to increase in coming years.

Energy consumption during 2021 (in kWh)

Electricity	207 360
Of which renewable	115 520
District heating	120 420
Of which renewable	120 420
Cooling	47 100
Total	374 880 kWh

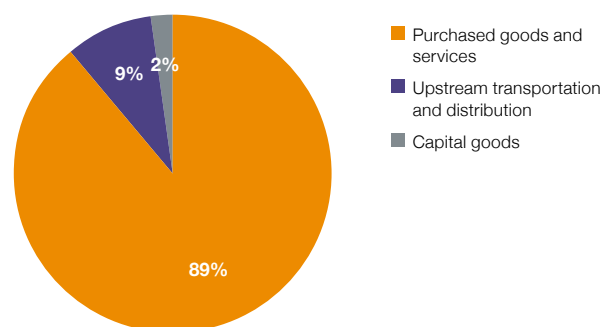
In this first report of its greenhouse gas emissions, the emissions stemming from Hansa's activities in 2021, including indirect emissions from purchased electricity, district heating and cooling (scope 2); as well as other indirect emissions from upstream activities (scope 3) can be seen in the below table. Hansa follows the Greenhouse Gas (GHG) protocol for calculating CO<sub>2</sub> emissions.

Emissions (in ton CO<sub>2</sub>-eq)

Scope 2	23
Scope 3	4 869

Of the measured emissions for 2021, purchased goods and services were the main source of emissions, followed by upstream transportation and distribution, and capital goods.

#### Breakdown of scope 3 emissions by category



Going forward, Hansa plans to extend its emissions reporting to identify further emission sources and take steps to minimize emissions from its value chain.

In our production, we also want to continue to reduce both the use of environmentally hazardous substances and the production of hazardous waste, as much as possible. Our current product is an organic molecule, an enzyme derived from a living bacteria, and therefore is completely degraded by the body on use. The limited discharges made from our laboratories consist of common salts and biodegradable organic substances. For more harmful byproducts and substances, strict handling and disposal routines are in place and are being sent to a recycling center for recycling and waste treatment. Hansa's operations are subject to a notification obligation under the Swedish Environmental Code with a reporting obligation to the municipality of Lund.



# GRI

GRI Standard	Disclosure	GRI Standard Disclosure description	Page	Comment
<b>General disclosures – GRI 102</b>	<b>Organisational Profile</b>			
	102-1	Name of the organization	66	
	102-2	Activities, brands, products, and services	3, 14, 59	
	102-3	Location of headquarters	66	
	102-4	Location of operations	3, 82	
	102-5	Ownership and legal form	64, 81, 128-130	
	102-6	Markets served	15, 25-26	
	102-7	Scale of the organization	63-64, 117	
	102-8	Information on employees and other workers	71, 117	
	102-9	Supply chain	70	
	102-10	Significant changes to the organization and its supply chain	6, 59-60	
	102-11	Precautionary Principle or approach	68-70	
	102-12	External initiatives	20	
	102-13	Membership of associations		Hansa Biopharma is a member of several industry associations.
	<b>Strategy and analysis</b>			
	102-14	Statement from senior decision-maker	5, 7-9	
	102-15	Key impacts, risks, and opportunities	18, 60-63	
	<b>Ethics and integrity</b>			
	102-16	Values, principles, standards, and norms of behavior	70	
	<b>Governance</b>			
	102-18	Governance structure	20, 128-129	
	<b>Stakeholder engagement</b>			
	102-40	List of stakeholder groups	19, 57	
	102-41	Collective bargaining agreements		Employees are not covered by collective bargaining agreements.
	102-42	Identifying and selecting stakeholders	18-19	
	102-43	Approach to stakeholder engagement	18-19	
	102-44	Key topics and concerns raised	18	



## GRI continued

GRI Standard	Disclosure	GRI Standard Disclosure description	Page	Comment
<b>General disclosures – GRI 102</b>	<b>Reporting practice</b>			
	102-45	Entities included in the consolidated financial statements	81-89	
	102-46	Defining report content and topic Boundaries	18-19, 81-89	
	102-47	List of material topics	18	
	102-48	Restatements of information		Not applicable. This is the first report.
	102-49	Changes in reporting		Not applicable. This is the first report.
	102-50	Reporting period	2021	
	102-51	Date of most recent report		Not applicable. This is the first report.
	102-52	Reporting cycle		Yearly
	102-53	Contact point for questions regarding the report		Katja Margell, Head of Corporate Communications, katja.margell@hansabiopharma.com
	102-54	Claims of reporting in accordance with the GRI Standards		This report has been prepared in accordance with the GRI Standards: Core level
	102-55	GRI content index	73-75	
	102-56	External assurance		This Sustainability Report has not been externally verified.
<b>Management approach – GRI 103</b>	103-1	Explanation of the material topic and its Boundary	18	
	103-2	The management approach and its components	18-20, 68-72	
	103-3	Evaluation of the management approach	18-20, 68-72	
<b>Topic-specific disclosures – GRI 200: Economic</b>	201-1	Direct economic value generated and distributed	77-80	
	203-2	Significant indirect economic impacts	68-69	
	205-1	Operations assess for risks of anti-corruption	70	
	205-2	Communication and training about anti-corruption policies and procedures	70	
	205-3	Confirmed incidents of corruption and actions taken	70	



## GRI continued

GRI Standard	Disclosure	GRI Standard Disclosure description	Page	Comment
<b>Topic-Specific Disclosures – GRI 300: Environmental</b>	302-1	Energy consumption within the organization	72	
	305-2	Energy indirect (Scope 2) GHG emissions	72	
	305-3	Other indirect (Scope 3) GHG emissions	72	
	306-2	Management of significant waste-related impact	72	
<b>Topic-specific disclosures – GRI 400: Social</b>	401-1	New employee hires and employee turnover	71, 117	
	404-2	Programs for upgrading employee skills and transition assistance programs	71	
	404-3	Percentage of employees receiving regular performance and career development reviews	71	
	405-1	Diversity of governance bodies and employees	71	
	413-1	Operations with local community engagement, impact assessments, and development programs	68-69	
	414-1	New suppliers that were screened using social criteria	70	
	416-1	Assessment of the health and safety impacts of product and service categories	69	
	417-1	Requirements for product and service information and labeling	69-70	
	418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data	70	

# Financials

The Group Financial Statements	77
Notes to the Group Financial Statements	81
Parent Company Financial Statements	108
Notes to the Parent Company Financial Statements	112
Signatures	122
Auditor’s Report	123



# The Group Financial Statements

## Consolidated statement of financial position

(in thousands of SEK)	Note	As of December 31,	
		2021	2020
<b>ASSETS</b>			
<b>Non-current assets:</b>			
Intangible assets	4	28,761	31,410
Property and equipment	5	6,432	5,206
Right-of-use assets	6	35,273	4,493
<b>Total non-current assets</b>		<b>70,466</b>	<b>41,109</b>
<b>Current assets:</b>			
Inventories	7	242	98
Trade receivables	8	9,712	110
Prepaid expenses and accrued income	9	20,889	5,716
Other receivables	10	22,538	9,957
Short-term investments	20	237,619	238,144
Cash and cash equivalents	20	651,342	1,139,362
<b>Total current assets</b>		<b>942,342</b>	<b>1,393,387</b>
<b>TOTAL ASSETS</b>		<b>1,012,808</b>	<b>1,434,496</b>
<b>EQUITY</b>			
Share capital	22	46,335	45,895
Share premium	23	2,572,925	2,509,458
Treasury share reserve	24,25	(1,862)	(1,421)
Other reserves	25	127	(137)
Accumulated deficit		(1,859,953)	(1,311,671)
<b>Total equity attributable to owners of the parent company</b>		<b>757,573</b>	<b>1,242,124</b>

(in thousands of SEK)	Note	As of December 31,	
		2021	2020
<b>LIABILITIES</b>			
<b>Non-current liabilities:</b>			
Lease liabilities	6	28,491	630
Deferred revenue	13	47,020	62,026
Contingent consideration	18	722	663
Provisions	15	7,357	14,426
Deferred tax liabilities	16	426	424
<b>Total non-current liabilities</b>		<b>84,016</b>	<b>78,169</b>
<b>Current liabilities:</b>			
Lease liabilities	6	6,888	4,415
Trade payables	20	53,360	26,669
Other liabilities	12	13,548	9,588
Deferred revenue	13	24,961	17,406
Accrued expenses	11	72,462	56,125
<b>Total current liabilities</b>		<b>171,219</b>	<b>114,203</b>
<b>Total liabilities</b>		<b>255,235</b>	<b>192,372</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>1,012,808</b>	<b>1,434,496</b>

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





## The Group Financial Statements continued

### Consolidated income statement

(in thousands of SEK, except for shares and per share data)	Note	Years Ended December 31,	
		2021	2020
Revenue	13	33,878	6,098
Cost of revenue		(15,425)	(997)
Other operating income	27	—	2,270
Sales, general and administrative expenses	28	(327,269)	(202,987)
Research and development expenses	28	(230,764)	(227,191)
Other operating expenses	27	(7,398)	—
<b>Loss from operations</b>		<b>(546,978)</b>	<b>(422,807)</b>
Finance income	21	67	2,170
Finance expenses	21	(1,219)	(257)
Loss before tax		(548,130)	(420,893)
Income tax benefit (expense)	16	(152)	40
<b>Loss for the year</b>		<b>(548,282)</b>	<b>(420,853)</b>
Loss for the year attributable to owners of the parent		(548,282)	(420,853)
Loss per share, basic and diluted	17	SEK (12.33)	SEK (9.98)
<b>Weighted-average number of ordinary shares outstanding, basic, and diluted</b>		<b>44,473,452</b>	<b>42,176,872</b>

### Statement of other comprehensive income

(in thousands of SEK, except for shares and per share data)	Note	Years Ended December 31,	
		2021	2020
<b>Loss for the year</b>		<b>(548,282)</b>	<b>(420,853)</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		264	(297)
<b>Other comprehensive income (loss) for the year</b>		<b>264</b>	<b>(297)</b>
<b>Total comprehensive loss for the year</b>		<b>(548,018)</b>	<b>(421,150)</b>
<b>Total comprehensive loss for the year attributable to owners of the parent</b>		<b>(548,018)</b>	<b>(421,150)</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, except for shares and per share data)	Note	Years Ended December 31,	
		2021	2020
<b>Cash Flows from Operating Activities</b>			
Loss for the year		(548,282)	(420,853)
<b>Adjustments to reconcile net loss to net cash flows:</b>			
Depreciation and amortization expenses		8,606	7,666
Expenses related to incentive programs		56,624	43,348
Costs related to pension plan		(226)	141
Unrealized currency differences		(6)	275
		<b>(483,284)</b>	<b>(369,423)</b>
<b>Changes:</b>			
(Increase) decrease of trade receivables	8	(9,602)	412
Increase of other operating receivables		(29,756)	(3,885)
Increase (decrease) trade payables		28,577	(23,897)
Increase of other operating liabilities		13,668	106,693
<b>Total changes</b>		<b>2,887</b>	<b>79,323</b>
Interest paid, net		(627)	(68)
Income taxes paid		(143)	(105)
<b>Net cash used in operating activities</b>		<b>(481,168)</b>	<b>(290,274)</b>
<b>Cash Flows from Investing Activities</b>			
Proceeds from sale of short-term investments		—	182,828
Acquisition of property and equipment	5	(2,399)	(294)
<b>Net cash (used in) from investing activities</b>		<b>(2,399)</b>	<b>182,534</b>

Note	Years Ended December 31,	
	2021	2020
<b>Cash Flows from Financing Activities</b>		
Proceeds from issue of ordinary shares, net of transaction costs <sup>(1)</sup>	—	1,070,581
<b>Payment of lease liabilities</b>	6	(4,674)
<b>Net cash (used in) from financing activities</b>	<b>(4,857)</b>	<b>1,065,906</b>
Net change in cash and cash equivalents	(488,424)	958,166
Cash and cash equivalents at beginning of year	1,139,362	181,697
<b>Effects of movements in exchange rate on cash held</b>	<b>403</b>	<b>(501)</b>
<b>Cash and cash equivalents at end of year</b>	<b>651,342</b>	<b>1,139,362</b>

<sup>(1)</sup> Total share issue cost amounted to SEK 41,255k in the year 2020.

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	Fair Value Reserve	Accumulated deficit	Total equity attributable to owners of the parent company
<b>Balance at January 1, 2020</b>		41,448	1,413,447	(1,421)	160	81,003	(971,821)	562,815
<b>Consolidated statement of profit or loss and other comprehensive income (loss):</b>								
Loss for the year		—	—	—	—	—	(420,853)	(420,853)
Other comprehensive loss for the year		—	—	—	(297)	—	—	(297)
<b>Total comprehensive loss for the year</b>		—	—	—	(297)	—	(420,853)	(421,150)
Reclassification of fair value reserve		—	—	—	—	(81,003)	81,003	—
Issue of ordinary shares <sup>(1)</sup>		4,447	1,066,133	—	—	—	—	1,070,581
<b>Long term incentive program</b>		—	29,878	—	—	—	—	29,878
<b>Balance at December 31, 2020</b>	22,23,24,25	45,895	2,509,458	(1,421)	(137)	—	(1,311,671)	1,242,124
<b>Consolidated statement of profit or loss and other comprehensive income (loss):</b>								
Loss for the year		—	—	—	—	—	(548,282)	(548,282)
Other comprehensive income for the year		—	—	—	264	—	—	264
<b>Total comprehensive loss for the year</b>		—	—	—	264	—	(548,282)	(548,018)
Issue of Class C shares <sup>(2)</sup>		440	—	(440)	—	—	—	—
Long term incentive program		—	63,467	—	—	—	—	63,467
<b>Balance at December 31, 2021</b>	22,23,24,25	46,335	2,572,925	(1,862)	127	—	(1,859,953)	757,573

<sup>(1)</sup> Total share issue cost amounted to SEK 41,255 in the year 2020.

<sup>(2)</sup> The year 2021 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 pioneering commercial-stage biopharmaceutical corporation on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. The Company has developed an immunoglobulin G (IgG) antibody cleaving enzyme therapy, imlifidase, which can enable kidney transplantation in highly sensitized patients and is also being developed as a potential treatment in different autoimmune indications. Hansa has received conditional approval of Idefix (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. and Hansa Biopharma Australia PTY LTD.

## 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 the 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, 2021, and for the comparative information as of and for the year ended December 31, 2020. 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, 2021, and for the year then ended were approved by the Board of Directors of the Group and authorized for issue on April 6, 2022.

### Changes in Accounting Policies and Disclosures

Several amendments to and interpretations of IFRS applied for the first time in 2021, 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.

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 consolidation. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.



## Notes to the Group Financial Statements continued

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

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

Subsidiaries	Registered office/Country	Share ownership percentage (%)	
		2021	2020
Cartela R&D AB	Lund, Sweden	100	100
Hansa Biopharma Ltd	Cheltenham, UK	100	100
Hansa Biopharma Inc	Delaware, USA	100	100
*Hansa Biopharma Australia Pty Ltd	Australia	100	—

\*Dormant company

Because the functional currency for Hansa Biopharma Ltd and Hansa Biopharma Inc is the UK Pound Sterling and the United States Dollar, respectively, 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 the SEK are translated into SEK at the monthly average 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:

- > (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.



## Notes to the Group Financial Statements continued

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

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. For the periods ended December 31, 2021, and 2020, there have been no sales returns.

#### 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 carries 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 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 and 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 is 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. The Group has not capitalized any research and development expenditure for the periods ended December 31, 2021, and 2020.

#### 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, 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

Plans where the Group's obligations are limited to the contribution the Group has undertaken to pay 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 generate. 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.



## Notes to the Group Financial Statements continued

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

#### 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, employee stock options or share warrants, 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 the 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 in order 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 nine peers over periods between one and seven years. By using peer publicly traded companies which it considers to be as closely comparable in addition to the Company's trading activity. 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 non-market conditions each reporting period.

The Company also has a share warrant program in which participants were given the opportunity to acquire warrants at market value calculated based on the Black-Scholes model. The share warrant program was subsidized by the Company and participants (except the CEO) in the share warrant program received a one-time subsidy when the warrants were purchased. The fair value of the subsidy is expensed over the vesting period.

#### Other operating income and expenses

##### Other income

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

##### Other expenses

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

#### Finance Income and Expenses

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

Interest income and interest expenses are stated on an accrual basis using the principal and the effective interest rate. The effective interest rate is the discount rate that is used to discount expected future cash payments or receipts through the expected life of the financial asset or financial liability to the amortized cost (the gross carrying amount), of such asset or liability.

#### 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





## Notes to the Group Financial Statements continued

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

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.

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	3–5 years



## Notes to the Group Financial Statements continued

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

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

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

#### Impairment

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, 2021 in-process development projects mainly 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.

#### 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 2021 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) 2021, as approved at the 2021 AGM.

The treasury shares reserves comprise own shares repurchased by the Group.

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, 2021, or 2020.

#### 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.



## Notes to the Group Financial Statements continued

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

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, accounts receivable and listed shares. On the liability side, 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. Accounts receivable (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).

The following describes how the Group's various holdings of financial assets have been classified: The Group's 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 payments of solely payments of principal and interest and do therefore not fulfil the amortized cost requirements.

Other financial assets 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 only consists solely of payments of principal and interest (SPPI) and 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.

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 loan losses according to IFRS 9. The loss reserve for accounts receivable is valued at an amount corresponding to the expected losses for the remaining term. However, no reserve was recognized in any period presented due to materiality, as the amount of accounts receivable is insignificant. 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.



## Notes to the Group Financial Statements continued

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

#### 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.

#### Treasury Shares

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 share premium reserve.

#### New Accounting Policies and Disclosures

In the year ended December 31, 2021, the Group has applied the below amendments to IFRS and interpretations issued by the Board. Their adoption has not had any material impact on the disclosure or on the amounts reported in these consolidated financial statements.

#### Interest Rate Benchmark Reform – Phase 2 (Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16)

The Phase 2 amendments provide practical relief from certain requirements in IFRS Standards. These reliefs relate to modifications of financial instruments and lease contracts triggered by a replacement of a benchmark interest rate in a contract with a new alternative benchmark rate. The amendments are effective for annual periods beginning on or after January 1, 2021.

#### Standards, amendments, and interpretations in issue but not yet effective

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
<i>IAS 16 Property, Plant and Equipment: Amendments</i> in relation to proceeds before intended use	January 1, 2022
COVID-19-Related Rent Concessions beyond 30 June 2021	January 1, 2022
<i>IAS 37 Provision Contingent Liabilities and Contingent Assets:</i> Amendments in relation to the costs of fulfilling a contract when assessing onerous contracts	January 1, 2022
<i>IFRS 3: Business Combinations:</i> Amendments to update references to Conceptual Framework	January 1, 2022
Annual Improvements to IFRSs (2018–2020 cycle)	January 1, 2022
<i>IAS 1 Presentation of Financial Statements:</i> Amendments in relation to the classification of liabilities as current or non-current	January 1, 2023
Disclosure of Accounting Policies (Amendments to IAS 1 and IFRS Practice Statement 2).	January 1, 2023
Deferred Tax related to Assets and Liabilities arising from a Single Transaction (Amendments to IAS 12)	January 1, 2023
Definition of Accounting Estimates (Amendments to IAS 8)	January 1, 2023

The Group has not elected to early adopt any of the above standards, amendments and interpretations in the years ended December 31, 2021, and 2020. 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, 2021, and 2020.

### 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.

### Pre-launch Inventories

In order to accommodate market demands, the Group initiates manufacturing of inventories for late-stage development product candidates prior to obtaining marketing approvals, or pre-launch inventories.

In determining the accounting for pre-launch inventories, management considers the probability of future benefits, and accordingly, whether pre-launch inventories qualify as assets. Manufacturing of pre-launch inventories are initiated for late-stage product candidates and are recognized as inventories. However, since pre-launch inventories are not realizable prior to obtaining marketing approvals, pre-launch inventories are immediately written down to zero through research and development costs. If the marketing approval is obtained, write-downs of pre-launch inventories will be reversed through research and development costs if there is future benefit.

### 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 vests, 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.



## Notes to the Group Financial Statements continued

### Note 4 Intangible Assets

The 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. Capitalized internal development expenditures for imlifidase's previous production process were completely amortized during the year 2018.

Acquired in-process development projects are assessed for possible impairment at least on an annual basis and the impairment assessment on December 31, 2021, and 2020 demonstrated that there was no need for impairment. The estimated recoverable amount supported by external and internal valuation reports by far exceed the assets carrying amount, resulting in no impairment charges for the year 2021 and 2020.

(in thousands of SEK)	Internally generated  Capitalized development expenditures	Acquired intangible assets		Total Intangible Assets
		Patents	In-process development projects	
<b>Cost:</b>				
Opening balance January 1, 2021	4,485	12,069	25,136	41,690
Effects of movements in exchange rates	—	270	—	270
Closing balance December 31, 2021	4,485	12,339	25,136	41,960
<b>Amortization:</b>				
Opening balance January 1, 2021	(4,485)	(5,794)	—	(10,280)
Amortization for the year	—	(747)	(2,094)	(2,841)
Effects of movements in exchange rates	—	(78)	—	(78)
Closing balance December 31, 2021	(4,485)	(6,619)	(2,094)	(13,199)
<b>Carrying amounts:</b>				
At January 1, 2021	—	6,275	25,136	31,410
At December 31, 2021	—	5,720	23,042	28,761

(in thousands of SEK)	Internally generated Capitalized development expenditures	Acquired intangible assets		Total Intangible Assets
		Patents	In-process development projects	
<b>Cost:</b>				
Opening balance January 1, 2020	4,485	12,479	25,136	42,100
Effects of movements in exchange rates	—	(410)	—	(410)
Closing balance December 31, 2020	4,485	12,069	25,136	41,690
<b>Amortization:</b>				
Opening balance January 1, 2020	(4,485)	(4,267)	—	(8,752)
Amortization for the year	—	(1,668)	—	(1,668)
Effects of movements in exchange rates	—	140	—	140
Closing balance December 31, 2020	(4,485)	(5,794)	—	(10,280)
<b>Carrying amounts:</b>				
At January 1, 2020	—	8,213	25,136	33,348
At December 31, 2020	—	6,275	25,136	31,410

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 25,136 k from the period of first sale in Q1-2021. The estimated useful life is 12 years.

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 2021 (2020: 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.





## Notes to the Group Financial Statements continued

### Note 5 Property and Equipment

(in thousands of SEK)	As of December 31,	
	2021	2020
<b>Cost:</b>		
Opening balance January 1	11,871	11,577
Additions during the year	2,580	294
Closing balance December 31	14,451	11,871
<b>Accumulated depreciation and impairment losses:</b>		
Opening balance January	(6,665)	(5,542)
Depreciation during the period	(1,354)	(1,123)
Closing balance December	(8,019)	(6,665)
<b>Carrying amounts:</b>		
<b>At January 1</b>	<b>5,206</b>	<b>6,035</b>
<b>At December 31</b>	<b>6,432</b>	<b>5,206</b>

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

(in thousands of SEK)	As of December 31,	
	2021	2020
<b>Leased assets:</b>		
Buildings	37,954	3,574
Equipment	673	440
Vehicles	725	480
<b>Total</b>	<b>35,273</b>	<b>4,493</b>
<b>Lease liabilities:</b>		
Non-current	28,491	630
Current	6,888	4,415
<b>Total</b>	<b>35,379</b>	<b>5,045</b>

For the years ended December 31, 2021, and 2020, there were SEK 36,071,000 and SEK 540,000, respectively, in additions of right-of-use assets.

#### Depreciation charge of leased assets

(in thousands of SEK)	As of December 31,	
	2021	2020
Buildings	(4,646)	(4,550)
Equipment	(169)	(169)
Vehicles	(174)	(161)
<b>Total</b>	<b>(4,989)</b>	<b>(4,880)</b>

Interest expense (included in finance cost) amounted to SEK 572,000. Expenses related to low-value leases and short-term leases amounted to SEK 1,298,000. Total cash outflow of leases amounted to SEK 6,727,000.

Most of the Group's operational leasing agreements involve leases of real property and premises on which the business operations are conducted. The initial duration of the lease for the Lund, Sweden, offices is three years from January 1, 2019. The agreement is automatically extended with two years at a time unless cancellation is made no later than nine months before the end of the contract period. There are no variable fees included in the leases. 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.

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 2023.

On April 1, 2021, the Company executed a lease amendment at Scheelevägen 22, 223 63 Lund, for its headquarters. The lease amendment includes both an extension of the existing space leased by the Company and an agreement to lease additional space. In addition, the lessor provided the Company with SEK 1.0 million of incentives to spend on its leasehold improvements. The Company determined that the existing space and additional space represent separate lease components. As the lease term extension for the existing space meets the definition of a lease modification, the Company accounted for the existing space lease component by allocating the consideration in the modified contract, determining the lease term of the modified lease, and remeasuring the lease liability by discounting the revised lease payments using a revised discount rate. The Company accounted for incentives by reducing its consideration used to determine the right of use asset and liability by the amount of the lease incentive. On November 1, 2021, the Company took control of the additional leased space associated with the April 1, 2021, lease amendment for the headquarters at Scheelevägen 22, 223 63 Lund. The future minimum lease payments associated with the extension of the existing





## Notes to the Group Financial Statements continued

### Note 6 Right-of-Use Assets, Lease Liabilities continued

space lease by the Company from April 1, 2021, until the estimated end date of October 31, 2026, is SEK 24,065,000 equivalent to approximately SEK 354,000 per month. The total future minimum lease payments associated with the additional leased space from January 1, 2022 until the estimated end date of October 31, 2026, is SEK 16,808,000 equivalent to approximately SEK 290,000 per month.

### Note 7 Inventories

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

(in thousands of SEK)	As of December 31,	
	2021	2020
Raw materials and supplies	3,141	2,078
Work in process	8,282	3,512
Packaging material	311	212
Finished goods	1,882	380
Total inventories, gross	13,616	6,182
Less: provision for excess & obsolete inventories	(13,374)	(6,084)
<b>Total inventories, net</b>	<b>242</b>	<b>98</b>

See further discussion in Note 3 related to write-down of pre-launch inventories.

### Note 8 Trade Receivables

(in thousands of SEK)	As of December 31,	
	2021	2020
Trade receivables	9,712	110

During the year ended December 31, 2021 and 2020, respectively, there were no losses related to receivables and the credit risk on receivables is considered to be limited. See further discussions in Note 20 related to credit risk.

### Note 9 Prepaid expenses and accrued income

(in thousands of SEK)	As of December 31,	
	2021	2020
Insurances	829	494
Healthcare conference	124	1,664
Software	1,177	1,378
Pension	1,644	—
Rent	2,512	1,161
Legal expenses	8,325	—
License fee	3,999	262
Other	2,279	757
<b>Total</b>	<b>20,889</b>	<b>5,716</b>

### Note 10 Other receivables

(in thousands of SEK)	As of December 31,	
	2021	2020
VAT receivables	9,827	3,786
Advance payments to suppliers	11,292	3,124
Other receivables	1,419	3,047
<b>Total</b>	<b>22,538</b>	<b>9,957</b>

Other receivables are mainly comprised of VAT receivables, advance payments to suppliers and other receivables.



## Notes to the Group Financial Statements continued

### Note 11 Accrued Expenses

(in thousands of SEK)	As of December 31,	
	2021	2020
Annual leave accrual	15,879	10,775
Accrued social security contribution on salaries	4,395	2,964
Accrued short term incentives, incl. related social security contributions	24,146	13,585
R&D project costs	7,791	13,223
Consulting fees	17,600	11,269
Other	2,651	4,311
<b>Closing balance December 31</b>	<b>72,462</b>	<b>56,125</b>

### Note 12 Other liabilities—Current

(in thousands of SEK)	As of December 31,	
	2021	2020
Personnel related liabilities	13,358	9,454
Current tax	190	134
<b>Closing balance December 31</b>	<b>13,548</b>	<b>9,588</b>

### Note 13 Revenue

The Group's revenue from its contracts with customers is primarily generated from product sales and two license agreements, as further described below, with its customers which were entered into in 2009 and 2020 with Axis-Shield and Sarepta Therapeutics, Inc. (Sarepta), respectively.

Revenue has been recognized in the consolidated statement of profit or loss and other comprehensive income (loss) with the following amounts:

(in thousands of SEK)	Years Ended December 31,	
	2021	2020
<b>Revenue from contracts with customers:</b>		
Product sales	15,017	—
Contract revenue, Axis-Shield agreement	2,624	2,864
Cost reimbursement, Axis-Shield agreement	527	636
Contract revenue, Sarepta agreement	15,710	2,599
<b>Total revenue</b>	<b>33,878</b>	<b>6,098</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, 2021, and 2020, with the exception of the Axis-Shield minimum royalty payment.

#### Product revenue

For the period ended December 31, 2021, the Group recorded product revenue of SEK 15.0 million (2020: nil). Product revenue is recognized net of any sales and value-added taxes and sales deductions based on contractually agreed payment terms.



## Notes to the Group Financial Statements continued

### Note 13 Revenue continued

#### 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 labor 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.

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, 2021, financial reporting period. Revenue from performance based and sales-based milestones and sales-based royalties will be constrained because it is not probable that a reversal of revenue will not occur if these were recognized.

For the period ended December 31, 2021, the Group recorded contract revenue in the amount of SEK 15.7 million (2020: SEK 2.6 million) related to its agreement with Sarepta in connection with the upfront payment received in July 2020.

#### License Agreement with Axis-Shield

In 2021, the Group recorded contract revenue in the amount of SEK 2.6 million (2020: SEK 2.9 million) under its agreement with Axis-Shield related to a minimum royalty payment of \$250,000 and a commercial milestone payment of \$60,000. 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. The minimum royalty amount was received in February 2021, initially recorded as a deferred revenue and recognized as revenue over the reporting period on a straight-line basis. The commercial milestone relates to achieved sales. Since it is a sales-based milestone it has been recognized as revenue when the sales occurred and the Company became entitled to receive the milestone payment.

In addition, the Group recorded revenue related to reimbursable costs upon rendering services related to maintaining licensed patents in an amount of SEK 0.5 million (2020: SEK 0.6 million).

#### Deferred revenue (contract balances)

(in thousands of SEK)	As of December 31,	
	2021	2020
<b>Opening balance January 1,</b>	<b>79,432</b>	<b>—</b>
Addition under existing contracts	18,168	3,500
Addition under new contracts (Sarepta agreement)	—	81,900
Revenue recognized	(33,878)	(6,098)
Adjustments, foreign exchange	8,259	130
<b>Closing balance December 31,</b>	<b>71,981</b>	<b>79,432</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 compensation-related expenses recorded in the Group broken down to senior management, which includes the Board of Directors and executive management, and other employees:

(in thousands of SEK)	Year Ended December 31, 2021		
	Senior Management	Other Employees	Total
Salaries, bonuses, and other benefits	32,282	122,304	154,586
Social security contribution	10,040	20,518	30,558
Pension cost, contribution plan	2,723	15,381	18,104
Share-based compensation	33,860	22,764	56,624
<b>Total compensation-related expenses</b>	<b>78,905</b>	<b>180,967</b>	<b>259,872</b>

(in thousands of SEK)	Year Ended December 31, 2020		
	Senior Management	Other Employees	Total
Salaries, bonuses, and other benefits	28,896	67,789	96,685
Social security contribution	8,894	10,185	19,079
Pension cost, contribution plan	1,357	9,330	10,688
Share-based compensation	23,882	19,466	43,348
<b>Total compensation-related expenses</b>	<b>63,029</b>	<b>106,770</b>	<b>169,800</b>

### Share-based payments

#### Long-term incentive program 2016 (LTIP 2016)

At Hansa's Extraordinary General Meeting on November 21, 2016, shareholders resolved to adopt a long-term incentive program (LTIP 2016) in the form of performance-based share rights (share rights) for all employees of the Group.

Each share right provides the right to acquire one ordinary share in the Company free-of-charge provided certain conditions are met in accordance with the terms of LTIP 2016. A share right may be exercised if the performance condition is met and provided that the participant, with certain exceptions, from the date of participation in LTIP 2016 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

The single performance condition is: Total shareholder return (TSR) during the Vesting Period compared to a starting value of SEK 112.51 (allotment November 2016) and SEK 142.34 (allotment May 2017). The performance condition is set at a "minimum level" of 25% and "maximum level" of 100%, whereby the number of shares granted to participants is increased linearly between the minimum level and maximum level in line with the TSR appreciation.

A total of 289,750 share rights were allotted to participants, of which 234,750 were allotted in November 2016 and 55,000 were allotted in May 2019. LTIP 2016 ended in 2020.

The Group used the following inputs when valuing the share rights under LTIP 2016 based on Monte Carlo simulation:

	Allotment Nov 26, 2016	Allotment May 19, 2017
Starting value (base-line share price) for TSR calculation, SEK	112.51	142.34
Risk-free interest rate, (%)	(0.52)	(0.51)
Expected volatility, (%)	55	55
Expected dividend, SEK	—	—
Calculated fair value per share right, SEK	62.01	89.30

	Years Ended December 31,	
	2021	2020
Share rights, Opening balance January 1	—	35,000
Allotted share rights during the period	—	—
Share rights expired during the period	—	(35,000)
Rights, Closing balance December 31	—	—
Recorded share-based compensation expenses, in thousands of SEK	—	395

#### Long-term incentive program 2018 (LTIP 2018)

At Hansa's Annual General Meeting (AGM) on May 29, 2018, shareholders resolved to adopt a long-term incentive program (LTIP 2018). Participants in the program were given the opportunity to acquire equity-based awards (warrants) at market value and/or receive share rights free of charge which, provided that certain conditions are met, may give the right to acquire shares in the Company.



## Notes to the Group Financial Statements continued

### Note 14 Staff Costs continued

#### Warrants under LTIP 2018

Each warrant gives the participant the right to exercise the warrant for subscription of one ordinary share in the Company at a price equal to the market value of the share at the time of the issuance of the warrants (SEK 223.10) adjusted upwards in the amount of 7% annually during the three-year vesting period, i.e., SEK 273.31. Provided the participant remains an employee of the Group, subscription for shares in accordance with the terms of the warrants may take place during the period from June 12, 2021 through June 12, 2022.

The warrants were sold to the participants on market terms at a price established on the basis of an estimated market value of the warrants using the Black Scholes model. In connection with the warrants program participants (except the CEO) received a subsidy of maximum 25% of the purchase price.

Should the participant's employment cease before the awards are exercised, the Group is entitled to repurchase the awards at market value less any subsidy provided to the participant.

A total of 6,701 warrants were sold under the program in June 2018.

The Group used the following inputs when valuing the warrants under LTIP 2018 based on Black Scholes model:

	Issuance June 2018
Underlying volume-weighted average share price, SEK	223.10
Risk-free interest rate, (%)	(0.178)
Expected volatility, (%)	43
Expected dividend, SEK	—
Calculated fair value per warrant, SEK	53.41

	Years Ended December 31,	
	2021	2020
Warrants, Opening balance January 1	6,701	6,701
Warrants expired or redeemed in advance during the period	—	—
<b>Warrants, Closing balance December 31</b>	<b>6,701</b>	<b>6,701</b>
Recorded share-based compensation expenses, in thousands of SEK	5	17

#### Share rights under LTIP 2018

Each share right provides a participant the right to acquire one ordinary share in the Company free-of-charge provided certain pre-defined conditions are met in accordance with the terms of LTIP 2018. A share right may be exercised if the performance condition is met and provided that the participant, with certain exceptions, from the date of the start of participation in LTIP 2018 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

The single performance condition is: TSR during the Vesting Period compared to a starting value of SEK 222.10 (allotment June 2018), SEK 278.70 (allotment November 2018) and SEK 178.60 (allotment May 2019). The performance condition is set at a "minimum level" of 25% and "maximum level" of 100%, whereby the number of shares granted to participants is increased lineally between the minimum level and maximum level in line with the TSR appreciation.

A total of 260,710 share rights were allotted to participants, of which 105,460 were allotted in June 2018, 72,671 were allotted in November 2018 and 82,579 were allotted in May 2019.

The Group used the following inputs when valuing the share rights under LTIP 2018 based on Monte Carlo simulation:

	Allotment June 15, 2018	Allotment Nov 30, 2018	Allotment May 14, 2019
Starting value (base-line share price) for TSR calculation, SEK	221.10	278.70	178.60
Risk-free interest rate, (%)	(0.36)	(0.28)	(0.55)
Expected volatility, (%)	43	43	43
Expected dividend, SEK	—	—	—
Calculated fair value per share right, SEK	94.08	117.43	76.02

	Years Ended December 31,	
	2021	2020
Share rights, Opening balance January 1	223,778	238,368
Share rights expired or forfeited during the period	(163,692)	(14,590)
<b>Share rights, Closing balance December 31</b>	<b>60,086</b>	<b>223,778</b>
Recorded share-based compensation expenses, in thousands of SEK	912	9,213



## Notes to the Group Financial Statements continued

### Note 14 Staff Costs continued

#### 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 (ConfIdes)
- > 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 (ConfIdes)".

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 June 17, 2019	Allotment Oct 24, 2019
Starting value (base-line share price) for TSR calculation, SEK	178.38	129.28
Risk-free interest rate, (%)	(0.59)	(0.41)
Expected volatility, (%)	43	43
Expected dividend, SEK	—	—
Calculated fair value per share right, SEK	122.12	89.00

#### Years Ended December 31,

	2021	2020
Share rights, Opening balance January 1	287,555	306,303
Share rights forfeited during the period	(9,374)	(18,748)
Share rights, Closing balance December 31	278,181	287,555
Recorded share-based compensation expenses, in thousands of SEK	12,906	12,459

#### Share options under LTIP 2019

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

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 June 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
Expected volatility, (%)	43
Expected dividend, SEK	—
Calculated fair value per warrant, SEK	45.54



## Notes to the Group Financial Statements continued

### Note 14 Staff Costs continued

	Years Ended December 31,	
	2021	2020
Warrants, Opening balance January 1	11,000	11,000
Warrants expired or redeemed in advance during the period	—	—
Warrants, Closing balance December 31	11,000	11,000
Recorded share-based compensation expenses, thousands of SEK	97	223

#### 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 June 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
Expected volatility, (%)	43
Expected dividend, SEK	—
Calculated fair value per ESO, SEK	45.19

	Years Ended December 31,	
	2021	2020
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	690	3,776

#### 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).

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%): US RCT study (Confldes) fully enrolled;
- > 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 to continue either of the two programs;
- > 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 (Confldes) fully enrolled".

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 July 23, 2020	Allotment Feb 12, 2021
Starting value (base-line share price) for TSR calculation, SEK	252.60	252.60
Risk-free interest rate, (%)	(0.33)	(0.25)
Expected volatility, (%)	43	43
Expected dividend, SEK	—	—
Calculated fair value per share right, SEK	173.26	120.07





## Notes to the Group Financial Statements continued

### Note 14 Staff Costs continued

	Years Ended December 31,	
	2021	2020
Share rights, Opening balance January 1	389,556	—
Allotted to participants July 23, 2020	—	401,556
Allotted to participants February 12, 2021	16,000	
Share rights forfeited	(5,000)	(12,000)
<b>Share Rights, Closing balance December 31</b>	<b>400,556</b>	<b>389,556</b>
Recorded share-based compensation expenses, thousands of SEK	21,205	12,678

#### 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 July 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	3
Expected volatility, (%)	43	43
Expected dividend, SEK	—	—
Calculated fair value per ESO, SEK	53.05	27.25

	Years Ended December 31,	
	2021	2020
ESO, Opening balance January 1	477,520	—
ESO allotted to participants July 23, 2020	—	487,520
ESO allotted to participants February 12, 2021	20,000	—
ESO forfeited	—	(10,000)
<b>ESO, Closing balance December 31</b>	<b>497,520</b>	<b>477,520</b>
Recorded share-based compensation expenses, thousands of SEK	7,658	4,588

#### 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.

A maximum of 624,615 share rights can be allotted under LTIP 2021. As of December 31, 2021, a total of 557,000 share rights have initially been allotted to participants.



## Notes to the Group Financial Statements continued

### Note 14 Staff Costs continued

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

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

	Years Ended December 31,	
	2021	2020
Share rights, Opening balance January 1	—	—
Allotted to participants June 7, 2021,	557,000	—
Share rights forfeited	—	—
<b>Share Rights, Closing balance December 31</b>	<b>557,000</b>	<b>—</b>
Recorded share-based compensation expenses, thousands of SEK	11,722	—

#### 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 maximum of 452,307 ESOs can be allotted under LTIP 2021. As of December 31, 2021, a total of 430,000 have initially been allotted to participants.

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

	Issuance June 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	

	Years Ended December 31,	
	2021	2020
ESO, Opening balance January 1	—	—
ESO allotted to participants June 7, 2021	430,000	—
ESO forfeited	—	—
<b>ESO, Closing balance December 31</b>	<b>430,000</b>	<b>—</b>
Recorded share-based compensation expenses, thousands of SEK	3,738	—

### 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.

The decrease in provisions for 2021 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.



## Notes to the Group Financial Statements continued

### Note 15 Provisions continued

	As of December 31,	
	2021	2020
<b>Opening balance January 1</b>	<b>14,426</b>	<b>818</b>
Provision related to LTIP 2016	—	1
Provision related to LTIP 2018	(2,999)	2,953
Provision related to LTIP 2019	(4,516)	6,778
Provision related to LTIP 2020	(1,194)	3,736
Provision related to LTIP 2021	1,866	—
Pension provision	(226)	140
<b>Closing balance December 31</b>	<b>7,357</b>	<b>14,426</b>

### Note 16 Income Taxes

(in thousands of SEK)	As of December 31,	
	2021	2020
Deferred Taxes, opening balance January 1	424	507
Tax income in the consolidated statement of profit or loss and other comprehensive income	(39)	(40)
Currency differences for the year	41	(43)
<b>Deferred Taxes, closing balance December 31</b>	<b>426</b>	<b>424</b>

#### Losses carried forward in 2021

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 Group's losses carried forward in as of December 31, 2021 amounted to SEK 1,855,251,000 (2020: SEK 1,369,949,000). 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:

	2021		2020	
	%	(in thousands of SEK)	%	(in thousands of SEK)
Result before tax	—	(548,130)	—	(420,893)
Tax according to current tax rate	20.6	112,915	21.4	90,071
Effect of other tax rates for foreign subsidiaries	0	(14)	—	—
Non-deductible expenses	(2.4)	(13,103)	(2.2)	(9,119)
Increase in loss carry-forwards without corresponding capitalization of deferred tax	(18.2)	(99,951)	(19.2)	(80,912)
Reported effective tax	—	(152)	—	40

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

### Note 17 Loss per Share

(in SEK)	Years Ended December 31,	
	2021	2020
Loss per share, basic and diluted	(12.33)	(9.98)

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, 2021, and 2020, share rights to receive 1,295,823 and 900,889 ordinary shares, respectively, options to purchase 1,076,668 and 626,668 ordinary shares, respectively, and warrants to purchase 17,701 and 17,701 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

### Note 17 Loss per Share continued

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

(in thousands of SEK)	Years Ended December 31,	
	2021	2020
Loss for the year attributable to owners of the parent	(548,280)	(420,853)
Loss attributable to ordinary shareholders, basic and diluted	(548,280)	(420,853)

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

(in thousands of SEK)	Years Ended December 31,	
	2021	2020
Issued ordinary shares January 1	44,473,452	40,026,107
Effect of issue of ordinary shares in July 2020	—	2,150,765
<b>Weighted average number of ordinary shares, basic and diluted</b>	<b>44,473,452</b>	<b>42,176,872</b>

### 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 is initiated in Europe or the U.S. The estimated payment date is July 19, 2023, resulting in fair value of contingent liability on December 31, 2021, amounting to SEK 722,000 (2020: SEK 663,000).

The estimated future cash flow is discounted using a 10% risk adjusted interest rate. See further discussions in 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, 2021, Hansa's cash position (including short-term investments) amounted to SEK 889 million.

The adequacy of our available funds will depend on many factors, including growth of ldefirix sales, progress in our research and development programs, the magnitude of those programs, our commitments to existing and new collaborators, our ability to establish commercial and licensing arrangements, our capital expenditures, market developments, and any potential future acquisitions. Accordingly, we 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 handled by the CFO and the corporate finance function.

To secure short-term liquidity, Hansa Biopharma's AB 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.



## Notes to the Group Financial Statements continued

### Note 20 Financial Risk and Financial Instruments continued

Cash and cash equivalents on December 31, 2021, amounted to SEK 651 million. Cash and cash equivalents on the reporting date consisted of bank deposits.

Short term investments were mainly invested in interest funds and amounted to SEK 238 million as of December 31, 2021.

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

(in thousands of SEK)	As of December 31, 2021			
	Nominal Amount	0–3 months	3–12 months	1–5 years
Contingent consideration	846	—	—	846
Non-current leasing liabilities	30,544	—	—	30,544
Current leasing liabilities	7,929	1,986	5,943	—
Trade payables	53,360	53,360	—	—
Accrued expenses (see note 11)	28,041	28,041	—	—
<b>Total</b>	<b>120,720</b>	<b>83,387</b>	<b>5,943</b>	<b>31,390</b>

(in thousands of SEK)	As of December 31, 2020			
	Nominal Amount	0–3 months	3–12 months	1–5 years
Contingent consideration	766	—	—	776
Non-current leasing liabilities	644	—	—	644
Current leasing liabilities	4,497	1,232	3,265	—
Trade payables	26,669	26,669	—	—
Accrued expenses (see note 11)	28,802	28,802	—	—
<b>Total</b>	<b>61,387</b>	<b>56,703</b>	<b>3,265</b>	<b>1,420</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.

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 manage 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 also has minimal amounts in trade and other receivables in foreign currencies.

The Group is exposed to translation risk that arise from consolidation of foreign subsidiaries. The Group net assets on December 31, 2021, relating to Hansa Biopharma Inc. amounted to USD 210k (full year 2020: USD 140k) and the Group net assets relating to Hansa Biopharma Ltd. amounted to GBP 50k (full year 2020: GBP 14k).

#### Sensitivity analysis

The Company purchases services mainly in USD, GBP, DKK and EUR. 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 receives licensing revenue which are paid in USD and GBP. A strengthening of the Swedish krona in relation to USD 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 EUR by an average of 10% would have negatively affected the Group's earnings before tax by approximately SEK 14,980,000. Correspondingly, a 10% weakening of SEK in relation to USD would have negatively affected earnings before tax by approximately SEK 4,847,000, a weakening of SEK in relation to GBP by an average of 10% would have negatively affected the Group's earnings before tax by approximately SEK 4,247,000 and a strengthening of SEK in relation to DKK by an average of 10 % would have negatively affected the Group's earnings before tax by approximately SEK 523,000. 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

### Note 20 Financial Risk and Financial Instruments continued

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 and holdings of short-term interest fund.

The Group has acquired shares in an interest fund. Changes in the general interest rate level affect the prices of the fund's interest investments in the opposite direction. If the general interest rate level drops 1 percentage point, prices will rise on the investment 0.25-0.50% and vice versa (modified duration 0.25-0.50% in the normal position). This would lead to impact on profit or loss of SEK 594,000 to SEK (1,188,000), before tax.

#### 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 contract assets 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 three Swedish banks with good credit ratings with no one bank holding more than 35% of the total amount as of December 31, 2021. 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 also has risk related to its trade receivables and other receivables.

The maximum credit exposure of financial assets amounted to SEK 662,473 and SEK 1,142,519 for the periods ended December 31, 2021, and 2020, 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.

At year-end 2021, SEK 198 million of the Group's short-term investments were invested in an investment grade fixed income fund denominated in SEK that invests primarily in Swedish interest-bearing securities with a remaining duration of maximum 360 days. Another SEK 40 million was invested in a housing bond fund which invests in investment grade assets denominated in SEK.

#### 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.

	Financial assets valued at amortized cost		Financial assets valued at fair value through the income statement	
(in thousands of SEK)	2021	2020	2021	2020
<b>Financial assets:</b>				
Short term investments	—	—	237,619	238,144
Trade receivables	9,712	110	—	—
Other receivables	1,419	3,047	—	—
Cash and cash equivalents	651,342	1,139,362	—	—
<b>Total financial assets</b>	<b>662,473</b>	<b>1,142,519</b>	<b>237,619</b>	<b>238,144</b>



## Notes to the Group Financial Statements continued

### Note 20 Financial Risk and Financial Instruments continued

(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	
	2021	2020	2021	2020
<b>Financial liabilities:</b>				
Contingent consideration	—	—	722	663
Trade payables	53,360	26,669	—	—
Accrued expenses (see note 11)	28,041	28,802	—	—
<b>Total financial liabilities</b>	<b>81,401</b>	<b>55,471</b>	<b>722</b>	<b>663</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.

	Valuation Hierarchy	2021	2020
		(In thousands of SEK)	
<b>Financial asset:</b>			
Holdings of short-term investments	Level 2	237,619	238,144
Contingent consideration	Level 3	722	663

The table below presents a reconciliation between the opening and closing balances for the contingent consideration valued in accordance with Level 3.

	As of December 31,	
	2021	2020
Opening balance January 1	663	730
Currency differences	42	(112)
Interest expense	67	45
<b>Closing balance December 31</b>	<b>772</b>	<b>663</b>

The contingent consideration will be at minimum 0 and at maximum GBP 70,000.

The Group's best estimate on December 31, 2021, is that the contingent consideration will be paid in 2023. The previous estimate made on December 31, 2020, was that the contingent consideration would be paid in 2022. The fair value of the contingent consideration is estimated based on management assessment when a clinical study 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 market interest rate.

As of December 31, 2021, the maturity profile of our marketable securities has maturities of less than one year. The fair value of the securities is based on quotes received from the counterparty managing the funds.

### Note 21 Finance Income and Expenses

(in thousands of SEK)	Years Ended December 31,	
	2021	2020
Interest income on bank deposits measured at amortized cost	67	388
Changes in the fair value of interest funds during the year	—	1,782
<b>Finance income</b>	<b>67</b>	<b>2,170</b>
Interest expense	(694)	(257)
Changes in the fair value of interest funds during the year	(525)	—
<b>Finance costs</b>	<b>(1,219)</b>	<b>(257)</b>
<b>Net finance costs/income</b>	<b>(1,152)</b>	<b>1,914</b>





## Notes to the Group Financial Statements continued

### Note 22 Share capital and number of shares

Number of shares	Years Ended December 31,	
	2021	2020
<b>Issued as of January 1</b>	<b>44,473,452</b>	<b>40,026,107</b>
Effect of issue of ordinary shares in July 2020	—	4,447,345
<b>Issued as of December 31</b>	<b>44,473,452</b>	<b>44,473,452</b>

The Group's shares have a par value of SEK 1.

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 23 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 deferred income and external expenses directly attributable to the offerings. The share premium reserve can be distributed.

### Note 24 Treasury shares included in equity

	Number of Shares		In thousands of SEK	
	2021	2020	2021	2020
<b>As of January 1,</b>	<b>1,421,457</b>	<b>1,421,457</b>	<b>1,421</b>	<b>1,421</b>
Additions	440,452	—	440	—
<b>As of December 31,</b>	<b>1,861,909</b>	<b>1,421,457</b>	<b>1,862</b>	<b>1,421</b>

Treasury shares have a par value of SEK 1.

The year 2021 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) 2021, as approved at the 2021 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.

### Note 25 Reserves

#### Treasury share reserve

The treasury share reserve comprise own shares repurchased by the Group.

#### 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.

#### Fair value reserves

Fair value fund includes the accumulated change in fair value after tax on the holding of shares and shares that the Group has chosen to report at fair value through other comprehensive income according to IFRS 9.

Please refer to Note 14 related to the Group's LTIP programs and respective vesting dates.

### Note 26 Royalty Agreements

The Company is party to two separate royalty agreements (the Royalty Agreements) with 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 exploitation of the patents, in each case as defined in the applicable agreement, and a low double-digit 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 Idefixir (imlifidase) in the EU for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor in August 2020 and the Company has initiated the commercial launch of Idefixir in the EU, above mentioned compensation payments under the Royalty Agreements may 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. The Company believes these claims are without merit. The arbitration proceedings are ongoing at an initial stage.



## Notes to the Group Financial Statements continued

### Note 27 Other operating income and expenses

	Years Ended December 31,	
	2021	2020
<b>Other operating income</b>		
Foreign currency gains on receivables/liabilities from operating activities	—	2,270
<b>Total other operating income</b>	<b>—</b>	<b>2,270</b>
<b>Other operating expenses</b>		
Foreign currency losses on receivables/liabilities from operating activities	(7,398)	—
<b>Total other operating expenses</b>	<b>(7,398)</b>	<b>—</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,	
	2021	2020
Personnel expenses	(266,611)	(180,080)
Third party expenses	(283,387)	(242,431)
Depreciation and amortization expenses	(8,606)	(7,666)
Other operating expenses	(6,827)	—
<b>Total operating expenses</b>	<b>(565,431)</b>	<b>(430,178)</b>

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).

	Years Ended December 31,	
	2021	2020
Research and development expenses	5,639	3,022
Sales, general and administrative expenses	2,967	4,644
<b>Total</b>	<b>8,606</b>	<b>7,666</b>

### Note 29 Supporting information to the cash flows

(in thousands of SEK)	As of December 31,	
	2021	2020
<b>Cash and cash equivalents consist of:</b>		
Cash and bank deposits	651,342	1,139,362
Total according to statement of financial position	651,342	1,139,362
Total according to cash flow analysis	651,342	1,139,362

Reconciliation of liabilities arising from financing activities:

(in thousands of SEK)	As of December 31,	
	2021	2020
<b>Opening balance January 1,</b>	<b>5,045</b>	<b>9,458</b>
Termination of lease agreement	(308)	(280)
New lease agreements	35,499	540
Payment of lease liabilities	(4,857)	(4,674)
<b>Closing balance December 31,</b>	<b>35,379</b>	<b>5,045</b>

### Note 30 Subsequent events

On January 3, 2022, Hansa entered into an agreement with AskBio to evaluate the potential use of imlifidase as a pre-treatment prior to the administration of AskBio's investigational gene therapy in Pompe disease in a pre-clinical and clinical feasibility program for patients with pre-existing neutralizing antibodies (Nabs). Upon execution, Hansa received a USD 5 million payment, while AskBio has an exclusive option to negotiate a full development and commercialization agreement.

### Russian invasion of Ukraine

On 24 February, 2022 Russia invaded Ukraine. Hansa does not have any own operations in nor collaborates 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 does already have or is expected to have general negative impacts on global economy, stock markets, energy prices, global supply and free trade, and as such may indirectly negatively impact Hansa's business. The Company continues to monitor the situation closely and will take appropriate measures as needed to manage any potential negative impact to its business.



# Parent Company Financial Statements

## Statement of financial position

(in thousands of SEK)	Note	As of December 31,	
		2021	2020
<b>ASSETS</b>			
<b>Non-current assets:</b>			
Intangible assets	2	26,518	29,171
Property and equipment	3	6,432	5,206
Right-of-use assets	4	35,273	4,493
Financial assets:			
Investment in subsidiaries	5	5,095	5,095
Receivables, group companies	6	2,203	1,972
<b>Total financial assets</b>		<b>7,298</b>	<b>7,067</b>
<b>Total non-current assets</b>		<b>75,521</b>	<b>45,937</b>
<b>Current assets:</b>			
Inventories	7	242	98
Trade receivables	8	9,712	110
Prepaid expenses and accrued income	9	20,820	5,394
Other receivables	10	22,381	9,763
Short-term investments	19	237,619	238,144
Cash and cash equivalents	19,28	644,975	1,133,647
<b>Total current assets</b>		<b>935,749</b>	<b>1,387,157</b>
<b>TOTAL ASSETS</b>		<b>1,011,270</b>	<b>1,433,094</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>			
Restricted shareholders' equity:			
Share capital	21	46,335	45,895
Unrestricted shareholders' equity:			
Share premium reserve	22	2,572,925	2,509,458
Treasury share reserve	23,24	(1,862)	(1,421)
Accumulated deficit		(1,312,353)	(890,710)
Loss for the year	16	(549,098)	(421,644)
<b>Total shareholders' equity</b>		<b>755,948</b>	<b>1,241,578</b>

(in thousands of SEK)	Note	As of December 31,	
		2021	2020
<b>LIABILITIES</b>			
<b>Non-current liabilities:</b>			
Lease liabilities	4	28,491	630
Deferred revenue	13	47,020	62,026
Contingent consideration	17	722	663
Provisions	15	7,357	14,426
<b>Total non-current liabilities</b>		<b>83,590</b>	<b>77,745</b>
<b>Current liabilities:</b>			
Liabilities, group companies	6	3,901	1,613
Lease liabilities	4	6,888	4,415
Trade payables	19	53,240	26,623
Other liabilities	12	13,358	8,325
Deferred revenue	13	24,961	17,406
Accrued expenses	11	69,384	55,387
<b>Total current liabilities</b>		<b>171,732</b>	<b>113,771</b>
<b>Total liabilities</b>		<b>255,322</b>	<b>191,516</b>
<b>TOTAL STOCKHOLDERS' EQUITY AND LIABILITIES</b>		<b>1,011,270</b>	<b>1,433,094</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,	
		2021	2020
Revenue	13	33,878	6,098
Cost of revenue		(15,425)	(997)
Other operating income	26	—	2,270
Sales, general and administrative expenses	27	(327,031)	(203,346)
Research and development expenses	27	(231,974)	(227,531)
Other operating expenses	26	(7,395)	—
<b>Loss from operations</b>		<b>(547,947)</b>	<b>(423,507)</b>
Finance income (expenses)			
Finance income	20	67	2,170
Finance expenses	20	(1,218)	(307)
<b>Net finance (expenses) income</b>	<b>20</b>	<b>(1,151)</b>	<b>1,863</b>
<b>Loss before tax</b>		<b>(549,098)</b>	<b>(421,644)</b>
Tax		—	—
<b>Loss for the year</b>	<b>16</b>	<b>(549,098)</b>	<b>(421,644)</b>

(in thousands of SEK)	Note	Years Ended December 31,	
		2021	2020
<b>Loss for the year</b>		<b>(549,098)</b>	<b>(421,644)</b>
Other comprehensive income (loss) for the year		—	—
<b>Total comprehensive loss for the year</b>		<b>(549,098)</b>	<b>(421,644)</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,	
		2021	2020
<b>Cash Flows from Operating Activities</b>			
Loss for the year		(549,098)	(421,644)
<b>Adjustments to reconcile net loss to net cash flows:</b>			
Depreciation and amortization expenses	27	8,418	6,350
Expenses related to incentive programs		56,624	43,348
Costs related to pension plan		(226)	141
Unrealized currency differences		(231)	275
		<b>(484,513)</b>	<b>(371,530)</b>
<b>Changes:</b>			
(Increase) decrease of trade receivables	8	(9,602)	412
(Increase) of other operating receivables		(30,083)	(1,409)
Increase (decrease) trade payables		28,513	(23,758)
Increase of other operating liabilities		14,895	104,698
<b>Total changes</b>		<b>3,723</b>	<b>79,943</b>
Interest (paid) received, net		(625)	79
Income taxes paid		—	—
<b>Net cash used in operating activities</b>		<b>(481,416)</b>	<b>(291,509)</b>
<b>Cash Flows from Investing Activities</b>			
Proceeds from sale of short-term investments		—	182,828
Acquisition of property and equipment	3	(2,399)	(294)
<b>Net cash (used in) from investing activities</b>		<b>(2,399)</b>	<b>182,534</b>

(in thousands of SEK)	Note	Years Ended December 31,	
		2021	2020
<b>Cash Flows from Financing Activities</b>			
Proceeds from issue of ordinary shares, net of transaction costs <sup>(1)</sup>		—	1,070,581
Payment of lease liabilities	4,28	(4,857)	(4,674)
<b>Net cash (used in) from financing activities</b>		<b>(4,857)</b>	<b>1,065,906</b>
Net change in cash and cash equivalents		(488,672)	956,932
Cash and cash equivalents at beginning of year		1,133,647	176,715
<b>Cash and cash equivalents at end of year</b>	<b>28</b>	<b>644,975</b>	<b>1,133,647</b>

<sup>(1)</sup> Total share issue cost amounted to SEK 41,255k in the year 2020.

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	Share Premium reserve	Treasury share reserve	Fair value reserve	Accumulated deficit	Loss for the year	
<b>Balance at January 1, 2020</b>		41,448	1,413,447	(1,421)	76,834	(607,146)	(360,398)	562,763
<b>Statement of profit or loss and other comprehensive income (loss):</b>								
Loss for the year		—	—	—	—	—	(421,644)	(421,644)
Other comprehensive income (loss) for the year		—	—	—	—	—	—	—
<b>Total comprehensive loss for the year</b>		—	—	—	—	—	<b>(421,644)</b>	<b>(421,644)</b>
Reclassification of fair value reserve		—	—	—	(76,834)	(76,834)	—	—
Appropriation of loss of the year 2019 carried forward		—	—	—	—	(360,398)	360,398	—
Issue of ordinary shares <sup>(1)</sup>		4,447	1,066,133	—	—	—	—	1,070,581
Long term incentive program		—	29,878	—	—	—	—	29,878
<b>Balance at December 31, 2020</b>	21,22,23,24	<b>45,895</b>	<b>2,509,458</b>	<b>(1,421)</b>	<b>—</b>	<b>(890,710)</b>	<b>(421,644)</b>	<b>1,241,578</b>
<b>Statement of profit or loss and other comprehensive income (loss):</b>								
Loss for the year		—	—	—	—	—	(549,098)	(549,098)
Other comprehensive income (loss) for the year		—	—	—	—	—	—	—
<b>Total comprehensive loss for the year</b>		—	—	—	—	—	<b>(549,098)</b>	<b>(549,098)</b>
Appropriation of loss of the year 2020 carried forward		—	—	—	—	(421,644)	421,644	—
Issue of Class-C shares <sup>(2)</sup>		440	—	(440)	—	—	—	—
Long term incentive program		—	63,467	—	—	—	—	63,467
<b>Balance at December 31, 2021</b>	21,22,23,24	<b>46,335</b>	<b>2,572,925</b>	<b>(1,862)</b>	<b>—</b>	<b>(1,312,353)</b>	<b>(549,098)</b>	<b>755,948</b>

<sup>(1)</sup> Total share issue cost amounted to SEK 41,255 in the year 2020.

<sup>(2)</sup> The year 2021 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 financial income and expenses, non-current assets and shareholders' equity.

Note 14 employees and accrued personnel cost and note 29 audit fees includes information for the Group and the Parent Company as required by the Swedish Annual Accounts Act.

## Note 2 Intangible Assets

The 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. Capitalized internal development expenditures for imlifidase's previous production process were completely amortized during the year 2018.

Acquired in-process development projects are assessed for possible impairment at least on an annual basis and the impairment assessment on December 31, 2021, and 2020 demonstrated that there was no need for impairment. The estimated recoverable amount supported by external and internal valuation reports by far exceed the assets carrying amount, resulting in no impairment charges for the year 2021 and 2020.

	Internally generated	Acquired intangible assets		
(in thousands of SEK)	Capitalized development expenditures	Patents	In-process development projects	Total Intangible Assets
<b>Cost:</b>				
Opening balance January 1, 2021	4,485	8,504	25,136	38,125
Closing balance December 31, 2021	4,485	8,504	25,136	38,125
<b>Amortization:</b>				
Opening balance January 1, 2021	(4,485)	(4,469)	—	(8,954)
Amortization for the year	—	(559)	(2,094)	(2,653)
Closing balance December 31, 2021	(4,485)	(5,028)	(2,094)	(11,607)
<b>Carrying amounts:</b>				
<b>At January 1, 2021</b>	—	<b>4,035</b>	<b>25,136</b>	<b>29,171</b>
<b>At December 31, 2021</b>	—	<b>3,476</b>	<b>23,042</b>	<b>26,518</b>

(in thousands of SEK)	Internally generated Capitalized development expenditures	Acquired intangible assets		Total Intangible Assets
		Patents	In-process development projects	
<b>Cost:</b>				
Opening balance January 1, 2020	4,485	8,504	25,136	38,125
Closing balance December 31, 2020	4,485	8,504	25,136	38,125
<b>Amortization:</b>				
Opening balance January 1, 2020	(4,485)	(4,118)	—	(8,603)
Amortization for the year	—	(351)	—	(351)
Closing balance December 31, 2020	(4,485)	(4,469)	—	(8,954)
<b>Carrying amounts:</b>				
At January 1, 2020	—	4,386	25,136	29,522
At December 31, 2020	—	4,035	25,136	29,171





## Notes to the Parent Company Financial Statements continued

### Note 2 Intangible Assets continued

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 25,136 k from the period of first sale in Q1-2021. The estimated useful life is 12 years. 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 2021 (full year 2020: 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.

### 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, 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,	
	2021	2020
<b>Opening balance January 1,</b>	<b>5,095</b>	<b>5,095</b>
*Additions	0	0
<b>Closing balance December 31,</b>	<b>5,095</b>	<b>5,095</b>

\*The paid in capital of Hansa Biopharma Pty Ltd amounted to AUD 1

(in thousands of SEK, except for number of shares and share percentage)	Number of shares	Share %	As of December 31,	
			2021	2020
Cartela R & D AB/556746-0083/Lund	1,000	100	2,630	2,630
Hansa Biopharma Ltd / 08361712 / Cheltenham, United Kingdom	100,000	100	2,456	2,456
Hansa Biopharma Inc, 6846164, Delaware, USA	1,000	100	9	9
*Hansa Biopharma Australia Pty Ltd	1	100	0	0
<b>Closing balance December 31,</b>	<b>—</b>	<b>—</b>	<b>5,095</b>	<b>5,095</b>

\*Dormant Company

### Note 6 Intercompany balances

#### Receivables, group companies

##### Non-current assets

(in thousands of SEK)	As of December 31,	
	2021	2020
<b>Opening balance January 1,</b>	<b>1,972</b>	<b>2,244</b>
Change in receivables, net	231	(272)
<b>Closing balance December 31,</b>	<b>2,203</b>	<b>1,972</b>

##### Current assets

(in thousands of SEK)	As of December 31,	
	2021	2020
<b>Opening balance January 1,</b>	<b>—</b>	<b>1,061</b>
Change in receivables, net	—	(1,061)
<b>Closing balance December 31,</b>	<b>—</b>	<b>—</b>

#### Liabilities, group companies

##### Current liabilities

(in thousands of SEK)	As of December 31,	
	2021	2020
<b>Opening balance January 1,</b>	<b>1,613</b>	<b>2,793</b>
Change in liabilities, net	2,288	(1,180)
<b>Closing balance December 31,</b>	<b>3,901</b>	<b>1,613</b>

### Note 7 Inventories

The Inventories held by the Parent Company is the same as for the Group, see note 7 for the Group.



## Notes to the Parent Company Financial Statements continued

### Note 8 Trade Receivables

The Trade receivables held by the Parent Company is 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,	
	2021	2020
Insurances	829	494
Healthcare conferences	124	1,664
Software	1,177	1,378
Pension	1,644	—
Rent	2,512	1,161
Legal expenses	8,325	—
Licence fees	3,999	262
Other	2,211	435
<b>Total</b>	<b>20,820</b>	<b>5,394</b>

### Note 10 Other receivables

(in thousands of SEK)	As of December 31,	
	2021	2020
VAT receivables	9,670	3,786
Advance payments to suppliers	11,292	3,124
Other receivables	1,419	2,853
<b>Total</b>	<b>22,381</b>	<b>9,763</b>

Other receivables are mainly comprised of VAT receivables, advance payments to suppliers and other receivables.

### Note 11 Accrued Expenses

(in thousands of SEK)	As of December 31,	
	2021	2020
Annual leave accrual	15,376	10,495
Accrued social security contribution on salaries	4,395	2,964
Accrued short term incentives, incl. related social security contributions	21,713	13,127
R&D project costs	7,791	13,223
Consulting fees	17,600	11,269
Other	2,509	4,311
<b>Closing balance December 31</b>	<b>69,384</b>	<b>55,387</b>

Other receivables are mainly comprised of VAT receivables, advance payments to suppliers and other receivables.

### Note 12 Other liabilities / Current

(in thousands of SEK)	As of December 31,	
	2021	2020
Personnel related liabilities	13,358	8,325
<b>Closing balance December 31</b>	<b>13,358</b>	<b>8,325</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 – Group and Parent Company

#### 2021 Guidelines for remuneration to senior executives

The 2021 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.



## Notes to the Parent Company Financial Statements continued

### Note 14 Employees and accrued personnel cost – Group and Parent Company continued

Please also visit the Company's website at [www.hansabiopharma.com](http://www.hansabiopharma.com) for information on the 2021 guidelines for remuneration to senior executives.

Total compensation-related expenses recorded in the Group, or the Parent Company are presented below in different break-downs.

#### Group 2021

##### Total compensation-related expenses in the Group broken down to geographical areas

(in thousands of SEK)	Parent Company	Subsidiaries	Total Group
Salaries, bonuses and other benefits	135,656	18,930	154,586
Social security contribution	29,342	1 216	30,558
Pension cost, contribution plan	17,557	547	18,104
Share-based compensation	56,624	–	56,624
<b>Total compensation-related expenses</b>	<b>239,179</b>	<b>20,693</b>	<b>259,872</b>

##### Total compensation-related expenses 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	32,282	103,374	135,656
Social security contribution	10,040	19,302	29,342
Pension cost, contribution plan	2 723	14,835	17,557
Share-based compensation	33,860	22,764	56,624
<b>Total compensation-related expenses</b>	<b>78,905</b>	<b>160,274</b>	<b>239,180</b>

#### Parent Company 2021

##### Compensation-related expenses related to Senior management

(in thousands of SEK)	Base salary Directors' fees	Variable compensation	Other benefits	Total Salaries, bonuses and other benefits	Social security contributions	Pension cost	Share-based compensation	Total
Chairman of the Board of Directors Ulf Wiinberg	946	–	–	946	297	–	–	1,243
Director ** Birgit Stattin-Norinder	134	–	–	134	14	–	–	147
Director Anders Gersel Pedersen	352	–	–	352	36	–	–	388
Director Andreas Eggert	415	–	–	415	130	–	–	545
Director Eva Nilsagård	425	–	–	425	133	–	–	558
Director *** Hilary Malone	319	–	–	319	100	–	–	420
Director Mats Blom	364	–	–	364	114	–	–	478
CEO Søren Tulstrup	*7,010	3,444	128	10,582	3,325	–	12,049	25,955
Other senior executives (5 persons)	12,877	5,579	291	18,746	5,890	2,723	21,811	49,171
<b>Total</b>	<b>22,840</b>	<b>9,023</b>	<b>419</b>	<b>32,282</b>	<b>10,040</b>	<b>2,723</b>	<b>33,860</b>	<b>78,905</b>

\* Includes 1,619 KSEK, representing 30% of base salary, intended for own pension contribution

\*\* Board member until AGM 2021.

\*\*\* Board member from AGM 2021.



## Notes to the Parent Company Financial Statements continued

### Note 14 Employees and accrued personnel cost – Group and Parent Company continued

#### Group 2020

##### Total compensation-related expenses in the Group broken down to geographical areas

(in thousands of SEK)	Parent Company	Subsidiaries	Total Group
Salaries, bonuses and other benefits	85,179	11,506	96,685
Social security contribution	18,243	836	19,079
Pension cost, contribution plan	10,074	613	10,688
Share-based compensation	43,348	–	43,348
<b>Total compensation-related expenses</b>	<b>156,844</b>	<b>12,956</b>	<b>169,800</b>

##### Total compensation-related expenses 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	28,896	56,283	85,179
Social security contribution	8,894	9,349	18,243
Pension cost, contribution plan	1,357	8,717	10,074
Share-based compensation	23,882	19,466	43,348
<b>Total compensation-related expenses</b>	<b>63,029</b>	<b>93,815</b>	<b>156,844</b>

#### Parent Company 2020

##### Compensation-related expenses related to Senior management

(in thousands of SEK)	Base salary Directors' fees	Variable compensation	Other benefits	Total Salaries, bonuses and other benefits	Social security contributions	Pension cost	Share-based compensation	Total
Chairman of the Board of Directors Ulf Wiinberg	925	–	–	925	291	–	–	1,216
Director Birgit Stättin-Norinder	365	–	–	365	37	–	–	402
Director Anders Gersel-Pedersen	350	–	–	350	36	–	–	386
Director Andreas Eggert	365	–	–	365	115	–	–	480
Director Eva Nilsagård	375	–	–	375	118	–	–	493
Director Mats Blom	340	–	–	340	107	–	–	447
CEO Søren Tulstrup	*6,341	2,406	107	8,854	2,748	–	9,493	21,095
Other senior executives (5 persons)**	13,054	4,230	38	17,322	5,443	1,357	14,389	38,510
<b>Total</b>	<b>22,115</b>	<b>6,636</b>	<b>145</b>	<b>28,896</b>	<b>8,894</b>	<b>1,357</b>	<b>23,882</b>	<b>63,029</b>

\* Includes 1 506 KSEK, representing 30% of base salary, intended for own pension contribution.

\*\* Includes remuneration for one new member of the Executive committee (CMO) appointed 1 June 2020 and one former member of the Executive committee who served through 30 September 2020.



## Notes to the Parent Company Financial Statements continued

### Note 14 Employees and accrued personnel cost – Group and Parent Company continued

#### Average number of employees

	2021		2020	
	Number	Of which are men	Number	Of which are men
<b>Total Group</b>	<b>116</b>	<b>40%</b>	<b>63</b>	<b>43%</b>
<b>Parent Company</b>				
Sweden	109	40%	58	42%
<b>Subsidiaries</b>				
UK	4	75%	1	100%
US	3	25%	4	25%
<b>Total subsidiaries</b>	<b>7</b>	<b>–</b>	<b>5</b>	<b>–</b>

#### Breakdown of senior management according to gender

	Share of women	
	2021	2020
<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 chairman of the Board of Directors and other directors pursuant to a resolution adopted by the annual general meeting ("AGM"). The 2021 AGM resolved that fees paid to directors for work during 2021 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 25,000 each to directors who are members of the Scientific Committee. 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

In 2021, the CEO received a total of SEK 10,582k in salaries, bonuses and other benefits.

##### 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 2021, executive management comprised of six people including the CEO.

Salaries, bonuses, and other benefits to the other members of the executive management amounted to SEK 18,746k in 2021.

#### 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.



## Notes to the Parent Company Financial Statements continued

### Note 14 Employees and accrued personnel cost – Group and Parent Company continued

#### Pension contributions

Other members of executive management, Donato Spota, Christian Kjellman and Anne Säfstöm Lanner, are entitled to retire at the age of 65 without any requirement of notice. However, they are entitled to continue working until 68 years of age. Henk Doude van Troostwijk's employment terminates without any requirement of notice at the age with right to retirement age according to Dutch Old Age Pension Act (AOW). Other members of executive management are entitled to pension benefits in accordance with the Company's insurance and pension policy.

#### Share-based compensation

The share-based compensation recorded and presented by the Parent Company is the same as for the Group, see note 14 for the Group.

### 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 2021 amounted to SEK 1,855,284,000 (2020: SEK 1,369,772,000). 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:

	2021		2020	
	%	(in thousands of SEK)	%	(in thousands of SEK)
Result before tax	—	(549,098)	—	(421,644)
Tax according to current tax rate	20.6	113,114	21.4	90,232
Non-deductible expenses	(2.4)	(13,099)	(2.2)	(9,119)
Increase in loss carry forwards without corresponding capitalization of deferred tax	(18.2)	(100,015)	(19.2)	(81,113)
Reported effective tax	—	—	—	—

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 and the Group is the same as for the Group, see note 19 for the Group.

### 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.

(in thousands of SEK)	Financial assets valued at amortized cost		Financial assets valued at fair value through the income statement	
	2021	2020	2021	2020
<b>Financial assets:</b>				
Short term investments	—	—	237,619	238,144
Receivables, group companies	2,203	1,972	—	—
Trade receivables	9,712	110	—	—
Other receivables	1,419	2,853	—	—
Cash and cash equivalents	644,975	1,133,647	—	—
<b>Total financial assets</b>	<b>658,309</b>	<b>1,138,582</b>	<b>237,619</b>	<b>238,144</b>



## Notes to the Parent Company Financial Statements continued

### Note 19 Financial Risk and Financial Instruments continued

(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	
	2021	2020	2021	2020
<b>Financial liabilities:</b>				
Contingent consideration	—	—	722	663
Liabilities, group companies	3,901	1,613		
Trade payables	53,240	26,623	—	—
Accrued expenses (see note 11)	27,900	28,802	—	—
<b>Total financial liabilities</b>	<b>85,041</b>	<b>57,039</b>	<b>722</b>	<b>663</b>

### Note 20 Finance Income and Expenses

(in thousands of SEK)	Years Ended December 31,	
	2021	2020
Interest income	67	388
Changes in the fair value of interest funds during the year	—	1,782
<b>Finance income</b>	<b>67</b>	<b>2,170</b>
Interest expenses	(693)	(307)
Changes in the air value of interest funds during the year	(525)	—
<b>Finance costs</b>	<b>(1,218)</b>	<b>(307)</b>
<b>Net finance costs/income</b>	<b>(1,151)</b>	<b>1,863</b>

### Note 21 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 22 Share Premium

The Share Premium stated by the Parent Company is the same as for the Group, see note 22 for the Group above.

### Note 23 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 24 for the Group.

### Note 24 Reserves

#### Treasury share reserve

The treasury share reserve comprise own shares repurchased by the Group.

#### Fair value reserves

Fair value fund includes the accumulated change in fair value after tax on the holding of shares and shares that the Group has chosen to report at fair value through other comprehensive income according to IFRS 9.

Please refer to Note 14 related to the Group's LTIP programs and respective vesting dates.

### Note 25 Royalty Agreements

The Parent Company is party to the same royalty agreements as the Group, see note 26 for the Group.

### Note 26 Other operating income and expenses

(in thousands of SEK)	Years Ended December 31,	
	2021	2020
<b>Other operating income</b>		
Foreign currency gains on receivables/liabilities from operating activities	—	2,270
<b>Total other operating income</b>	<b>—</b>	<b>2,270</b>
<b>Other operating expenses</b>		
Foreign currency losses on receivables/liabilities from operating activities	(7,395)	—
<b>Total other operating expenses</b>	<b>(7,395)</b>	<b>—</b>





## Notes to the Parent Company Financial Statements continued

### Note 27 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,	
	2021	2020
Personnel expenses	(245,189)	(165,173)
Third party expenses	(305,969)	(259,354)
Depreciation and amortization expenses	(8,418)	(6,350)
Other operating expenses	(6,824)	—
<b>Total operating expenses</b>	<b>(566,400)</b>	<b>(430,877)</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)	Years Ended December 31,	
	2021	2020
Research and development expenses	5,516	1,894
Sales, general and administrative expenses	2,902	4,456
<b>Total</b>	<b>8,418</b>	<b>6,350</b>

### Note 28 Supporting information to the cash flows

(in thousands of SEK)	As of December 31,	
	2021	2020
<b>Cash and cash equivalents consist of:</b>		
Cash and bank deposits	644,975	1,133,647
Total according to the statement of financial position	644,975	1,133,647
Total according to the cash flow	644,975	1,133,647

Reconciliation of liabilities arising from financing activities:

(in thousands of SEK)	2021	2020
<b>Opening balance January 1,</b>	<b>5,045</b>	<b>9,458</b>
Termination of lease agreement	(308)	(280)
New lease agreements	35,499	540
Payment of lease liabilities	(4,857)	(4,674)
<b>Closing balance December 31,</b>	<b>35,379</b>	<b>5,045</b>



## Notes to the Parent Company Financial Statements continued

### Note 29 Audit fees – Group and Parent Company

(in thousands of SEK)	Years Ended December 31,	
	2021	2020
<b>Group</b>		
KPMG AB:		
*Auditing services	9,892	695
Other services closely related to audit services	300	160
Tax services	—	—
Azets Audit Services		
Auditing services	68	64
<b>Parent Company</b>		
KPMG AB:		
*Auditing services	9,842	545
Other services closely related to audit services	300	160
Tax services	—	—

\* Thereof PCAOB Audit services related to the preparation for dual listing on NASDAQ, USA, amounts to 8,832.

### Note 30 Collateral provided, contingent liabilities and contingent assets

Nothing to report related to the financial year 2021 and 2020.

### Note 31 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 32 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 2021 and 2020 cover the Parent Company and its subsidiaries, jointly referred to as the Group.

### Note 33 Appropriation of loss carried forward

Unrestricted shareholders' equity in the Parent Company:

(in SEK)	As of December 31,	
	2021	2020
Share premium reserve	2,572,925,209	2,509,457,908
Treasury shares	(1,861,909)	(1,421,457)
Loss carried forward	(1,312,352,987)	(890,710,056)
Loss for the year	(549,097,916)	(421,642,931)
<b>Total</b>	<b>709,612,397</b>	<b>1,195,683,464</b>

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

(in SEK)	As of December 31,	
	2021	2020
Share premium reserve	2,572,925,209	2,509,457,908
Treasury shares	(1,861,909)	(1,421,457)
Loss carried forward	(1,861,450,903)	(1,312,352,987)
<b>Total</b>	<b>709,612,397</b>	<b>1,195,683,464</b>

### Note 34 Subsequent events

The subsequent events for the Parent Company are the same as for the Group, see note 30 for the Group.



# 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 6 April 2022

**Ulf Wiinberg**

*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 6 April 2022. 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 16 June 2022.

Our auditors' report was submitted on 7 April 2022.

KPMG AB

**Jonas Nihlberg**

*Authorized Public Accountant*



# Auditor's Report

Translation from the Swedish original

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 2021. The annual accounts and consolidated accounts of the company are included on pages 58-66 and 76-122 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 31 December 2021 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 31 December 2021 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. 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 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 in note 13 and accounting principles on pages 82-83 in the annual account and consolidated accounts for detailed information and description of the matter.

### Description of key audit matter

During 2021, the Company recognize contract revenue in the amount of SEK 15.7 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

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 2-57, 67-75 and 127-155. The other information comprises also of the remuneration report on pages 147-152. 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.



## Auditor's Report continued

Translation from the Swedish original

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.

### 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 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

Translation from the Swedish original

### 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 2021 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members 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 any 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 2021.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report #[checksum] has been prepared in a format that, in all material respects, enables uniform electronic reporting.



## Auditor's Report continued

Translation from the Swedish original

### 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 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 ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and 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 technical validation of the Esef report, i.e. if the file containing the Esef report meets the technical specification set out in the Commission's Delegated Regulation (EU) 2019/815 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 Esef report has been marked with iXBRL which enables a fair and complete machine-readable version of the consolidated statement of financial performance, financial position, changes in equity and cash flow.

KPMG AB, Box 227, 201 22, Malmö, was appointed auditor of Hansa Biopharma AB by the general meeting of the shareholders on the 12 May 2021. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2014.

Malmö April 7, 2022

KPMG AB

**Jonas Nihlberg**

*Authorized Public Accountant*





# Governance

General principles	129
The Board	133
Executive management	138
Internal controls and risk management in respect of the financial reporting	141
Compliance	143
Auditor statement on the corporate governance report	144



# 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 2021 Corporate Governance Report in accordance with the requirements of the Swedish Annual Accounts Act (1995:1554) (Sw. årsredovisningslagen) and the Swedish Code of Corporate Governance (the “Code”); see the Swedish Corporate Governance Board website at <https://www.bolagsstyrning.se/>.**

The Company's shares were admitted for trading on Nasdaq Stockholm in November 2015. The Company's shares were previously, since 2007, listed on Nasdaq First North. 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.

The 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.

The Group comprises the Parent Company, Hansa Biopharma AB, and its wholly owned subsidiaries Cartela R & D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc, and Hansa Biopharma Australia Pty Ltd.

There are no deviations from the Code to report for the financial year 2021. 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 2021.

## Shareholders

There are no limitations on the transferability of Hansa Biopharma'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 December 31, 2021, Redmile Group LLC is the only shareholder owning more than 10 percent of the Company's shares, by its shareholdings of 13 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
- > Financial handbook
- > Staff handbook
- > Executive remuneration policy
- > Code of Conduct
- > Supplier Code
- > Global Data Privacy policy
- > Information policy

### Significant external regulations

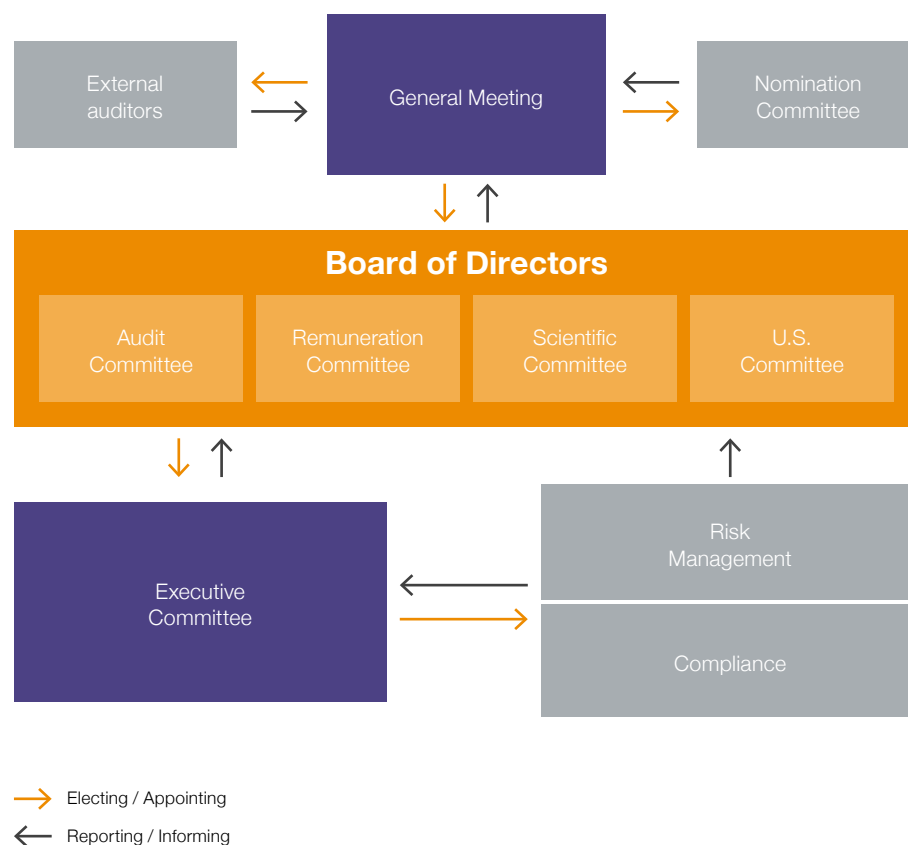
- > Market Abuse Regulation
- > Swedish Companies Act
- > Swedish Accounting Act
- > Swedish Annual Accounts Act
- > International standards for audits and financial reporting (IFRS)
- > Nordic Main Market Rulebook for Issuers of Shares
- > Swedish Code of Corporate Governance



## General principles continued

### Hansa's corporate governance structure

#### Overview of Hansa's corporate governance structure during 2021



### Information regarding Hansa Biopharma AB shares

The shares in the Company are divided into ordinary shares and C-shares. On December 31, 2021, the total number of shares issued was 46,335,361 with 44,473,452 ordinary shares outstanding and 1,861,909 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.

Each ordinary share confers the right to an equally large percentage of the Company's distributable profits. The C-shares do not entitle 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 to senior executives.

### 2021 Annual General Meeting

The 2021 AGM was held on May 12, 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, 20 439 930 of the shares in the Company were represented, meaning that 45.81 percent of the total number of votes and 44.54 percent of the total number of shares in the Company were represented.



## General principles continued

The AGM adopted the 2020 annual accounts, adopted a resolution regarding that the members of the Board shall be six with no deputy members, and granted the directors and CEO a discharge from liability. The general meeting resolved that no dividend would be paid. The AGM resolved that Ulf Wiinberg, Anders Gersel Pedersen, Andreas Eggert, Eva Nilsagård and Mats Blom are re-elected as members of the Board, and resolved election of Hilary Malone as new member of the Board, all for the period until the end of the next AGM. Birgit Stattin Norinder, previous member of the Board until the end of the AGM 2021, was not standing for re-election. The AGM further resolved to re-elect Ulf Wiinberg as chairman of the Board for the period until the end of the next AGM. The AGM resolved to re-elect KPMG AB as auditor, with Jonas Nihlberg as the auditor in charge, for the period until the end of the next AGM.

The AGM resolved that the fees for the Board, for the period until the end of the next AGM, should remain unchanged from the previous year and shall be SEK 900,000 to the chairman 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 should be SEK 150,000 and SEK 75,000 to each other member in the Audit Committee, SEK 40,000 to the chair of the Remuneration Committee and SEK 25,000 to each other member in the Remuneration Committee, and SEK 25,000 to each board member in the Scientific Committee. For the chair of the new U.S. Committee the remuneration should be USD 20,000. It was further resolved that the remuneration to the auditor shall be paid as per approved current account.

The AGM further resolved, in accordance with the Board's proposal, to adopt new guidelines for executive remuneration, to amend the articles of association, adopt a long-term incentive program based on performance-based share rights for employees at Hansa Biopharma, adopt a long-term incentive program based on employee stock options for employees in Hansa Biopharma and to amend the terms of the long-term incentive programs based on employee stock options adopted in 2019 and 2020.

It was further resolved, in accordance with the Board's proposal, to authorize the Board, for the period up to the next AGM, to adopt decisions, whether on one or several occasions and whether with or without pre-emptive rights for the shareholders, to issue new ordinary shares, and warrants and/or convertibles; provided however that such issues, or number of shares created in connection with conversion of warrants and/or convertibles, in aggregate, may not

correspond to a dilution of more than 20 per cent of the total number of shares outstanding after full exercise of the authorization. It should also be possible to make such an issue resolution stipulating payment in cash, in kind payment, the right to offset debt or other conditions. The purpose of the authorization is to increase the financial flexibility of the Company and the acting scope of the Board as well as to potentially broaden the shareholder base.

Minutes from the AGM 2021 are available at Hansa Biopharma's website ([www.hansabiopharma.com](http://www.hansabiopharma.com)). The 2022 AGM will take place on 16 June 2022.

### Remuneration to senior executives

The remuneration guidelines for senior executives adopted by the 2021 AGM, amending the 2020 guidelines, entail those senior executives are 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 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 (including STI), share-based long-term incentive programs (LTIP) as resolved by the AGM, severance remuneration, and other benefits. The variable salary shall be on market terms and be based on the achievement of quantitative and qualitative targets and should 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 percent of the annual fixed base salary. Contributions to pension plans shall not exceed 30 percent 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.

If notice of termination is made by the Company, the notice period may not exceed six months and the fixed cash salary during the period of notice and severance pay may together not exceed an amount equivalent to the fixed cash salary for 18 months for the CEO, and, for other senior executives, may not exceed an amount equivalent to the fixed cash salary for 6 months, and in exceptional cases, 12 months. When termination is made by the senior executive, the period of notice may not exceed six months and no severance pay will be paid.



## General principles continued

Share and share based long-term incentive programs shall be decided by the Annual General Meeting. For information regarding the adopted ongoing long-term incentive programs, please refer to the Directors Report and Note 2 and Note 14 to the Consolidated Financial Statements elsewhere in this Annual Report 2021.

The Board of Directors may temporarily resolve to derogate from the executive remuneration guidelines, in whole or in part, if in a specific case there is special cause for the derogation and a derogation is necessary to serve the Company's long-term interests, including its sustainability, or to ensure the Company's financial viability.

Please refer to Note 14 to the Financial Statements of the Parent Company and the Remuneration report in this Annual Report 2021 for further information on the 2021 guidelines.

The Board of Directors will propose an amendment to the current guidelines at the 2022 AGM by which a tailored employee incentive program that balances individual achievement and organisational contribution is to be implemented in which it is proposed that the performance criteria for the "Annual Short-Term Incentive ("STI") shall include both corporate and individual objectives. Furthermore, it is proposed that the performance criteria, weighting and targets for the individual objectives under the STI are to be proposed, evaluated and approved annually CEO as manager for members of the executive committee or, if it is not the CEO, then the respective manager for such members of the executive committee, and for the CEO the Remuneration Committee. The proposed adjustments have been reflected in these guidelines which will be subject to the shareholders' approval at the annual general meeting 2022 and are appended to this document as an appendix to this Corporate Governance Section.

During 2021, neither the Remuneration Committee nor the Board of Directors received any comments or questions from the shareholders on the remuneration guidelines adopted at the 2021 AGM.

### Nomination Committee

Prior to the 2022 AGM, Hansa's Nomination Committee comprises of Laura Feinleib (temporary replacement for Natalie Berner and representing Redmile Group), Lotta Sjöberg (representing Handelsbanken Fonder), and Jannis Kitsakis (chair of the Nomination Committee and representing AP4). Ulf Winberg (chairman of the Board) is the convenor of the Nomination Committee.

According to the Code, Hansa is required to have a Nomination Committee, which is not a standing committee of the Board. The AGM shall appoint the members of the Nomination Committee or resolve on procedures for appointing the members. Such procedures were adopted by the 2021 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's responsibilities include preparing a proposal for the number of directors and persons to be elected as directors, including the chairman of the Board, and a proposal for remuneration to the chairman and the other Board members, as well as a proposal for remuneration for the Board members' committee work. The Nomination Committee also proposes election of a chairman of the annual general meeting, and election of auditors including remuneration to the auditor. Finally, the Nomination Committee proposes principles for the Nomination Committee prior to the AGM 2023. The proposals will be published in connection with the notice to the 2022 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, was 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 2018 AGM certified public accountant Jonas Nihlberg is auditor in charge. From the 2014 AGM up to and including the 2018 AGM, certified public accountant Dan Kjellqvist was auditor in charge. Dan Kjellqvist personally was the Company's auditor commencing at the time of the 2014 AGM up to and including the 2015 AGM. Jonas Nihlberg and Dan Kjellqvist are members of the Swedish Institute of Authorized Public Accountants. For information regarding fees paid to the auditors, please refer to Note 29 to the Financial Statements of the Parent Company elsewhere in this 2021 annual report.



# The Board

## 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 rules of procedure which are adopted annually, and which govern the frequency and agenda of Board 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 chairman, and the CEO, and which defines the CEO's authority.

The Board, including the chairman, 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 to be independent under the corporate governance standards of the Code and Nasdaq Stockholm. The chairman must keep himself well informed about, and monitor, the Company's business. The chairman 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. The chairman is also responsible for ensuring that the Board carries out the decisions that are made and that their work is evaluated. Further on, the chairman is also responsible for ensuring that the directors regularly update their knowledge about the Company and that new directors receive necessary introductory training.

The chairman represents the Company in ownership questions and is responsible for the day-to-day contact with the CEO and senior executives. The chairman must also approve remuneration and other employment terms and conditions for senior executives. The chairman is also responsible for the Company's archives, in which minutes from all Directors' meetings and general meetings must be saved.

The chairman prepares Board meetings together with the CEO. The notice of the meeting and the agenda are sent to the directors only after they have been approved by the chairman. After this, the notice is sent together with sufficient decision-making documentation to the directors. As the case may be, 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 articles of association, the Board must comprise not less than three and not more than ten directors elected by the general meeting. 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' fees were set at the 2021 AGM for a period up to and including the next AGM. The fees for the Board's work in 2021 were set as follows: The chairman is paid SEK 900,000, and each other director is paid SEK 300,000. Further, SEK 150,000 is paid to the chairman and SEK 75,000 is paid to each other board member in the Audit Committee, SEK 40,000 is paid to the chairman and SEK 25,000 is paid to each other board member in the Remuneration Committee and SEK 25,000 is paid to each board member in the Scientific Committee. For the U.S. Committee, which was adopted in 2021, USD 20,000 is paid to the chairman. No remuneration other than the abovementioned fees have been paid to the Board except for travel cost reimbursements. The Board members are not entitled to any share-based compensation.

No pension premiums or similar benefits were paid to directors. None of the directors are entitled to benefits after completion of their duties. Please see the Remuneration Report and Note 14 to the Financial Statements of the Parent company elsewhere in this 2021 annual report for additional information regarding employment terms and conditions for the Board and senior executives.

### Directors

The Board currently comprises six individuals, including the chairman.

The 2021 AGM re-elected Ulf Wiinberg, Anders Gersel Pedersen, Andreas Eggert, Eva Nilsagård, and Mats Blom as members of the Board. Further, Hilary Malone was elected as new member of the Board. Birgit Stattin Norinder, previous member of the Board, was not standing for re-election. The AGM further resolved to re-elect Ulf Wiinberg as chairman of the Board. Each director's term continues until the end of the next AGM.

Prior to the 2021 AGM, the Nomination Committee announced that it had applied the provisions of rule 4.1 of the Code as 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 taken into account. 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 board members elected by the AGM are women.



## The Board continued

The following is a list of the directors, containing information regarding their years of birth and election to the Board, education, work experience, engagement in the Company and other significant engagements and holdings in the Company as of 31 December 2021. Holdings in the Company includes one's own holdings as well as those of closely related persons.

### Tenure (years)

5

LONGEST

1

SHORTEST

### Gender diversity

33%

FEMALE

67%

MALE

### Meetings

11

BOARD MEETINGS

98%

ATTENDANCE



#### Ulf Wiinberg

Member and Chairman of the Board since 2016.  
Member of the Board and acting CEO from November 9, 2017 until March 20, 2018.

Shareholding: 124,350 shares

Ulf Wiinberg has served as the chairman of the Board since May 2016. Ulf also served as the acting Chief Executive Officer from November 2017 until March 2018. Ulf is an experienced healthcare industry professional with over 40 years of experience, and has served on the boards of several healthcare industry associations. He serves as the Chief Executive Officer of X-Vax Technology, Inc., a company seeking to develop a vaccine against herpes, since April 2017. Ulf also served as Chief Executive Officer of H. Lundbeck A/S (CSE: LUN), a pharmaceutical company specialized in psychiatric and neurological disorders, from June 2008 to December 2014. Prior to that, he held multiple executive roles at Wyeth, LLC (acquired by Pfizer Inc. (NYSE: PFE)), serving as worldwide President from 2002 to 2005 and President of the European, Middle Eastern and African region from February 2002 to June 2008, and has also been President of the Global consumer health care business. Ulf also serves as a non-executive member of the board of Alfa Laval AB (STO: ALFA), Agenus Inc. (NASDAQ: AGEN), MiNK Therapeutics, Inc. (NASDAQ: INKT), a clinical-stage precision oncology company developing cell therapies for cancer and other immune-mediated diseases (subsidiary of Agenus Inc.), and at the Belgian pharmaceutical Company Union Chimique Belge (UCB) (Euronext: UCB). He is also chairman of the board of Sigrid Therapeutics AB. He was born in 1958.

Ulf is member of Hansa's Remuneration Committee, Scientific Committee and U.S. Committee.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



#### Eva Nilsagård

Member of the Board since 2019.

Shareholding: 3,000 shares

Eva Nilsagård has served as a member of the Board and chair of the Audit Committee since May 2019. Since July 2015, Eva has served as the founder and Chief Executive Officer of Nilsagård Consulting AB. She previously served as interim Chief Financial Officer of various companies, including OptiGroup AB from January 2019 to October 2019 and April 2020 to December 2020, Plastal from September 2016 to September 2017, and Vitrolife AB (STO: VITR) from March 2009 to August 2010. She also served in various senior positions at the Volvo Group, or Volvo (STO: VOLV), including Senior Vice President Strategy & Business Development from September 2010 to June 2014. Earlier in her career, Eva also held senior positions in finance and business development at AstraZeneca plc (LSE: AZN) and AB SKF (STO: SKF). She is a board member and chair of the audit committee of SEK (Swedish Export Credit Company), AddLife (STO: ALIF), Bufab Group (STO: BUFAB), Irras AB (STO: IRRAS), Nimbus Group AB (STO: BOAT), Nanexa (STO: NANEXA) and Xbrane Biopharma (STO: XBRANE), the chair of Spermosens AB (Spotlight: SPERM) and Diagonal Bio AB (STO: DIABIO), and a 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. She was born in 1964.

Eva is Chair of Hansa's Audit Committee.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



#### Mats Blom

Member of the Board since 2019.

Shareholding: 1,000 shares

Mats Blom has served as a member of the Board since May 2019. Mats has served as the Chief Financial Officer of NorthSea Therapeutics B.V. since September 2019. Prior to that, he served as Chief Financial Officer of Modus Therapeutics AB (STO: MODTX) from April 2019 to July 2019, Zealand Pharma A/S (CSE: ZELA) from March 2010 to March 2019, and Swedish Orphan International AB (acquired by BioVitrum, now Swedish Orphan Biovitrum AB (publ) (STO:SOBI)) from October 2007 to March 2010. Mats also served as Chief Financial Officer at Active Biotech AB (publ) (STO:ACTI) and Anoto Group AB (STO: ANOT). Earlier in his career, he also served as a management consultant at Gemini Consulting and Ernst & Young. Mats is a board member of Egetis Therapeutics AB (STO: EGTX), Altamira Therapeutics Ltd. (NASDAQ: CYTO) and Pephexia Therapeutics ApS. He holds a B.A. in Business Administration and Economics from the University of Lund and an M.B.A. from the IESE University of Navarra, Barcelona. He was born in 1965.

Mats is member of Hansa's Audit Committee.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.





## The Board continued



### Andreas Eggert

Member of the Board since 2018.

**Shareholding: 5,500 shares**

Andreas Eggert has served as a member of the Board since May 2018. Andreas has over 25 years of cross-functional leadership experience including commercial operations, launch and portfolio management, brand strategy, market access, and strategic consulting. He has served as the Chief Operating Officer at X-Vax Technology Inc. in the U.S. since October 2018. Previously, he 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 from November 2010 to June 2015, where he was responsible for multiple new product launches and the commercial leadership for shaping the product portfolio and development pipeline. Previously, Andreas served in various senior commercial roles at Wyeth, LLC (acquired by Pfizer Inc. (NYSE: PFE)) in the U.S., Japan and in Germany from 1999 to 2010, including as Vice President & Global Business Manager from September 2005 to April 2010. Earlier in his career, Andreas also was a Management Consultant at A.T. Kearney. He holds an M.B.A. from Azusa Pacific University. He was born in 1967.

Andreas is Chair of Hansa's Remuneration Committee, and member of the Audit Committee and Scientific Committee.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



### Anders Gersel Pedersen

Member of the Board since 2018.

**Shareholding: 2,500 shares**

Anders Gersel Pedersen, M.D., Ph.D., has served as a member of the Board since May 2018. Anders has over 32 years of experience in the international pharmaceutical industry. From January 2000 to December 2018, he served in various roles at H. Lundbeck A/S in Denmark (CSE: LUN), including most recently as Executive Vice President of Research & Development, where he was responsible for the discovery and development of the product pipeline from preclinical activities to post-launch marketing studies. Prior to that, he served in various roles at Eli Lilly and Company (NYSE: LLY) from August 1988 to December 1999, including most recently as a director overseeing worldwide clinical research in oncology. He is a member of the European Society of Medical Oncology, the International Association for the Study of Lung Cancer and the American Society of Clinical Oncology. Anders serves on the supervisory boards of Avillion LLP, Bavarian Nordic A/S (CSE: BAVA), 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. He was born in 1951.

Anders is Chair of Hansa's Scientific Committee, and member of the Remuneration Committee.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



### Hilary Malone

Member of the Board since 2021.

**Shareholding: –**

Hilary M. Malone, Ph.D., has served as a member of the Board since May 2021. Hilary has over 25 years of experience in global drug development, regulatory and government affairs, manufacturing and commercialization within the pharmaceutical industry. She has served as Chief Executive Officer of a private life sciences company in start-up phase since November 2021. She previously served as Chief Operating Officer and Executive Vice President at Valo Health Inc. from January 2020 to September 2021. Prior to that, Hilary served as the Chief Regulatory Officer and Senior Vice President & Head of Global Regulatory Affairs at Sanofi Inc. (subsidiary of Sanofi SA (Euronext: SAN)). Her previous experience also includes senior regulatory and drug development roles at Reata Pharmaceuticals, Inc. (NASDAQ: RETA), Pfizer Inc. (NYSE:PFE), Wyeth, LLC (acquired by Pfizer Inc.), AstraZeneca plc (LSE: AZN) and GlaxoSmithKline plc (LSE: GSK). Hilary served on the board of Inhibikase Therapeutics (NASDAQ: IKT) from 2016 to 2019. She holds a Ph.D. in Molecular Neuropharmacology and a B.Sc. in Physiology from the University of Dundee, Scotland. She was born in 1965 and is a U.S., U.K., and Irish citizen.

Hilary is Chair of Hansa's U.S. Committee and member of the Scientific Committee.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.



## The Board continued

### The Board of Directors' work in 2021

During 2021, the Board has held 11 meetings, all of which were held via Teams, of which one was the inauguration meeting and one was a combined board meeting and remuneration committee meeting. The Board has also made resolutions per capsulam at four occasions.

At the Board meetings held during the 2021 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 chairman of the Board by an independent evaluation company, in the end of 2021, interviewing the directors with questions about the work of the Board. The result of the responses has been verbally declared to the directors and the members of the nomination committee.

#### Board members and meeting presence for the reporting period, 1 January – 31 December 2021<sup>1</sup>

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	Independent in relation to the Company and Executive management	Independent in relation to the Company's largest shareholders
Ulf Wiinberg <sup>1</sup>	2016	11(11)	4(4)	–	2(2)	Yes	Yes
Hilary Malone <sup>1,2</sup>	2021	6(6)	–	–	2(2)	Yes	Yes
Anders Gersel Pedersen	2018	10(11)	4(4)	–	2(2)	Yes	Yes
Birgit Stattin Norinder <sup>3</sup>	2012	5(5)	2(2)	–	–	Yes	Yes
Andreas Eggert <sup>4</sup>	2018	11(11)	2(2)	7(7)	2(2)	Yes	Yes
Eva Nilsagård	2019	11(11)	–	7(7)	–	Yes	Yes
Mats Blom	2019	11(11)	–	7(7)	–	Yes	Yes

<sup>1</sup> The U.S. Committee did not have any separate meetings, as U.S. topics were discussed during regular Board meetings.

<sup>2</sup> Board member since AGM 2021.

<sup>3</sup> Board member until AGM 2021.

<sup>4</sup> Member of Remuneration Committee since AGM 2021.



## The Board continued

### Board committees

#### Audit Committee

After the 2021 AGM, the Audit Committee consisted of Eva Nilsagård, chair, Mats Blom and Andreas Eggert. The Audit Committee is obligated to keep 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 2021 AGM, the Remuneration Committee has consisted of Andreas Eggert, chair, Ulf Wiinberg 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 2021 AGM, the Scientific Committee consists of Anders Gersel Pedersen, chair, Andreas Eggert, Ulf Wiinberg 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 was adopted by the Board at a meeting held on July 14, 2021. After the 2021 AGM, the U.S. Committee consists of Hilary Malone, chair, and Ulf Wiinberg. 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 individuals who together make up Company executive management:

- > President and Chief Executive Officer
- > Senior Vice President, Chief Financial Officer
- > Senior Vice President, Chief Commercial Officer
- > Senior Vice President, Chief Scientific Officer and Chief Operating 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 bookkeeping 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; however 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 below.

## Senior executives

Hansa Biopharma's senior executives currently comprise six individuals: President and CEO Søren Tølstrup; Senior Vice President, Chief Scientific Officer and Chief Operating Officer



## Executive management continued

Christian Kjellman; Senior Vice President, Chief Financial Officer Donato Spota; Senior Vice President, Chief Commercial Officer Henk Doude van Troostwijk; Senior Vice President, Chief Medical Officer Achim Kaufhold and Senior Vice President, Chief Human Resources Officer Anne Säfström Lanner.

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 2021 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.

The number of share rights refers to the maximum number of ordinary shares which the executive may obtain as a result of the implementation of the incentive programs LTIP2018, LTIP2019, LTIP2020, and LTIP2021. Following the maturity of the incentive programs and provided that certain performance conditions have been fulfilled, the share rights will entitle the holder to receive a certain number of ordinary shares free of charge. Allocation of shares could be lower or zero depending on the share price development and whether or not performance conditions are met.



### Søren Tulstrup CEO

**Shareholding: 15,000**  
**Share rights: 172,429**  
**ESOPs: 315,107**

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, he served as Chief Executive Officer of Vifor Pharma AG (SIX: VIFN), (now part of CSL Behring), a Glattbrugg, Switzerland-based global pharmaceutical company. Søren also previously served as Chief Executive Officer of Santaris Pharma A/S (now part of F. Hoffmann-La Roche AG, or Roche (SIX: ROG)), a leading clinical stage biopharmaceutical Company developing RNA-targeted drugs for various therapeutic areas including rare genetic diseases. 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. He was born in 1965.



### Christian Kjellman Senior Vice President, Chief Scientific Officer and Chief Operating Officer

**Shareholding: –**  
**Share rights: 94,356**  
**ESOPs: 134,380**

Christian Kjellman has served as Chief Scientific Officer since January 2008 and Chief Operating Officer since January 2020. Prior to joining Hansa, he served as Principal Scientist at Biolnvent AB (STO: BINV) from 2007 to 2008, 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 from 2004 to 2007, mainly focusing on novel drug target evaluation. 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. He was born in 1967.



### Donato Spota Senior Vice President, Chief Financial Officer

**Shareholding: –**  
**Share rights: 102,073**  
**ESOP's: 176,842**

Donato Spota has served as Chief Financial Officer since May 2019. Donato brings more than 20 years of pharmaceutical industry experience in international environments, including strategic finance, business development, investor relations and international capital markets transactions to the Company. Prior to joining Hansa, he served in various roles at Basilea Pharmaceutica AG, or Basilea (SIX: BSLN), including as Chief Financial Officer from November 2013 to April 2019. 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. He was born in 1971.



## Executive management continued

The number of ESOP's refers to the number of employee stock options which the executive holds following the implementation of the incentive programs LTIP2019, LTIP2020 and LTIP2021. In LTIP2019, each employee stock option entitles the holder to subscribe for one new ordinary share at a subscription price corresponding to 110 per cent of the volume weighted average share price during the ten (10) trading days immediately prior to the offer to subscribe for the employee stock options. In LTIP2020 and LTIP2021, each employee stock option entitles the holder to subscribe for one new ordinary share at an exercise price corresponding to the higher of (i) 125 per cent of the volume weighted average share price during the 10 and 30 trading days, respectively, immediately preceding the respective allotment of the employee stock options. The employee stock options were allotted free of charge and have a vesting period of three years.



**Henk Doude van Troostwijk**  
Senior Vice President, Chief Commercial Officer

**Shareholding:** –  
**Share rights:** 71,717  
**ESOPs:** 91,231

Henk Doude van Troostwijk has served as Senior Vice President and Chief Commercial Officer since June 2019. In addition, Henk served as Hansa's Vice President Global Commercial Operations from March 2016 to June 2019. Prior to joining Hansa, he served as General Manager of European Commercial Operations and Emerging Markets at Raptor Pharmaceutical Corp. (acquired by Horizon Pharma plc (NASDAQ: HZNP)), an orphan disease focused global biopharma company based in the U.S., from April 2012 to March 2016. Prior to that, he served as Business Unit Director Oncology and Transplantation at Genzyme Europe B.V. (acquired by Sanofi S.A. (Euronext: SAN)) from January 2008 to April 2012. Henk holds an M.B.A. from Henley Management College at the University of Reading, UK. He was born in 1965.



**Anne Säfström Lanner**  
Senior Vice President,  
Chief Human Resources Officer

**Shareholding:** 610  
**Share rights:** 89,618  
**ESOPs:** 70,000

Anne Säfström Lanner has served as Chief Human Resources Officer since June 2020. In addition, Anne served as Hansa's Vice President Global Human Resources from January 2019 to June 2020. She brings 18 years of human resources experience in international environments. Prior to joining Hansa, she served in various senior roles at the European Spallation Source, a European multi-disciplinary research facility, from August 2011 to January 2019, including Head of Resourcing from January 2017 to January 2019. Prior to that, Anne served as Head of Human Resources at Cellavision AB (STO:CEVI), a provider of digital solutions for medical microscopy within hematology, from April 2010 to August 2011. She has held positions both as Head of HR, Head of Resourcing, HR Manager & Deputy Head of HR and has extensive experience from fast growing start-up international companies. Anne holds a Bachelor of Social Science in Human Resource Management, focusing on strategic organizational development & leadership, from Lund University. She was born in 1969.



**Achim Kaufhold**  
Senior Vice President, Chief Medical Officer

**Shareholding:** –  
**Share rights:** 60,000  
**ESOPs:** 70,000

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 and has a successful track record in taking products from early discovery through development and to the market. Prior to joining Hansa, Achim served in various senior executive positions in general management, product and business development. He served as Chief Executive Officer of Affitech AS in 2009 and Pharmexa A/S in 2008 (which companies merged), Chief Medical Officer of Basilea Pharmaceutica AG, or Basilea (SIX: BSLN) from February 2010 to December 2017, Pharmexa A/S from 2007 to 2008, Chiron (acquired by Novartis (NYSE: NVS)) from 2005 to 2006 and Berna Biotech AG (now Johnson & Johnson (LSE: JNJ)) from 2001 to 2005. Prior to that, he headed the worldwide clinical development of the pediatric vaccine portfolio of GlaxoSmithKline plc (LSE: GSK). He currently also serves on the board of directors of Biosergen AB (STO: BIOSGN). Achim 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. He was born in 1957.





# 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 the 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 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 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, financial handbook 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. Policies, 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 the 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, financial handbook, 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. 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 3rd 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 analyzed and commented upon.





## Internal controls and risk management in respect of the financial reporting continued

### Information and communication

The informational activities are governed by an information 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. A uniform strategy for external communications reduces the risk of erroneous information, rumours, and misunderstandings. All communications must take place in accordance with Nasdaq Stockholm's Issuer Rules, the Swedish Code of Corporate Governance, 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)) after having first been 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 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.



# Executive Remuneration – to be approved by AGM'22

The senior executives, the CEO and members of the executive committee, fall within the provisions of this policy. To the extent a board member conducts work for the Company, in addition to the board work, consulting fees and other compensation for such work may be paid. The policy is forward looking, i.e. applicable to remuneration agreed, and amendments to remuneration already agreed, after adoption of the policy by the annual general meeting in 2022.

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.

For information regarding Hansa Biopharma's strategic priorities, please visit <https://hansabiopharma.com/this-is-hansa/our-commitment/>

For information regarding Hansa Biopharma's equity story, please visit <https://investors.hansabiopharma.com/English/our-equity-story/default.aspx>

Long-term (share-based) incentive programs have been implemented in the company. Such programs have been resolved by the general meeting and are therefore excluded from these guidelines. The program include, among others, the CEO and other senior executives in the company. The performance criteria used to assess the outcome of the plans are distinctly linked to the business strategy and thereby to the company's long-term value creation, including its sustainability.

For more information regarding these incentive programs, including the criteria which the outcome depends on, please see <https://hansabiopharma.com/this-is-hansa/corporate-governance/>.

This policy enables the company to offer senior executives a competitive remuneration. The remuneration 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 components, their purpose and link to the company's business strategy are described below.

## The decision-making process to determine, review and implement the policy

The Board of Directors has established a Committee within the Board (the Remuneration Committee), with the tasks of preparing, within the Board of Directors, the policy for remuneration for senior executives. The Board of Directors shall propose a revised policy at least every fourth

year and submit it to the general meeting. The guidelines shall be in force until new guidelines are adopted by the general meeting. The Remuneration Committee shall also monitor and evaluate programs for variable remuneration for senior executives, the application of the guidelines for executive remuneration as well as the current remuneration structures and compensation levels in the company. The members of the Remuneration Committee are independent of the company and its executive management.

Unless otherwise stated herein, the Board of Directors shall resolve on matters regarding remuneration and employment provisions for all other senior executives. The CEO may decide upon Variable Cash Remuneration, including STI, for the other senior executives. The Remuneration Committee and the CEO, as applicable, shall continuously report to the Board of Directors. The CEO and the other senior executives shall not be present when their respective remuneration terms are decided.

Additionally, the general meeting may – irrespective of this policy – resolve on, among other things, share-related or share price-related remuneration.

Purpose and link to strategy	Supports the attraction and retention of the best talent. Ensures competitiveness while controlling fixed costs to maximise efficiency.
Operational Details	<ul style="list-style-type: none"> <li>&gt; Normally reviewed annually and increases will usually be effective from 1 April or following a change in responsibilities.</li> <li>&gt; The Remuneration Committee will consider, among other things, the following parameters when reviewing fixed base salary: <ul style="list-style-type: none"> <li>– Economic and salary conditions and trends</li> <li>– The individual's performance and responsibilities</li> <li>– Base salaries and total remuneration at other companies that operate in the same markets, typically benchmarked against similar roles.</li> </ul> </li> </ul>

## Variable Cash Remuneration

A portion of the total remuneration for the senior executives are linked to business performance so that total remuneration will increase or decrease in line with performance, thus promoting the company's business strategy and long-term interests (see "Annual Short-Term Incentive (STI)" below).

For retention or recruitment purposes or extraordinary performance beyond the individual's ordinary tasks the Remuneration Committee, based on proposal of CEO, may, on an individual



## Executive Remuneration – to be approved by AGM'22 continued

basis, decide on an additional variable cash remuneration. Such remuneration may not exceed an annual amount corresponding to 30 percent of the total fixed annual cash salary and may not be paid more than once each year per individual.

### Annual Short-Term Incentive (STI)

Purpose and link to strategy	Supports the attraction and retention of the best talent. Ensures competitiveness while controlling fixed costs to maximise efficiency.
Operational Details	<ul style="list-style-type: none"> <li>&gt; The performance criteria, weighting and targets for the corporate objectives are to be proposed by the Remuneration Committee annually, evaluated and approved by the Board of Directors. Stretched targets shall be set by reference to the company's operating plan and historical and projected performance.</li> <li>&gt; The performance criteria, weighting and targets for the individual objectives are to be proposed, evaluated and approved annually by the CEO as manager for members of the executive committee or, if it is not the CEO, then the respective manager for such members of the executive committee, and for the CEO the Remuneration Committee.</li> <li>&gt; The outcome of criteria for awarding STI is to be measured over a period of one year and depend on the degree of fulfilment of predetermined targets.</li> <li>&gt; The Board of Directors shall have the possibility, under applicable law or contractual provisions, subject to the restrictions that may apply under law or contract, to reclaim in whole or in part STI paid on incorrect grounds (claw-back).</li> </ul>
Opportunity Levels	<p>The maximum opportunity for STI can amount up to max 75 percent of fixed base salary.</p> <p>The Remuneration Committee shall have the possibility to review the opportunity levels in order to ensure market competitiveness.</p>
Performance criteria	<p>The STI plan awards shall be based on corporate objectives and individual objectives and be linked to predetermined and measurable criteria.</p> <p>The criteria shall be designed so as to contribute to the company's business strategy and long-term interests.</p> <p>For financial objectives, the evaluation shall be based on the latest financial information made public by the company.</p>

### Pension Benefits

Purpose and link to strategy	Provide competitive and cost-effective benefits.
Operational Details	<ul style="list-style-type: none"> <li>&gt; Other benefits may include but is not limited to life insurance, survivor benefit, accidental death and disability insurance, medical insurance/cover (Sw.: sjukvårdsförsäkring), and a company car or car allowance.</li> <li>&gt; For executive officers governed by rules other than Swedish, benefits may be duly adjusted for compliance with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of this policy.</li> <li>&gt; Executive officers who are international assignees (for example expatriates) to or from Sweden may receive additional remuneration and other benefits to the extent reasonable in light of the special circumstances associated with the international assignment arrangement, taking into account, to the extent possible, the overall purpose of this policy.</li> </ul>
Opportunity Levels	<p>Other benefits may amount to not more than 10 percent of the fixed annual cash salary and shall be set at a level which the Remuneration Committee considers to:</p> <ul style="list-style-type: none"> <li>&gt; provide the relevant level of benefit depending on role and the individual circumstances,</li> <li>&gt; be in line with comparable roles in companies with similar size and complexity in the relevant market, and</li> <li>&gt; be appropriate compared to the benefits offered to the wider workforce in the relevant market.</li> </ul>

### Other Benefits

Purpose and link to strategy	Provide competitive and cost-effective benefits.
Operational Details	<ul style="list-style-type: none"> <li>&gt; Other benefits may include but is not limited to life insurance, survivor benefit, accidental death and disability insurance, medical insurance/cover (Sw.: sjukvårdsförsäkring), and a company car or car allowance.</li> <li>&gt; For executive officers governed by rules other than Swedish, benefits may be duly adjusted for compliance with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of this policy.</li> <li>&gt; Executive officers who are international assignees (for example expatriates) to or from Sweden may receive additional remuneration and other benefits to the extent reasonable in light of the special circumstances associated with the international assignment arrangement, taking into account, to the extent possible, the overall purpose of this policy.</li> </ul>



## Executive Remuneration – to be approved by AGM'22 continued

Opportunity Levels	<p>Other benefits may amount to not more than 10 percent of the fixed annual cash salary and shall be set at a level which the Remuneration Committee considers to:</p> <ul style="list-style-type: none"> <li>&gt; provide the relevant level of benefit depending on role and the individual circumstances,</li> <li>&gt; be in line with comparable roles in companies with similar size and complexity in the relevant market, and</li> <li>&gt; be appropriate compared to the benefits offered to the wider workforce in the relevant market.</li> </ul>
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### Termination of employment

Details	<ul style="list-style-type: none"> <li>&gt; If notice of termination of employment is made by the company: <ul style="list-style-type: none"> <li>– The notice period may not exceed six months.</li> <li>– Fixed cash salary during the period of notice and severance pay may together not exceed an amount equivalent to the fixed cash salary for 18 months for the CEO, i.e. 6 + 12 months.</li> <li>– Fixed cash salary during the period of notice and 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 senior executives.</li> </ul> </li> <li>&gt; When termination is made by the senior executive the period of notice may not exceed six months. No severance pay will be paid.</li> <li>&gt; Repatriation – If the senior executive is an international assignee the company may reimburse reasonable cost for the repatriation of good leavers, taking into account, to the extent possible, the overall purpose of this policy.</li> </ul> <p>For senior executives governed by rules other than Swedish, payments in connection with termination may be duly adjusted for compliance with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of this policy.</p>
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### Salary and employment conditions for employees

In the preparation of the Board of Directors' proposal for this remuneration policy, salary and employment conditions for employees of the company have been taken into account by including information on the employees' total income, the components of the remuneration and increase and growth rate over time.

### Derogation from the policy

The Board of Directors may temporarily resolve to derogate from the policy, in whole or in part, if in a specific case there is special cause for the derogation and a derogation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability. As set out above, the Remuneration Committee's tasks include preparing the Board of Directors' resolutions in remuneration-related matters. This includes any resolutions to derogate from the policy.

Additional information regarding executive remuneration is available in the Hansa Biopharma Annual Report.

### Description of material changes to the guidelines and how the views of shareholders' have been taken into consideration (this informative element to be removed once approved by AGM'22)

In order to drive the business outcomes through a tailored employee incentive program that balances individual achievement and organisational contribution it is proposed that the performance criteria for the "Annual Short-Term Incentive ("STI") shall include both corporate and individual objectives. Furthermore, it is proposed that the performance criteria, weighting and targets for the individual objectives under the STI are to be proposed, evaluated and approved annually CEO as manager for members of the executive committee or, if it is not the CEO, then the respective manager for such members of the executive committee, and for the CEO the Remuneration Committee. The proposed adjustments have been reflected in these guidelines which will be subject to the shareholders' approval at the annual general meeting 2022.

During 2021, neither the Remuneration Committee nor the Board of Directors received any comments or questions from the shareholders on the remuneration guidelines adopted at the annual general meeting 2021.



# Auditor statement on the corporate governance report

To the general meeting of the shareholders in Hansa Biopharma AB, corporate identity number 556734-5359

## Engagement and responsibility

It is the board of directors who is responsible for the corporate governance statement for the year 2021 on pages 127-145 and that it has been prepared in accordance with the Annual Accounts Act.

## The scope of the audit

Our examination has been conducted in accordance with FAR's auditing standard RevU 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.

## Opinions

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Malmö 7 April 2022

KPMG AB

## Jonas Nihlberg

Authorized public accountant



# Remuneration

Remuneration Report

148





# Remuneration Report

## Introduction

This remuneration report provides an outline of how Hansa's guidelines for remuneration (the "Remuneration guidelines"), adopted by Hansa's Annual General Meeting 2021, were implemented in 2021. 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 Financial Statements of the Parent Company elsewhere in this annual report 2021. Information on the work of the remuneration committee in 2021 is set out in the corporate governance report available on pages 128 – 143 in the annual report 2021.

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 elsewhere in this annual report 2021.

## Key Developments 2021

### Overall Company performance in 2021

The CEO summarizes the Company's overall performance in his statement on pages 7 – 9 in the annual report 2021. In addition, the directors report on pages 58 – 66 of the annual report 2021 summarizes the Company's 2021 business and operations.

### 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 2021.

Name of Director, position	Financial year	1 Fixed remuneration		2 Variable remuneration			4 Pension expense	5 Total remuneration	6 Proportion of fixed and variable remuneration in %
		Base salary	Other benefits	One-year variable	Multi-year variable	3 Extraordinary items			
Søren Tulstrup (CEO)	2021	7,010 <sup>2</sup>	128 <sup>3</sup>	3,444	0	0	0	10,582	67/33

<sup>1</sup> Except for Multi-year variable remuneration, the table reports remuneration earned in 2021. Multi-year variable remuneration is reported if vested in 2021, 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 1,619, representing 30% of base salary, intended for own pension contribution

<sup>3</sup> Company car

## 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 2021, can be found on pages 86 – 93 in the annual report 2021. During 2021, 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 resolved to implement long-term share-based incentive plans for certain groups of Hansa employees and on remuneration guidelines for the Board of Directors.



## Remuneration Report continued

### Share based remuneration

#### Outstanding share-based long-term incentive programs

The Company has three long-term incentive programs outstanding in which amongst others also the CEO participates; long-term incentive program ("LTIP") 2019, 2020 and 2021. The Company has LTIP 2018 partly outstanding and partly lapsed during 2021. The CEO did participate in the portion of the program which lapsed during 2021.

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 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 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 ordinary shares that each participant is entitled to receive is 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 (Confldes), 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 can 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 employee stock options allotted free-of-charge. The employee stock options have a vesting period of three years and an exercise period of three years. Each warrant or employee stock option entitles the holder to receive 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 employee stock options and 11,000 warrants were outstanding under the long-term incentive program 2019 as of 31 December 2021, which corresponds to a maximum dilution of approximately 0.9% on a fully diluted basis.

#### 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 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 US RCT study (Confldes) is fully enrolled, (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 to continue either of the two programs, (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).



## Remuneration Report continued

The option program 2020 consists of employee stock options allotted free-of-charge. Each employee stock option entitles the holder to subscribe for one new ordinary share in Hansa Biopharma AB. The employee stock options have a vesting period of three years, and an exercise period of three years. Each employee stock option entitles the holder to acquire one share in the Company, 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 the volume weighted average share price during the 10 trading days immediately preceding the respective allotment of the employee stock options.

In total, 400,556 share rights and 497,520 employee stock options were outstanding under the long-term incentive program 2020 as of 31 December 2021, which corresponds to a maximum dilution of approximately 1.9% on a fully diluted basis.

### 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 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 the U.S. FDA has accepted a BLA filing for approval of imlifidase in the U.S., (b) 11 percent of the shares in the event that 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, (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 employee stock options allotted free-of-charge. Each employee stock option entitles the holder to subscribe for one new ordinary share in Hansa Biopharma AB. The employee stock options have a vesting period of three years, and an exercise period of three years. Each employee stock option entitles the holder to acquire one share in the Company, 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 employee stock options.

In total, 557,000 share rights and 430,000 employee stock options were outstanding under the long-term incentive program 2021 as of 31 December 2021, which corresponds to a maximum dilution of approximately 2.1% on a fully diluted basis.



## Remuneration Report 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						
						Opening balance	During the year 2021			Closing balance 31 Dec 2021		
	1 Name of plan	2 Performance period	3 Award date	4 Vesting date	5 End of retention period	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 Shares subject to a retention period
Søren Tulpstrup (CEO)	LTIP2018	2018-2021	2018-06-15	2021-06-15	2021-06-15	51,389	0	0	51,389	0	0	0
	LTIP2019	2019-2022	2019-06-17	2022-06-17	2022-06-17	35,151	0	0	0	35,151	35,151	35,151
	LTIP2020	2020-2023	2020-07-23	2023-07-23	2023-07-23	57,278	0	0	0	57,278	57,278	57,278
	LTIP2021	2021-2024	2021-05-12	2024-05-12	2024-05-12	0	80,000 <sup>1</sup>	0	0	80,000	80,000	80,000
						143,818	80,000	0	51,389	172,429	172,429	172,429

<sup>1</sup> Each of the 80,000 Share rights represents a computed fair value of SEK 98.94 per share right calculated based on a Monte Carlo simulation. For further information please refer to Note 14 to the Consolidated Financial Statements elsewhere in this annual report 2021

Table 3 – Remuneration of the CEO in stock options

The main conditions of share rights								Information regarding the reported financial year						
								Opening balance		During the year 2021			Closing balance 31 Dec 2021	
Name, position	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)	6 Stock options held at the beginning of the year	7 Awarded	8 Vested	9 Expired	10 Stock options subject to a performance condition	11 Stock Options Awarded and unvested	12 Stock options subject to a retention period
Søren Tulpstrup (CEO)	LTIP2019	2019-2022	2019-06-17	2022-06-17	2022-06-17	2022-06-17 2025-06-17	196.20	66,347		0	0	66,347	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		0	0	128,760	128,760	128,760
	LTIP2021	2021-2024	2021-05-12	2024-05-12	2024-05-12	2024-05-12 2027-05-12	192.20	0	120,000 <sup>1</sup>	0	0	120,000	120,000	120,000
								195,107	120,000	0	0	315,107	315,107	315,107

<sup>1</sup> Each of the 128,760 Stock options represents a computed fair value of SEK 42.98 per stock option calculated based on a Black-Scholes valuation. For further information please refer to Note 14 to the Consolidated Financial Statements elsewhere in Hansa Biopharma's annual report 2021



## Remuneration Report continued

### Application of performance criteria related to the 2021 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 taken into account.

In 2021, a portion of the share rights program under the LTIP 2018 vested, in which the CEO held 51,389 performance share rights. The single pre-defined performance condition related to the portion which vested was *Total shareholder return of at least 125% of the base value of SEK 221.10*. Since the performance criteria was not met upon vesting on June 15, 2021, the share rights expired without value and no shares were granted. No other share-based long-term compensation vested during 2021.

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 2021. Such criteria are based on the annual corporate objectives and form the basis for the short-term performance measurement of the CEO and all other members of the executive management.

**Table 4 – Criteria for payment of variable short-term compensation**

Name, Position	Description of the criteria related to the corporate goals	2021 corporate goals	Overall weight	a) Measured goal achievement and
				b) Actual weighted outcome
Søren Tulstrup, (CEO)	Imlifidase commercial launch and launch readiness in key EU countries	4 sub-goals	20%	a) 84% b) 17%
	Progressing pipeline activities in transplantation, autoimmune indications and NiceR	5 sub-goals	50%	a) 75% b) 37%
	Business development and financial strength	2 sub-goals	25%	a) 104% b) 26%
	Corporate Social Responsibility	1 sub-goal	5%	a) 100% b) 5%
				<b>Total: 85%</b>

### Comparative information on remuneration and Company performance

	2021	2020
<b>CEO remuneration</b>		
Søren Tulstrup, CEO	<b>kSEK 10,582</b>	kSEK 8,854
<b>Company's performance</b>		
Achievement of the annual corporate objectives	<b>85%</b>	100%
Operating profit / loss	<b>kSEK (548,282)</b>	kSEK (422,807)
<b>Average remuneration (base salary) on a full-time equivalent basis of employees</b>		
Non-executive employees of the Company	<b>kSEK 827</b>	kSEK 822

# Glossary

Glossary

154



# 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. The different isotypes have slightly different structures and they play different roles in the immune system. Immunoglobulin G, IgG, is the most common type in the blood and tissue and provides the majority of antibody-based immunity against invading pathogens. IgA is mainly found in mucosal areas and prevents colonization by pathogens. IgD mainly functions as receptor on B-cells that have not yet been activated. IgE binds to allergens and is involved in allergy. IgM is mainly found in the blood and is part of the first response against an infection.

**Anti-GBM disease (Goodpasture syndrome)**

Anti-GBM antibody disease is a disorder in which circulating antibodies are 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 U.S.

**Biopharmaceutical**

A pharmaceutical drug that is manufactured using biotechnology.

**Biotechnology**

The use of live cells or components of cells, to produce or modify products used in health care, food and agriculture.

**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.





## Glossary continued

### FDA

The U.S. Food and Drug Administration is the agency responsible for, among other things, protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices.

### 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 human cells. 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 substance 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.

### *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 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 life-threatening 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.

### RCT

Randomized Controlled Trial (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.



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