Pioneering innovative lifesaving treatments

Annual Report 2022

HANSA BIOPHARMA

Contents

The Swedish version of the 2022 Annual Report represents the legally binding version and prevails

Hansa Biopharma in brief

Hansa Biopharma ("Hansa", "the Company", "we") is a commercial-stage biopharmaceutical company pioneering the development and commercialization of innovative, lifesaving and life altering treatments for patients with rare immunological conditions.

Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer.

Hansa Biopharma 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

Dear Shareholders,

2022 was another exciting and successful year for Hansa Biopharma, with continued progress and achievement of several key milestones in both R&D and commercial operations. Despite an unpredictable and challenging geopolitical environment, we were able to pivot quickly to meet unexpected operational demands, while continuing to advance our key priorities.

I began my role as the Chairman of the Board of Directors at Hansa Biopharma in June of 2022 and have been impressed with the progress to date. Additionally, the entire organization has demonstrated strong dedication and perseverance.

I remain impressed by the Company's strong purpose-driven culture and how colleagues across the organization work together to deliver on our mission to develop innovative, lifesaving and life altering therapies to patients with rare conditions. It is a pleasure to now be part of this journey and I look forward to continuing to work with the Board and the leadership team while setting a strategic direction for Hansa to advance its IgG-antibody cleaving technology platform and products to the patients who need them.

During 2022, the Company set a strong foundation for the commercialization of Idefirix® including successful market reimbursement in four of the five largest markets in Europe. This further validates the important role Idefirix® can play in kidney transplantation. Additionally, several countries consider Idefirix® a lifesaving and cost effective treatment option. With the emergence of imlifidase, new international consensus guidelines for a management pathway for kidney transplant patients with high unmet need has been created.

The Company progressed several important phase 2 and 3 trials increasing the total number of programs in the clinic to seven – a significant accomplishment for a company of this size and a testament to our fierce commitment to advancing our science and exploring the potential of our leading technology platform.

Two new phase 3 programs were advanced including the Post Approval Efficacy Study (PAES) of Idefirix in highly sensitized kidney transplant patients and a global study in anti-GBM disease. A phase 2 trial in antibody mediated rejection (AMR) also moved ahead and the positive top line data demonstrating statistically significant superiority compared to current standard of care was communicated in Q4 2022. Additionally, two pre-clinical projects progressed – the NiceR program including our second-generation antibody-cleaving enzyme candidate HNSA-5487 targeting repeat dosing and a program in Duchenne Muscular Dystrophy (DMD) in partnership with Sarepta. Both of these programs will advance to clinical stage later this year.

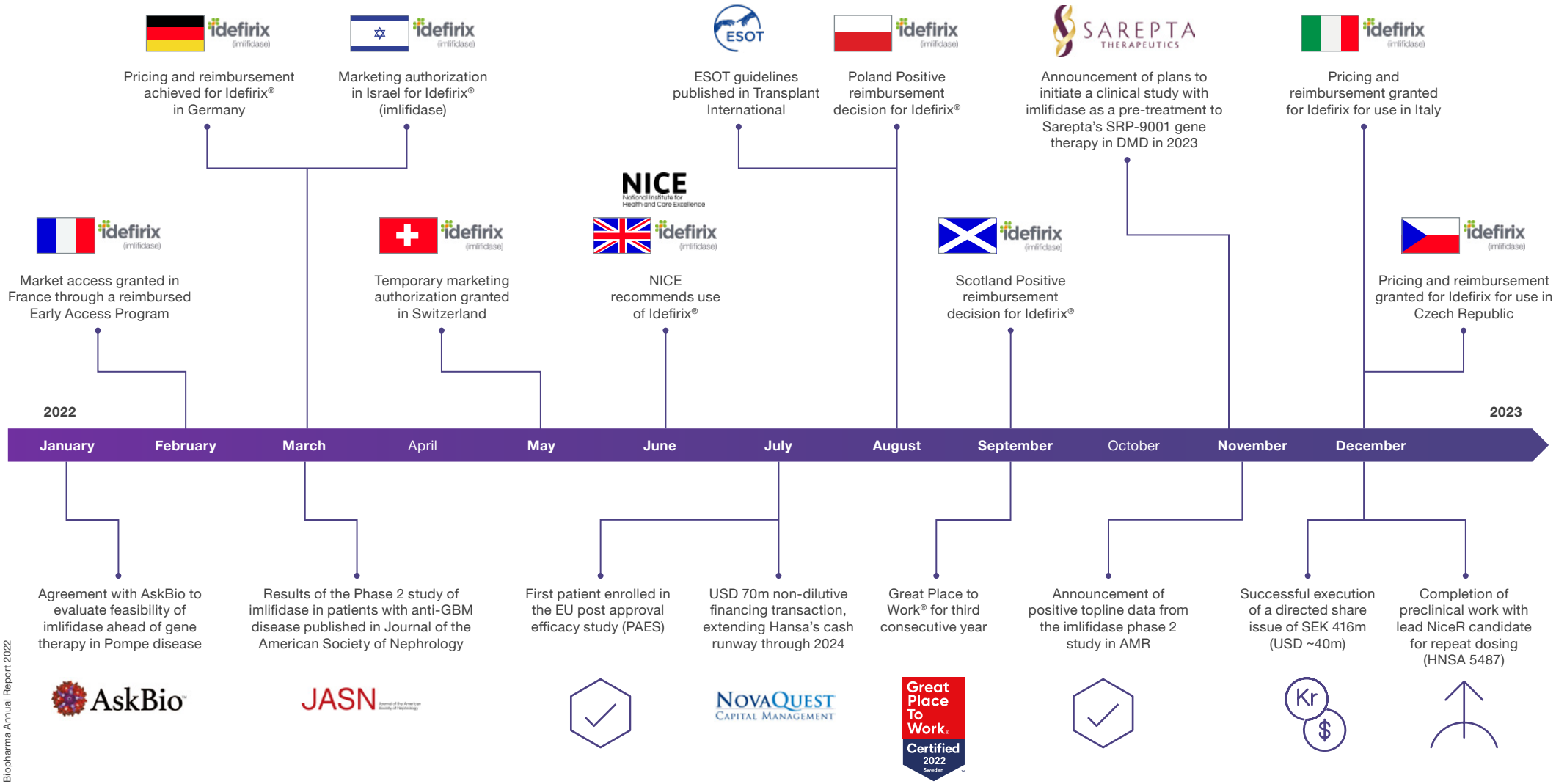
> One immediately senses a strong purpose driven culture among the Hansa colleagues

2022 remained challenging for the technology and biotech industries as a whole. The direct and indirect impact to companies caused by rising interest rates, sector rotation and geopolitical uncertainties, remain and have resulted in weak valuations of many biotech companies. Despite this, the Board was pleased with the successful execution of two financing events last year. This enabled the Company to extend its cash runway into 2025. With financing secured, a validated technology platform with an exciting late-stage pipeline and a highly engaged and committed organization, Hansa is well-positioned to deliver on its strategic priorities in 2023 and become a leading player in rare immunologic diseases.

On behalf of the Board of Directors,

Peter Nicklin
Chairman, Hansa Biopharma AB
Lund, Sweden, March 2023

2022 highlights



CEO statement

2022 was a successful year at Hansa, with solid performance and strong progress across the organization.

Søren Tulstrup
President and CEO,
Hansa Biopharma AB

While the global geopolitical and financial environment made 2022 a very challenging year for the biotech sector overall, I am very pleased with the solid performance and strong progress across our R&D and commercial operations.

Commercial launch activities and market access efforts for Idefirix® in Europe continued to progress as planned. Importantly, by year-end 2022, commercial access had been obtained in eleven European countries, including four of the five largest markets: Germany, UK, Italy and France. Additional market access procedures are ongoing in nine countries, including Spain.

In August, the first medical guidelines for desensitization treatment of highly sensitized kidney transplant patients were published by the European Society for Organ Transplantation, ESOT. These guidelines are the first to include Idefirix® and represent the first international consensus on a management pathway for kidney transplant patients with high unmet need. The early publication of these guidelines underscores the important role that Idefirix® can play as a new, transformative therapy to enable kidney transplantation, and is an important step in ensuring its use as a potential new "Gold Standard" in desensitization protocols.

On the clinical development side, we continued to make progress across our pipeline. In November, we presented topline data from our phase 2 program in kidney transplant AMR (post transplantation episodes or organ rejection), demonstrating significantly superior capacity of imlifidase to rapidly reduce donor specific antibodies (DSA) levels in comparison to plasma exchange in the five days following the start of the treatment.

During the year, we initiated two new phase 3 studies:
- the European Post Approval Efficacy Study in kidney transplantation and the pivotal, global phase 3 study in anti-GBM disease. Both studies will target 50 patients and involve a significant number of clinics as we broaden our experience with imlifidase to become a potential new standard of care in both transplantation and acute autoimmune diseases.

In the U.S., patient enrollment continues in our third ongoing phase 3 study, the pivotal ConfIdeS trial in kidney transplantation. The ConfIdeS 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 complete enrollment in the first half of 2023, while completion of randomization is expected in the second half of this year. There has been strong interest from leading transplantation centers to participate in this trial, and we expect to initiate around 20 leading centers across the U.S.

The enrollment in the phase 2 program in Guillain-Barré Syndrome (GBS) was impacted by the COVID-19 pandemic due to staff constraints in trial centers and a shortage of IVIg at a subset of participating hospitals. We have worked to mitigate these hurdles and saw an increase in patient enrollment at the

I am very pleased with the solid performance and strong progress across our R&D and commercial operations

CEO statement continued

A clear reflection of our successful efforts in this regard was the certification as a Great Place to Work® for the third consecutive year

end of 2022. A completion of enrollment in the GBS trial is expected in the first half of 2023, with a top line data expected in the second half 2023, as previously guided.

I am pleased with the achievements made in our preclinical development programs, in particular in the Duchenne Muscular Dystrophy (DMD) project with Sarepta Therapeutics in gene therapy and the NiceR program, which is exploring utilization of second-generation enzymes for repeat dosing. In DMD, imlifidase is being investigated as a potential pre-treatment in patients with pre-existing IgG antibodies to Sarepta's SRP-9001. To date, the data appears promising, and plans have been announced to initiate a clinical study in 2023. In the NiceR program, we completed IND enabling toxicology studies at the end of the year for our lead candidate, HNSA-5487. A CTA approval has since been obtained and we expect to begin a clinical trial in the first half of 2023.

In addition, while the capital markets for biotech companies remained challenging throughout 2022, I am pleased that we were able to successfully secure additional financing through two transactions last year, enabling us to extend our cash runway into 2025. In July, we raised USD 70m through a non-dilutive financing transaction with NovaQuest, and in December we raised USD 40m in a directed share issue targeting U.S. and other international healthcare specialist investors. The funds raised will help finance preparations for a potential U.S. launch of imlifidase in kidney transplantation and further advance our exciting pipeline of drug candidates.

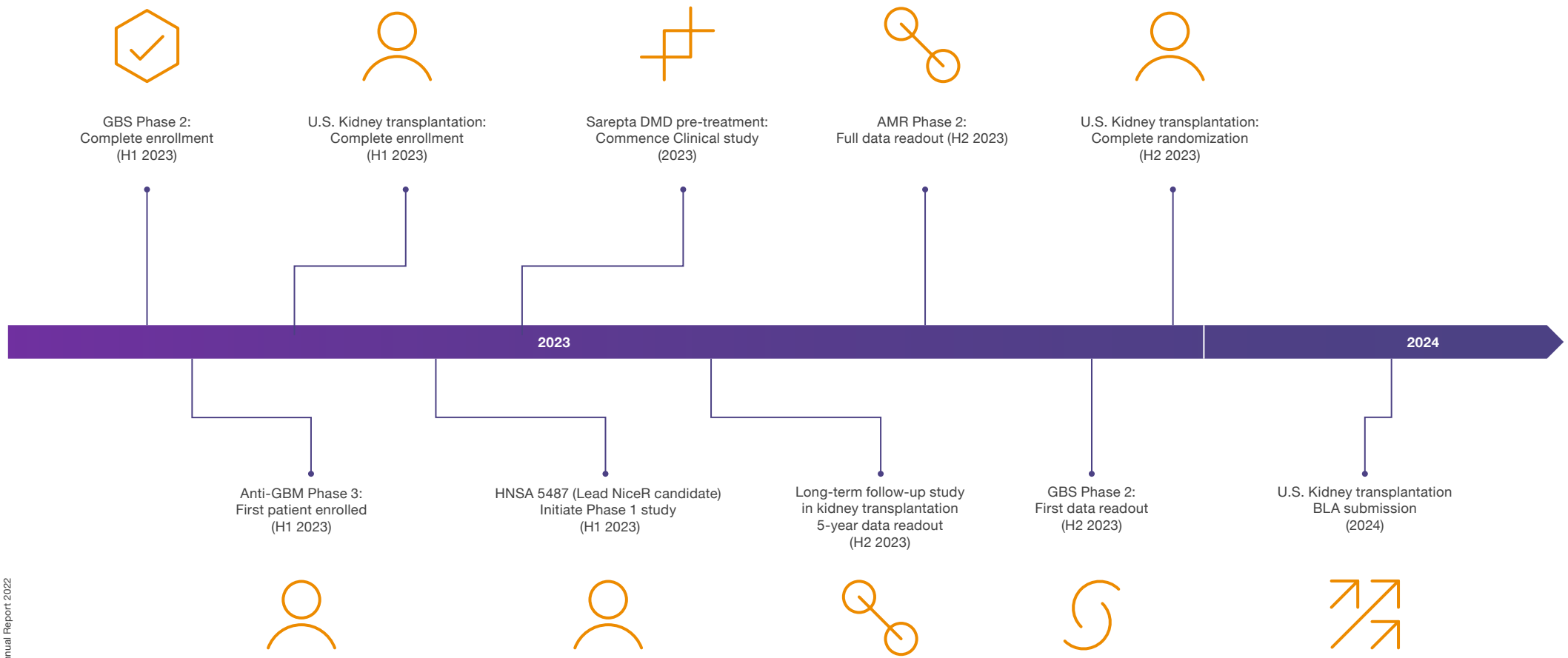
I am particularly grateful to our employees for their commitment, passion, and hard work over the past year. We are dedicated to building and maintaining a high-performance team, while also creating a rewarding and stimulating workplace for our employees. A clear reflection of our successful efforts in this regard was the certification as a Great Place to Work® for the third consecutive year.

At Hansa, sustainability is at the core of all we do, and during 2022 we continued to build on the formalized ESG framework which was created in 2021. Embarking on this journey, we have identified key objectives for our environmental, social and governance priorities, which will be addressed separately in our CSR Report.

We now have an exciting year ahead with several key milestones across our platform and therapeutic areas as we continue to pursue the development and launch of new, transformative medicines that will enable patients with rare immunologic diseases to lead long and healthy lives.

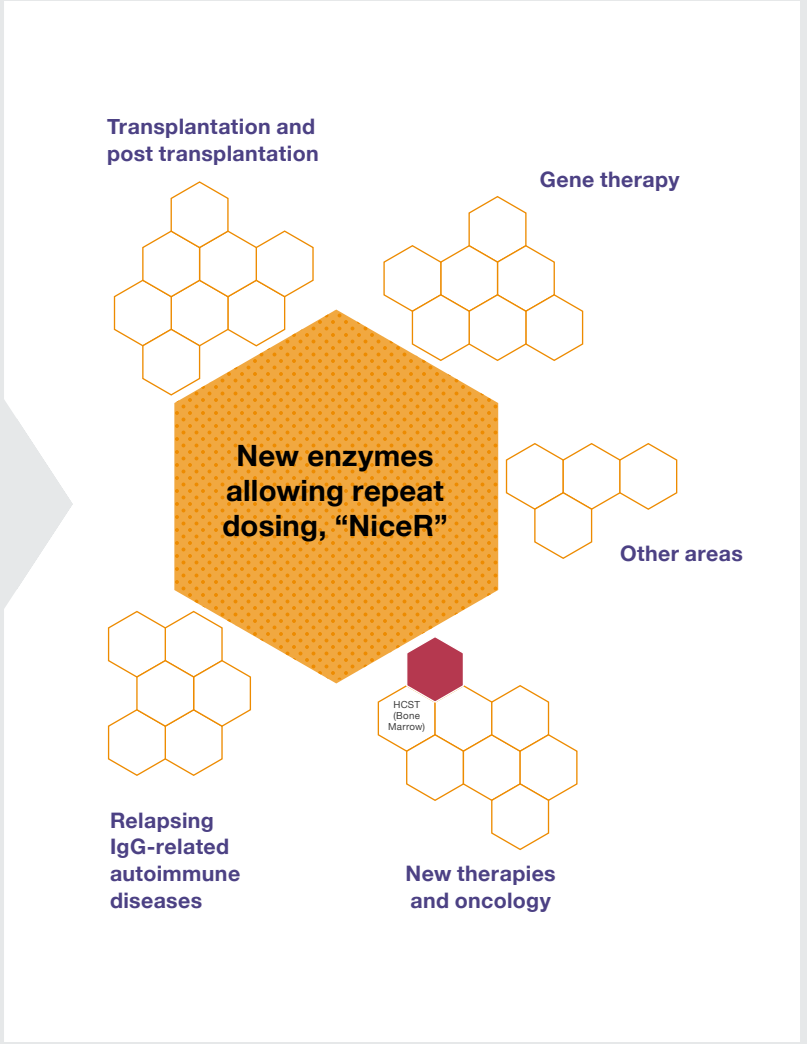
Søren Tulstrup
President and CEO,
Hansa Biopharma AB
Lund, Sweden, March 2023

Anticipated future milestones



Strategy

Potential indication universe



- First generation antibody cleaving enzyme technology
- Obtained EU conditional approval [1,2]
- Planned clinical program
- Clinical program
- Research program
- Opportunities currently not pursued
- Partnership Preclinical program (Sarepta Therapeutics Inc. and AskBio)

[1] The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients
[2] In the U.S. a new study has commenced targeting a BLA filing by 2024

Potential indication universe continued

Hansa's 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.

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

We are also investigating the potential use of imlifidase as a treatment of active antibody mediated rejection (AMR) episodes in kidney transplantation and in solid organ transplants, both pre- and post-transplantation (e.g., heart and lung).

Looking beyond transplantation, there are several other growth vectors and areas where imlifidase may play a role, including acute autoimmune diseases, gene therapy and oncology. More specifically, we are investigating rare life-threatening conditions such as anti-GBM antibody disease and Guillain-Barré Syndrome (GBS), which are both ongoing clinical programs in phase 3 and 2 respectively.

In addition, Hansa, with its partners, is investigating imlifidase as a pre-treatment to potentially enable gene therapy in patients with pre-existing neutralizing antibodies (NAbs) against the viral vectors used by the gene therapy. Through the partnership with Sarepta Therapeutics, imlifidase is being investigated in Duchenne Muscular Dystrophy (DMD) and Limb-Girdle Muscular Dystrophy (LGMD) and through the partnership with AskBio, a subsidiary of Bayer AG, in Pompe disease.

Further, we are exploring potential indications within oncology such as 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 due to the current absence of adequate desensitization methods.

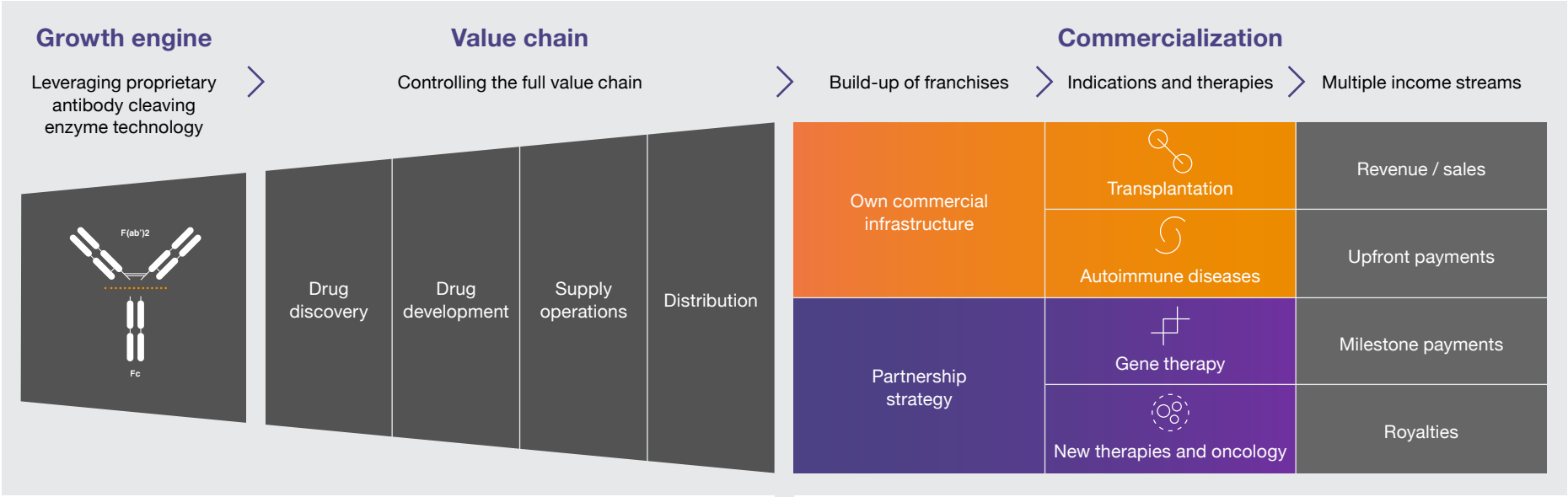
Beyond imlifidase for the acute treatment in IgG mediated conditions and diseases, we are also developing new IgG-cleaving enzymes under the program "NiceR" (Novel Immunoglobulin Cleaving Enzymes for Repeat Dosing). These "next-generation" enzymes from the NiceR program will be designed to have a lower propensity to induce immunity in order to increase the therapeutic window. The new enzymes are being developed to be potentially utilized in several IgG-driven autoimmune diseases where patients experience flares, or in transplantation where repeat dosing would be beneficial and add further value. Following completion of IND enabling toxicology studies late 2022 and the subsequent approval of a Clinical Trial Application early 2023, Hansa expects to initiate a clinical trial during the first half 2023 with HNSA-5487, its lead IgG-cleaving enzyme candidate for repeat dosing.

Lastly, Hansa and argenx BV have been evaluating the therapeutic potential of combining imlifidase and efgartigimod, argenx's FcRn antagonist. A combination of imlifidase and efgartigimod or other FcRn antagonists could potentially be used in both the acute and the chronic setting of autoimmune diseases and transplantation. Any potential next steps will be evaluated.

Looking beyond transplantation, there are several other growth vectors and areas where imlifidase may play a role, including acute autoimmune diseases, gene therapy and oncology

Business model

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



Evolution into a fully integrated biopharmaceutical company

Hansa's ambition is to become a leading player in rare disease by expertly leveraging the Company's unique and proprietary antibody-cleaving enzyme technology platform and supporting scientific and commercial innovation. The evolution to a fully integrated biopharmaceutical company begins with the technology platform – the growth engine of the current and future pipeline. From discovery and development to commercialization, the intention is to retain strategic control and capture much of the economic upside generated.

There are four priority franchises within Hansa – autoimmune, gene therapy, oncology and transplantation. Given the diverse and complex nature of these four disease areas the Company has employed an agile approach to commercialization. The Company will leverage its strong commercial and medical expertise in autoimmune and transplantation where we have existing experience and relationships, and the customer base is relatively concentrated. In complex disease areas or in certain markets, the Company will consider strategic partnerships and agreements. To date, we have a commercial partnership with Medison Pharma in select countries in Central Eastern Europe and Israel and strategic development partnerships with AskBio and Sarepta Therapeutics in gene therapy.

Our strategic priorities

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

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

1. Commercialize Idefirix® in first indication and markets

Successfully launch Idefirix® in Europe*
Achieve market access in remaining countries and ensure successful, repeat and growing usage in key clinics

Secure FDA approval and launch Idefirix in the U.S.
Complete phase 3 study and submit BLA under the accelerated approval pathway

Geographical expansion
Explore opportunities to commercialize Idefirix beyond core markets

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

Achieve approval/usage of imlifidase in follow-on indications
- Anti-GBM
- GBS
- AMR

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

Explore gene therapy opportunity
Develop imlifidase and other enzymes as enablers and enhancers of AAV-based gene therapies through implementation of development and commercialization agreements with leading gene therapy partners

Explore opportunities in oncology/HSCT
- Initiate trial in HSCT
- Explore other indications through partnerships

Develop next generation IgG-cleaving enzymes
Initiate and complete clinical trial of HNSA-5487

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

* Idefirix approved in EEA under conditional approval for kidney transplantation

Our strategic priorities continued

1. Commercialize Idefirix® in first indication and markets

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

We have launched Idefirix® in several major European countries driving reimbursement and partnering closely with leading clinical experts. In 2022, commercial access was obtained in eleven European countries, including Germany, UK, France (through a reimbursed Early Access Program) and Italy. We continue to advance access and reimbursement in nine other countries including Spain, Portugal, and Switzerland. Following completion of our post-approval commitments, we will seek full approval from the European Commission.

In the U.S. we have initiated ConfIdeS, a pivotal phase 3 study to support the submission of a Biologics License Application (BLA). The ConfIdeS trial is currently enrolling patients and the Company expects to submit a BLA for accelerated approval in 2024. Given that 10-15% of patients waiting for a kidney transplant in the U.S. are considered highly sensitized, the approval and availability of Idefirix® would be an important option for these patients.

Beyond Europe and the U.S., the Company is exploring commercial opportunities for Idefirix in markets where the EMA approval can be leveraged to gain approval and market access.

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

We have an ongoing clinical program in phase 2 in AMR and GBS as well as we end of December 2022 initiated a pivotal phase 3 program in anti-GBM.

In active AMR, we are investigating imlifidase in acute and chronic acute AMR episodes post kidney transplantation. Today there is no approved drug in this indication. AMR episodes occur in 5-7%[1] of patients and is a significant challenge to long-term graft survival.

In November, 2022, Hansa announced top-line data from the imlifidase phase 2 study in AMR post kidney transplantation, demonstrating a statistically significantly difference of imlifidase versus plasma exchange to reduce levels of donor-specific antibodies (DSAs) in the five days following treatment. The full data set is expected to be announced in the second half of 2023.

We also have two ongoing clinical-stage programs in rare acute autoimmune diseases – anti-GBM antibody disease and GBS. In anti-GBM, we initiated a pivotal global phase 3 study at the first sites in the U.S. end of December 2022 with the first patient expected to be treated in the first half of 2023. Anti-GBM is an acute autoimmune disease where antibodies are directed against an antigen intrinsic to the glomerular basement membrane (GBM), causing acute injury of kidney and/or lung function. Anti-GBM is an ultra-rare and very serious disease that annually affects approximately 1.6 people per million worldwide. In 2022 key data from the investigator-initiated phase 2 trial were published in the Journal of American Society of Nephrology (JASN) showing that two-thirds of patients achieved dialysis independence six months after treatment with imlifidase, compared to typically two-thirds of patients losing their kidney function and ending up on dialysis after six months. The positive data from the phase 2 trial supported a new pivotal study targeting 50 patients with anti-GBM disease across 30-40 sites in the U.S., U.K., and Europe.

We are also developing imlifidase for the treatment of GBS for which we have an ongoing clinical program in phase 2 targeting 30 patients at ten centers across the U.K., Netherlands and France. GBS is an acute autoimmune attack on the peripheral nervous system, which affects approximately 1 in 100,000 people[2].

Completion of enrollment in the GBS trial is anticipated in the first half of 2023 with a first high level data read-out expected in the second half of 2023.

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

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

In gene therapy, Hansa is working with two partners, Sarepta Therapeutics and AskBio (Bayer AG) in three programs, namely DMD, LGMD and Pompe disease, where imlifidase is being evaluated as a potential pre-treatment to gene therapy in patients with pre-existing neutralizing antibodies (NAbs) against adeno-associated virus (AAV). Nabs against the AAV-based vector commonly used in gene therapies remain a major challenge and make these patients ineligible to receive gene therapy treatment. We see significant potential for our antibody-cleaving enzyme technology to help overcome this barrier.

Another major therapeutic area Hansa is looking into, is oncology, where one of the key indications Hansa intends to explore further is 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 allogenic HSCT. Desensitization treatment of patients with high levels of donor specific antibodies (DSA) prior to allogeneic HSCT transplant is a challenge where imlifidase may have the potential to transform the standard of care by enabling clinicians to inactivate DSAs prior to transplantation, thus having the potential to enable successful transplantation.

Lastly, we are aiming at developing next generation IgG-cleaving enzymes with the objective of enabling repeat dosing across our four franchises and where patients may benefit from more than one dose of an IgG-modulating enzyme (e.g., dealing with flares). HNSA-5487 has been selected as our lead IgG-eliminating enzyme candidate from the NiceR program. Following the completion of IND enabling toxicology studies and a CTA, which subsequently was approved, it is our intention to initiate a clinical trial for HNSA-5487 during the first half 2023.

[1] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724
[2] McGrogan et al., "The Epidemiology of Guillain-Barré Syndrome Worldwide", Neuroepidemiology;2009, 32(2):150-63

Market

3

Helping highly sensitized patients who cannot access a kidney

The kidney transplantation landscape

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

During the last few years, transplantation and organ donation rates in Europe experienced a significant decline, mainly due to the pandemic, as the Covid-19 outbreak posed unique challenges for both organ procurement and transplantation, and the fact that a large number of transplant centers would not allow the use of deceased donor organs with evidence of previous infection or exposure. The U.S. experienced less of a decline compared to Europe due to a series of new initiatives implemented including the acceptance of organs from a higher age group than previously included, and from individuals who died of cardiorespiratory failure.

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

In 2020, the European Commission granted a conditional approval in the European Union for Idefirix® (imlifidase), representing the first conditionally approved treatment for adult patients waiting for a kidney transplant who are highly sensitized against tissue from the donor and who have a positive crossmatch test against an available kidney from deceased donor. The basis for this conditional approval was based on two completed phase 1 studies in healthy subjects and four completed phase 2 studies in highly sensitized kidney patients. In total, 53 healthy subjects have been exposed to imlifidase and 46 patients were 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. A post approval efficacy study (PAES) in 50 highly sensitized patients in Europe was initiated in 2022 and will run in parallel with the commercial launch until 2025 at the latest. The PAES will support integrating the commercial and scientific approach and help broadening the clinical experience with imlifidase.

~170,000

Total number of patients waitlisted in 2021[1]
across U.S./EU

~50,000

Transplants performed across U.S. and Europe in 2021[1]
73% of kidneys from deceased donors

10-15%

Highly sensitized patients awaiting kidney transplant[1]

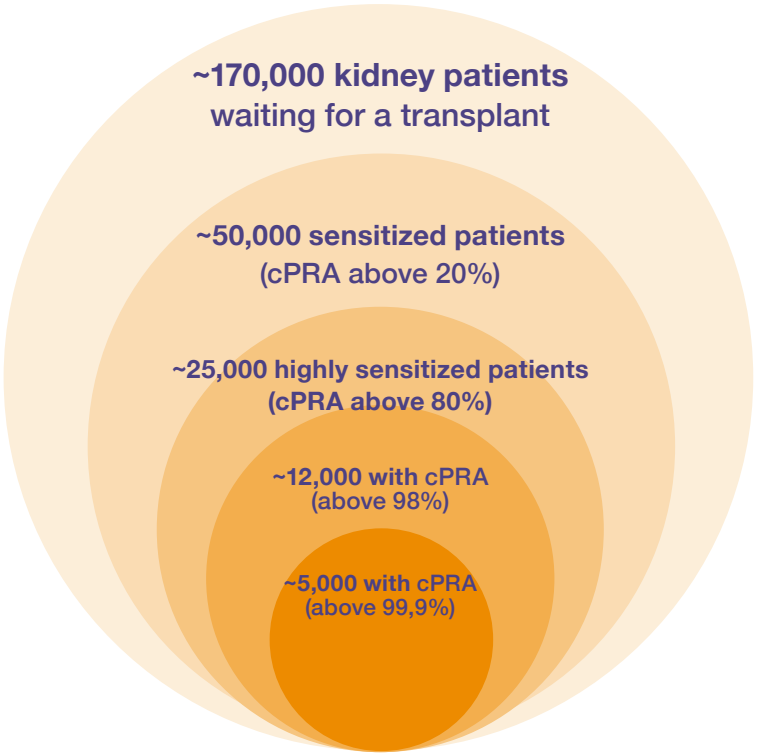
[1] Source: The U.S. Department of Health and Human Services and .irodat.org

Helping highly sensitized patients who cannot access a kidney continued

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

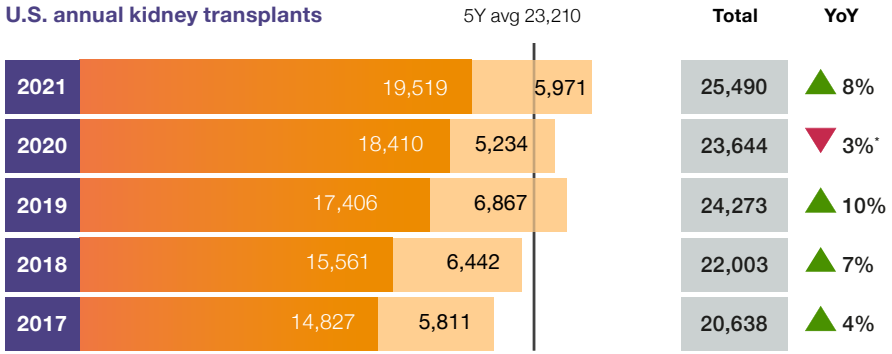
Up to 15% of the patients waiting for a new kidney are highly sensitized

Breakdown of the kidney transplant waitlist in U.S. and EU[1]

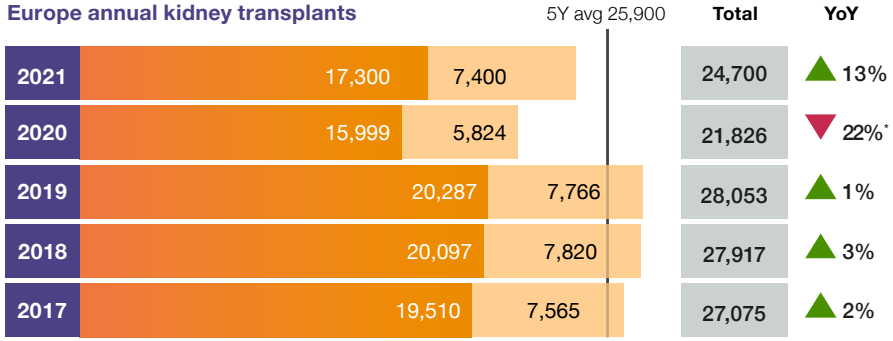


~50,000 transplants are done annually across the U.S. and Europe

U.S. annual kidney transplants



Europe annual kidney transplants



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/

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

Highly focused and sequenced launch strategy

Our European launch strategy

Idefirix® 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 payers as enabling a paradigm shift towards equity of access for highly sensitized patients to potentially lifesaving and life altering kidney transplants. To reach this goal we work closely with the transplant community to reshape the area of desensitization and integrate Idefirix® into clinical practice as a new standard of care.

As part of our launch strategy, we are initially focused on targeting leading centers with the potential to become centers of excellence. At Hansa, we believe that the long-term market uptake of this innovative therapy is highly dependent on successful early experiences in key early adopter centers. It is critical for a successful launch of Idefirix®, that positive outcomes are generated in the first patients and for clinical centers to build the foundation necessary for expanded use of Idefirix® 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 accelerated growth occurs, which is anticipated mid-term, as the Company expands beyond the first wave of early-launch countries and leading clinics, leverages the full potential in the five largest European markets and prepare for a U.S. launch, following FDA approval. Longer term, Hansa may consider expanding the label to include other solid organs such as heart and lung and living donor transplantation.

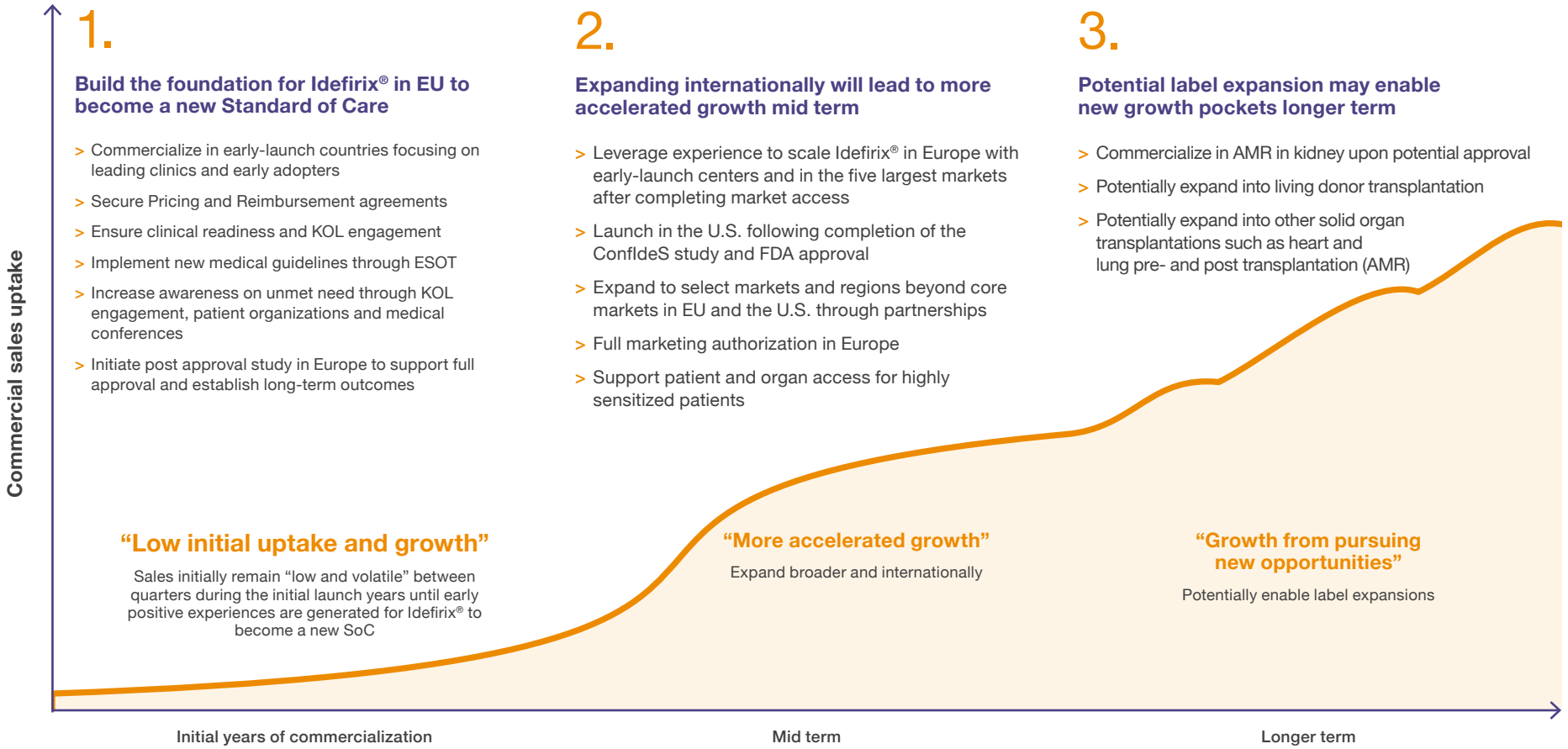
During 2022, Hansa secured positive pricing and reimbursement decisions in four of the five largest markets - the U.K., Germany, Italy and France, through a reimbursed early access program. In total, market access has now been secured in eleven countries, while market access procedures are ongoing in nine countries including Spain,[1] which represents the last of the five major European markets.

[1] A positive recommendation for pricing and reimbursement of Idefirix® in Spain was published on February 6, 2023 https://www.sanidad.gob.es/profesionales/farmacia/pdf/20230202_ACUERDOS_CIPM_230.pdf

Scaling Idefirix® globally as we transform the desensitization treatment landscape and advance a new way of transplanting patients

Idefirix® is the first and only approved drug 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

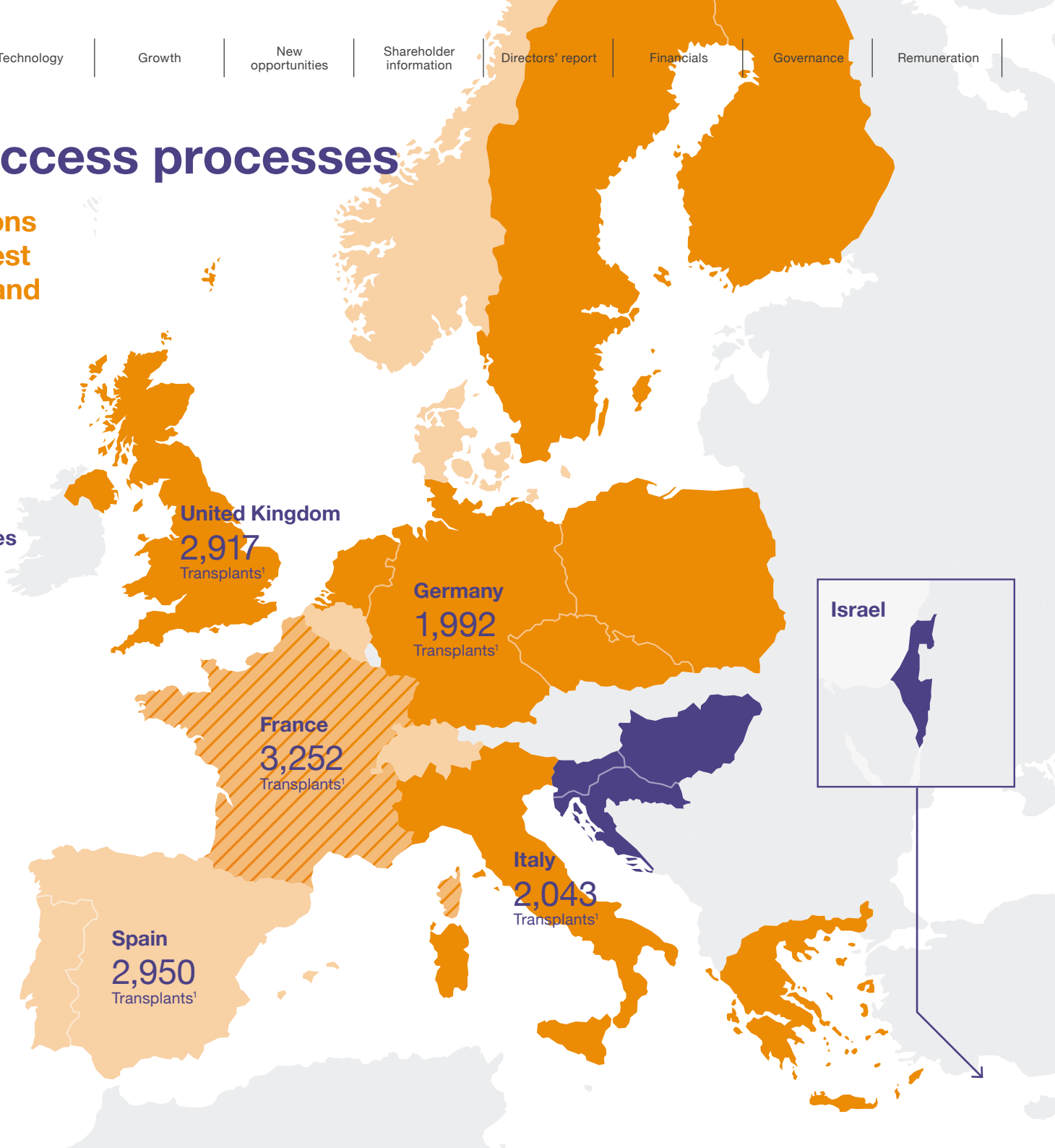


Ongoing market access processes

Positive reimbursement decisions received in four of the five largest markets - Italy, U.K., Germany and France (early access)

Market access has now been secured in eleven European countries and procedures are ongoing in nine countries including Spain[2], which represents the last of the five major European markets

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



[1] Annual kidney transplantations 2019 (pre COVID-19) Transplantation data is from Global Observatory on Donation and Transplantation, 2019

[2] A positive recommendation for pricing and reimbursement of Idefirix® in Spain was published on February 6, 2023 https://www.sanidad.gob.es/profesionales/farmacia/pdf/20230202_ACUERDOS_CIPM_230.pdf

Providing a new opportunity to a growing number of highly sensitized patients on kidney transplants lists

Pierre-Henri Patin, VP Commercial Europe, and Gina Ewy, VP Global Market Access

Q. In 2022 Hansa secured pricing and reimbursement for Idefirix® in several key European countries – how did you do it?

A. Pierre-Henri: We made significant progress commercialising Idefirix® in Europe last year. We have a dedicated team of highly skilled colleagues who understand both the healthcare system in each country as well as the transplantation community. With strong capabilities and data that demonstrates the value of our product, we were able to expand our footprint in key markets in Europe. Inclusive of all national authorizations, early access decisions, and authorizations on a hospital basis, by the end of 2022 we secured pricing and reimbursement in eleven European countries including four of the five largest markets. Additionally, we secured reimbursement in Israel in March 2022 making commercial progress outside of Europe. Currently, we have access and marketing authorization procedures ongoing in nine countries, including Spain, where in early February 2023 Idefirix® received a positive recommendation by the Inter-Ministerial Pricing Commission for Pharmaceuticals[1].

Q. Why is achieving access in the five largest markets in Europe important to the success of Idefirix®?

A. Pierre-Henri: Achieving reimbursement in the five most populated countries in Europe is an important objective and a priority in our European launch strategy, as it secures access to Idefirix® for a significant portion of European highly sensitized patients. Germany, UK, France, Italy, and Spain together account for the largest waiting lists and two thirds of all transplantations from deceased donors performed in Europe.[2] These countries also have several specialised centres with the capability to include Idefirix®-induced transplantation into clinical practice.

Q. Beyond these five markets, how are you progressing commercialisation efforts in Central and Eastern Europe?

A. Pierre-Henri: We recognize there is high unmet need for transplantation patients in many markets including Central/Eastern Europe. For some of these markets we have identified commercial partners that can help accelerate the pricing and reimbursement process. We have achieved reimbursement in Poland in partnership with Medison Pharma, and in Czech Republic in partnership with ExceedOrphan. We are very satisfied with the progress, and the results so far prove that we have selected the right partners, establishing valuable collaborations that can effectively help us increase our reach.

[1] Acuerdos de la Comision Interministerial de Precios de los Medicamentos. Sesión 230 de 15 de diciembre de 2022. Available at: https://www.sanidad.gob.es/profesionales/farmacia/pdf/20230202_ACUERDOS_CIPM_230.pdf

[2] Global Observatory on Donation and Transplantation. Available at: https://www.transplant-observatory.org/export-database/ Last accessed January 2023

Providing a new opportunity to a growing number of highly sensitized patients on kidney transplants lists continued

Q. Gina, as the VP of Global Market Access you and your team are involved in every step of the pricing and reimbursement negotiations. What are you hearing from regulators and health decision makers?

A. Gina: We believe the progress we've made in several countries in Europe is largely due to our ability to demonstrate the high unmet need of highly sensitized transplant patients and the clear value that Idefirix® can bring to this patient population. Regulators and decisions makers recognise the important role Idefirix® can play in enabling patients to receive a life altering kidney transplant and eliminate the need for timely and costly dialysis treatments. I think the recommendation by NICE in the UK is a great example where the unmet needs of highly sensitized kidney transplant patients drove the conversation resulting in reimbursement and access of Idefirix® for patients and clinicians

Q. You mentioned the value of Idefirix® in providing the opportunity for lifesaving kidney transplantation. Can you elaborate on this?

A. Gina: Transplantation is the preferred treatment for all chronic kidney disease patients. This includes many highly sensitized patients, who currently have very few chances to receive an organ offer due to the presence of donor specific antibodies. By rapidly inactivating Immunoglobulin G, Idefirix® enables an otherwise incompatible kidney transplant to occur. Clinical evidence confirms that successful kidney transplants are associated with a better survival and quality of life outcomes compared to remaining on dialysis[3,4]. Idefirix® works alongside allocation systems to increase equity in access to transplant for highly sensitized patients, who otherwise have little to no hope for a transplant due to sensitization status.

Q. Considering the countries Pierre-Henri mentioned, how many highly sensitized patients could potentially be eligible for Idefirix®?

A. Gina: In Europe, the classification of highly sensitized patients and eligibility vary from country to country and is dependent on the allocation system. Highly sensitized patients account for approximately 10% to 15% of patients waiting for kidney transplants.[5] This number is even higher in some countries including Spain where one patient in five, so 20% is classified as highly sensitized against potential donor tissues.[6] These are patients in urgent need of innovative treatments as they have so far been unable to find a suitable donor and have been left on transplant waiting lists. With these authorizations in place, a growing number of highly sensitized patients can be considered for transplantation from a deceased donor with the use of Idefirix®.

[3] Pankhurst L, Hudson A et al. 2017,
[4] Heidt and Claas 2018
[5] EDQM. (2020). International figures on donation and Transplantation 2019 and SRTR Database and individual assessments of allocation systems
[6] PATHI – Plan nacional de acceso a trasplante de pacientes hiperinmunizados. Available at https://sgan.es/ponencias-6-o-congreso-de-la-sociedad-gallega-de-nefrologia/. Last accessed: January 2023

Building experience with imlifidase-enabled kidney transplantations

Dr Lucrezia Furian, Associate Professor of Surgery, Department of Surgical Oncological and Gastroenterological Sciences, University of Padova, Italy, shares her experience in performing the first imlifidase-enabled kidney transplantation in Italy.[1]

Q. Dr Furian, you and your team at the University Hospital of Padova recently performed a successful kidney transplantation following desensitization with imlifidase in a highly sensitized patient. Can you tell us more about this?

A. On November 1st, 2022, following desensitization with imlifidase we were able to successfully perform a kidney transplantation in a very highly sensitized patient who had been on dialysis for almost 14 years and had previously rejected another donor kidney. The patient is doing well and at home with their family. This is a great example of how new innovative treatments can help patients who may previously had little to no other treatment options.

Q. How important was it to appropriately and effectively desensitize the patient before attempting transplantation?

A. Achieving an effective desensitization through a rapid inactivation of IgG, and specifically of pre-formed donor-specific antibodies, was crucial to enable transplantation. The patient had been listed in the national kidney allocation system for many years, and still it took 14 years to be able to perform a transplant due to their significantly high level of sensitization. We were able to successfully perform the transplant because of the almost complete inactivation of pathogenic antibodies using imlifidase. Without imlifidase we would not have been in the position to offer this patient a kidney transplant.

Q. Why was this patient so immunologically complex and why was it decided to treat this candidate?

A. For some kidney patients, identified as highly sensitized, finding a compatible donor is particularly challenging. These patients present antibodies against potential donors, usually developed following a previous transplant, blood transfusion or pregnancies. Therefore, those patients are often waiting a long time for a suitable organ. The patient we decided to treat with imlifidase presented all these complexities. We knew it was going to be challenging, but we also knew that this patient had high unmet need and was left with no other treatment option.

Q. You are also one of the authors of the European Society for Organ Transplantation's (ESOT) guidelines for desensitization. How important is it to have a comprehensive desensitization strategy in place that physicians can use to predict and address potential problems in the treatment of highly sensitized patients?

A. Imlifidase, although crucial, is not sufficient without a thorough desensitization and post-transplant strategy. After years of research, we believe we have refined this approach for the best patient outcomes. Together with other leaders in the field, we have worked with ESOT to develop the first international consensus protocol, published in 2022. It took us four years of research to be able to define a deimmunization protocol suited for treating highly sensitized patients such as this one. Now we have a potent tool at our disposal, and a protocol defined by experts to maximise our chances of success.

Q. The picture you're depicting is that of an advancement in renal transplantation, do you see this as a pathway to new opportunities for highly sensitized patients?

A. Highly sensitized kidney transplant patients have so far lived with limited to no hope of receiving a kidney transplant. With the introduction of new treatment options and approaches, we can address the unmet need in of these patients. It is also critically important to ensure we identify appropriate candidates who can benefit the most from this desensitization treatment, and that clinicians are familiar with the desensitization guidelines to ensure that appropriate protocols are put in place to manage these patients during and after transplantation.

In medicine, there are no silver bullets. There is hard work, innovation, and forward progress that create new options for better patient outcomes particularly in those cases where there remains high unmet need. I think the success we had with the highly sensitized patient at the University Hospital of Padova is a good example of where innovation has given hope.

[1] As of December 2022, imlifidase is available in Italy under the name Idefirix® for the desensitization of highly sensitized adult patients prior to kidney transplant from a deceased donor

Technology

4

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, 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.

	IgM	IgG	IgA	IgE	IgD
% 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

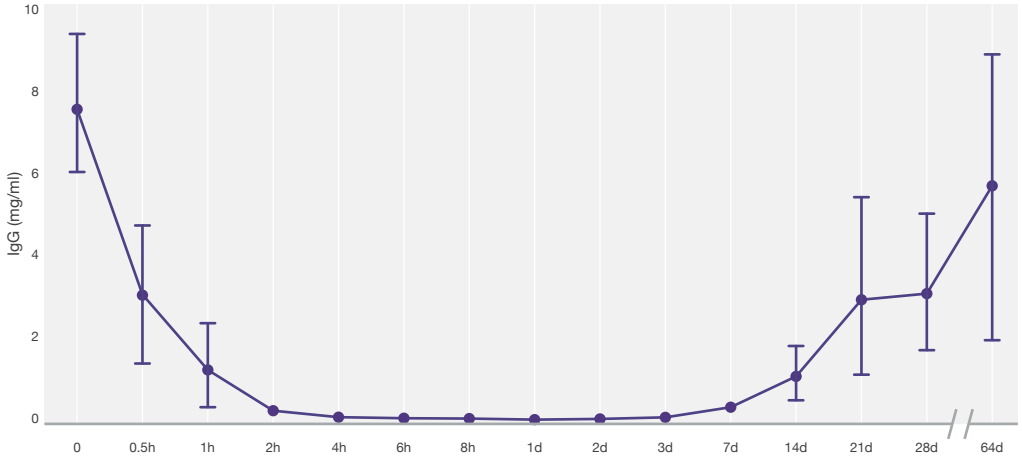
Imlifidase is an enzyme originating from a human pathogen, a bacterium called *Streptococcus pyogenes* which is a species of Gram-positive, spherical bacteria in the genus *Streptococcus* and is usually known for causing a strep throat infection

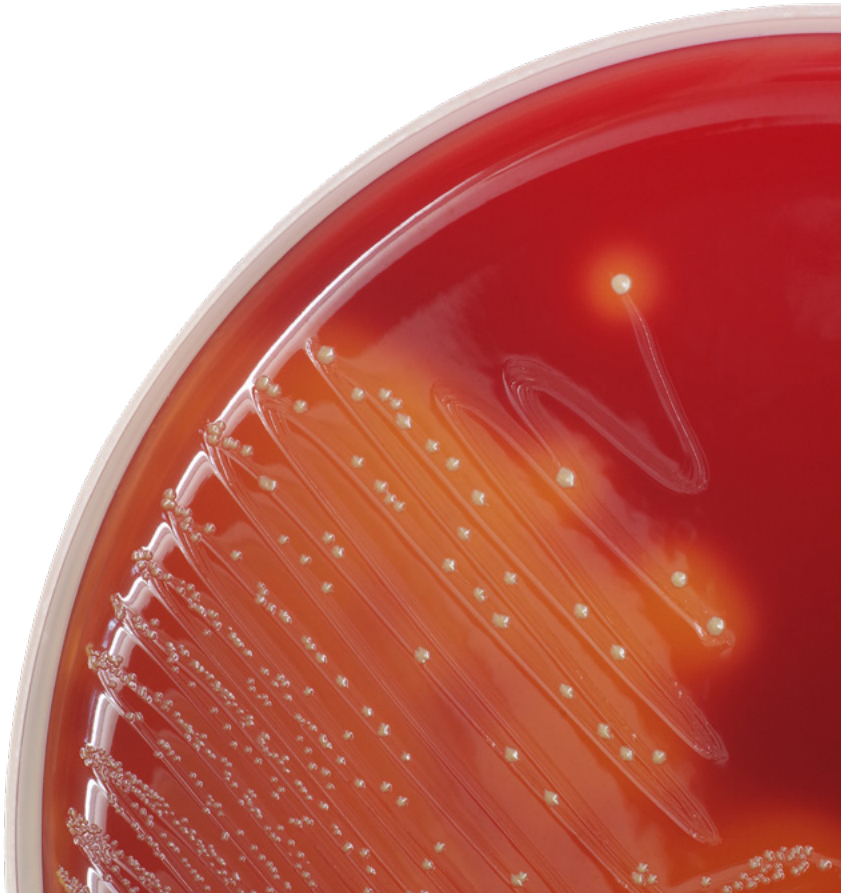
Imlifidase's *Mode of Action* is that it very rapidly and effectively cleaves Immunoglobulin G (IgG) within 2-6 hours from a 15-minute infusion. The IgG is cleaved below the so-called 'hinge region', creating an F(ab')2 and an Fc component.

After treatment, intact IgG levels will drop below detectable levels and stay supressed for approximately 5-7 days, creating a window for a kidney 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.

Imlifidase inactivates IgG in 2-6 hours from infusion

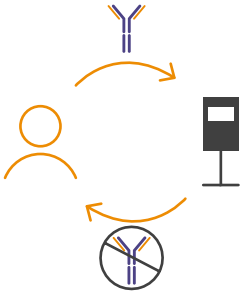
- Rapid onset of action that inactivates IgG below detectable level in 2-6 hours from a 15-minute infusion
- IgG antibody-free window for approximately one week



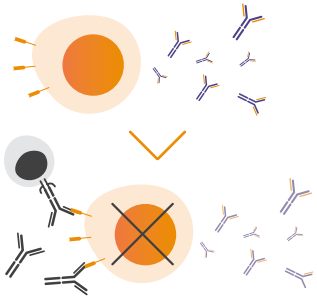


Progress of IgG-modulating technologies

Mechanisms can be both complementary and competing



PLEX, plasmapheresis, immunoadsorption
Mechanically removes antibodies from circulation

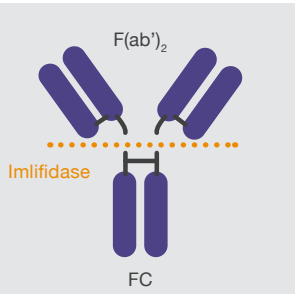


B-cell depleting mAbs
Lowering antibody levels through B-cell elimination

Imlifidase – IgG-cleaving enzyme

Deactivates IgG within 2-6 hours through enzymatic cleavage. IgG-free window for approximately one week

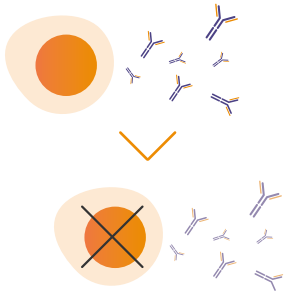
Unique mechanism-of-action is the basis for competitive advantage vs other IgG-modulating therapies



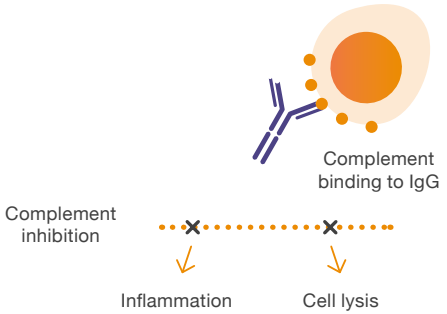
1950s | 1980s | 1990s | 2000s | 2010s | 2020s

IV/SC immunoglobulins
IVIg/SCIg contains healthy antibodies that replaces pathogenic antibodies

Proteasome inhibitors
Depletes antibody producing long-lived plasma cells and lowers overall immunoglobulin levels



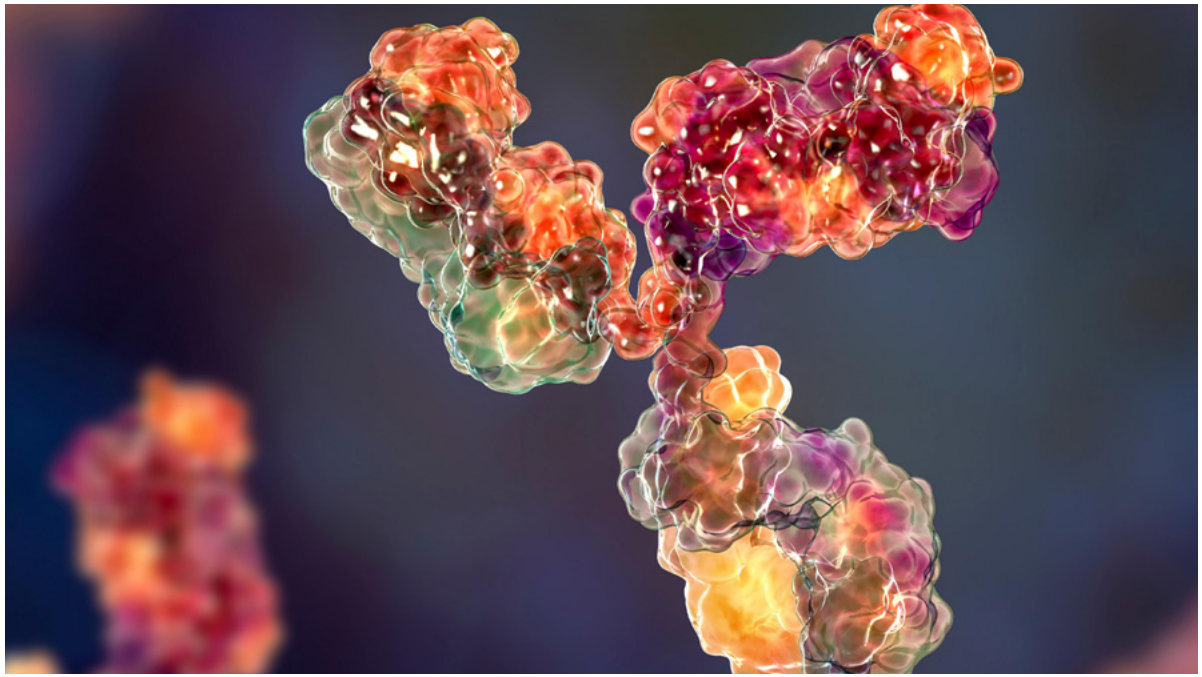
Complement inhibitors
Prevents binding of complement protein to antibodies



FcRn-inhibitors
Lowering IgG through blocking of antibody recycling

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

Our proprietary antibody-cleaving enzyme technology platform targeting 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.



Imlifidase is designed to inactivate IgG antibodies in both plasma and tissue, with a single intravenous treatment in monophasic autoimmune diseases, transplantation, and gene therapy. We are also developing a second generation of IgG-cleaving enzymes under the umbrella "NiceR". The new enzymes are designed to have lower immunogenicity, thereby potentially enabling multiple administration for inactivation of flares in relapsing diseases. Specifically, we completed IND enabling toxicology studies at the end of 2022 for the lead NiceR candidate HNSA-5487. A CTA approval has since been obtained and we expect to start a clinical trial in the first half 2023. These new enzymes 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 exploring how our unique antibody-cleaving enzyme technology potentially can be used in 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.

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

Targeting rare IgG mediated diseases

Autoimmune diseases

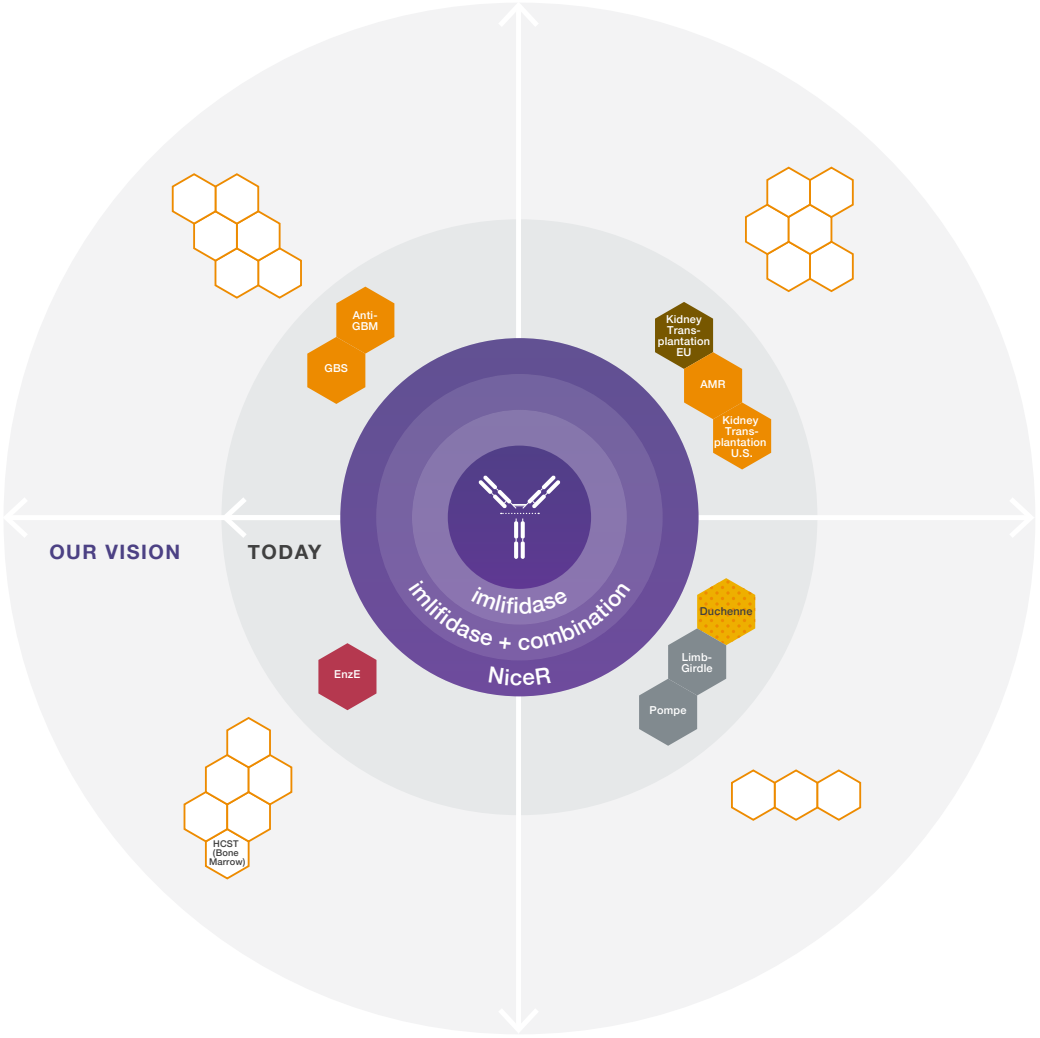
Anti-GBM paves the way for development in other autoimmune diseases

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

New therapies and oncology

IgG-cleaving enzymes to enable or even potentiate cancer therapy

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



Expanding our commercial franchises

- Regulatory approval (conditional)
- Clinical development
- Planned clinical trial
- Partnership (preclinical development)
- Preclinical development
- Potential indications (currently not pursued)

Transplantation

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

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

Gene therapy

Exploring opportunities in gene therapy

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

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.

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

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

Our lead product, imlifidase, is protected by six patent families including both granted patents and pending applications and cover the use of 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 orphans drug designations by EMA/EC and the FDA across transplantation, anti-GBM antibody disease and GBS (only FDA).

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)

EMA/AC 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)

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

Growth

Our development programs

Broad clinical pipeline in transplantation and autoimmune diseases

	Next anticipated milestone
Imlifidase	
EU: Kidney transplantation in highly sensitized patients[1,2]	EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
U.S.: Kidney transplantation in highly sensitized patients[1,2]	Completion of enrollment (64 patients) H1 2023
Anti-GBM antibody disease[3]	First patient enrolled (50 patients)
Antibody mediated kidney transplant rejection (AMR)	Full data read-out H2 2023
Gullain-Barre Syndrome (GBS)	Completion of enrollment (30 patients) H1 2023
Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)	Preclinical research
Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)	Initiate clinical study of imlifidase as pre-treatment in DMD 2023
Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)	Preclinical research
NiceR	
Recurring treatment in autoimmune diseases, transplantation and oncology	Initiate Phase I study of HNSA-5487 (Lead NiceR candidate) H1 2023
EnzE	
Cancer immunotherapy	Research

[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7)
[2] Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

Completed
Ongoing
Planned
Post approval study running in parallel with commercial launch

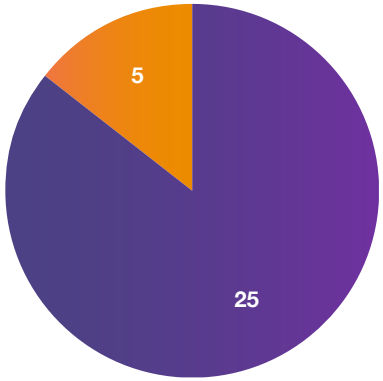
Continuous progress in our ongoing clinical programs

Enrollment status February 1, 2023

Antibody Mediated Rejection phase 2

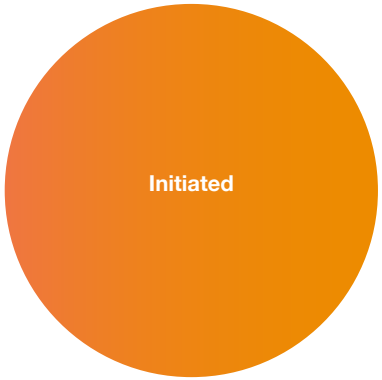
- 30/30 patients enrolled in the AMR phase 2 study
- Data read out demonstrates a statistically significantly superior capacity of imlifidase to rapidly reduce levels of DSAs compared to plasma exchange (SoC) in the five days following the start of the treatment
- Full data read out expected H2 2023, which will determine the path forward for imlifidase in patients with active AMR

Guillain-Barré Syndrome phase 2



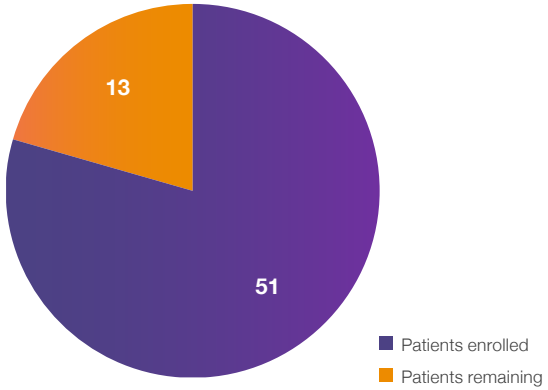
- 25/30 patients enrolled in the GBS phase 2 study
- 10 centers are active and open for recruitment
- Aim to complete enrolment of GBS patients H1 2023
- Aim to communicate first high-level data read out in H2 2023

Anti-GBM phase 3



- New pivotal Phase 3 study initiated in first sites in the U.S and U.K. end of 2022
- Open label, randomised controled study targeting 50 patients to be treated with imlifidase and SoC or SoC alone
- Kidney function (eGFR) will be evaluated as the primary endpoint
- The first patient is expected to be enrolled in H1 2023

U.S. ConfIdeS trial in kidney transplantation phase 3



- 51/64 patients enrolled for randomization
- 13 centers active and open for recruitment; continously adding new clinics, with a goal of at least 20, to further increase entollment capacity
- Expect to complete enrollment H1 2023 and complete randomization in H2 2023
- BLA submission is expected in 2024 under the accelerated approval path

U.S. randomized control trial "ConfIdeS"

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

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

Robert A. Montgomery, M.D., Professor of Surgery and Director, NYU Langone Transplant Institute in New York City, has been appointed National Coordinating Investigator for the ConfIdeS trial. The trial will enroll patients at up to 20 leading transplantation centers in the U.S (13 leading centers were active on December 31, 2022).

Completion of enrollment in the study is expected in the first half of 2023, while randomization is aimed for completion by the second half of 2023. Following a 12-month follow-up period, results are expected to support a BLA under the accelerated approval pathway in 2024, as previously guided.

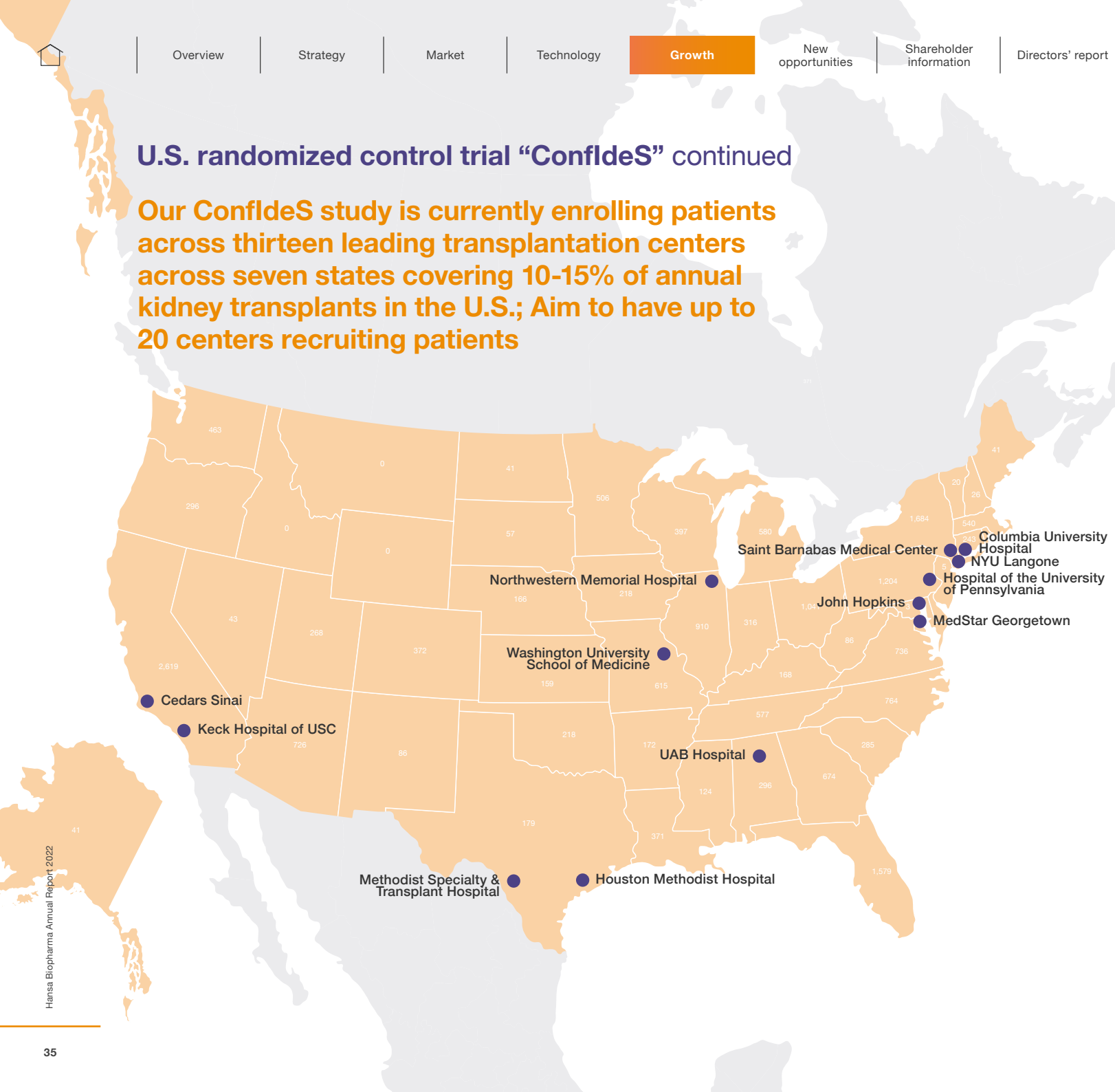
In addition to the ongoing ConfIdeS trial in kidney transplantation, Hansa is also carrying out a post approval efficacy study (PAES) in parallel with the commercial launch in Europe. The PAES was initiated in July 2022 and is an obligation under the European conditional marketing authorization and will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

In addition to this, a long-term follow-up study is also done in patients who have undergone kidney transplantation after imlifidase administration as part of the four phase two studies. In 2021 the three-year follow-up data was published demonstrating graft survival of 84% after imlifidase treatment and transplantation and a mean eGFR of 55 mL/min/1.73 m2, which is in line with expectations in imlifidase treated transplant patients compared to outcomes in patients undergoing HLA-incompatible transplantation. The next read-out on the long-term follow-up trial is expected in the second half 2023, when the five-year data is expected to be published.

Lastly, Hansa is conducting a rebound study in patients treated with imlifidase prior to kidney transplantation. The study aims at including twelve patients to assess whether imlifidase, in combination with bortezomib, belatacept, rituximab and IVIg, can suppress DSA and the occurrence of AMR in highly sensitized crossmatch positive patients undergoing living or deceased donor transplantation.

U.S. randomized control trial "ConfIdeS" continued

Our ConfIdeS study is currently enrolling patients across thirteen leading transplantation centers across seven states covering 10-15% of annual kidney transplants in the U.S.; Aim to have up to 20 centers recruiting patients



23,000[1]
Annual kidney transplantations

71%[1]
Deceased donor

~90,000[2]
Waiting for a kidney transplant

~10-15%[3]
Waitlisted patients are highly sensitized

13 leading transplantation centres
With experience in desensitization and highly sensitized patients are currently active

>2,500[1]
Combined annual kidney transplants

>300[1]
Highly sensitized (>80% cPRA)

[1] 2019 data from Organ Procurement & Transplantation Network
[2] United Network for Organ Sharing
[3] EDQM. (2020). International figures on donation and Transplantation 2019 and SRTR Database and individual assessments of allocation systems

Hansa's Post Authorization Efficacy Study (PAES) in highly sensitized kidney transplant patients

Jan Tollermar, Senior Medical Director, Lina Nilsson Senior Clinical Resource Manager

Q. Why is Hansa conducting a post-authorization efficacy and safety trial?

A. Jan: In 2020, Hansa received a conditional authorization by the European Commission for Idefirix®. With that authorization came the obligation to run a post-authorization efficacy study, a confirmatory trial. The PAES we are now running is a truly international European study, involving patients and transplant centers across many different European countries. Its completion will allow us to collect the necessary evidence to turn the conditional authorization in the European Union into a full marketing authorization by the end 2025 at the latest.

Q. Can you describe the trial design? What's its advancement status?

A. Lina: The study is set to include a total of 50 patients across 20 centers in Europe. The patients will receive imlifidase and subsequently undergo a kidney transplantation. As of February 2023, thirteen sites are open for recruitment with several imlifidase-ready patients having been identified. End of 2022 seven patients have been transplanted following desensitization with imlifidase.

Q. What challenges does this trial pose?

A. Jan: Imlifidase represents a paradigm shift in the management of highly sensitized kidney patients. With imlifidase, we enable incompatible kidney transplantation by turning a positive crossmatch to negative. That is done by inactivating the donor-specific antibodies with a broad reactivity against human leukocyte antigens, which can cause an immune response against non-self tissues such as a donor's organ. Historically, incompatible transplantation has not been considered a viable option and as a result, we must ensure desensitization is smoothly integrated into the treatment process. This demands that a high degree of coordination is ensured at transplant centers early on in the initiation process with multi-disciplinary teams being established.

Furthermore, since this is a cross-European trial, we work with different regions and allocation systems and criteris for sensitization. Importantly, we strive to accommodate imlifidase at a country-by-country basis to complement the allocation systems and local practices.

Another challenge comes with the complex immunological status of the patients identified. With imlifidase we want to provide an opportunity to those highly sensitized kidney patients that so far have had very few or no chances to receive a transplant due to their immunological status. Even in the face of these complexities, we are seeing very positive results, and this is thanks to the preparedness of the treating physicians and the medical support we provide to them.

Q. From your description it seems that the collaboration and communication with the transplant centres are key to ensure the functioning of this trial. Can you elaborate on that?

A. Lina: Not only communication and collaboration, but also proper preparation and support. We have established a very good interaction with healthcare professionals from a safety and initiation perspective, aimed at ensuring that they are prepared when their transplant center starts enrolling and possess the knowledge needed to start using imlifidase in the an effective and controlled manner, in accordance with the clinical trial protocol. This starts with the collaboration with HLA laboratories, which assist in identifying the best possible donor organ for a certain patient, continues with the desensitization procedure, and extends into the follow up during the post-operative phase.

Q. Do you feel this approach is working? What is the response you are seeing by healthcare professionals?

A. Lina: Yes, we can definitively say that this approach has so far been successful, and a good part of its success is thanks to the unique commitment we see from physicians themselves. Most of the professionals we are in contact with through the trial have known imlifidase for long time and are eager to use it, because ultimately, they are driven by the desire to treat these highly sensitized patients who have been left waiting for long time. They are aware of the complexities that come with treating these patients, but this doesn't discourage them. On the contrary, they find being able to assist these patients and accompany them through the process very rewarding. They want to study, learn, and perfect the procedure, they are truly involved and committed, and we can see this in every meeting and scientific exchange we have with them.

Jan: Putting all these aspects together, we are confident that this PAES trial will be beneficial for Hansa, the transplant community, and, most importantly, for patients, because we believe it will help build the knowledge on imlifidase-enabled transplantations in Europe and further strengthen the confidence on the role imlifidase can play in enabling kidney transplant for those highly sensitized patients with the highest unmet medical need.

Opportunities beyond kidney transplantation

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

What is an Autoimmune disease?

> Humoral or cell-mediated immune responses to self-antigens (breaking of tolerance)

> Requires genetic predisposition, and often triggered by viral, bacterial and/or other environmental factors

> 3-5%[1] of populations affected; mainly women (75%)[2]

1 **Brain**
Multiple sclerosis, Neuromyelitis optica

2 **Thyroid**
Hashimoto's disease, Graves' disease

3 **Bone and muscle**
Rheumatoid arthritis, Dermatomyositis

4 **Kidney**
Anti-GBM disease

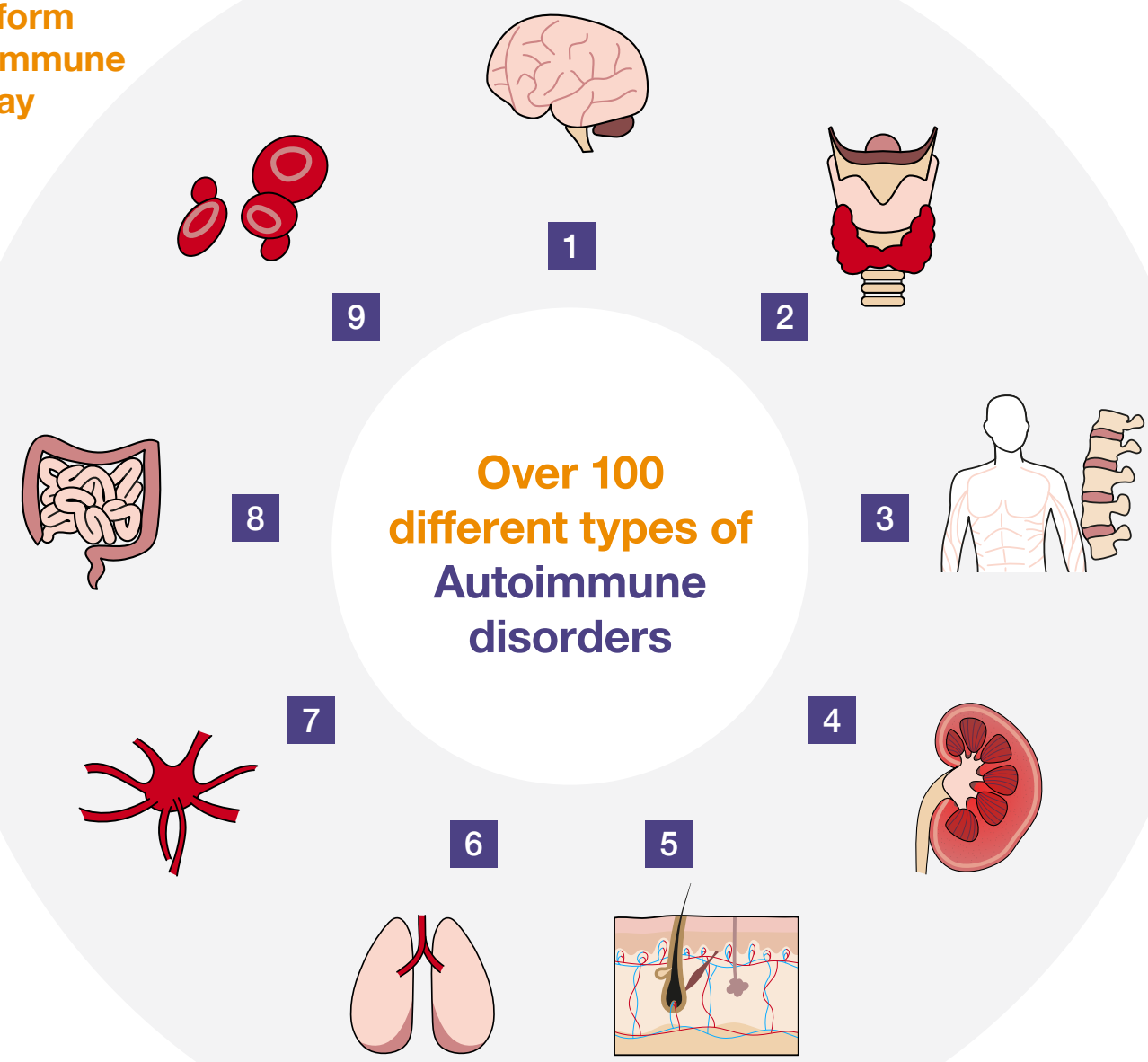
5 **Skin**
Psoriasis, Pemphigus

6 **Lung**
Wegner's granulomatosis

7 **Nerves**
Guillain-Barré Syndrome, Myasthenia gravis

8 **GI Tract**
Crohn's disease

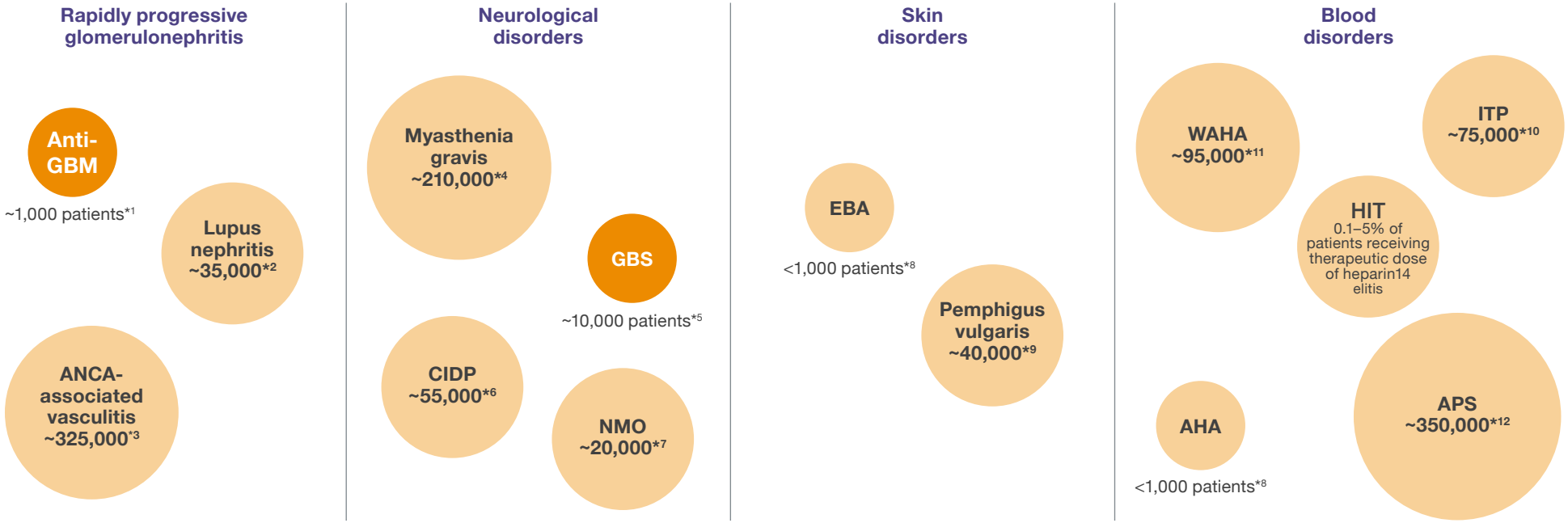
9 **Blood**
Autoimmune hemolytic anemia, Immune thrombocytopenia



[1] Wang et al., J. Intern. Med., 2015
[2] Desai et al., Front. Endocrinol., 2019

Hansa's antibody cleaving enzyme technology

May have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis



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

Clinical programs
Potential indications (currently not pursued)
Total disease populations in EU & US, based on prevalence and population data

1 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]
2 Patel, M et al. The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK. Arthritis & Rheumatism, 2006
3 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
4 Myasthenia Gravis. National Organization for Rare Disorders, https://rarediseases.org/rare-diseases/myasthenia-gravis/ [accessed 2021-03-29]
5 Guillain-Barré Syndrome. Orpha.net, https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Lng=GB&Expert=2103 [accessed 2021-03-29]
6 Chronic Inflammatory Demyelinating Polyneuropathy: Considerations for Diagnosis, Management, and Population Health. The American Journal of Managed Care, https://www.ajmc.com/view/chronic-infammatory-demyelinating-polyneuropathy-considerations-for-diagnosis-management-and-population-health [accessed 2021-03-29]
7 Marrie, R.A. The Incidence and Prevalence of Neuromyelitis Optica. International Journal of MS Care, 2013 Fall: 113-118
8 Mehren, C.R. and Gniadecki, R. Epidermolysis bullosa acquisita: current diagnosis and therapy. Dermatol Reports, 2011-10-05
9 Wertenteil, S. et al. Prevalence Estimates for Pemphigus in the United States. JAMA Dermatol, May 2019: 627-629
10 Immune Thrombocytopenia. National Organization for Rare Disorders, https://rarediseases.org/rare-diseases/immune-thrombocytopenia// [accessed 2021-03-29]
11 Warm Autoimmune Hemolytic Anemia. National Organization for Rare Disorders, https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/ [accessed 2021-03-29]
12 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.

Anti-GBM is an ultra-rare disease that affects approximately 1.6 per million people globally, every year[1,2] (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[3]. Only one in three anti-GBM patients will have a preserved renal function after six months with current treatment[4].

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

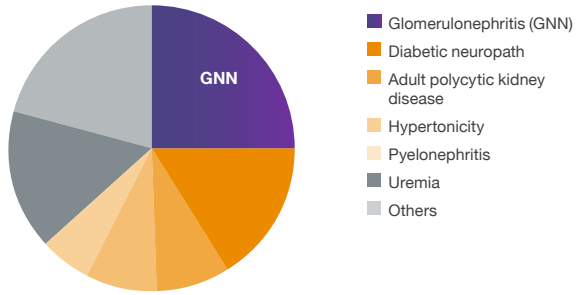
The publication recognizes the study's significance in autoimmune diseases as it suggests that deactivation of autoantibodies could alter the course of an autoimmune disease, allowing restoration of kidney function. These positive results mark an important milestone for the expansion of imlifidase outside transplantation and into autoimmune diseases.

Following the successful data in the phase 2 trial we have commenced a pivotal phase 3 with the first sites initiated in December of last year. The new global study is an open-label, 1:1 randomized, controlled study targeting 50 patients to be treated with either imlifidase and Standard-of-Care or Standard-of-Care alone at up to 50 sites in the U.S. and Europe. Today's Standard-of-Care consists of a combination of plasma exchange, cyclophosphamide and steroids. For patients randomized to the imlifidase arm, the first round of plasma exchange after randomization will be replaced by the administration of imlifidase.

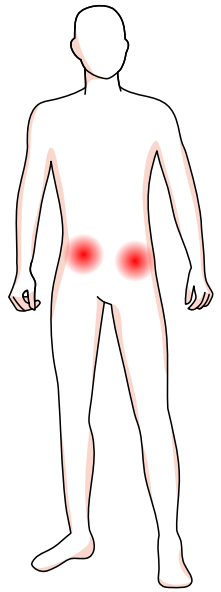
As a primary endpoint, kidney function will be evaluated by eGFR at 6 months from randomization, while anti-GBM antibody levels, pulmonary symptoms, safety, pharmacokinetic/pharmacodynamic (PK/PD) and health related quality of life measures, among others, will be assessed as secondary endpoints.

More information about the trial is available at: ClinicalTrials.gov under NCT05679401 (2022).

GN is a leading cause for kidney disease

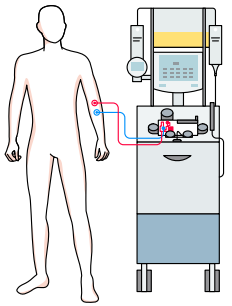


Inflamation in the glomeruli



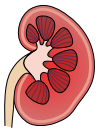
Todays treatments are inadequate

Early diagnostics and treatments are crucial



Early symptoms are unspecific

But can lead to rapid destruction of the kidney and/or the lung



[1] Kluth et al. J Am Soc Nephrol. 1999 Nov;10(11):2446-53
[2] Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12
[3] Cohort of 13 studies (661 patients in anti-GBM 1993-2017) Treating anti-GBM disease with imlifidase Mårten Segelmark, Professor OF Nephrology
[4] 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
[5] Uhlin F. et al. JASN. 2022; https://jasn.asnjournals.org/content/early/2022/03/08/ASN.2021111460

Active antibody mediated rejection (AMR)

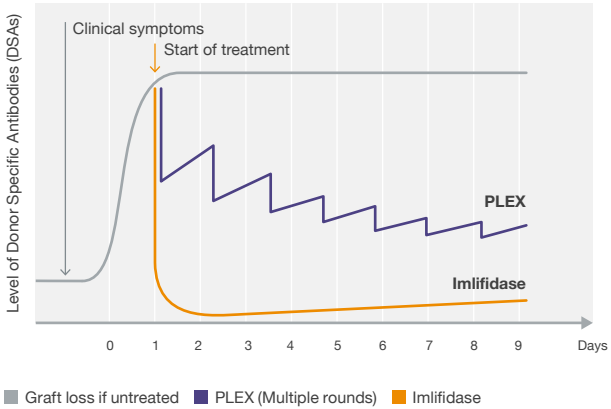
Long term graft survival is challenged by AMR episodes post transplantation

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

Hansa has run a randomized, open-label, multi-center, controlled phase 2 study in AMR. 30 patients with acute or chronic acute AMR were enrolled across centers in France, Germany, Austria, Australia and the U.S. The study is designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in acute AMR patients, post transplantation. Twenty patients were randomized to receive imlifidase treatment comprised of one intravenous dose of 0.25mg/kg, while 10 patients in the active control arm received 5-10 sessions of plasma exchange. Efficacy and safety are monitored over a 6-month period, post treatment. More information about the trial is available at ClinicalTrials.gov under NCT03897205 (2019).

In November 2022, Hansa announced positive topline data from the AMR study demonstrating a statistically significantly superior capacity of imlifidase to rapidly reduce levels of donor-specific antibodies (DSAs) compared to plasma exchange in the five days following the start of the treatment. These first results are another important milestone in executing on Hansa's strategy to expand the reach of our IgG antibody cleaving technology platform to address significant unmet medical needs in a wide spectrum of disease areas and indications. We plan to publish the full dataset from the AMR study in the second half of 2023.

Potential of using imlifidase vs. PLEX in AMR
Illustrative



[1] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724
[2] Puttarajappa et al., 2012; Jordan et al., 2015

Guillain-Barré Syndrome (GBS)

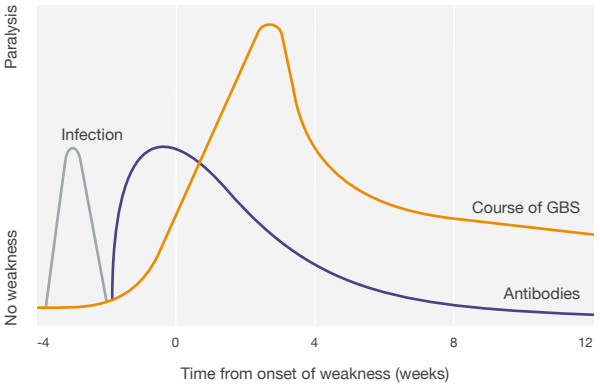
Guillain-Barré Syndrome is an acute autoimmune attack on the peripheral nervous system

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.[1] 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.

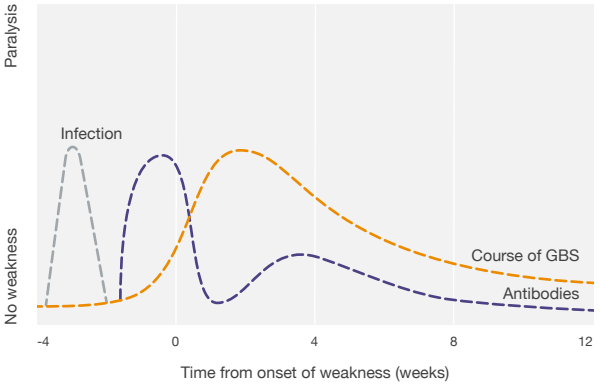
Two thirds of GBS patients have severe symptoms, resulting in an inability to walk unaided, and 20-30% require mechanical ventilation for weeks or months[2]. While patients are typically treated with either IVIg or plasmapheresis, a significant unmet medical need remains, as not all patients fully recover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

Hansa is investigating imlifidase in an open-label, single arm, multicenter phase 2 study evaluating the safety, tolerability and efficacy of imlifidase in GBS patients, in combination with standard of care intravenous immunoglobulin (IVIg). We are targeting 30 GBS patients to be enrolled across clinics in France, the UK and the Netherlands. GBS patients enrolled in the study will receive a single dose of 0.25 mg/kg of imlifidase and will be compared with a matched control group of GBS patients treated with IVIg, from the International GBS Outcome Study (IGOS) database. Completion of enrollment in the GBS trial is anticipated H1 2023 with a first, high level data read out in the second half of 2023.

Today's Standard of Care IVIg or PLEX
Illustrative



Potential with imlifidase
Illustrative



[1] Seven Major Markets Seven major markets include US, Germany, UK, France, Spain, Italy, and Japan
[2] Fletcher DD, Lawn ND, Wolter TD, et al. Long-term outcome in patients with GuillainBarré syndrome requiring mechanical ventilation. Neurology 2000;54:2311–5
[3] McGrogan et al.," The Epidemiology of Guillain-Barré Syndrome Worldwide", Neuroepidemiology;2009, 32(2):150-63
[4] van den Berg et al., 2014

Exploration of Hematopoietic Stem Cell Transplantation (HSCT)

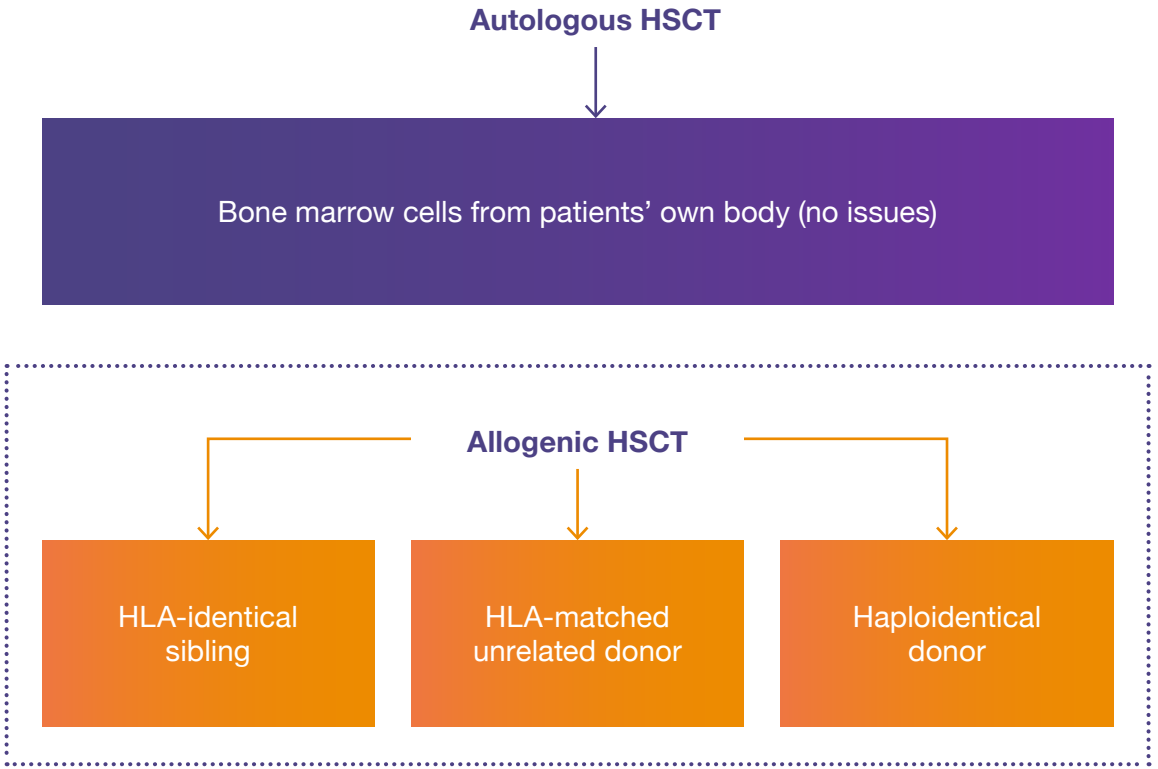
As part of the Company's platform strategy and objective to broaden the application of our antibody-cleaving enzymes as a potential therapy to change the course of IgG-mediated immunological diseases and conditions, we are exploring new indications with high unmet need

One such indication is allogeneic HSCT, also known as "bone marrow" 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.

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[1]. 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%[2]. 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.

It is our belief that our antibody-cleaving enzymes may have the potential to transform the standard of care by enabling clinicians to inactivate DSAs prior to transplantation thereby creating the basis the basis for successful transplantation.

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



[1] https://ashpublications.org/blood/article/134/Supplement_1/2035/427903/One-and-Half-Million-Hematopoietic-Stem-Cell

[2] 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/

New opportunities

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.

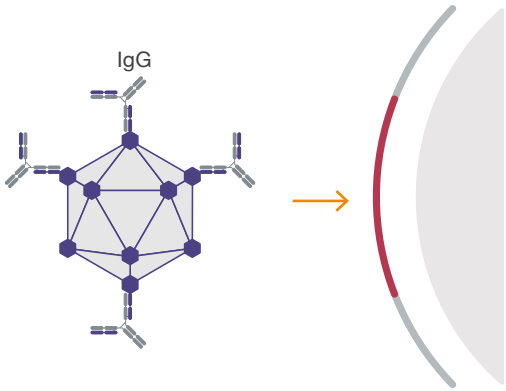
There are vectors that can be administered locally to selected target tissues including specific cells in the eye and the brain. There are also vectors that can be distributed systemically, targeting liver or muscle cells. Since most people have been exposed to adenoviruses at some point in their lives, 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)[1]. 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 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[2]. In particular, highly encouraging results from preclinical studies were published, demonstrating 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.

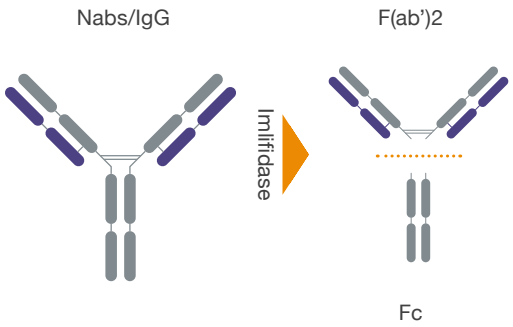
[1] Boutin et al (2010), Griffin et al (2019), Wang et al (2018), Calcedo & Wilson (2013), Falese et al (2017), Haiyan et al (2017), Ellsworth et al (2018), Greig et al (2017)

[2] 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

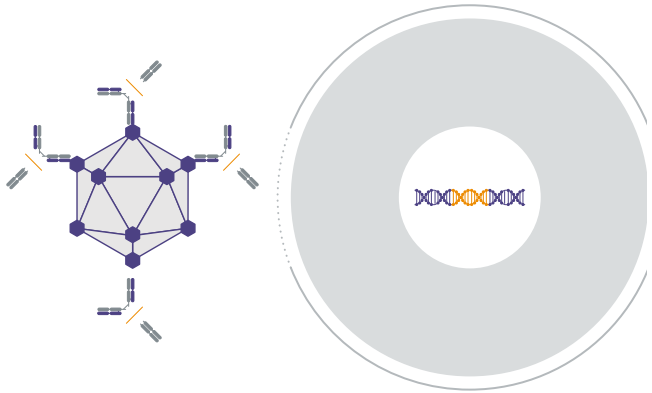
Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



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



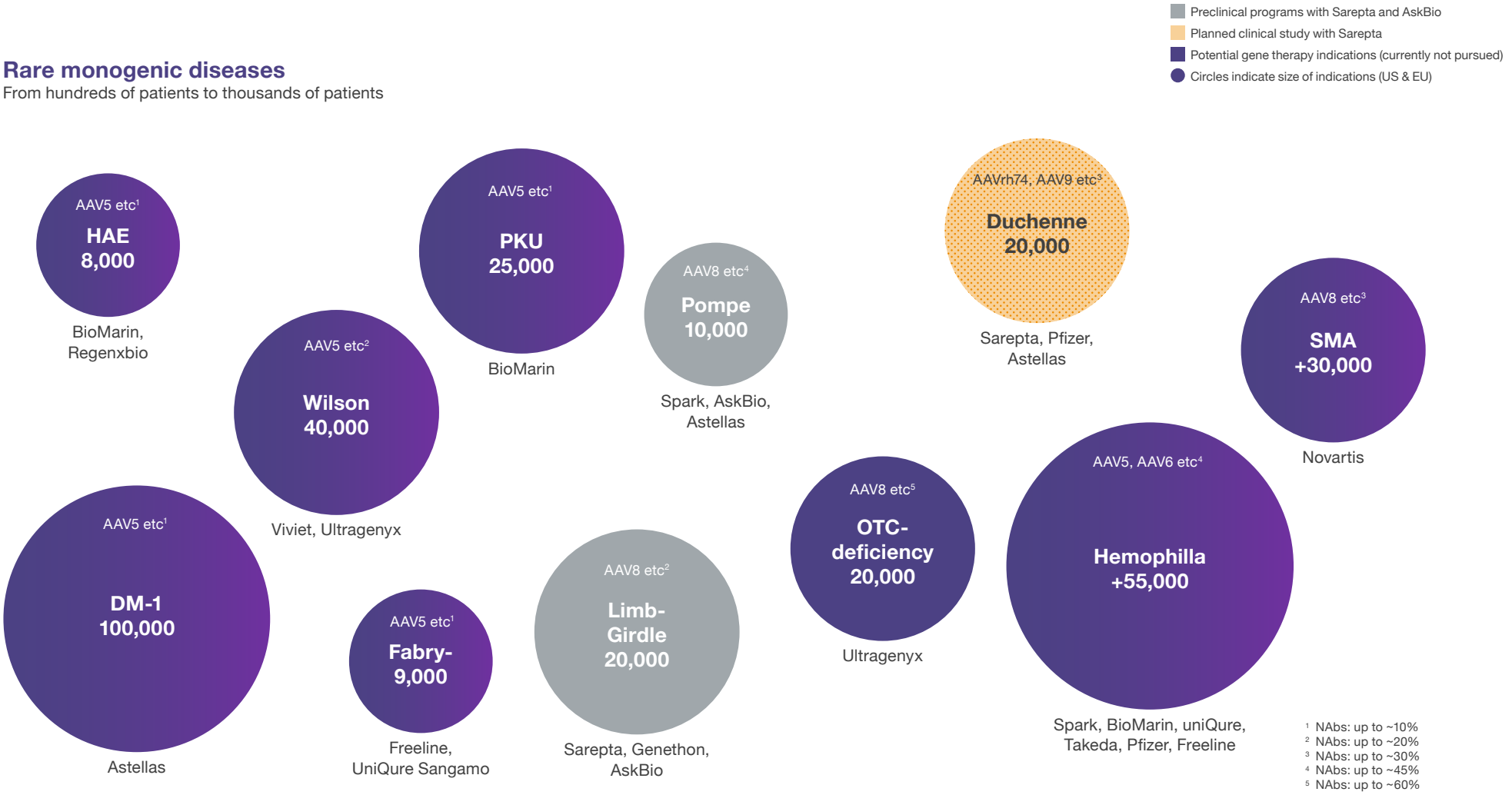
The idea is to eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy



Systemic gene therapy is an emerging opportunity

Rare monogenic diseases

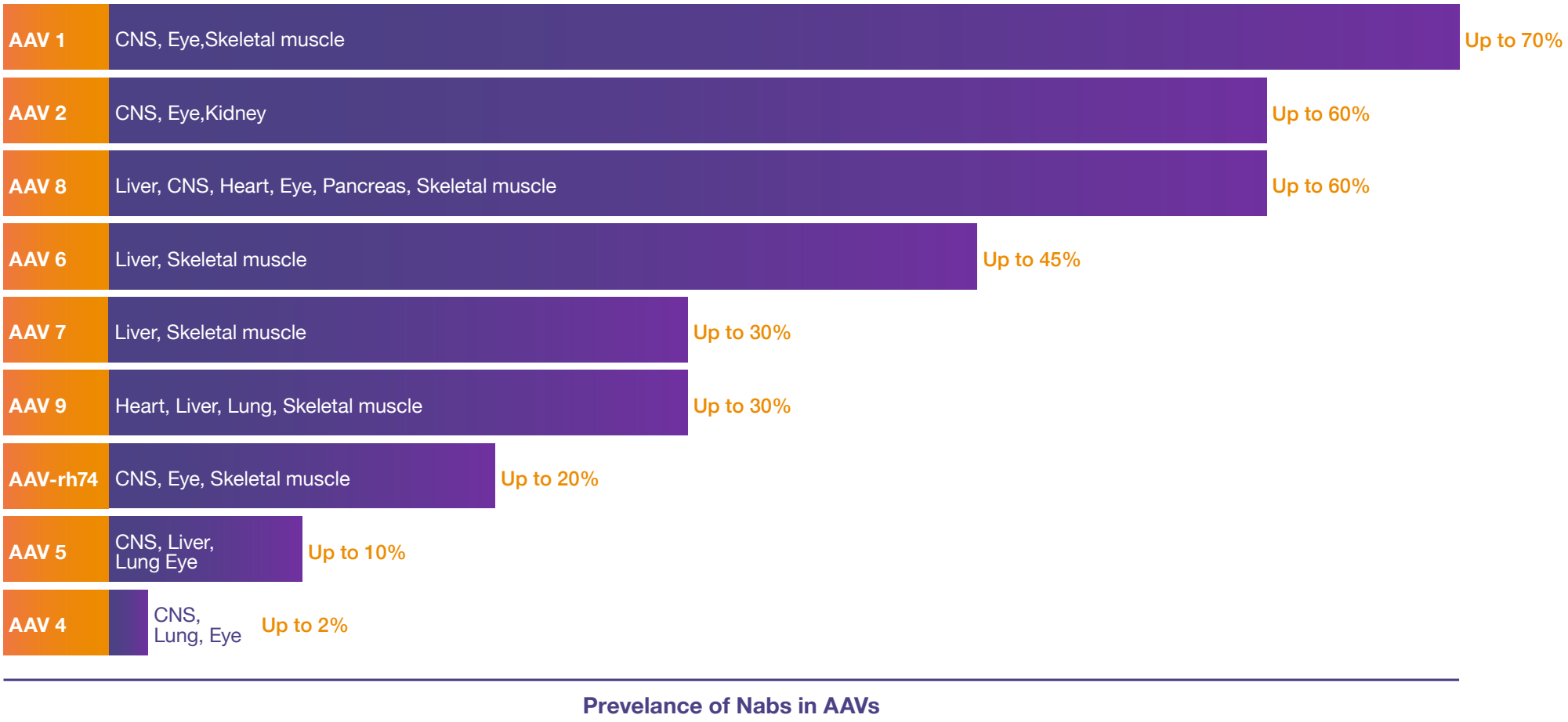
From hundreds of patients to thousands of patients



[1] NAbs: up to ~10%
[2] NAbs: up to ~20%
[3] NAbs: up to ~30%
[4] NAbs: up to ~45%
[5] NAbs: up to ~60%

Neutralizing antibodies are a barrier that precludes gene therapies

The prevalence of Nabs varies significantly across the different vectors



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

Collaborations in gene therapy with Sarepta and AskBio

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

Collaboration with Sarepta Therapeutics

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

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

The partnership is progressing as planned, with preclinical investigations completed during 2022. In November 2022, the two companies announced plans to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD in 2023. The announcement followed an earlier release from Sarepta Therapeutics in September 2022, in which Sarepta Therapeutics announced that it had submitted a BLA to the U.S. FDA for the accelerated approval of SRP-9001 to treat ambulant patients with DMD.

In LGMD the collaboration is progressing as planned, currently at a preclinical stage.

About Duchenne Muscular Dystrophy (DMD)

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

About Limb-girdle muscular dystrophy (LGMD)

Limb-Girdle muscular dystrophy is a group of distinct diseases that cause weakness and wasting of the muscles, generally starting with the muscles around the hips and shoulders and eventually progressing to the arms and legs. However, some subtypes start distally at the leg or arm muscles and then progress to the hip and shoulder muscles. LGMD can be caused by a single gene defect that affects specific proteins within the muscle cell, including those responsible for keeping the muscle membrane intact. Taking into account the various subtypes, limb-girdle muscular dystrophy has a global prevalence of approximately 1.63 per 100,000 individuals worldwide. Over 30 subtypes exist, and both genders are affected equally.

Collaboration with AskBio

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

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

AskBio's gene therapy candidate, AAV2/8-LSPhGAA, 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.

About Pompe disease

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

Pompe disease is estimated to affect 1 in 40,000 births in the U.S.[1], 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[2]. The percentage of patients that are expected to have NAbs against the AAV8-vector components used in AskBio's gene therapy is 40-60%[3].

[1] Pompe disease, https://rarediseases.org/rare-diseases/pompe-disease/
[2] 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
[3] 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 & 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/

Research and preclinical development projects

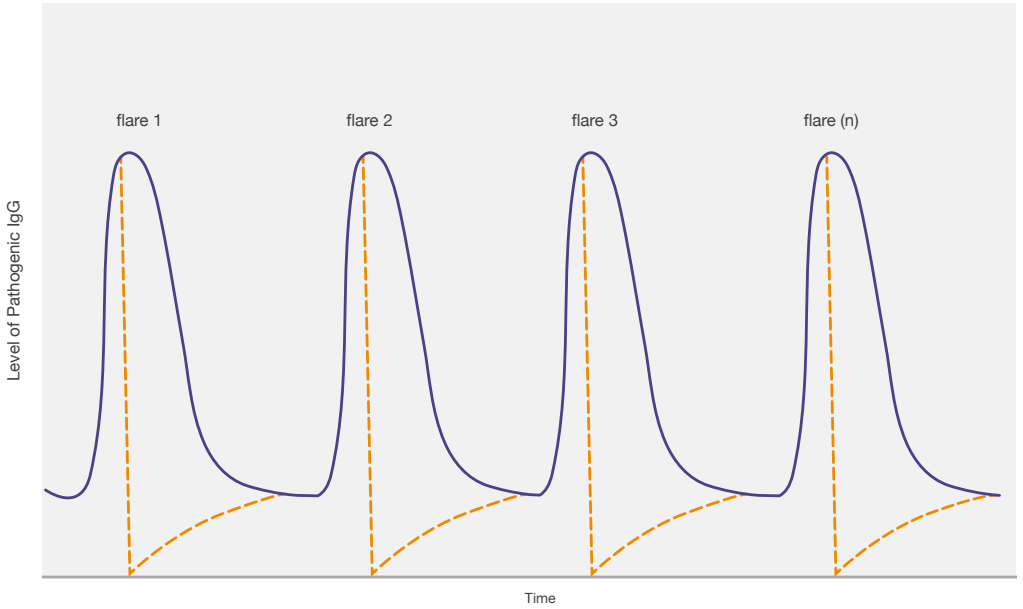
"NiceR" program and lead candidate "HNSA5487"
– new set of enzymes for repeat dosing; potentially enabling treatment of relapsing diseases.

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. At the end of 2022 Hansa announced completion of IND-enabling toxicology studies and that a CTA approval had been obtained for the lead candidate "HNSA-5487" to start a first clinical trial in the first half 2023.

EnzE – Enzyme-based antibody Enhancement
Hansa is exploring 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. The project is currently in a research stage.

NiceR can potentially inactivate flares
Illustrative



Shareholder information

7

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 Stockholm Health Care
- OMX Stockholm Mid Cap
- OMX Stockholm Pharmaceuticals & Biotechnology
- STOXX Europe Total Market Small Index

Brief facts, the Hansa Biopharma-share

According to the shareholder register maintained by Euroclear Sweden AB, as of 31 December 2022, Hansa Biopharma had approximately 19,000 shareholders, compared to approximately 18,000 shareholders as of 31 December 2021. Information regarding shareholders and shareholdings is updated each quarter on the Company's website, www. hansabiopharma.com.

Share capital

Total shares issued as of 31 December 2022 amounted to 52,443,962 ordinary shares outstanding and 2,590,279 C-shares. At year end 2022, the share capital amounted to SEK 55,034,241. At the general meeting, each ordinary share entitles the holder to one vote and each shareholder may vote the full number of shares held by him or her. All outstanding shares are fully paid up. The Company's share capital is denominated in Swedish kronor (SEK) and divided among the Company's shares with a quotient value of SEK 1 per share.

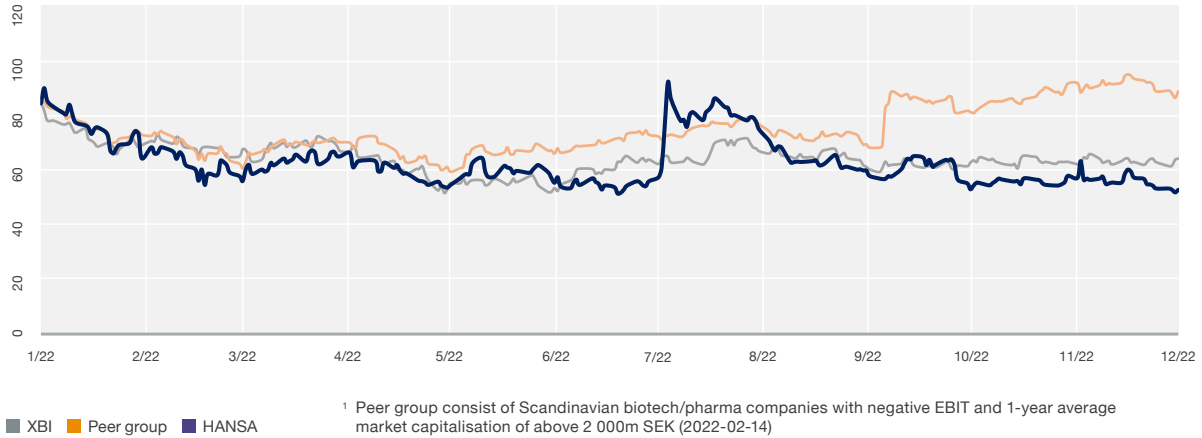
Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares	55,034,241 (52,443,962 A shares and 2,590,279 C-shares)
Market Cap December 31, 2021	SEK ~2.7bn (USD ~261m)
Ticker	HNSA
ISIN	SE0002148817

Price development for the HNSA share in 2021 and 2022

	2022		2021	
SEK	**High**	**Low**	**High**	**Low**
1st quarter	97.8	50.8	245.6	144.5
2nd quarter	70.5	47.5	180.9	132.2
3rd quarter	105.8	47.2	151.6	105.9
4th quarter	66.9	47.7	120.5	80.6

Hansa share price development versus peer group[1] during 2022



[1] Peer group consist of Scandinavian biotech/pharma companies with negative EBIT and 1-year average market capitalisation of above 2 000m SEK (2022-02-14)

Ownership and analyst coverage

Top 10 largest shareholders, 31 December 2022

Owners	Number of shares HNSA	Capital (%)
Redmile Group, LLC	10 896 553	20.8
Försäkrings AB Avanza Pension	2 209 783	4.2
Fjärde AP-Fonden (AP 4)	2 207 397	4.2
Nexttobe AB	2 155 379	4.1
Olausson, Thomas	1 917 000	3.7
Tredje AP-Fonden (AP 3)	1 389 650	2.6
Braidwell, L.P.	974 528	1.9
Handelsbanken Asset Management	908 266	1.7
C WorldWide Asset Management	799 749	1.5
Heights Capital Management, Inc.	667 169	1.3
Other	28 318 488	54.0
Total	52 443 962	100.0

Analyst coverage 2022 and 2023

Analyst	Bank / Research institution (year of initiation)	Location	Email	Phone
Christopher Uhde	SEB (2016)	Stockholm	christopher.uhde@seb.se	+46 (0) 876-385 53
Gonzalo Artiach Castañón	ABG Sundal Collier (2018)	Stockholm	Gonzalo.Artiach@abgsc.se	+46 (0) 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@hcwresearch.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	Bryan Garnier (2022)	Paris	ingrid.Gafanhao@kempen.com	+31 689 937 525
Suzanne van Voorthuizen	Kempen (2019)	Amsterdam	s.vanvoorthuizen@vanlanschotkempen.com	+31 6 29 71 3490

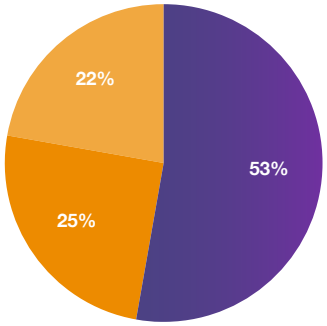
Hansa Biopharma shareholders

~19,000

As of 31 December 2022

Ownership by type and location, 31 December 2022

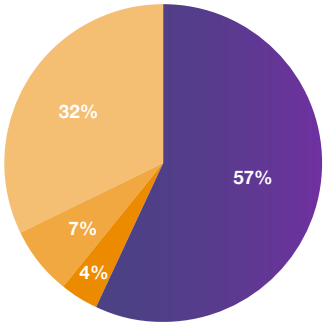
Ownership by country



Split by region

- Sweden
- Europe
- United States

Ownership by type



Investor type

- Institutions
- High net-worth
- VC
- Retail

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

Directors' report

2022 Directors' report

Operations

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

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

Hansa is also currently evaluating imlifidase across a wide spectrum of both potential disease areas and indications in an effort to address significant unmet medical needs. Its broad pipeline spans pre-kidney transplantation desensitization and post-transplantation antibody-mediated organ rejection, or AMR, and rare 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 is also pursuing a second-generation IgG-cleaving enzyme program, NiceR. It is designed to enable expansion into a large spectrum of potential indications, including relapsing autoimmune diseases and gene therapy, as well as oncology indications. Through its preclinical EnzE program, Hansa is exploring the potential of an IgG-cleaving agent as a pre-treatment for cancer therapy.

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

2022 Business review

2022 was a successful year at Hansa with solid performance and strong progress across the organization. Hansa executed throughout the year on key priorities, including R&D, commercial and operations.

The Company progressed the launch of and market access efforts for Idefirix® in Europe, securing reimbursement in a number of additional important markets, such as Germany, the UK, France and Italy. Market access is now secured in 11 European countries, including four of the five largest markets. Outside the EU Hansa recently signed a distribution agreement with iQone Healthcare, a leading Swiss healthcare product supplier, to cover the distribution of Idefirix® in Switzerland. Product sales in 2022 increased by almost 6-fold compared to 2021 and reached SEK 87 million, while total revenue increased to SEK 155 million.

Also, the first medical guidelines for desensitization treatment of highly sensitized kidney transplant patients were published by the European Society for Organ Transplantation (ESOT). These guidelines are the first to include Idefirix® and represent the first international consensus on a management pathway for kidney transplant patients with high unmet need.

On the development side, Hansa continued to make progress across its pipeline.

In November, the Company presented top-line data from its phase 2 program in AMR, post transplantation, demonstrating significantly superior capacity of imlifidase to rapidly reduce DSA levels in comparison to plasma exchange in the five days following the start of the treatment. The full data set from the phase 2 study in AMR is planned to be published in the second half of 2023.

Hansa also continued to progress recruitment into its ConfIdeS study, the ongoing pivotal, phase 3 trial in kidney transplantation in the US. As of February 1, 2023, 51 out of the targeted 64 patients were enrolled for randomization in that study. A potential BLA submission is targeted for 2024. Further, recruitment into the ongoing phase 2 study in GBS continued to progress with enrolment reaching 25 out of targeted 30 patients as of February 1, 2023 and an expected completion of enrolment during the first half of 2023.

In addition, the Company initiated two new phase 3 studies, namely the European Post Approval Efficacy Study in kidney transplantation, a key study under the EMA post-approval commitments and the pivotal, global phase 3 study in anti-GBM disease building upon the strong results from the phase 2 investigator-initiated trial completed in 2020.

On the pre-clinical side, significant achievements were accomplished during 2022; specifically, in the DMD program with Sarepta Therapeutics in gene therapy and in the NiceR program, which is exploring utilisation of second-generation enzymes for repeat dosing. With regard to the NiceR program, the lead compound HNSA-5487, has successfully completed IND-enabling toxicology studies during 2022 and is now expected to enter the clinic in the first half of 2023. And with regard to the DMD program, following successful pre-clinical work, Hansa and Sarepta announced plans to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD in 2023.

2022 Directors' report continued

Through the agreement with AskBio, a subsidiary of Bayer AG, announced in January 2022 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), Hansa further expanded its potential footprint in the gene therapy space.

A key focus of Hansa during 2022 was also to secure additional financing. Despite challenging capital markets throughout 2022, the Company successfully completed a USD 70 million non-dilutive debt financing in July and a USD ~40 million equity financing in December 2022, extending its cash runway into 2025.

And finally, Hansa continued to build a high-performance team by attracting and integrating highly 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 2022 as it received certification as a "Great Place to Work" for the third consecutive year by the GPTW Institute.

However, beyond the significant achievements during 2022, the Company has also seen its commercialization and pipeline activities, specifically related to the recruitment of patients in the ongoing studies, still negatively impacted by issues resulting from the COVID-19 pandemic.

Risk management

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

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

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

Risk factors

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

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

Risks related to public health crisis and geopolitical factors

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

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

Product development, regulatory approval, and commercialization

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

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

The Company cannot give any assurance that any product candidate will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized. Hansa's business and future success is substantially dependent on its ability to develop successfully, obtain regulatory approval for, and then successfully commercialize its product candidate imlifidase and its other product candidates. Hansa is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA, the

2022 Directors' report continued

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 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, IQone Healthcare Switzerland and Asklepios BioPharmaceutical, Inc. Such partnerships and agreements may be terminated, unsuccessful, not achieve the intended results and outcomes, not meet Hansa's objectives or expectations, and therefore materially negatively impact Hansa's business, its financial position, and earnings prospects.

Reliance on Contract Manufacturing Organisations (CMOs)

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

Hansa is dependent on the quality of the manufacturing and packaging processes, as well as the availability and maintenance of the production facilities. Regulatory authorities require that all manufacturing processes and methods, as well as all equipment, comply with current requirements of Good Manufacturing Practice (GMP) 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.

2022 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 Biopharma is largely dependent on its ability to obtain and defend patents and its ability to protect specific know-how. Patent protection for biomedical and biotech companies may be uncertain and involve complicated legal and technical questions. There is significant risk that a patent sought will not be granted for an invention, that the patent granted will not provide sufficient protection, or that the patent granted will be circumvented or revoked.

If the Company fails to obtain and/or maintain patent protection and trade secret protection 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 negatively 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, and in addition, in 2022, took up a long-term loan to help financing future operations.

2022 Directors' report continued

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 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.

The Company is committed to driving its business forward in a sustainable way. In 2022, Hansa conducted a stakeholder engagement and material assessment and developed a strategic approach to align with the United Nations (UN) Sustainable Development Goals - action for people, the planet, and prosperity. Hansa also took into consideration the Global Reporting Initiative's (GRI) reporting standard. You can find the Company's 2022 Sustainability Report on its website at www.hansabiopharma.com, including its impact on economy, people, and environment.

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 Hansa's Sustainability Report at www.hansabiopharma.com

Revenue and financial result for the Group

The Group consists of the parent company, Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc. and Hansa Biopharma Australia PTY LTD. Hansa Biopharma Inc had six employees at the end of December 2022. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had four employees at the end of December 2022.

Revenue for 2022 amounted to SEK 154.5 million (2021: SEK 33.9m) and comprises of product sales in the amount of SEK 86.7 million (2021: 15.0m), revenue recognition from the upfront payment the Company received under the Sarepta and AskBio agreements in the amount of SEK 64.3 million (2021: 15.7m), and royalty income and cost reimbursements from Axis-Shield Diagnostics (Abbott group) in an amount of SEK 3.5 million (2021: 3.2m).

The loss from operations for 2022 amounted to SEK 588.6 million (2021: SEK 547.0m). Compared to 2021, 2022 expenses have increased primarily in line with the progress in and expansion of Hansa's R&D activities; more specifically, the ongoing ConfIdeS study in the U.S., the post-approval commitments in Europe and the preparations for the pivotal phase 3 program in anti-GBM disease. Further, Hansa did also increase its investments into its second-generation enzyme program in preparation of taking the lead candidate HNSA-5487 into the clinic in 2023. The result for 2022 includes non-cash expenses related to the Company's long-term incentive programs (LTIP) amounting to SEK 58.2 million (2021: SEK 56.6m).

Finance income for 2022 amounted to SEK 27.2 million (2021: SEK 0.1m) and is mainly resulting from foreign exchange rate gains, particularly USD and EUR, and interest income. Finance expenses amount to SEK 48.6 million (2021: SEK 1.2m) and mainly relate to interest expenses related to the long-term loan taken-up in 2022 and changes in fair value of interest fund investments Hansa held during a part of 2022.

The loss for 2022 amounted to SEK 611.1 million (2021: SEK 548.3m).

Cash flow and financial position

Net cash used in operating activities amounted to SEK 502.7 million in 2022 (2021: 481.2m). The increase in cash consumption is in line with the growth in Hansa's R&D investments, partly offset by increased product sales.

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

Cash and cash equivalents including short term investments amounted to SEK 1,496.2 million as of December 31, 2022 (SEK 889.0m as of December 31, 2021), which is expected to finance Hansa's operations into 2025.

Capital expenditures

Capital expenditures during 2022 amounted to SEK 3.3 million (2021: SEK 2.4m).

Shareholders' equity

On December 31, 2022, shareholders equity amounted to SEK 602.9 million compared to SEK 757.6 million at the end of the financial year 2021.

2022 Directors' report continued

Parent Company

The Parent Company's revenue for 2022 amounted to SEK 154.5 million (2021: SEK 33.9m). The loss for the period for the Parent Company amounted to SEK 596.7 million for 2022 (2021: SEK 549.1m). On December 31, 2022, cash and cash equivalents including short-term investments amounted to SEK 1,486.5 million compared to SEK 882.6 million at the end of the year 2021.

The Parent Company's shareholders equity amounted to SEK 615.8 million as per December 31, 2022, compared to SEK 755.9 million at the end of 2021.

Five-year summary, consolidated for the Group

KSEK, unless other stated	2022	2021	2020	2019	2018
Revenue	**154,525**	33,878	6,098	3,364	3,358
Sales, general and administration expenses	**(337,861)**	(327,269)	(202,987)	(167,310)	(90,387)
Research and development expenses	**(346,244)**	(230,764)	(227,191)	(192,949)	(154,558)
Other operating income (expenses)	**(20,532)**	(7,398)	2,270	(1,907)	(3,995)
Loss from operations	**(588,588)**	(546,978)	(422,807)	(359,668)	(246,498)
Loss for the period	**(611,134)**	(548,282)	(420,853)	(360,009)	(247,974)
Net cash used in operating activities	**(502,733)**	(481,168)	(290,274)	(334,775)	(204,560)
Cash and cash equivalents, including short-term investments	**1,496,179**	888,961	1,377,506	601,094	858,187
Shareholder's equity	**602,912**	757,573	1,242,124	562,815	859,876
Earnings per share before and after the dilution (SEK)	**(13.60)**	(12.33)	(9.98)	(9.00)	(6.47)
Number of outstanding shares at the end of the period	**52,443,962**	44,473,452	44,473,452	40,026,107	39,959,890
Weighted average number of shares before and after dilution	**44,923,998**	44,473,452	42,176,872	40,020,429	38,326,098
Number of FTE's end of the period	**150**	131	87	74	52

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 2022 comprised of 52,443,962 ordinary shares and 2,590,279 C-shares held by the Company as treasury shares. During 2022 the Company issues 7,848,111 new ordinary shares and issued and repurchased 850,769 C-shares, held as treasury shares. Each share has a nominal value of SEK 1 resulting in SEK 55,034,241 share capital and SEK 52,443,962 in outstanding share capital as of 31 December 2022.

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, 2022, the single largest shareholder in Hansa was Redmile Group LLC, with a total of 10,896,553 shares, representing 20.8 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's Board of Directors, the AGM resolved to adopt a long-term, share-based compensation program in 2022.

2022 Long-term incentive program

Hansa's Annual General Meeting (the "AGM") on June 30, 2022 resolved to adopt a long-term incentive program, LTIP2022, based on (a) performance-based share rights and (b) employee stock options.

LTIP2022 based on performance-based share rights

Under the terms of LTIP2022 key employees may participate in the program and may receive so-called performance-based share awards free-of charge (a "Share Right") which, provided certain pre-defined Performance Conditions (as briefly summarized below) and other criteria are met, give the participants the right to acquire ordinary shares in Hansa Biopharma AB at no cost. Each Share Right represents the right to acquire one share in Hansa Biopharma AB and carries a vesting period of three years commencing on the day of its allotment to a participant (the "Vesting Period").

2022 Directors' report continued

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 approved imlifidase in the U.S. in any indication
> Condition 2: Imlifidase has been approved, or a Marketing Authorization Application/Biologics License Application has been submitted, in any jurisdiction in an indication outside kidney transplant
> Condition 3: More than 80 per cent of the targeted transplantation centers in Europe had repeat business, i.e. used Idefirix® more than once
> Condition 4: Total shareholder return of at least 25%

A maximum of 624,615 Share Rights may be allotted to participants under the LTIP 2022 from the day following the 2022 AGM up and until the day prior to the AGM in 2023.

As of December 31, 2022, 543,000 Share Rights have been allotted to plan participants.

LTIP2022 based on stock options

The 2022 AGM also resolved to adopt an employee stock option program under the terms of LTIP2022. Senior executives may participate in the program and receive employee stock options free-of-charge.

Each employee stock option entitles the holder to receive one new ordinary share in Hansa Biopharma AB at an exercise price of SEK 70.00 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, and provided that the participant, with certain exceptions, from the date of the start of participation in LTIP 2022 up until and including the date three years thereafter (the Vesting Period) maintains his or her employment within the Group.

A maximum of 452,307 employee stock options may be allotted to participants under the LTIP2022 from the day following the 2022 AGM up and until the day prior to the AGM in 2023.

As of December 31, 2022, 384,000 employee stock options have been allotted to the plan participants under the LTIP2022.

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 LTIP2022 allotted as of December 31, 2022, is expected to amount to approximately SEK 66.8 million, of which SEK 10.2 million is included in the results for the Group for the year 2022.

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

2022 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 2022 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 which 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.

2023 proposed changes to remuneration guidelines for senior executives

No changes to the guidelines are proposed for 2023.

Dividend

The Board proposes that no dividend will be paid for the financial year 2022. For more information about Hansa Biopharma's dividend policy, please refer to the Hansa Biopharma Corporate Governance Report available on the Company's website at https://hansabiopharma.com/this-is-hansa/corporate-governance/

Other information

For additional information, please see the Corporate governance report and the Remuneration report on the Company's website or elsewhere in this Annual Report.

2022 Directors' report continued

Annual general meeting 2023

The annual general meeting of Hansa Biopharma AB (publ) will take place on June 14, 2023. Notice to attend the annual general meeting will be published on Hansa Biopharma's website at: www.hansabiopharma.com.

Financial calendar 2023

March 30, 2023	Annual Report 2022
April 20, 2023	Interim report for January - March 2023
June 14, 2023	Annual General Meeting 2023
July 20, 2023	Half year 2023 report
October 18, 2023	Interim Report for January-September 2023

Appropriation of loss carried forward

Unrestricted shareholders' equity in the Parent Company

SEK	
Share premium reserve	3,021,541,484
Treasury shares	(2,590,279)
Loss carried forward	(1,882,303,903)
Result for the year	(596,735,718)
Total	**539,911,584**

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

SEK	
Share premium reserve	3,021,541,484
Treasury shares	(2,590,279)
Profit/loss carried forward	(2,479,039,621)
Total	**539,911,584**

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

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

Financials

The Group Financial Statements

Consolidated statement of financial position

(in thousands of SEK)	Note	As of December 31, 2022	2021
ASSETS			
Non-current assets:			
Intangible assets	4	46,866	28,761
Property and equipment	5	8,113	6,432
Right-of-use assets	6	27,723	35,273
Total non-current assets		**82,702**	**70,466**
Current assets:			
Inventories	7	973	242
Trade receivables & unbilled revenues	8,13	42,959	9,712
Prepaid expenses and accrued income	9	33,278	20,889
Other receivables	10	31,315	22,538
Short-term investments	20	-	237,619
Cash and cash equivalents	20	1,496,179	651,342
Total current assets		**1,604,704**	**942,342**
TOTAL ASSETS		**1,687,406**	**1,012,808**
EQUITY			
Share capital	23	55,034	46,335
Share premium	24	3,021,541	2,572,925
Treasury share reserve	25,26	(2,590)	(1,862)
Other reserves	26	13	127
Accumulated deficit		(2,471,087)	(1,859,953)
Total equity attributable to owners of the parent company		**602,912**	**757,573**

(in thousands of SEK)	Note	As of December 31, 2022	2021
LIABILITIES			
Non-current liabilities:			
Long-term loan	21	762,601	-
Lease liabilities	6	21,326	28,491
Deferred revenue	13	29,500	47,020
Contingent consideration	18	757	722
Provisions	15	5,192	7,357
Deferred tax liabilities	16	405	426
Total non-current liabilities		**819,781**	**84,016**
Current liabilities:			
Current tax liabilities		604	-
Lease liabilities	6	7,165	6,888
Trade payables	20	62,476	53,360
Other liabilities	12	18,278	13,548
Deferred revenue	13	40,430	24,961
Refund liabilities	8	27,013	-
Accrued expenses	11	108,747	72,462
Total current liabilities		**264,713**	**171,219**
Total liabilities		**1,084,495**	**255,235**
TOTAL EQUITY AND LIABILITIES		**1,687,406**	**1,012,808**

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

The Group Financial Statements continued

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

(in thousands of SEK, except for shares and per share data)	Note	Years Ended December 31, 2022	2021
Revenue	13	154,525	33,878
Cost of revenue		(38,477)	(15,425)
Sales, general and administrative expenses	29	(337,861)	(327,269)
Research and development expenses	29	(346,244)	(230,764)
Other operating expenses	28	(20,532)	(7,398)
Loss from operations		**(588,588)**	**(546,978)**
Finance income	22	27,248	67
Finance expenses	22	(48,639)	(1,219)
Loss before tax		**(609,979)**	**(548,130)**
Income tax expense	16	(1,155)	(152)
Loss for the year		**(611,134)**	**(548,282)**
Loss for the year attributable to owners of the parent		(611,134)	(548,282)
Loss per share, basic and diluted (SEK)	17	(13.60)	(12.33)
Weighted-average number of ordinary shares outstanding, basic, and diluted		**44,923,998**	**44,473,452**

(in thousands of SEK)	Note	Years Ended December 31, 2022	2021
Loss for the year		**(611,134)**	**(548,282)**
Other comprehensive income (loss):			
Items that are or may be reclassified subsequently to profit or loss, net of tax:			
Exchange differences on translating foreign operations		(114)	264
Other comprehensive income (loss) for the year		**(114)**	**264**
Total comprehensive loss for the year		**(611,248)**	**(548,018)**
Total comprehensive loss for the year attributable to owners of the parent		**(611,248)**	**(548,018)**

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

The Group Financial Statements continued

Consolidated statement of cash flow

(in thousands of SEK)	Note	Years Ended December 31, 2022	2021
Cash Flows from Operating Activities			
Loss for the year		(611,134)	(548,282)
Adjustments to reconcile net loss to net cash flows:			
Depreciation and amortization expenses		12,054	8,606
Capitalized development cost	4	(20,853)	—
Expenses related to incentive programs		58,226	56,624
Costs related to pension plan		—	(226)
Accrued interest and unrealized currency differences		34,006	(6)
		(527,701)	**(483,284)**
Changes:			
(Increase) decrease of trade receivables & unbilled revenues	8	(33,247)	(9,602)
Increase of other operating assets		(21,897)	(29,756)
Increase (decrease) trade payables		9,116	28,577
Increase of other operating liabilities		67,460	13,668
Total changes		**21,432**	**2,887**
Interest received, (paid), net		5,101	(627)
Income taxes paid		(1,565)	(143)
Net cash used in operating activities		**(502,733)**	**(481,168)**
Cash Flows from Investing Activities			
Proceeds from sale of short-term investments		232,644	—
Acquisition of property and equipment	5	(3,331)	(2,399)
Net cash (used in) from investing activities		**229,313**	**(2,399)**

	Note	Years Ended December 31, 2022	2021
Cash Flows from Financing Activities			
Proceeds from long-term loan, net of transaction costs[1]		728,373	—
Proceeds from issue of ordinary shares, net of transaction costs[2]		396,196	—
Payment of lease liabilities	6,30	(6,888)	(4,857)
Net cash (used in) from financing activities		**1,117,681**	**(4,857)**
Net change in cash and cash equivalents		844,261	(488,424)
Cash and cash equivalents at beginning of year		651,342	1,139,362
Effects of movements in exchange rate on cash held		**576**	**403**
Cash and cash equivalents at end of year		**1,496,179**	**651,342**

[1] Total long-term loan transaction cost amounted to SEK 8.027k.

[2] Total share issue cost amounted to SEK 19,754k.

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

The Group Financial Statements continued

Consolidated statement of changes in equity

(in thousands of SEK)	Note	Share Capital	Share Premium	Treasury Share Reserve	Translation Reserve	Accumulated deficit	Total equity attributable to owners of the parent company
Balance at January 1, 2021		**45,895**	**2,509,458**	**(1,421)**	**(137)**	**(1,311,671)**	**1,242,124**
Consolidated statement of profit or loss and other comprehensive income (loss):							
Loss for the year		—	—	—	—	(548,282)	(548,282)
Other comprehensive income for the year		—	—	—	264	—	264
Total comprehensive loss for the year		**—**	**—**	**—**	**264**	**(548,282)**	**(548,018)**
Issue of Class C shares[1]		440	—	(440)	—	—	—
Long term incentive program		—	63,467	—	—	—	63,467
Balance at December 31, 2021	23,24,25,26	**46,335**	**2,572,925**	**(1,862)**	**127**	**(1,859,953)**	**757,573**
Consolidated statement of profit or loss and other comprehensive income (loss):							
Loss for the year		—	—	—	—	(611,134)	(611,134)
Other comprehensive loss for the year		—	—	—	(114)	—	(114)
Total comprehensive loss for the year		**—**	**—**	**—**	**(114)**	**(611,134)**	**(611,248)**
Issue of ordinary shares[2]		7,848	388,348		—	—	396,196
Issue of Class C shares[3]		851	—	(851)	—	—	—
Exercise of share rights		—	(122)	122	—	—	—
Long term incentive program		—	60,391	—	—	—	60,391
Balance at December 31, 2022	23,24,25,26	**55,034**	**3,021,541**	**(2,590)**	**13**	**(2,471,087)**	**602,912**

[1] 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.
[2] Total share issue cost amounted to SEK 19,754k.
[3] The year 2022 additions of Class C shares refer to the new issue and subsequent repurchase of Class C shares that have taken place in accordance with the respective long term incentive plan (LTIP) program.

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

Notes to the Group Financial Statements

Note 1 General Information

Hansa Biopharma AB (Hansa, the Company; and together with its subsidiaries, the Group) is a commercial-stage biopharmaceutical company pioneering the development and commercialization of innovative, life-saving and life-altering treatments for patients with rare immunological conditions. The Company has developed a proprietary antibody-cleaving enzyme technology platform to target pathogenic or disease-causing antibodies. Its broad therapeutic pipeline has potential applications across transplantation, autoimmune diseases, gene therapy and oncology indications addressing significant unmet medical needs. Hansa has received conditional approval of Idefirix (imlifidase) by the European Commission for desensitization treatment of highly sensitized kidney transplant patients. Hansa is a public limited liability company under the laws of Sweden, based in Lund, Sweden, and has operations in Europe and the United States. The Group consists of the parent company, Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc. 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 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, 2022, and for the comparative information as of and for the year ended December 31, 2021.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, 2022, and for the year then ended were approved by the Board of Directors of the Group and authorized for issue on March 30, 2023.

Changes in Accounting Policies and Disclosures

Several amendments to and interpretations of IFRS applied for the first time in 2022, 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

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

Subsidiaries	Registered office/Country	Share ownership percentage (%) 2022	2021
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	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.

Notes to the Group Financial Statements continued

Product revenue

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

Sales returns are generally estimated and recorded based on historical sales and returns information. Sales returns allowances represent a reserve for products that may be returned due to expiration, damage or potential other reasons typically calculated as a percent of gross revenues. For the periods ended December 31, 2022, and 2021, 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 operating income, when the relevant expenditure has been incurred and there is reasonable assurance that the grants or research and development incentives are receivable.

Research and Development Expenses

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

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

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

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

Sales, General and Administrative Expenses

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

Notes to the Group Financial Statements continued

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 generates. Consequently, it is the employee who bears the actuarial risk (that the benefits will be lower than anticipated) and the investment risk (that the invested assets will be insufficient to generate the anticipated benefits). The Group's obligations regarding fees paid to defined contribution plans are reported as an expense in the consolidated statement of profit or loss and other comprehensive income (loss) when they are earned by the employees performing their services on behalf of the Group during a given period of time.

Employee Benefits

Short-term employee benefits

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

Long-term employee benefits

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

Termination benefits

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

Share-based Payments

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

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

The fair value of the options is calculated based on the Black-Scholes model and expensed over the vesting period. During the vesting period, the expense is adjusted 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, as a benchmark, for several peers over periods between one and seven years. The yield curve for Swedish government bonds is used to determine the risk-free interest rate. After the value of the awards were determined, the Company estimated the probability of achieving the non-market conditions and adjusted the number of awards that would expense over the amortization period. The Company re-evaluates the probability of achieving the non-market conditions each reporting 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.

Notes to the Group Financial Statements continued

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

Income Taxes

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

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

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

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

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

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

Property and Equipment

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

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.

Notes to the Group Financial Statements continued

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	3–4 years

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

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

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

Intangible Assets

Internally generated intangible assets

Development expenditure is capitalized only if all respective requirements under IAS 38 are fully met, particularly, the expenditure can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable and the Group intends to and has sufficient resources to complete the development and to use or sell the asset. Otherwise, it is recognized in profit or loss as incurred. Subsequent to initial recognition, capitalized development expenditure is measured at cost less accumulated amortization and any accumulated impairment losses.

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

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

Amortization is calculated to write off the cost of intangible assets less their estimated residual value using the straight-line method over their estimated useful life and is generally recognized in consolidated statement of profit or loss and other comprehensive income (loss).

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

Development costs:	10 years

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

Acquired intangible assets

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

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

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, 2022 in-process development projects and capitalized development cost relating to imlifidase. The basis for the review is the recoverable amount of the assets, determined as the greater of the fair value less costs of disposal or its value in use. Such review uses an analysis of current market value (market cap of the Company) as the fair value less cost of disposal. If the carrying amount of an asset is greater than the recoverable amount, the asset is written down to the recoverable amount. An impairment loss is recognized in the consolidated statement of profit or loss and other comprehensive income (loss) when the impairment is identified. The Group assesses at the end of each reporting period whether there is any indication that an asset may be impaired. If any such indication exists, the Group will estimate the recoverable amount of the asset.

Notes to the Group Financial Statements continued

Inventories

Inventories are assets:

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

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

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

Unbilled revenues & refund liabilities

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

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

Trade receivables

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

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

Cash and Cash Equivalents

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

Shareholders' Equity

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

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

The year 2022 additions of Class C shares refer to the new issue and subsequent repurchase of Class C shares related to the funding of the long-term incentive plan (LTIP) 2022, as approved by the 2022 AGM.

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, 2022, or 2021.

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

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

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

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

Trade Payables

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

Other Liabilities

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

Financial Instruments

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

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

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

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

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

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

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

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

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

Impairment of financial assets

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

Notes to the Group Financial Statements 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 treasury share reserve.

New Accounting Policies and Disclosures effective 2022

In the year ended December 31, 2022, the Group has applied the below amendments to IFRS and interpretations issued by the Board, as applicable. Their adoption has not had any material impact on the disclosure or on the amounts reported in these consolidated financial statements.

Amendments to IFRS 3 Business Combinations

Amendments to IFRS 3 to update the references to the Conceptual Framework for Financial Reporting. The amendment also adds an exception for the recognition of liabilities and contingent liabilities within the scope of IAS 37 Provisions, Contingent liabilities and Contingent Assets and Interpretation 21 Levies. The amendments also confirm that contingent assets should not be recognized at the acquisition date. The amendments are effective for periods beginning on January 1, 2022.

Amendment to IAS 37 Provisions, Contingent Liabilities and Contingent Assets

The amendment to IAS 37 clarifies that the direct costs of fulfilling a contract include both the incremental costs of fulfilling the contract and an allocation of other costs directly related to fulfilling contracts. The amendment is effective for periods beginning on January 1, 2022.

Amendments to IAS 16 Property, Plant and Equipment

The amendment to IAS 16 prohibits an entity from deducting from the cost of an item of property, plant and equipment any proceeds received from selling items produced while the entity is preparing the asset for its intended use. The amendment is effective for periods beginning on January 1, 2022.

Standards, amendments, and interpretations in issue

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

	Effective date periods beginning on or after
IAS 1 *Presentation of Financial Statements:* Amendments in relation to the classification of liabilities as current or non-current	January 1, 2024
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, 2022, and 2021. 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, 2022, and 2021.

Significant judgements made in the application of the Group's accounting policies

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

Revenue

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

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

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

Share-Based Payment

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

Note 4 Intangible Assets

Internally generated intangible assets

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

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

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

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

Notes to the Group Financial Statements continued

For the year ending December 31, 2022 the Company capitalized development cost in the amount of SEK 20.9 million related to performing its Idefirix® (imlifidase) EMA post-approval commitments. Capitalized development cost mainly include fees paid to 3rd party service providers, personnel expenses of Hansa staff and approportionate finance cost.

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

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

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

Acquired intangible assets

Patents

The 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 2022 (2021: SEK 559 k). The patent cost is amortized over sales, general and administration line item in the consolidated statement of profit or loss and other comprehensive income.

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

In-process development projects

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

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

Acquired in-process development projects are assessed for possible impairment at least on an annual basis and the impairment assessment on December 31, 2022, and 2021 demonstrated that there was no need for impairment. The estimated recoverable amount supported by external and internal valuation reports by far exceeds the assets' carrying amount, resulting in no impairment charges for the year 2022 and 2021.

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

Notes to the Group Financial Statements continued

	Internally generated	Acquired intangible assets		
(in thousands of SEK)	Capitalized development expenditures	Patents	In-process development projects	Total Intangible Assets
Cost:				
Opening balance January 1, 2021	4,485	1, 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
Amortization:				
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)
Carrying amounts:				
At January 1, 2021	—	6,275	25,136	31,410
At December 31, 2021	—	5,720	23,042	28,761

Note 5 Property and Equipment

	As of December 31,	
(in thousands of SEK)	2022	2021
Cost:		
Opening balance January 1	14,451	11,871
Reclassification	(2,403)	—
Adjusted opening balance	12,048	11,871
Additions during the year	3,332	2,580
Closing balance December 31	15,380	14,451
Accumulated depreciation and impairment losses:		
Opening balance January	(8,019)	(6,665)
Reclassification	2,403	—
Adjusted opening balance	(5,616)	(6,665)
Depreciation during the period	(1,651)	(1,354)
Closing balance December	(7,267)	(8,019)
Carrying amounts:		
At January 1	6,432	5,206
At December 31	8,113	6,432

Notes to the Group Financial Statements continued

Note 6 Right-of-Use Assets, Lease Liabilities

	As of December 31,	
(in thousands of SEK)	2022	2021
Leased assets:		
Buildings	27,250	34,446
Equipment	135	271
Vehicles	338	556
	27,723	**35,273**
Lease liabilities:		
Non-current	21,326	28,491
Current	7,165	6,888
	28,491	**35,379**

For the years ended December 31, 2022, and 2021, there were SEK 0.- and SEK 36,071k respectively, in additions of right-of-use assets.

Depreciation charge of leased assets for the period

	As of December 31,	
(in thousands of SEK)	2022	2021
Buildings	(7,195)	(4,646)
Equipment	(135)	(169)
Vehicles	(220)	(174)
	(7,550)	**(4,989)**

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

Most of the Group's operational leasing agreements involve leases of real property and premises on which the business operations are conducted. The initial duration of the lease for the Lund, Sweden, headquarters 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.

Note 7 Inventories

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

	As of December 31,	
(in thousands of SEK)	2022	2021
Raw materials and supplies	3,783	3,141
Work in process	13,455	8,282
Packaging material	502	311
Finished goods	3,814	1,882
Total inventories, gross	21,555	13,616
Less: provision for excess & obsolete inventories	(20,582)	(13,374)
Total inventories, net	**973**	**242**

In 2022, the Company recorded a provision for excess and obsolete inventories in the amount of SEK 20.6 million (2021: SEK 13,4m) to account for the potential expiry of inventories ahead of their commercial use.

Notes to the Group Financial Statements continued

Note 8 Trade Receivables, unbilled revenues and refund liabilities

Trade receivables and unbilled revenues

	As of December 31,	
(in thousands of SEK)	**2022**	**2021**
Trade receivables, net of provisions	8,360	9,712
Unbilled revenue, net of provisions	34,600	—
Total trade receivables and unbilled revenues	**42,959**	**9,712**

Trade receivables primarily consist of receivables from product sales to healthcare organisations in European countries. During the periods ended December 31, 2022, and December 31, 2021 respectively, the Company did not incur any losses from defaults related to its trade receivables.

Unbilled revenues primarily relate to product sales to healthcare organisations in European countries with the Group's right to consider product sold despite not billed at the reporting date. During the periods ended December 31, 2022, and December 31, 2021 respectively, the Company did not incur any losses from defaults related to its unbilled revenues.

A provision for expected credit losses amounting to SEK 78k was recorded for 2022 (2021: SEK 0), see further discussion about credit risk in Note 20.

Refund liabilities

	As of December 31,	
(in thousands of SEK)	**2022**	**2021**
Volume discounts	14,039	—
All other	12,974	
Total refund liabilities	**27,013**	**—**

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

Note 9 Prepaid expenses and accrued income

	As of December 31,	
(in thousands of SEK)	**2022**	**2021**
Insurances	1,137	829
Healthcare conference	2,604	124
Software	1,777	1,177
Pension	1,770	1,644
Rent	2,385	2,512
Legal expenses	9,989	8,325
License fees	3,857	230
R&D expenses	7,587	3,769
Other	2,171	2,279
Total	**33,278**	**20,889**

Note 10 Other receivables

	As of December 31,	
(in thousands of SEK)	**2022**	**2021**
VAT receivables	21,179	9,827
Advance payments to suppliers	9,262	11,292
Other receivables	874	1,419
Total	**31,315**	**22,538**

Notes to the Group Financial Statements continued

Note 11 Accrued Expenses

	As of December 31,	
(in thousands of SEK)	2022	2021
Annual leave accrual	18,267	15,879
Accrued social security contribution on salaries	5,243	4,395
Accrued short term incentives, incl. related social security contributions	33,138	24,146
R&D project costs	26,701	7,791
License fees	5,500	—
Consulting fees	16,845	17,600
Other	3,052	2,651
Closing balance December 31	**108,747**	**72,462**

Note 12 Other liabilities—Current

	As of December 31,	
(in thousands of SEK)	2022	2021
Personnel related liabilities	18,121	13,358
VAT liabilities	158	190
Closing balance December 31	**18,278**	**13,548**

Note 13 Revenue

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

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Revenue from contracts with customers:		
Product sales	86,735	15,017
Contract revenue, Axis-Shield agreement	2,892	2,624
Cost reimbursement, Axis-Shield agreement	624	527
Contract revenue, Sarepta, AskBio agreements	64,273	15,710
Total revenue	**154,525**	**33,878**

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

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Geography:		
Sweden	4,678	—
North America	64,273	15,710
Europe (ex Sweden)	85,573	18,168
Total revenue	**154,525**	**33,878**

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.

Notes to the Group Financial Statements continued

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, 2022, and 2021, with the exception of the Axis-Shield minimum royalty payment.

Product sales

For the period ended December 31, 2022, the Group recorded product sales of SEK 86.7 million (2021: SEK 15.0 million). Product sales are recognized net of any sales and value-added taxes and sales deductions based on contractually agreed payment terms.

License Agreement with Sarepta

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

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

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

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

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

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, 2022, financial reporting period. Revenue from performance-based and sales-based milestones and sales-based royalties will be constraint because it is not probable that a reversal of revenue will not occur if these were recognized.

For the period ended December 31, 2022, the Group recorded contract revenue in the amount of SEK 26.8 million (2021: SEK 15.7 million) related to its agreement with Sarepta in connection with the upfront payment received in July 2020.

License Agreement with AskBio

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

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

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

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

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

Notes to the Group Financial Statements continued

License Agreement with Axis-Shield

In 2022, the Group recorded contract revenue in the amount of SEK 2.9 million (2021: SEK 2.6 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 0.6 million (2021: SEK 0.5 million).

Deferred revenue

	As of December 31,	
(in thousands of SEK)	2022	2021
Opening balance January 1,	**71,981**	**79,432**
Addition under existing contracts	90,251	18,168
Addition under new contracts (AskBio agreement)	45,750	—
Revenue recognized	(154,525)	(33,878)
Adjustments, foreign exchange	16,473	8,259
Closing balance December 31,	**69,930**	**71,981**

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

Note 14 Staff Costs

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

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

	Year Ended December 31, 2021		
(in thousands of SEK)	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
Total personnel expenses	**78,905**	**180,967**	**259,872**

Share-based payments

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

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,	
	2022	2021
Warrants, Opening balance January 1	6,701	6,701
Warrants expired or redeemed in advance during the period	(6,701)	—
Warrants, Closing balance December 31	**0**	**6,701**
Recorded share-based compensation expenses, thousands of SEK	0	5

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 SEK178.60 (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,	
	2022	2021
Share rights, Opening balance January 1	60,086	223,778
Share rights expired or forfeited during the period	(60,086)	(163,692)
Share rights, Closing balance December 31	**0**	**60,086**
Recorded share-based compensation expenses, thousands of SEK	294	912

Notes to the Group Financial Statements 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,	
	2022	2021
Share rights, Opening balance January 1	278,181	287,555
Share rights lapsed or forfeited during the period	(155,781)	(9,374)
Share rights vested during the period	122,400	—
Share rights, Closing balance December 31	0	278,181
Recorded share-based compensation expenses, thousands of SEK	3,509	12,906

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

	Years Ended December 31,	
	2022	2021
Warrants, Opening balance January 1	11,000	11,000
Warrants expired or redeemed in advance during the period	(11,000)	—
Warrants, Closing balance December 31	0	11,000
Recorded share-based compensation expenses, thousands of SEK	28	97

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,	
	2022	2021
ESO, Opening balance January 1	149,148	149,148
ESO forfeited or expired during the period	—	—
ESO, Closing balance December 31	**149,148**	**149,148**
Recorded share-based compensation expenses, thousands of SEK	930	690

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

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

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

Notes to the Group Financial Statements continued

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

	Years Ended December 31,	
	2022	2021
Share rights, Opening balance January 1	400,556	389,556
Allotted to participants February 12, 2021		16,000
Share rights forfeited	(2,245)	(5,000)
Share Rights, Closing balance December 31	**398,311**	**400,556**
Recorded share-based compensation expenses, thousands of SEK	21,607	21,205

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,	
	2022	2021
ESO, Opening balance January 1	497,520	477,520
ESO allotted to participants February 12, 2021		20,000
ESO forfeited	(10,000)	—
ESO, Closing balance December 31	**487,520**	**497,520**
Recorded share-based compensation expenses, thousands of SEK	7,808	7,658

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).

Notes to the Group Financial Statements continued

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

- Condition 1 (accounting for 22%): 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 total of 557,000 share rights were allotted to participants in June 2021.

	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,	
	2022	2021
Share rights, Opening balance January 1	557,000	—
Allotted to participants June 7, 2021		557,000
Share rights forfeited	(5,737)	—
Share Rights, Closing balance December 31	**551,263**	**557,000**
Recorded share-based compensation expenses, thousands of SEK	7,948	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 total of 430,000 ESOs were issued to participants in June 2021.

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,	
	2022	2021
ESO, Opening balance January 1	430,000	—
ESO allotted to participants June 7, 2021		430,000
ESO forfeited	—	—
ESO, Closing balance December 31	**430,000**	**430,000**
Recorded share-based compensation expenses, thousands of SEK	5,892	3,738

Notes to the Group Financial Statements continued

Long-term incentive program 2022 (LTIP 2022)

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

Share rights under LTIP 2022

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

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

- Condition 1 (accounting for 22%): U.S. FDA has approved imlifidase in the U.S.;
- Condition 2 (accounting for 11%): Imlifidase has been approved, or a Marketing Authorization Application/Biologics License Application has been submitted, in any jurisdiction in an indication outside kidney transplant;
- Condition 3 (accounting for 11%): At least 80% of the targeted transplantation centers in Europe have had repeat business
- 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 2022. As of December 31, 2022, a total of 543,000 share rights have initially been allotted to participants.

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

	Allotment July 20, 2022
Starting value (base-line share price) for TSR calculation, SEK	56.0
Risk-free interest rate, (%)	(1.87)
Expected volatility, (%)	58.6
Expected dividend, SEK	—
Calculated fair value per share right, SEK	80.29

	Year Ended December 31, 2022
Share rights, Opening balance January 1	—
Allotted to participants July 20, 2022,	543,000
Share rights forfeited	—
Share Rights, Closing balance December 31	**543,000**
Recorded share-based compensation expenses, thousands of SEK	7,277

Employee Stock Options under LTIP 2022

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

A maximum of 452,307 ESOs can be allotted under LTIP 2022. As of December 31, 2022, a total of 384,000 have initially been allotted to participants.

Notes to the Group Financial Statements continued

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

	Issuance July 20, 2022
Underlying volume-weighted average share price, SEK	56.01
Exercise price, SEK	70.0
Risk-free interest rate, (%)	(1.86)
ESO term, years	4.5
Expected volatility, (%)	58.6
Expected dividend, SEK	—
Calculated fair value per ESO, SEK	52.45

	Year Ended December 31, 2022
ESO, Opening balance January 1	—
ESO allotted to participants July 20, 2022	384,000
ESO forfeited	—
ESO, Closing balance December 31	**384,000**
Recorded share-based compensation expenses, thousands of SEK	2,934

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 2022 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.

	As of December 31,	
	2022	2021
Opening balance January 1	**7,357**	**14,426**
Change in provision related to LTIP 2018	—	(2,999)
Change in provision related to LTIP 2019	(2,910)	(4,516)
Change in provision related to LTIP 2020	(216)	(1,194)
Change in provision related to LTIP 2021	(357)	1,866
Change in provision related to LTIP 2022	1,318	—
Change in pension provision	—	(226)
Closing balance December 31	**5,192**	**7,357**

Note 16 Income Taxes

	As of December 31,	
(in thousands of SEK)	2022	2021
Deferred Taxes, opening balance January 1	**426**	**424**
Tax income in the consolidated statement of profit or loss and other comprehensive income	(41)	(39)
Currency differences for the year	20	41
Deferred Taxes, closing balance December 31	**405**	**426**

Losses carried forward in 2022

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 2022 amounted to SEK 2,361,926,000 (2021: SEK 1,855,521,000). The losses carried forward is, in all material respects, attributable to Swedish companies and therefore has no due date.

Notes to the Group Financial Statements continued

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

	2022		2021	
	%	(in thousands of SEK)	%	(in thousands of SEK)
Result before tax	—	(609,979)	—	(548,130)
Tax according to current tax rate	20.6	125,656	20.6	112,915
Effect of other tax rates for foreign subsidiaries	0	(21)	0	(14)
Non-deductible expenses	(3.6)	(21,920)	(2.4)	(13,103)
Increase in loss carry-forwards without corresponding capitalization of deferred tax	(17.2)	(104,869)	(18.2)	(99,951)
Reported effective tax	(0.2)	(1,155)	—	(152)

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

Note 17 Earnings per share

	Years Ended December 31,	
(in SEK)	2022	2021
Loss per share, basic and diluted	(13.60)	(12.33)

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, 2022, and 2021, share rights to receive 1,492,574 and 1,295,823 ordinary shares, respectively, options to purchase 1,450,668 and 1,076,668 ordinary shares, respectively, were not included in the computation of diluted loss per share since their inclusion would be antidilutive.

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

Loss attributable to ordinary shareholders, basic and diluted

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Loss for the year attributable to owners of the parent	(611,134)	(548,280)
Loss attributable to ordinary shareholders, basic and diluted	(611,134)	(548,280)

Weighted average number of ordinary shares, basic and diluted

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Outstanding ordinary shares January 1	44,473,452	44,473,452
Effect of conversion of C to A shares in June 2022	62,202	—
Effect of conversion of C to A shares in October 2022	1,314	—
Effect of issue of ordinary shares in December 2022	387,030	—
Weighted average number of ordinary shares, basic and diluted	44,923,998	44,473,452

Note 18 Contingent Consideration

The Group acquired Immago Ltd (today Hansa Biopharma Ltd) on July 19, 2016. The agreed upon purchase price was GBP 170,000. An additional GBP 70,000 milestone payment is to be paid if a clinical study based on the acquired technology is initiated in Europe or the U.S. The estimated payment date is July 2024, resulting in a fair value of the contingent liability on December 31, 2022 amounting to SEK 757,000 (2021: SEK 722,000).

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, 2022, The Group's cash position (including short-term investments) amounted to SEK 1,496 million.

Notes to the Group Financial Statements continued

The adequacy of available funds will depend on many factors, including growth of Idefirix sales, progress in research and development programs, the magnitude of those programs, commitments to existing and new collaborators, the ability to establish commercial and licensing arrangements, capital expenditures, market developments, and any potential future acquisitions. Accordingly, Hansa may require additional funds and may attempt to raise additional funds through equity or debt financings, collaborative agreements with partners, or from other sources.

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

Note 20 Financial Risk and Financial Instruments

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

A. Liquidity risk

B. Market risk

C. Credit risk

Risk management framework

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

Liquidity Risk

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

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

Cash and cash equivalents on December 31, 2022, amounted to SEK 1,496 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. The Group sold all its investments in interest funds during the year 2022 – see further information in the Cash Flow Statement.

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

	As of December 31, 2022				
(in thousands of SEK)	Nominal Amount	0–3 months	3–12 months	1–5 years	5–7 years
Long-term loan	1,458,800			820,575	638,225
Contingent consideration	887	—	—	887	
Non-current leasing liabilities	22,582	—	—	22,582	
Current leasing liabilities	7,962	1,990	5,971	—	
Trade payables	62,476	62,476	—	—	
Accrued expenses (see note 11)	52,099	52,099	—	—	
Total	**1,604,805**	**116,565**	**5,971**	**844,044**	**638,225**

Notes to the Group Financial Statements continued

	As of December 31, 2021			
(in thousands of SEK)	Nominal Amount	0–3 months	3–12 month	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	—	—
Total	**120,720**	**83,387**	**5,943**	**31,390**

Market Risk

Market risk is the risk that changes in market prices, e.g. foreign exchange rates, interest rates and equity prices will affect the Group's income or the value of its holdings of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimizing the return.

Currency risk

The Group is exposed to transactional foreign currency risk to the extent that there is a mismatch between the currencies in which sales, purchases, receivables and borrowings are denominated and the respective functional currencies of Group companies. The functional currencies of Group companies are primarily the SEK, GBP and USD. The currencies in which transactions are primarily denominated are SEK, EUR, GBP and USD. In 2022, the Company took up a long-term loan in the amount of USD 70 million. The Company is exposed to USD currency risk related to such loan as per the contractual repayment dates. Refer to Note 21 for further information on the loan.

To manage the currency risk exposure, the Group may in its normal course of business, hold funds in foreign currency or enter into currency forward contracts or similar instruments to benefit from trends in exchange rates on the basis of a sophisticated analysis considering exchange rate forecasts published by banks or other analysts as well as short and mid-term currency needs of the Group.

All cash and investments shall only be made and held in Swedish Krona. In case of investments in funds or the like, an investment can only be made if the currency fluctuation risk is fully hedged by the fund.

As an exception to the above, the Group may hold cash in foreign currency in the normal course of business to pay any trade payables in foreign currencies. Subsidiaries will hold cash in their local currency within their normal course of business. The Group 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, 2022, relating to Hansa Biopharma Inc. amounted to USD 574k (full year 2021: USD 210k) and the Group net assets relating to Hansa Biopharma Ltd. amounted to GBP 102k (full year 2021: GBP 50k).

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, USD, GBP and DKK by an average of 10% would have negatively affected the Group's earnings before tax by approximately SEK 14.6 million, SEK 4.4 million, SEK 2.5 million, and SEK 0.5 million, respectively. This analysis assumes that all other variables, in particular interest rates, remain constant and ignores any impact of forecast sales and purchases.

The Company has taken up a long-term loan in the amount of USD 70 million in 2022. As of December 31, 2022, the carrying amount of such loan is SEK 762.6 million. A strengthening of the USD by 10% would have resulted in an increase in long-term liabilities in the amount of approximately SEK 76.3 million.

The sensitivity analysis is based on approximated cash flows in foreign currencies. Income and expenses of foreign operations are translated into Swedish kronor at an average exchange rate that approximates the exchange rates presented at each transaction date.

Interest rate risk

The interest rate risk consists of the risk that a change in market interest rates will have a negative effect on earnings. The Group's exposure to interest rate risks is considered to be low as the Group only has very limited interest-bearing liabilities. There is certain exposure to interest rate risks in cash and cash equivalents in the form of bank deposits and holdings of short-term interest fund.

The Group sold all its investments in interest funds during the year – see further information in the Cash Flow Statement.

In 2022, the Company took up a long-term loan in the amount of USD 70 million. The Company is not exposed to any material interest rate risk with regard to such loan as the repayment amount is fixed at twice the principal loan amount.

Notes to the Group Financial Statements continued

Credit risk

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Group's receivables from customers and investments in debt securities. The carrying amounts of financial assets and unbilled revenues represent the maximum credit exposure.

The Group's credit risk is primarily related to bank deposits. However, this risk is considered to be low since the bank deposits are held with four Swedish banks with good credit ratings. See further discussions in Note 2. According to the Group's treasury policy, The Company may only hold bank deposits with, or initiate payments through, Swedish and foreign banks under the supervision of the Swedish Financial Supervisory Authority or similar foreign agency.

The Group has risk related to its trade receivables. The Company determined that the country risk premium was the appropriate factor to use as the default rate as this factor represents the expected losses from default on the sovereign debt. The Company concluded these factors could be generalized to its receivables from the Product sold in these geographies due to direct or indirect involvement of the respective governments.

The Group has also risk related to other receivables that consist mainly of advance payments to suppliers. The credit risk is considered to be low as the Group uses trading history as an evaluation factor and the amounts outstanding at year end 2022 are immaterial.

The maximum credit exposure of financial assets amounted to SEK 1,505,412 and SEK 662,473 for the periods ended December 31, 2022, and 2021, 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. The Group sold all its investments in interest funds during the year – see further information in the Cash Flow Statement.

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)	2022	2021	2022	2021
Financial assets:				
Short term investments	–	–	–	237,619
Trade receivables	8,360	9,712	–	–
Other receivables	874	1,419	–	–
Cash and cash equivalents	1,496,179	651,342	–	–
Total financial assets	**1,505,412**	**662,473**	**–**	**237,619**

	Financial liabilities valued at amortized cost		Financial liabilities valued at fair value through the consolidated statement of profit or loss and other comprehensive income	
(in thousands of SEK)	2022	2021	2022	2021
Financial liabilities:				
Long-term loan	762,601	–	–	–
Contingent consideration	–	–	757	722
Trade payables	62,476	53,360	–	–
Accrued expenses (see note 11)	52,099	28,041	–	–
Total financial liabilities	**877,176**	**81,401**	**757**	**722**

Notes to the Group Financial Statements continued

Levels of financial assets and financial liabilities per valuation hierarchy

Management considers the carrying amounts for all financial assets and financial liabilities to be a reasonable approximation of their fair value.

The table below presents the carrying amount of financial assets and financial liabilities per valuation hierarchy in IFRS 13.

(In thousands of SEK)	Valuation Hierarchy	2022	2021
Financial asset:			
Holdings of short-term investments	Level 2	—	237,619
Contingent consideration	Level 3	757	722

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

	As of December 31,	
(In thousands of SEK)	2022	2021
Opening balance January 1	**722**	**663**
Currency differences	89	42
Interest (expense) / income	(54)	17
Total financial liabilities	**757**	**722**

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

The Group's best estimate on December 31, 2022, is that the contingent consideration will be paid in 2024. The previous estimate made on December 31, 2021, was that the contingent consideration would be paid in 2023. The fair value of the contingent consideration is estimated based on management assessment when a clinical study utilizing the relevant technology is initiated in Europe or the U.S resulting in a milestone payment under the share purchase agreement. The estimated future cash flow is discounted using a market interest rate.

As of December 31, 2021, the maturity profile of our investments in interest funds had maturities of less than one year. The fair value of the securities was based on quotes received from the counterparty managing the funds. The Group sold all its investments in interest funds during the year 2022 – see further in the Cash Flow Statement.

Note 21 Long-term loan

On July 18, 2022, the Company entered into a $70.0 million funding agreement with NovaQuest. The funding was accounted for as liability classified debt as the Company has an unavoidable obligation to settle the funding in cash. The debt is accounted for at amortized cost.

The net proceeds from the funding were $69.2 million after the deduction of transaction costs. The transaction costs were capitalized and offset against the carrying value of the debt and will be amortized over the term of the debt.

The debt is secured by certain of the Company's intellectual property and assets.

Under the terms of the debt, the Company will make quarterly mid-single-digit royalty percentage payments to NovaQuest on future worldwide annual net sales of imlifidase, commencing upon approval of imlifidase in the U.S. in kidney transplantation or anti-GBM. In addition, Hansa will make certain milestone payments to NovaQuest upon U.S. approval of imlifidase in kidney transplantation or anti-GBM. Total payments by Hansa to NovaQuest are capped at $140 million. The agreement also provides for time-based catch-up payments within the payment cap if specified payment amounts have not been received by NovaQuest by specified dates, with the last potential catch-up payment due on December 31, 2028.

The Company will record the difference between the principal and the total payments as interest expense over the forecasted term of the debt by applying the effective-interest-rate method. Based on the actual repayment pattern, the Company will recalculate the effective interest each reporting period until the debt is satisfied.

On 31 December 2022, the loan amounted to SEK 762.6 million, thereof SEK 41.2 million in accrued interest.

Note 22 Finance Income and Expenses

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Interest income on bank deposits measured at amortized cost	8,833	67
Net exchange rate variances	18,415	—
Finance income	**27,248**	**67**
Interest expense on long-term loan at amortized cost	(42,470)	—
Interest expenses, other	(1,196)	(694)
Changes in the fair value of interest funds during the year	(4,973)	(525)
Finance costs	**(48,639)**	**(1,219)**
Net finance costs/income	**(21,391)**	**(1,152)**

Notes to the Group Financial Statements continued

Note 23 Share capital and number of shares

	Years Ended December 31,	
Number of shares	**2022**	**2021**
Outstanding as of January 1	**44,473,452**	**44,473,452**
Effect of conversion of C to A in June	114,666	–
Effect of conversion of C to A shares in October	7,733	–
Effect of new share issue in December	7,848,111	–
Outstanding as of December 31	**52,443,962**	**44,473,452**

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 24 Share Premium

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

Note 25 Treasury shares included in equity

	Number of Shares		Amount, In thousands of SEK	
	2022	**2021**	**2022**	**2021**
As of January 1,	**1,861,909**	**1,421,457**	**1,862**	**1,421**
Additions	850,769	440,452	851	440
Exercise of share rights	(122,399)	–	(122)	–
As of December 31,	**2,590,279**	**1,861,909**	**2,590**	**1,862**

Treasury shares have a par value of SEK 1.

The year 2022 additions of Class C shares result from the new issue and subsequent repurchase of Class C shares related to the funding of the long-term incentive plan (LTIP) 2022, as approved at the 2022 AGM. Class C shares correspond to treasury shares held by the Company and are reserved to fund the respective LTIP programs. Each Class C share entitles the holder to 0.1 vote per share.

Note 26 Reserves

Treasury share reserve

The treasury share reserve comprises own shares repurchased by the Group. Please refer to Note 14 related to the Group's LTIP programs and respective vesting dates.

Translation reserve

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

Note 27 Royalty Agreements

Royalty agreement with researchers

The Company is a party to two separate royalty agreements (the "Royalty Agreements") with certain researchers and an affiliated entity (collectively, the "Counterparties") of certain patents related to methods of use of imlifidase. Under each agreement, in consideration of the assignment of these patents, the Counterparties are entitled to receive a low single-digit royalty percentage of the Company's net income related to the utilization of the patents, in each case as defined in the applicable agreement, and a low-teens percentage of any once-only considerations, milestones, royalties, license income, consideration for transfer of patents, patent applications and other intellectual property rights and other payments received by the Company related to the exploitation of rights related to these patents, in each case subject to certain specified reductions.

On April 20, 2021, the Company received a request for arbitration from the Counterparties claiming they were entitled to 10% of the upfront payment the Company received under its 2020 collaboration agreement with Sarepta as well as entitlement to participate in payments the Company may receive under the Sarepta agreement in the future.

In the third quarter 2022, the Company and the Counterparties settled the dispute by entering into an amendment and settlement agreement (the "Agreement"), which covers all compensation obligations under the Royalty Agreements. Under the Agreement, the Royalty Agreements will be treated as one agreement with respect to the Researchers' right to consideration entitling the Counterparties to low single-digit royalties on net sales as well as mid-single-digit participation in any once-only consideration received by Hansa in respect of imlifidase. The settlement also includes a one-off settlement payment.

Notes to the Group Financial Statements continued

Note 28 Other operating income and expenses

	Years Ended December 31,	
	2022	2021
Total other operating income	—	—
Other operating expenses		
Foreign currency losses on receivables/liabilities from operating activities	(12,469)	(7,398)
Other operating expenses	(8,063)	—
Total other operating expenses	**(20,532)**	**(7,398)**

Note 29 Operating expenses by nature

The table below presents an analysis of operating expenses presented in profit or loss in classification based on the nature of the expenses:

	Years Ended December 31,	
(in thousands of SEK)	**2022**	**2021**
Personnel expenses	(315,924)	(266,611)
Third party expenses	(358,222)	(283,387)
Depreciation and amortization expenses	(9,959)	(8,606)
Other operating expenses	(20,532)	(6,827)
Total operating expenses	**(704,637)**	**(565,431)**

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,	
(in thousands of SEK)	**2022**	**2021**
Research and development expenses	7,027	5,639
Sales, general and administrative expenses	2,932	2,967
Total	**9,959**	**8,606**

Note 30 Supporting information to the cash flows

	As of December 31,	
(in thousands of SEK)	**2022**	**2021**
Cash and cash equivalents consist of:		
Cash and bank deposits	1,496,179	651,342
Total according to statement of financial position	1,496,179	651,342
Total according to cash flow analysis	1,496,179	651,342

Reconciliation of liabilities arising from financing activities:

	As of December 31,	
(in thousands of SEK)	**2022**	**2021**
Opening balance January 1,	**35,379**	**5,045**
Termination of lease agreement	(25)	(308)
New lease agreements	—	35,499
Payment of lease liabilities	(6,863)	(4,857)
Net present value of long-term loan	687,221	—
Accrued interest on long-term loan	41,152	—
Unrealized currency differences on long-term loan	34,228	—
Closing balance December 31,	**791,092**	**35,379**

Note 31 Subsequent events

There are no subsequent events to report.

Parent Company Financial Statements

Statement of financial position

(in thousands of SEK)	Note	As of December 31, 2022	2021
ASSETS			
Non-current assets:			
Intangible assets	2	44,718	26,518
Property and equipment	3	8,113	6,432
Right-of-use assets	4	27,723	35,273
Financial assets:			
Investment in subsidiaries	5	24,264	5,095
Receivables, group companies	6	—	2,203
Total financial assets		**24,264**	**7,298**
Total non-current assets		**104,818**	**75,521**
Current assets:			
Inventories	7	973	242
Trade receivables & unbilled revenue	8,13	42,959	9,712
Prepaid expenses and accrued income	9	33,226	20,820
Other receivables	10	31,142	22,381
Short-term investments	19	—	237,619
Cash and cash equivalents	19,29	1,486,502	644,975
Total current assets		**1,594,802**	**935,749**
TOTAL ASSETS		**1,699,620**	**1,011,270**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Restricted shareholders' equity:			
Share capital	22	55,034	46,335
Development cost reserve	25	20,853	—
Unrestricted shareholders' equity:			
Share premium reserve	23	3,021,541	2,572,925
Treasury share reserve	24,25	(2,590)	(1,862)
Accumulated deficit		(1,882,304)	(1,312,353)
Loss for the year	16	(596,735)	(549,098)
Total shareholders' equity		**615,799**	**755,948**

(in thousands of SEK)	Note	As of December 31, 2022	2021
LIABILITIES			
Non-current liabilities:			
Long-term loan	20	762,601	—
Lease liabilities	4	21,326	28,491
Deferred revenue	13	29,500	47,020
Contingent consideration	17	757	722
Provisions	15	5,192	7,357
Total non-current liabilities		**819,376**	**83,590**
Current liabilities:			
Current tax liabilities		604	—
Liabilities, group companies	6	5,738	3,901
Lease liabilities	4	7,165	6,888
Trade payables	19	62,357	53,240
Other liabilities	12	17,868	13,358
Deferred revenue	13	40,430	24,961
Refund liabilities	8	27,013	—
Accrued expenses	11	103,270	69,384
Total current liabilities		**264,445**	**171,732**
Total liabilities		**1,083,821**	**255,322**
TOTAL STOCKHOLDERS' EQUITY AND LIABILITIES		**1,699,620**	**1,011,270**

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, 2022	2021
Revenue	13	154,525	33,878
Cost of revenue		(38,477)	(15,425)
Sales, general and administrative expenses	28	(330,071)	(327,031)
Research and development expenses	28	(340,192)	(231,974)
Other operating expenses	27	(20,532)	(7,395)
Loss from operations		**(574,747)**	**(547,947)**
Finance income (expenses)			
Finance income	21	27,245	67
Finance expenses	21	(48,629)	(1,218)
Net finance (expenses) income	**21**	**(21,384)**	**(1,151)**
Loss before tax		**(596,131)**	**(549,098)**
Income tax expense		(604)	—
Loss for the year	**16**	**(596,735)**	**(549,098)**

(in thousands of SEK)	Note	Years Ended December 31, 2022	2021
Loss for the year		**(596,735)**	**(549,098)**
Other comprehensive income (loss) for the year		—	—
Total comprehensive loss for the year		**(596,735)**	**(549,098)**

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, 2022	2021
Cash Flows from Operating Activities			
Loss for the year		(596,735)	(549,098)
Adjustments to reconcile net loss to net cash flows:			
Depreciation and amortization expenses		11,854	8,418
Capitalized development cost	2	(20,853)	—
Expenses related to incentive programs		41,566	56,624
Costs related to pension plan		—	(226)
Accrued interest and unrealized currency differences		33,923	(231)
		(530,245)	**(484,513)**
Changes:			
(Increase) decrease of trade receivables & unbilled revenue	8	(33,247)	(9,602)
(Increase) of other operating assets		(21,897)	(30,083)
Increase (decrease) trade payables		9,117	28,513
Increase of other operating liabilities		65,705	14,895
Total changes		**19,678**	**3,723**
Interest (paid) received, net		5,101	(625)
Income taxes paid		—	—
Net cash used in operating activities		**(505,467)**	**(481,416)**
Cash Flows from Investing Activities			
Proceeds from sale of short-term investments		232,644	—
Acquisition of property and equipment	3	(3,331)	(2,399)
Net cash (used in) from investing activities		**229,313**	**(2,399)**

(in thousands of SEK)	Note	Years Ended December 31, 2022	2021
Cash Flows from Financing Activities			
Proceeds from long-term loan, net of transaction costs[1]		728,373	—
Proceeds from issue of ordinary shares, net of transaction costs [2]		396,196	—
Payment of lease liabilities	4,29	(6,888)	(4,857)
Net cash (used in) from financing activities		**1,117,681**	**(4,857)**
Net change in cash and cash equivalents		841,527	(488,672)
Cash and cash equivalents at beginning of year		644,975	1,133,647
Cash and cash equivalents at end of year	**29**	**1,486,502**	**644,975**

[1] Total long-term loan transaction cost amounted to SEK 8.027k.

[2] Total share issue cost amounted to SEK 19,754k.

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

Parent Company Financial Statements continued

Statement of changes in shareholders' equity

		Restricted shareholders' Equity		Unrestricted shareholders' Equity				
(in thousands of SEK)	Note	Share Capital	Development cost reserve	Share Premium reserve	Treasury share reserve	Accumulated deficit	Loss for the year	Total shareholders' Equity
Balance at January 1, 2021		**45,895**	**—**	**2,509,458**	**(1,421)**	**(890,710)**	**(421,644)**	**1,241,578**
Statement of profit or loss and other comprehensive income (loss):								
Loss for the year		—	—	—	—	—	(549,098)	(549,098)
Other comprehensive income (loss) for the year		—	—	—	—	—	—	—
Total comprehensive loss for the year		**—**	**—**	**—**	**—**	**—**	**(549,098)**	**(549,098)**
Appropriation of loss of the year 2020 carried forward		—	—	—	—	(421,644)	421,644	**—**
Issue of Class-C shares [1]		440	—	—	(440)	—	—	—
Long term incentive program		**—**	—	63,467	**—**	**—**	**—**	63,467
Balance at December 31, 2021	22,23,24,25	**46,335**	**—**	**2,572,925**	**(1,862)**	**(1,312,353)**	**(549,098)**	**755,948**
Statement of profit or loss and other comprehensive income (loss):				**—**				
Loss for the year		—	**—**	—	—	—	(596,735)	(596,735)
Other comprehensive income (loss) for the year		—	**—**	—	—	—	—	—
Total comprehensive loss for the year		**—**	—	**—**	**—**	**—**	**(596,735)**	**(596,735)**
Appropriation of loss of the year 2021 carried forward		**—**	—	**—**	**—**	(549,098)	549,098	**—**
Capitalization of development cost			20,853	–	**—**	(20,853)	**—**	**—**
Issue of ordinary shares [2]		7,848	**—**	388,346	—	—	—	**396,196**
Issue of Class-C shares [3]		**—**	**—**	—	(851)	—	—	—
Exercise of share rights		**—**	**—**	(122)	122	—	—	—
Long term incentive program		**—**	**—**	60,391	**—**	**—**	**—**	60,391
Balance at December 31, 2022	22,23,24,25	**55,034**	**20,853**	**3,021,541**	**(2,590)**	**(1,882,304)**	**(596,735)**	**615,799**

[1] 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.
[2] Total share issue cost amounted to SEK 19,754k.
[3] The year 2022 additions of Class C shares refer to the new issue and subsequent repurchase of Class C shares that have taken place in accordance with the respective long term incentive plan (LTIP) program.

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

Notes to the Parent Company Financial Statements

Note 1 Accounting policies

Hansa Biopharma AB (the Parent Company) has prepared its annual report in accordance with the Swedish Annual Accounts Act (SFS 1995:1554) and Recommendation RFR 2 issued by the Swedish Financial Reporting Board, Reporting for legal entities. The statements issued by the Swedish Financial Reporting Board applicable to listed companies have also been applied. RFR 2 entails that in the annual report for the legal entity the Parent Company must apply all of IFRS and the statements adopted by the EU to the extent possible within the scope of the Swedish Annual Accounts Act, the Securing of Pension Obligations Act, and taking into consideration the connection between reporting and taxation. The Recommendation sets forth which exceptions from, and additions to, IFRS are to be made.

Differences between the Group's and the Parent Company's accounting principles

The differences between the Group's and the Parent Company's accounting principles are set forth below. The accounting principles set forth below for the Parent Company have been applied consistently to all periods presented in the Parent Company's financial statements.

Subsidiaries

Investment in subsidiaries is recognized at cost after deducting for potential impairment. Cost includes acquisition-related expenses and potential additional purchase considerations. When there is an indication that investment in subsidiaries is impaired, recoverable amount is measured. If the recoverable amount is lower than the carrying amount, an impairment is recognized. Impairment is recognized in the statement of profit or loss.

Presentation and classification

The differences in the Parent Company's income statement and statement of financial position as compared with the Group's statements consist primarily of the reporting of financial income and expenses, non-current assets and shareholders' equity.

Note 14 employees and accrued personnel cost and note 30 audit fees includes information for the Group and the Parent Company as required by the Swedish Annual Accounts Act.

Note 2 Intangible Assets

Internally generated intangible assets

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

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

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

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

For Q4-2022 and the year ending December 31, 2022 the Company capitalized development cost in the amount of SEK 20.9 million related to performing its Idefirix® (imlifidase) EMA post-approval commitments. Capitalized development cost mainly include fees paid to 3rd party service providers, personnel expenses of Hansa staff and approportionate finance cost.

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

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses, on the same basis as intangible assets that are acquired separately. If circumstances or changes in the Group's operations indicate that the carrying amount of non-current assets in a cash-generating unit may not be recoverable, management reviews the asset for impairment. An annual impairment test is also performed for assets yet to be brought into use, i.e. per December 31, 2022 in-process development projects (see below) and capitalized development cost relating to imlifidase.

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

Notes to the Parent Company Financial Statements continued

Acquired intangible assets

Patents

The HBP-assay patent cost is amortized over the finite useful life of the underlying patent in the amount of SEK 559 k for the year 2022 (2021: SEK 559 k). The patent cost is amortized over sales, general and administration line item in the consolidated statement of profit or loss and other comprehensive income.

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

In-process development projects

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

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

Acquired in-process development projects are assessed for possible impairment at least on an annual basis and the impairment assessment on December 31, 2022, and 2021 demonstrated that there was no need for impairment. The estimated recoverable amount supported by external and internal valuation reports by far exceeds the assets' carrying amount, resulting in no impairment charges for the year 2022 and 2021.

	Internally generated	Acquired intangible assets		
(in thousands of SEK)	Capitalized development expenditures	Patents	In-process development projects	Total Intangible Assets
Cost:				
Opening balance January 1, 2022	4,485	8,504	25,136	38,125
Write-off	(4,485)	—	—	(4,485)
Internally developed	20,853	—	—	20,853
Closing balance December 31, 2022	**20,853**	**8,504**	**25,136**	**54,493**
Amortization:				
Opening balance January 1, 2022	(4,485)	(5,028)	(2,094)	(11,607)
Write-off	4,485	—	—	4,485
Amortization for the year	—	(559)	(2,094)	(2,653)
Closing balance December 31, 2022	**—**	**(5,587)**	**(4,188)**	**(9,775)**
Carrying amounts:				
At January 1, 2022	—	3,476	23,042	26,518
At December 31, 2022	**20,853**	**2,917**	**20,948**	**44,718**

	Internally generated	Acquired intangible assets		
(in thousands of SEK)	Capitalized development expenditures	Patents	In-process development projects	Total Intangible Assets
Cost:				
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
Amortization:				
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)
Carrying amounts:				
At January 1, 2021	—	4,035	25,136	29,171
At December 31, 2021	—	3,476	23,042	26,518

Notes to the Parent Company Financial Statements continued

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

	As of December 31,	
(in thousands of SEK)	**2022**	**2021**
Opening balance January 1,	**5,095**	**5,095**
Shareholder contribution to Hansa Biopharma Inc.*	12,882	—
Shareholders contribution to Hansa Biopharma Ltd.*	6,286	—
Paid in capital of Hansa Biopharma Pty Ltd (amounted to AUD 1)	—	0
Closing balance December 31,	**24,264**	**5,095**

*The shareholders contribution relates to push down of the LTIP expenses for the year 2018 to 2022 from the parent company to the subsidiaries and the subsequent conversion to equity.

			As of December 31,	
(in thousands of SEK, except for number of shares and share percentage)	**Number of shares**	**Share %**	**2022**	**2021**
Cartela R & D AB/556746-0083/Lund	1,000	100	2,630	2,630
Hansa Biopharma Ltd / 08361712 / Cheltenham, United Kingdom	100,000	100	8,742	2,456
Hansa Biopharma Inc, 6846164, Delaware, USA	1,000	100	12,891	9
Hansa Biopharma Australia Pty Ltd*	1	100	—	—
Closing balance December 31,	**—**	**—**	**24,264**	**5,095**

*Dormant Company

Note 6 Intercompany balances

Receivables, group companies

Non-current assets

	As of December 31,	
(in thousands of SEK)	**2022**	**2021**
Opening balance January 1,	**2,203**	**1,972**
Change in receivables, net*	(2,203)	231
Closing balance December 31,	**—**	**2,203**

*Converted to equity

Liabilities, group companies

Current liabilities

	As of December 31,	
(in thousands of SEK)	**2022**	**2021**
Opening balance January 1,	**3,901**	**1,613**
Change in liabilities, net*	1,837	2,288
Closing balance December 31,	**5,738**	**3,901**

*Increase due to increased intercompany services received.

Note 7 Inventories

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

Note 8 Trade Receivables, unbilled revenue & refund liabilities

The Trade receivables, unbilled revenue and refund liabilities held by the Parent Company are the same as for the Group, see note 8 for the Group.

Notes to the Parent Company Financial Statements continued

Note 9 Prepaid expenses and accrued income

	As of December 31,	
(in thousands of SEK)	2022	2021
Insurances	1,137	829
Healthcare conferences	2,604	124
Software	1,777	1,177
Pension	1,770	1,644
Rent	2,385	2,512
Legal expenses	9,989	8,325
Licence fees	3,857	230
R&D expenses	7,587	3,769
Other	2,120	2,211
Total	**33,226**	**20,820**

Note 10 Other receivables

	As of December 31,	
(in thousands of SEK)	2022	2021
VAT receivables	21,006	9,670
Advance payments to suppliers	9,262	11,292
Other receivables	874	1,419
Total	**31,142**	**22,381**

Note 11 Accrued Expenses

	As of December 31,	
(in thousands of SEK)	2022	2021
Annual leave accrual	17,459	15,376
Accrued social security contribution on salaries	5,243	4,395
Accrued short term incentives, incl. related social security contributions	28,652	21,713
R&D project costs	26,701	7,791
License fees	5,500	—
Consulting fees	16,664	17,600
Other	3,050	2,509
Closing balance December 31	**103,270**	**69,384**

Note 12 Other liabilities / Current

	As of December 31,	
(in thousands of SEK)	2022	2021
Personnel related liabilities	17,868	13,358
Closing balance December 31	**17,868**	**13,358**

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

2022 Guidelines for remuneration to senior executives

The 2022 guidelines proposed by the Board of Directors entail that executive management is offered a remuneration which is competitive and on market terms. The level of the remuneration for the individual manager shall be based on factors such as position, expertise, experience, and performance. The remuneration consists of a fixed salary and pension benefits and, in addition, may consist of variable salary, share based long-term incentive programs, severance remuneration and non-monetary benefits. The variable salary is based on the achievement of quantitative and qualitative targets and should not exceed 75 percent of the annual fixed salary. Salary during the notice of termination period and severance remuneration can be a maximum amount of 18 months salaries.

Please refer to the Governance section in this Annual Report 2022 or visit the Company's website at www.hansabiopharma.com for information on the 2022 guidelines for remuneration to senior executives.

Total personnel expenses recorded in the Parent Company are presented below in different break-downs:

Parent Company 2022

Total personnel expenses recorded in the Parent Company broken down to senior management and other employees

(in thousands of SEK)	Senior management	Other employees	Total Parent Company
Salaries, bonuses and other benefits	36,927	129,428	166,354
Social security contribution	11,423	23,008	34,431
Pension cost, contribution plan	2,812	20,550	23,362
Share-based compensation	32,844	20,121	52,965
Total personnel expenses	**84,005**	**193,107**	**277,113**

Notes to the Parent Company Financial Statements continued

Personnel expenses recorded in the Parent Company related to Senior management

(in thousands of SEK)	Base salary / Directors' fees	Variable compen-sation	Total Salaries, bonuses and other benefits	Social security contri-butions	Pension cost	Share-based compen-sation	Total
Chairman of the Board of Directors Ulf Wiinberg**	471	–	471	148	–	–	619
Chairman of the Board of Directors Peter Nicklin***	479	–	479	46	–	–	525
Director Anders Gersel Pedersen	350	–	350	36	–	–	386
Director Andreas Eggert	440	–	440	138	–	–	578
Director Eva Nilsagård	450	–	450	141	–	–	591
Director Hilary Malone	531	–	531	167	–	–	698
Director Mats Blom	375	–	375	118	–	–	493
CEO Søren Tulstrup	*7,586	4,024	11,610	3,648	–	11,223	26,481
Other senior executives (5 persons)	15,435	6,786	22,221	6,982	2,812	21,622	53,635
Total	**26,117**	**10,810**	**36,927**	**11,423**	**2,812**	**32,844**	**84,005**

* Includes 1,694 KSEK, representing 30% of base salary, intended for own pension contribution
** Chairman of the board until AGM 2022.
*** Chairman of the board from AGM 2022.

Parent Company 2021

Total personnel expenses recorded in Parent Company broken down to senior management and other employees

(in thousands of SEK)	Senior management	Other employees	Total Parent Company
Salaries, bonuses, and other benefits	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
Total personnel expenses	**78,905**	**160,274**	**239,180**

Personnel expenses recorded in the Parent Company related to Senior management

(in thousands of SEK)	Base salary / Directors' fees	Variable compen-sation	Other benefits	Total Salaries, bonuses and other benefits	Social security contri-butions	Pension cost	Share-based compen-sation	(in thousand s of SEK)
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
Total	**22,840**	**9,023**	**419**	**32,282**	**10,040**	**2,723**	**33,860**	**78,905**

* 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

Average number of employees

	2022		2021	
	Number	Of which are men	Number	Of which are men
Total Group	144	37%	116	40%
Parent Company				
Sweden	135	37%	109	40%
Subsidiaries				
UK	4	75%	4	75%
US	5	25%	3	25%
Total subsidiaries	**9**	**–**	**7**	**–**

Breakdown of senior management according to gender

	Share of women	
	2022	2021
Total Group		
Board of Directors	33%	33%
Other senior management	17%	17%
Parent Company		
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 2022 AGM resolved that fees paid to directors for work during 2022 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

Please refer to the Company's Remuneration Report elsewhere in this 2022 Annual Report for further information on the CEOs compensation.

Notice of termination periods and severance compensation

If notice of termination of employment is made by the Company, the notice period may not exceed six months. Fixed cash salary during the period of notice and any severance pay may together not exceed an amount equivalent to the fixed cash salary for 18 months for the CEO, i.e., 6 plus 12 months.

Pension contributions

The CEO is responsible for his pension provision, thus the Company has no direct pension cost for the CEO.

Salaries and other remuneration to other members of executive management

Salaries and other remuneration to the other members of the executive management is determined by the CEO and approved by the chair of the Board of Directors. In 2022, executive management comprised of six people including the CEO.

Notice period of termination and severance payments

Fixed cash salary during the period of notice and any severance pay may together not exceed an amount equivalent to the fixed cash salary for 6 months, and in exceptional cases, 12 months for the other members of the executive management. When termination is made by the executive officer the period of notice may not exceed six months.

During their notice period, other members of executive management are entitled to full salary and other employment benefits.

Pension contributions

Hansa provides pension contributions and benefits in accordance with local statutory requirements and in accordance with the Company's insurance and pension policy.

Share-based compensation

The share-based compensation recorded and presented by the Parent Company amounted to SEK 52,965 and SEK 56,624k for the years ended on December 31, 2022 and 2021, respectively. The total amount of LTIP expenses pushed down from the parent company to the subsidiaries at year end 2022, that relates to the years 2018 to 2021, amounted to SEK 11,399k, resulting in net amount of SEK 41,566k as presented in the Parent Company´s Cash Flow Statement for the year ended December 31, 2022. Please refer to Note 14 for the Group for further information on Hansa's LTIP programs.

Notes to the Parent Company Financial Statements continued

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 2022 amounted to SEK 2,361,668,000 (2021: SEK 1,855,284,000). The losses carried forward are, in all material respects, attributable to Swedish companies and therefore have no due date. A reconciliation of Hansa's effective tax rate relative to the Swedish statutory tax rate is as follows:

	2022		2021	
	%	(in thousands of SEK)	%	(in thousands of SEK)
Result before tax	—	(596,131)	—	(549,098)
Tax according to current tax rate	20.6	122,803	20.6	113,114
Non-deductible expenses	(3.1)	(18,488)	(2.4)	(13,099)
Increase in loss carry forwards without corresponding capitalization of deferred tax	(17.6)	(104,919)	(18.2)	(100,015)
Reported effective tax	(0.1)	(604)	—	—

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

Note 17 Contingent Consideration

The Contingent consideration recorded by the Parent Company is the same as for the Group, see note 18 for the Group.

Note 18 Capital Management

The Capital management of the Parent Company is the same as for the Group, see note 19 for the Group.

Note 19 Financial Risk and Financial Instruments

The Parent Company has exposure to the same financial risks arising from financial instruments as the Group, see note 20 for the Group.

Carrying amounts of financial assets and financial liabilities

The table below shows the carrying amounts for financial assets and financial liabilities broken down by measurement categories under IFRS 9 in the Parent Company.

	Financial assets valued at amortized cost		Financial assets valued at fair value through the income statement	
(in thousands of SEK)	2022	2021	2022	2021
Financial assets:				
Short term investments	—	—	—	237,619
Receivables, group companies	—	2,203	—	—
Trade receivables	8,360	9,712	—	—
Other receivables	874	1,419	—	—
Cash and cash equivalents	1,486,502	644,975	—	—
Total financial assets	**1,495,735**	**658,309**	**—**	**237,619**

	Financial liabilities valued at amortized cost		Financial liabilities valued at fair value through the consolidated statement of profit or loss and other comprehensive income	
(in thousands of SEK)	2022	2021	2022	2021
Financial liabilities:				
Long-term loan	762,601	—	—	—
Contingent consideration	—	—	757	722
Liabilities, group companies	5,738	3,901	—	—
Trade payables	62,357	53,240	—	—
Accrued expenses (see note 11)	51,915	27,900	—	—
Total financial liabilities	**882,611**	**85,041**	**757**	**722**

Note 20 Long-term Loan

The long-term loan stated by the Parent Company is the same as for the Group, see note 21 for the Group.

Notes to the Parent Company Financial Statements continued

Note 21 Finance Income and Expenses

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Interest income	8,829	67
Changes in the fair value of interest funds during the year	—	—
Net exchange rate variances	18,416	
Finance income	**27,245**	**67**
Interest expense on long-term loan at amortized cost	(42,470)	—
Interest expenses, other	(1,186)	(693)
Changes in the fair value of interest funds during the year	(4,973)	(525)
Finance costs	**(48,629)**	**(1,218)**
Net finance costs/income	**(21,384)**	**(1,151)**

Note 22 Share capital and number of shares

The Share Capital stated and number of shares for the Parent Company is the same as for the Group, see note 23 for the Group.

Note 23 Share Premium

The Share Premium stated by the Parent Company is the same as for the Group, see note 24 for the Group.

Note 24 Treasury shares included in equity

The Treasury shares included in equity stated by the Parent Company is the same as for the Group, see note 25 for the Group.

Note 25 Reserves

Treasury share reserve

The treasury share reserve represents own shares repurchased by the Group. Please refer to Note 14 related to the Group's LTIP programs and respective vesting dates.

Development cost reserve

The development cost reserve represents the capitalized development cost. Amounts capitalized in respect of internally generated development expenditure are transferred from unrestricted equity to development cost reserve in restricted equity. The capitalized amounts are amortized over their useful lives, reducing the reserve accordingly. Please refer to Note 2 for further information on the capitalized development cost.

Note 26 Royalty Agreements

The Parent Company is party to the same royalty agreements as the Group, see note 27 for the Group.

Note 27 Other operating income and expenses

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Total other operating income	—	—
Other operating expenses		
Foreign currency losses on receivables/liabilities from operating activities	(12,469)	(7,395)
Other operating expenses	(8,063)	—
Total other operating expenses	**(20,532)**	**(7,395)**

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:

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Personnel expenses	(303,746)	(245,189)
Third party expenses	(356,757)	(305,969)
Depreciation and amortization expenses	(9,760)	(8,418)
Other operating expenses	(20,533)	(6,824)
Total operating expenses	**(690,796)**	**(566,400)**

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).

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Research and development expenses	7,027	5,516
Sales, general and administrative expenses	2,733	2,902
Total	**9,760**	**8,418**

Note 29 Supporting information to the cash flows

	As of December 31,	
(in thousands of SEK)	2022	2021
Cash and cash equivalents consist of:		
Cash and bank deposits	1,486,502	644,975
Total according to the statement of financial position	1,486,502	644,975
Total according to the cash flow	1,486,502	644,975

Notes to the Parent Company Financial Statements continued

Reconciliation of liabilities arising from financing activities:

(in thousands of SEK)	2022	2021
Opening balance January 1,	**35,379**	**5,045**
Termination of lease agreement	(25)	(308)
New lease agreements	—	35,499
Payment of lease liabilities	(6,863)	(4,857)
Net present value of long-term loan	687,221	—
Accrued interest on long-term loan	41,152	—
Unrealized currency differences on long-term loan	34,228	—
Closing balance December 31,	**791,092**	**35,379**

Note 30 Audit fees – Group and Parent Company

	Years Ended December 31,	
(in thousands of SEK)	2022	2021
Group		
KPMG AB:		
Auditing services	2,565	9,892*
Other services closely related to audit services	385	300
Tax services	—	—
Wilkins Kennedy Audit Services		
Auditing services	110	68
Parent Company		
KPMG AB:		
Auditing services	2,565	9,842
Other services closely related to audit services	385	300
Tax services	—	—

*Thereof PCAOB Audit services related to the preparation for Dual listing on NASDAQ, USA, in 2021 amounts to 8,832.

Note 31 Collateral provided, contingent liabilities and contingent assets

Nothing to report related to the financial year 2022 and 2021.

Note 32 Related party transactions

Subsidiaries

Interest in subsidiaries and intercompany receivables and liabilities are set out in Note 6.

Transactions with key persons in a senior management position

Transactions with key persons in a senior management position are set forth in Note 14.

Note 33 Information regarding the Parent Company

Hansa Biopharma AB (publ) is a Swedish registered public company (Company reg. no. 556734-5359).

The registered office is located in Lund. The Parent Company's shares are registered on NASDAQ Stockholm. The address of the headquarters is Scheelevägen 22, 223 63 Lund.

The consolidated accounts for 2022 and 2021 cover the Parent Company and its subsidiaries, jointly referred to as the Group.

Note 34 Appropriation of loss carried forward

Unrestricted shareholders' equity in the Parent Company:

	As of December 31,	
(in SEK)	2022	2021
Share premium reserve	3,021,541,484	2,572,925,209
Treasury shares	(2,590,279)	(1,861,909)
Loss carried forward	(1,882,303,903)	(1,312,352,987)
Loss for the year	(596,735,718)	(549,097,916)
Total	**539,911,584**	**709,612,397**

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

	As of December 31,	
(in SEK)	2022	2021
Share premium reserve	3,021,541,484	2,572,925,209
Treasury shares	(2,590,279)	(1,861,909)
Loss carried forward	(2,479,039,621)	(1,861,450,903)
Total	**539,911,584**	**709,612,397**

Note 35 Subsequent events

The subsequent events for the Parent Company are the same as for the Group, see note 31 for the Group.

Definitions

Equity ratio
Shareholders' equity as percentage of total statement of financial position assets at the end of the period.

Shareholders' equity per share
Shareholders' equity in relation to number of outstanding shares at the end of the period.

Legal disclaimer
This financial report includes statements that are forward looking, and actual future results may differ materially from those stated. In addition to the factors discussed, among other factors that may affect results are development within research programs, including development in preclinical and clinical trials, the impact of competing research programs, the effect of economic conditions, the effectiveness of the Company's intellectual property rights and preclusions of potential second party's intellectual property rights, technological development, exchange rate and interest rate fluctuations and political risks.

Signatures

The Board of Directors and the CEO affirm that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and give a fair view of the Group's financial position and results. The annual report has been prepared in accordance with generally accepted accounting principles for the Group and the Parent Company and gives a fair overview of the development of the Group's and the Parent Company's operations, financial positions and results, and describes material risks and uncertainties facing the Parent Company and the companies included in the Group.

Lund 29 March 2023

Peter Nicklin
Chairman of the Board

Hilary Malone
Director

Mats Blom
Director

Andreas Eggert
Director

Eva Nilsagård
Director

Anders Gersel Pedersen
Director

Søren Tulstrup
CEO and Executive President

The Board of Directors and CEO approved the annual report for publication on 29 March 2023. 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 14 June 2023.

Our auditors' report was submitted on 30 March 2023.

KPMG AB

Stefan Lundberg
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 2022. The annual accounts and consolidated accounts of the company are included on pages [52-112] 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 2022 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 2022 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 statement of comprehensive income and statement of financial position for the group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

Revenue

See disclosure 13 and accounting principles on page/pages 67-68 in the annual account and consolidated accounts for detailed information and description of the matter..

Description of key audit matter	Response in the audit
During 2022, the Company recognize contract revenue in the amount of SEK 26.8 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.	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. Furtheremore 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 2-51 and 117-140. The other information comprises also of the remuneration report which we obtained prior to the date of this auditor's report. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

Auditor's Report continued

Translation from the Swedish original

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

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

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.

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 2022 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.

Auditor's Report continued

Translation from the Swedish original

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 2022.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report has been prepared in a format that, in all material respects, enables uniform electronic reporting.

Basis for opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the Esef report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of Hansa Biopharma AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical 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 validation that the Esef report has been prepared in a valid XHMTL format and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the consolidated statement of financial performance, financial position, changes in equity, cash flow and disclosures in the Esef report have been marked with iXBRL in accordance with what follows from the Esef regulation.

KPMG AB, Box 382, 101 27, Stockholm, was appointed auditor of Hansa Biopharma AB by the general meeting of the shareholders on the 30 June 2022 KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2014.

Stockholm, 30 March, 2023

KPMG AB

Stefan Lundberg
Authorized Public Accountant

Governance

10

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 2022 Corporate Governance Report in accordance with the requirements of the Swedish Annual Accounts Act (1995:1554) (Sw. årsredovisningslagen) and the Swedish Corporate Governance Code (the "Code").

The Company's corporate governance is mainly regulated by the provisions of the Company's articles of association, the Swedish Companies Act (2005:551) (Sw. aktiebolagslagen) and other Swedish legislation, the Nordic Main Market Rulebook for Issuers of Shares and the Code.

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.

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 2022.

During 2022, Hansa deviated from the Code by not announcing the names of the members of the Nomination Committee at least six months before the Annual General Meeting. The reason for this deviation is that the members of the Nomination Committee were not fully confirmed in time.

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.

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 31 December 2022, Redmile Group LLC is the only shareholder owning more than 10 percent of the Company's shares, in its shareholdings of 20.8 percent.

Significant external and internal regulations and policies which affect corporate governance:

Significant internal regulations and policies:

> Articles of association
> Instruction for the CEO, including the financial reporting instruction
> Work procedures for the Board
> Disclosure policy
> Insider policy
> Procurement and expenditure policy
> Treasury policy
> Finance policy
> Risk management policy
> Staff handbook
> Executive remuneration policy
> Code of Conduct
> Supplier Code
> Global Data Privacy policy

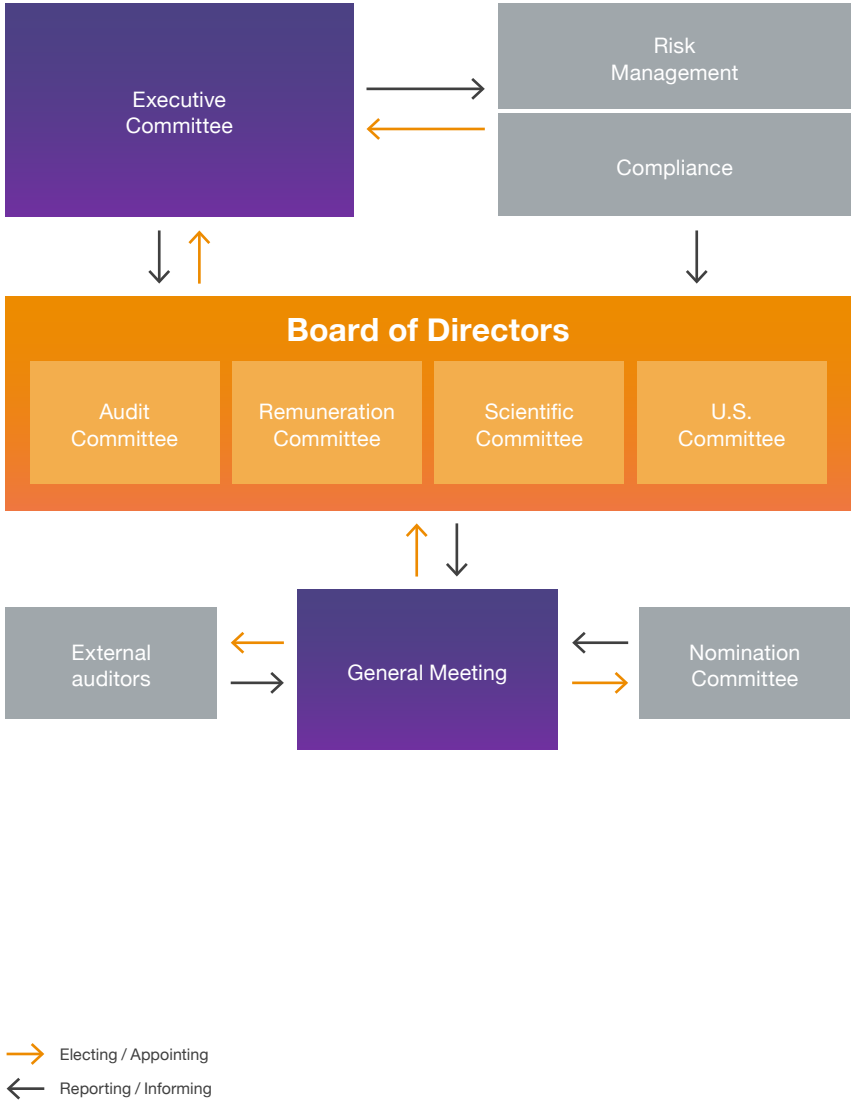
Significant external regulations:

> Market Abuse Regulation
> Swedish Companies Act
> Swedish Accounting Act
> Swedish Annual Accounts Act
> International standards for audits and financial reporting (IFRS)
> Nordic Main Market Rulebook for Issuers of Shares
> Swedish Corporate Governance Code

General principles continued

Hansa's corporate governance structure

Overview of Hansa's corporate governance structure during 2022



Information regarding Hansa Biopharma AB's shares

The Company's shares were admitted for trading on Nasdaq Stockholm, Small Cap, in November 2015. The Company's shares were previously, since 2007, listed on Nasdaq First North.

The Company's shares are divided into ordinary shares and C-shares. On 31 December 2022, the total number of shares issued was 55,034,241 with 52,443,962 ordinary shares outstanding and 2,590,279 C-shares, with a quotient value of SEK 1. Each ordinary share carries one vote, and each C-share carries one tenth. All C-shares are owned by the Company. Each person entitled to vote may vote for his or her full number of shares. The number of votes in the Company amounts to 52,702,989.9.

Each ordinary share confers the right to an equally large percentage of the Company's distributable profits. The C-shares are not entitled to dividends and are subject to a redemption and reclassification clause.

General meeting

The Company's highest decision-making body is the general meeting, where the shareholders' influence over the Company is exercised. In addition to what follows from applicable law regarding shareholders' right to participate at general meetings, shareholders who wish to participate at a general meeting, personally or through a proxy, must give notice of their attendance.

Notices to attend general meetings are given through advertisement as well as on the Company's website (www.hansabiopharma.com). The Annual General Meeting ("AGM") must be held within six months from the close of the financial year. At the AGM, the shareholders adopt resolutions regarding, among other things: the Board and auditors; the procedure for appointing the nomination committee; and discharge from liability for the Board and the CEO in respect of the preceding year. Resolutions are also adopted regarding adoption of the annual report; disposition of profits or treatment of losses; fees for the directors and auditors; and, if applicable, guidelines for remuneration for senior executives.

2022 Annual General Meeting

The 2022 AGM was held on 30 June, with participation through advance voting according to sections 20 and 22 in the Act on temporary exemptions in order to facilitate the conduction of general meetings (Sw. lag (2020:198) om tillfälliga undantag för att underlätta genomförandet av bolags- och föreningsstämmor). In total, 16,427,831 of the shares in the Company were represented, meaning that 36.7 percent of the total number of votes and 35.45 percent of the total number of shares in the Company were represented.

The AGM adopted the 2021 annual accounts and granted the directors and CEO a discharge from liability. The AGM resolved that no dividend would be paid. The AGM resolved that Anders Gersel Pedersen, Andreas Eggert, Eva Nilsagård, Hilary Malone and Mats Blom are re-elected as members of the Board, and resolved election of Peter Nicklin as new member of the Board, all for the period until the end of the next AGM. Ulf Wiinberg, previous chair of the

General principles continued

Board until the end of the 2022 AGM, was not standing for re-election. The AGM further resolved to elect Peter Nicklin as chair of the Board for the period until the end of the next AGM. The AGM resolved to re-elect KPMG AB as auditor, with Stefan Lundberg 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 chair of the Board and SEK 300,000 each to the other board members. It was further resolved that the remuneration to the chair of the Audit Committee 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, SEK 25,000 to each board member in the Scientific Committee, and USD 20,000 to the chair of the U.S. Committee. 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 guidelines for executive remuneration, to amend the articles of association, adopt a long-term incentive program based on performance-based share rights for certain employees in Hansa Biopharma, and adopt a long-term incentive program based on employee stock options for certain employees in Hansa Biopharma.

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 2022 AGM are available at Hansa Biopharma's website (www.hansabiopharma.com). The 2023 AGM will take place on 14 June 2023.

Remuneration to senior executives

The remuneration guidelines for senior executives adopted by the 2022 AGM entail that 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.

Share and share based long-term incentive programs shall be decided by the AGM. 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 2022.

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 2022 for further information on the 2022 guidelines.

During 2022, neither the Remuneration Committee nor the Board of Directors received any comments or questions from shareholders on the remuneration guidelines adopted at the 2022 AGM.

Nomination Committee

Prior to the 2023 AGM, Hansa's Nomination Committee comprises of Natalie Berner (representing Redmile Group and chair of the Nomination Committee), Jannis Kitsakis (representing AP4), and Arne Myhrman (representing Thomas Olausson). Peter Nicklin (chair of the Board) is the convenor of the Nomination Committee.

Procedures for appointing members of the Nomination Committee were adopted by the 2022 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.

General principles continued

The Nomination Committee shall prepare proposals for the 2023 AGM for the chair of the AGM, board members, chair of the Board of Directors, remuneration to the Board, auditors, remuneration to the auditors, and the principles for the Nomination Committee before the 2023 AGM.

External auditors

The external audit of the accounts of the Parent Company and the Group, as well as of the management by the Board and the CEO, is carried out in accordance with generally accepted accounting standards in Sweden. The auditor participates in at least one Board meeting per year, going through the accounts for the year and leading a discussion with the directors without the CEO or any other senior executive present.

Pursuant to the articles of association, Hansa must have a registered accounting firm as its external auditor. The accounting firm KPMG AB has been the auditor of the Company since the 2014 AGM. As from the 2022 AGM, certified public accountant Stefan Lundberg is auditor in charge. Stefan Lundberg is a member of the Swedish Institute of Authorized Public Accountants. For information regarding fees paid to the auditors, please refer to Note 30 to the Financial Statements.

The Board

The Board is the highest management body beneath the AGM

The overall task of the Board is to manage the affairs of the Company in the best possible manner on behalf of the shareholders. The Board must continuously evaluate the Group's operations, development and financial situation, as well as the operative management including identifying how sustainability issues impact risks to and business opportunities for the Group. The Board decides upon, among other things: issues concerning the Group's strategic focus and organization; business plans; financial plans and budget; significant agreements; major investments and commitments; and finance, disclosure, and risk management policies. The Board must also ensure that the Company prepares insider instructions. The Board works according to written rules of procedure which are adopted annually, and which regulate the framework for the Board meetings, including the frequency and agenda of meetings, distribution of materials for meetings, and matters to be presented to the Board for information or for a decision. The rules of procedure also govern how the board work is allocated among the Board and its committees. The Board has also adopted CEO instructions which govern the allocation of work among the Board, the chair of the Board, and the CEO, and which defines the CEO's authority.

The Board is elected by the shareholders at the AGM up until the end of the next AGM, with the possibility of re-election. In addition, the Company's employees may, pursuant to statutory rules regarding the representation of employees on the Board, elect employee representatives to the Board. Currently, the Board has no employee representatives. All current board members are considered independent under the corporate governance standards of the Code and Nasdaq Stockholm.

The chair of the Board is responsible for contacts with the shareholders regarding ownership issues and for communicating the shareholders' views to the Board of Directors. The chair is further responsible for the day-to-day contact with the CEO and senior executives and must keep himself well informed about, and monitor, the Company's business. The chair is responsible for ensuring that the Board's work is carried out efficiently and that the Board fulfils its obligations in accordance with applicable laws and regulations, the Code, the articles of association, resolutions of the general meeting, and the Board's own rules of procedure, and that the Board carries out the decisions that are made and that their work is evaluated. Further, the chair is responsible for ensuring that the directors regularly update their knowledge about the Company and that new directors receive necessary introductory training. The chair must also approve remuneration and other employment terms and conditions for senior executives, and is responsible for the Company's archives, in which minutes from all Directors' meetings and general meetings must be saved.

The chair prepares Board meetings together with the CEO and Corporate Secretary. The notice of the meeting and the agenda are sent to the directors together with sufficient decision-making documentation. A Board meeting includes a review of the business, including development and advances within research and development, business development, consolidated earnings and financial position, financial reports, and forecasts.

Pursuant to the Company's articles of association, the Board must comprise of not less than three and not more than ten directors elected by the AGM. The Board is quorate when more than half of the directors are present. The articles of association do not contain any provisions regarding appointment or dismissal of directors or regarding amendment of the articles of association.

Directors' fees were set at the 2022 AGM for a period up to and including the 2023 AGM. The fees for the Board's work in 2022 were set as follows: SEK 900,000 to the chair of the Board and SEK 300,000 each to the other board members. It was further resolved that the remuneration to the chair of the Audit Committee 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, SEK 25,000 to each board member in the Scientific Committee, and USD 20,000 to the chair of the U.S. Committee. 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, for additional information regarding employment terms and conditions for the Board and senior executives.

Directors

The Board currently comprises six individuals, including the chair.

The 2022 AGM re-elected Anders Gersel Pedersen, Andreas Eggert, Eva Nilsagård, Mats Blom, and Hilary Malone as members of the Board. Further, Peter Nicklin was elected as a new member and chair of the Board. Ulf Wiinberg, previous chair of the Board, was not standing for re-election. Each director's term continues until the end of the next AGM. There are no rules about how long a member may serve on the Board if being re-elected.

The Board continued

Prior to the 2022 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 considered. The result of the Nomination Committee's application of the diversity policy is a Board that represents a mix of both professional experience and knowledge as well as geographical and cultural backgrounds. One third (1/3) of the board members elected by the AGM are women.

Information about Board members as of 31 December 2022

Holdings in the Company include 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

18
BOARD MEETINGS

99%
ATTENDANCE

Peter Nicklin

Born 1963

Member and chair of the Board since 2022, member of the Remuneration Committee, the Scientific Committee and the US Committee.

Shareholding: 14,500 shares

Peter Nicklin has more than 30 years of extensive experience and background in the pharmaceutical and healthcare sector in both developed, as well as emerging markets and significant experience in leading global teams. Chair of the Board at Tunstall Healthcare and Sciensus. Previously, CEO and member of the Board of Amann Girrbach AG, Corporate Vice President and EMEA President of Baxter International (NYSE: BAX), as well as senior executive roles at Bayer Healthcare (XETRA: BAYN), Novartis (SWX: NOVN) and Bristol-Myers Squibb (NYSE:BMY). Peter holds a Bachelor of Arts with Honours in Finance from Lancaster University. He is also a Chartered Accountant having qualified at PriceWaterhouseCoopers in London.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.

Eva Nilsagård

Born 1964

Member of the Board since 2019 and chair of the Audit Committee.

Shareholding: 3,000 shares

Eva Nilsagård is the founder and Chief Executive Officer of Nilsagård Consulting AB. Previous interim Chief Financial Officer of various companies, including OptiGroup AB, Plastal, and Vitrolife AB (STO: VITR). She has also served in various senior positions at the Volvo Group, or Volvo (STO: VOLV), including Senior Vice President Strategy & Business Development. Earlier in her career, Eva also held senior positions in finance and business development at AstraZeneca plc (LSE: AZN) and AB SKF (STO: SKF). Board member and chair of the audit committee of SEK (Swedish Export Credit Company), AddLife (STO: ALIF), Bufab Group (STO: BUFAB), Irras AB (STO: IRRAS), Nimbus Group AB (STO: BOAT), Nanexa (STO: NANEXA), Ernströmgruppen and Xbrane Biopharma (STO: XBRANE), the chair of Spermosens AB (Spotlight: SPERM) and Diagonal Bio AB (STO: DIABIO), and board member of eEducation Albert AB (STO: ALBERT). Eva has more than ten years of experience as a mentor for young female managers with high potential. She holds an Executive M.B.A. in Economics and a B.Sc. in accounting and finance from School of Business, Economics and Law in Gothenburg.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.

The Board continued

Mats Blom
Born 1965

Member of the Board since 2019 and member of the Audit Committee.

Shareholding: 1,000 shares

Mats Blom serves as Chief Financial Officer of NorthSea Therapeutics B.V. Previous Chief Financial Officer of Modus Therapeutics AB (STO: MODTX), Zealand Pharma A/S (CSE: ZELA), Swedish Orphan International AB (acquired by BioVitrum, now Swedish Orphan Biovitrum AB (publ) (STO:SOBI)), Active Biotech AB (publ) (STO:ACTI), and Anoto Group AB (STO: ANOT). Previously also management consultant at Gemini Consulting and Ernst & Young. Board member of Egetis Therapeutics AB (STO: EGTX), Altamira Therapeutics Ltd. (NASDAQ: CYTO), and Pephexia Therapeutics ApS. Mats holds a B.A. in Business Administration and Economics from Lund University and an M.B.A. from the IESE University of Navarra, Barcelona.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.

Andreas Eggert
Born 1967

Member of the Board since 2018, chair of the Remuneration Committee, and member of the Audit Committee and the Scientific Committee.

Shareholding: 5,500 shares

Andreas Eggert has over 25 years of cross-functional leadership experience including commercial operations, launch and portfolio management, brand strategy, market access, and strategic consulting. Chief Operating Officer at X-Vax Technology Inc. in the U.S. Previously, 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. Previously, also served in various senior commercial roles at Wyeth, LLC (acquired by Pfizer Inc. (NYSE: PFE)) in the U.S., Japan and in Germany, including as Vice President & Global Business Manager. Earlier in his career, Andreas also was a Management Consultant at A.T. Kearney. He holds an M.B.A. from Azusa Pacific University.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.

Anders Gersel Pedersen
Born 1951

Member of the Board since 2018, chair of the Scientific Committee, and member of the Remuneration Committee.

Shareholding: 2,500 shares

Anders Gersel Pedersen has over 33 years of experience in the international pharmaceutical industry. Served in various roles at H. Lundbeck A/S in Denmark (CSE: LUN), including most recently as Executive Vice President of Research & Development, as responsible for the discovery and development of the product pipeline from preclinical activities to post-launch marketing studies. Prior to that, served in various roles at Eli Lilly and Company (NYSE: LLY), including most recently as a director overseeing worldwide clinical research in oncology. Member of the European Society of Medical Oncology, the International Association for the Study of Lung Cancer and the American Society of Clinical Oncology. Serves on the supervisory boards of Avillion LLP, Bavarian Nordic A/S (CSE: BAVA), AELIS Farma SA, and Genmab A/S (CSE: GMAB). He received his medical degree and a doctoral degree in neuro-oncology from the University of Copenhagen and a B.Sc. in Business Administration from Copenhagen Business School.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.

Hilary Malone
Born 1965

Member of the Board since 2021, chair of the US Committee, and member of the Scientific Committee.

Shareholding: –

Hilary Malone 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., and as the Chief Regulatory Officer and Senior Vice President & Head of Global Regulatory Affairs at Sanofi Inc. (subsidiary of Sanofi SA (Euronext: SAN)). Previous experience also includes senior regulatory and drug development roles at Reata Pharmaceuticals, Inc. (NASDAQ: RETA), Pfizer Inc. (NYSE:PFE), Wyeth, LLC (acquired by Pfizer Inc.), AstraZeneca plc (LSE:AZN) and GlaxoSmithKline plc (LSE: GSK). Hilary has also served on the board of Inhibikase Therapeutics (NASDAQ: IKT). She holds a Ph.D. in Molecular Neuropharmacology and a B.Sc. in Physiology from the University of Dundee, Scotland.

Independent of Hansa and its executive management.

Independent of major shareholders of Hansa.

The Board continued

The Board of Directors' work in 2022

During 2022, the Board has held 18 meetings, of which one was the inauguration meeting, and seven was held via Teams. The Board has also made resolutions per capsulam at six occasions.

At the Board meetings held during the 2022 financial year, the directors were present as set forth below. The number of meetings and the maximum number of meetings each director could have been present at during the financial year are stated in parentheses.

Evaluation of the Board of Directors' work

Pursuant to the Code, the Board is to evaluate its work annually, using a systematic and structured process, with the aim of developing the Board's working methods and efficiency. The evaluation has been carried out by the chair of the Board and an independent evaluation company, in the beginning of 2022, 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 2022

Board member	Elected	Present at meetings of the Board	Present at meetings of the Remuneration Committee	Present at meetings of the Audit Committee	Present at meetings of the Scientific Committee	Present at meetings of the US Committee	Independent in relation to the Company and Executive management	Independent in relation to the Company's largest shareholders
Ulf Wiinberg[2]	2016	10(10)	5(5)	–	–	–	Yes	Yes
Peter Nicklin[1,3]	2022	8(8)	1(1)	–	1(1)	1(1)	Yes	Yes
Hilary Malone	2021	18(18)	–	–	1(1)	1(1)	Yes	Yes
Anders Gersel Pedersen	2018	18(18)	5(6)	–	1(1)	–	Yes	Yes
Andreas Eggert	2018	18(18)	6(6)	7(7)	1(1)	–	Yes	Yes
Eva Nilsagård	2019	17(18)	–	7(7)	–	–	Yes	Yes
Mats Blom	2019	18(18)	–	7(7)	–	–	Yes	Yes

[1] Board member since 2022 AGM.
[2] Board member until 2022 AGM.
[3] Member of Remuneration Committee, Scientific Committee and U.S. Committee since 2022 AGM.

The Board continued

Board committees

Audit Committee

After the 2022 AGM, the Audit Committee consisted of Eva Nilsagård, chair, Mats Blom and Andreas Eggert. The Audit Committee is obligated to keep the minutes of its meetings and make the minutes available to the Board. The Audit Committee shall perform the duties incumbent upon audit committees as required by law and the Code.

The Audit Committee assists the Board in overseeing the Company's accounting and financial reporting processes. The Audit Committee consists exclusively of members of the Board who are financially literate and are each considered an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. The Board has determined that all of the members of the Audit Committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act. The Audit Committee is governed by a charter that complies with Nasdaq rules.

The primary duties of the Audit Committee are to:

- Assist the Board in overseeing the Company's financial position, performance, and reporting;
- With respect to the financial reporting, monitor the effectiveness of the Company's internal control system, internal audit and risk management;
- Keep itself informed of the audit of the annual accounts and consolidated accounts;
- Review and monitor the auditor's impartiality and independence, and, in this context, particularly monitor whether the auditor is providing the Company with services other than auditing services; and
- Take decisions regarding guidelines for services other than the auditing services which the external auditor can provide.

Remuneration Committee

After the 2022 AGM, the Remuneration Committee has consisted of Andreas Eggert, chair, Anders Gersel Pedersen and Peter Nicklin. 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; and
- Oversee and administer the Company's employee share option scheme or equity incentive plans in operation from time to time.

Scientific Committee

After the 2022 AGM, the Scientific Committee consists of Anders Gersel Pedersen, chair, Andreas Eggert, Peter Nicklin and Hilary Malone. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board.

The primary duties of the Scientific Committee are to:

- Assist the Board with recommendations regarding the Company's research and development strategies and possibilities; and
- 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

After the 2022 AGM, the U.S. Committee consists of Hilary Malone, chair, and Peter Nicklin. The U.S. Committee is obligated to keep minutes of its meetings and make the minutes available to the Board.

The primary duties of the U.S. Committee are to:

- Discuss and provide input to significant issues and aspects related to the Company's U.S. operations and environment, including R&D, regulatory and commercial aspects; and
- Provide advice and proposals for resolutions, subject to final approval by the Board or the CEO, as the case may be, regarding matters related to the Company's and the group's U.S. operations and development.

Executive management

The Board appoints a CEO to manage the Company. In addition to the CEO, there are five individuals who together make up Company executive management:

> 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 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 (except for 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 chair informs him that he need not to attend. The CEO must also attend all general meetings of the Company.

The CEO may not have any engagements outside of the Company without the Board's approval.

The CEO is 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 chair 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 chair 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 comprise six individuals per 31 December 2022: President and CEO Søren Tulstrup; Senior Vice President, Chief Scientific Officer and Chief Operating Officer 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 2022 are listed further below in this Corporate Governance report.

Holdings in the Company include 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 LTIP2020, LTIP2021 and LTIP2022. 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. The allocation of shares could be lower or zero depending on the share price development and whether the performance conditions are met.

Executive management continued

The number of ESOs refers to the number of employee stock options which the executive holds following the implementation of the incentive programs LTIP2019, LTIP2020, LTIP2021 and LTIP2022. In LTIP2019, each employee stock option entitles the holder to subscribe for one new ordinary share at a subscription price corresponding 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 employee stock options. In LTIP2020, LTIP2021 and LTIP2022, each employee stock option entitles the holder to subscribe for one new ordinary share at an exercise price corresponding to 125 percent 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 and an exercise period of three years.

Søren Tulstrup

Born 1965

President and CEO

Shareholding: 26,541
Share rights: 217,278
ESOs: 435,107

Søren Tulstrup has served as President and Chief Executive Officer since March 2018. He has extensive experience as a senior executive in the global biopharma industry. Prior to joining Hansa, Søren served as Chief Executive Officer of Vifor Pharma AG (SIX: VIFN), (now part of CSL Behring), and he has also served as President & Chief Executive Officer of Santaris Pharma A/S (now part of F. Hoffmann-La Roche AG (SIX: ROG)). Furthermore, Søren has served in several senior general management and commercial roles within Shire Pharmaceuticals (now The Takeda Pharmaceutical Company Limited (TSE: 4502)), Merck & Co., Inc. (NYSE: MRK) and Sandoz Pharma AG (now Novartis AG, or Novartis (NYSE: NVS)) in both Europe and the United States. He holds a Master of Science, Economics and Business Administration from Copenhagen Business School.

Christian Kjellman*

Born 1967

Senior Vice President, Chief Scientific Officer and Chief Operating Officer

Shareholding: 6,213
Share rights: 123,639
ESOs: 197,296

Christian Kjellman has served as Chief Scientific Officer since 2008 and Chief Operating Officer since 2020. Prior to joining Hansa, he served as Principal Scientist at BioInvent AB (STO: BINV), where he focused on novel target evaluation and antibody technology. Prior to that, Christian served as Head of Research at the biopharmaceutical development company Cartela AB. He has extensive research experience in cell and molecular biology and as an Assistant Professor in Molecular Genetics at Lund University. Christian holds a M.Sc. in Chemical Biology and a Ph.D. in Tumour Immunology from Lund University.

* On 30 January 2023 Hansa announced the planned departure of Christian Kjellman by 2024. As of 1 February 2023 Christian Kjellman no longer serves as Chief Scientific Officer nor Chief Operating Officer.

Donato Spota

Born 1971

Senior Vice President, Chief Financial Officer

Shareholding: 5,673
Share rights: 123,639
ESOs: 236,842

Donato Spota has served as Chief Financial Officer since May 2019. He has more than 25 years of pharmaceutical industry experience in international environments, including strategic finance, business development, investor relations and international capital markets transactions. Prior to joining Hansa, he served in various roles at Basilea Pharmaceutica AG (SIX: BSLN), including as Chief Financial Officer. Prior to that, he held different finance roles at F. Hoffmann-La Roche AG (SIX: ROG). He holds a B.A. in Information Technology from the Swiss BBT (Bundesamt für Berufsbildung und Technologie) and an M.B.A. from the Hochschule für Wirtschaft und Umwelt Nürtingen-Geislingen.

Executive management continued

Henk Doude van Troostwijk*

Born 1965

Senior Vice President, Chief Commercial Officer

Shareholding: 2,564
Share rights: 95,000
ESOs: 131,231

Henk Doude van Troostwijk has served as Senior Vice President and Chief Commercial Officer since June 2019, and previously as Vice President Global Commercial Operations for three years. Prior to joining Hansa, Henk served as General Manager of European Commercial Operations and Emerging Markets at Raptor Pharmaceutical Corp. (acquired by Horizon Pharma plc (NASDAQ: HZNP)). Prior to that, he served as Business Unit Director Oncology and Transplantation at Genzyme Europe B.V. (acquired by Sanofi S.A. (Euronext: SAN)). Henk holds an M.B.A. from Henley Management College at the University of Reading, UK.

* As of 16 March 2023, Henk holds the role as Vice President, Commercial Excellence.

Anne Säfström Lanner

Born 1969

Senior Vice President,
Chief Human Resources Officer

Shareholding: 3,565
Share rights: 95,000
ESOs: 110,000

Anne Säfström Lanner has served as Chief Human Resources Officer since June 2020, and served as Vice President Global Human Resources from 2019 to June 2020. Prior to joining Hansa, she served in various senior roles at the European Spallation Source, a European multi-disciplinary research facility, including Head of Resourcing. Prior to that, Head of Human Resources at Cellavision AB (STO:CEVI). Anne has held positions as Head of HR, Head of Resourcing, HR Manager & Deputy Head of HR and has extensive experience from fast growing start-up international companies. Holds a Bachelor of Social Science in Human Resource Management, focusing on strategic organizational development & leadership, from Lund University.

Achim Kaufhold*

Born 1957

Senior Vice President, Chief Medical Officer

Shareholding: –
Share rights: 81,000
ESOs: 94,000

Achim Kaufhold has served as Chief Medical Officer since June 2020. He is a highly experienced senior leader in immunology, infectious diseases and oncology. Achim has over 25 years of international experience within the biotechnology and pharmaceutical industry. Prior to joining Hansa, Achim served in various senior executive positions in general management, product and business development. Has served as Chief Executive Officer of Affitech AS and Pharmexa A/S (both companies merged), Chief Medical Officer of Basilea Pharmaceutica AG (SIX: BSLN), Pharmexa A/S, Chiron (acquired by Novartis (NYSE: NVS)) and Berna Biotech AG (now Johnson & Johnson (LSE: JNJ)). Prior to that, he headed the worldwide clinical development of the pediatric vaccine portfolio of GlaxoSmithKline plc (LSE: GSK). Currently also serves on the board of directors of Biosergen AB (STO: BIOSGN). Graduated as a Doctor of Medicine from the University of Cologne and holds a professorship in Medical Microbiology and Infectious Diseases at the University of Aachen, Germany.

* As of 1 February 2023, Achim also serves as ad-interim Chief Scientific Officer.

Matthew Shaulis*

Born 1973

Chief Commercial Officer and US President, effective 16 March 2023

Shareholding: –
Share rights: –
ESOs: –

Matthew Shaulis has served as Chief Commercial Officer and President of the U.S. affiliate, Hansa Biopharma Inc since March 2023. Prior to his role at Hansa Biopharma, Matthew gained over 20 years of US and international experience in the pharmaceutical industry in general management, global strategic and in-line marketing, sales management, business development, and product and indication launches. He held several senior executive roles at Pfizer Inc. (NYSE: PFE), including President of Inflammation & Immunology for International markets in Europe and Asia, President of Oncology for North America, and more recently as the Senior Vice President responsible for leading the company's global commercial and medical go-to-market model transformation. Prior to that, Matthew served in various leadership roles at Teva Pharmaceutical Industries (NYSE: TEVA), Cephalon, Johnson & Johnson (LSE: JNJ), and Schering-Plough (now part of Merck & Co., Inc. (NYSE: MRK)). He holds a B.S. in Accounting from Pennsylvania State University and an M.B.A. from The Fuqua School of Business, Duke University, North Carolina.

* As of 16 March 2023, Matthew Shaulis joins Hansa as Chief Commercial Officer and US President.

Internal controls and risk management in respect of the financial reporting

Introduction

The following description is based on guidelines issued in 2008 by the Confederation of Swedish Enterprise and FAR.

The Company's internal control procedures in respect of financial reporting have been formulated to ensure, with reasonable certainty, quality, and accuracy in the reporting. The procedures are designed to ensure that the reporting is prepared in accordance with applicable laws and regulations as well as the requirements which are imposed on companies with shares admitted for trading on a regulated market in Sweden. The important prerequisites for achieving this are: (i) the existence of a satisfactory control environment; (ii) the execution of reliable risk assessments; (iii) the existence of established control structures and control activities; and (iv) satisfactory information, communications, and follow-up.

Internal audit

The Board has evaluated the need for an internal audit function and has concluded that it is not warranted for Hansa due to the scope and size of the operations and because the Board's follow-up of the internal control is deemed sufficient to ensure that the internal control is effective. The Board will review the need in the event of changes which may give rise to re-evaluation and at least once annually.

Control environment

Internal control is based on Hansa's control environment, which comprises the values and ethics from which the Board, the Audit Committee, the CEO, the Executive Committee, and other employees communicate and operate. The control environment also includes the Company's organizational structure, leadership, decisional structure, decision-making authority, responsibility, and employee proficiency.

Risk assessment

Risk identification and evaluation are carried out in a manner to also include risks regarding financial reporting. As part of this procedure, items in the income statement and statement of financial position entailing a great risk of significant error are identified. For Hansa, accrued project costs in the Company's clinical projects have, at various times, involved significant amounts. The size of these is based, to a great extent, on management's assessment of the degree of completion. More recently, product sales, contract revenue and inventory valuation became items which could include an elevated risk of significant error as they may involve a significant amount of judgement and estimates. Further, cash and equivalents, as well as current investments, comprise a significant percentage of the Company's total assets and are therefore deemed to give rise to a risk in the financial reporting. Moreover, the fact that Hansa's administration is handled by a relatively small number of individuals is listed as a risk since the dependency on a small number of key individuals becomes great and the possibility to allocate tasks and responsibility becomes limited. The Company's risk management policy and further policies include controls to prevent and detect shortcomings in these and other areas.

Control structure and control activities

The Board's rules of procedure and the instructions for the CEO and Board committees ensure a clear allocation of roles and responsibility. The Board has overall responsibility for internal controls. The CEO is responsible for the development of the system of routines, procedures, and controls for the day-to-day operations. This includes, among other things, guidelines, and role descriptions for the various decision-makers as well as regular reporting to the Board based on established routines. Procedures, routines, instructions and templates for the financial reporting and the day-to-day administrative financial operations and financial issues are documented in Hansa's policies. Routines and activities have been designed to manage and rectify significant risks which are related to financial reporting, and which are identified in the risk analysis. The most significant, overall, group-wide corporate governance documents are the work procedures for the Board, instructions for the CEO, disclosure policy, insider policy, risk management policy, and Code of Conduct.

The primary purpose of control activities is the prevention and early-stage detection of errors in the financial reporting so that they can be addressed and corrected. The Group has implemented entity level controls as well as process controls. Access to IT systems is limited and controlled in accordance with powers and authorization. Manual and automated control steps are incorporated throughout the accounting, financial closing and financial reporting process. The CFO compiles monthly financial reports which, among other things, are to report earnings and cash flow for the preceding period and state budget deviations. These reports, and above all the budget deviations, are analysed and commented upon by Company management. Follow-up takes place through regular meetings for review of these reports and analyses with the various managers and project managers. The work involved with annual accounts and annual reports are processes which pose additional risks for errors in the financial reports. This work is of a less repetitive nature and contains more evaluative elements. Important control activities include, among other things, external confirmations (e.g. bank statements or third party vendor confirmations) as well as ensuring that there is a properly functioning reporting structure in which the various managers and project managers report pursuant to standardized templates, and that important income statement and statement of financial position items are analyzed and commented upon.

Information and communication

The informational activities are governed by a disclosure policy. There are guidelines for external communications which ensure that the Company meets high standards for providing correct information to the shareholders and the financial market. Hansa's communications must be characterized by transparency and must be correct, relevant, reliable and clear; they may not be misleading. All communications must take place in accordance with Nordic Main Market Rulebook for Issuers of Shares, the Swedish Corporate Governance Code, and the laws and requirements imposed on Swedish companies whose shares are admitted for trading on a regulated market. The policy applies to all employees and directors of Hansa Biopharma and applies to both oral and written information.

Internal controls and risk management continued

The Board releases annual reports, financial statements and interim reports. All financial reports are published on the website (www.hansabiopharma.com) simultaneously as being published pursuant to Nasdaq Stockholm's rules and regulations. The annual report is made available on the website and is provided as a hard copy to those shareholders who so wish.

Follow-up

The Board's follow-up on internal controls in respect of the financial reporting takes place, among other things, through follow-up by and through the Audit Committee, on the work and reports of the CFO and the external auditors. The work includes ensuring that measures are taken in respect of the shortcomings and proposed measures generated in conjunction with the external audit. The focus of the follow-up is Hansa compliance with policies, rules and guidelines; and the existence of efficient and suitable processes for risk management, operational management, and internal control. Each year, the external auditor follows up on the selected elements of the internal control within the scope of the statutory audit.

The auditor reports the results of the examination to the Audit Committee and Company management. Significant observations are reported, where applicable, directly to the Board.

The CEO is responsible for compiling all experience from the Company's risk management work and, following discussions with Company management, proposing any changes which the CEO deems necessary or applicable. The Board will decide on any changes.

Compliance

Hansa has adopted a Code of Conduct for all of its directors, officers, and associates which sets forth the standards for business behaviours that apply throughout the Company and describes the expectations Hansa has for its business partners, and those acting on behalf of the Company.

The Code of Conduct contains guidance in the areas of personal and corporate integrity, responsibility toward the Company, its associates and the community as well as responsible and comprehensive compliance management.

Aligned with the Code of Conduct, Hansa has established a global compliance framework. This compliance framework includes, but is not limited to, compliance and business unit policies and procedure documents, compliance risk mitigation and violation reporting processes, data privacy precautions as well as internal auditing and monitoring activities.

Executive Remuneration – to be approved by the 2023 AGM

The following remuneration guidelines were approved at the 2022 AGM and are proposed for re-approval at the 2023 AGM without changes.

The senior executives, the CEO and members of the executive committee, fall within the provisions of these guidelines. 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 guidelines by the 2023 AGM.

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 can recruit and retain qualified personnel, consequently, it is necessary that the Company offers market competitive remuneration.

Long-term (share-based) incentive programs have been implemented in the Company. Such programs have been resolved by the AGM and are therefore excluded from these guidelines. The program includes, 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.

The guidelines enable 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.

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.

The decision-making process to determine, review and implement the guidelines

The Board of Directors has established a committee (the Remuneration Committee), with the task of preparing, within the Board of Directors, the guidelines for remuneration for senior executives. The Board of Directors shall propose revised guidelines at least every fourth year and submit it to the AGM. 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 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 these guidelines – resolve on, among other things, share-related or share price-related remuneration.

Fixed Base Salary

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	> Normally reviewed annually and increases will usually be effective from 1 April or following a change in responsibilities. > The Remuneration Committee will consider, among other things, the following parameters when reviewing fixed base salary: — Economic and salary conditions and trends. — The individual's performance and responsibilities. — Base salaries and total remuneration at other companies that operate in the same markets, typically benchmarked against similar roles.

Executive Remuneration – to be approved by the AGM 2023 continued

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 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	To incentivise and create focus on the delivery of corporate objectives and strategic criteria.
Operational Details	> 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. > 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. > 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. > 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).
Opportunity Levels	The maximum opportunity for STI can amount up to max 75 percent of fixed base salary. The Remuneration Committee shall have the possibility to review the opportunity levels in order to ensure market competitiveness.
Performance criteria	The STI plan awards shall be based on corporate objectives and individual objectives and be linked to predetermined and measurable criteria. The criteria shall be designed so as to contribute to the Company's business strategy and long-term interests. For financial objectives, the evaluation shall be based on the latest financial information made public by the Company.

Pension Benefits

Purpose and link to strategy	Provide competitive and cost-effective pension benefits.
Operational Details	Pension benefits shall be defined contribution (premium defined) unless the individual concerned is subject to defined benefit pension under mandatory collective agreement provisions. > Variable cash remuneration shall not qualify for pension benefits unless the executive officer is part of mandatory collective agreed provisions where this is stipulated. > Early retirement may be offered selectively and only after a special decision by the Remuneration Committee, with a defined contribution early retirement scheme. > For executive officers governed by rules other than Swedish, pension 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.
Opportunity Levels	The pension premiums for defined contribution pension shall amount to not more than 30 percent of the fixed base salary.

Other Benefits

Purpose and link to strategy	Provide competitive and cost-effective benefits.
Operational Details	> 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. > 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. > 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.
Opportunity Levels	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: > Provide the relevant level of benefit depending on role and the individual circumstances. > Be in line with comparable roles in companies with similar size and complexity in the relevant market. > Be appropriate compared to the benefits offered to the wider workforce in the relevant market.

Executive Remuneration – to be approved by the AGM 2023 continued

Termination of employment

Details	> 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 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. — 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. > When termination is made by the senior executive the period of notice may not exceed six months. No severance pay will be paid. > 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. 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.

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 Hansa's 2022 Annual Report.

Remuneration

11

Remuneration report 2022

Introduction

This remuneration report provides an outline of how Hansa's guidelines for remuneration (the "Remuneration guidelines"), adopted by the annual general meeting 2022, were implemented in 2022. The report also provides information on remuneration to the CEO and a summary of Hansa's outstanding share-based long-term incentive programs. The report has been prepared in accordance with the Swedish Companies Act and the Remuneration Rules issued by the Swedish Corporate Governance Board.

Further information on senior executive remuneration is available in Note 14 to the Consolidated Financial Statements in the Annual Report 2022. Information on the work of the remuneration committee in 2022 is set out in the corporate governance report included in the Annual Report 2022.

Remuneration of the Board of Directors is not covered by this report. Such remuneration is resolved annually by the annual general meeting and disclosed in Note 14 to the Financial Statements of the Parent Company in the Annual Report 2022.

Key Developments 2022

Company performance in 2022

The CEO summarizes the Company's overall performance in his statement in the Annual Report 2022. In addition, the directors report included in the Annual Report 2022 summarizes the Company's 2022 business and operations.

The Company's remuneration guidelines: scope, purpose and deviations

A prerequisite for the successful implementation of the Company's business strategy and safeguarding of its long-term interests, including its sustainability, is that the Company is able to recruit and retain highly qualified personnel, consequently, it is necessary that the Company offers market competitive remuneration. This has been becoming of paramount importance as the Company is required to attract talent from and in Sweden, other European countries and the US. Under Hansa's remuneration guidelines, remuneration of senior executives shall be on market terms and may consist of the following components: fixed base salary, variable cash remuneration (including STI), pension benefits and other benefits.

The Remuneration guidelines, adopted by the annual general meeting 2022, can be found in the Governance section in the Annual Report 2022. During 2022, 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. No remuneration has been reclaimed.

In addition to remuneration covered by the Remuneration guidelines, the annual general meetings of Hansa have also resolved to implement long-term share-based incentive plans for certain groups of Hansa employees and on remuneration guidelines for the Board of Directors.

Table 1 – Total remuneration of the CEO (kSEK)[1]

Table 1 below sets out the total remuneration related to Hansa's CEO for 2022.

		1 Fixed remuneration		2 Variable remuneration					
Name of Director, position	Financial year	Base salary	Other benefits	One-year variable	Multi-year variable	3 Extraordinary items	4 Pension expense	5 Total remuneration	6 Proportion of fixed and variable remuneration in %
Søren Tulstrup (CEO)	2022	7,586[2]	-	4,024	779[3]	0	0	12,389	61% / 39%

1 Except for Multi-year variable remuneration, the table reports remuneration earned in 2022. Multi-year variable remuneration is reported if vested in 2022, 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

2 Includes KSEK 1,694, representing 30% of base salary, intended for own pension contribution

3 Corresponds to 15,466 ordinary Hansa shares at a value of SEK [open] each received under the LTIP 2019 and 66,347 stock options at no value vested and earned under the LTIP 2019. The stock options do not carry value as of the date of vesting since share price was below the exercise price.

Remuneration report 2022 continued

Share based remuneration

Outstanding share-based long-term incentive programs

As of December 31, 2022, the Company has four long-term incentive programs outstanding in which amongst others also the CEO participates; long-term incentive program ("LTIP") 2019, 2020, 2021 and 2022.. LTIP 2019 partly vested and partly lapsed during 2022.

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 a employee stock option ("ESO") series. The CEO was granted 35,151 share rights and 66,347 employee stock options but chose not to acquire any warrants under incentive program 2019.

Under the performance-based share rights program, each share right entitled the holder to receive one ordinary share in Hansa Biopharma AB free-of-charge provided that the below performance conditions were met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of ordinary shares that each participant was entitled to receive was conditional upon the following performance conditions being met during the vesting period: (a) 22 percent of the shares in the event that market approval is obtained by EMEA within the EU, (b) 22 percent of the shares in the event that at least 10 patients enrolled in US RCT (ConfIdeS), 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 ESOs allotted free-of-charge. The ESOs have a vesting period of three years and an exercise period of three years. Each warrant or ESO entitles the holder to acquire one new ordinary share in Hansa Biopharma AB at a strike price of SEK 196.20, which corresponds to 110 percent of the volume weighted average share price during the ten (10) trading days immediately prior to the offer to subscribe for the options and/or warrants.

In total, 278,181 share rights, 149,148 ESOs and 11,000 warrants were outstanding under the LTIP 2019 as of 1 January 2022. During 2022, 122,400 share rights and 149,148 ESOs vested, while 155,781 share rights and 11,000 warrants lapsed.

Long-term incentive program 2020

On June 23, 2020, the annual general meeting in Hansa Biopharma resolved to adopt a long-term incentive program for certain employees of the Group. The long-term incentive program 2020 includes two elements; one performance-based share rights program, and one employee stock option program. The CEO has been granted 57,278 share rights and 128,760 employee stock options ("ESO") under the long-term incentive program 2020.

Under the performance-based share rights program, each share right entitles the holder to receive one ordinary share in Hansa Biopharma AB free-of-charge provided that the below performance conditions are met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of shares that each participant is entitled to receive is also conditional upon the following performance conditions being met during the vesting period: (a) 22 percent of the shares in the event the U.S. randomized controlled trial (ConfIdeS) has enrolled 64 patients, (b) 11 percent of the shares in the event that top-line data read out of the ongoing Phase 2 study in either AMR or GBS is completed with data providing a solid scientific rational for a path forward, (c) 11 percent of the shares in the event that at least 70 percent of the targeted transplantation centres in Europe have been initiated, and (d) up to 56 percent of the shares related to the total shareholder return on the Company's ordinary shares (if the total shareholder return for the Company's ordinary share during the vesting period reaches or exceeds 75 percent, the participant will be awarded 56 percent of the performance shares and if the total shareholder return for the Company's ordinary share falls below 25 percent, no allotment of performance shares will be made under this performance condition. In between the percentages, allotment will be made linearly.

Remuneration report 2022 continued

The option program 2020 consists of ESOs allotted free-of-charge. The ESOs have a vesting period of three years, and an exercise period of three years. Each ESO entitles the holder to acquire one ordinary share in Hansa Biopharma AB, provided that the participant, with certain exceptions, remains employed within the Group, at an exercise price of SEK 315.75 which corresponds to 125 percent of the volume weighted average share price during the 10 trading days immediately preceding the respective allotment of the ESOs.

In total, 398,311 share rights and 487,520 ESOs were outstanding under the long-term incentive program 2020 as of 31 December 2022.

Long-term incentive program 2021

On May 12, 2021, the annual general meeting in Hansa Biopharma resolved to adopt a long-term incentive program for certain employees of the Group. The long-term incentive program 2021 includes two elements: one performance-based share rights program, and one employee stock option program. The CEO has been granted 80,000 share rights and 120,000 employee stock options ("ESO") under the long-term incentive program 2021.

Under the performance-based share rights program, each share right entitles the holder to receive one ordinary share in Hansa Biopharma AB free-of-charge provided that the below performance conditions are met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of shares that each participant is entitled to receive is also conditional upon the following performance conditions being met during the vesting period: (a) 22 percent of the shares in the event 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 ESOs allotted free-of-charge. The ESOs have a vesting period of three years, and an exercise period of three years. Each ESO entitles the holder to acquire one ordinary share in Hansa Biopharma AB, provided that the participant, with certain exceptions, remains employed within the Group, at an exercise price of SEK 192.20 which corresponds to 125 percent of the volume weighted average share price during the 30 trading days immediately preceding the respective allotment of the ESOs.

In total, 551,263 share rights and 430,000 employee stock options were outstanding under the long-term incentive program 2021 as of 31 December 2022.

Long-term incentive program 2022

On June 30, 2022, the annual general meeting in Hansa Biopharma resolved to adopt a long-term incentive program for certain employees of the Group. The long-term incentive program 2022 includes two elements: one performance-based share rights program, and one employee stock option program. The CEO has been granted 80,000 share rights and 120,000 employee stock options ("ESO") under the long-term incentive program 2022.

Under the performance-based share rights program, each share right entitles the holder to receive one ordinary share in Hansa Biopharma AB free-of-charge provided that the below performance conditions are met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of shares that each participant is entitled to receive is also conditional upon the following performance conditions being met during the vesting period: (a) 22 percent of the shares in the event the U.S. FDA has approved imlifidase in the U.S. (b) 11 percent of the shares in the event that Imlifidase has been approved, or a Marketing Authorization Application/Biologics License Application has been submitted, in any jurisdiction in an indication outside kidney transplant, (c) 11 percent of the shares in the event that at least 80% of the targeted transplantation centers in Europe have had repeat business, and (d) up to 56 percent of the shares related to the total shareholder return on the Company's ordinary shares (if the total shareholder return for the Company's ordinary share during the vesting period reaches or exceeds 75 percent, the participant will be awarded 56 percent of the

performance shares and if the total shareholder return for the Company's ordinary share falls below 25 percent, no allotment of performance shares will be made under this performance condition. In between the percentages, allotment will be made linearly.

The option program 2022 consists of ESOs allotted free-of-charge. The ESOs have a vesting period of three years, and an exercise period of three years. Each ESO entitles the holder to acquire one ordinary share in Hansa Biopharma AB, provided that the participant, with certain exceptions, remains employed within the Group, at an exercise price of SEK 70.00 which corresponds to 125 percent of the volume weighted average share price during the 30 trading days immediately preceding the respective allotment of the ESOs.

In total, 543,000 share rights and 384,000 employee stock options were outstanding under the long-term incentive program 2022 as of 31 December 2022.

Remuneration report 2022 continued

Remuneration of the CEO in share rights and employee stock options

Table 2 – Remuneration of the CEO in share rights

	The main conditions of share rights					Information regarding the reported financial year						
						Opening balance	During the year 2022			Closing balance 31 Dec 2022		
Name, position	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 Tulstrup (CEO)	LTIP2019	2019-2022	2019-06-17	2022-06-17	2022-06-17	35,151	0	15,466	19,685	0	0	0
	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	2021-06-07	2024-06-07	2024-06-07	80,000	0	0	0	80,000	80,000	80,000
	LTIP2022	2022-2025	2022-07-20	2025-07-20	2025-07-20	0	80,000[1]	0	0	80,000	80,000	80,000
						172,429	**80,000**	**15,460**	**19,685**	**217,278**	**217,278**	**217,278**

1 Each of the 80,000 Share rights represents a computed fair value of SEK 80.29 per share right calculated based on a Monte Carlo simulation. For further information please refer to Note14 to the Consolidated Financial Statements in Hansa Biopharma's Annual Report 2022

Table 3 – Remuneration of the CEO in stock options

	The main conditions of stock options					Information regarding the reported financial year								
							Opening balance		During the year 2022			Closing balance 31 Dec 2022		
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)	8 Stock options 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 Tulstrup (CEO)	LTIP2019	2019-2022	2019-06-17	2022-06-17	2022-06-17	2022-06-17 2025-06-17	196.20	66,347	0	66,347	0	66,347	0	0
	LTIP2020	2020-2023	2020-07-23	2023-07-23	2023-07-23	2023-07-23 2026-07-23	315.75	128,760	0	0	0	128,760	128,760	128,760
	LTIP2021	2021-2024	2021-06-07	2024-06-07	2024-06-07	2024-06-07 2027-06-07	192.20	120,000	0	0	0	120,000	120,000	120,000
	LTIP2022	2022-2025	2022-07-20	2025-07-20	2025-07-20	2025-07-20 2028-07-20	70.00	0	120,000[1]	0	0	120,000	120,000	120,000
								315,107	**120,000**	**66,347**	**0**	**435,107**	**368,760**	**435,107**

1 Each of the 120,000 Stock options represents a computed fair value of SEK 52.45 per stock option calculated based on a Black-Scholes valuation. For further information please refer to Note14 to the Consolidated Financial Statements in Hansa Biopharma's Annual Report 2022

Remuneration report 2022 continued

Application of performance criteria related to the 2022 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 2022, the share rights program under the LTIP 2019, in which the CEO held 35,151 performance share rights, hit the vesting date. Since the pre-defined performance criteria were only partly met, plan participants received 44% of the maximum potential share allocations. In total, 122,400 shares were allocated under the plan of which the CEO received 15,466 shares. Further, in 2022, the employee stock option ("ESO") program under the LTIP 2019, in which the CEO holds 66,347 ESOs, vested. In accordance with the terms of the LTIP 2019, plan participants may exercise the vested ESOs over a 3-year period from vesting through 17 June 2025 at an exercise price of SEK 196.20.

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 2022. Such criteria are based on the annual corporate objectives and form the basis for the short-term performance measurement of the CEO and, together with pre-defined individual objectives, accounting for up to 80% of the performance targets for all other members of the executive management.

Table 4 – Criteria for payment of variable short-term compensation

Name, Position	Description of the criteria related to the corporate goals	2022 corporate goals	Overall weight	a) Measured goal achievement and b) Actual weighted outcome
Søren Tulstrup, CEO	Imlifidase commercial launch – Sales, market access, EMA post-approval commitments	3 sub-goals	19%	a) 130% b) 24%
	Progressing pipeline activities in transplantation, autoimmune indications, gene therapy and NiceR	7 sub-goals	49%	a) 76% b) 37%
	Business development and financial strength	2 sub-goals	27%	a) 108% b) 30%
	Corporate Social Responsibility	1 sub-goal	5%	a) 100% b) 5%
				Total: 95%

Comparative information on remuneration and Company performance

	2022	2021
CEO remuneration		
Søren Tulstrup, CEO	**kSEK 12,451**	kSEK 10,582
Company's performance		
Achievement of the annual corporate objectives	**95%**	85%
Operating profit / (loss)	**kSEK (611,134)**	kSEK (548,282)

Glossary

12

Glossary

Adeno-associated virus (AAV)
AAV is a versatile viral vector technology that can be engineered for very specific functionality in gene therapy applications.

Allogeneic hematopoietic stem cell transplantation (HSCT)
Allogeneic HSCT, also known as "bonemarrow" transplantation, involves transferring stem cells from a healthy person (the donor) to the patient's body after high-intensity chemotherapy or radiation. The donated stem cells can come from either a related or an unrelated donor.

AMR
Antibody mediated transplant rejection.

Antibody
One type of protein produced by the body's immune system with the ability to recognize foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM.

Anti-Glomerular Basement Membrane (anti-GBM) disease (Goodpasture syndrome)
Anti-GBM antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

Autoimmune disease
Diseases that occur when the body's immune system reacts against the body's own structures.

B-cells
B-cells, also known as B-lymphocytes, are a type of white blood cell of the lymphocyte subtype. They are an important part of the adaptive immune system and secrete antibodies.

Biologics License Application (BLA)
A Biologics License Application (BLA) is submitted to the Food and Drug Administration (FDA) to obtain permission for distribution of a biologic product across the United States.

CD20
B-lymphocyte antigen CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

Clinical studies
Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

Clinical Phase 1
The first time a drug under development is administered to humans. Phase I studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

Clinical Phase 2
Refers to the first time a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

Clinical Phase 3
Trials that involve many patients and often continue for a longer time; they are intended to identify the drug's effects and side effects during ordinary but still carefully controlled conditions.

DSA
Donor specific antibodies. Donor specific antibodies are antibodies in a transplant patient which bind to HLA and/or non-HLA molecules on the endothelium of a transplanted organ, or a potential donor organ. The presence of pre-formed and de novo (newly formed) DSA, specific to donor/recipient mismatches are major risk factors for antibody-mediated rejection.

EMA
The European Medicines Agency (EMA) is a European Union agency for the evaluation of medicinal products.

Enzyme
A protein that accelerates or starts a chemical reaction without itself being consumed.

ESOT
The European Society for Organ Transplantation (ESOT) is an umbrella organization which oversees how transplantations are structured and streamlined.

FDA
U.S. Food and Drug Administration.

Guillian-Barré syndrome
GBS, Guillian-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.

Glossary continued

HLA
Human Leukocyte Antigen is a protein complex found on the surface of all cells in a human. The immune system uses HLA to distinguish between endogenous and foreign.

IgG
IgG, Immunoglobulin G, is the predominant type of antibody in serum.

Imlifidase
Imlifidase, is the immunoglobulin G-degrading enzyme of Streptococcus pyogenes, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

IND
An Investigational New Drug (IND) application is required to get approval from the FDA to administer an investigational drug or biological product to humans.

INN
International Nonproprietary Name (INN) is a generic and non-proprietary name to facilitate the identification of a pharmaceutical substances or active pharmaceutical ingredient. Each INN is a unique name that is globally recognized and is public property. The INN system has been coordinated by the World Health Organization (WHO) since 1953.

In vitro
Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

In vivo
Term within biomedical science to indicate that experiments or observations are made in living organisms.

IVD
IVD, In vitro diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

Marketing Authorization Application (MAA)
A Marketing Authorization Application (MAA) is an application submitted to the European Medicines Agency (EMA) to market a medicinal product in the EU member states.

Neutralizing Antibodies (NAbs)
NAb is an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically.

Pivotal trial
A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase 2 studies can be used as pivotal studies if the drug is intended to treat lifethreatening or severely debilitating conditions.

PRA
Panel Reactive Antibody (PRA) is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as a percentage between 0% and 99%. It represents the proportion of the population to which the person being tested will react via pre-existing antibodies.

Preclinical development
Testing and documentation of a pharmaceutical candidate's properties (e.g. safety and feasibility) before initiation of clinical trials.

Randomized Control Trial (RCT)
(RCT) is a study design where the trial subject is randomly allocated to one of two or more study cohorts to test a specific intervention against other alternatives, such as placebo or standard of care. The study participants are followed up to compare outcomes of different cohorts.

Streptococcus pyogenes
A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

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

Phone: +46 46 16 56 70
E-mail: info@hansabiopharma.com

www.hansabiopharma.com