HANSA BIOPHARMA

Building a global leader in rare diseases

Annual Report 2020

Contents

Overview

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Hansa Biopharma in brief

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize 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 can enable kidney transplantation in highly sensitized patients. The Company 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.

Actual patient has given consent to provide images

Chairman letter

> We remain confident Hansa has what it takes to become a leading player in rare diseases

Dear Shareholders,

2020 was a landmark year for Hansa Biopharma. The Company took a major step forward towards becoming a fully integrated commercial stage biopharmaceutical Company with the conditional approval of Idefirix® (imlifidase) in Europe.

This milestone is not only a great achievement for Hansa but, more importantly, it is great news for highly sensitized patients in need of kidney transplantation. Moreover, it is a testimony to the successful efforts by the highly dedicated team at Hansa since the Company's foundation in 2007.

This achievement could not have been accomplished without the talented and committed team at Hansa, who have been steadfast in turning an idea into reality through great science and innovation. The Board and I are truly impressed by the passion and dedication the Hansa team has shown for more than a decade.

Hansa Biopharma's long-term goal is to become a recognized global leader in rare diseases across multiple broad therapeutic areas through the development of new transformative drugs that can be life altering for patients suffering from rare immunologic diseases. Given the versatility and flexibility of the scientific platform, the strength of the team and the support from shareholders, we remain confident Hansa has what it takes to become a leading player in rare diseases.

Hansa's IgG enzyme-cleaving platform received clinical and regulatory validation across multiple indications in 2020, which is unusual for a Company at this stage. Beyond receiving conditional approval for imlifidase in kidney transplantation in Europe, Hansa also obtained proof-of-concept for imlifidase in anti-GBM disease with positive data readouts from its phase 2 program in this autoimmune disease. Last but not least, the Company also entered into an exciting partnership with Sarepta Therapeutics to develop and promote imlifidase in gene therapy.

The agreement with Sarepta underscores the significant potential this platform holds in the large and promising gene therapy field. Enabling a larger share of patients to benefit from gene therapy by providing an antibody-free environment for patients suffering from rare genetic diseases in advance of administering the gene therapy would clearly be of critical value for these patients.

Finally, we are happy to see the successful continuation of our efforts to build and diversify our shareholder base. Since 2014, Hansa's shareholder base has expanded 14x to approximately 17,000 shareholders today. We continue to see increasing interest from institutional investors, which now make up more than 70% of the capital, including some of the most renowned and leading global life science funds. We have also diversified our shareholder base outside of Sweden and now have more than half of Hansa's capital represented by institutions from the US, UK and continental Europe. Securing a strong and international shareholder base is of great importance for the continued support for Hansa Biopharma to leverage its highly investable platform.

We are building Hansa into a global leader in rare diseases, and this is just the beginning. An exciting journey lies ahead as Hansa expands across multiple broad therapeutic areas with new transformative therapies for patients who need them to lead long and healthy lives.

On behalf of the Board
of Directors,

Ulf Wiinberg
Chairman, Hansa Biopharma
Lund Sweden, April 2021

2020 highlights

March

Hansa Biopharma announces long term follow-up data demonstrating 2-year graft survival of 89% after imlifdase treatment and transplantation.

June

CHMP adopts a positive opinion, recommending conditional approval of Idefirix® (imlifidase) for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

July

Hansa Biopharma announces an exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as a pre-treatment to enable Sarepta gene therapy treatment in Duchenne muscular dystrophy (DMD) and Limb-girdle muscular dystrophy (LGMD).

August

The EU Commission grants conditional approval for Idefirix® in highly sensitized kidney transplant patients in the European Union.

September

Hansa Biopharma strengthens its balance sheet with the successful completion of SEK 1.1bn (USD 121m) placement of newly issued shares. The share issue was multiple times oversubscribed due to high demand from US, European and Swedish institutional investors.

October

Hansa Biopharma AB certified as a Great Place to Work®.

Hansa Biopharma hosted its third Capital Markets Day in Copenhagen.

January | February | **March** | April | May | **June** | **July** | **August** | **September** | **October** | November | December

CEO statement

> Hansa Biopharma's evolution into a fully integrated, commercial-stage biopharmaceutical company is becoming a reality

2020 was a highly successful and transformative year for Hansa Biopharma – a year where we saw significant progress across all areas important to building a leading biopharmaceutical company: Pipeline development, medical and commercial operations and organizational development.

Most notably, we received conditional approval of Idefirix® by the European Commission for desensitization treatment of highly sensitized kidney transplant patients – our first market approval. We are also very excited about our continued progress in advancing Hansa's valuable pipeline of drug candidates in therapeutic areas beyond transplantation. In July, we achieved a landmark milestone with the exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as a potential pre-treatment prior to the administration of gene therapy for Duchenne muscular dystrophy and Limb-girdle muscular dystrophy in patients with neutralizing antibodies (NAbs) to adeno-associated virus (AAV). The partnership is progressing as planned, and in the second half of 2020 Sarepta initiated ongoing pre-clinical investigations with imlifidase in the gene therapy setting.

There is ongoing strong interest from companies active in the gene therapy space in using our IgG-cleaving enzymes as a potential preconditioning therapy to enable gene therapy in patients that are not eligible today due to NAbs against AAV vectors. Our enzymes, used as a pre-treatment before the introduction of gene therapy, could potentially improve both the efficacy and safety of gene therapy and enable a larger group of patients to benefit from the very promising gene therapies now being investigated and becoming available. We see the gene therapy setting as an important value driver for Hansa and we will continue to build our footprint in this space, including through potential additional partnerships.

In 2020, we also announced positive high-level data from an investigator-initiated phase 2 trial with imlifidase in anti-GBM antibody disease, a serious, ultra-rare disease with no approved therapies on the market. We are very encouraged by the positive outcome, which demonstrated that two-thirds of the anti-GBM patients in the trial achieved dialysis independence six months after treatment. These positive results mark another important milestone for Hansa and serve as validation of the potential of our technology platform to develop valuable drug candidates for indications beyond transplantation.

The COVID-19 global pandemic materially impacted our pipeline activities during 2020, as patient recruitment in the GBS and AMR Phase 2 programs was temporarily halted for a large part of the year.

Søren Tulstrup
President and CEO,
Hansa Biopharma

Enrollment was reinitiated in December 2020 under a risk-based, site-by-site approach and, depending on the development and impact of the COVID-19 pandemic, we expect to finalize recruitment in both studies towards the end of 2021.

In the U.S., we are in ongoing discussions with the U.S. Food and Drug Administration (FDA) around a proposed study protocol for a randomized, controlled study of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients. Assuming a near term approval of the final study protocol and depending on the development of the COVID-19 pandemic in the U.S. and its impact on patient enrollment, the Company expects to complete patient recruitment for this study in 2022, enabling us to potentially submit a Biologics License Application (BLA) by 2023 under the accelerated approval pathway.

In addition to the multiple opportunities to develop imlifidase as a drug candidate for a variety of indications, we see significant potential for our next generation enzymes from the NiceR program that we are developing for repeat dosing. Drug candidates from this program have the potential to address high unmet medical needs within chronic autoimmune diseases, transplantation, repeat dosing gene therapy and oncology. Throughout the past year we have worked on completing a GMP process for our lead candidate and expect to commence IND-enabling toxicology studies during the first half of 2021. Once the toxicology studies are completed, we anticipate to move forward into human trials with this very promising program.

Again in 2020, we were able to productively expand the organization by attracting highly talented and experienced life science professionals across a range of functional areas. We are building a purpose driven, agile high-performance team, and we are very pleased to see our strong culture and work ethics reflected in the certification in 2020 of Hansa Biopharma as a "Great Place to Work" by the Great Place to Work Institute based on employee feedback.

We are also taking steps to sharpen our focus and commitment in advancing Hansa's platform beyond transplantation as we transition into the next phase of our development as a platform Company with the establishment of four distinct franchises in transplantation, autoimmune diseases, gene therapy and oncology/new therapies.

We will build on the strong foundation laid through our accomplishments in 2020 and are well positioned to execute successfully on our key priorities and objectives for 2021, which are to:

1. Ensure the successful launch of Idefirix® (imlifidase) in leading transplantation centres in select European markets

2. Initiate a randomized, controlled clinical study in the U.S. to support a future filing of a Biologics License Application (BLA) for imlifidase in highly sensitized patients waiting for a kidney transplant in the U.S.

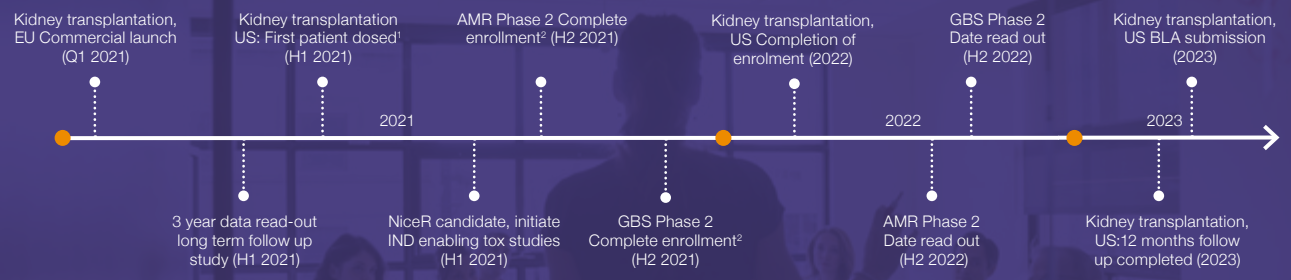
3. Continue to build on the strong momentum behind our efforts to advance our pipeline of drug candidates within autoimmune diseases and gene therapy

Hansa Biopharma's evolution into a fully integrated, commercial-stage biopharmaceutical Company is becoming a reality. An exciting year lies ahead for Hansa as we launch the commercial roll-out of the Company's first approved drug, Idefirix®, to help highly sensitized patients get off dialysis by enabling a potentially lifesaving transplantation.

I look forward to updating you on our progress as we deliver on our mission to bring lifesaving and life altering therapies to patients with rare diseases who need them, while generate value to society at large.

Søren Tulstrup
President and CEO, Hansa Biopharma
Lund Sweden, April 2021

Upcoming milestones
Milestones subject to potential COVID-19 impact



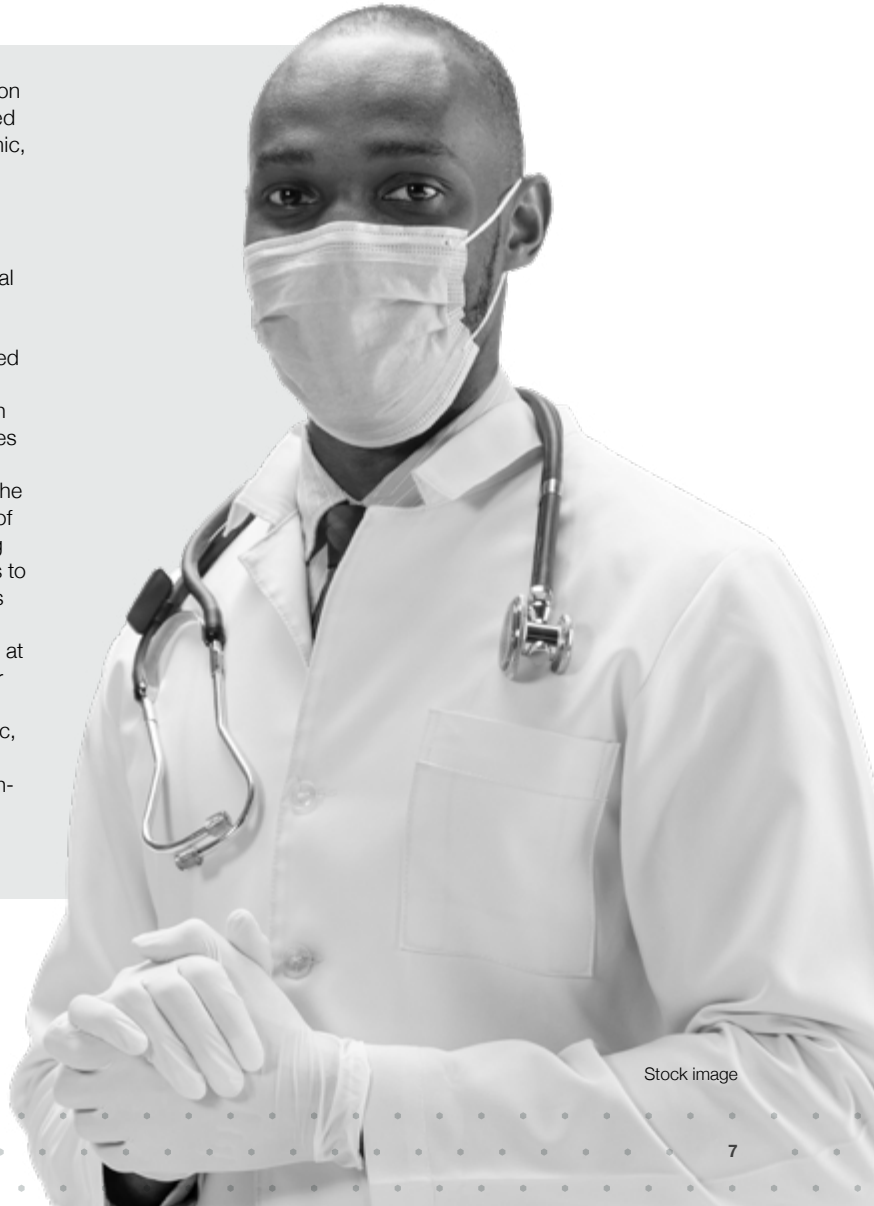
[1] FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients.
[2] AMR/GBS Due to the impact from the COVID-19 pandemic, the enrollment in GBS and AMR were temporarily halted during large parts of 2020. Hansa Biopharma reinitiated enrollment in Q4 2020 under a risk-based, site-by-site approach.

Impact from the COVID-19 pandemic

While 2020 was a transformative year for Hansa Biopharma marked by significant progress, the Company was also impacted by the negative effects of the escalating COVID-19 pandemic, as certain trials and activities were paused. Depending on the development of the pandemic in 2021, Hansa Biopharma may still see adverse impact to its operational business and trial activities this year. The Company will however continue to take appropriate measures to protect employees and take social responsibility.

Hansa Biopharma has identified the following key areas, which potentially may be impacted from the global healthcare crisis in the course of 2021:

- Following an expected near-term approval of the study protocol for a new randomized controlled study of imlifidase in highly sensitized patients in the US; Hansa expects to set up centres in the US and prepare for commencement of patient enrollment. Depending on the development of the global pandemic, Hansa expects the first patient to be enrolled in the first half of 2021. Assuming the recruitment of patients is initiated as expected, patient enrollment is expected to be completed by 2022 with a potential BLA filing under the accelerated approval pathway in 2023.
- The commercial roll out of Idefirix® to leading transplantation centres in early launch European markets has been initiated this spring. Depending on the development of the pandemic, Hansa Biopharma's commercial launch activities may be delayed in some markets due to limited access to, and reduced decision-making ability of, market access authorities, potentially causing delays in the granting of reimbursement status to Idefirix® by authorities in traditional early launch countries.
- Patient enrollment into the two phase 2-programs in AMR and GBS was reinitiated in December 2020. Five of targeted 10 centers have now been reopened in the GBS program, while six of targeted eleven centres have been reopened in the AMR program as of March 31, 2021. Opening of centres and recruitment is being carried out under a risk-based, site-by-site approach. Depending on the development of the COVID-19 pandemic, timelines for completing enrollment of patients at the clinics may be adversily affected. Assuming recruitment is progressing as expected, Hansa anticipates to complete enrollment in the AMR and GBS studies towards the end of this year, as previously guided.
- Preparations for upcoming interactions with the regulators at EMA and FDA to determine the regulatory path forward for imlifidase in anti-GBM disease are being carried out. Depending on the development of the COVID-19 pandemic, the regulatory path forward for approval of imlifidase in anti-GBM disease may be impacted from delayed decision-making or repriotizations by the regulators.



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Strategy

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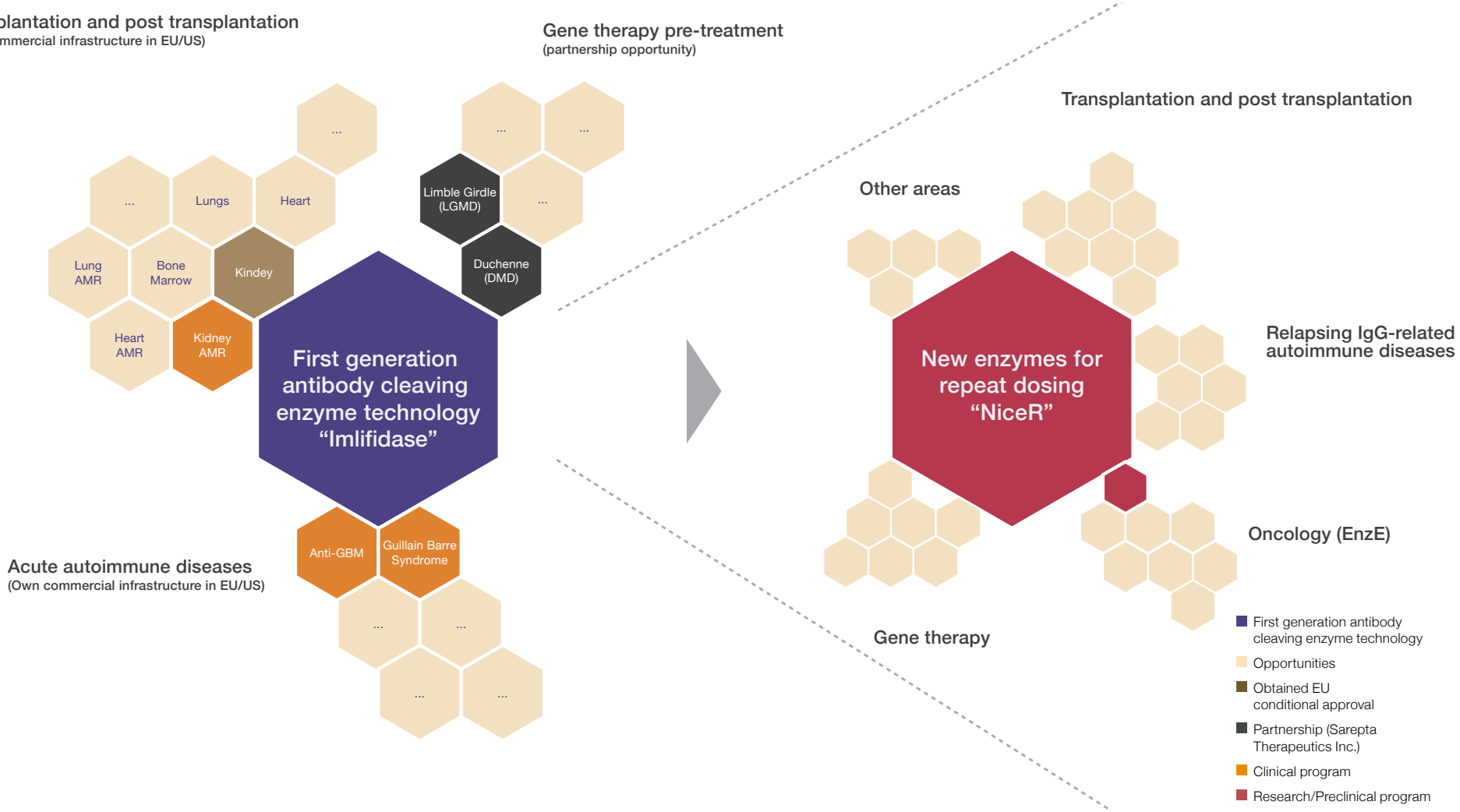
Potential indication universe



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

Potential indication universe continued

The Company's first-generation antibody-cleaving enzyme, imlifidase, is a very efficacious protein with properties to fast and effectively inactivate IgG antibodies. Since imlifidase is derived from the human pathogen *Streptococcus pyogene*s it has certain limitations due its immunogenicity. As such it is only being developed for treating and preventing diseases caused by IgG antibodies in the acute phase or to enable transplantation for highly sensitized patients.

Even though the imlifidase molecule is immunogenic, there are a large number of relevant indications and specific disease areas that can be targeted within this universe. Beyond kidney transplantation, which has received conditional approval for marketing in Europe, Hansa Biopharma is also investigating imlifidase as a potential drug candidate for treatment of AMR (active Antibody-Mediated Rejection episodes) in kidney transplantation. In addition, there are other solid organs which may be relevant for imlifidase, both pre- and post transplantation, including heart, lung and bone marrow.

Beyond transplantation, there are a number of growth vectors in the acute autoimmune disease space relevant for imlifidase. Specifically, Hansa will be targeting monophasic acute autoimmune diseases. If a patient suffering from such a disease can successfully defend against an acute attack in time to prevent further disease progression, patients can overcome these autoimmune diseases and potentially return to a normal life. In the acute autoimmune disease space, Hansa Biopharma has two ongoing programs. The first program is in anti-GBM antibody disease, which is an ultra-rare acute autoimmune disease affecting the kidneys. The second program is in Guillain-Barré Syndrome (GBS). GBS is an acute autoimmune attack on the peripheral nervous system, which rapidly and progressively weakens extremities if not stopped in time.

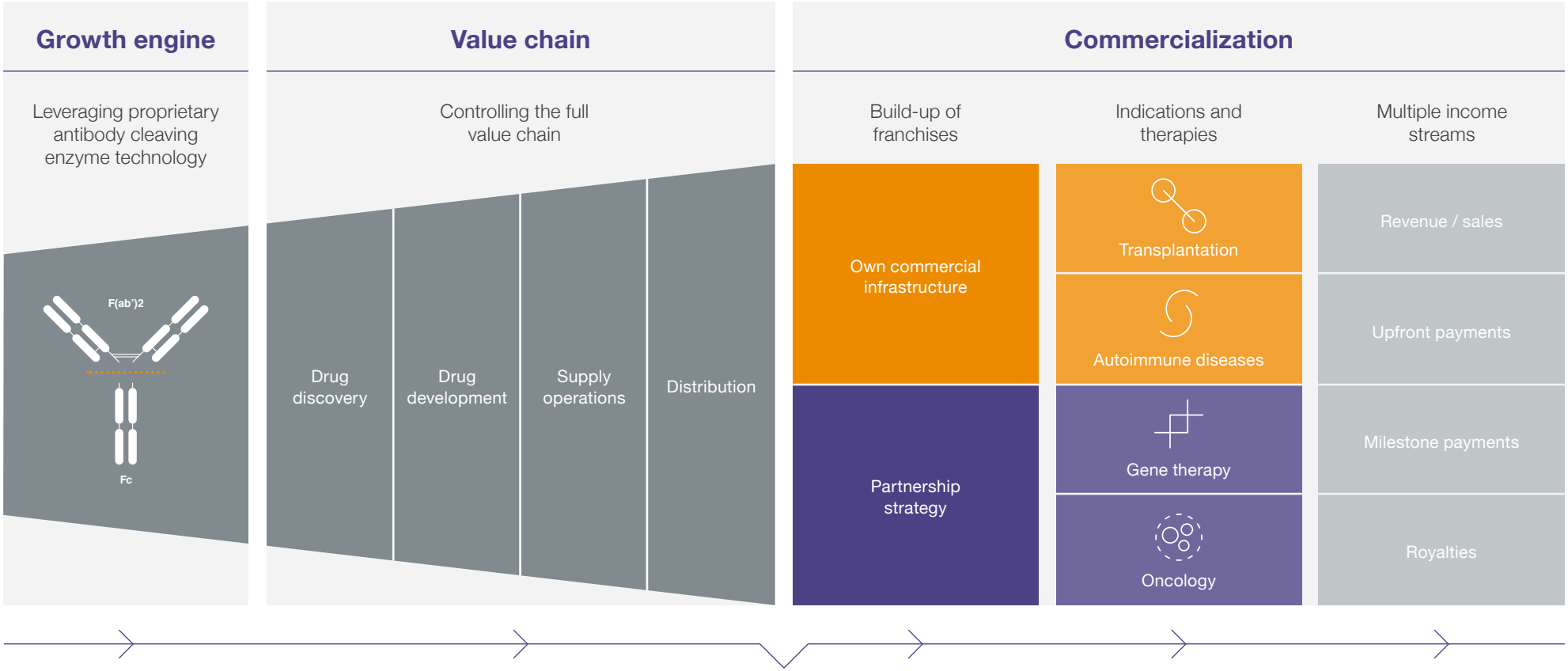
A third area Hansa is pursuing for imlifidase is in gene therapy as a pre-treatment to potentially enable gene therapy in patients with pre-existing neutralizing antibodies (NAbs). In July 2020, Hansa announced its first partnership agreement with Sarepta Therapeutics to develop and promote imlifidase as a pre-treament in Limb-Girdle Muscular Dystrophy and Duchenne Muscular Dystrophy. While the Sarepta partnership is exclusive in these two indications, there are a large number of other active programs in the gene therapy space where the issues with pre-existing NAbs are similarly challenging, depending on the vector used and the specific indication.

Imlifidase is not being developed for chronic diseases due to its immunogenicity. Instead, Hansa is developing a next generation of enzymes for repeat dosing administration through the NiceR program (Novel Immunoglobulin Cleaving Enzymes for Repeat dosing). The NiceR program may be relevant in a number of chronic autoimmune diseases where patients experience flares or in situations in the transplant space where repeat dosing would be beneficial and add further value, particularly post-transplant. The NiceR program is expected to enable a large universe of potential indications including a number of gene therapy programs and/or oncology programs, where the potential for enhancing the efficacy of current immunooncology therapies is already being considered.

> Hansa's antibody-cleaving enzyme technology opens a variety of significant potential growth opportunities across multiple therapeutic areas

Leveraging the Company's technology platform

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



Evolution into a fully integrated biopharmaceutical Company

Leveraging the Company's technology platform continued

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

At the core of the business model is Hansa's "growth engine" – the Company's proprietary antibody cleaving enzyme technology platform. As new drug candidates advance from discovery through to regulatory approval and commercialization, it is the Company's intention to retain strategic control at the different stages to capture the majority of the economic upside generated.

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

In other areas where the target audiences and the marketplaces are more complex and fragmented, the Company will consider alternative pathways for commercial success. In these markets, the Company may employ a partnering strategy similar to the agreement with Sarepta Therapeutics in gene therapy.

Actual patient has given consent to provide images

> "It is the Company's intention to retain strategic control at the different stages of the value chain to capture the majority of the economic upside generated

Hansa Biopharma's strategic priorities

Hansa Biopharma has embarked on a mission to become a global leader in rare diseases through the development of innovative, life-saving and life-altering treatments for patients with rare immunological conditions. To achieve this mission the Company has three overall strategic priorities to deliver on:

Building tomorrow's Hansa Biopharma

1	2	3
Advance platform in new indications and therapeutic areas	Commercialize Idefirix® in first markets and indications	Build organizational capablitlies and expand technology platform

1. Advance platform in new indications and therapeutic areas

Build new franchises to capture full value of technology platform

- Transplantation
- Autoimmunity
- Gene therapy
- Oncology and new therapies

Hansa seeks to leverage its immunology platform to develop valuable drug candidates for new indications and therapeutic areas. In order to secure optimal focus and alignment of resources within each therapeutic area, the Company has established four organizational franchises: Transplantation, Autoimmune Diseases, Gene Therapy and Oncology/New Therapies.

In transplantation, beyond the recently approved indication for pre-treatment of highly sensitized patients to enable kidney transplantation, Hansa believes that there are many other promising market opportunities for its antibody cleaving enzyme technology to pursue longer term both in pre and post transplantation management (AMR), including kidney, heart and lung transplantation. In addition, the Company also sees near-term opportunities for label expansion as well as expansion into new geographical markets.

In autoimmune diseases, Hansa reported its first validation outside transplantation with positive high-level data from an investigator-initiated phase 2 trial of imlifidase in anti-GBM antibody disease. Anti-GBM antibody disease is one of many currently known autoimmune diseases that are driven by IgG autoantibodies as a key component of the disease pathophysiology. These autoimmune diseases typically cause very severe conditions and have no or few approved therapies available for treatment. Hansa believes the autoimmunity space may hold significant opportunities for its antibody cleaving technology in both acute and more chronic indications.

A third area for the Company to pursue is within gene therapy. Gene therapy is a very exciting and growing field with a lot of promise and progress. A number of products have already been approved and more than 200 drug development programs are currently ongoing. A great challenge for many gene therapy drug candidates is neutralizing antibodies, which can make it very difficult to secure transduction of the healthy gene. Based on very promising preclinical data published in *Nature Medicine* in 2020[1], we believe that imlifidase and other enzymes given as pre-treatment ahead of the gene therapy may have the potential to overcome the challenge posed by neutralizing antibodies and thus enable effective and safe gene therapy in a larger group of patients.

Lastly, in the Company's fourth franchise, oncology and new therapies, Hansa sees opportunities medium to long term in areas such as bonemarrow transplantation and immuno-oncology. Early but very encouraging pre-clinical data have been generated indicating that imlifidase and other enzymes potentially can potentiate the effect of immuno-oncology therapies. This is an exciting area with significant market opportunity, and the Company is currently working to generate additional proof-of-mechanism within the oncology space.

2. Commercialize Idefirix® in first markets and indications

Successfully launch Idefirix® in Europe*
Generate positive first experiences in key clinics and expand to targeted clinics with a patient focus

Geographical expansion
Explore opportunities to commercialize Idefirix® beyond core markets

Secure FDA approval and launch Idefirix® in the US
Complete Randomized Control Trial (RCT) and submit BLA under the accelerated approval pathway (2023)

Secure the successful commercialization of Idefirix® in kidney transplantation for highly sensitized patients through a focused launch strategy targeting a limited number of leading transplantation centres with the potential to become early adopters and centres of reference – initially in Europe based on the conditional approval and subsequently in other key markets of the world once regulatory approval has been obtained in these markets.

3. Build organizational capabilities and expand technology platform

Build a first-class commercial organization
Build commercial team and competences in transplantation and autoimmune diseases

Expand R&D capabilities
Pursue innovation, further strengthen scientific expertise and capabilities in rare diseases

Create technology partnerships
Initially focused around gene therapy and potentially oncology

Hansa's third and final key strategic priority is to continue to build its organizational capabilities and expand the Company's technology platform. The Company has spent the last few years establishing and building a core commercial and medical affairs infrastructure to support launch activities for Idefirix® in the early launch countries in Europe. As the product roll out advances, we expect to increase our footprint in other key markets, including the United States. Moving ahead, Hansa intends to leverage its established medical and commercial infrastructure as launch vehicles for other products emerging from the Company's pipeline.

Finally, Hansa plans to further strengthen its pipeline building efforts by expanding the Company's R&D capabilities through potential acquisition of complementary platform assets and/or by leveraging a partnership pathway to access external sources of innovation.

[1] 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

* Idefirix® approved in EU under conditional approval for kidney transplantation

Mid-term financial priorities

Funding the broad exploitation of the technology platform while securing a successful European launch

Hansa is financed into 2023

Fund commercial expansion across Europe, targeting mid-term product profitability

Continue investments in kidney transplantation to approach US market

Accelerate advancements in new therapeutic areas including autoimmunity, gene therapy and oncology

Develop next generation enzymes for repeat dosing

USD ~160m (SEK ~1.4bn) in cash and short-term investments (Dec 31, 2020)

In July 2020, Hansa Biopharma successfully closed a direct placement of 4.4 m shares (10% of issued share capital after placing), which raised approximately SEK 1.1bn (USD 121 m) before issue costs.

The successful completion of the financing is expected to fund Hansa into 2023. The net proceeds will be used to continue the development and expansion of the Company's R&D pipeline as well as to fund the launch and commercialization of imlifidase in kidney transplantation.

More specifically, the proceeds will enable the Company to:

- Support the Company's ongoing and future R&D efforts, including development of imlifidase for additional indications such as antibody-mediated kidney transplant rejection (AMR), Guillain-Barré syndrome (GBS) and anti-GBM disease (anti-GBM);
- Fund Hansa Biopharma's ongoing commercial build-up, including sales force expansion to support the launch of imlifidase in kidney transplantation in highly sensitized patients in Europe;
- Invest in the Company's development of next generation IgG-eliminating enzymes for repeat dosing; and
- Fund working capital and general corporate purposes.

Hansa Biopharma ended 2020 with SEK 1.4bn (USD ~160 m) in cash and short-term investments, which allows for investing in future growth and value creation. In addition to the newly raised capital the Company has seen strong interest from leading life science investors in the US and Europe helping to diversify the Company's shareholder base as well as support the Company's efforts in building a global leader in rare diseases.

Hansa's key financial priorities over the coming years will be focused on ensuring a successful European launch of Idefirix® in European markets, while targeting mid-term product profitability. In tandem, Hansa will maintain investment in further strengthening its position in kidney transplantation by pursuing clinical studies and regulatory approval for imlifidase in the U.S., which represents a very large market potential.

In addition, Hansa expects to accelerate its investment in new therapeutic areas such as autoimmunity, gene therapy and oncology. Hansa will also continue to support promising partnership structures, such as it established with Sarepta Therapeutics, by engaging in the development of potential partnerships in gene therapy, oncology and other technology areas, where it make sense to explore combination therapies.

People

Stock image

Becoming a commercial-stage biopharmaceutical company

Great Place To Work. Certified 2020 SWEDEN

Interview

Q 2020 was a year of transition for Hansa with the Company poised to launch Idefirix® in Europe – how has the organization developed?

A We are working hard to ensure our organization is prepared for the next stage as a commercial company. We grew from being an R&D focused organization to one with many additional functions such as Medical Affairs and Commercial, and we have integrated these functions and we work in cross functional clusters across the organization so employees identify with the goals and ambitions of Hansa as a Company and not only with the department they belong to according to an organogram. This model is strengthened by the fact that we have a dual function of Chief Operating Officer and Chief Science Officer under Christian Kjellman. This illustrates that to succeed we need to be good at both science and business & strategy and have an organization that excels at both.

Q How will you continue to develop the organization at Hansa?

A We have a very skilled and experienced team at Hansa, with an average of 20 years life science experience and around 50% of our employees in R&D holding PhDs. We are a global Company with 23 nationalities working here but we still have a lot to do, and it helps to have such a strong culture to grow our organization. We will continue to build the international profile of our organization, attracting highly qualified staff from across the world, who are motivated to use their top-class skills within a strong team environment.

Q How do you retain and attract employees?

A We create an atmosphere of teamwork and support but we also offer employees a large amount of freedom in the way that they work. We encourage pushing boundaries and innovation to progress and succeed in projects. Many people see this as an attractive attribute for a workplace. We applaud bravery from employees so that we can go further than the norm – we want to go from good to great on everything we do even if this sometimes means things do not work out as we had hoped. We also have an equal gender balance at Hansa and the fact that we are a purpose driven organization – helping patients with rare diseases – attracts people to working for Hansa but also works as a strong motivation for current employees to go the extra mile.

Q How would you describe the culture at Hansa?

A Culture is everything at Hansa and our collaborative Company culture is a key element to our success. There are no sharp elbows at Hansa – we have some great individuals who then work together to make a superb team. I think our strong culture was core in Hansa being awarded A Great Place to Work Company in 2020, by the global independent institute Great Place to Work®. Our employees are proud to contribute to the journey we are on and are motivated to accomplish something together. When choosing new employees, we don't compromise on organizational fit – you may have outstanding skills but to enjoy working at Hansa and to achieve success you also have to have the mindset to collaborate with colleagues. I believe that brilliant people like working with other brilliant people, which is why we have been able to create a passionate, proud and persistent team at Hansa.

> "Our culture is driven by people passionate about making changes

Anne Säfström Lanner
SVP & Chief HR Officer

Market

Stock image

Helping highly sensitized patients who cannot access a kidney

An introduction to chronic kidney disease

End Stage Renal Disease poses a significant global health burden, affecting almost 2.5 m patients worldwide[2]. Chronic kidney disease (CKD) is a progressive disorder indicated by the gradual loss of kidney function over time[3], with a global prevalence of 9.1%.[4] As CKD worsens it can progress to kidney failure, also referred to as end-stage renal disease (ESRD), which is the final and most critical stage of CKD where the kidneys can no longer function without support.[5]

People who progress to ESRD will require renal replacement therapy (RRT) which involves either dialysis or kidney transplantation. The number of kidney patients requiring RRT is growing and in Europe there are approximately 63,000 new patients each year[6]. Organ transplantation is a life-saving treatment for patients with ESRD, offering a better quality of life at lower societal cost[7].

Patients with failed kidneys end up in dialysis, which requires four to six hours of treatment three to four times per week, which for most patients results in significantly impaired quality of life. Long-term dialysis is also associated with risks of cardiovascular complications and premature death. Kidney transplantation, in most cases, enables patients to return to a normal life, even though all transplanted patients need to be treated with immunosuppressive treatment.[8]

There are approximately 80,000 kidney patients on transplant waiting lists across the European Union[9]. Risk factors for developing HLA antibodies include previous transplantation, blood product transfusion and pregnancy, and patients with HLA antibodies are classed as highly sensitized. The more antibodies, the lower the likelihood of finding a donor organ that will be a match.

Highly sensitized patients make up roughly 10-15% of patients added to the kidney waiting list annually[10]. In some countries highly sensitized patients make up as much as 30% of the waiting list[11]. Since these highly sensitized patients are unlikely to be offered a transplant, they spend much longer time on waiting lists 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.[12]

[2] Jordan SC et al. Transplantation:October 21 2020 – volume online first issue.
[3] National Institute for Healthcare and Excellence (NICE). Chronic kidney disease in adults: assessment and management. Available at: https://www.nice.org.uk/guidance/cg182/chapter/introduction.
[4] Council of Europe. Newsletter Transplant 2020. pg 58-60. Available at: https://www.edqm.eu/en/news/newsletter-transplant-2020-now-available. Last accessed February 2021
[5] Johns Hopkins Medicine. End Stage Renal Disease (ESRD). Available at: https://www.hopkinsmedicine.org/health/conditions-and-diseases/end-stage-renal-failure. Last accessed: February 2021
[6] Lamiere N et al. Kidney International 2005; 68;30,38e
[7] Marfo K et al. Clin J Am Soc Nephrol 2011; 6(4)L 922-936.
[8] Global Observatory on donation & transplant
[9] Newsletter Transplant 2020. pg 58-60. Available at: https://www.edqm.eu/en/news/newsletter-transplant-2020-now-available. Last accessed February 2021
[10] EDQM. (2020). International figures on donation and Transplantation 2019 and SRTR Database and individual assessments of allocation systems
[11] EDQM. (2020). International figures on donation and Transplantation 2019 and SRTR Database and individual assessments of allocation systems
[12] Orandi et al., "Survival Benefit with KidneyTransplants from HLA-Incompatible LiveDonors", N Engl J Med (2016;374:940-50) Data from Global Observatory on Donation and Transplantation, http://www.transplant-observatory.org

Highly sensitized patients are difficult to match

> Causes of sensitization include pregancy, blood transfusion and previous transplantations.

Pregnancy | Blood transfusion | Previous transplantations

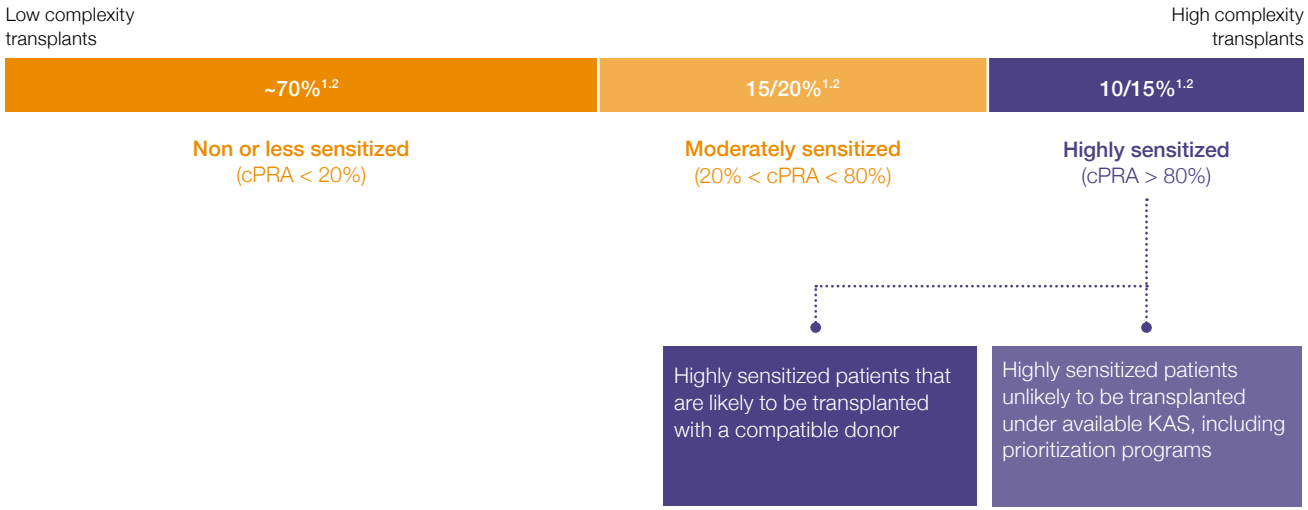
> Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA sensitization.
> Inability to match or effectovely desensitize patients reamins a barrier for transplantation in highly sensitzed patients.
> Allocation Systems such as KAS and Eurotransplant rely on PRA score to characterize patients for transplant.

Idefirix® obtains conditional approval

Idefirix® label

On August 26, 2020 Hansa Biopharma received conditional approval for Idefirix® by the EU Commission. Idefirix® is indicated for desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor.

A post approval study will be initiated in parallel with the commercial launch and Hansa plans to start recruitment of the first patients in the second half of 2021. The post approval study will be key in integrating the commercial and scientific approach and to broaden the experience with imlifidase.



Idefirix® label

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

Potential Patients

idefirix (imlifidase)

Actual patient has given consent to provide images

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

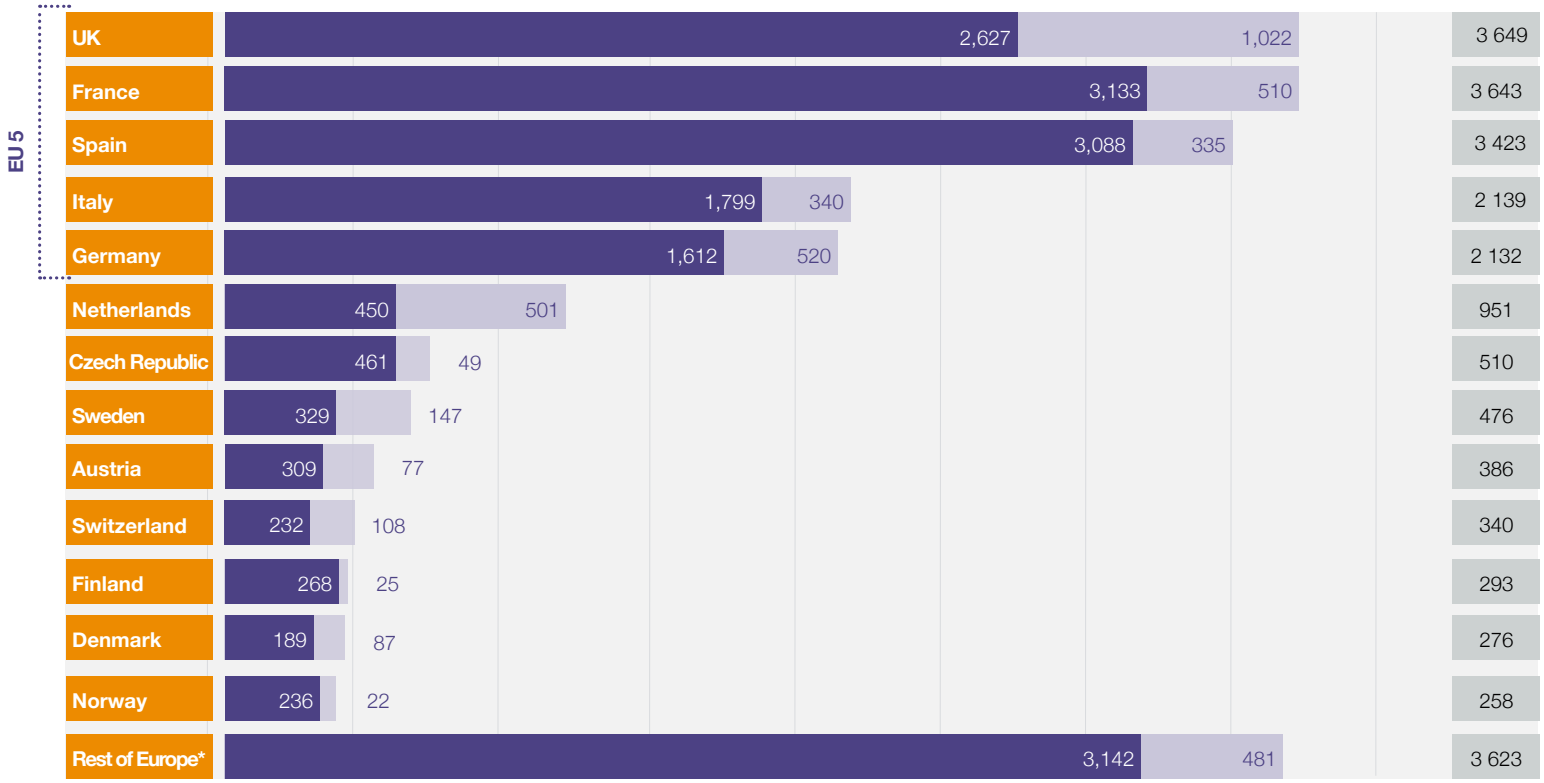
Idefirix® obtains conditional approval continued

22 000

ANNUAL KIDNEY TRANSPLANTS IN EUROPE

European kidney transplantation landscape

Approximately 22,000 annual kidney transplants in Europe of which approximately 15,000 transplants in EU5 (2019). ~80% of transplants are from deceased donors[1]



[1] Transplant data from 2019.
* Belgium, Croatia, Cyprus, Greece, Hungary, Iceland, Ireland, Lithuania, Poland, Portugal, Romania, Slovakia, Slovenia

Source: Global Observatory on Donation & Transplantation, 2019

Clinical perspectives on desensitization in kidney transplantation

Interview

Professor Nizam Mamode. M.D.
Professor of Transplant Surgery,
Guys and St Thomas Hospital, London

Q How much of a burden on society is kidney failure?

A Kidney failure is a major problem, and one that is rising. Today, if you're 65 years old and have kidney failure, your 5-year survival is about 30%. A paper published recently in the Lancet[13] suggests that in 2017 nearly 10% of the world's population had chronic kidney disease – that is nearly 700 m people globally and resulted in 1.2 m deaths annually – and these numbers are predicted to almost double by 2040.

Dialysis is a major burden on society. Not only is quality of life for a dialysis patient very poor, but there is a high risk of complications for patients on dialysis. And then there is the economic burden on society and healthcare systems of dialysis. In the UK where I am based for example, the treatment cost for dialysis alone is more than £45,000 per patient every year.

Q What challenges do patients face with transplantation?

A One of the challenges for successful transplantation is the existence of so-called HLA (human leukocyte antigen) antibodies, which can cause a patient's immune system to reject an organ being transplanted into their body. HLAs are proteins that appear on the cell's surface – and they differ between different people. For an optimal transplantation we want the HLAs on the donor organ to match those from the recipient patient. If they don't match, we can still do the transplant, but the kidney won't last that long as the patient will create HLA antibodies to reject the organ.

This process where HLA antibodies are created is called sensitization and occurs when a patient has been exposed to foreign human proteins not created in their own body – for example due to a previous organ transplant, a blood transfusion or pregnancy.

Q How much of a problem is sensitization?

A We are actually very good at transplanting kidneys for young people, and as transplanted organs only last for between 20-25 years, patients will very likely need a second or third transplantation. This means that a high number of patients become sensitized and develop HLA antibodies, making that second or third transplant more difficult.

There are fewer organs available to sensitized patients due to the risk of rejection. Patients are scored using the Calculated Reaction Frequency (CRF) on the amount of HLA antibodies they have developed, and in short, if the patient has a CRF score of 100%, they won't be offered any of the organs on the transplant list. Patients are categorized as highly sensitized with a CRF of over 85% and currently that accounts for between 20% and 30% of the transplant population – and that percentage is rising.

> "I think Idefirix® offers a very promising desensitization treatment for patients, who otherwise will have very few options

[13] https://www.thelancet.com/article/S0140-6736(20)30045-3/fulltext

Clinical perspectives on desensitization in kidney transplantation continued

Q How can a patient be desensitized?

A There are different approaches used today, for example by filtering blood, by using drugs to absorb the HLA antibodies or by using complement inhibitors – antibodies that prevent the immune system from harming healthy cells and tissues. However, there are challenges with all these approaches so there's a real need for an effective and safe treatment option to deal with HLA antibodies so that we can have a higher chance of a successful transplantation.

Q How does Idefirix® (imlifidase) compare vs. today's current standard of care?

A A recent study with imlifidase in highly sensitized patients (with a CFR score of close to or at 100%) showed good results in terms of both kidney function and graft survival in patients transplanted with the help of Idefirix®. The study showed that after getting Idefirix® prior to transplantation, patients' HLA antibody levels were reduced allowing the kidney transplant to be carried out.

Patients were then followed for 6 months and it was shown that HLA antibodies in patients returned but at levels much lower than before the transplantation – and these low levels were maintained. Normally in sensitized patients we would expect reduced graft survival too, but in this study graft survival was almost 90% which is very very good in this population. So, I think Idefirix® offers a very promising desensitization treatment for patients, who otherwise will have very few options.

Q How would Idefirix® be received by the medical community?

A Treatment of highly sensitized patients has been increasingly concentrated in specialist centers because of the challenges of desensitization. A drug which allows us to remove antibodies with minimal side effects, and early results from Idefirix® seem to suggest that, could really change the transplant treatment landscape.

The majority of transplant centers could deal with highly sensitized patients, opening up the number of transplants that can happen, impacting transplant waiting lists and more importantly, allowing patients to get off dialysis and return to a more normal life to the benefit of the healthcare systems and the society at large.

Professor Nizam Mamode M.D.
Professor of Transplant Surgery,
Guys and St Thomas Hospital, London

Highly focused and co-ordinated launch strategy

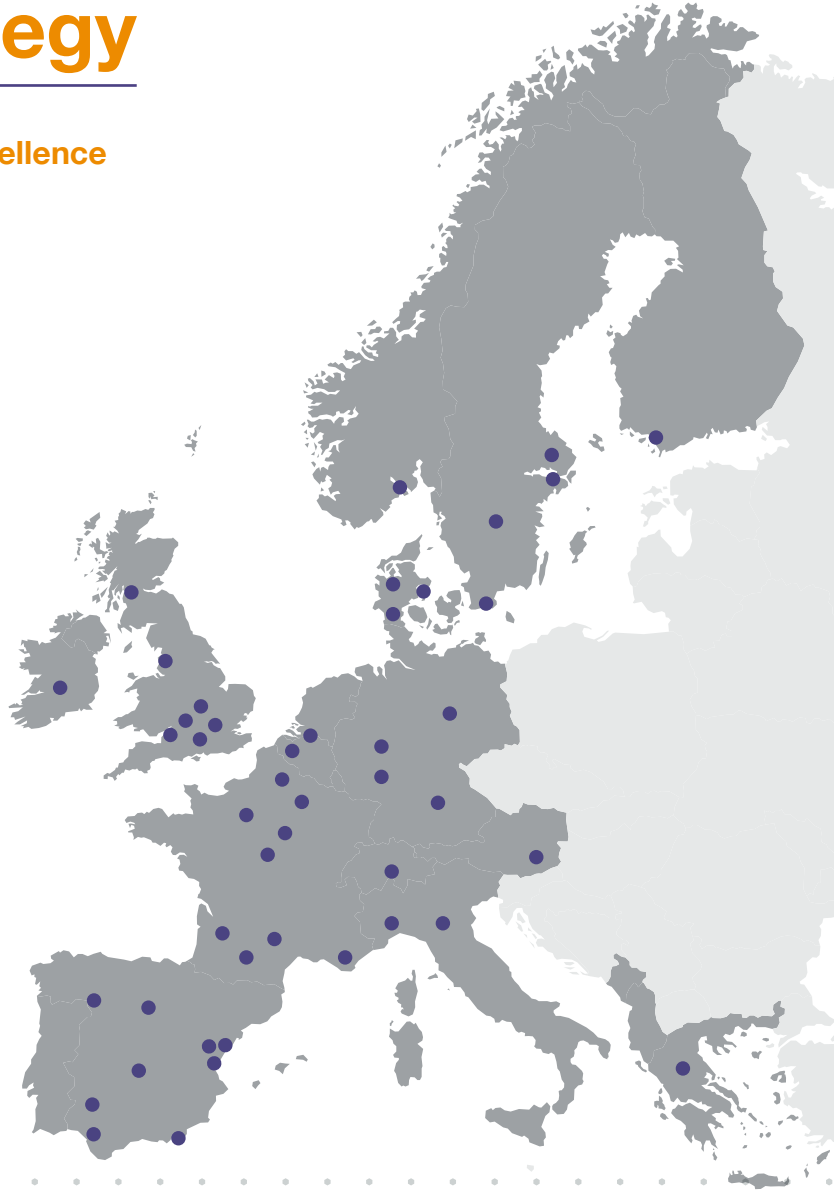
Early launch in centres of excellence

First launch wave defined by:

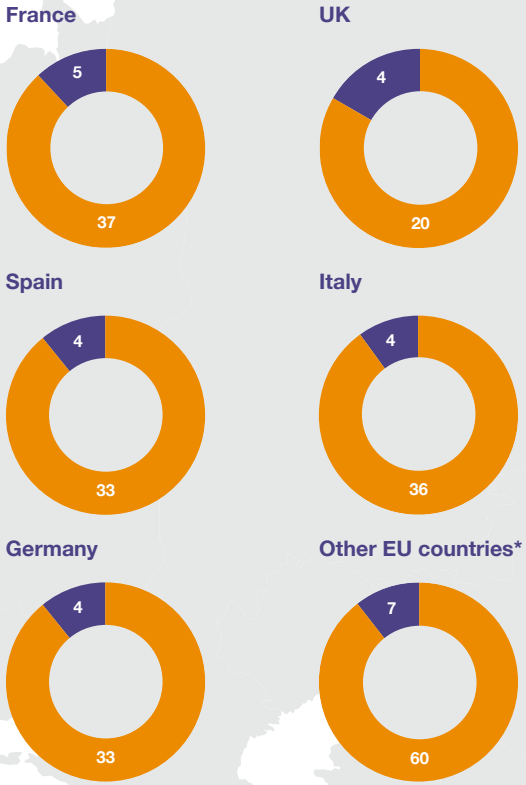
1. Launch Idefirix® with kidney transplant specialists who have experience in desensitization
2. Create positive momentum with Idefirix® as the new Gold Standard in desensitization protocols
3. Prepare post approval study to confirm filing data

● Leading transplant clinics

Idefirix® approved in EU under conditional approval for kidney transplantation



Leading transplantation centres perform the majority of all transplantations in EU



■ Hospitals with experience in desensitization & transplantation of highly sensitized patients

■ Other transplantation clinics

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

Highly focused and co-ordinated launch strategy continued

Our EU launch strategy

In Europe approximately 22,000 transplantations were conducted in 2019, with approximately 80% of transplants performed from deceased donors[14]. The five largest European markets including UK, France, Spain, Germany and Italy remain the most important ones from a volume perspective with approximately 15,000 annual kidney transplantations[15].

The introduction of Idefirix® is by many leading experts and clinicians and the payer community viewed as enabling a paradigm shift towards equity of access for highly sensitized patients to potentially lifesaving and life altering kidney transplant. Idefirix® is the first and only treatment licensed throughout the European Union for desensitization treatment of highly sensitized patients.

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

To ensure optimal use of the product in the right patients Hansa will apply a centre-focused, sequenced launch strategy, initially targeting leading centres that may become early adopters and centres of excellence. Idefirix® is intended to be provided to the centres through pre-arranged agreements, in which the transplantation teams are first onboarded with information about the treatment with imlifidase and associated procedures, in relation to the healthcare situation of the patient. In most centers contracts will be in place to secure supply and funding.

It is critical for the patients and a successful launch of Idefirix® that positive outcomes are generated in the first clinics so as to build the foundation for expanded use of Idefirix® as a potential new Gold Standard in desensitization protocols. As part of the launch preparations, Hansa Biopharma has increased its presence in key markets over the last 12 months through recruitment of Medical Science Liaison and commercial personnel to build awareness around desensitization among Key Opinion Leaders (KOL's) and clinical experts.

Providing access to medicines is a shared responsibility and Hansa is committed to working with the patient community and other stakeholders, such as governments, payers, HTA bodies, healthcare professionals and other pharmaceutical companies, to help bring new treatments to the patients that need them in a timely manner.

Plans for global expansion

Hansa's global launch strategy will be carried out in waves.

The initial wave will focus on early adopters and potential centres of reference in European markets where national pricing, reimbursement and funding regulations and procedures allow earlier access for patients to innovative new therapies following approval by the European Medicines Agency.

The second wave will focus on European hospitals in countries with longer lead time before national pricing, reimbursement and therapy access for patients can be secured, as well as on hospitals in early launch countries with some knowledge around desensitization, but where a more complex framework may need to be established before Idefirix® can be adopted.

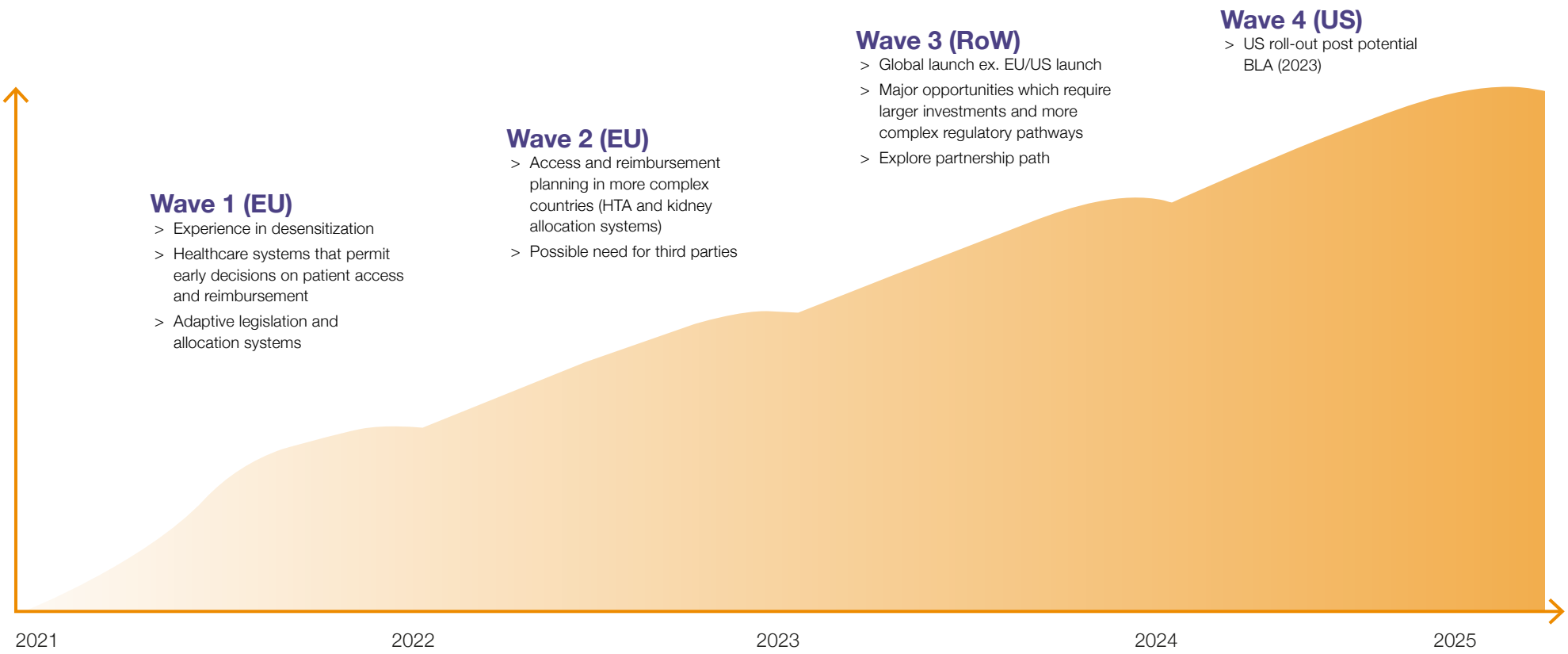
The third wave will consist of countries outside EU and the US. These markets are currently being explored to prepare for a potential expansion medium term into new markets where Hansa can build on the EMA approval to obtain local regulatory approval. A significant volume of kidney transplants are performed in some of these markets annually and, as in Europe and the United States, highly sensitized patients on dialysis have a high degree of unmet medical need. In the countries outside of EU and US we are aiming for establishing relationships with local partners. These partners have a profound knowledge and relationships in their respective territories.

The fourth wave is the launch in the US following a potential BLA submission and subsequent accelerated approval upon successful conclusion of a planned randomized controlled trial.

[14] Global Observatory on Donation & Transplantation, 2019
[15] Global Observatory on Donation & Transplantation, 2019

Plans for global expansion

Launching in overlapping waves with a centre-by-centre approach in Europe (illustrative)



Building awareness around a new transformative therapy

Interview

Our integrated launch approach

Q Henk, Can you give us an overview of the launch strategy for Idefirix®?

A We have established a very strong and integrated commercial and medical team to be very close to the physicians and the hospitals to move Idefirix® further to support our launch activities in Europe. Obviously, physicians are key, and although our clinical activities have facilitated initial awareness in the community, we are strengthening this among key opinion leader. We have good contacts with key opinion leaders in the transplantation landscape to further enhance this we have also put commercial field-based presence in place to support the launch. In Europe we have territory managers to co-ordinate market access, marketing and sales activities.

To help with awareness we have created a so-called initiation package of medical information and pharmacovigilance to support the medical teams at centers. Awareness will further be supported by personal interactions, meetings, conventions, satellite symposia and marketing activities. We have also ensured a robust supply chain to make sure Idefirix® is available at the relevant hospitals.

Lastly, we have implemented a structure by which we can be highly efficient by ensuring learnings are shared from country to country and we don't reinvent the wheel. This is also a financially efficient way of working, as we can allocate resources where and when they are needed rather than building up structures in each country which duplicate functions.

Q Vincenza, How have you engaged with the transplant community?

A We work through the key centers and have published supporting data in abstracts and presentations and have sponsored educational symposia at major scientific conferences so far. Also, it is very good to see the data from our pivotal international trial published in the prestigious peer reviewed *Journal of Transplantation*[16].

We have a unique collaboration and partnership with the European Society of Transplantation, where Hansa has sponsored "Workstream 06:HLA Desensitization" with their Transplant Learning Journey 2.0 program. It is a recent initiative to develop a more consensus-driven and standardized approach in Europe to transplanting this challenging patient group who have high levels of preformed human leukocyte antigen (HLA) antibodies.

Henk Doude van Troostwijk
SVP and CCO

Vincenza Nigro
VP Head of Medical Affiars

[16] Jordan SC, et al Imlifidase desensitization in crossmatch-positive, highly-sensitized kidney transplant recipients: Results of an international phase 2 trial (Highdes). Transplantation. 2020 Oct 21.

Building awareness around a new transformative therapy continued

Q Vincenza, How are you helping medical professionals to understand Idefirix® and identify the right patients?

A Our approach is clinic by clinic, so we can shape the area of desensitization as we integrate Idefirix® into the transplant community. We work with hospitals, making sure we can give the multidisciplinary teams information and knowledge to help inform their desensitization protocols and safely operationalize Idefirix®.

Idefirix® is indicated for desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor and reserved for patients unlikely to be transplanted under the current kidney allocation systems including prioritization programs. These are immunologically complex patients that face predicted longer waiting times without access to transplantation[17].

Q Henk, How much attention are you giving the transplant centers in Europe for the launch, and how are you dealing with reimbursement?

A The specialist centers are very important, as they have the structures in place so that introducing Idefirix® can be efficient. Clinician and patient experience is also vital to gain more information that can be used to support the ongoing launch.

Reimbursement is a route that we are actively pursuing, and we have many submissions in place and are exploring decentral funding options. We engage with payers on a day to day basis and have conducted several payer advisory boards. Our finalized and validated Global Value Dossier is the blue print for the local submissions. In parallel we are crafting our ongoing value story. In some countries in Europe, for example in Spain, we may start with a named patient program so patients can get access to Idefirix® in the interim until reimbursement is in place.

Q Vincenza, How do you work with KOLs to harmonize different approaches across Europe?

A The European Union does not have a single allocation system; it is very fragmented. The systems are regional and national, as well as international (e.g. the cross border systems such as Eurotransplant and Scandia Transplant).

Although the allocation systems have improved access to transplantation for highly sensitized patients – and are aimed at prioritizing them – there is still a population of highly sensitized patients who are not able to get the transplantation treatment they need. Desensitisation remains under-utilised across Europe, is variable in efficacy and lacks consensus regarding best practice. It is here that we are working with the transplant community so that they learn how Idefirix® can enable kidney transplantation in these patients.

Q Henk, What is the status of the launch here in the beginning of April 2021?

A As stated above the most important aspect is to secure a safe and positive patient experience. In order to implement this strategy we are preparing the defined centers of excellence. These preparations consist out of several activities. In the first place to train the transplantation staff on treatment with Idefirix®. This training is driven by our Initiation Package. These Hospitals also need the funding in place to obtain Idefirix®. Current hospital budgets are not sufficient to get access to Idefirix®.

Our market access activities are focused on getting additional funding to bolster the hospital budgets, and secure a per patient price. Most hospitals will get Idefirix® in a consignment stock delivery. This means that Idefirix® is available in the hospital pharmacy so it is ready available for the transplantation.

There are currently hospitals ready to start treatment and for other hospitals it is work in progress. In parallel we are increasing and enhancing the KOL base, and preparing the market for the Post Approval Study. More centers are being profiled and targeted, account plans are being devised and implemented. We are monitoring progress on a daily basis.

> Our approach is clinic by clinic, so we can shape the area of desensitization as we integrate Idefirix® into the transplant community

[17] Jordan SC, et al. Br Med Bull 2015; 114(1):113-125.

Technology

Stock image

The role of immunoglobulin antibodies

An immune response begins with the recognition of a pathogen or foreign molecules 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 molecule binds to one of many molecules on the microorganism's surface and hence there may be several different antibodies for a given pathogen.

Through this binding mechanism, one or several antibodies can tag a pathogen or infected cell. This tagging 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 different isotypes have slightly different structures and they play different roles in the immune system. Immunoglobulin G, IgG, is the most common type in the blood and tissue and provides the majority of antibody-based immunity against invading pathogens.

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

In transplantation, by design foreign material is introduced to an individual's immune system. In order to prevent the immune system from fulfilling its duty to recognize and reject the transplanted organ, all transplanted patients are treated with immunosuppressant drugs in order to prevent or mitigate transplant rejection. Also, donors and potential recipients 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 antibody-mediated rejection (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. These pre-formed anti-HLA antibodies have been 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 carefully tested with respect to donor-specific antibodies (DSA) prior to an actual transplantation. Highly sensitized patients have a broad 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.

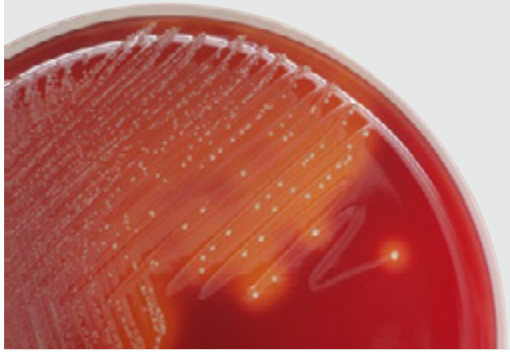
The broader reactivity of the antibodies, the lower the likelihood of finding a donor organ that will be a match. Many of these highly sensitized patients will indefinitely remain in a debilitating disease state on long-term dialysis treatment, which is associated with high cost, a poor quality of life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

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

Imlifidase – a novel approach to eliminating pathogenic IgG

Origins from a bacteria *Streptococcus pyogenes*

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

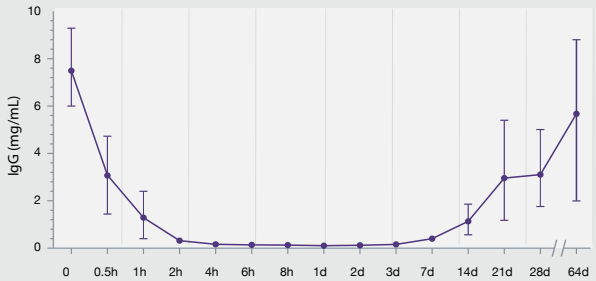


Imlifidase, a unique IgG antibody-cleaving enzyme to eliminate pathogenic IgG

> Interacts with Fc-part of IgG with extremely high specificity
> Cleaves IgG at the hinge region, generating one $F(ab')_2$ fragment and one homo-dimeric Fc-fragment

Imlifidase inactivates IgG in 2-6 hours from infusion

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



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

Imlifidase's *Mode of Action* is that it very quickly and effectively cleaves *Immunoglobolin* 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 to below detectable levels and stay supressed for approximately 5-7 days, creating a window for transplantation before it gradually returns back to normal levels during the weeks following treatment. The imlifidase enzyme is highly specific to IgG and all subclasses of IgG, and has been demonstrated to not affect other Ig-isotypes.

How our unique antibody cleaving enzyme technology can transform Hansa Biopharma

Interview

Q You've been a key driver in Hansa's journey to bring Idefirix® to the market in Europe – how do you feel about this?

A We are extremely proud of gaining our first ever approval, particularly as Idefirix® is a first-in-class drug. From a development perspective this is also a huge achievement as we are a relatively small Swedish biotechnology Company, but it is even more impressive because it marks a real breakthrough for patients waiting for kidney transplants. Launching Idefirix® validates our technology for use in clinical practice and demonstrates what the team at Hansa is capable of – creating something big and truly transformative that will make a difference for patients. Not only has the team done this within the normal drug development timeliness but also at significantly lower cost compared to peers. This approval really emphasizes the solid scientific foundation and the strength of the team at Hansa.

Q The technology foundation of your antibody-cleaving enzyme suggests much broader potential: What makes you most excited longer term?

A Our technology is at the core of our business. As well as identifying the right indications for our enzymes, we are also looking at how we can use our technology to leverage its potential in combination with other technologies targeting IgG antibodies. For example, FcRn blockers, which do not give the same rapid and effective response as imlifidase but can be useful for long-term management.

Our first generation enzyme, imlifidase, could potentially also be used as induction therapy with an FcRn blocker for maintenance therapy. In line with this idea, we could also combine imlifidase with other types of therapies such as complement inhibitors and new technologies that are targeting the cells producing IgG antibodies.

I am also quite excited about our next generation enzyme technology under the program name "NiceR". With NiceR we are working on genetically modifying our enzymes to reduce the immunogenicity and the immune response against the enzymes, so that we can use them for repeated dosing. Combining NiceR with imlifidase could really open a new treatment paradigm and could potentially be used in a much broad range of indications.

Q Hansa has been awarded its first product approval in kidney transplantation and has three clinical programs in anti-GBM, AMR and GBS ongoing – where else could you use imlifidase?

A We see great potential to use our antibody cleaving enzyme technology in bone marrow transplantation. The challenges found in bone marrow transplantation are similar to those within kidney transplantation, where patients have developed antibodies to donor bone marrow cells which threaten the success of the treatment. We are currently looking at the kind of development program that would be needed for a regulatory pathway in bone marrow transplantation. Other areas to consider could include heart and lung pre- and post-transplantation.

Going one step further, CAR T-cell treatments are emerging as important new options within some oncology indications. Current therapies are based on the patient's own CAR T-cells, but we believe it would expand the landscape if doctors could use off the shelf CAR T-cells derived from another donor to treat the cancer. So, there is a need for a technology such as ours, that is designed to hinder an acute response from the immune system. We are looking at this pre-clinically as a potential future opportunity for us.

Christian Kjellman
SVP & CSO/COO

How our unique antibody cleaving enzyme technology can transform Hansa Biopharma continued

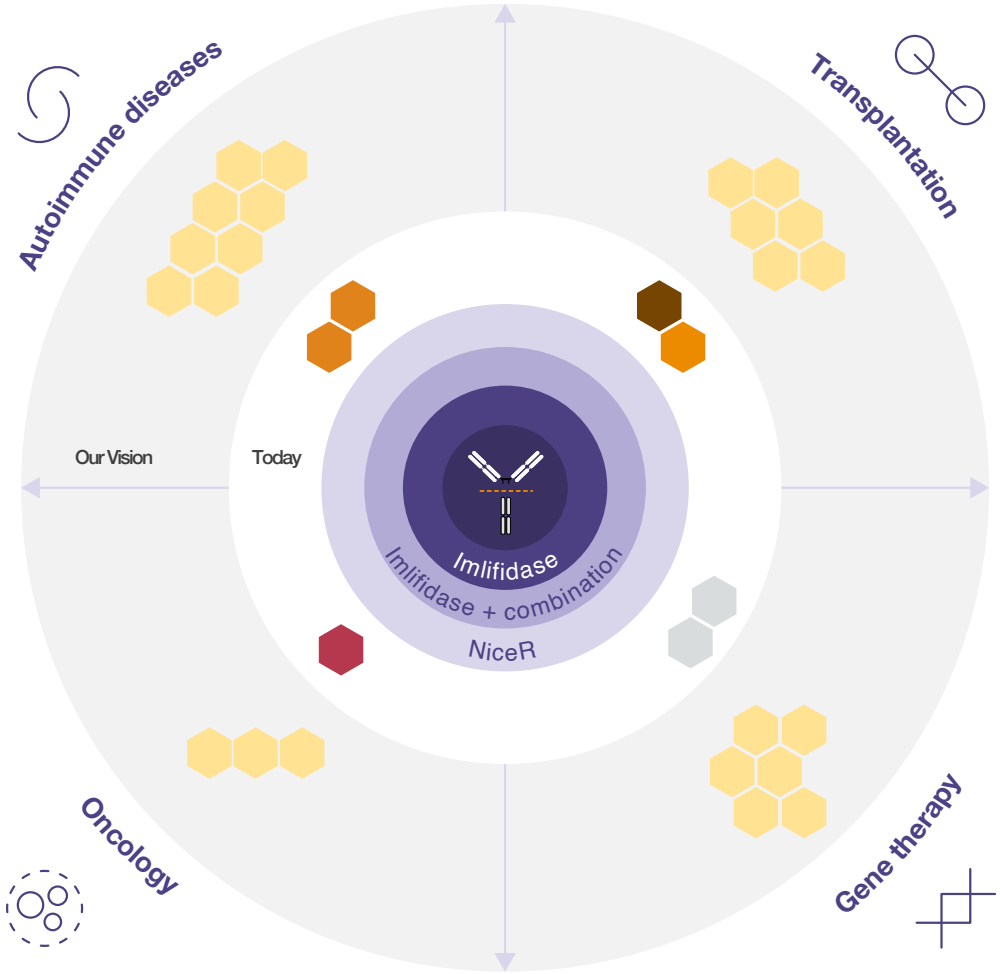
Q You have a lot going on right now. Are you open to partnering opportunities?

A Collaboration is key to Hansa's success and allows us to remain focused whilst ensuring we can leverage new options for patients. We are working very hard on the opportunities for partnering and development in the field of gene therapy, and we were very pleased during 2020 to announce the first partnership in this area, with Sarepta, where we collaborate on Duchenne muscular dystrophy and Limb-girdle muscular dystrophy.

We also focus on partnering in other areas, for example in oncology we have our EnzE concept. This is part of the NiceR program and tackles the challenge that cancer patients often have high levels of IgG antibodies in their plasma, which prevents the efficient killing of tumor cells by the therapeutic antibodies they are being treated with. In EnzE animal models we have tested how pre-treatment with imlifidase in cancer patients could increase the efficacy of currently available antibody-based cancer therapies. We have seen very encouraging results initially in a mouse model and continue work on demonstrating proof-of-mechanism. It could well be a future partnering opportunity for us.

Expanding our commercial franchises

- Regulatory approval*
- Clinical development
- Partnership (preclinical development)
- Preclinical development
- Opportunity



* Idefirix® approved in EU under conditional approval

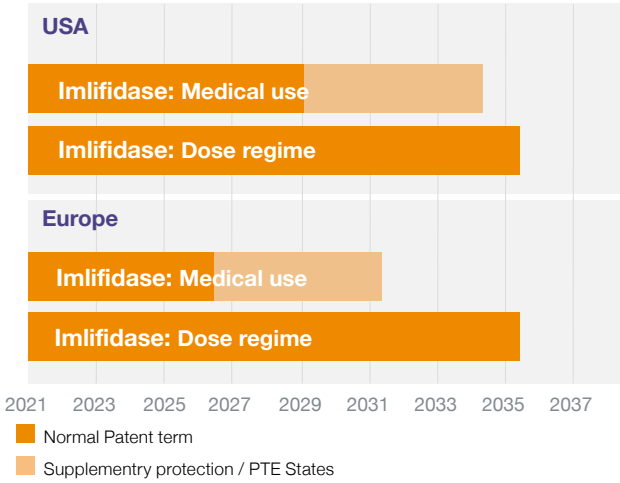
Intellectual property rights and orphan drug designation

Hansa Biopharma's IP portfolio consists of 11 separate patent families including 7 patent families in relation to the use of imlifidase with patent coverage out to 2035 in key markets.

In addition, the Company has been granted five orphan drug designations by EMA and the FDA across transplantation, anti-GBM antibody disease and Guillain Barré Syndrome (only FDA).

Lead product imlifidase is protected by seven patent families including both granted patents, as well as pending patent applications. These patent families cover the use of isolated imlifidase.

- Create antibody fragments
- Medical use in IgG mediated medical conditions
- Treatment of transplant rejection
- Autoimmune diseases
- Dosing in combination therapies transplantation
- Dosing in combination therapies oncology
- New IgG moduling molecules



Geographically, these patent families cover a large number of jurisdictions including the United States, Europe and Japan. The most significant patent families protecting imlifidase and similar molecules are covered with expirations up to 2035, with the possibility of up to five years of supplemental protection.

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

Orphan drug designation is granted to drugs intended for the treatment of 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 Biopharma has been granted five exclusive orphans drug designations by EMA and the FDA across transplantation, anti-GBM antibody disease and Guillain Barré Syndrome (only FDA).

EMA Orphan drug designation

- Imlifidase for the prevention of graft rejection following solid organ transplantation (2017)
- Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

FDA Orphan drug designation

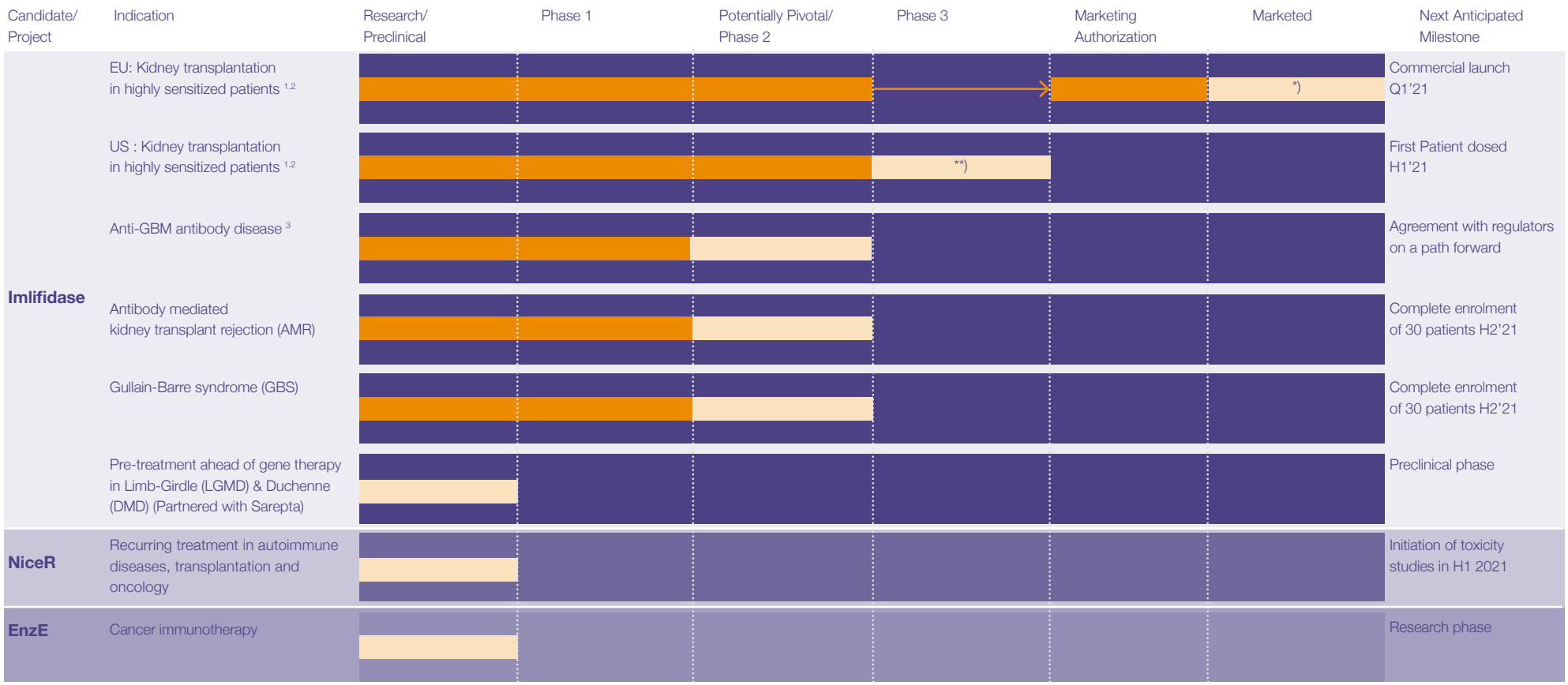
- Imlifidase for the prevention of antibody-mediated organ rejection in solid organ transplantation (2015)
- Imlifidase for the treatment of Guillain-Barre Syndrome (2018)
- Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

Growth

Actual patient has given consent to provide images

Our development programs

Broad pipeline in transplantation and auto-immune diseases



[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, Jordan et al New England Journal of Medicine)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund
*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch
**) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients. The COVID-19 pandemic may impact the timeline

Completed
Ongoing

Opportunities beyond kidney transplantation

Interview

Q You joined Hansa in June 2020 as the CMO at Hansa Biopharma, what do you bring to the job?

A I was particularly motivated to join Hansa by the focus of the role to expand opportunities outside of kidney transplantation. With a long career working in immunology, infectious diseases and oncology in biotech and the pharmaceutical industry, I can also use my experience and track record of taking products from early discovery through to the market. Having held leading positions in a number of biotech companies, most recently as CMO at Basilea Pharmaceutica in in Switzerland, I enjoy advancing an innovative technology platform and the ambitious and international mindset at Hansa.

Q Where else could imlifidase have potential?

A I believe there is broad potential within transplantation as well as in areas such as gene therapy and autoimmune diseases. We have a saying – If it works in kidney there are also good chances that it works in other solid organs such as the heart and lung, but also in bone-marrow transplantation. However, I am particularly thrilled by the potential use of imlifidase in the treatment of a variety of autoimmune diseases, where the body damages its own tissue. Imlifidase targets IgG antibodies and there are many autoimmune conditions where IgG antibodies are known to play an important role in the pathogenesis of the disease. These include diseases such as lupus nephritis, ANCA-associated vasculitis and anti-GBM antibody disease.

Imlifidase could also play a role in the treatment of neurological diseases, such as Guillain-Barré syndrome (GBS) – which is caused by an acute autoimmune attack on the peripheral nervous system and can potentially affect anyone at any age and can lead to permanent disability. We achieved encouraging data with imlifidase in animal studies and launched our Phase 2 study in GBS, and we expect to see data in the second half of 2022. Finally, there are skin disorders, for example, pemphigus vulgaris; and blood disorders such as immune thrombocytopenia and autoimmune hemolytic anemia.

Q How could imlifidase be used in bone-marrow transplantation?

A Bone-marrow transplantation is a curative treatment of several malignant and non-malignant diseases such as sickle cell anaemia or aplastic anaemia. When carrying out bone-marrow transplants using donor bone-marrow from family members – so-called haploidentical donors – there can be a high prevalence of donor-specific anti-HLA antibodies (DSA) which makes transplantation challenging particularly for highly sensitized patients. So we believe there is a clear potential to use imlifidase to pre-treat before the transplant and reduce the DSAs and thus increase the chances of success.

Q And you recently showed proof of concept with the anti-GBM study?

A This was our first validation outside of transplantation, so an important milestone for the technology. Anti-GBM antibody disease, also known as Goodpasture's disease, is a severe autoimmune disease where the immune system mistakenly develops IgG antibodies directed against the glomerular basement membrane (GBM), resulting in an acute immune attack causing severe kidney injury and, in some patients, also injuring the lungs. It can be fatal so it is a very serious disease. The proof-of-concept Phase 2 study showed that imlifidase led to rapid clearance of anti-GBM antibodies, with two-thirds of patients achieving dialysisindependence six months after treatment. These data are very encouraging for patients and we are now eager to move ahead with the development of imlifidase in this indication.

Prof. Achim Kaufhold M.D.
SVP and Chief Medical Officer

Hansa's unique antibody-cleaving platform

> I believe there is broad potential for imlifidase within transplantation as well as in areas such as gene therapy and autoimmune diseases

May have relevance in numerous autoimmune diseases, where IgG autoantibodies play an important role

Rapidly progressive glomerulonephritis

- Lupus nephritis
- **Anti-GBM**
- ANCA-associated vasculitis

Neurological disorders

- **Guillain-Barré syndrome**
- Myasthenia gravis
- CIDP
- NMO

Skin disorders

- Pemphigus vulgaris
- EBA

Blood disorders

- ITP
- WAHA
- APS

CIDP: Chronic inflammatory demyelinating polyradiculoneuropathy
NMO: Neuromyelitis optica
EBA: Epidermolysis bullosa acquisita

ITP: Immune thrombocytopenia
WAHA: Warm antibody hemolytic anemia
APS: Antiphospholipid syndrome

Idefirix® approved in EU under conditional approval

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

Anti-GBM, a rare acute autoimmune disease affecting kidneys and lungs

Anti-GBM (anti-glomerular basement disease), also known as "Goodpasture´s disease" is an acute and very severe inflammatory disease impacting the kidneys. For various reasons, the immune system develops IgG-antibodies that recognize a membrane associated antigen in the kidney and sometimes the lungs. This results in 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 resulting in death.

Anti-GBM is an ultra rare disease affecting approximately 1.6 per m annually globally[18,19] (e.g. 500 cases in the U.S. annually). One out of six anti-GBM patients can become fatal during the acute phase of the disease, while the majority of patients will end up on chronic dialysis[20]. Only one in three anti-GBM patients will have a preserved renal function after six months with current treatment[21].

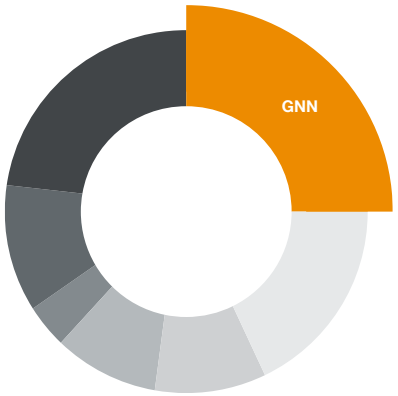
Anti-GBM disease is one form of glomerulonephritis (GNN), which is a term for inflammatory diseases in the kidney and one of the leading causes for kidney disease. In glomerulonephritis the inflammation starts in the glomeruli and the small blood vessels. The glomerulus is the filtering unit of the kidney. Autoantibodies of IgG-class are directed toward the body itself and are a very important reason for disease progression.

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

Early diagnosis and treatment is however crucial for the patient as deterioration of the kidney function progresses rapidly into the acute stage. The only way to halt an immunologic attack is through elimination of the antibodies as early as possible. Today's standard of care in anti-GBM disease involves medications such as cytotoxic drugs (e.g. corticosteroids and cyclophosphamide), but these treatments can take several months for the autoantibody production to halt. An alternative is to wash out the antibodies in the blood through different techniques, such as plasma exchange, but this is often insufficient since it typically takes several weeks to work effectively and only a fraction of the total IgG antibodies are removed.

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

Glomerulonephritis is a leading cause for kidney disease



- Glomerulonephritis (GNN)
- Adult polycytic kidney diease
- Pyelonephritis
- Others
- Diabetic neuropathy
- Hypertonicity
- Uremia

[18] Kluth et al. J Am Soc Nephrol. 1999 Nov;10(11):2446-53
[19] [8] Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12
[20] Cohort of 13 studies (661 patients in anti-GBM 1993-2017) Treating anti-GBM disease with imlifidase Mårten Segelmark, Professor OF Nephrology
[21] 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

Study design and read-out

An investigator-led Phase 2 study was initiated in anti-GBM antibody disease in 2017 lead by sponsor and coordinating principle investigator, Mårten Segelmark, Professor of Nephrology at Lund University and Linköping University. The study which is an open-label, single-arm multicenter study was conducted in 17 major hospitals from five European countries, including Sweden, Denmark, Czech Republic, France and Austria.

15 patients with poor prognosis (defined in the trial as patients with an eGFR <15% of normal kidney function) were enrolled into the anti-GBM study. Upon recruitment patients were given a single dose of imlifidase, (0.25 mg/kg) on top of standard of care consisting of corticosteroids and cyclophosphamide combined with plasmapheresis with 180 days follow-up. Out of the 15 subjects, six females and nine males (median age of 61 years of age; ranging from 19-79 years of age) were recruited. The last patient was enrolled in January 2020.

The main objective of the study was to assess the efficacy of imlifidase based on renal function at six months after treatment. Normally, 2/3 of patients lose kidney function after six months, requiring chronic dialysis or resulting in death for certain patients. The study also evaluated the safety and tolerability of imlifidase on top of standard of care. Only patients with circulating anti-GBM antibodies and severely reduced renal function (eGFR <15% of normal function) where included into the study, while patients without a functioning kidney were excluded, meaning patients who had not been producing urine for 48 hours or who had been on dialysis for more than 5 days.

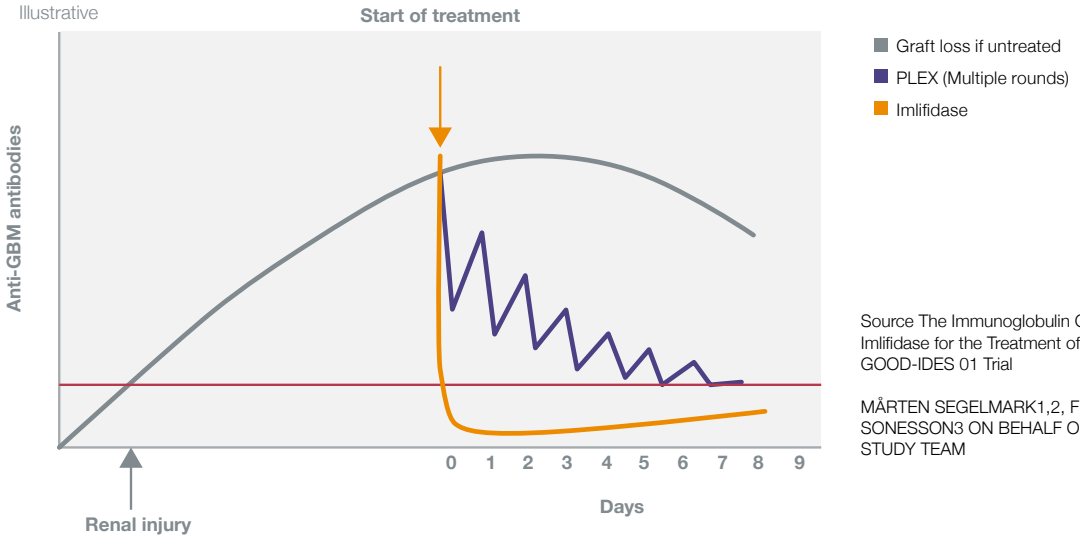
In September 2020, Hansa Biopharma announced positive high-level data from the Phase 2 study of imlifidase in anti-GBM disease. At study inclusion, ten of the patients were dialysis dependent, including five that were oliguric/anuric, while five patients were dialysis independent but had eGFR levels below 15 ml/min. Six hours after imlifidase treatment, no patient had anti-GBM antibody levels above the normal range. Relapses of antibodies were seen in about half of the patients, but were handled with plasma exchanges in most cases.

At six months, ten patients were dialysis independent. Four patients were dialysis dependent, while one patient had died (unrelated to imlifidase treatment). The data read-out concluded that imlifidase treatment may lead to increased renal survival in patients with anti-GBM antibody disease due to rapid clearance of IgG antibodies. The safety profile of imlifidase in the study population was favourable.

Hansa Biopharma was granted orphan drug designation for imlifidase for Anti-GBM antibody disease in both the EU and the US in 2018.

More information about the study is available at ClinicalTrials.gov under NCT03157037.

Potential of using imlifidase vs PLEX in anti-GBM



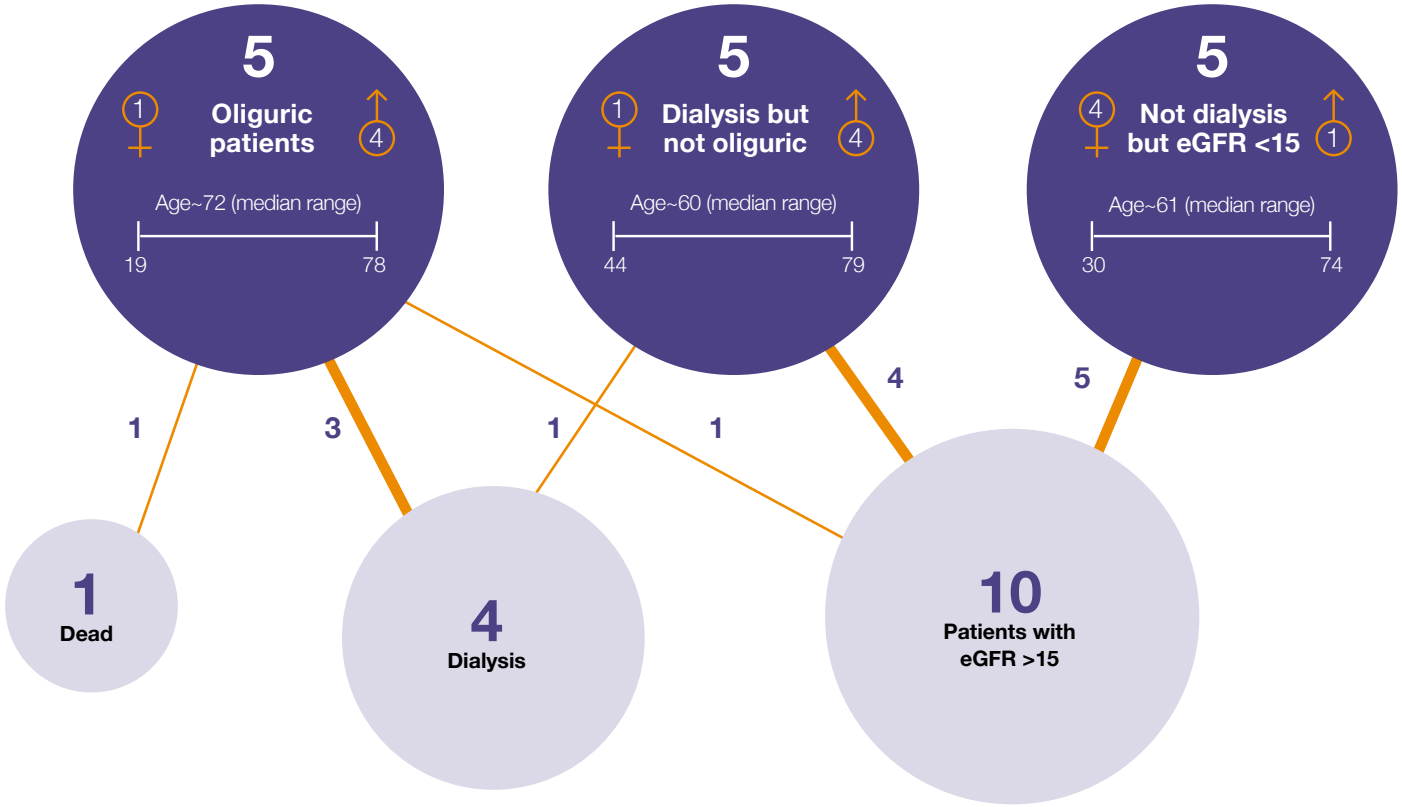
Source The Immunoglobulin G Degrading Enzyme Imlifidase for the Treatment of Anti-GBM Disease – the GOOD-IDES 01 Trial

MÅRTEN SEGELMARK1,2, FREDRIK UHLIN2, ELISABETH SONESSON3 ON BEHALF OF THE GOOD-IDES -1.0 STUDY TEAM

Results show that imlifidase leads to clearance of anti-GBM antibodies

With 2/3 of patients achieving dialysis independence six months after treatment.

Normally 2/3 of patients will lose kidney function and end up in dialysis after six months.*



* Herody et al 1993, Merkel et al 1994, Daly et al 1996, Levy et al 2001, Li et al 2003, Segelmark et al 2003, Cui et al 2005, Taylor et al 2011, Dammacco et al 2013, Zhang et al 2014, Alchi et al 2015, Huart et al, 2016, MacAdoo et al 2017

Active kidney transplant antibody-mediated rejection (AMR)

Long term graft survival is challenged by antibody mediated rejection (AMR) post transplantation

In the U.S. and Europe, there are approximately 45,000 patients who receive kidney transplants annually and approximately 400,000, who currently live with a kidney transplant[22]. Today, one of the leading causes of graft loss is antibody mediated rejection (AMR). AMR is one of the most challenging adverse events after kidney transplantation, occurring in approximately 10% of patients[23], and there is no approved therapy.

Today's praxis for AMR treatment include plasma exchange and treatment with steroids and IVIg. AMR patients not treated successfully risk graft failure, dialysis and return to the waitlist.[24]

Phase 2 program and study design in AMR

Imlifidase is currently being investigated in a phase 2 trial aiming at including 30 AMR patients across centers in France, Germany, Austria, Australia and the U.S. The AMR trial is a randomized, open-label multi-center, active control trial. The study is designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in acute AMR patients post transplantation. Twenty subjects will be randomized to receive imlifidase treatment, one intravenous dose of 0.25mg/kg, while 10 subjects in the active control arm will receive 5-10 sessions of plasma exchange. Efficacy and safety will be monitored over a 6-month period post treatment.

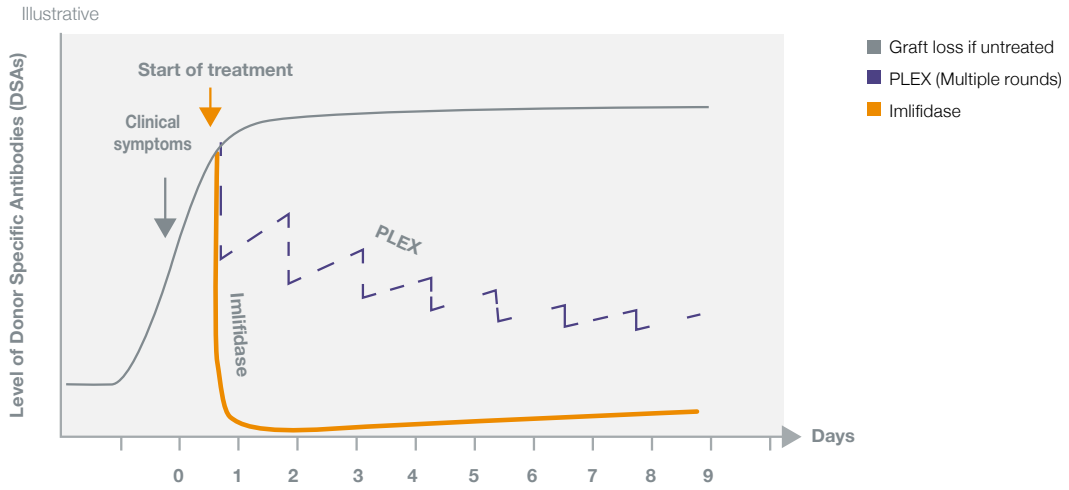
As of March 31, 2021 eight of the targeted thirty patients have been enrolled at six of the targeted eleven clinics. Enrollment is expected to be completed in the second half of 2021 with the first data read out expected in the second half of 2022.

A long-term follow-up study with patients from Hansa's completed AMR phase II trial has been initiated. The primary endpoint of this trial b study is graft survival and patients will be followed for 3 years. Three patients have performed the 1-year visit to this date.

More information about the trial is available at ClinicalTrials.gov under NCT03897205 (2019).

[22] Global Observatory on donation & transplant
[23] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724
[24] Puttarajappa et al., 2012; Jordan et al., 2015

Potential of using imlifidase vs. PLEX in AMR



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, which represents an addressable population of ~ 11,000 per year in the seven major markets[25]. GBS can affect anyone at any age and with many patients deteriorating despite standard of care treatment.

Two thirds of GBS patients have severe symptoms resulting in their inability to walk unaided, and 20-30% require mechanical ventilation for weeks or months[26]. 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 pain and mortality is between 3-5%.[27,28]

Phase 2 program and study design in GBS

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

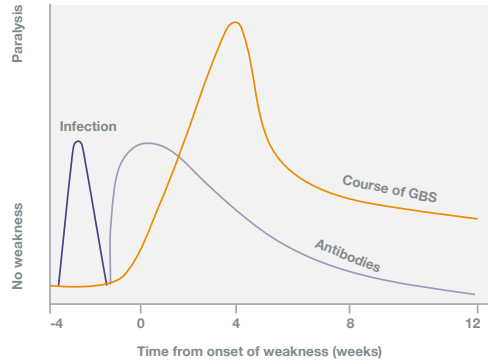
As of March 31, 2021 six of the targeted thirty patients have been enrolled at five of the targeted ten clinics. Enrollment is expected to be completed in the second half of 2021 with the first data read out expected in the second half of 2022.

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

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

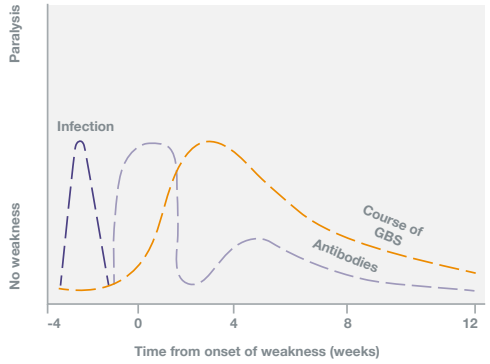
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with Imlifidase

Illustrative



Imlifidase in gene therapy
An emerging opportunity

Neutralizing antibodies (Nabs) are immunological barriers in gene therapy

Genetic disorders are caused by a defect gene failing in producing a functioning protein. Gene therapy treatments are designed to introduce genetic material into cells to compensate for these non-functioning genes to make a functional protein. 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, components from harmless viruses, usually Adeno Associated Viral vectors (AAVs) are used. The transfer and insertion of the healthy gene and it's vector into the cells is called transduction.

There are vectors that can be administered locally to target select 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 before, 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)[29]. 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 curing gene therapy treatment.

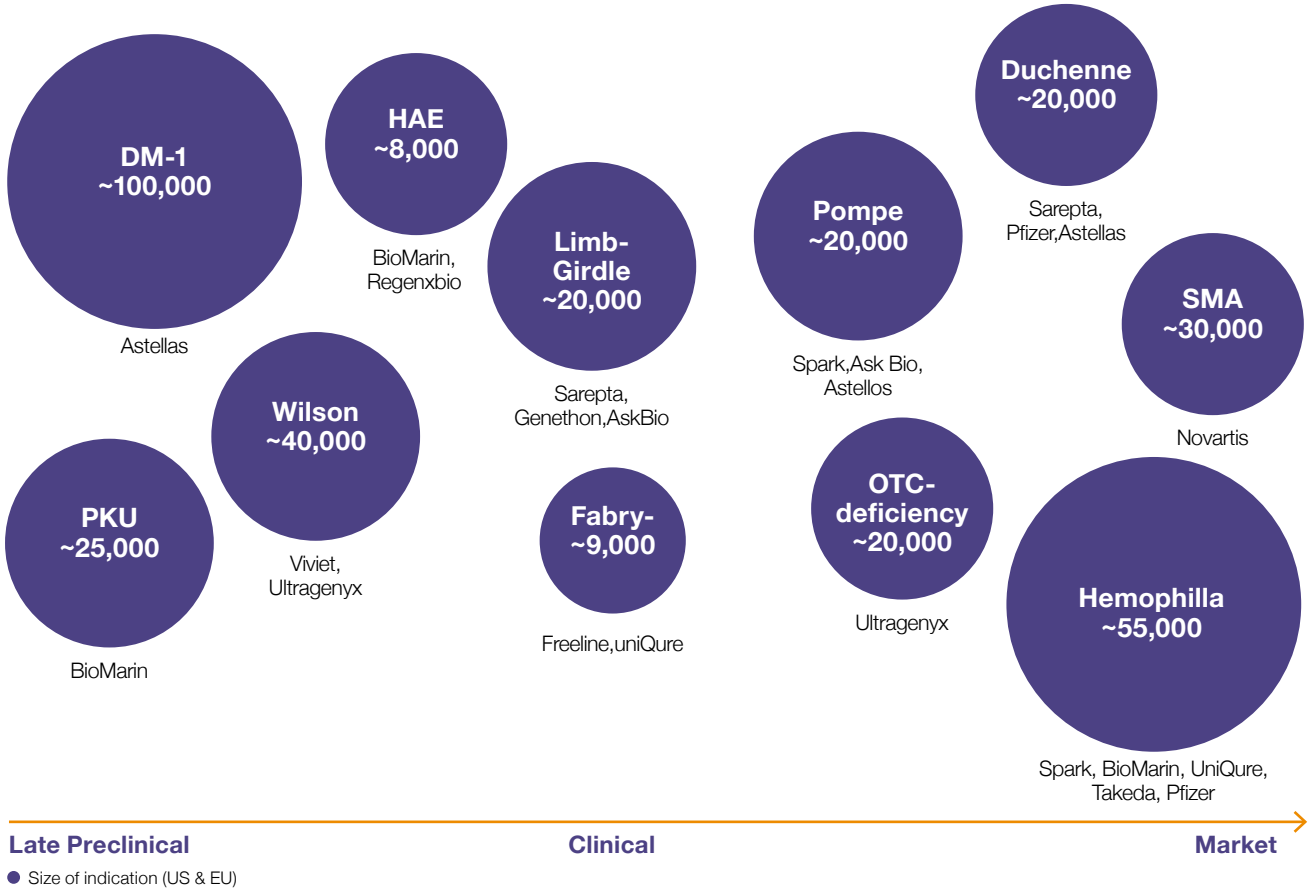
[29] Boutin et al (2010), Griffin et al (2019), Wang et al (2018), Calcedo & Wilson (2013), Falese et al (2017), Haiyan et al (2017), Ellsworth et al (2018), Greig et al (2017)

Systemic gene therapy is an emerging opportunity

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

Rare monogenic diseases

From hundreds of patients to thousands of patients



Imlifidase in gene therapy
An emerging opportunity continued

The hypothesis is that Hansa's antibody cleaving enzyme, imlifidase has the potential to eliminate antibodies that can bind and inhibit the gene therapy and thereby enable effective transfer of a healthy gene sequence in patients with antibodies. The concept of imlifidase effectively and fast cleaving IgG-antibodies has been proven in five clinical studies leading to the Company's first Market authorization in Europe, a conditional approval in highly sensitized kidney transplant patients.

The concept of using imlifidase as a potential pre-treatment to overcome pre-existing antibodies to AAV based gene therapy was highlighted in a recognized medical journal "*Nature Medicine*" in 2020[30]. Results from preclinical studies were published with very encouraging outcome where imlifidase was shown to eliminate the blocking effect of AAVs in a mouse model, in non-human primates (NHP) as well as in human plasma samples from patients with antibodies against AAVs.

With validated clinical data from five clinical studies in kidney transplantation and promising preclinical data in gene therapy, Hansa Biopharma sees growing interest among peer biopharma companies for the possibility to combine imlifidase with gene therapy treatment to reach new patient populations for already approved drugs or drugs in late clinical development. This was evidenced with the announcement a license agreement between U.S. based Sarepta Therapeutics and Hansa Biopharma in July 2020. Under the terms of the agreement Sarepta will get the exclusive right to develop and promote imlifidase as a pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy and Limb-Girdle Muscular Dystrophy.

Tropism and target tissue

Eye (local target)
~$1x10^{11}$ vg

AAV 1, 2 & 5

Brain (local target)
~$1x10^{12}$ vg

AAV 4 & 8

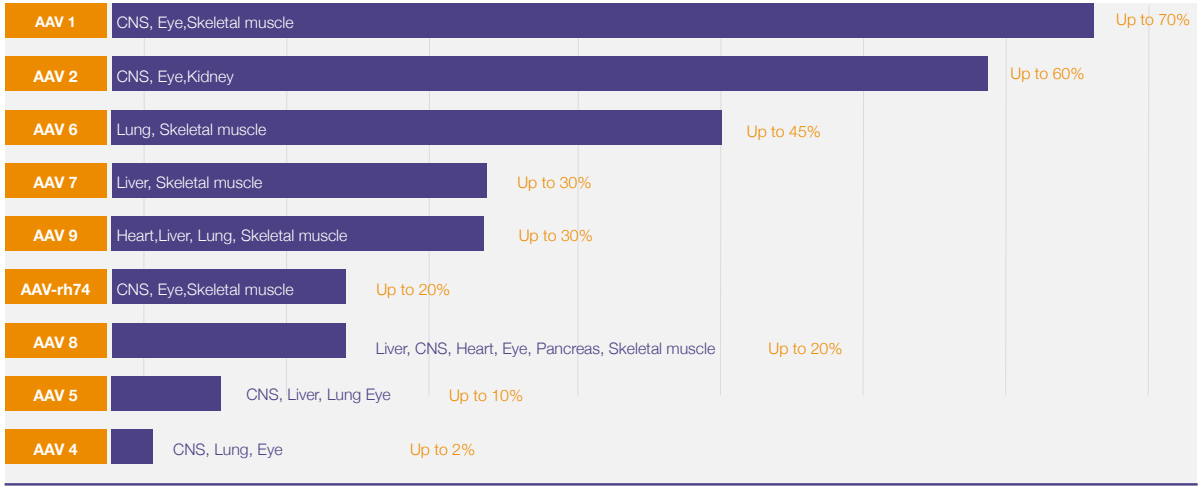
Liver (systemic)
~$1x10^{14}$ vg

AAV 3,7 & 8

Muscle (systemic)
~$1x10^{15}$ vg

AAV 6, 7, rh74

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



Prevalence of Nabs in AAVs

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)

[30] 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

Exclusive license agreement with Sarepta Therapeutics to promote and develop imlifidase in Duchenne (DMD) and Limb-Girdle (LGMD)

Sarepta Therapeutics is a global leader within gene therapy targeting DMD and LGMD.

In July 2020, Hansa entered into an agreement with Sarepta Therapeutics Inc. ("Sarepta") through which Sarepta is granted an exclusive, worldwide license to develop and promote imlifidase as a pre-treatment to enable Sarepta gene therapy treatment in Duchenne muscular dystrophy (DMD) and Limb-girdle muscular dystrophy (LGMD) 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 pre-clinical and clinical studies with imlifidase and any subsequent regulatory approvals. Sarepta will also be responsible for the promotion of imlifidase as a pre-treatment to Sarepta's gene therapies following potential approval.

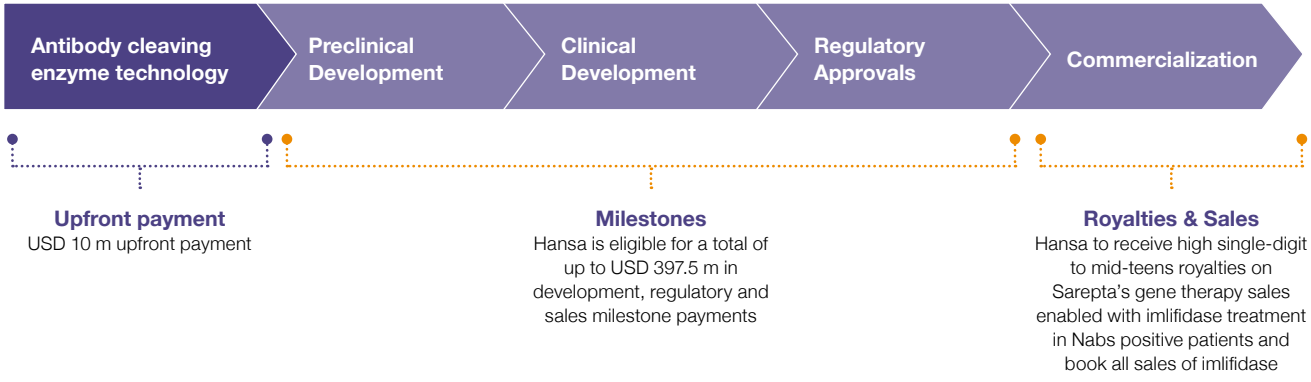
Under the terms of the agreement, the Company received a USD 10 m upfront payment, and is eligible for a total of up to USD 397.5 m in development, regulatory and sales milestone payments.

The partnership has been progressing as planned, and during the second half of 2020 Sarepta initiated ongoing pre-clinical investigations with imlifidase as a potential pre-treatment in the gene therapy setting. For further information regarding the progress in Sarepta's gene therapy programs in DMD and LGMD please refer to www.sarepta.com.

HANSA BIOPHARMA + SAREPTA THERAPEUTICS

Hansa's key resources
- Imlifidase know how
- Clinical data and EMA approval
- GMP-grade imlifidase

Serepta's key resources
- World leader within gene therapy targeted at muscular dystrophies
- Pre-clinical plan: PoC and IND-tox
- Clinical / Regulatory
- Promotion



Exclusive license agreement with Sarepta Therapeutics to promote and develop imlifidase in Duchenne (DMD) and Limb-Girdle (LGMD) continued

About Duchenne Muscular Dystrophy (DMD)[31]

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 is a mutation in the DMD gene, that 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 is caused by a change or mutation in the gene that encodes instructions for creating dystrophin, an essential protein for muscle strength. Dystrophin is a protein that plays a key structural role in muscle fiber function. In healthy muscle, dystrophin interacts with other proteins at the cell membrane to stabilize and protect the cell during regular activity involving muscle contraction and relaxation. Genetic testing can confirm the diagnosis and identify the disease-causing mutation in the dystrophin gene.

Individuals with Duchenne produce little or no dystrophin in their muscle. Without dystrophin, normal activity causes excessive damage to muscle cells, and over time is replaced with fat and fibrotic tissue.

Duchenne affects approximately 1 in 3,500 to 5,000 males born worldwide[32]. Approximately 15% of DMD patients have pre-existing IgG antibodies to the AAV-vector rh74[33].

About Limb-Girdle Muscular Dystrophy (LGMD)[34]

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.

Symptoms may appear at any age, depending on the type of LGMD, and in some subtypes tend to progress faster in younger patients. Individuals may have trouble getting out of chairs or climbing stairs. Eventually, they may need a wheelchair to get around. Some forms of the disease lead to heart and breathing problems and early death.

Taking into account the various subtypes, limb-girdle muscular dystrophy has a global prevalence of approximately 1.63 per 100,000 individuals worldwide[35]. Over 30 subtypes exist, and both genders are affected equally. Approximately 15% of patients have pre-existing IgG antibodies to the rh74 vector[36].

[31] https://www.sarepta.com/disease-areas/duchenne-muscular-dystrophy
[32] https://www.duchenne.com/about-duchenne
[33] GriffinDA, PotterRA, PozsgaiER, et al. Adeno-associated virus serotype rh74 prevalence in muscular dystrophy population. Presented at the American Society of Gene and Cell Therapy (ASGCT) 22nd Annual Meeting.April 29-May 2, 2019. Washington, DC.
[34] https://www.sarepta.com/disease-areas/limb-girdle-muscular-dystrophy
[35] https://limbgirdle.com/what-is-lgmd
[36] GriffinDA,PotterRA,PozsgaiER, et al.Adeno-associated virus serotype rh74 prevelence in muscular dystrophy population. Presented at the American Society of Gene and Cell Therapy (ASGCT) 22nd Annual Meeting.April 29-May 2, 2019. Washington, DC.


Stock image

Imlifidase in a gene therapy setting

Interview

Q What is gene therapy and why is it relevant to Hansa?

A Gene therapy is an exciting emerging treatment paradigm that offers the potential to cure some rare diseases. Genetic disorders are caused when a gene is either missing completely or is not producing the desired or functioning protein it should do. Previously treatments of genetic disorders often tackled symptoms, but with gene therapy you can introduce a normal functioning gene into a cell to replace a missing or defective gene. However, a barrier to gene therapy can be pre-existing antibodies developed previously by a person's immune system.

These antibodies inhibit the viral vector that is used to carry the gene into a cell. This is where Hansa's technology comes to play. With the imlifidase technology we can pre-treat the patient to reduce the level of antibodies before the gene therapy is given to the patient, so the normal functioning gene can make the proteins that were missing.

Q How important is the control of antibodies for the success of gene therapy?

A The body's immune response can be a significant barrier to successful treatment of many rare diseases with gene therapy. It differs depending on the disease but for Duchenne muscular dystrophy where we are working with Sarepta, around 20% of patients have antibodies which make them not eligible for gene therapy treatment.

Q How does imflidase work to tackle antibodies produced against the viral vector?

A Our technology is used to cleave the antibodies and thereby inactivate them and, in this way, potentially enable the gene therapy treatment to work to enter the cells and be exposed. This is a scientifically validated approach, and we were very pleased that this proof of concept has been published in the prestigious journal Nature Medicine[37].

Q The Sarepta deal signed in 2020 was a first of its kind for Hansa, how is that going?

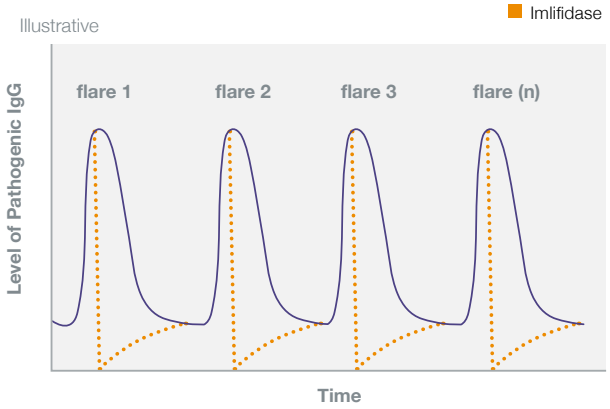
A We are focusing on two diseases under this collaboration – Duchenne muscular dystrophy and Limb-girdle muscular dystrophy – for patients that have pre-existing antibodies to Sarepta's gene therapy treatment. Of course, this could be important for other diseases where gene therapy is considered but is limited due to the creation of antibodies. It is exciting to be part of the Sarepta collaboration and both teams from Hansa and Sarepta are learning a lot. We have a good way of working together and everyone involved understands the potential that, if proved to work, pretreatment with Imflidase could create for patients and parents of children who have these rare diseases. It's very inspiring to be working with such a focused purpose.

Lena Winstedt
Head of Science

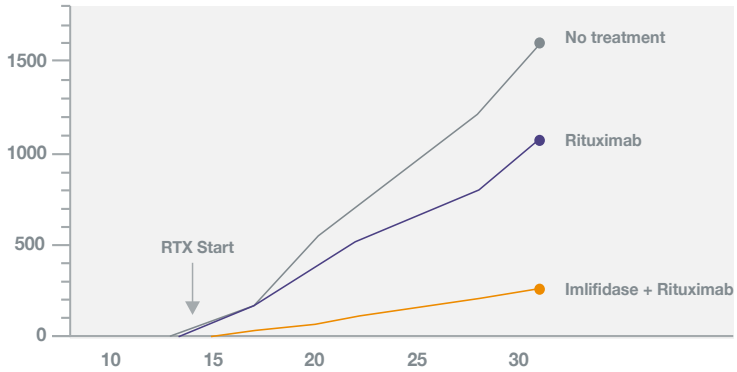
[37] Leborgne, C., Barbon, E., Alexander, J.M. et al. IgG-cleaving endopeptidase enables in vivo gene therapy in the presence of anti-AAV neutralizing antibodies. Nat Med 26, 1096–1101 (2020). https://doi.org/10.1038/s41591-020-0911-7

Research and preclinical development projects

NiceR can potentially inactivate flares



Mice with human IgG (~9mg/mL)



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

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

Hansa's NiceR-program (Novel Immunoglobulin Cleaving Enzymes for Repeat dosing) is a new set of enzymes for repeat dosing for potential inactivation of flares in relapsing diseases. The new IgG-cleaving enzymes may have lower immunogenicity, which potentially may enable applications in a broad array of indications with significant unmet medical need, including reoccurring, relapsing autoimmune diseases and oncology.

A broad repertoire of novel immunoglobulin cysteine endopeptidases have been developed and patented within the program and a lead candidate was selected in 2019 for clinical development from the NiceR program.

The first selected promising new drug candidate from the NiceR program is an IgG-cleaving enzyme (cysteine peptidase) with characteristics based on a homolog to imlifidase, but with potential for lowered immunogenicity.

EnzE – Enzyme-based antibody Enhancement

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

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

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

Other

Stock image

Shareholder information

The Hansa Biopharma share is listed on Nasdaq OMX Stockholm, under the ticker HNSA and included in several indexes including but not limited to:

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

Listing	Nasdaq OMX Stockholm
Number of shares	45,894,909 (44,473,452 A-shares and 1,421,457 C-shares)
Market capitalization (Dec. 31, 2020)	SEK ~11 bn
Ticker	HNSA
ISIN	SE0002148817

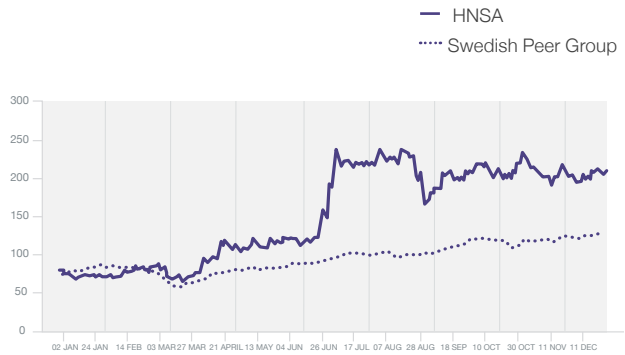
Brief facts, the Hansa Biopharma-share

According to the shareholder register maintained by Euroclear Sweden AB, as of 31 December 2020, Hansa Biopharma had approximately 17,000 shareholders shareholders. On 31 December 2019, Hansa Biopharma had approximately 14,000 shareholders. Information regarding shareholders and shareholdings is updated each quarter on the Company's website, www.hansabiopharma.com.

Share capital

Total shares outstanding as of 31 December 2020 amounted to 44,473,452 ordinary shares and 1,421,457 C-shares. At year end the share capital amounted to SEK 45,894,909. At the general meeting, each 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 amongst the Company's outstanding shares with a quotient value of SEK 1 per share.

Hansa share price development versus peer group* during 2020



*Peer group consist of biotech companies listed on NASDAQ OMX Stockholm with a market capitalization above 1bn SEK (as of 2020-02-01) and negative EBITDA on a rolling 12 months basis.

Closing price for the HNSA share in 2019 and 2020

	2019		2020	
SEK	**High**	**Low**	**High**	**Low**
1st quarter	299.0	211.0	89.0	63.6
2nd quarter	230.2	161.3	177.2	78.2
3rd quarter	195.7	129.6	276.0	164.9
4th quarter	159.8	65.1	272.0	220.0

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

Ownership and analyst coverage

Top 10 largest shareholders, 31 December 2020

Owners	Number of shares HNSA	Capital (%)
Redmile Group	4,625,590	10.4
Consonance Capital Management LP	2,212,527	5.0
NXT2B	2,155,379	4.8
Invesco	1,999,188	4.5
Handelsbanken Fonder AB	1,936,783	4.4
Thomas Olausson	1,770,474	4.0
Fourth Swedish National Pension Fund	1,564,846	3.5
Avanza Pension	1,257,577	2.8
Gladiator	1,025,000	2.3
ClearBridge, LLC	1,012,786	2.3
Other	24,913,302	56.0
Outstanding ordinary shares in total	44,473,452	100.0

As of 31 December 2020, Hansa Biopharma had approximately 17,000 shareholders.

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

~17,000

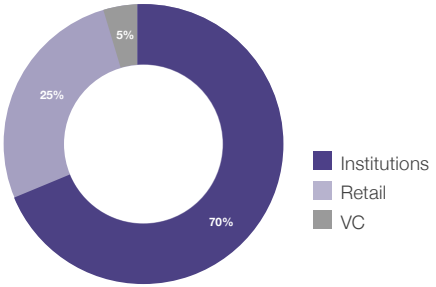
SHAREHOLDERS

Analyst coverage 2020

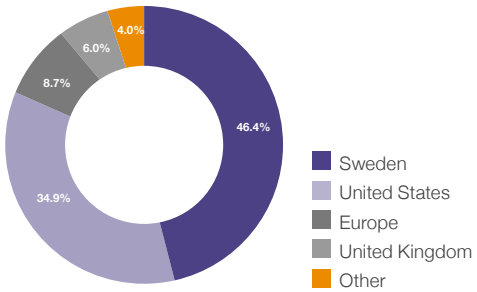
Analyst	Bank / Research institution (year of initiation)	Location	Email	Phone
Christopher Uhde	SEB (2016)	Stockholm	christopher.uhde@seb.se	+46 (0) 876-385 53
Viktor Sundberg	ABG Sundal Collier (2018)	Stockholm	viktor.sundberg@abgsc.se	+46 (0) 856-628 641
Charles Weston	RBC (2017)	London	charles.Weston@rbccm.com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

Ownership by type and location, 31 December 2020

Split by investor type



Split by region



Other information

Forward looking statements

This Annual Report may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future.

Some of these forward-looking statements, by their nature, could have an impact on Hansa Biopharma's business, financial condition and results of operations or that of its parent, affiliate, or subsidiary companies. Terms such as "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements.

There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to, changes in implementation of Hansa Biopharma's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Hansa Biopharma's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize imlifidase if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Hansa Biopharma's potential market and industry; the ability to develop new products and enhance existing products; the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

The factors set forth above are not exhaustive and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment, and it is not possible to predict all factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

Hansa Biopharma expressly disclaims any obligation to update or revise any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or otherwise, and disclaims any express or implied representations or warranties that may arise from any forward-looking statements. You should not rely upon these forward-looking statements after the date of this presentation.

Imlifidase regulatory status

Imlifidase is subject to conditional authorisation in the EU for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor.

Imlifidase is an investigational product candidate in the U.S. and is currently under development for desensitization treatment of highly sensitized adult kidney transplant patients. Imlifidase has not been approved by the U.S. Food and Drug Administration (FDA).

Dividend

The Board proposes no dividend for the financial year 2020. For more information about Hansa Biopharma's dividend policy, please refer to the Hansa Biopharma Corporate Governance Report available at the Company website at https://hansabiopharma.com/this-is-hansa/corporate-governance/

Long-term incentive programs

Hansa Biopharma has three ongoing incentive programs for the Company's employees as of December 31, 2020:

A performance based share program and a warrant program (LTIP 2018) adopted by the Annual General Meeting on May 29, 2018.

A performance based share program, a warrant program and an option program (LTIP 2019) adopted by the Annual General Meeting on May 22, 2019.

A performance based share program and an option program (LTIP 2020) adopted by the Annual General Meeting on June 23, 2020.

Descriptions of the various programs can be found in the respective section of the Directors' Report

Financial calendar 2021

Annual Report 2020	April 8, 2021
Interim report for January – March 2021	April 22, 2021
Annual General Meeting	May 12, 2021
Interim report for January – June 2021	July 15, 2021
Interim report for January – September 2021	October 21, 2021

Contacts

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Glossary

AMR
Antibody mediated transplant rejection.

Antibody
One type of protein produced by the body's immune system with the ability to recognize foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM. The different isotypes have slightly different structures and they play different roles in the immune system. Immunoglobulin G, IgG, is the most common type in the blood and tissue and provides the majority of antibody-based immunity against invading pathogens. IgA is mainly found in mucosal areas and prevents colonization by pathogens. IgD mainly functions as receptor on B-cells that have not yet been activated. IgE binds to allergens and is involved in allergy. IgM is mainly found in the blood and is part of the first response against an infection.

Anti-GBM disease (Goodpasture syndrome)
Anti-GBM antibody disease is a disorder in which circulating antibodies 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.

Biopharmaceutical
A pharmaceutical drug that is manufactured using biotechnology.

Biotechnology
The use of live cells or components of cells, to produce or modify products used in health care, food, and agriculture.

CD20
B-lymphocyte antigen CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

Clinical studies
Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

Clinical Phase 1
The first time a drug under development is administered to humans. Phase I studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

Clinical Phase 2
Refers to the first time a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

Clinical Phase 3
Trials that involve many patients and often continue for a longer time; they are intended to identify the drug's effects and side effects during ordinary but still carefully controlled conditions.

DSA
Donor specific antibodies. Donor specific antibodies are antibodies in a transplant patient which bind to HLA and/or non-HLA molecules on the endothelium of a transplanted organ, or a potential donor organ. The presence of pre-formed and de novo (newly formed) DSA, specific to donor/recipient mismatches are major risk factors for antibody-mediated rejection.

EMA
The European Medicines Agency (EMA) is a European Union agency for the evaluation of medicinal products.

Enzyme
A protein that accelerates or starts a chemical reaction without itself being consumed.

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.

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.

Pivotal trial
A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase 2 studies can be used as pivotal studies if the drug is intended to treat life-threatening or severely debilitating conditions.

PRA
Panel Reactive Antibody (PRA) is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as a percentage between 0% and 99%. It represents the proportion of the population to which the person being tested will react via pre-existing antibodies.

Preclinical development
Testing and documentation of a pharmaceutical candidate's properties (e.g. safety and feasibility) before initiation of clinical trials.

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.

Directors' Report

Stock image

2020 Directors' report

Operations

Hansa Biopharma is leveraging its proprietary enzyme technology platform to enable immunomodulatory treatments for transplants, rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer

The Company's lead product candidate, imlifidase, is an antibody-cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation and acute autoimmune indications. The European Commission has conditionally approved Idefirix® (imlifidase) for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

Hansa Biopharma's research and development program is also advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

2020 Business review

2020 was overall a very successful and transformative year for Hansa Biopharma – a year with significant milestones achieved paving the Company's evolution into a fully integrated, commercial-stage biopharmaceutical Company:

- The EU Commission granted conditional approval for Idefirix® (imlifidase) in highly sensitized kidney transplant patients in the European Union. The conditional approval by the European Commission serves as a landmark milestone for Hansa Biopharma, as Idefirix® is the Company's first approved drug and will transform Hansa Biopharma into a commercial-stage biopharmaceutical Company.
- The Company entered into an exclusive agreement with Sarepta Therapeutics, the leader in precision genetic medicine for rare diseases. Through the agreement Sarepta is granted an exclusive, worldwide license to develop and promote imlifidase as a pre-treatment to Sarepta's gene therapy treatment in Duchenne muscular dystrophy (DMD) and Limb-girdle muscular dystrophy (LGMD).
- Hansa successfully completed the placement of 4.4 m newly issued shares raising gross proceeds of SEK 1.1 billion. The share issue was multiple times oversubscribed due to high demand from US, European and Swedish institutional investors.
- Early 2020, Hansa announced long term follow-up data that demonstrates 2-year graft survival of 89% after imlifidase treatment and transplantation. Data was highlighted at the Cutting Edge of Transplantation summit 2020.
- An important milestone was achieved related to Hansa's potential expansion into autoimmunity – positive high-level data from an investigator-initiated phase 2 trial with imlifidase to treat anti-GBM disease was reported in autumn 2020. The study concludes that imlifidase leads to rapid clearance of anti-GBM antibodies, with two-thirds of patients achieving dialysis independence six months after treatment.
- In the U.S, Hansa continued its dialogue with the U.S. Food and Drug Administration (FDA) around the proposed study protocol for a new, randomized controlled study of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients.
- In October, Hansa hosted its third Capital Markets Day. The CMD event was focused on Hansa Biopharma's transformation into a fully integrated and commercial stage biopharmaceutical company and highlighted the potential of the Company's unique antibody-cleaving enzyme platform in and beyond transplantation. The three-hour virtual CMD event was attended by more than 500 live viewers.
- Professor Achim Kaufhold, M.D. appointed CMO and member of the Hansa executive committee.
- Hansa highly values its people and their dedication to Hansa's vision and common goals. This is reflected in Hansa's certification as Great Place to Work® in 2020 based on the results of a Company-wide employee survey and a review of policies.

However, beyond the significant achievements during 2020, the Company has also seen its pipeline activities, specifically related to the recruitment of patients in the ongoing AMR and GBS phase 2 studies, as well as its activities to prepare for a commercial launch of Idefirix® in Europe, significantly impacted by the COVID-19 pandemic.

Given the current status and uncertainties around the COVID-19 pandemic, the Company may continue to see negative impact on its operational business and clinical trial activities in 2021, including potentially related to:

- Recruitment timelines for ongoing and planned clinical studies.
- Completion of FDA interaction related to and initiation of recruitment into the planned US phase 3 study.
- Commercial launch of imlifidase in Europe.

Hansa Biopharma will continue to monitor the situation very closely and diligently, maintain measures to protect employees and take social responsibility, implement further measures as required and keep the markets informed should the assessment of any potential impact change substantially.

2020 Directors' report continued

Risk management

Hansa Biopharma 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 Biopharma´s risk management policy was launched in 2015 and reviewed and revised in 2020. It provides management with a facilitating framework providing guidance when dealing with risks inherent in achieving the organization's objectives and to:

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

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

Risk factors

Hansa Biopharma'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.

Product development, regulatory approval and commercialization

The Company operates procedures to secure the integrity and protection of its R&D activities and data, and to optimize allocation of budgets and resources. The progress of the R&D programs is monitored by its executive committee and discussed with the Board of Directors. Board members with expertise in clinical and scientific matters may occasionally attend meetings with the Company's scientific staff to discuss and assess such programs.

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

The Company cannot give any assurance that any product candidate will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized. Hansa's business and future success is substantially dependent on its ability to develop successfully, obtain regulatory approval for, and then successfully commercialize its product candidate imlifidase and its other product candidates. Hansa is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA, the EMA or any other comparable regulatory authority, and Hansa may never receive such regulatory approval for any of its product candidates.

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 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 harmed, and Hansa's ability to generate revenues from any of these product candidates will be delayed and may be 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 complete 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.

2020 Directors' report continued

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 affect patient recruitment or the ability of enrolled patients to complete the trial 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 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 product candidates, if approved, that could materially affect the opportunity to commercialize.

Collaboration and partnerships

Hansa Biopharma is involved in the research and development of pharmaceuticals and, for many years, has cooperated with well-established researchers with whom the Company has had long-term relationships. However, some of these cooperation projects are governed by agreements with terms of only one year each time. Were these agreements to terminate or not be renewed, it might have negative consequences both for the Company's business operations as well as its earnings and financial position.

Hansa 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 products, if approved. Such partnerships and agreements may be terminated, unsuccessful, not achieve the intended results and outcomes, not met Hansa's objectives or expectations and therefore materially negatively impact Hansa's business, its financial position and earnings prospects.

Reliance on Contract Research Organisations (CROs)

Hansa Biopharma has relied upon and plan to 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 and clinical trials and control only certain 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 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 ad 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 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 a 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 fail to obtain and/or maintain patent protection and trade secret protection of its product candidates and/or products, it could lose its competitive advantage and the competition the Company face would increase, reducing or eliminating any potential revenues and adversely affecting its ability to attain or maintain profitability and the end result could be a significant lower market value, and thus share price, of Hansa Biopharma.

2020 Directors' report continued

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 Biopharma has under development, 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 Biopharma's success is dependent on its ability to induce potential customers to replace known products or methods with those of Hansa Biopharma.

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 Biopharma. This may lead to the Company not being able to sell its products which may negatively affect the Company's earnings.

Reliance on Contract Manufacturing Organisations (CMOs)

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

Hansa Biopharma 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 may 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 sell its products which may negatively affect the Company's earnings.

Pricing and reimbursement

On many markets, purchases of pharmaceuticals of the type being developed 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 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 Biopharma 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 Biopharma carries out capital-intensive and value generating pharmaceuticals development and commercialization. Future financing of the operations is expected to take place through new issues of shares, loans, licensing revenue, cooperation with other parties, and the sales of rights and/or patents. Hansa Biopharma has financed its business operations thus far partially with the help of milestone compensation and one-time compensation amounts from the Company's current and previous cooperating partners and with royalty revenue from licensing agreements. However, the operations have mostly been financed with shareholders' equity through new issues of shares, primarily rights issues to the shareholders.

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 25.

2020 Directors' report continued

Sustainability, social responsibility and employee relations

Hansa Biopharma strives to create sustainable value by developing drugs that can give people a better and longer life. Hansa's vision, *a world where patients with rare immunologic diseases can lead long and healthy lives*, reflects that sustainability is central to the Company.
Hansa Biopharma has sustainability at its heart. Indeed, by developing drugs that seek to prolong and significantly enhance the lives of people around the world, sustainability is why Hansa exists and works tirelessly to bring pioneering and life changing treatments to those who need them most. Hansa's vision is simple yet compelling, and whilst not easy to achieve is something that unites everybody associated with Hansa Biopharma; *a world where patients with rare immunological diseases can lead long and healthy lives*.

Social and environmental sustainability are vital aspects of the way Hansa operates, ensuring the long-term success of the Company for the benefit of patients. Its operations are conducted in compliance with regulatory guidelines and industry standards that naturally integrates many of the most important sustainability issues. Hansa's sustainability work focuses on conducting clinical development in compliance with ethical rules and guidelines, taking into account the environmental impact of both Hansa's operations and those of its suppliers.

Hansa Biopharma's pharmaceutical development takes place in a strictly regulated environment. Trials and studies are required throughout the preclinical and clinical phases of development to ensure that the resulting drugs are both efficacious and safe. Regulatory approvals are always required for clinical studies, which are carried out within the framework of the regulatory and ethical regulations of the countries in question. The trials and studies are structured in compliance with applicable standards, guidelines, and directives, e.g. Good Clinical Practice (GCP).

Hansa Biopharma works actively with environmental issues and consistently endeavours to reduce the use of environmentally hazardous substances and to ensure that the environmental impact is as little as possible. The Company makes limited discharges from laboratories and development facilities. Discharges consist of common salts and easily decomposable organic substances.

Waste is sorted and special routines are applied for the handling of environmentally hazardous waste. Hansa Biopharma uses genetically modified microorganisms (GMM) in its research and development work (research activities). The Company's operations are subject to a notification obligation under the Swedish Environmental Code with a reporting obligation to the municipality of Lund.

As a knowledge-intensive Company, Hansa wants its employees to be able to attend international conferences and meetings to promote the development and the exchange of ideas and experiences. Hansa is, however, also keen to reduce the environmental impact caused by unnecessary business trips by encouraging conference calls and online meetings.

Personal development

Besides ensuring Hansa's employees operate sustainably, Hansa Biopharma as an organisation also values the employee with a sustainable approach. Hansa strives to ensure that every employee can make a difference with their extensive experience and highly developed competencies. The Company's employees play a key role in fulfilling and reaching Hansa's vision and are therefore its most valued asset. These values are something Hansa looks at as an integral skill and characteristic during recruitment, alongside a clear compatibility with the Company's mission statement.

Hansa Biopharma is responsible for providing personal and professional development opportunities. The model for this is the Hansa Biopharma PR (performance review).

Work Environment

As an employer, Hansa's responsibility is to ensure good working conditions in a healthy and sustainable work environment. The Company and its employees design the work environment collaboratively. Employee satisfaction is measured through an annual survey. Hansa as the employer has however the principal responsibility to ensure that necessary measures are taken and followed. Each manager shall thereby ensure that tasks and workplaces are designed and further-developed so that employees are protected. All factors causing accidents, sickness and psycho-social problems are taken into consideration in preventive and systematic work environment processes. Hansa takes responsibility to ensure that the work environment is safe, but the employee must participate in the processes to keep it safe. This does for instance include following work instructions, participation in training or the use of protective equipment provided by the employer. In some instances, this will be mandatory.

Hansa Biopharma encourages staff to openly discuss things that affect them negatively, such that the immediate supervisor, or responsible individual, can in turn take responsibility for the work environment and take corrective actions. Indeed, communication is proactively sought through a number of channels over the course of the year.

2020 Directors' report continued

Recruitment & gender

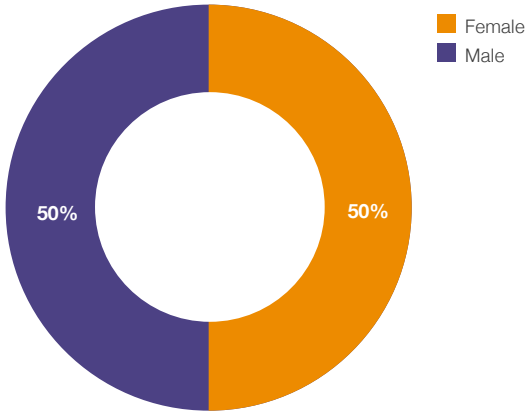
Each of Hansa's employees is equally valued and has an important role to play and Hansa must have the right capabilities throughout its business. It is therefore critical that the Company is successful in its recruitment strategies, using a fair and transparent recruitment process free of discrimination. Hansa's dedicated talent acquisition team are focused on promoting equal treatment of all employees and job applicants and see both the commercial and human value of a diverse workforce. During 2020, Hansa attracted 20 new colleagues to meet the demands as the Company grew as an organization. This equated to a global growth for Hansa Biopharma of 19%, and including all summer workers the turnover for Hansa Biopharma was 7% during 2020.

Hansa actively promotes gender equality, for example, through conducting a yearly salary survey to ensure that men and women have the same salary for the same and equivalent work. The yearly salary survey also serves as a tool for the organization to avoid salary drift and to discover any unconscious discrimination. Hansa's recruitment approach strives to deliver diverse candidate shortlists that incorporate not just a balance in terms of gender, but where individuals with any protected characteristics are afforded equal opportunity to be successful. The Company is immensely proud of its people and continues to search globally for the best talent.

In December 2020, gender distribution at Hansa Biopharma was 59% women and 41% men. The Company's management, comprised of all people managers globally, was divided into 50% women and 50% men.

Hansa Biopharma's success is based on its ability to collaborate, both internally and externally. The Company does its utmost to provide a secure and safe workplace and a positive working environment based upon a conviction that a good working climate lays the foundation for job satisfaction, superior performance and good relationships. With this in mind Hansa has an ongoing Great Place to Work process with trust as the main ingredient in building a great workplace for all. Establishing a sustainable foundation of trust is the best investment the Company can do for its organization in order to recruit, retain and develop employees.

Global Company management



2020 Directors' report continued

Revenue and financial result

Revenue for 2020 amounted to SEK 6.1 m (2019: SEK 3.4m) and comprises of revenue recognition from the upfront payment the Company received under the Sarepta agreement, royalty income from Axis-Shield Diagnostics (Abbott group) and patent cost reimbursements.

Other operating income for 2020 amounted to SEK 2.2m (2019: SEK 0.2m). The other operating income for 2020 comprise mainly of a net foreign currency gain on receivable/liabilities. The other operating income 2019 comprise of a research grant from Vinnova. No other operating expense was recognized for 2020 (2019: SEK -2.1m).

The operating result for 2020 amounted to SEK -422.8m (2019: SEK -359.7m). Compared to 2019, 2020 expenses have increased primarily due to preparatory activities throughout the organization related to the commercial launch of imlifidase and increased investments in ongoing R&D activities. The result for 2020 includes non-cash expenses related to the Company's long-term incentive programs (LTIP) amounting to SEK 43.3m (2019: SEK 7.2m). The increase in the LTIP-related non-cash expenses is primarily driven by the increase in the Company's share price relevant to the calculation of the respective expenses.

Net loss for 2020 amounted to SEK 420.9m (2019: SEK 360.0m).

Cash flow and financial position

Cash flow from operating activities amounted to SEK -290.3m in 2020 (2019: -334.8m). The cash flow was positively impacted by the USD 10 m (SEK 81.9m) upfront payment Hansa received in July 2020 upon entering into the agreement with Sarepta Therapeutics.

Five-year summary

KSEK, unless other stated	2020	2019	2018	2017	2016
Revenue	6,098	3,364	3,358	3,442	2,579
Sales, general and administration expenses	-202,987	-167,310	-90,387	-43,723	-29,703
Research and development expenses	-227,191	-192,949	-154,558	-137,060	-82,850
Other operating income/expense	2,270	-1,907	-3,995	1,479	-944
Operating profit/loss	-422,807	-359,668	-246,498	-176,083	-111,135
Net profit/loss	-420,853	-360,009	-247,974	-176,660	-111,129
Cash flow from operating activities	-290,274	-334,775	-204,560	-150,105	-94,563
Cash and cash equivalents, including short-term investments	1,377,506	601,094	858,187	616,061	253,578
Shareholder's equity	1,242,124	562,815	859,876	630,661	283,693
Earnings per share before and after the dilution (SEK)	-9.98	-9.00	-6.47	-4.97	-3.37
Number of outstanding shares at the end of the period	44,473,452	40,026,107	39,959,890	37,087,386	35,054,860
Weighted average number of shares before and after dilution	42,176,872	40,020,429	38,326,098	35,519,029	32,773,304
Number of FTE' end of the period	87	74	52	33	27

2020 Directors' report continued

Cash and cash equivalents including short term investments amounted to SEK 1,377.5m as of December 31, 2020 (SEK 601.1m as of December 31, 2019). In July 2020, Hansa successfully completed the placement of 4.4 m ordinary shares raising net proceeds of SEK 1,071m.

Capital expenditures

Capital expenditures during 2020 amounted to SEK 0.3m (2019: SEK 3.4m).

Shareholders' equity

On December 31, 2020 shareholders equity amounted to SEK 1,242.1m compared to SEK 562.8m at the end of the financial year 2019.

Parent Company

The Parent Company's revenue for 2020 amounted to SEK 6.1m (2019: SEK 3.4m). The net loss for the Parent Company amounted to SEK 421.6m for 2020 (2019: SEK 360.4m). On December 31, 2020, cash and cash equivalents including short-term investments amounted to SEK 1,371.8m compared to SEK 596.1m at the end of the year 2019.

The Parent Company's shareholders equity amounted to SEK 1,241.6m as per December 31, 2020, compared to SEK 562.8m at the end of 2019.

The Group consists of the Parent Company Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd and Hansa Biopharma Inc. Hansa Biopharma Inc had three employees at the end of December 2020. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had two employees at the end of 2020.

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 2020 comprised of 44,473,452 ordinary shares and 1,421,457 C-shares held by the Company as treasury shares. Each share has a nominal value of SEK 1 resulting in SEK 45,894,909 share capital and SEK 44,473,452 in outstanding share capital as of 31 December 2020.

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, 2020, the single largest shareholder in Hansa Biopharma was Redmile Group LLC, with a total of 4,625,590 shares, representing 10.4 percent of the voting rights and the capital.

Share-based compensation programs

Hansa Biopharma uses-share based long-term compensation programs to create conditions for motivating and retaining key employees and to align interests and long-term objectives between the shareholders and the Company, as well as to incentivise meeting and exceeding the Company's business and financial targets.

As in certain previous years, and upon the proposal of Hansa Biopharma's Board of Directors, the AGM resolved to adopt a long-term, share-based compensation program in 2020.

2020 Long-term incentive program

Hansa Biopharma's Annual General Meeting (the "AGM") on June 23, 2020 resolved to adopt a long-term incentive program, LTIP2020, based on (a) performance-based share rights and (b) employee stock options.

LTIP2020 based on performance-based share rights

Under the terms of LTIP2020 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 and shall carry a vesting period of three years commencing on the day of its allotment to a participant (the "Vesting Period").

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

- Condition 1: The U.S. randomised controlled trial is completed during the Vesting Period;
- Condition 2: Top line data read out of the ongoing phase 2 study in either AMR or GBS is completed during the Vesting Period with data providing a solid scientific rational to continue either of the two programs;
- Condition 3: At least 70 per cent of the targeted transplantation centers in Europe have been initiated during the Vesting Period;
- Condition 4: Total shareholder return of at least 25%.

A maximum of 505,096 Share Rights may be allotted to participants under the LTIP 2020 from the day following the 2020 AGM up and until the day prior to the AGM in 2021.

2020 Directors' report continued

As of December 31, 2020, 389,556 Share Rights have been allotted to plan participants.

LTIP2020 based on stock options

The 2020 AGM also resolved to adopt an employee stock option program under the terms of LTIP2020. 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 315.75 corresponding to 125 per cent of the volume weighted average share price during the 10 trading days immediately prior to the offer to subscribe for the employee stock options.

A maximum of 506,280 employee stock options may be allotted to participants under the LTIP2020 from the day following the 2020 AGM up and until the day prior to the AGM in 2021.

As of December 31, 2020, 477,520 employee stock options have been allotted to the plan participants under the LTIP2020.

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 31.42 percent) for the share rights and options under LTIP2020 allotted as of December 31, 2020, is expected to amount to approximately SEK 120.7m, of which SEK 17.3m is included in the results for the Parent Company and the Group for the year 2020.

Please refer to Notes 1 and 5 for further information and previously adopted share-based compensation programs.

2020 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 2020 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 manager 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 50 percent of the annual fixed base salary. The variable cash remuneration is intended to support recruitment or retention of key personnel or to reward extraordinary performance beyond the individual's ordinary responsibilities and shall not exceed 30% of the annual fixed base salary. Contributions to pension plans shall not exceed 30% of the annual fixed base salary. Salary during the notice of termination period and severance remuneration shall be possible in a total maximum amount of 18 monthly base salaries.

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

Please refer to Note 5 for further information on remuneration to senior executives.

2021 proposed changes to remuneration guidelines for senior executives

The changes to the guidelines proposed by the Board of Directors stipulate that 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. No further changes are proposed.

Other information

For additional information, please see the Corporate governance report and the Remuneration report.

Annual general meeting 2021

The annual general meeting of Hansa Biopharma AB (publ) will takeplace on May 12, 2021. Notice to attend the annual general meeting will be published on Hansa Biopharma's website at: www.hansabiopharma.com.

Financial calendar 2021

Annual Report 2020	April 8, 2021
Interim report for January – March 2021	April 22, 2021
Annual General Meeting	May 12, 2021
Interim report for January – June 2020	July 15, 2021
Interim report for January – September 2020	October 21, 2021

Appropriation of loss carried forward

Unrestricted shareholders' equity in the Parent Company

SEK	
Share premium reserve	2,509,457,908
Treasury shares	-1,421,457
Loss carried forward	-890,710,056
Result for the year	-421,642,931
Total	**1,195,683,464**

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

SEK	
Share premium reserve	2,509,457,908
Treasury shares	1,421,457
Profit/loss carried forward	-1,312,352,987
Total	**1,195,683,464**

The Group's and the Parent Company's results and financial position are shown in the following income statement, statement of financial position, cash flow statements and statements of shareholders' equity and accompanying notes and supplementary information, which are an integral part of these financial statements.

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Hansa Biopharma AB (publ)
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Postal address
P.O. Box 785, SE-220 07 Lund, Sweden

Registration number
556734-5359

Financial statements

Stock image

The Group

Consolidated income statement

KSEK	Note	1 January – 31 December 2020	2019
Revenue	2, 3, 31	6,098	3,364
Cost of revenue		-997	-866
Gross profit		**5,101**	**2,498**
Other operating income	4	2,270	166
Sales, general and administration expenses	7, 11	-202,987	-167,310
Research and development expenses	7	-227,191	-192,949
Other operating expenses	4	–	-2,073
Operating profit/loss	5, 6, 7, 25	**-422,807**	**-359,668**
Result from financial items:			
Finance income		2,170	563
Finance costs		-257	-487
Net finance costs/income	8	**1,914**	**76**
Result before tax		**-420,893**	**-359,592**
Tax	9	40	-417
Result for the year		**-420,853**	**-360,009**
Attributable to:			
Parent Company shareholders		-420,853	-360,009
Total		**-420,853**	**-360,009**
Earnings per share	10		
before dilution (SEK)		-9.98	-9.00
after dilution (SEK)		-9.98	-9.00

Statement of other comprehensive income

KSEK	Note	1 January – 31 December 2020	2019
Result for the year		-420,853	-360,009
Other comprehensive income			
Items that have been, or may be reclassified to profit or loss for the year			
Translation differences for the year		-297	143
Changes in fair value for the year in financial assets		–	207
Items that cannot be reclassified to profit or loss for the year			
Shares at fair value through other comprehensive income		–	49,597
Other comprehensive income for the year		**-297**	**49,947**
Total comprehensive income for the year		**-421,150**	**-310,062**
Total comprehensive income attributable to:			
The Parent Company's owner		-421,150	-310,062
Total		**-421,150**	**-310,062**

The Group continued

Consolidated statement of financial position

KSEK	Note	As of 31 December 2020	2019
ASSETS			
Non-current assets			
Intangible assets	11	31,410	33,348
Property and equipment	12	5,206	6,035
Leased assets	26	4,493	9,109
Total non-current assets		**41,109**	**48,493**
Current assets			
Inventories	14	98	–
Accounts receivable	17	110	522
Prepaid expenses and accrued income	18	5,716	2,979
Other receivables	16	9,957	11,149
Short term investments	25	238,144	419,397
Cash and cash equivalents	19, 25	1,139,362	181,697
Total currents assets		**1,393,387**	**615,743**
TOTAL ASSETS		**1,434,496**	**664,236**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	20		
Share capital		45,895	41,448
Share premium reserve		2,509,458	1,413,447
Treasury shares		-1,421	-1,421
Reserves		-137	81,163
Retained earnings including result for the year		-1,311,671	-971,821
Shareholders' equity attributable to Parent Company shareholders		**1,242,124**	**562,815**
Total shareholders' equity		**1,242,124**	**562,815**

KSEK	Note	As of 31 December 2020	2019
Non-current liabilities			
Deferred tax liabilities	9	424	507
Provisions	21	14,426	818
Lease liabilities	26	630	4,827
Deferred revenue	2, 31	62,026	–
Contingent consideration	22	663	730
Total non-current liabilities		**78,169**	**6,881**
Current liabilities			
Lease liabilities	26	4,415	4,632
Accounts payable		26,669	50,573
Other liabilities	23	9,588	6,940
Deferred revenue	2, 31	17,406	–
Accrued expenses	24	56,125	32,395
Total current liabilities		**114,203**	**94,540**
Total liabilities		**192,372**	**101,421**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,434,496**	**664,236**

The Group continued

Consolidated statements of changes in shareholders' equity

KSEK	Note	Equity attributable to the owners of the Parent Company							
		Share capital	Share premium reserve	Treasury shares reserve	Translation reserve	Fair value reserve	Retained earnings including results for the year	Total	Total shareholders' equity
Balance at 1 January 2019	20	40,682	1,400,512	-722	17	31,199	-611,812	859,876	859,876
Total comprehensive income for the year									
Result for the year		–	–	–	–	–	-360,009	-360,009	-360,009
Other comprehensive income for the year		–	–	–	143	49,804	–	49,947	49,947
Total comprehensive income for the year		**–**	**–**	**–**	**143**	**49,804**	**-360,009**	**-310,062**	**-310,062**
Transactions with the owners of the Parent Company									
New share issue[1]		716	–	–	–	–	–	716	716
Cost of new share issue[2]		-	-7,646	–	–	–	–	-7,646	-7,646
Issued warrants		–	193	–	–	–	–	193	193
Long term incentive program		–	17,268	–	–	–	–	17,268	17,268
Treasury shares acquired		–	–	-716	–	–	–	-716	-716
Treasury shares sold		–	861	16	–	–	–	877	877
Issuance of ordinary shares upon exercise of stock options		50	2,259	–	–	–	–	2,309	2,309
Total transactions with the owners of the Parent Company		**766**	**12,935**	**-700**	**–**	**–**	**–**	**13,001**	**13,001**
Balance at 31 December 2019		**41,448**	**1,413,447**	**-1,421**	**160**	**81,003**	**-971,821**	**562,815**	**562,815**

[1] In 2019, 50,000 shares where issued due to the TO 2015 program and 16,217 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program,

[2] 2019 expenses relate to the directed share issue in 2018 (KSEK -7,586) and the LTIPs (KSEK -60).

The Group continued

Consolidated statements of changes in shareholders' equity (continued)

KSEK	Note	Equity attributable to the owners of the Parent Company							
		Share capital	Share premium reserve	Treasury shares reserve	Translation reserve	Fair value reserve	Retained earnings including results for the year	Total	Total shareholders' equity
Balance at 1 January 2020	20	41,448	1,413,447	-1,421	160	81,003	-971,821	562,815	562,815
Total comprehensive income for the year									
Result for the year		–	–	–	–	–	-420,853	-420,853	-420,853
Other comprehensive income for the year		–	–	–	-297	–	–	-297	-297
Total comprehensive income for the year		**–**	**–**	**–**	**-297**	**–**	**-420,853**	**-421,150**	**-421,150**
Reclassification of fair value reserve		**–**	**–**	**–**	**–**	**-81,003**	**81,003**	**–**	**–**
Transactions with the owners of the Parent Company									
Issue of shares, net of share issue cost*		4,447	1,066,133	–	–	–	–	1,070,581	1,070,581
Long term incentive program		–	29,878	–	–	–	–	29,878	29,878
Total transactions with the owners of the Parent Company		**4,447**	**1,096,011**	**–**	**–**	**–**	**–**	**1,100,459**	**1,100,459**
Balance at 31 December 2020		**45,895**	**2,509,458**	**-1,421**	**-137**	**–**	**-1,311,671**	**1,242,124**	**1,242,124**

* Share issue cost amounted to SEK 41,255k.

The Group continued

Consolidated statement of cash flow

KSEK	Note	1 January – 31 December 2020	2019
Cash flow from operating activities			
Operating profit/loss		-422,807	-359,668
Adjustment for items not included in cash flow	30	51,430	14,613
Interest paid, net		-68	-337
Income taxes paid		-105	-123
Cash flow from operating activities before changes in working capital		**-371,550**	**-345,516**
Changes in working capital			
Increase (-)/Decrease (+) of account receivable		412	-464
Increase (-)/Decrease (+) of other operating receivables		-1,715	-6,157
Increase (+)/Decrease (-) of accounts payable		-23,897	10,146
Increase (+)/Decrease (-) of other operating liabilities		106,476	7,215
Net cash from operating activities		**-290,274**	**-334,775**
Cash flows from Investing activities			
Acquisition of intangible assets	11	–	-729
Acquisition of property and equipment	12	-294	-2,699
Proceeds from sale of equipment	12	–	87
Sale of short term investments		182,828	–
Proceeds from sale of shares in Genovis AB	15	–	89,125
Net cash used in investing activities		**182,534**	**85,784**

KSEK	Note	1 January – 31 December 2020	2019
Cash flows from financing activities			
Proceeds from new share issuance, net of issue cost**		1,070,581	–
Transaction cost*		–	-7,646
Sale of treasury shares		–	877
Issue of warrants		–	2,309
Repayment of lease liabilities		-4,674	-4,424
Net cash from financing activities		**1,065,906**	**-8,884**
Net change in cash and cash equivalent		958,166	-257,875
Cash and cash equivalents, beginning of year		181,697	439,441
Effects of movements in exchange rate on cash held		-501	131
Cash and cash equivalents at 31 December		**1,139,362**	**181,697**

*Cash paid for transaction cost that relates to 2018 share issuance.
** The total share issue cost amounted to SEK 41,255k.

Parent Company

Income statement

KSEK	Note	1 January – 31 December 2020	2019*
Revenue	2, 3, 31	6,098	3,364
Cost of revenue		-997	-866
Gross profit		**5,101**	**2,498**
Other operating income	4	2,270	166
Sales, general and administration expenses	7, 11	-203,346	-168,520
Research and development expenses	7	-227,531	-192,565
Other operating expenses	4	–	-2,052
Operating profit/loss	5, 6, 26	**-423,507**	**-360,474**
Result from financial items:			
Finance income	8	2,170	563
Finance costs	8	-307	-487
Net finance costs/income	8	1,863	76
Result after financial items		**-421,644**	**-360,398**
Result before taxes		**-421,644**	**-360,398**
Tax	9	–	–
Result for the year		**-421,644**	**-360,398**

Statement of other comprehensive income

KSEK	Note	1 January – 31 December 2020	2019*
Result for the year		-421,644	-360,398
Other comprehensive income			
Items that cannot be reclassified to profit or loss for the year			
Shares at fair value through other comprehensive income		–	49,804
Other comprehensive income for the year		**–**	**49,804**
Total comprehensive income for the year		**-421,644**	**-310,594**

* Restated due to change in accounting policy regarding IFRS 9 and IFRS 16.

Parent Company continued

Statement of financial position

KSEK	Note	As of 31 December 2020	2019**	1 January 2019*
ASSETS				
Non-current assets				
Intangible assets	11	29,171	29,522	30,163
Property and equipment	12	5,206	6,035	5,290
Leased assets	26	4,493	9,109	13,354
Financial assets				
Other long term holdings of securities	15	–	–	39,529
Participation in group companies	29	5,095	5,095	5,095
Receivables, group companies	13	1,972	2,244	–
Total financial assets		7,067	7,339	44,624
Total non-current assets		**45,937**	**52,005**	**93,431**
Current assets				
Current receivables				
Inventories	14	98	–	–
Accounts receivable	17	110	522	58
Receivables, group companies	13	–	1,061	2,834
Other receivables	16	9,763	11,138	7,038
Prepaid expenses and accrued income	18	5,394	2,709	939
Total currents receivables		15,365	15,430	10,869
Short term investments	25	238,144	419,397	418,746
Cash and cash equivalents	19, 25	1,133,647	176,715	433,875
Total current assets		**1,387,157**	**611,542**	**863,490**
TOTAL ASSETS		**1,433,094**	**663,547**	**956,921**

KSEK	Note	As of 31 December 2020	2019**	1 January 2019*
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity	20			
Restricted shareholders' equity				
Share capital		45,895	41,448	40,682
Unrestricted shareholders' equity				
Share premium reserve		2,509,458	1,413,447	1,400,456
Treasury shares		-1,421	-1,421	-722
Fair value reserves		–	76,834	27,030
Retained earnings		-890,710	-607,146	-358,849
Result for the year		-421,644	-360,398	-248,297
Total shareholders' equity		**1,241,578**	**562,763**	**860,300**
Non-current liabilities				
Provisions	21	14,426	818	10,948
Lease liabilities	26	630	4,827	9,015
Deferred revenue	2, 31	62,026	–	–
Contingent consideration	22	663	730	679
Total non-current liabilities		**77,745**	**6,375**	**20,642**
Current liabilities				
Lease liabilities	26	4,415	4,632	4,340
Liabilities, group companies		1,613	2,793	–
Accounts payable		26,623	50,262	40,333
Other liabilities	23	8,325	6,621	5,095
Deferred revenue	2, 31	17,406	–	–
Accrued expenses	24	55,387	30,102	26,212
Total current liabilities		**113,771**	**94,410**	**75,980**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,433,094**	**663,547**	**956,921**

* 2019 Restated opening balance 1 Jan 2019 due to change in accounting policy.
**2019 Restated due to change in accounting policy regarding IFRS 9 and IFRS 16.

Parent Company continued

Statement of changes in shareholders' equity

	Restricted shareholders' equity	Unrestricted shareholders' equity					
KSEK	Share capital	Share premium reserve	Treasury share reserve	Fair value Reserve	Retained Earnings	Result for the year	Total shareholders' equity
Balance at 1 January 2019 as previously reported	**40,682**	**1,400,456**	**-722**	**–**	**-358,849**	**-248,297**	**833,270**
Change in accounting policy, IFRS 9	–	–	–	27,030	–	–	27,030
Restated balance at 1 of January 2019	40,682	1,400,456	-722	27,030	-358,849	-248,297	860,300
Result for the year	–	–	–	–	–	-360,398	-360,398
Other comprehensive income for the year	–	–	–	49,804	–	–	49,804
Net comprehensive income	**–**	**–**	**–**	**49,804**	**–**	**-360,398**	**-310,594**
Appropriation of profits	–	–	–	–	-248,297	248,297	–
New share issue [1]	716	–	–	–	–	–	716
Cost of new share issue [2]	–	-7,646	–	–	–	–	-7,646
Issued warrants	–	193	–	–	–	–	193
Equity settled share based payment	–	17,324	–	–	–	–	17,324
Treasury share acquiered	–	–	-716	–	–	–	-716
Sale of treasury shares	–	861	16	–	–	–	877
Issuance of ordinary shares upon exercise of stock options	50	2,259	–	–	–	–	2,309
Balance at 31 December 2019	**41,448**	**1,413,447**	**-1,421**	**76,834**	**-607,146**	**-360,398**	**562,763**

[1] In 2019, 50,000 shares where issued due to the TO 2015 program and 16,217 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program,
[2] 2019 expenses relate to the directed share issue in 2018 (KSEK -7,586) and the LTIPs (KSEK -60).

Parent Company continued

Statement of changes in shareholders' equity (continued)

	Restricted shareholders' equity	Unrestricted shareholders' equity					
KSEK	Share capital	Share premium reserve	Treasury share reserve	Fair value Reserve	Retained Earnings	Result for the year	Total shareholders' equity
Balance at 1 January 2020	**41,448**	**1,413,447**	**-1,421**	**76,834**	**-607,146**	**-360,398**	**562,763**
Result for the year	–	–	–	–	–	-421,644	-421,644
Other comprehensive income for the year	–	–	–	–	–	–	–
Net comprehensive income	**–**	**–**	**–**	**–**	**–**	**-421,644**	**-421,644**
Reclassification of fair value reserve	**–**	**–**	**–**	**-76,834**	**76,834**	**–**	**–**
Appropriation of profits	–	–	–	–	-360,398	360,398	–
New share issue, net of share issue cost*	4,447	1,066,133	–	–	–	–	1,070,581
Equity settled share based payment	–	29,878	–	–	–	–	29,878
Balance at 31 December 2020	**45,895**	**2,509,458**	**-1,421**	**–**	**-890,710**	**-421,644**	**1,241,578**

* Total share issue cost amounted to SEK 41,255k.

Parent Company continued

Statement of cash flow

KSEK	Note	1 January – 31 December 2020	2019*
Operating activities			
Operating profit/loss		-423,507	-360,474
Adjustment for items not included in cash flow	30	50,114	14,679
Interest paid, net		79	-435
Cash flow from operating activities before changes in working capital		**-373,314**	**-346,230**
Changes in working capital			
Increase (-)/Decrease (+) of account receivable		412	-464
Increase (-)/Decrease (+) of other operating receivables		-1,409	-6,345
Increase (+)/Decrease (-) of accounts payable		-23,758	9,929
Increase (+)/Decrease (-) of other operating liabilities		106,560	8,321
Net cash from operating activities		**-291,509**	**-334,789**
Cash flow from investing activities			
Acquisition of equipment	12	-294	-2,699
Sale of equipment	12	–	87
Sale of Financial Assets	15	–	89,125
Sale of short-term investments		182,828	–
Net cash used in investing activities		**182,534**	**86,513**

KSEK	Note	1 January – 31 December 2020	2019*
Cash flow from financing activities			
Proceeds from new share issuance, net of issue cost**		1,070,581	–
Transaction cost		–	-7,646
Sale of treasury shares		–	877
Exercise of stock options		–	2,309
Repayment of lease liabilities		-4,674	-4,424
Net cash from financing activities		**1,065,906**	**-8,884**
Net change in cash		956,932	-257,160
Cash and cash equivalents, beginning of year		176,715	433,875
Cash and cash equivalents at 31 December		**1,133,647**	**176,715**

* Restated due to change in accounting policy regarding IFRS 9 and IFRS 16.
**Total share issue cost amounted to SEK 41,255 k.

Notes

Note 1 Significant accounting principles

(A) Basis of accounting

The consolidated financial statements have been prepared in compliance with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) as adopted by the EU. In addition, recommendation RFR 1 issued by the Swedish Financial Reporting Board (Supplemental Accounting Rules for Corporate Groups) has been applied.

The Parent Company applies the same accounting principles as the Group except for those cases set forth below under the section entitled "The Parent Company's accounting principles".

The annual report and the consolidated accounts were approved for issuance by the Board and the Chief Executive Officer on April 7, 2021. The consolidated income statement, statement of other comprehensive income and statement of financial position and the Parent Company's income statement and statement of financial position are subject to approval at the Annual General Meeting on May 12, 2021.

(B) Basis of measurement

Assets and liabilities are measured at historical cost, except for certain financial assets and liabilities which are measured at fair value. Financial assets and liabilities measured at fair value consist of listed shares in Genovis AB that where sold during 2019, short term investments and contingent consideration, not yet paid.

(C) Functional currency and reporting currency

The functional currency of the Parent Company is Swedish kronor, which is also the reporting currency for the Parent Company and for the Group. This means that the financial reports are presented in Swedish kronor. Unless otherwise stated, all amounts are rounded off to the nearest thousand.

(D) Use of judgement and estimates in the financial reports

In preparing these consolidated financial statements, management has made judgements and estimates that affect the application of the Group's accounting policies and the carrying value of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to estimates are recognized prospectively.

Information about key judgements and estimates made in applying accounting policies that have the most significant effects on the amounts recognized in the financial statements is described in more detail in Note 33.

(E) Changes in accounting principles

(i) Changes in accounting principles due to new or amended IFRS

Changes in IFRS effective as of 1 January 2020 has not had a material impact on the Group's financial statements.

(ii) Standards issued but not yet effective

A number of new standards are effective for annual periods beginning after 1 January 2020 and earlier application is permitted; however, the Group has not early adopted the new or amended standards in preparing these consolidated financial statements.

New and amended IFRSs with future application are not expected to have any significant effect on the Company's financial reports.

(F) Classification

Non-current assets and non-current liabilities consist, in all material respects, of amounts expected to be recovered or paid after more than 12 months from the reporting date. Current assets and current liabilities consist, in all material respects, of amounts expected to be recovered or paid within 12 months from the reporting date.

(G) Operating segment reporting

An operating segment is a component of an entity:

- (1) that engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same entity),
- (2) whose operating results are regularly reviewed by the entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance, and
- (3) for which discrete financial information is available.

The earnings of an operating division are monitored by the chief operating decision maker in order to evaluate the earnings and to be able to allocate resources to the operating division. The financial information available for evaluation by management in deciding how to allocate resources and assess performance is that of the business as a whole. For these reasons the Group had a single reportable segment during the reporting period.

(H) Basis of Consolidation

(i) Subsidiary

Subsidiaries are companies controlled by Hansa Biopharma AB.

Subsidiaries are accounted for using the acquisition method. The acquisition method entails that the acquisition of a subsidiary is regarded as a transaction whereby the Group indirectly acquires the

Notes continued

Note 1 Significant accounting principles continued

subsidiary's assets and assumes its liabilities. The purchase price allocation determines the fair value at the acquisition date of the identifiable assets acquired and liabilities assumed and any non-controlling interest.

Contingent consideration is recognized at fair value at the acquisition date. Contingent purchase price is remeasured at each reporting date and the change in fair value is recognized in net income.

(ii) Transactions eliminated on consolidation
Intercompany receivables and liabilities, income and expenses and unrealized gains or losses arising from transactions between Group companies are eliminated in full on consolidation.

(I) Foreign currency
(i) Transactions in foreign currencies
Transactions in foreign currencies are translated into the respective functional currencies of Group companies at the exchange rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rate at the reporting date. Non-monetary assets and liabilities that are measured at fair value in a foreign currency are translated into the functional currency at the exchange rate when the fair value was determined. Non-monetary items that are measured based on historical cost in a foreign currency are translated at the exchange rate at the date of the transaction. Foreign currency differences are generally recognized in profit or loss and presented within finance costs.

(ii) Financial statements of foreign operations
Assets and liabilities of foreign operations, including goodwill and fair value adjustments arising on acquisition, are translated from the functional currency of the foreign operation to the Group's reporting currency, Swedish kronor at the exchange rate at the reporting date. The 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. Translation differences arising from foreign currency translation of foreign operations are reported in other comprehensive income and is accumulated in a separate component of shareholders' equity, referred to as the translation reserve.

(J) Revenue
(i) Revenue recognition
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 Company received or expects to receive in exchange for those goods or services.

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

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligation(s) in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, the Company satisfies a performance obligation

(ii) 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 Company receives and revenue the Company recognizes varies based on actual or estimated rebates, discounts, returns and charge backs. The Company adjusts its estimate of revenue at the earlier of when the most likely amount of consideration the Company 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.

(iii) Contract revenue
The Company 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. However, 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.

For further information on the Company's revenue and revenue recognition please refer to Notes 2 and 31.

Notes continued

Note 1 Significant accounting principles continued

Revenue related to costs incurred in performing a service is recognized when recoverable costs are incurred.

(K) Research and development expenses

Research and development costs are expensed as incurred. No amount was capitalized in any period presented. 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 Company'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.

(L) Leasing

The Group leases various offices, laboratory facilities, equipment and vehicles. Rental contracts are typically made for fixed periods of 3 to 4 years but may have extension options as described further in (ii) below.

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. However, for leases of real estate for which the Group is a lessee, 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 a leased asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the lease payments and they are discounted using the lessee's incremental borrowing rate.

Right-of-use 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 asset is 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 income statement. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise mainly of IT equipment and small items of office furniture.

(i) Extension and termination options

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.

(M) Financial income and expenses

Financial income consists of interest income, positive changes in fair value of fund units, exchange rate differences and other financial income. Financial expenses consist of interest expenses, negative changes in fair value of fund units, exchange rate differences and other financial expenses. Exchange rate differences are reported net.

(N) Taxes

Income tax consists of current taxes and deferred taxes. Income tax is reported in the profit and loss for the year except for cases where the underlying transaction has been reported in other comprehensive income or in shareholders' equity in which case the associated tax effect is reported in other comprehensive income or shareholders' equity.

Current tax is tax to be paid or received for the current year upon application of the tax rates in effect, or in effect in practice, on the reporting date. The current tax also includes adjustments of current tax related to earlier periods.

Deferred tax is calculated in accordance with the balance sheet method based upon temporary differences between reported values and tax values for assets and liabilities. Temporary differences are not taken into consideration in Group goodwill, nor is the difference which arises upon the first reporting of assets and liabilities which are not business acquisitions and which, at the time of the transaction, do not affect either reported or taxable earnings. Furthermore, temporary differences related to shares in subsidiaries and affiliated companies that are not expected to be reversed within the foreseeable future are not taken into consideration. The valuation of deferred tax is based on how the underlying assets or liabilities are expected to be realized or settled. Deferred tax is calculated applying the tax rates and tax rules in effect, or in effect in practice, on the reporting date.

Deferred tax claims regarding deductible temporary differences and loss carryforwards are reported only to the extent it is probable that these can be utilized in the foreseeable future. The value of deferred tax claims is reduced when it is no longer considered probable that they can be utilized.

Notes continued

Note 1 Significant accounting principles continued

(O) Financial instruments

Financial instruments which are recognized in the statement of financial position include, on the assets side, cash and equivalents, short term investments, other receivables, accounts receivable and listed shares. On the liability side, accounts payable and contingent consideration.

(ii) Recognition and initial measurement

Accounts receivable and debt instruments are initially recognized when they are originated. Regular way purchases and spot 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 income statement for which transaction expenses are instead expensed when they arise. Accounts receivable (without a significant financing component) are initially valued at the transaction price as determined in accordance with IFRS 15.

(iii) Classification and subsequent measurement

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 income statement. The following describes how the Group's various holdings of financial assets have been classified:

Holdings of listed shares

The Group did hold shares in Genovis which where listed on First North. Since this was a long-term holding, Hansa Biopharma AB had chosen to report the shares at fair value through other comprehensive income, instead of at fair value through the income statement.

The shares in Genovis were sold during 2019.

Holdings of interest rate funds

The Group's holdings of units in interest funds are reported at fair value through the income statement. The shares (seen from the fund's perspective) constitute financial liabilities and as such do not gives rise to payments of solely payments of principal and interest and do therefore not fulfill the amortized cost requirements.

(i) Other financial assets

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

(ii) Classification and valuation of financial liabilities

Financial liabilities are classified as valued at amortized cost or valued at fair value through the income statement. Financial liabilities that are measured at fair value through the income statement consist of contingent consideration, not yet paid. Other financial liabilities are valued at amortized cost.

(iii) Derecognition from the statement of financial position

Financial assets

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.

Financial liabilities

The Group derecognizes a financial liability from the 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.

(P) Property and equipment

Property and equipment are reported by the Group at acquisition cost after deductions of accumulated depreciation and any write-downs. The acquisition cost includes the purchase price and expenses directly attributable to bring it in place and in accordance with the purpose of the acquisition.

The carrying amount of property and equipment is derecognized from the statement of financial position upon disposal or sale or when it is determined that no future economic benefits are anticipated from the use or disposal/sale of the asset. Profits or losses which arise upon the sale or disposal of an asset consist of the difference between the sales price and the carrying amount of the asset less any direct costs of sale. Profits and losses are reported as other operating income/expenses.

Depreciation is carried out using the straight-line method over the anticipated useful life of the asset. Land is not depreciated.

Anticipated useful life:	
Office equipment, tools and fixtures and fittings	3–10 years

Notes continued

Note 1 Significant accounting principles continued

(Q) Intangible assets

(i) 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 where originally recognized at the acquisition date fair value. Subsequently, they are measured at cost less accumulated amortization and any impairment (see accounting principle (R)). 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.

Anticipated useful life:	
Patents	17 years
In-process development projects	10-15 years

Acquired in-process development projects that are still in development phase are not amortized.

(i) Internally generated intangible assets

Expenditure on research activities is recognized in the income statement as incurred. Development expenditure is 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 income statement as research and development expenses as incurred. Subsequent to initial recognition, capitalized development expenditure is measured at cost less accumulated amortization and any accumulated impairment losses. No amount was capitalized in any period presented.

(R) Impairment

(i) Impairment of intangible assets

For intangible assets with an indefinite useful life and intangible assets which are not yet subject to amortization, an annual impairment test is carried out. If the asset's recoverable amount is estimated to be lower than the assets carrying amount, an appropriate impairment loss is recognized in the income statement.

(ii) Reversal of impairment losses

Impairment of assets included in the area of application for IAS 36 is reversed if there is both, an indication that the need for the impairment no longer exists and that there has been a change in the assumptions which formed the basis for the calculation of the recovery value. However, Impairment of goodwill are never reversed. A reversal is only made to the extent the reported value of the asset after reversal does not exceed the reported value which would have been reported, following a deduction for amortization where relevant, if no write-down had been made.

(iii) Impairment of financial assets

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

(S) Inventories

Costs related to the manufacturing of inventories are expensed as research and development expenses when incurred prior to obtaining regulatory approval or evidence being available that regulatory approval for respective product can reasonably be expected. If regulatory approval is subsequently obtained, the recorded expenses are not reversed. Costs related to the manufacturing of inventories which occurred after the receipt of regulatory approval for respective product or evidence being available that regulatory approval can reasonably be expected are capitalized. Inventories are valued at the lower of cost and net realizable value. Cost is determined based on the first-in first-out principle (FIFO). If costs exceed the net realizable value, a provision is recorded. In addition, provisions are recorded due to obsolescence or lack of demand.

(T) Dividends

Dividends are reported as a liability after the annual general meeting has approved the dividend.

(U) Earnings per share

The calculation of earnings per share is based on the Group's earnings for the year attributable to the Parent Company's owner and on the weighted average number of shares outstanding during the year.

There are potential ordinary shares for the reported financial year and for the comparative period since the Company had warrants and share rights outstanding as part of its long-term incentive programs. These shares are not earnings dilutive because the result for the year is negative and diluted earnings per share may not show a lower loss per share than basic earnings per share. If the Company shows positive results in the future, these potential ordinary shares may result in dilution.

(V) Employee benefits

(i) 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.

Notes continued

Note 1 Significant accounting principles continued

(ii) 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.

(iii) 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.

(iv) Defined contribution pension plans
Plans where the Company's obligations are limited to the contribution the Company 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 Company pays into the plan, or to an insurance Company, and the return on capital which the contribution generate. Consequently, it is the employee who bears the actuarial risk (that the benefits will be lower than anticipated) and the investment risk (that the invested assets will be insufficient to generate the anticipated benefits). The Company's obligations regarding fees paid to defined contribution plans are reported as an expense in the income statements when they are earned by the employees performing their services on behalf of the Company during a given period of time.

(W) Share-based compensation
Share-based compensation pertains to employee benefits, including executive management, in accordance with long-term share-based compensation schemes that the Company initiated following respective AGM approval. Costs for employee benefits are recognised in accordance with IFRS 2 as the value of services received, allocated over the vesting periods for the plans, calculated as the fair value of the allotted equity instruments. The fair value is determined on the allotment date. Since the plans are settled with equity instruments, they are classified as "equity settled" and an amount corresponding to the recognised personnel cost for employee benefits is recognised directly in shareholders' equity. Social security costs relating to share-based compensation are recognised 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 recognised expense is recognised as a liability.

Share warrant programs and Employee stock option programs
As of December 31, 2020, the Company had two (2018 and 2019) ongoing Share warrant programs and two (2019 and 2020) ongoing Employee stock option programs.

Under a share warrant program, participants are given the opportunity to acquire warrants at market value calculated based on the Black-Scholes model. Each warrant entitles the holder to subscribe for one new ordinary share in accordance with the terms of the respective program. Each share warrant program is subsidized by the Company and participants (except the CEO) in the share warrant program receive a one-time subsidy when purchasing warrants. The fair value of the subsidy is expensed in accordance with IFRS 2, as described above, over the vesting period under each program, which typically is three (3) years. During the vesting period, the expense is adjusted in order to account for the number of warrants that are expected to vest.

Under an employee stock option program, participants are given the opportunity to receive Employee stock options free of charge. Each option has a vesting period of three (3) years and entitles the holder to subscribe for one new ordinary share in accordance with the terms of the program. The fair value of the options is calculated based on the Black-Scholes model and expensed in accordance with IFRS 2, as described above, 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.

Performance-share programs
As of December 31, 2020, the Company had three (2018, 2019 and 2020) Performance-shares based compensation programs ongoing.

Under a Performance-share based program, participants receive share awards free-of-charge which provide for the opportunity to receive ordinary shares In Hansa Biopharma AB subject to certain performance and other criteria being met in accordance with the terms of the respective program.

The fair value of the allotted share rights is calculated at the time of grant based on a Monte-Carlo-Simulation. The fair value of allocated share rights is expensed in accordance with IFRS 2, as described above, over the vesting period under each program, which typically is three (3) years. The expense recognized corresponds to the fair value of an estimate of the number of share rights expected to be earned, taking into account the terms of service and the conditions for earning ordinary shares during the vesting period. This expense is adjusted in subsequent periods in order to ultimately reflect the actual number of earned share rights.

(X) Provisions
A provision differs from other liabilities because there is uncertainty about the timing or the amount required to settle the provision. A provision is recognized in the statement of financial position when there is a present legal or constructive obligation as a result of a past event, and it is probable that an outflow of resources will be required to settle the obligation and a reliable estimate of the amount can be made.

Notes continued

Note 1 Significant accounting principles continued

(Y) Contingent liabilities

A contingent liability is:

> (1) a possible obligation that arises from past events and whose existence will be confirmed only by the occurrence or non occurrence of one or more uncertain future events not wholly within the control of the entity; or
> (2) a present obligation that arises from past events but is not recognized because it is not probable that an outflow of resources embodying economic benefits will be required to settle the obligation; or the amount of the obligation cannot be measured with sufficient reliability.

(Z) The Parent Company's accounting principles

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.

(i) 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.

(ii) Change in accounting principles

During previous periods, Hansa Biopharma has used the exemptions provided in RFR 2 Accounting for legal entities that allow a parent company not to apply IFRS 9 Financial instruments and IFRS 16 Leases in its financial statements. In order to provide more relevant information about financial instruments and leases in the parent company, Hansa Biopharma has chosen to apply IFRS 9 and IFRS 16 in the parent company. The accounting principles for financial instruments and for leases are therefore the same in the parent company as in the Group. The change in accounting principle has been applied retrospectively as of 1 January 2019 and therefore comparative period of 2019 has been restated for the parent company.

Effects of the change to IFRS 9.

The change to IFRS 9 led to an increase in the opening balance of equity as per 1 January 2019 amounting to SEK 27,030k. The change to IFRS 9 led to an increase in other comprehensive income of 49,804k for the year 2019, while profit and loss changed by -76,626k for the year 2019.

The change also led to an increase in the balance sheet related to the investment in Genovis AB at 1 January 2019 of SEK 27,030k and the contra entry was recorded in equity. The investment in Genovis was sold in April 2019.

Further, the change led to an increase in the balance sheet of short-term investment at 31 December 2019 amounting to SEK 207k. There was no change in the statement of cash flows.

Effects of the change to IFRS 16

The change to IFRS 16 led to the parent company recognizing leasing liabilities of SEK 13,354k and right-of-use assets of SEK 13,354k as per 1 January 2019.

The change to IFRS 16 led to the parent company recognizing leasing liabilities of SEK 9,459k and right of-use assets of SEK 9,109k as per 31 December 2019.

The change to IFRS 16 also led to an impact on the parant company's income statement for the year 2019 of depreciation amounting to SEK -4,680k and interest expenses amounting to SEK -376k, partly offset by lease expenses amounting SEK 4,708k for the full 2019. The net impact on the profit and loss before tax was SEK 348k.

(iii) 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 2 Revenue

Disaggregation of revenue

	1 January – 31 December	
KSEK	**2020**	2019
Group and Parent Company		
Revenue		
Contract revenue, Axis-Shield agreement	2,864	2,838
Cost reimbursement, Axis-Shield agreement	636	526
Contract revenue, Sarepta agreement	2,599	–
Total revenue	**6,098**	**3,364**

Notes continued

Note 2 Revenue continued

In 2020, the Company recorded contract revenue in the amount of SEK 2.9 m (2019: SEK 2.8 m) related to its agreement with Axis-Shield Diagnostics Ltd related to a minimum royalty payment of USD 250,000 (SEK 2.3 m) (2019: USD 250,000 (SEK 2.3 m)) and a milestone payment of USD 60,000 (SEK 0.6 m) (2019: USD 60,000 (SEK 0.5 m)).w The agreement entails a license to access Hansa Biopharma's intellectual property regarding HBP analysis during the license period. The agreement requires the Company to conduct activities that substantially affect the intellectual property rights during the license period, which in turn affects Axis-Shield Diagnostics as a license holder. According to IFRS 15, a license entails that the licensee has the right to access the intellectual property of an entity and the payment for that right is recognized as revenue over the contract period. Received payments of minimum royalty is thus accrued and recognized as income during the period to which the royalty refers. The minimum royalty amount was received in January 2020, initially recorded as a deferred revenue and recognized as revenue over the reporting period on a straight line basis. The milestone payment was received in December 2020 and recorded as revenue when received as the Company had no outstanding performance obligations related to such milestone.

In addition, the Company recorded revenue related to reimbursable costs upon rendering services related to maintaining licensed patents in an amount of SEK 0.6 m (2019: SEK 0.5m).

Further, in 2020, the Company recorded contract revenue in the amount of SEK 2.6 m (2019: Nil) related to its agreement with Sarepta Therapeutics Ltd. in connection with an upfront payment of USD 10 m (SEK 81.9 m) received in July 2020. The upfront payment was recorded as deferred revenue and is recognized over a period of approximately up to 51 months as the Company fulfils its performance obligation under the agreement.

The performance obligation consists of one combined obligation including the right and professional support, access to know-how and data as well as imlifidase material to develop and promote imlifidase as a potential pre-treatment to Sarepta's gene therapies. At each reporting date the Company measures fulfilment of its performance obligation against a pre-defined budget with such actual fulfilment forming the basis for recognizing the related revenue.

Deferred revenue roll forward (contract balances)
Group and Parent Company

KSEK	2020	2019
Opening balance 1 January	–	–
Addition under existing contracts	3,500	3,364
Addition under new contracts (Sarepta agreement)	81,900	–
Revenue recognized	-6,098	-3,364
Adjustments, foreign exchange	130	–
Closing balance 31 December	**79,432**	**–**

Accounts receivable are reported on a separate line in the statement of financial position.

For further information please refer to Note 31.

Note 3 Operating segment

The Company operates in one segment, which is the discovery, development and commercialization of innovative, lifesaving and life altering immunomodulating therapies. The Company's most senior executive officer reviews the statement of operations and further financial information on a consolidated basis, makes decisions, allocates resources, manages the operations and measures the performance of the Company as a single operating segment.

Note 4 Other operating income and expenses

Group

KSEK	1 January – 31 December 2020	2019
Other operating income		
Government grant	–	166
Foreign currency gains on receivables/liabilities from operating activities	2,270	–
Total other operating income	**2,270**	**166**
Other operating expenses		
Foreign currency losses on receivables/liabilities from operating activities	–	-2,073
Total other operating expenses	**–**	**-2,073**

Parent Company

KSEK	1 January – 31 December 2020	2019*
Other operating income		
Government grant	–	166
Foreign currency gains on receivables/liabilities from operating activities	2,270	–
Total other operating income	**2,270**	**166**
Other operating expenses		
Foreign currency gains/losses on receivables/liabilities from operating activities	–	-2,052
Total other operating expenses	**–**	**-2,052**

* Restated due to change in accounting policy related to IFRS 16.

Notes continued

Note 5 Employees and personnel costs

2020 Guidelines for remuneration to senior executives

The 2020 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 50 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 also visit the Company's web-site at www.hansabiopharma.com for information on the 2020 guidelines for remuneration to senior executives.

Group 2020

Total personnel expenses in the Group broken down to geographical areas

KSEK	Parent in Sweden	Subsidiaries in UK and US	Total Group
Salaries, bonuses and other benefits	85,179	11,506	96,685
Social security contribution	18,243	836	19,079
Pension cost, contribution plan	10,074	613	10,688
Share-based compensation	43,348	–	43,348
Total personnel expenses	**156,844**	**12,956**	**169,800**

Total personnel expenses in Parent company in Sweden broken down to senior management and other employees

KSEK	Senior management	Other employees	Total Parent company in Sweden
Salaries, bonuses and other benefits	28,896	56,283	85,179
Social security contribution	8,894	9,349	18,243
Pension cost, contribution plan	1,357	8,717	10,074
Share-based compensation	23,882	19,466	43,348
Total personnel expenses	**63,029**	**93,815**	**156,844**

Parent Company in Sweden 2020

Personnel expenses related to Senior management

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

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

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

Notes continued

Note 5 Employees and personnel costs continued

Group 2019

Total personnel expenses in the Group broken down to geographical areas

KSEK	Parent in Sweden	Subsidiaries in UK and US	Total Group
Salaries, bonuses and other benefits	66,350	10,079	76,430
Social security contribution	17,213	790	18,003
Pension cost, contribution plan	7,447	342	7,789
Share-based compensation	7,246	–	7,246
Total personnel expenses	**98,256**	**11,211**	**109,467**

Personnel expenses in Parent company in Sweden broken down to senior management and other employees

KSEK	Senior management	Other employees	Total Parent company in Sweden
Salaries, bonuses and other benefits	21,303	45,047	66,350
Social security contribution	6,510	10,703	17,213
Pension cost, contribution plan	888	6,559	7,447
Share-based compensation	2,026	5,220	7,246
Total personnel expenses	**30,727**	**67,529**	**98,256**

Parent Company in Sweden 2019

Personnel expenses related to Senior management

KSEK	Base salary Directors' fees	Variable compen-sation	Other benefits	Total salaries, bonuses and other benefits	Social charges	Pension cost	Share-based compensation	Total
Chairman of the Board of Directors Ulf Wiinberg	950	–	–	950	298	–	–	1,248
Director Birgit Stattin-Norinder	382	–	–	382	39	–	–	421
Director Stina Gestrelius**	128	–	–	128	13	–	–	141
Director Angelica Loskog**	–	–	–	–	–	–	–	–
Director Anders Gersel-Pedersen	355	–	–	355	36	–	–	391
Director Andreas Eggert	360	–	–	360	113	–	–	473
Director Eva Nilsagård***	232	–	–	232	73	–	–	305
Director Mats Blom***	211	–	–	211	66	–	–	277
CEO Søren Tulstrup	*5,435	1,472	107	7,014	2,204	–	2,277	11, 495
Other senior executives (5 persons)	9,057	2,601	13	11,671	3,667	888	-251	15,975
Total	**17,110**	**4,073**	**120**	**21,303**	**6,510**	**888**	**2,026**	**30,727**

* Includes 1 226 KSEK, representing 30% of base salary, intended for own pension contribution
** Board member until AGM 2019.
*** Board member from AGM 2019.

Notes continued

Note 5 Employees and personnel costs continued

Average number of employees

	2020		2019	
	Number	**of which are men**	Number	of which are men
Total Group	82	43%	63	43%
Parent Company				
Sweden	76	42%	58	42%
Subsidiaries				
UK	2	100%	1	100%
US	4	25%	4	25%
Total subsidiaries	**6**	**–**	**5**	**–**

Breakdown of senior management according to gender

	Share of women	
	31 December 2020	31 December 2019
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 2020 AGM resolved that fees paid to directors for work during 2020 will be SEK 900,000 to the chairman of the Board of Directors and SEK 300,000 to each of the other directors, SEK 75,000 to the chairman and SEK 40,000 each to the other directors who are members of the Audit Committee, SEK 40,000 to the chairman and SEK 25,000 each to other directors who are members of the Remuneration 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 chairman of the Board of Directors or other directors.

Salaries and other remuneration to the CEO

Salaries, bonuses and other benefits

In 2020, the CEO received a total of SEK 8,854k in salaries, bonuses and other benefits.

Notice of termination periods and severance compensation

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

Pension remuneration

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 chairman of the Board of Directors. In 2020, executive management comprised of six people including the CEO except for a period from June through September where it comprised 7 people on an interim basis.

Salaries, bonuses and other benefits to the other members of the executive management amounted to SEK 17,322k in 2020.

Notice period of termination and severance payments

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

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

Notes continued

Note 5 Employees and personnel costs continued

Pension compensation

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

Share-based compensation

Long-term incentive program 2016 (LTIP 2016)

Hansa Biopharma's Extraordinary General Meeting on November 21, 2016 resolved to adopt a long-term incentive program (LTIP 2016) in the form of a performance-based share program for all employees of the Group. Participants will, provided that the performance condition is met and provided a continued employment throughout the vesting period of three (3) years (the "Vesting Period"), be granted the right to obtain ordinary shares free of charge (the "Right") after the vesting period. The performance condition is set at a "minimum level" and "maximum level", whereby the number of shares granted under the Rights is increased lineally between the minimum level and maximum level. However, in order for the Rights to entitle to the granting of shares, the minimum level has to be reached or exceeded. If the specified minimum level of the performance condition of 25 percent shareholder return during the Vesting Period is achieved, 25 percent of each participant's Rights will entitle to shares. If the maximum level of 100 percent shareholder return during the Vesting Period is reached , 100 percent of each participant's Rights will entitle to shares. A maximum of 305,000 Rights could be allotted to participants under LTIP 2016 and 289,750 rights were alloted in total. LTIP 2016 ended in 2020.

LTIP 2016: Key figures

	2020	2019
Rights, Opening balance 1 January	35,000	211,500
Allotted Rights during the period	–	–
Rights expired	-35,000	-176,500
Rights, Closing balance 31 December	**–**	**35,000**
Recorded share-based compensation expenses, KSEK	395	-5,991

Long-term incentive program 2018 (LTIP 2018)

Hansa Biopharma's Annual General Meeting on May 29, 2018 resolved to adopt a long-term incentive program (LTIP 2018). Participants in the program were given the opportunity to acquire warrants at market value and/or receive so called performance-based share rights free of charge which, provided that certain conditions are met, may give the right to acquire shares in the Company. A maximum of 491,419 warrants or 297,902 share awards could be allotted to participants under LTIP 2018 from the day after the AGM in 2018 through the day of the AGM in 2019.

Warrants under LTIP 2018

Each warrant gives the participant the right to exercise the warrants for subscription of shares 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 seven percent annually during the 3 years 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 warrant program participants (exept the CEO) received a subsidy of maxiumum 25% of the price.

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

Notes continued

Note 5 Employees and personnel costs continued

LTIP 2018, Warrants: Key figures

	2020	2019
Warrants, Opening balance 1 January	6,701	6,701
Warrants acquired by participants during the period	–	–
Warrants expired or redeemed in advance	–	–
Warrants, Closing balance 31 December	**6,701**	**6,701**
Recorded share-based compensation expenses, KSEK	17	40

Share rights under LTIP 2018

A share right (the "Right") provides the right to aquire a share in the Company free-of-charge provided certain conditions are met in accordance with the terms. A 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 LTIP 2018 for each participant, up until and including the date three years thereafter (the "Vesting Period"), maintains his or her employment within the Group. The performance condition is set at a "minimum level" and "maximum level", whereby the number of shares granted under the Right is increased lineally between the minimum level and maximum level. However, in order for the Rights to entitle to the granting of shares, the minimum level has to be reached or exceeded. If the specified minimum level of the performance condition of 25 percent shareholder return during the Vesting Period is achieved, 25 percent of each participant's Rights will entitle to shares. If the maximum level of 100 percent shareholder return during the Vesting Period is reached , 100 percent of each participant's Rights will entitle to shares.

LTIP 2018, Share rights: Key figures

	2020	2019
Share rights, Opening balance 1 January	238,368	171,556
Alloted to participants 14 May 2019	–	82,579
Share rights forfeited	-14,590	-15,767
Share rights, Closing balance 31 December	**223,778**	**238,368**
Recorded share-based compensation expenses, KSEK	9,213	4,837

Long-term incentive program 2019 (LTIP 2019)

Hansa Biopharma's Annual General Meeting (the "AGM") on May 22, 2019 resolved to adopt a long-term incentive program, LTIP 2019. Under the terms of LTIP 2019 key employees could participate in the program and could receive so-called performance-based share awards free of charge (a "Share Right") and/or share options, as further described below.

Share rights under LTIP 2019

Share rights give the participants the right to acquire ordinary shares in Hansa Biopharma AB at no cost provided certain pre-defined Performance Conditions (as briefly summarized below) and the employment is maintained during the Vesting Period. Each Share Right represents the right to acquire one share and carries a vesting period of three (3) years commencing on the day of its allotment to a participant (the "Vesting Period").

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

- Condition 1 (accounting for 22%): Obtain market approval in the EU by EMA
- Condition 2 (accounting for 22%): Obtain market approval in the United States by the FDA
- Condition 3 (accounting for 56%): Total shareholder return (TSR) of at least 25% against the baseline share price at the date of allotment.

A maximum of 550,699 Share Rights could be allotted to participants under the LTIP 2019 from the day following the 2019 AGM up and until the day prior to the AGM in 2020. In order to fund LTIP 2019 (including social security contribution), the 2019 AGM further resolved to authorize the Board of Directors to issue a maximum of 715,910 Class C shares which may be converted to ordinary shares whereby the Company's share capital may not be increased by more than SEK 715,910. The Class C shares were issued and purchased by the Company in September 2019.

Notes continued

Note 5 Employees and personnel costs continued

LTIP 2019, Share rights: Key figures

	2020	2019
Share Rights, Opening balance 1 January	306,303	–
Allotted to participants 17 June 2019	–	288,727
Allotted to participants 24 October 2019	–	17,576
Share rights forfeited	-18,748	–
Share Rights, Closing balance 31 December	**287,555**	**306,303**
Recorded share-based compensation expenses, KSEK	12,459	6,981
Allotment date 17 June 2019 – Fair value calculation (Monte Carlo simulation)		
Base line share price TSR, SEK	N/A	178.40
Calculated fair value per Share Right, SEK	N/A	122.12
Risk-free interest rate, (%)	N/A	-0.59
Expected volatility, (%)	N/A	43
Expected dividend, SEK	N/A	–
Allotment date 24 October 2019 – Fair value calculation (Monte Carlo simulation)		
Base line share price TSR, SEK	N/A	129.30
Calculated fair value per Share Right, SEK	N/A	89.00
Risk-free interest rate, (%)	N/A	-0.41
Expected volatility, (%)	N/A	43
Expected dividend, SEK	N/A	–

Share options under LTIP 2019

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

Series 1 consists of not more than 169,848 warrants that can be transferred to senior executives who are taxable in Sweden. The warrants can be exercised after approximately three (3) years (the "Vesting Period"), after which the holder is entitled to exercise the warrants to subscribe for ordinary shares in the Company during a period of one month. The transfer to participants is made at a price corresponding to the market value of the warrants at the time of transfer. The Company did subsidise up to 100 per cent, pre taxation, of the price for the transfer of the warrants through a one-time subsidy offered to participants.

Series 2 consists of not more than 268,705 employee stock options that can be allotted to senior executives. Each employee stock option entitles the holder to subscribe for one new ordinary share in Hansa Biopharma AB. The options are allotted free of charge. The employee stock options have a vesting period of three (3) years (the "Vesting Period"), after which the holder is entitled to exercise the options during a period of one month.

Each warrant or employee stock option entitles the holder to receive one new ordinary share in Hansa Biopharma AB at an exercise price corresponding to 110 per cent of the volume weighted average share price during the ten (10) trading days immediately prior to the offer to subscribe for the warrants.

In order to fund SOP 2019 (including resulting social security contribution), the 2019 AGM further resolved to authorize the Board to issue a maximum of 438,553 ordinary shares, whereby the Company's share capital shall not be increased by more than SEK 438,553.

LTIP 2019, Warrants: Key figures

	2020	2019
Warrants, Opening balance 1 January	11,000	–
Warrants acquired by participants 17 June 2019	–	11,000
Rights expired or redeemed in advance	–	–
Closing balance 31 December	**11,000**	**11,000**
Recorded share-based compensation expenses, KSEK	223	153
Proceeds from exercise of warrants during the period, KSEK	–	–
Estimated total proceeds if all outstanding warrants are exercised, KSEK	2,158	2,158
Acquisition date 17 June 2019 – Fair value calculation (Black Scholes model)		
Calculated fair value per warrant, SEK	N/A	45.54
Volume-weighted average share price, SEK	N/A	178.38
Exercise price, SEK	N/A	196.20
Risk-free interest rate, %	N/A	-0.59
Expected volatility, %	N/A	43
Warrant life, years	N/A	3
Expected dividend, SEK	N/A	–

Notes continued

Note 5 Employees and personnel costs continued

LTIP 2019, Employee Stock Options (ESO): Key figures

	2020	2019
ESO, Opening balance 1 January	149,148	–
ESO alloted to participants 17 June 2019	–	149,148
ESO forfeited or expired	–	–
ESO, Closing balance 31 December	**149,148**	**149,148**
Recorded share-based compensation expenses, KSEK	3,776	1,226
Proceeds from exercise of ESO during the period, KSEK	–	–
Estimated total proceeds if all outstanding ESO are exercised, KSEK	29,265	29,265
Allotment date 17 June 2019 – Fair value calculation (Black Scholes model)		
Calculated fair value per ESO, SEK	N/A	45.19
Volume-weighted average share price, SEK	N/A	178.38
Exercise price, SEK	N/A	196.20
Risk-free interest rate, %	N/A	-0.59
Expected volatility, %	N/A	43
ESO life, years	N/A	3
Expected dividend, SEK	N/A	–

Long-term incentive program 2020 (LTIP 2020)

Hansa Biopharma's Annual General Meeting (the "AGM") on June 23, 2020 resolved to adopt a long-term incentive program, LTIP 2020. Under the terms of LTIP 2020 key employees can participate in the program and receive so called performance-based share awards free of charge (a "Share Right") and/or employee stock options ("ESO"), as further described below.

Share rights under LTIP 2020

Share rights give the participants the right to acquire ordinary shares in Hansa Biopharma AB at no cost provided certain pre-defined Performance Conditions (as briefly summarized below) and the employment is maintained during the vesting period. Each Share Right represents the right to acquire one share and carries a vesting period of three (3) years commencing on the day of its allotment to a participant (the "Vesting Period").

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

- Condition 1 (accounting for 22%): The U.S. randomised controlled trial is completed during the Vesting Period;
- Condition 2 (accounting for 11%): Top line data read out of the ongoing phase 2 study in either AMR or GBS is completed during the Vesting Period with data providing a solid scientific rational to continue either of the two programs;
- Condition 3 (accounting for 11%): At least 70 per cent of the targeted transplantation centers in Europe have been initiated during the Vesting Period;
- Condition 4 (accounting for 56%): Total shareholder return (TSR) of at least 25% against the baseline share price at the date of allotment.
- .

A maximum of 505,096 Share Rights can be allotted to participants under the LTIP 2020 from the day following the 2020 AGM up and until the day prior to the AGM in 2021.

LTIP 2020, Share Rights: Key figures

	2020
Share Rights, Opening balance 1 January	–
Allotted to participants 23 July 2020	401,556
Share rights forfeited	-12,000
Share Rights, Closing balance 31 December	**389,556**
Recorded share-based compensation expenses, KSEK	12,678
Allotment date 23 July 2020 – Fair value calculation (Monte Carlo simulation)	
Base line share price TSR, SEK	252.60
Calculated fair value per Share Right, SEK	216.00
Risk-free interest rate, (%)	-0.33
Expected volatility, (%)	43
Expected dividend, SEK	–

Notes continued

Note 5 Employees and personnel costs continued

Employee Stock Options under LTIP 2020

Each Employee Stock Option entitles the holder to subscribe for one new ordinary share in Hansa Biopharma AB. The options are allotted free of charge. The employee stock options have a vesting period of three (3) years (the "Vesting Period"), after which the holder is entitled to exercise the options during a period of one month.
Each Employee Stock Option entitles the holder to receive one new ordinary share in Hansa Biopharma AB at a subscription price corresponding to 125 per cent of the volume weighted average share price during the ten (10) trading days immediately prior to the offer to subscribe for the warrants.

A maximum of 506,280 Employee Stock Options can be allotted to participants under the LTIP 2020 from the day following the 2020 AGM up and until the day prior to the AGM in 2021.

LTIP 2020, Employee Stock Options (ESO): Key figures

	2020
ESO, Opening balance 1 January	–
ESO alloted to participants 23 July 2020	487,520
ESO forfeited	-10,000
ESO, Closing balance 31 December	**477,520**
Recorded share-based compensation expenses, KSEK	4,588
Proceeds from exercise of ESO during the period, KSEK	–
Estimated total proceeds if all outstanding ESO are exercised, KSEK	150,777
Allotment date 23 July 2020 – Fair value calculation (Black Scholes model)	
Calculated fair value per ESO, SEK	53.05
Volume- weighted average share price, SEK	252.60
Exercise price, SEK	315.75
Risk-free interest rate, %	-0.33
Expected volatility, %	43
ESO life, years	3
Expected dividend, SEK	–

Note 6 Fees and remuneration to auditors

	1 January – 31 December	
KSEK	**2020**	2019
Group		
KPMG AB		
Auditing services	695	597
Other services closely related to audit services	90	143
Tax services	–	265
Wilkins Kennedy Audit Service		
Auditing services	64	58
Parent Company		
KPMG AB		
Auditing services	545	597
Other services closely related to audit service	160	143
Tax services	–	265

Auditing services refer to the legally required audit of the annual report and the accounts as well as the Board of Directors' and the executive management's practice and other audit and examinations agreed upon or determined by contract. This includes other work assignments which rest upon the Company's auditor to conduct and advising, or other support justified by observations in the course of examination or execution of such other work assignments.

Note 7 Operating costs by nature

Group

	1 January – 31 December	
KSEK	**2020**	2019
Personnel costs	-180,271	-114,752
Third party expenses	-242,241	-238,595
Depreciation, amortization, write-offs	-7,666	-6,912
Total operating costs by nature	**-430,178**	**-360,259**

Notes continued

Note 7 Operating costs by nature continued

Parent Company

KSEK	1 January – 31 December 2020	2019*
Personnel costs	-165,173	-101,064
Third party expenses	-259,354	-253,373
Depreciation, amortization, write-offs	-6,350	-6,647
Total operating costs by nature	-430,877	-361,085

* Restated due to change in accounting policy related to IFRS 16.

Note 8 Net finance costs/income

Group

KSEK	1 January – 31 December 2020	2019
Interest income, other	388	118
Changes in the fair value of interest funds during the year	1,782	445
Finance income	**2,170**	**563**
Interest expenses, other	-257	-466
Net exchange rate gains/losses	–	-21
Finance costs	**-257**	**-487**
Net finance costs/income	**1,914**	**76**

Parent Company

KSEK	1 January – 31 December 2020	2019
Interest income, other	389	118
Changes in the fair value of interest funds during the year	1,782	445
Finance income	**2,170**	**563**
Interest expenses, other	-307	-466
Net exchange rate gains/losses	–	-21
Finance costs	**-307**	**-487**
Net finance costs/income	**1,863**	**76**

Note 9 Taxes

Deferred tax liabilities

Deferred tax due to fair value adjustments related to intangible assets at acquisition.

KSEK	2020	2019
Opening balance 1 January	507	511
Tax income in the income statement*	-40	-42
Currency differences for the year	-43	38
Closing balance 31 December	**424**	**507**

* The reported tax income refers to the revaluation of deferred tax liability attributable to amortization of acquired patents.

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 group's losses carried forward in 2020 amounted to SEK 1,370,080 k (2019: SEK 990,873 k). The losses carried forward is, in all material respects, attributable to Swedish companies and therefore has no due date.

Reconciliation effective tax
Group

KSEK	2020 (%)	2020	2019 (%)	2019
Result before tax	–	-420,893	–	-359,592
Tax according to current tax rate for the Parent Company	21.4	90,071	21.4	76,953
Effect of other tax rates for foreign subsidiaries	–	–	–	-62
Non-deductable expenses	-2.2	-9,119	-0.5	-1,701
Increase in loss carry-forwards without corresponding capitalization of deferred tax	-19.2	-80,912	-21.0	-75,606
Reported effective tax	–	40	–0.1	-417

Notes continued

Note 9 Taxes continued

Parent Company

KSEK	2020 (%)	2020	2019* (%)	2019*
Result before tax	–	-421,644	–	-360,398
Tax according to current tax rate for the Parent Company	21.4	90,232	21.4	77,125
Non-deductable expenses	-2.2	-9,119	-0,5	-1,613
Increase in loss carry-forwards without corresponding capitalization of deferred tax	-19.2	-81,113	-20.9	-75,512
Reported effective tax	–	–	–	–

* Restated due to change in accounting policy regarding IFRS 9 and IFRS 16

Note 10 Earnings per share

Earnings per share

SEK	2020	2019
Earnings per share prior to and after dilution	-9.98	-9.00

The outstanding potential ordinary shares that existed at the reporting date are not earnings dilutive. Earnings per share before and after dilution is therefore the same. The outstanding potential stock of ordinary shares may become earnings dilutive in the future if the result is positive and the share price goes up to a level above the exercise price for the warrants included in the long-term incentive programs.

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

Profit/loss attributable to the Parent Company's shareholders prior to and after dilution

KSEK	2020	2019
Profit/loss for the year attributable to the Parent Company's shareholders	-420,853	-360,009
Earnings attributable to the Parent Company's shareholders prior to and after dilution	**-420,853**	**-360,009**

Weighted average number of outstanding shares prior to and after dilution

Number of shares	2020	2019
Total number of shares 1 January	40,026,107	39,959,890
Efffect of new share issue in July 2020	2,150,765	–
Effect of conversion of C to A shares in January 2019	–	12,062
Effect of new share issue in January 2019	–	45,890
Effect of conversion of C to A shares in February 2019	–	2,586
Weighted average number of shares during the year prior to and after dilution	**42,176,872**	**40,020,429**

Note 11 Intangible assets

Group

2020, KSEK	Developed in-house	Acquired intangible assets		Total
	Capitalized development expenditures	Patents	In-process development projects	
Cost				
Opening balance 1 January 2020	4,485	12,479	25,136	42,100
Effects of movements in exchange rates	–	-410	–	-410
Closing balance 31 December 2020	4,485	12,069	25,136	41,690
Amortization				
Opening balance 1 January 2020	-4,485	-4,267	–	-8,752
Amortization for the year	–	-1,668	–	-1,668
Effects of movements in exchange rates	–	140	–	140
Closing balance 31 December 2020	-4,485	-5,794	–	-10,280
Carrying amounts				
At 1 January 2020	–	8,213	25,136	33,348
At 31 December 2020	–	6,275	25,136	31,410

Notes continued

Note 11 Intangible assets continued

2019, KSEK	Developed in-house	Acquired intangible assets		
	Capitalized development expenditures	Patents	In-process development projects	Total
Cost				
Opening balance 1 January 2019	4,485	3,643	33,515	41,643
Reclassification	–	8,379	-8,379	–
Adjusted opening balance	4,485	12,022	25,136	41,643
Additions	–	729	–	729
Effects of movements in exchange rates	–	-272	–	-272
Closing balance 31 December 2019	4,485	12,479	25,136	42,100
Amortization				
Opening balance 1 January 2019	-4,485	-609	-3,352	-8,446
Reclassification	–	-3,352	3,352	–
Adjusted opening balance	-4,485	-3,961	–	-8,446
Amortization for the year	–	-812	–	-812
Effects of movements in exchange rates	–	506	–	506
Closing balance 31 December 2019	-4,485	-4,267	–	-8,752
Carrying amounts				
At 1 January 2019	–	3,034	30,163	33,197
Reclassification	–	5,027	-5,027	–
Adjusted opening balance at 1 January 2019	–	8,061	25,136	33,197
At 31 December 2019	–	8,213	25,136	33,348

Parent Company

2020, KSEK	**Developed in-house**	**Acquired intangible assets**		
	Capitalized development expenditures	**Patents**	**In-process development projects**	**Total**
Cost				
Opening balance 1 January 2020	4,485	8,504	25,136	38,125
Closing balance 31 December 2020	4,485	8,504	25,136	38,125
Amortization				
Opening balance 1 January 2020	-4,485	-4,118	–	-8,603
Amortization for the year	–	-351	–	-351
Closing balance 31 December 2020	-4,485	-4,469	–	-8,954
Carrying amounts				
At 1 January 2020	–	4,386	25,136	29,522
At 31 December 2020	–	4,035	25,136	29,171

Notes continued

Note 11 Intangible assets continued

2019, KSEK	Developed in-house	Acquired intangible assets		
	Capitalized development expenditures	Patents	In-process development projects	Total
Cost				
Opening balance 1 January 2019	4,485	125	33,515	38,125
Reclassification	–	8,379	-8,379	–
Adjusted opening balance 1 January 2019	4,485	8,504	25,136	38,125
Closing balance 31 December 2019	4,485	8,504	25,136	38,125
Amortization				
Opening balance 1 January 2019	-4,485	-125	-3,352	-7,962
Reclassification	–	-3,352	3,352	–
Adjusted opening balance 1 January 2019	-4,485	-3,477	–	-7,962
Amortization for the year	–	-641	–	-641
Closing balance 31 December 2019	-4,485	-4,118	–	-8,603
Carrying amounts				
At 1 January 2019	–	–	30,163	30,163
Reclassification	–	5,027	-5,027	–
Adjusted opening balance 1 January 2019	–	5,027	25,136	30,163
At 31 December 2019	–	4,386	25,136	29,522

The projects pending in the Group are a combination of acquired development projects and continued activities in these projects. Of the total acquisition cost for acquired in-process development projects, approximately 75% relates to imlifidase and 25% relates to HBP-assay. Capitalized internal development expenditures for imlifidase's previous production process were completely amortized during the year 2018.

Project overview	Indication/Purpose	Status
Imlifidase	Imlifidase is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as in acute autoimmune indications.	The EU Commission granted Hansa Biopharma conditional approval for Idefirix® (imlifidase) in highly sensitized kidney transplant patients in the European Union in August 2020 and the approval serves as a landmark milestone for Hansa Biopharma, as Idifirix will be the Company's first approved drug and will transform Hansa Biopharma into commercial stage biopharmaceutical company. Imlifidase is also being evaluated in two Phase 2 programs within autoimmune diseases, namely anti-GBM antibody disease and Guillain Barré syndrome. Lastly, imlifidase is also being evaluated for active antibody mediated rejection (AMR) after kidney transplantation.
HPB-assay	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 product has been licensed to a cooperating partner, Axis-Shield Diagnostics, which is currently developing a fully commercial product. Hansa Biopharma AB receives milestone compensation and additional royalty revenue upon the sale of the sublicensed technology.

Acquired in-process development projects are assessed for possible impairment at least on an annual basis and the impairment assessment on December 31, 2020 and 2019 demonstrated that there was no need for impairment. The estimated recoverable amount supported by external and internal valuation reports by far exceed the assets carrying amount, resulting in no impairment charges for the year 2020 and 2019.

The capitalized in-process R&D cost will be amortized over the finite useful life of the underlying asset. The first commercial sale of imlifidase was in Q1-2021 and useful life is estimated to be 12 years.

The HBP patent cost is amortized over the finite useful life of the underlying patent in the amount of SEK 559 k for 2020 (2019: SEK 559 k). The patent cost is amortized over sales, general and administration line item in the income statement.

Notes continued

Note 12 Property and equipment

Group

KSEK	Equipment, tools and facilities 2020	2019
Cost		
Opening balance 1 January	11,577	8,878
Additions during the year	294	2,699
Closing balance 31 December	11,871	11,577
Accumulated depreciation and write-offs		
Opening balance 1 January	-5,542	-3,588
Depreciation during the year	-1,009	-1,315
Scrapping during the year	-114	-551
Disposals during the year	–	-87
Closing balance 31 December	-6,665	-5,542
Carrying amounts		
At 1 January	6,035	5,290
At 31 December	5,206	6,035

Parent Company

KSEK	Equipment, tools and facilities 2020	2019
Cost		
Opening balance 1 January	11,577	8,878
Additions during the year	294	2,699
Closing balance 31 December	11,871	11,577
Accumulated depreciation and write-offs		
Opening balance 1 January	-5,542	-3,588
Depreciation during the year	-1,009	-1,315
Scrapping during the year	-114	-551
Disposals during the year	–	-87
Closing balance 31 December	-6,665	-5,542
Carrying amounts		
At 1 January	6,035	5,290
At 31 December	5,206	6,035

For leased assets please refer to Note 26.

Notes continued

Note 13 Receivables, group companies

Parent company, non-current assets

KSEK	2020	2019
Cost		
Opening balance on 1 January	2,244	–
Additional receivables	–	2,244
Effects of movements in exchange rates	-272	–
Closing balance 31 December	**1,972**	**2,244**

Parent company, current assets

KSEK	2020	2019
Cost		
Opening balance on 1 January	1,061	2,834
Additional receivables	–	1,949
Effects of movements in exchange rates	-1,061	-3,723
Closing balance 31 December	**–**	**1,061**

Note 14 Inventories

Group and Parent Company

KSEK	2020	2019
Raw materials	212	–
Semi-finished products	5,590	–
Finished products	380	–
Gross Inventory Value	6,182	–
Inventory provisions	-6,084	–
Balance 31 December	**98**	**–**

The Company owns inventories valued at cost which were mainly produced prior to obtaining regulatory approval for Idefirix® in Europe in August 2020 (Pre-approval Inventories). Inventory value is presented gross in the inventory table above. Inventory provisions in the total amount of SEK 6.1 m were recorded to account for Pre-approval Inventories as well as potential excess quantities.

Note 15 Other long term holdings of securities

Parent Company

KSEK	2020	2019*
As previously reported per 31 December 2018	–	12,499
Change in accounting principle IFRS 9	–	27,030
Adjusted opening balance 1 January	–	39,529
Change in fair value through other comprehensive income	–	49,597
Sale of securities	–	-89,125
Closing balance 31 December	–	–
Carrying amounts		
At 31 December	–	–

* Restated due to change in accounting policy, IFRS 9

Note 16 Other receivables

Group

KSEK	2020	2019
Other receivables (current)		
VAT receivables	3,786	2,058
Advanced payment to suppliers	3,124	6,414
Other receivables	3,047	2,676
Balance 31 December	**9,957**	**11,149**

Parent Company

KSEK	2020	2019
Other receivables (current)		
VAT receivables	3,786	2,054
Advanced payment to suppliers	3,124	6,414
Other receivables	2,853	2,670
Balance 31 December	**9,763**	**11,138**

Notes continued

Note 17 Accounts receivable

Accounts receivable amounting to SEK 110 k (2019: 522 k) are reported after consideration of bad debt losses during the year which amounted to SEK 0 (2019: SEK 0) for the Group and Parent Company.

Note 18 Prepaid expenses

Group

KSEK	2020	2019
Prepaid insurance	494	1,384
Prepaid marketing	1,664	579
Prepaid software	1,621	320
Other	1,937	696
Balance 31 December	**5,716**	**2,979**

Parent Company

KSEK	2020	2019
Prepaid insurance	494	1,384
Prepaid marketing	1,664	579
Prepaid software	1,621	320
Other	1,615	426
Balance 31 December	**5,394**	**2,709**

Note 19 Cash and cash equivalents

Group

KSEK	2020	2019
Subcomponents of cash and cash equivalents:		
Cash and bank deposits	1,139,362	181,697
Total according to statement of financial position	1,139,362	181,697
Total according to cash flow analysis	1,139,362	181,697

Parent Company

KSEK	2020	2019
Subcomponents of cash and cash equivalents:		
Cash and bank deposits	1,133,647	176,715
Total according to statement of financial position	1,133,647	176,715
Total according to cash flow analysis	1,133,647	176,715

Note 20 Shareholders' equity

Group

Share capital and number of shares

Number of shares	2020	2019
Issued as of 1 January	40,026,107	39,959,890
Effect of new share issue in July 2020	4,447,345	–
Effect of conversion of C to A shares in January 2019	–	13,142
Effect of new share issue in January 2019	–	50,000
Effect of conversion of C to A shares in February 2019	–	3,075
Issued as of 31 December	**44,473,452**	**40,026,107**

The Company's shares have a quotient value of SEK 1.

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

Treasury shares included in equity

	Number of shares		Reported value SEK '000	
	2020	2019	2020	2019
Opening balance of Treasury shares	1,421,457	721,764	1,421	722
Additions during the year	–	715,910	–	716
Disposals during the year	–	-16,217	–	-16
Closing balance of Treasury shares	**1,421,457**	**1,421,457**	**1,421**	**1,421**

Treasury shares have a quotient value of SEK 1.

The year 2019 additions of C shares refers to the new issue and subsequent repurchase of C shares that have taken place in accordance with the respective LTIP program.

Notes continued

Note 20 Shareholders' equity continued

Other contributed capital
Refers to shareholders' equity contributed by the shareholders. This includes premiums paid in conjunction with share issues.

Reserves
Treasury shares reserve
The treasury shares reserves comprises own shares repurchased by the Parent Company.

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 Parent Company and the Group present their financial statements in Swedish kronor.

Fair value reserves
Fair value fund includes the accumulated change in fair value after tax on the holding of shares and shares that the Group has chosen to report at fair value through other comprehensive income according to IFRS 9. When the holdings are sold the accumulated change in value attributable to the sold asset is transferred from the fair value reserve to retained earnings.

Please refer to Note 5 related to the Company's LTIP programs and respective vesting dates.

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

Dividends
The dividend proposal will be submitted to the annual general meeting on May 12, 2021. No dividend was paid for 2020.

Parent Company
Unrestricted shareholders' equity
Together with the profit/loss for the year, the following reserves constitute unrestricted shareholders' equity, i.e. the amounts available for payment of a dividend to the shareholders.

Fair value reserves
Fair value fund includes the accumulated change in fair value after tax on the holding of shares and shares that the parent company has chosen to report at fair value through other comprehensive income according to IFRS 9. When the holdings are sold the accumulated change in value attributable to the sold asset is transferred from the fair value reserve to retained earnings.

Retained earnings
Retained earnings consists of last year's retained earnings plus the profit/loss after deductions for dividends paid during the year.

Management of capital
The Group endeavors to maintain a sound financial position which contributes to retaining the confidence of creditors and the market and which constitutes the foundation for the continued development of the business. The Group defines "management of capital" as total reported shareholders' equity.

Note 21 Provisions

Provisions relate to social security contributions linked to outstanding share or option rights in the Company'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 5 related to the Company's LTIP programs and respective vesting dates.

Group

KSEK	**2020**	2019
Opening balance 1 January	818	10,948
Provision related to LTIP 2016	1	-10,112
Provision related to LTIP 2018	2,953	-791
Provision related to LTIP 2019	6,778	688
Provision related to LTIP 2020	3,736	–
Pension provision	140	85
Closing balance 31 December	**14,426**	**818**

Notes continued

Note 21 Provisions continued

Parent Company

KSEK	2020	2019
Opening balance 1 January	818	10,948
Provision related to LTIP 2016	1	-10,112
Provision related to LTIP 2018	2,953	-791
Provision related to LTIP 2019	6,778	688
Provision related to LTIP 2020	3,736	–
Pension provision	140	85
Closing balance 31 December	**14,426**	**818**

Note 22 Contingent consideration

Group and Parent Company

The Company acquired Immago Ltd (Hansa Biopharma Ltd) on 19 July 2016. The agreed upon purchase price was GBP 170 k and additional GBP 70 k milestone payment is to be paid if certain milestones were achieved. The estimated payment date is 19 July 2022, resulting in fair value of contingent liability at 31 December 2020 amounting to SEK 663 k (2019: SEK 730 k).

Note 23 Other liabilities – current

Group

KSEK	2020	2019
Personnel related liabilities	9,454	6,621
Current tax	134	319
Balance 31 December	**9,588**	**6,940**

Parent Company

KSEK	2020	2019
Personnel related liabilities	8,325	6,621
Balance 31 December	**8,325**	**6,621**

Note 24 Accrued expenses

Group

KSEK	2020	2019
Annual leave accrual	10,775	7,317
Accrued social security contribution on salaries	2,964	2,020
Accrued social security contribution related to the Company's incentive plan	13,585	9,683
R&D project costs	13,223	7,328
Consulting fees	11,269	555
Other	4,311	5,492
Balance 31 December	**56,125**	**32,395**

Parent Company

KSEK	2020	2019
Annual leave accrual	10,495	7,317
Accrued social security contribution on salaries	2,964	2,020
Accrued social security contribution related to the Company's incentive plan	13,127	9,683
R&D project costs	13,223	7,328
Consulting fees	11,269	555
Other	4,311	3,199
Balance 31 December	**55,387**	**30,102**

Note 25 Financial risk management and financial instruments

Financial risk management

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

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

Notes continued

Note 25 Financial risk management and financial instruments continued

Risk management framework

The Company'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.

A. 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.

In order to secure short-term liquidity, Hansa Biopharma's AB treasury policy prescribes that an appropriate level of liquidity in the form of cash and cash equivalents shall be held in an amount sufficient to cover the expected Company financial obligations over at least the next nine (9) months 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 31 December 2020 amounted to SEK 1,139 m (31 December 2019: SEK 182 m). 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 m as of 31 December 2020 (31 December 2019: 419 m.

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

2020

KSEK	Nominal amount	0 – 3 months	3 – 12 months	1 – 5 years
Contingent consideration	776	–	–	776
Non-current leasing liabilities	644	–	–	644
Current leasing liabilities	4,497	1,232	3,265	–
Accounts payable	26,669	26,669	–	–
Total	**32,585**	**27,901**	**3,265**	**1,420**

2019

KSEK	Nominal amount	0 – 3 months	3 – 12 months	1 – 5 years
Contingent consideration	730	–	–	730
Non-current leasing liabilities	4,827	–	–	4,827
Current leasing liabilities	4,632	1,143	3,488	–
Accounts payable	50,573	50,573	–	–
Total	**60,762**	**51,716**	**3,448**	**5,557**

B. Market Risk

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

Currency risk

The Group is exposed to transactional foreign currency risk to the extent that there is a mismatch between the currencies in which sales, purchases, receivables and borrowings are denominated and the respective functional currencies of Group companies. The functional currencies of Group companies are primarily the SEK, GBP and USD. The currencies in which these transactions are primarily denominated are SEK, EUR, GBP and USD.

In order 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 Company.

Notes continued

Note 25 Financial risk management and financial instruments continued

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 Company may hold cash in foreign currency in the normal course of business to pay any accounts payable in foreign currencies. Subsidiaries will hold cash in their local currency within their normal course of business.

Sensitivity analysis

Hansa Biopharma AB purchases research-related services 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 Company expressed in SEK, all else remaining the same.

A change in SEK in relation to EUR by an average of 10% would affect the Group's earnings before tax by approximately SEK +/-7,989 k (2019: SEK +/-8,742). Correspondingly, a 10 % strengthening of SEK in relation to USD would affect earnings before tax by approximately SEK +/-6,601 k (2019: SEK +/-6,201), a strengthening of SEK in relation to GBP by an average of 10% would affect the Group's earnings before tax by approximately SEK +/-2,320 k (2019: SEK +/-2,476) and a strengthening of SEK in relation to DKK by an average of 10 % would affect the Group's earnings before tax by approximately SEK +/-105 k (2019: SEK +/-125). This analysis assumes that all other variables, in particular interest rates, remain constant and ignores any impact of forecast sales and purchases.

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

Interest rate risk

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

The Group has acquired shares in an interest fund. Changes in the general interest rate level affect the prices of the fund's interest investments in the opposite direction. If the general interest rate level suddenly drops 1 percentage point, prices will rise on the investment 0.25-0.50% and vice versa (modified duration 0.25 – 0.50% in the normal position). This would lead to impact on profit or loss of SEK +/-595 k to SEK +/-1,191 k, before tax (2019: SEK +/-1,048 k to SEK +/-2,096 k).

Share price risk

Hansa Biopharma AB was exposed to a share price risk through its holdings of shares in Genovis AB which is listed on First North. The investment in Genovis AB was sold during 2019.

C. 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 Group's credit risk is primarily related to bank deposits. However, this risk is considered to be low since the bank deposits are held in Swedish banks with good credit ratings. See further discussions in Note 17. According to the Group's treasury policy, Hansa Biopharma AB 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.

Investment policy

The Company 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 Company may only invest in investment grade issuers, measured at the day of the investment.

Therefore, the following applies:

> Minimum credit rating of one of the following rating agencies (or comparable):

Investment term	S&P rating	Moody's rating
Up to one year	A-2	P2
More than one year	A	A

> 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 of the Audit Committee.
> The duration management within the portfolio of investments is the responsibility of the CFO. The maximum maturity of an individual investment shall not exceed 2 years.

Notes continued

Note 25 Financial risk management and financial instruments continued

At year-end 2020, SEK 198 m of the Company'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. Other SEK 40 m were invested in a housing bond fund which invests in investment grade assets denominated in SEK.

Financial instruments

The fair value of financial assets and financial liabilities

The carrying amount of financial assets and financial liabilities are deemed to be the reasonable estimates of the fair value of each class of financial assets and financial liabilities.

The fair value of the short-term investments is calculated based on the closing price at the reporting date.

The fair value of contingent consideration is calculated at the discounted value of expected future cash flows. The purchase price will increase by GBP 70 k if a clinical trial is registered and linked to the acquired patent rights. Contingent purchase price is expected to be paid in 2022.

The carrying amounts of financial assets and financial liabilities per valuation category

The table below shows the reported value for financial assets and financial liabilities broken down by valuation category under IFRS 9.

Group

	Financial assets valued at amortized cost		Financial assets valued at fair value through the income statement	
KSEK	**2020**	2019	**2020**	2019
Financial assets				
Short term investments	–	–	238,144	419,397
Accounts receivable	110	522	–	–
Other receivables	3,047	2,676	–	–
Cash and cash equivalents	1,139,362	181,697	–	–
Total financial assets	**1,142,519**	**184,895**	**238,144**	**419,397**

	Financial liabilities valued at amortized cost		Financial liabilities valued at fair value through the income statement	
KSEK	**2020**	2019	**2020**	2019
Financial liabilities				
Contingent consideration	–	–	663	730
Accounts payable	26,669	50,573	–	–
Total financial liabilities	**26,669**	**50,573**	**663**	**730**

Parent company

	Financial assets valued at amortized cost		Financial assets valued at fair value through the income statement	
KSEK	**2020**	2019	**2020**	2019
Financial assets				
Short term investments	–	–	238,144	419,397
Accounts receivable	110	522	–	–
Receivables, group companies	–	1,061	–	–
Other receivables	2,853	2,670	–	–
Cash and cash equivalents	1,133,647	176,715	–	–
Total financial assets	**1,136,610**	**180,968**	**238,144**	**419,397**

	Financial liabilities valued at amortized cost		Financial liabilities valued at fair value through the income statement	
KSEK	**2020**	2019	**2020**	2019
Financial liabilities				
Contingent consideration	–	–	663	730
Liabilities, group companies	1,613	2,793	–	–
Accounts payable	26,623	50,262	–	–
Total financial liabilities	**28,236**	**53,055**	**663**	**730**

Notes continued

Note 25 Financial risk management and financial instruments continued

Levels of financial assets and financial liabilities per valuation hierarchy

The table below present the carrying amount of financial assets and financial liabilities per valuation hierarchy in IFRS 7.

Group and the Parent Company

KSEK	Valuation hierarchy	2020	2019
Financial asset			
Holdings of short term investments	Level 2	238,144	419,397
Contingent consideration	Level 3	663	730

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

Group and the Parent Company

	Contingent consideration	
KSEK	2020	2019
Opening balance	730	679
Currency differences	-112	51
Interest expense	45	–
Closing balance 31 December	**663**	**730**

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

Management best estimate at 31 December 2020 is that the contingent consideration will be paid in 2022. Previous estimate made at 31 December 2019 was the contingent consideration would be paid in 2021.

Note 26 Leases

This Note provides information for leases where the Group and parent company is lessee.

The statement of financial position shows the following amounts related to leases:

Group and Parent Company

KSEK	2020	2019
Leased assets		
Buildings	3,574	8,124
Equipment	440	345
Vehicles	480	640
	4,493	9,109
Lease liabilities		
Non-current	630	4,827
Current	4,415	4,632
	5,045	**9,459**

Depreciation charge of leased assets

KSEK	2020	2019
Buildings	-4,550	-4,550
Equipment	-169	-116
Vehicles	-161	-118
	-4,880	**-4,784**

Additions to rights of use-assets during the period amounted to SEK 540k (2019: SEK 528k).

Interest expense (included in finance cost) amounted to SEK 253 k (2019: SEK 392 k). Expenses related to low-value leases and short-term leases amounted to SEK 1,230 k (2019: SEK 852 k). Total cash outflow of leases amounted to SEK 6,157 k (2019: SEK 5,677).

Most of the Group's operational leasing agreements involve leases of real property and premises on which the business operations are conducted. The duration of the lease for the Lund offices is three years from January 1, 2019. The agreement is automatically extended with two years at a time unless

Notes continued

cancellation is made no later than nine months before the end of the contract period. There are no variable fees included in the leases.

See further cash flow analysis in Note 30 and term based analysis in Note 25.

Note 27 Collateral provided, contingent liabilities and contingent assets

Nothing to report related to the financial year 2020 and 2019.

Note 28 Related party transactions

Subsidiaries

Interest in subsidiaries are set out in Note 29.

See further Note 13 – Receivables from group companies.

Transactions with key persons in a senior management position

Transactions with key persons in a senior management position are set forth in Note 5.

Note 29 Group companies

Holdings in subsidiaries

		Share ownership percentage (%)	
Subsidiaries	Registered office/Country	**2020**	2019
Cartela R & D AB	Lund/Sweden	100	100
Hansa Biopharma Ltd	Cheltenham/United Kingdom	100	100
Hansa Biopharma Inc	Delaware, USA	100	100

Parent Company

KSEK	**2020**	2019
Cost		
Opening balance on 1 January	5,095	5,095
Closing balance 31 December	**5,095**	**5,095**

Specification of Parent Company's direct holdings of shares in subsidiaries

Subsidiaries/Company reg. no./Registered office	Number of shares	Share (%)	**2020**	2019
Cartela R & D AB/556746-0083/Lund	1,000	100	2,630	2,630
Hansa Biopharma Ltd / 08361712 / Cheltemham, United Kingdom	100,000	100	2,456	2,456
Hansa Biopharma Inc, 6846164, Delaware, USA	1,000	100	9	9
Closing balance 31 December			**5,095**	**5,095**

Note 30 Cash flow analysis

Adjustment for items not included in cash flow

Group

	1 January – 31 December	
KSEK	**2020**	2019
Depreciation/amortization/write-offs	7,666	7,463
Expenses related to incentive programs	43,348	7,246
Costs related to pension plan	141	85
Unrealized currency differences	275	-181
Total adjustment for items not included in cash flow	**51,430**	**14,613**

Parent Company

	1 January – 31 December	
KSEK	**2020**	2019
Depreciation/amortization/write-offs	6,350	7,292
Expenses related to incentive programs	43,348	7,302
Costs related to pension plan	141	85
Unrealized currency differences	275	–
Total adjustment for items not included in cash flow	**50,114**	**14,679**

Notes continued

Note 30 Cash flow analysis continued

Reconciliation of liabilities arising from the financing activities

Group

KSEK	Balance at 31 December 2019	Termination of leases	New leasing agreements*	Payment of lease liabilities	Balance at 31 December 2020
Lease liabilities	9,458	-280	540	-4,674	5,044

KSEK	Opening balance 1 January 2019	Effect of IFRS 16	Restated balance at 1 January 2019	New leasing agreements*	Payment of lease liabilities	Balance at 31 December 2019
Lease liabilities	578	12,776	13,354	528	-4,424	9,458

* Non cash flow changes of debt

Parent Company

KSEK	Adjusted Balance at 31 December 2019	Termination of leases	New leasing agreements*	Payment of lease liabilities	Balance at 31December 2020
Lease liabilities	9,458	-280	540	-4,674	5,044

KSEK	Opening balance 1 January 2019	Effect of IFRS 16	Restated balance at 1 January 2019	New leasing agreements*	Payment of lease liabilities	Balance at 31 December 2019
Lease liabilities	578	12,776	13,354	528	-4,424	9,458

* Non cash flow changes of debt

Note 31 Agreements

Agreement with Sarepta Therapeutics Inc.

In July 2020, Hansa entered into an agreement with Sarepta Therapeutics Inc. ("Sarepta") through which Sarepta is granted an exclusive, worldwide license to develop and promote imlifidase as a pre-treatment to enable Sarepta gene therapy treatment in Duchenne muscular dystrophy (DMD) and Limb-girdle muscular dystrophy (LGMD) 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 pre-clinical and clinical studies with imlifidase and any subsequent 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 USD 10 m upfront payment, and is eligible for a total of up to USD 397.5 m in development, regulatory and sales milestone payments. The Company will book 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 through pre-treatment with imlifidase.

The Company received the upfront payment of USD 10 m (SEK 81.9 m) in July 2020. The upfront payment is recognized over a period of approximately up to 51 months as the Company fulfils its performance obligation under the agreement. In 2020, Hansa recognized SEK 2.6 m in revenue related to the Sarepta upfront payment.

As of December 31, 2020, the Company presented deferred revenue of SEK 79.4 m on its balance sheet of which SEK 17.4 m is presented as current liabilities.

Agreement with Axis-Shield Diagnostics Ltd.

In 2009, Hansa entered into an agreement with Axis-Shield Diagnistics Ltd. (Abbott group) ("Axis-Shield") by which it licensed certain rights to develop, manufacture and commercialize a Hansa-owned method for HBP analysis to predict severe sepsis in emergency clinics.

Under the terms of the agreement, Hansa is, during the license period and as long as patent protection is maintained, eligible to receive royalties with a minimum annual amount of USD 250 k (SEK 2.6 m), milestone payments if and when Axis-Shield achieves certain pre-defined regulatory and other milestones, and cost compensation for maintaining licensed patents related to the HBP analysis method as services are rendered and reimbursable cost are incurred.

In January 2020, the Company received a total of USD 250k (SEK 2.9m) (2019: USD 250 k (SEK 2.8 m)) in royalty payments. The amount was initially recorded as a deferred revenue and recognized as revenue over the reporting period on a straight line basis.

Further, in December 2020, the Company received a milestone payment amounting to USD 60k (SEK 0.6 m) (2019: USD 60k (SEK 0.5 m)). Such milestone payment was recognized as revenue when received as the Company had no outstanding performance obligations related to such milestone.

Notes continued

Note 31 Agreements continued

In addition, the Company recorded revenue related to reimbursable costs upon rendering services related to maintaining licensed patents during 2020 in an amount of SEK 0.6 m (2019: SEK 0.5m).

As of the reporting date, there was no deferred revenue recorded in the balance sheet related to the Axis-Shield agreement.

Royalty Agreements

In the past, the Company has entered into several royalty agreements (the "Royalty Agreements") with researchers and institutions (the "Counterparties") related to IdeS or imlifidase pursuant to which the Counterparties assign certain IP, patent and other rights (the "Rights") to the Company. As a compensation for the assignment of the Rights to the Company, the Counterparties are granted rights to receive royalties on net income and/or other compensation related to other payments the Company may receive related to IdeS or imlifidase in accordance with the terms of the Royalty Agreements. As the Company has received conditional regulatory approval for Idefirix® (imlifidase) in the EU for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor in August 2020 and the Company plans to commercially launch Idefirix® in the EU during 2021, above mentioned compensation obligations under the Royalty Agreements may become effective during 2021.

Note 32 Events after the end of the reporting period – IFRS non-adjusting events

On March 30, 2021 the Company announced that it has entered into a preclinical research collaboration agreement with argenx BV to evaluate the therapeutic potential of combining the two companies' IgG-modulating technologies.

Under the agreement, both parties will contribute equally in terms of resource allocation and will share all intellectual property and data developed through the collaboration. Both parties will maintain exclusive rights to their respective technologies and products.

Note 33 Use of judgments and estimates

In preparing these consolidated financial statements, management has made judgements and estimates that affect the application of the Group's accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to estimates are recognised prospectively.

Revenue recognition under the agreement with Sarepta Therapeutics

Management has concluded that there is significant integration and a highly dependent and highly interrelated relationship among the granted license, the supply of materials and the support from Hansa Biopharma professionals. Therefore, management has made the assessment that the license is not distinct and there is one single performance obligation to be accounted for under the guidance in IFRS 15. Revenue is therefore recognized over time as Hansa fulfils its performance obligation under the agreement.

Internally generated intangible assets

Expenditure on research activities is recognized in the income statement as incurred. Development expenditure is 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 income statement as incurred. Subsequent to initial recognition, development expenditure is measured at cost less accumulated amortization and any accumulated impairment losses.

This means in practice that expenditure is not capitalized before the pharmaceutical authorities have given approval due to the level of uncertainty associated with the approval process. The Company has not capitalized any R&D expenditure in the periods included in this report.

Note 34 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 2020 cover the Parent Company and its subsidiaries, jointly referred to as the Group.

Notes continued

Note 35 Appropriation of loss carried forward

Unrestricted shareholders' equity in the Parent Company:

KSEK	
Share premium reserve	2,509,457,908
Treasury shares	-1,421,457
Loss carried forward	-890,710,056
Result for the year	-421,642,931
Total	**1,195,683,464**

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

KSEK	
Share premium reserve	2,509,457,908
Treasury shares	-1,421,457
Loss carried forward	-1,312,352,987
Total	**1,195,683,464**

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 7 April 2021

Ulf Wiinberg
Chairman of the Board

Birgit Stattin Norinder
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 7 April 2021. 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 May 12, 2021.

Our auditors' report was submitted on 7 April 2021.

KPMG AB

Jonas Nihlberg
Authorized Public Accountant

Auditor's Report

Translation from the Swedish original

To the general meeting of the shareholders of Hansa Biopharma AB, corp. id 556734-5359

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of Hansa Biopharma AB for the year 2020. The annual accounts and consolidated accounts of the company are included on pages 56 – 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 2020 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 2020 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

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

Basis for Opinions

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

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

Key Audit Matters

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

Accounting of revenue

See disclosure 2 and accounting principles on page 79 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 2020, the Company recognize contract revenue in the amount of SEK 2.6 m related to its agreement with Sarepta Therapeutics Ltd. This relates to an upfront payment of USD 10 m 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 judgment and knowledge and a detailed review of the contract terms and accounting standards.	We have reviewed the agreement as to the terms and the performance obligation identified by management. We have assessed management's assessment and assumptions regarding the allocating of the transaction price to the performance obligation. The revenues from Sarepta Therapeutics Ltd. has also been verified against upfront payment. We have also assessed accounting principles and the disclosures related to revenue included in the annual accounts and consolidated accounts.

Auditor's Report continued

Translation from the Swedish original

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 – 55 and pages 134 – 138. The Board of Directors and the Managing Director are responsible for this other information.

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

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

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

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

Auditor's Report continued

Translation from the Swedish original

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.

Report on other legal and regulatory requirements

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 2020 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.

Auditor's Report continued

Translation from the Swedish original

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.

KPMG AB, Box 227, 201 22 , Malmö, was appointed auditor of Hansa Biopharma AB by the general meeting of the shareholders on the 23 June 2020. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2014.

Malmö 7 April 2021

KPMG AB

Jonas Nihlberg
Authorized Public Accountant

Corporate Governance Report

Stock image

General principles

Introduction

The Board of Directors of Hansa Biopharma AB (publ) (the "Board"), Company reg. no. 556734-5359 ("Hansa Biopharma" or the "Company") hereby submits the 2020 corporate governance report in accordance with the requirements of the Swedish Annual Accounts Act (1995:1554) (Sw. årsredovisningslagen) and the Swedish Code of Corporate Governance (the "Code"; see the Swedish Corporate Governance Board website at www.corporategovernanceboard.se).

The Company's shares were admitted for trading on Nasdaq Stockholm in November 2015. The Company's shares were previously, since 2007, listed on Nasdaq First North. The Company's corporate governance is mainly regulated by the provisions of the Company's articles of association, the Swedish Companies Act (2005:551) (Sw. aktiebolagslagen) and other Swedish legislation, the Nordic Main Market Rulebook for Issuers of Shares and the Code.

The corporate governance report has been reviewed by the Company's auditors in accordance with the Swedish Annual Accounts Act. It does not constitute a part of the formal annual report documents.

The Group comprises the Parent Company, Hansa Biopharma AB, and its wholly owned subsidiaries Cartela R&D AB, Hansa Biopharma Ltd and Hansa Biopharma Inc.

There are no deviations from the Code to report for the financial year 2020. No infringements of Nasdaq's rules and no breach of good practice on the securities market was reported by the stock exchange's disciplinary committee or the Swedish Securities Council during the financial year 2020.

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 between any shareholders which might limit the transferability of the shares. As of December 31, 2020, Redmile Group LLC is the only shareholder owning more than 10 percent of the Company's shares, by its shareholdings of 10.4 percent.

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

Significant internal regulations and policies:

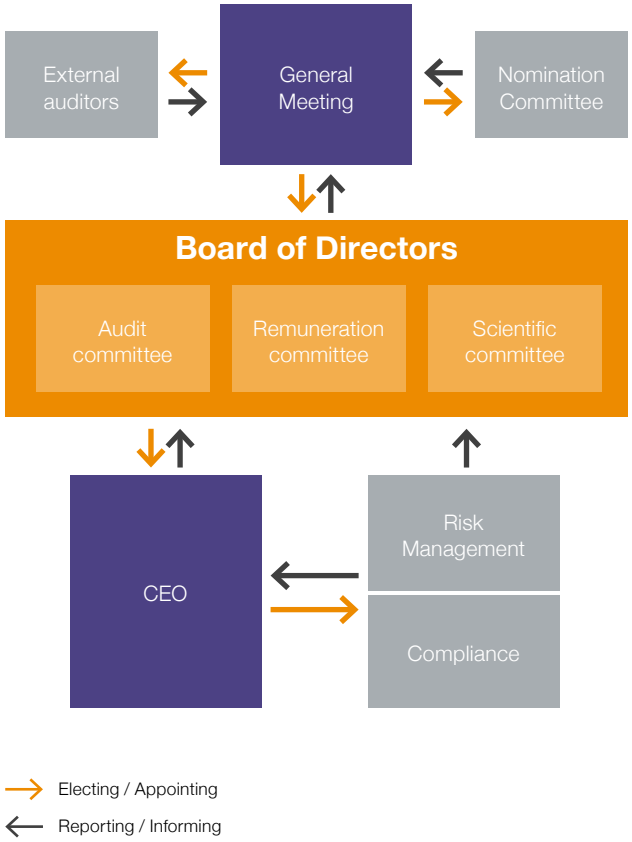
- Articles of association
- Instruction for the CEO, including the financial reporting instruction
- Disclosure policy
- Insider policy
- Procurement and expenditure policy
- Treasury policy
- Finance policy
- Risk management policy
- Financial handbook
- Staff handbook
- Executive remuneration policy
- Code of Conduct

Significant external regulations:

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

Hansa Biopharma corporate governance model

Overview of Hansa Biopharma's corporate governance structure during 2020[1]



General principles continued

Information regarding Hansa Biopharma AB shares

The shares in the Company are divided into ordinary shares and C-shares. On December 31, 2020, the total number of shares issued was 45,894,909 with 44,473,452 ordinary shares outstanding and 1,421,457 C-shares, with a quotient value of SEK 1. Each ordinary share carries one vote and each C-share carries one tenth. All C-shares are owned by the Company. Each person entitled to vote may vote for his or her full number of shares.

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

General meeting

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

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

2020 Annual General Meeting

At the 2020 AGM, which was held on June 23, 87 shareholders representing 37.36 percent of the total number of votes and 36.2 percent of the total number of shares in the Company were represented.

The AGM adopted the 2019 annual accounts, adopted a resolution regarding that the members of the Board shall be six with no deputy members, and granted the directors and CEO a discharge from liability. The general meeting resolved that no dividend would be paid. The AGM resolved that Ulf Wiinberg, Birgit Stattin Norinder, Anders Gersel Pedersen, Andreas Eggert, Eva Nilsagård and Mats Blom are re-elected as members of the Board for the period until the end of the next AGM. The AGM further resolved to re-elect Ulf Wiinberg as chairman of the Board for the period until the end of the next AGM. The AGM resolved to re-elect KPMG AB as auditor, with Jonas Nihlberg as the auditor in charge, for the period until the end of the next AGM.

The AGM resolved that the fees for the Board, for the period until the end of the next AGM, should remain unchanged from the previous year and shall be SEK 900,000 to the chairman of the Board and SEK 300,000 each to the other Board members. It was further resolved that the remuneration to the chairman of the Audit Committee should be SEK 75,000 and SEK 40,000 to each other member in the Audit Committee, SEK 40,000 to the chairman of the Remuneration Committee and SEK 25,000 to each other member in the Remuneration Committee, and SEK 25,000 to each board member in the Scientific Committee. 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 Boards' proposal, to adopt new guidelines for executive remuneration, to amend the articles of association, adopt a long-term incentive program based on performance-based share rights for employees at Hansa Biopharma, adopt a long-term incentive program based on employee stock options for employees in Hansa Biopharma and to 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 10 per cent of the total number of shares outstanding after full exercise of the authorization. It should also be possible to make such an issue resolution stipulating payment in cash, in kind payment, the right to offset debt or other conditions. The purpose of the authorization is to increase the financial flexibility of the Company and the acting scope of the Board as well as to potentially broaden the shareholder base.

Minutes from the AGM are available at Hansa Biopharma's website (www.hansabiopharma.com). The 2021 AGM will take place on 12 May 2021.

Remuneration to senior executives

The remuneration guidelines for senior executives adopted by the 2020 AGM entail that senior executives is offered 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 base salary, variable cash remuneration (including STI), pension benefits 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 50 per cent of the annual fixed salary.

General principles continued

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 programmes shall be decided by the Annual General Meeting. For information regarding the adopted long-term incentive programs, please refer to the Directors Report on page 56 and Note 1 and Note 5 to the Consolidated Financial Statements on page 78 and 86 respectively.

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 5 for further information on the 2020 guidelines.

The Board will propose an amendment to the current guidelines at the 2021 AGM by which the variable salary shall not exceed 75% of the annual fixed salary. Please refer to the Directors report on page 56 for further information.

Nomination committee

Prior to the 2021 AGM, Hansa Biopharma's nomination committee comprises Natalie Berner (representing Redmile Group), Thomas Olausson (representing himself), Jannis Kitsakis (representing AP4) and Ulf Wiinberg (chairman of the Board). Ulf Wiinberg is the convener of the committee.

The nomination committee prepares a proposal regarding the number of directors and persons to be elected as directors, including the chairman, and a proposal for remuneration to the chairman and the other Board members, as well as a proposal for remuneration for the Board members' committee work. The nomination committee also proposes election of auditors including remuneration to the auditor. Finally, the nomination committee proposes principles for the nomination committee prior to the AGM 2022. The proposals will be published in connection with the notice to the 2021 AGM.

External auditors

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

Pursuant to the articles of association, Hansa Biopharma must have a registered accounting firm as its external auditor. The accounting firm KPMG AB has been the auditor of the Company since the 2014 AGM. As from the 2018 AGM certified public accountant Jonas Nihlberg is auditor in charge. From the 2014 AGM up to and including the 2018 AGM, certified public accountant Dan Kjellqvist was auditor in charge. Dan Kjellqvist personally was the Company's auditor commencing at the time of the 2014 AGM up to and including the 2015 AGM. Jonas Nihlberg and Dan Kjellqvist are members of the Swedish Institute of Authorized Public Accountants. For information regarding fees paid to the auditors, please refer to Note 6 in the 2020 annual report.

The Board

The overall task of the Board is to manage the affairs of the Company in the best possible manner on behalf of the shareholders.

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

The chairman must keep himself well informed about, and monitor, the Company's business. The chairman is responsible for ensuring that the Board's work is carried out efficiently and that the Board fulfils its obligations in accordance with applicable laws and regulations, the Code, the articles of association, resolutions of the general meeting, and the Board's own rules of procedure. The chairman is also responsible for ensuring that the Board carries out the decisions that are made and that their work is evaluated. Further on, the chairman is also responsible for ensuring that the directors regularly update their knowledge about the Company and that new directors receive necessary introductory training.

The chairman represents the Company in ownership questions and is responsible for the day-to-day contact with the CEO and senior executives. The chairman must also approve remuneration and other employment terms and conditions for senior executives. The chairman is also responsible for the Company's archives, in which minutes from all Directors' meetings and general meetings must be saved.

The chairman prepares Board meetings together with the CEO. The notice of the meeting and the agenda are sent to the directors only after they have been approved by the chairman. After this, the notice is sent together with sufficient decision-making documentation to the directors. Each and every Board meeting includes a review of the business, including development and advances within research and development, business development, consolidated earnings and financial position, financial reports, and forecasts.

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

Directors' fees were set at the 2020 AGM for a period up to and including the next AGM. The fees for the Board's work in 2020 were set as follows. The chairman is paid SEK 900,000, and each other director is paid SEK 300,000. Further on SEK 75,000 is paid to the chairman and SEK 40,000 is paid to each other board member in the audit committee, SEK 40,000 is paid to the chairman and SEK 25,000 is paid to each other board member in the remuneration committee and SEK 25,000 is paid to each board member in the scientific committee. No remuneration other than the above-mentioned 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 management report and Note 5 in the 2020 annual report for additional information regarding employment terms and conditions for the Board and senior executives.

Directors

The Board currently comprises six individuals, including the chairman.

The 2020 AGM re-elected Ulf Wiinberg, Birgit Stattin Norinder, Anders Gersel Pedersen, Andreas Eggert Eva Nilsagård and Mats Blom as members of the Board. The AGM further resolved to re-elect Ulf Wiinberg as chairman of the Board. Each director's term continues until the end of the next AGM.

Prior to the 2020 AGM, the Nomination Committee announced that it had applied the provisions of rule 4.1 of the Code as Board diversity policy. The aim is that the Board as a collective should possess the required mix in terms of background and knowledge, whereby an even gender distribution is taken into particular account. The result of the Nomination Committee's application of the diversity policy is a Board that represents a mix of both professional experience and knowledge as well as geographical and cultural backgrounds. One third (1/3) of the Board members elected by the AGM are women.

The following is a list of the directors, containing information regarding their years of birth and election to the Board, education, work experience, engagement in the Company and other significant engagements and holdings in the Company as of 31 December 2020. Holdings in the Company includes one's own holdings as well as those of closely related persons.

The Board continued

Ulf Wiinberg

Member and Chairman of the Board since 2016.
Member of the Board and acting CEO during the period from November 9, 2017 until March 20, 2018.

Ulf Wiinberg is an experienced healthcare industry professional who has served on the boards of several healthcare industry associations. At Wyeth, he has been both President of the Global consumer health care business and President of the European pharma business. He also held the position of CEO of H Lundbeck A/S, a pharmaceutical Company specialized in psychiatric and neurological disorders, for several years. Ulf is the CEO of X-Vax Therapeutic Inc, a Company seeking to develop a vaccine against Herpes, as well as a non-executive member of the board of Alfa Laval AB, Agenus Inc and at the Belgian pharmaceutical Company UCB. He is also chairman of the board of Sigrid Therapeutics AB. He was born in 1958.

Ulf is member of Hansa Biopharma's Remuneration Committee and Scientific Committee. Independent of Hansa Biopharma and its executive management. Independent of major shareholders of Hansa Biopharma.

Shareholding: 114,900 shares

Birgit Stattin Norinder

Member of the Board since 2012.
Chairman of the Board during the periods September 2014 until June 2016 as well as November 9, 2017 until March 20,2018.

Birgit Stattin Norinder has extensive experience from international pharmaceutical and biotechnology companies in Sweden, the USA and the United Kingdom. She has managed several research and development departments, resulting in a number of novel and approved pharmaceuticals. Amongst many things she has served as CEO and Chairman at Prolifix Ltd., Senior VP Worldwide Product Development, Pharmacia & Upjohn and Dir. Int. Reg. Affairs Division, Glaxo Group Research Ltd. Birgit Stattin Norinder has also held several board and chairman positions of European biotechnology companies. She is a member of the board of AddLife AB and Jettesta AB and as of May 2020, Oasmia Pharmaceutical AB. Chairman of the Board of Hansa Biopharma 2014-2016. Birgit Stattin Norinder holds an M.Sc. in Pharmacy from Uppsala University. She was born in 1948.

Birgit Stattin Norinder is member of Hansa Biopharma's Scientific Committee, and Chairman of the Remuneration Committee. Independent of Hansa Biopharma and its executive management. Independent of major shareholders of Hansa Biopharma.

Shareholding: 42,205 shares

Anders Gersel Pedersen

Member of the Board since 2018.

Anders Gersel Pedersen has a long experience in the international pharmaceutical industry. Following his degree in medicine and research fellow positions at Copenhagen hospitals, he worked for Eli Lilly for 11 years. In January 2000 he joined H. Lundbeck A/S in Denmark and most recently served as Executive Vice President of the Research & Development organization, responsible for the discovery and development of the product pipeline from pre-clinical activities to post-launch marketing studies. He is a member of the Danish Society of Internal Medicine and serves on the supervisory boards of Avillion LLP, Bavarian Nordic A/S, and Genmab A/S. Anders Gersel Pedersen received his medical degree and a doctoral degree in neuro-oncology from the University of Copenhagen and a B.Sc. in Business Administration from Copenhagen Business School. He was born in 1951.

Anders is Chairman of Hansa Biopharma's Scientific Committee, and member of the Remuneration Committee. Independent of Hansa Biopharma and its executive management. Independent of major shareholders of Hansa Biopharma.

Shareholding: 2,500 shares

The Board continued

Andreas Eggert
Member of the Board since 2018.

Andreas Eggert has more than 25 years of cross-functional leadership experience including commercial operations, launch and portfolio management, brand strategy, market access, and strategic consulting. He is the Chief Operating Officer at X-Vax Technology Inc. in the U.S. Previously, he served as Senior Group Vice President, Global Product Strategy & Portfolio Development, and Member of the Corporate Management Committee at H. Lundbeck A/S in Denmark, where he was responsible for multiple new product launches and the commercial leadership for shaping the product portfolio and development pipeline. Previously, Andreas served as Vice President & Global Business Manager at Wyeth/Pfizer in the U.S. He held several senior commercial positions for Wyeth in the US, Japan and in Germany. Andreas also was a Management Consultant at A.T. Kearney. Andreas Eggert holds an MBA from Azusa Pacific University. He was born in 1967.

Andreas is member of Hansa Biopharma's Audit Committee and Scientific Committee. Independent of Hansa Biopharma and its executive management. Independent of major shareholders of Hansa Biopharma.

Shareholding: 5,500 shares

Eva Nilsagård
Member of the Board since 2019.

Eva Nilsagård is founder and currently CEO of Nilsagård Consulting AB. She has served as CFO of OptiGroup, Vitrolife and Plastal, Senior Vice President Strategy & Business Development at Volvo Group and held senior positions in finance and business development at Volvo, AstraZeneca and SKF. Eva is a board member and chairman of the Audit Committee of Addlife, Bufab, Irras, Nimbus Group and Xbrane Biopharma, chairman of Spermosens and board member of SEK (Swedish Export Credit Company). Eva Nilsagård has more than ten years of experience as a mentor for young female managers with high potential. Eva Nilsagård holds an Executive MBA in Economics and a BSc in accounting and finance from School of Business, Economics and Law in Gothenburg. She was born in 1964.

Eva is Chairman of Hansa Biopharma's Audit Committee. Independent of Hansa Biopharma and its executive management. Independent of major shareholders of Hansa Biopharma.

Shareholding: 3,000 shares

Mats Blom
Member of the Board since 2019.

Mats Blom has extensive managerial experience and is Chief Financial Officer (CFO) of NorthSea Therapeutics. He has served as CFO of Zealand Pharma A/B, a biotechnology Company focused on the discovery, design and development of innovative peptide-based medicines, and Swedish Orphan International, an orphan drug Company acquired by BioVitrum in 2009. In addition, Mats Blom has held CFO positions at Modus Therapeutics, Active Biotech AB and Anoto Group AB. He has also served as a management consultant at Gemini Consulting and Ernst & Young. Mats is a board member of Auris Medical AG and Pephexia A/S. Mats Blom holds a BA in Business Administration and Economics from the University of Lund and an MBA from IESE University of Navarra, Barcelona. He was born in 1965.

Mats is member of Hansa Biopharma's Audit Committee. Independent of Hansa Biopharma and its executive management. Independent of major shareholders of Hansa Biopharma.

Shareholding: 1,000 shares

The Board continued

The Board of Directors' work in 2020

During 2020, the Board has held fourteen meetings, all of which were held via Teams, of which one was the inauguration meeting and one was a combined board meeting and remuneration committee meeting. The Board has also made resolutions per capsulam at four occasions.

At the Board meetings held during the 2020 financial year, the directors were present as set forth below. The number of meetings and the maximum number of directors who could have been present are stated in parentheses during the financial year.

Evaluation of the Board of Directors' work

Pursuant to the Code, the Board is to evaluate its work annually, using a systematic and structured process, with the aim of developing the Board's working methods and efficiency. The evaluation has been carried out by the chairman of the Board by an independent evaluation company, in the end of 2020, 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 2020

Board member	Elected	Present at meetings of the Board	Present at meetings of the remuneration committee	Present at meetings of the audit committee	Present at meetings of the scientific committee	Independent in relation to the Company and executive management	Independent in relation to the Company's largest shareholders
Ulf Wiinberg	2016	14(14)	5(5)	–	3(3)	Yes	Yes
Birgit Stattin Norinder	2012	13(14)	5(5)	–	3(3)	Yes	Yes
Anders Gersel Pedersen	2018	14(14)	4(5)		2(3)	Yes	Yes
Andreas Eggert	2018	14(14)	–	6(6)	3(3)	Yes	Yes
Eva Nilsagård	2019	13(14)	–	6(6)	–	Yes	Yes
Mats Blom	2019	13(14)	–	6(6)	–	Yes	Yes

Board committees

Remuneration committee

After the 2020 AGM, the remuneration committee has consisted of Birgit Stattin Norinder, chairman, Ulf Wiinberg and Anders Gersel Pedersen. The remuneration committee is charged with performing the duties set forth in the Swedish Corporate Governance Code. The 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:

- Prepare decisions for the Board regarding remuneration principles, remuneration and other employment terms and conditions for executive management, among other things by proposing to the Board, if applicable, the guidelines for remuneration to executive management, to be adopted at the AGM of the shareholders;
- Monitor and evaluate any programs pending or adopted during the year for variable compensation for executive management; and
- Monitor and evaluate the application of the guidelines for remuneration adopted by the AGM, as well as applicable remuneration structures and levels for the Company.

The Board continued

Audit committee

After the 2020 AGM, the Audit Committee consisted of Eva Nilsagård, chairman, Mats Blom and Andreas Eggert. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board. The Audit Committee shall perform the duties incumbent upon audit committees as required by law and the Swedish Code of Corporate Governance.

The primary duties of the audit committee are to:

- Monitor the Company's financial performance and reporting;
- With respect to the financial reporting, monitor the effectiveness of the Company's internal controls, internal audit and risk management;
- Inform itself of the audit of the annual reports and group 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;
- Take decisions regarding guidelines for services other than the auditing services which the external auditor can provide.

Scientific committee

After the 2020 AGM, the Scientific Committee consists of Anders Gersel Pedersen, chairman, Birgit Stattin Norinder and Andreas Eggert. The committee is obligated to keep minutes of its meetings and make the minutes available the Board.

The primary duties of the scientific committee are to:

- Assist the Board with recommendations regarding the Company's research and development strategies and possibilities;
- Perform such other duties as are considered necessary and appropriate in conjunction with the work set forth above; and perform such other duties as instructed by the Board from time to time.

Executive management

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

President and Chief Executive Officer

Senior Vice President, Chief Financial Officer

Senior Vice President, Chief Commercial Officer

Senior Vice President, Chief Scientific Officer and Chief Operating Officer

Senior Vice President, Chief Human Resources Officer

Senior Vice President, Chief Medical Officer

The executive management holds meetings every month to discuss the Group's earnings and financial position, the status of research and development projects, operational and strategic issues, and follow-up on budgets and forecasts.

The CEO's responsibility

The CEO is responsible for managing the Company's day-to-day operations pursuant to the Board's guidelines and instructions. The CEO is also responsible, in accordance with the Board's written instructions, for preparing and presenting to the Board issues which fall beyond the scope of day-to-day management and he must act in accordance with the instructions to the CEO adopted by the Board, the decisions of the Board and the general meeting, and in the best interests of all shareholders.

He must also respect the fiduciary duty and duty of confidentiality which apply to affairs and circumstances which might cause damage to the Company if disclosed, as well as the duty to report matters and circumstances which are material to the Company.

The CEO must take any and all measures which are necessary to ensure that the Company's bookkeeping is legally compliant and to ensure that funds are managed in a satisfactory manner. Accordingly, it is the CEO's responsibility to ensure that the Company has good internal management and routines to ensure application of the adopted principles for financial reporting and internal control.

The CEO shall each month (with the exception of January and July) compile a report regarding the Company's financial situation. He is responsible for ensuring that the Company complies with applicable laws and guidelines, including Swedish law, the Nordic Main Market Rulebook for Issuers of Shares and the Code. The CEO must ensure, at a minimum, that the six-month report or the nine-month report is examined by an auditor. The CEO also has specific responsibility to ensure the competitive supply of all purchases of goods or services exceeding SEK 1 m. The CEO must provide the Board with all necessary background information and documentation, both before and between Board meetings. The CEO must attend Board meetings unless the chairman informs him that he need not to attend.

The CEO must also attend all general meetings of the Company, including both AGM's and extraordinary general meetings. The CEO may not have any engagements outside of the Company without the Board's approval.

The CEO is also responsible for implementing the strategy approved by the Board and to propose such other strategies and operational measures to the Board which he deems appropriate. The CEO is responsible for the Company's internal organization, but must obtain the Board's approval prior to major organizational changes. The CEO is responsible for issuing and maintaining instructions for delegation to senior executives of the Company. He is also responsible for entering into or terminating employment agreements and for other employment terms and conditions; however the Chairman of the Board's approval is necessary for such issues in respect of senior executives.

In a serious crisis situation, it is the CEO's responsibility to inform the Board immediately and, if necessary, to form and instruct a crisis committee and to prepare a contingency plan for the business. The CEO must immediately report any event or procedure which he suspects may be significantly adverse to the business or the Company's financial position, e.g. a liquidity crisis, to the Chairman of the Board.

Information regarding the CEO's age, primary education, work experience, significant engagements outside of Hansa Biopharma, and his holdings of shares in the Company and those of closely related persons are set forth below.

Executive management continued

Senior executives

Hansa Biopharma's senior executives currently comprise six individuals: President and CEO Søren Tulstrup; Senior Vice President, Chief Scientific Officer 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 2020 are listed on pages 128 – 129.

Holdings in the Company includes both one's own holdings and/or those of closely-related persons.

The number of share rights refers to the maximum number of share rights which the executive may obtain as a result of the implementation of the incentive programs LTIP2018, LTIP2019 and LTIP2020. 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 performance shares free of charge where each performance share represent one ordinary share. Allocation of shares could be lower or zero depending on the share price development and whether or not performance conditions are met.

The number of ESOP's refers to the number of employee stock options which the executive received following the implementation of the incentive programs LTIP2019 and LTIP2020. In LTIP2019, each employee stock option entitles the holder to subscribe for one new ordinary share at a subscription price corresponding to 110 per cent of the volume weighted average share price during the ten (10) trading days immediately prior to the offer to subscribe for the employee stock options. In LTIP2020, each employee stock option entitles the holder to subscribe for one new ordinary share at an exercise price corresponding to the higher of (i) 125 per cent of the volume weighted average share price during the 10 trading days immediately preceding the respective allotment of the employee stock options, or (ii) SEK 125. The employee stock options were allotted free of charge and have a vesting period of three years.

Executive management continued

Søren Tulstrup
CEO

Søren Tulstrup has broad and extensive experience as senior executive in the global biopharma industry. Before joining Hansa in 2018, he served as CEO of Vifor Pharma AG (VTX:VIFN), a Glattbrugg, Switzerland-based global pharmaceutical company. Søren Tulstrup has also served as CEO of Santaris Pharma A/S, now part of Roche, a leading clinical stage biopharmaceutical Company developing RNA-targeted drugs for various therapeutic areas including rare genetic diseases. Furthermore, Søren Tulstrup has served in several senior general management and commercial roles within Shire Pharmaceuticals (now Takeda), Merck & Co., Inc. and Sandoz Pharma AG (now Novartis) in both Europe and the United States and he holds a Master of Science, Economics and Business Administration from Copenhagen Business School. He was born in 1965.

Shareholding: 10,000
Share rights: 143,818
ESOPs: 195,107

Christian Kjellman
Senior Vice President, Chief Scientific Officer and Chief Operating Officer

Christian Kjellman is an experienced researcher and senior executive that joined Hansa Biopharma in 2008. Last year, Christian expanded his duties within Hansa Biopharma, serving as Chief Operating Officer as well as continuing to serve as Chief Scientific Officer. Christian has previously served as Senior Scientist at BioInvent AB focusing on novel target evaluation and antibody technology. Prior to that, he functioned as Head of Research at the biopharmaceutical development company Cartela AB, mainly focusing on novel drug target evaluation. He has extensive research experience in cell and molecular biology and as an Assistant Professor in Molecular Genetics at Lund University. Christian Kjellman holds a M.Sc. in Chemical Biology and a Ph.D. in Tumour Immunology from Lund University. He was born in 1967.

Shareholding: –
Share rights: 58,440
ESOPs: 64,380

Donato Spota
Senior Vice President, Chief Financial Officer

Donato Spota joined Hansa Biopharma in 2019 and brings more than 20 years of pharmaceutical industry experience in international environments, including strategic finance, business development, investor relations and international capital markets transactions to the Company. Prior to joining Hansa, Donato Spota served as Chief Financial Officer at Basilea Pharmaceutica AG. He holds a degree in Information Technology from the Swiss BBT (Bundesamt für Berufsbildung und Technologie) and a master's degree in business administration from the Hochschule für Wirtschaft und Umwelt Nürtingen-Geislingen. He was born in 1971.

Shareholding: –
Share rights: 52,073
ESOP's: 106,842

Executive management continued

Henk Doude van Troostwijk
Senior Vice President, Chief Commercial Officer

Henk Doude van Troostwijk has extensive management experience in sales and marketing in the areas of transplantation and orphan drugs. Before joining Hansa Biopharma in 2016, Henk Doude van Troostwijk served as General Manager of European Commercial Operations and Emerging Markets at Raptor Pharmaceuticals, an orphan disease focused global biopharma Company based in the US. Prior to that, he held the position of Business Unit Director Oncology and Transplantation at Genzyme Europe BV. Henk Doude van Troostwijk holds an MBA from Henley Management College at the University of Reading, UK. He was born in 1965.

Shareholding: –
Share rights: 33,817
ESOPs: 51,231

Anne Säfström Lanner
Senior Vice President, Chief Human Resources Officer

Anne Säfström Lanner joined Hansa Biopharma in January 2019 and brings 15 years of HR experience in international environments. Prior to joining Hansa, Anne Säfström Lanner served at European Spallation Source (ESS), a European multi-disciplinary research facility and at Cellavision, a provider of digital solutions for medical microscopy within hematology. She has held positions both as Head of HR, Head of Resourcing, HR Manager & Deputy Head of HR and has extensive experience from fast growing start-up international companies. Anne holds a Bachelor of Social Science in Human Resource Management, focusing on strategic organizational development & leadership, from Lund University. She was born in 1969.

Shareholding: 610
Share rights: 49,618
ESOPs: 32,000

Achim Kaufhold
Senior Vice President, Chief Medical Officer

Achim Kaufhold joined Hansa Biopharma in June 2020. He is a highly experienced senior leader in immunology, infectious diseases and oncology. He has extensive international experience within the biotech and pharmaceutical industry and has a successful track record in taking products from early discovery through development and to the market. He has served in senior executive positions in general management, product and business development. He served as CEO of Affitech and Pharmexa (both companies merged), CMO of companies such as Basilea Pharmaceutica, Pharmexa, Chiron (acquired by Novartis) and Berna Biotech (now Johnson & Johnson). Prior to that, he was heading the worldwide clinical development of the pediatric vaccine portfolio of GlaxoSmithKline. Achim Kaufhold graduated as a Doctor of Medicine from the University of Cologne and holds a professorship in Medical Microbiology and Infectious Diseases at the University of Aachen, Germany. He was born in 1957

Shareholding: -
Share rights: 20,000
ESOPs: 30,000

Internal controls and risk management in respect of the financial reporting

Introduction

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

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

Internal audit

The Board has evaluated the need for an internal audit function and has concluded that it is not warranted for Hansa Biopharma due to the scope 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 Biopharma'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 the manner described above including regarding risks in respect of the 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 Biopharma, accrued project costs in the Company's clinical projects have, at various times, involved significant amounts. The size of these is based, to great extent, on management's assessment of the degree of completion. For Hansa Biopharma, 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 Biopharma's administration is handled by a 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 financial handbook and further policies include controls to prevent and detect shortcomings in these and other areas.

Control structure and control activities

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

The primary purpose of control activities is the prevention and early-stage detection of errors in the financial reporting so that they can be addressed and corrected. There are manual and automated control activities on both the overall and more detailed levels. Access to IT systems is limited in accordance with powers and authorization. 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

Internal controls and risk management in respect of the financial reporting continued

analyses with the various managers and project managers. In this way, significant fluctuations and deviations are followed-up, minimizing the risk of errors in the financial reporting. The work involved with annual accounts and annual reports are processes which pose additional risks for errors in the financial reports. This work is of a less repetitive nature and contains more evaluative elements. Important control activities include, among other things, external confirmations (e.g. bank statements or 3rd party vendor confirmations) as well as ensuring that there is a properly functioning reporting structure in which the various managers and project managers report pursuant to standardized templates, and that important income statement and statement of financial position items are analyzed and commented upon.

Information and communication

The informational activities are governed by an information policy. There are guidelines for external communications which ensure that the Company meets high standards for providing correct information to the shareholders and the financial market. Hansa Biopharma's communications must be characterized by transparency and must be correct, relevant, reliable and clear; they may not be misleading. A uniform strategy for external communications reduces the risk of erroneous information, rumours, and misunderstandings. All communications must take place in accordance with Nasdaq Stockholm's Issuer Rules, the Swedish Code of Corporate Governance, and the laws and requirements imposed on Swedish companies whose shares are admitted for trading on a regulated market. The policy applies to all employees and directors of Hansa Biopharma and applies to both oral and written information.

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

Follow-up

The Board's follow-up of internal controls in respect of the financial reporting takes place, among other things, through follow-up of 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 Biopharma's compliance with its own rules 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 parameters of the statutory audit.

The auditor reports the results of the examination to the Board 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 Biopharma has adopted a Code of Conduct for all of its directors, officers, and associates which sets forth the standards for business behavior that apply throughout the Company and describes the expectations Hansa Biopharma has for its business partners, and those acting on behalf of the Company. The Code contains guidance in the areas of personal and corporate integrity, responsibility toward the Company, the colleagues and the community as well as responsible and comprehensive compliance management.

Aligned with the Code of Conduct, Hansa Biopharma 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.

Auditor statement on the corporate governance report

To the general meeting of the shareholders in Hansa Biopharma AB, corporate identity number 556734-5359

Engagement and responsibility

It is the board of directors who is responsible for the corporate governance statement for the year 2020 on pages 117 – 132 and that it has been prepared in accordance with the Annual Accounts Act.

The scope of the audit

Our examination has been conducted in accordance with FAR's auditing standard RevU 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

Opinions

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Malmö 7 April 2021

KPMG AB

Jonas Nihlberg
Authorized public accountant

Remuneration

Stock image

Remuneration Report 2020

Introduction

This remuneration report provides an outline of how Hansa Biopharma's guidelines for remuneration (the "Remuneration guidelines"), adopted by the annual general meeting 2020, were implemented in 2020. The report also provides information on remuneration to the CEO and a summary of Hansa Biopharma'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 5 (Employees and personnel costs) on pages 86 – 93 in the annual report 2020. Information on the work of the remuneration committee in 2020 is set out in the corporate governance report available on pages 117 – 132 in the annual report 2020.

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 5 on pages 86 – 93 in the annual report 2020.

Key Developments 2020

Overall Company performance in 2020

The CEO summarizes the Company's overall performance in his statement on page 5 – 6 in the annual report 2020.

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 Biopharma'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 2020, can be found on pages 86 – 93 in the annual report 2020. During 2020, 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 Biopharma have resolved to implement long-term share-based incentive plans for certain groups of Hansa employees and on remuneration guidelines for the Board of Directors.

Table 1 – Total remuneration of the CEO (kSEK)*

Table 1 below sets out the total remuneration related to Hansa Biopharma's CEO for 2020.

		1 Fixed remuneration		2 Variable remuneration					6 Proportion of fixed and variable remunera-tion in %
Name, position	Financial year	Base salary	Other benefits	One-year variable	Multi-year variable	3 Extra-ordinary items	4 Pension expense	5 Total remunera-tion	
Søren Tulstrup (CEO)	2020	6,341**	107***	2,406	0	0	0	8,854	73/27

* Except for Multi-year variable remuneration, the table reports remuneration earned in 2020. Multi-year variable remuneration is reported if vested in 2020, 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.

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

*** Company car

Share based remuneration

Outstanding share-based long-term incentive programs

The Company has three long-term incentive programs outstanding in which amongst others also the CEO participates; long-term incentive program ("LTIP") 2018, 2019 and 2020. The Company had a long-term incentive program 2016 which lapsed during 2020 in which the CEO did not participate.

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 2018

On May 29, 2018, the annual general meeting in Hansa Biopharma resolved to adopt a long-term incentive program for certain employees of Hansa Biopharma. The participants in the program were given the opportunity to acquire warrants at market value and/or receive so called performance-based share rights free of charge which, provided that certain conditions are met, may give the right to acquire shares in Hansa Biopharma AB. The CEO choose not to acquire any warrants under the long-term incentive program 2018 but received 51,389 share rights.

A share right under the incentive program 2018 entitles the holder to receive one ordinary share in Hansa Biopharma AB for free provided the performance condition is met during the vesting period. The performance condition states that the total shareholder return of the Company's ordinary share during the vesting period must reach or exceed certain percentage rates. If the specified minimum level is achieved, 25 percent of each participant's rights will entitle to performance shares but if the maximum level is reached, 100 percent of each participant's rights will entitle to performance shares.

A warrant under incentive program 2018 entitles the participant to subscribe for one share in Hansa Biopharma AB at a price equal to the market value of the share at the time of the warrant issuance, adjusted upwards with seven percent annually during the vesting period. Provided the participant remains an employee of the Group, subscription for shares may take place from June 12, 2021 through June 12, 2022. The warrants were sold on market terms and participants received a subsidy of maximum 25% of the price.

In total, 223,778 share rights and 6,701 warrants were outstanding under the long-term incentive program 2018 as of 31 December 2020, which corresponds to approximately 0.5 percent of the shares in the Company on a fully diluted basis as of December 31, 2020.

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 Hansa Biopharma. 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 series. The CEO was granted 35,151 share rights and 66,347 employee stock options but chose not to acquire any warrants under incentive program 2019.

Under the performance-based share rights program, each share right entitles the holder to receive one ordinary share in Hansa Biopharma AB for free provided that the performance conditions are met during the vesting period. The final number of performance shares that each participant is entitled to receive is conditional upon the following performance conditions being met during the vesting period: (a) 22 percent of the performance shares in the event that market approval is obtained by EMEA within the EU, (b) 22 percent of the performance shares in the event that market approval is obtained by the FDA in the US, and (c) up to 56 percent of the performance 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 shares during the period from 15 June 2022 up to and including 15 July 2022. The transfer to participants is made at a price corresponding to the market value of the warrants at the time of transfer. The ompany subsidized up to 100 percent of the price for the transfer of the warrants. Series 2 consists of employee stock options allotted free of charge. The employee stock options have a vesting period of three years. Each warrant or employee stock option entitles the holder to receive one new ordinary share in Hansa Biopharma AB 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 options and/or warrants.

In total, 287,555 share rights, 149,148 employee stock options and 11,000 warrants were outstanding under the long-term incentive program 2019 as of 31 December 2020, which corresponds to approximately 1.0 percent of the shares in the Company on a fully diluted basis as of December 31, 2020.

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 Hansa Biopharma. The long-term incentive program 2020 includes two elements; one performance-based share rights program, and one employee stock option program. The CEO has been granted 57,278 share rights and 128,760 employee stock options under the long-term incentive program 2020.

Under the performance-based share rights program, each share right entitles the holder to receive one ordinary share in Hansa Biopharma AB for free provided that the performance conditions are met during the vesting period. In addition to the requirement for the participant's continued employment, the final number of performance 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 performance shares in the event the US randomised controlled trial is completed, (b) 11 percent of the performance 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 to continue either of the two programs, (c) 11 percent of the performance 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 performance shares related to the total shareholder return on the Company's ordinary shares (if the total shareholder return for the Company's ordinary share during the vesting period reaches or exceeds 75 percent, the participant will be awarded 56 percent of the performance shares and if the total shareholder return for the Company's ordinary share falls below 25 percent, no allotment of performance shares will be made under this performance condition. In between the percentages, allotment will be made linearly).

The option program 2020 consists of employee stock options allotted free of charge and each employee stock option entitles the holder to subscribe for one new ordinary share in Hansa Biopharma AB. The employee stock options have a vesting period of three years, after which the holder is entitled to exercise the options during a period of one month. Each employee stock option that is transferred entitles the holder to acquire one share in the Company, provided that the participant, with certain exceptions, is still employed within the Group, at an exercise price corresponding to the higher of (i) 125 percent of the volume weighted average share price during the 10 trading days immediately preceding the respective allotment of the employee stock options, or (ii) SEK 125.

In total, 389,556 share rights and 477,520 employee stock options were outstanding under the long-term incentive program 2020 as of 31 December 2020, which corresponds to approximately 3.4 percent of the shares in the Company on a fully diluted basis as of December 31, 2020.

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 2020		Closing balance, 31st December 2020		
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 Subject to a performance condition(s)	10 Awarded and unvested at year end	11 Shares rights subject to a retention period
Søren Tulstrup, CEO	LTIP2018	2018-2021	2018-06-15	2021-06-15	2021-06-15	51,389	0	0	51,389	51,389	51,389
	LTIP2019	2019-2022	2019-06-17	2022-06-17	2022-06-17	35,151	0	0	35,151	35,151	35,151
	LTIP2020	2020-2023	2020-07-23	2023-07-23	2023-07-23	0	57,278**	0	57,278	57,278	57,278
						86,540	**57,278**	**0**	**143,818**	**143,818**	**143,818**

* In 2020, no changes occurred regarding the long-term incentive program 2018 or the long-term incentive program 2019, where the CEO holds 51,389 share rights and 35,151 share rights, respectively. In the long-term incentive program 2020, the CEO was awarded 57,278 share rights.

** Each of the 57,278 Share rights represents a computed fair value of SEK 216.00 per share right calculated based on a Monte Carlo simulation. For further information please refer to Note 5 in Hansa Biopharma's annual report 2020.

Table 3 – Remuneration of the CEO in stock options

	The main conditions of share rights							Information regarding the reported financial year*					
								Opening balance	During the year 2020		Closing balance, 31st December 2020		
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	9 Stock options awarded	10 Stock options vested	11 Stock options subject to a performance condition	12 Stock options awarded and unvested	13 Stock options subject to a retention period
Søren Tulstrup, CEO	LTIP2019	2019-2022	2019-06-17	2022-06-17	2022-06-17	2022-06-17 2022-07-17	196.20	66,347	0	0	66,347	0	66,347
	LTIP2020	2020-2023	2020-07-23	2023-07-23	2023-07-23	2023-07-27 2023-08-24	315.75	0	128,760**	0	128,760	0	128,760
								66,347	**128,760**	**0**	**195,107**	**0**	**195,107**

* In 2020, no changes occurred regarding the long-term incentive program 2019, where the CEO holds 66,347 stock options. In the long-term incentive program 2020, the CEO was awarded 128,760 stock options.

** Each of the 128,760 Stock options represents a computed fair value of SEK 53.05 per stock option calculated based on a Black-Scholes valuation. For further information please refer to Note 5 in Hansa Biopharma's annual report 2020

Application of performance criteria related to the 2020 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 2020, none of the above-described share-based long-term compensation of the CEO vested. Thus, no performance criteria had to be applied during 2020 in relation to such long-term incentive programs.

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 2020. Such criteria are based on the annual corporate objectives and form the basis for the short-term performance measurement of the CEO and all other members of the executive management.

Table 4 – Criteria for payment of variable short-term compensation

Name, Position	1 Description of the criteria related to the remuneration component	2 Relative weighting of the performance criteria	3 a) Measured performance and b) actual award/remuneration outcome
Søren Tulstrup, CEO	Imlifidase EU approval in kidney transplantation and commercial KPIs	20%	a) 75% b) 15%
	Submission of protocol to FDA for BLA enabling study and study KPIs	20%	a) 50% b) 10%
	Development KPIs related to ongoing clinical studies in anti-GBM, AMR and GBS	20%	a) 100% b) 20%
	Business development and financing KPIs	40%	a) 137.5% b) 55%

Comparative information on remuneration and Company performance

Table 5 – Company performance and CEO remuneration

	2020
CEO remuneration	
Søren Tulstrup, CEO	kSEK 8,854
Company's performance	
Achievement of the annual corporate objectives	100%
Operating profit / loss	kSEK -422,807
Average remuneration (base salary) on a full-time equivalent basis of employees	
Non-executive employees of the Company	kSEK 822

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