Annual Report **2018**

HANSA BIOPHARMA

Annual report 2018

Hansa Biopharma in brief

Hansa Biopharma AB is harnessing its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.

The company's lead product IDEFIRIX™ (imlifidase) is a unique antibody-degrading enzyme in late-stage clinical development to enable kidney transplantation in highly sensitized patients, with additional clinical studies in acute autoimmune conditions.

Hansa's research and development program is advancing the company's technology to develop the next generation of IgG-cleaving enzymes with lower immunogenicity, potentially enabling repeat dosing in relapsing autoimmune diseases, chronic transplant rejection, oncology and repeat dosing of gene therapy.

Hansa Biopharma is headquartered in Lund, Sweden with operations in both Europe and the U.S.

With positive clinical results from the company's lead clinical program, Hansa readies for transition to a commercial-stage company

January–December 2018 Business Highlights

- Hansa successfully completed two Phase 2 clinical studies evaluating imlifidase for kidney transplantation in highly sensitized patients. Imlifidase met all primary and secondary endpoints in each study. Treatment with imlifidase enabled transplantation in all 35 highly sensitized patients and at study completion, six months post-transplantation, graft survival was 91%.
- Clinical results from Hansa's first Phase 2 study of imlifidase were published in the American Journal of Transplantation. The publication describes the results from Hansa's initial clinical study in sensitized patients, which included the first transplantation which was enabled by treatment with imlifidase. To date, stable kidney function has been maintained in this very first patient for more than four years.
- Hansa initiated a long-term observational prospective follow-up study evaluating graft survival in patients who have undergone kidney transplantation after treatment with imlifidase. The objective of the study is to collect long-term outcome data to provide further support to future prescribers, payers and patients.
- The U.S. Food and Drug Administration (FDA) and the European Commission, following EMA recomendation, granted Orphan Drug Designation for imlifidase for the treatment of anti-glomerular basement membrane (anti-GBM) antibody disease, also known as Goodpasture's disease.
- The FDA granted Orphan Drug Designation for imlifidase for the treatment of Guillain-Barré syndrome (GBS).
- The FDA granted imlifidase Fast Track Designation for the investigation of imlifidase for kidney transplantation.
- In November, Hansa raised SEK 453 /$50 million in a directed share issue of 1.8 million ordinary shares.
- Søren Tulstrup was appointed President and CEO of Hansa and Vincenza Nigro was appointed Vice President, Global Medical Affairs.
- The board of directors was strengthened through the appointments of Anders Gersel Pedersen and Andreas Eggert.
- Hansa formed a U.S. subsidiary as a basis for a U.S. organization.
- Hansa Medical AB changed its name to Hansa Biopharma AB.

Significant events after the end of the reporting period

- The European Medicines Agency (EMA) accepted the company's Marketing Authorization Application (MAA) for IDEFIRIX (imlifidase). Hansa is seeking approval of IDEFIRIX as a treatment to enable kidney transplantation in highly sensitized patients.
- Hansa provided an update on its interactions with regulatory agencies regarding imlifidase in kidney transplantation. The company's dialogue with the FDA to determine the path forward for regulatory filing and approval in the U.S. is ongoing, and Hansa will provide updated guidance regarding the timeline for a potential Biologic License Application (BLA) following a subsequent meeting with the agency.
- A lead candidate was selected from the NiceR (Novel IgG Cleaving Enzymes for Repeat dosing) program. The selected molecule was developed to potentially enable repeat dosing in indications with significant unmet medical needs such as relapsing autoimmune diseases, chronic transplant rejection, oncology and repeat dosing of gene therapy.
- Donato Spota was appointed Chief Financial Officer, effective mid-May 2019 and Anne Säfström Lanner joined Hansa as Vice President, Global Human Resources.

Financial summary for the Group

	1 January – 31 December	
KSEK, unless other stated	2018	2017
Net revenue and profit		
Net revenue	3,358	3,442
Operating profit/loss	-246,498	-176,083
Net profit/loss	-247,974	-176,660
Per share data		
Earnings/loss per share before and after dilution (SEK)	-6,47	-4.97
Shareholders' equity per share (SEK)	21,52	16.68
Other information		
Shareholders' equity	859,876	630,661
Equity ratio (%)	91%	93
Cash flow from operating activities	-204,560	-150,105
Cash and cash equivalents including short term investments	858,187	616,061
Number of employees end of the year	52	33

CEO message

When I joined Hansa in the spring of 2018, I was eager to be part of this highly regarded company pursuing the opportunity to radically improve the lives of people living with rare immuno-pathologies. With a clear focus on filling unmet medical needs, Hansa's proprietary enzymology platform had already demonstrated early success, thus setting expectations high for our lead candidate imlifidase to make a difference for tens of thousands of patients. I'm extremely proud of all that we accomplished this past year to prove the potential of the Company's immunomodulatory enzyme technology and imlifidase.

Imlifidase in kidney transplantation

Imlifidase is a novel enzyme that specifically and rapidly cleaves immunoglobulin G (IgG) antibodies, thereby eliminating immunological barriers in e.g. transplantation, as well as abrogating acute disease progression in immune-mediated diseases. Our lead clinical program is the development of imlifidase as a treatment to enable kidney transplantation in highly sensitized patients. These patients carry high levels of anti-HLA antibodies, which can target and significantly compromise a transplanted organ. The more anti-HLA antibodies, the lower the likelihood of finding a donor organ that will be a match. The unmet medical need in highly sensitized patients is high with many patients indefinitely remaining in a debilitating disease state including long-term dialysis treatment, which is associated with high cost, a poor quality of life and an increased mortality rate.

We further advanced the clinical development of our lead program in 2018, most notably in the third quarter, when we announced six-month follow up data from two Phase 2 clinical studies of imlifidase for kidney transplantation in highly sensitized patients. The results demonstrated that treatment with imlifidase enabled transplantation in all 35 highly sensitized patients and at study completion, six months post-transplantation, graft survival was 91%. Imlifidase may have the potential to significantly improve highly sensitized patients' access to kidney transplantation. The outcomes of the Phase 2 studies are described in greater detail on page 12 in this report.

Imlifidase also continued to receive further validation from the scientific community. In May, clinical results from our first Phase 2 study of imlifidase were published in the American Journal of Transplantation, the peer-reviewed medical journal of the American Society of Transplant Surgeons and the American Society of Transplantation. In June, at the important American Transplant Congress, Stanley Jordan, M.D., Director of Kidney Transplantation and Transplant Immunology at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center, Los Angeles, USA, presented additional data and conclusions from his investigator-initiated Phase 2 study of imlifidase. In October at the American Society of Nephrology's Kidney Week, Dr. Jordan highlighted graft survival and stable renal function at up to 24 months following transplantation enabled by imlifidase.

In October, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for imlifidase in kidney transplantation. Much like the European Medicines Agency's (EMA) PRIME designation, which was granted to imlifidase for kidney transplantation in 2017, Fast Track designation is designed to facilitate the development and expedite the review of new drugs to treat serious or life-threatening conditions. This designation is further endorsement of imlifidase's potential to address the significant unmet medical need for highly sensitized patients, for whom transplantation is extremely difficult or impossible and who otherwise face mortality risks associated with long-term dialysis. The FDA's Fast Track program provides more frequent communication with the agency regarding drug development and eligibility for priority review.

We are actively engaged with the European and U.S. regulatory agencies regarding the path to approval for imlifidase in kidney transplantation. In February 2019, the European Medicines Agency (EMA) accepted our Marketing Authorization Application (MAA)

for review of IDEFIRIX (imlifidase). Hansa is seeking approval of IDEFIRIX as a treatment to enable kidney transplantation in highly sensitized patients. The filing included data collected across all four Phase 2 clinical studies demonstrating the efficacy and safety of imlifidase to enable kidney transplantation, including six-month follow-up data, and evidence of the significant medical need for highly sensitized patients who currently have very limited opportunity for transplantation.

Our dialogue with the FDA to determine the path forward for regulatory filing and approval in the U.S. is ongoing and we will provide updated guidance regarding the timeline for a potential Biologic License Application following a subsequent meeting with the agency. The FDA has granted IDEFIRIX Orphan Drug Designation and Fast Track Designation in kidney transplantation.

Imlifidase in additional indications

Imlifidase also may have potential applications in transplantation of other solid organs and bone marrow as well as in an array of acute autoimmune diseases. We are evaluating imlifidase in a Phase 2 clinical study for the treatment of anti-glomerular basement membrane (anti-GBM) antibody disease. Anti-GBM, also known as Goodpasture's disease, is a rare autoimmune disorder where the immune system mistakenly develops IgG-antibodies, resulting in an acute immune attack on the kidneys and, in some patients, the lungs. There are no approved treatment options, and severe anti-GBM disease may progress to renal failure or death, with less than one third of patients surviving with preserved kidney function after six months.

In early July, the FDA granted Orphan Drug Designation for imlifidase for the treatment of anti-GBM disease. In November, the European Commission also designated imlifidase as an orphan drug for the treatment of anti-GBM. These designations both confirm the high unmet medical need of patients with this devastating disease, and recognize the potential of imlifidase to potentially help prevent acute kidney damage and the progression to kidney failure and dialysis. Currently eight patients with this ultra-rare disease of the targeted 15 patients have been enrolled in the Phase 2 study, which aims to evaluate the safety and tolerability of imlifidase, and to assess efficacy based on renal function at six months after treatment. Data generated from the first seven patients indicate that all seven have responded favorably, and imlifidase seems to be well tolerated. We anticipate completing enrollment in this study during 2019.

The next two indications in which we will evaluate imlifidase are Guillain-Barré syndrome (GBS) and acute Antibody Mediated Rejection (AMR) post kidney transplantation. Guillain-Barré syndrome (GBS) is a rare, acute neurological disease in which the peripheral nervous system is attacked by the immune system and IgG-antibodies. Last year, the FDA granted Orphan Drug Designation for imlifidase for the treatment of GBS.

At the end of the first quarter we received Ethics and Regulatory approvals for a Phase 2 study of imlifidase in acute AMR and we expect to enroll approximately 30 patients at eight clinical trial centers across Europe, Australia and the U.S. A similar enrollment is expected to be commenced in a Phase 2 study of imlifidase in GBS during the second quarter 2019. To support imlifidase's clinical development across these indications, we have expanded Hansa's research and development team.

Next generation of immunomodulatory enzymes

We believe that our unique and proprietary technology platform in immunomodulatory enzymes extends beyond imlifidase to other novel IgG-cleaving enzymes. In our next generation program, NiceR, we are developing candidates with lower immunogenicity that may potentially enable repeat dosing. This program may have the potential to apply to a broad array of indications, including relapsing autoimmune diseases, chronic transplant rejection, oncology and repeat dosing of gene therapy. In 2018, we made significant advancements in our corresponding research and development, and in the first quarter of 2019 we announced the selection of a lead candidate from the NiceR program.

Looking ahead

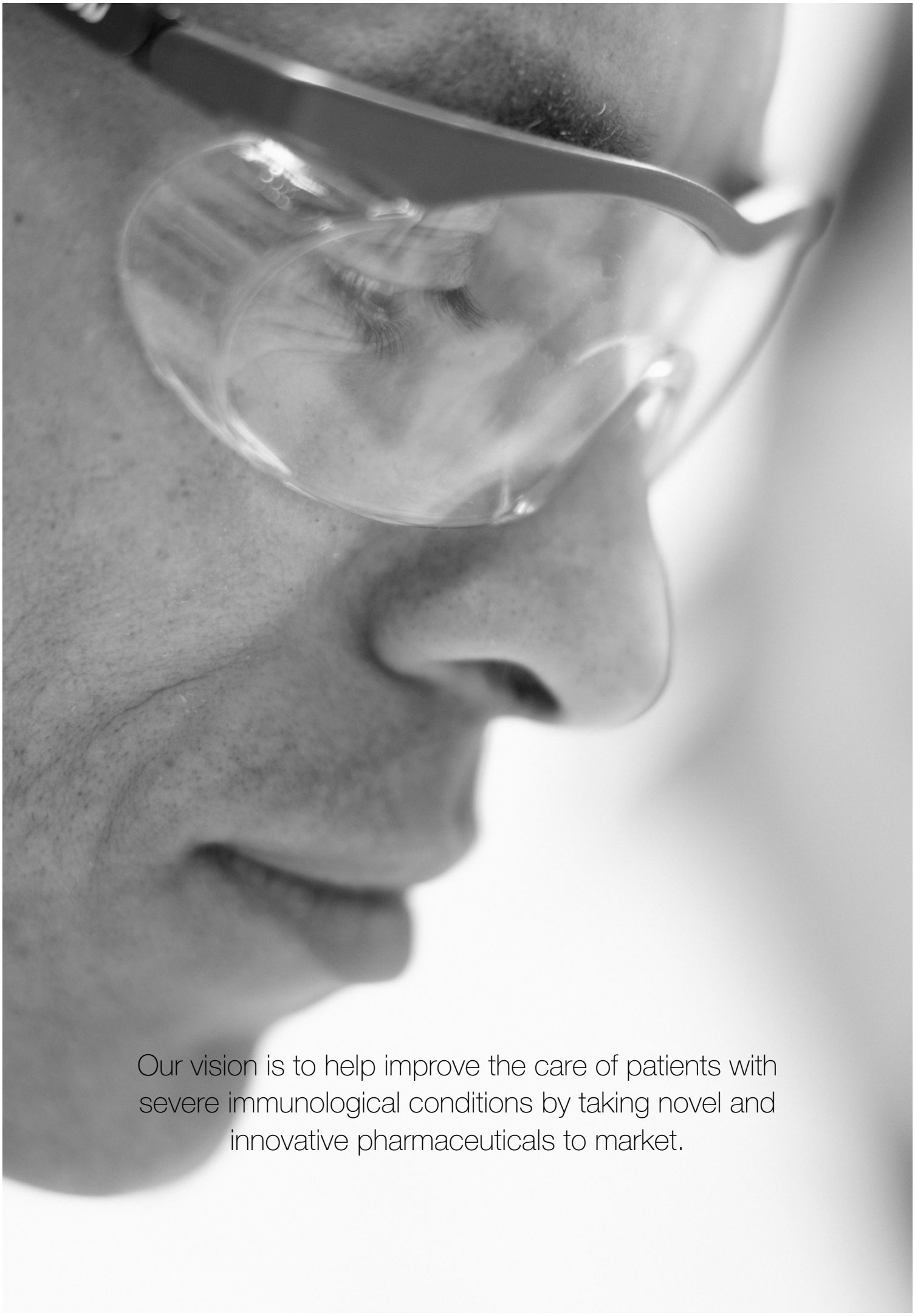
Hansa's progress across our platform of immunomodulatory enzymes has been well received by investors. In November, we raised SEK 453 m ($50 m) in a directed share issue, which was significantly oversubscribed due to high demand from U.S., UK, Swiss and Swedish institutional investors. This funding will enable us to accelerate our commercial preparations for the potential launch of imlifidase and continue advancing the development of our other pipeline projects.

As part of our launch preparations we are expanding our organization. In September, we appointed Vincenza Nigro as Vice President, Global Medical Affairs. Vincenza brings more than two decades of international life sciences industry expertise in medical affairs, clinical development and commercial leadership roles, including deep experience in transplantation and orphan diseases. In early 2019, Anne Säfström Lanner joined Hansa as Vice President, Global Human Resources, and Donato Spota was appointed Chief Financial Officer. They are valuable additions to our team as we transform Hansa into a global, commercial-stage biopharma company.

To better reflect this evolution and our long-term aspirations, we decided to rebrand the company as Hansa Biopharma. The new name represents the next stage in our lifecycle and emphasizes our focus on the development and commercialization of biopharmaceuticals. This refinement of our profile is particularly salient as we continue the international expansion of our business and investor base. The new name, which will be fully implemented during 2019, was approved at an Extraordinary General Meeting held on December 4.

At Hansa, we are driven by our passion to deploy our unique enzymology platform to significantly improve the lives of people living with rare immuno-pathologies. We are well positioned for success in 2019, with a growing body of clinical evidence supporting the profile of imlifidase, multiple opportunities in additional indications, and a potential pipeline of next-generation candidates. I am grateful for the talented team at Hansa for their outstanding work, our distinguished partners for their collaboration, the patients in our clinical studies for their trust in us, and our shareholders for their continued support. I look forward to updating you on our continued progress.

Søren Tulstrup
President and CEO of Hansa Biopharma
Lund, Sweden, April 15, 2019



Our vision is to help improve the care of patients with severe immunological conditions by taking novel and innovative pharmaceuticals to market.

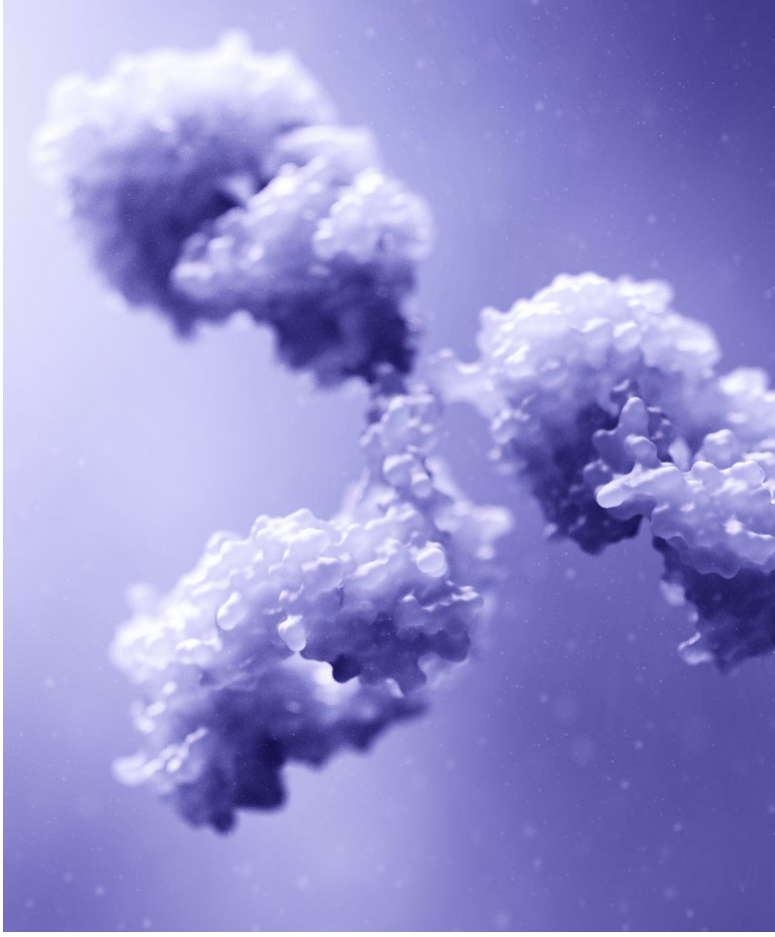
Strategic priorities

Our initial clinical focus is on imlifidase, a single dose treatment of acute IgG-mediated conditions. In parallel, we are also developing novel IgG-inactivating drug candidates for repeat dosing under the project name NiceR, which may provide the opportunity for wider usage of an IgG-removing agent.

Our short term strategic priorities are:

- to quickly attain market approval for the lead candidate imlifidase as pre-treatment of sensitized patients prior to kidney transplantation, and to further build a commercial infrastructure.
- to further investigate the potential of imlifidase in additional transplant and autoimmune indications.
- to investigate imlifidase in other indications with significant unmet medical need where imlifidase may have the potential to treat or prevent IgG-mediated pathophysiology.
- to advance our lead candidate from the next generation of immunomodulatory enzymes for repeat dosing into clinical development.

Antibodies for better or worse



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 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.

The molecule that the antibody binds to is called an antigen. 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 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.

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 auto-antibodies.

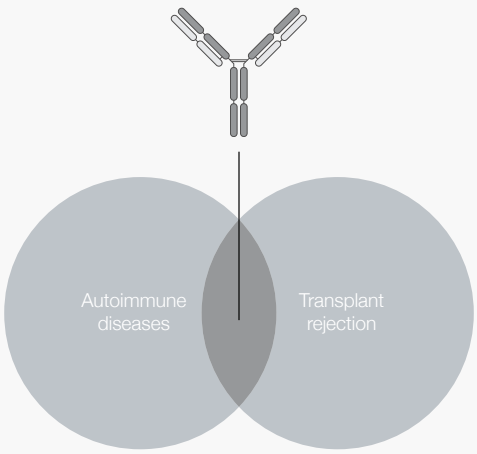


Figure A. In IgG-mediated acute conditions, pathogenic IgG-antibodies are at the center of disease progression. In several autoimmune diseases, autoantibodies engage the immune system to attack self-antigens. In organ and tissue transplantation, donor-specific antibodies can form a barrier for transplantation or cause rejection episodes after a transplantation.

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 of it. This process is referred to as antibody-mediated rejection (AMR).

Patients in need of a new organ, such as kidney or heart, can also develop pre-formed anti-HLA (Human Leukocyte Antigen) antibodies prior to the transplantation. These pre-formed anti-HLA antibodies have been developed earlier in life due to pregnancies, blood transfusions or previous transplantations when exposed to foreign HLA. These individuals are referred to as HLA-sensitized or HLA-immunized patients. In general, it is more difficult to allocate donor organs to 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 high levels of anti-HLA antibodies and often DSAs are identified preventing these patients from receiving a transplant since DSAs are likely to target and significantly compromise a transplanted organ. The higher the level of 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.

Introduction to Hansa Biopharma development programs

Imlifidase is a novel enzyme that specifically and rapidly cleaves immunoglobulin G (IgG), thereby eliminating immunological barriers and enabling treatment of immune-mediated diseases. Imlifidase, proposed product name IDEFIRIX, is in late-stage clinical development for kidney transplantation. Imlifidase is also being evaluated in IgG-mediated autoimmune disorders.

NiceR (Novel immunoglobulin cleaving enzymes for Repeat dosing) is a program developing novel IgG-inactivating drug candidates for repeat dosing, which may enable broader usage in relapsing autoimmune diseases and oncology. In the first quarter of 2019, a lead candidate was selected for preparation for clinical development from the NiceR program.

EnzE (Enzyme-based antibody Enhancement) is a NiceR preclinical research and development program under which the combined use of approved antibody-based cancer treatments with IgG-modulating enzymes is explored in order to potentially increase the efficacy of presently available antibody-based cancer therapies.

Pipeline

Candidate/ Method/Project	Indication	Research/ Preclinical	Phase 1 [1]	Phase 1/2	Phase 2	Reg. interactions	Registration
THERAPEUTICS							
Imlifidase	Kidney transplantation in highly sensitized patients						
	Anti-GBM antibody disease						
	Antibody mediated kidney transplant rejection (AMR)						
	Guillain-Barré syndrome (GBS)						
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology						
EnzE	Cancer immunotherapy						
DIAGNOSTICS							
HBP-assay (IVD) [2]	Prediction of severe sepsis						

In planning Ongoing Completed

[1] Present and future imlifidase Phase 2 studies to be based on the same Phase 1 study. Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7).

[2] Out-licensed to Axis-Shield Diagnostics Ltd.

"Imlifidase – a potential game-changer for the highly sensitized patients"

– Professor Stanley Jordan M.D., Ph.D., Director of Kidney Transplantation and Transplant Immunology, Kidney and Pancreas Transplant Center and Director of Division of Pediatric and Adult Nephrology, Cedars-Sinai Medical Center, Los Angeles, California

Imlifidase – A novel therapeutic approach

Hansa Biopharma's lead drug candidate imlifidase represents a unique and novel approach to rapidly and effectively eliminating IgG-antibodies. Imlifidase cleaves immunoglobulin G (IgG) with a high degree of specificity. Several rare autoimmune diseases are characterized by pathogenic IgG-antibodies and, in organ and tissue transplantation, IgG-antibodies can prohibit patients from being transplanted or cause organ rejection after transplantation. Hansa is developing imlifidase as a single intravenous treatment for fast and effective elimination of IgG-antibodies in transplantation and acute autoimmune diseases.

Overview of imlifidase clinical program

IDEFIRIX (imlifidase) in kidney transplantation

The Company's lead clinical development program for imlifidase is focused on treatment with imlifidase prior to kidney transplantation. The long-term vision for Hansa is to establish imlifidase as a therapy for fast and effective elimination of IgG in several transplant-related indications and acute autoimmune diseases.

Imlifidase has been evaluated in a Phase 1 study[1] in healthy subjects and in four Phase 2 studies in sensitized patients awaiting kidney transplantation[2, 3]. The results from these studies demonstrate that imlifidase is highly effective in reducing donor specific antibodies (DSAs) to levels that enable transplantation, and that imlifidase is well-tolerated.

Based on the successful outcome from these five clinical studies, Hansa is seeking a path towards regulatory approval in Europe and the U.S. The Company submitted a Marketing Authorisation Application (MAA) for review of IDEFIRIX (imlifidase) with the EMA on February 5, 2019. On March 1, 2019 EMA accepted the submission of the MAA. An opinion of the Committee for Medicinal Products for Human Use (CHMP) is expected within 210 days (plus any clock-stops for the applicant to provide answers to questions which may arise during the review). After adoption of a CHMP opinion, a final decision regarding the MAA for IDEFIRIX is made by the European Commission.

The dialogue with the U.S. Food and Drug Administration (FDA) to determine the path forward for U.S. regulatory approval is ongoing and Hansa will provide updated guidance regarding expected timeline for a Biologic License Application filing. The FDA has granted Orphan Drug Designation and Fast Track Designation for IDEFIRIX in kidney transplantation.

A short introduction to transplantation[4]

Organ transplantation is potentially a life-saving treatment where a failed organ is replaced with a donated organ from a living or deceased donor. In 2015, approximately 280,000 patients were on transplant waitlists in the U.S. and Europe, with around 200,000 waiting for a kidney. In 2015, approximately 44,000 kidney transplantations were performed in the U.S. and Europe. Around 70 percent of the kidney transplantations were performed with kidneys from deceased donors. Around 9,000 patients died while waiting for a kidney transplant.The alternative treatment for patients with failed kidneys is dialysis, a treatment that requires five 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 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.

Enabling kidney transplantation for highly sensitized patients

Highly sensitized patients have high levels of anti-HLA antibodies, which are likely to target and significantly compromise a transplanted organ. The more antibodies, the lower the likelihood of finding a donor organ that will be a match. Many 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[5].

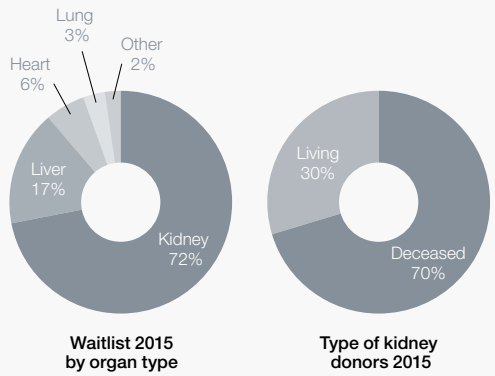


Figure B. Waitlist 2015 in the U.S. and Europe by organ type and type of kidney transplantation (deceased donation vs living donation)[6]

Interview with Dr. Tomas Lorant

Transplant surgeon and Senior Medical Director at Hansa Biopharma AB

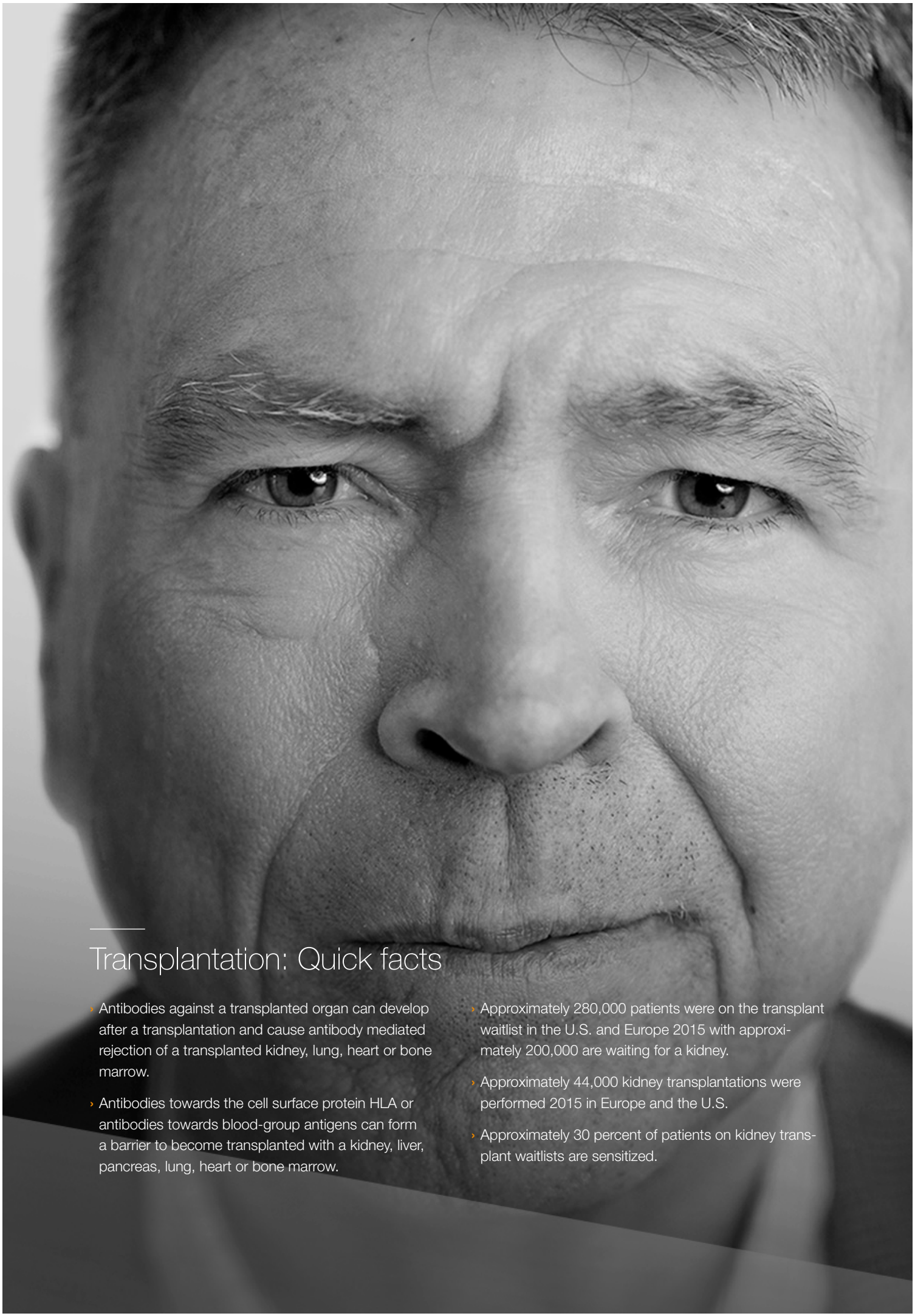
You are one of the clinicians who has the longest experience from applying imlifidase as a treatment prior to transplantation. What differentiates imlifidase from other treatments?
The big difference with imlifidase, compared to what is already present today, is that it adds a new approach to eliminate the patient's HLA antibodies incredibly quickly and effectively and thereby create a "window" that enables transplantation that otherwise would not have been possible. For those patients who are highly sensitized and have a very high level of HLA-antibodies, the waiting time for a matching kidney is very long. Some of these patients may never receive a compatible kidney transplant.

If a suitable kidney suddenly would become available for a highly sensitized patient, it should be possible to act quickly. Time is of essence and you have to be able to eliminate the patient's donor specific antibodies very quickly. Imlifidase enables what has not previously been possible, namely to rapidly – less than an hour - and effectively cleave and eliminate the antibodies and thus make transplantation possible for the patient. With today's methods of desensitization, the process takes far too long, nor does it give as good results as the patient's antibody levels are not eliminated as effectively.

If a transplant can't be carried out, what happens to the donated organ?
When the desensitization is not successful and the patient's level of antibodies is too high, the transplant cannot be performed. In European countries, such as Sweden, this leads to the kidney being offered to someone else who doesn't have the same high level of antibodies. In the United States, the kidney is offered to the next sensitized patient according to their allocation system. In some cases, it leads to the kidney not being used but simply being discarded.

For whom would you say imlifidase can do the most?
The waiting time for the highly sensitized patients is, as said, very long, often ten years or longer. During this time, patients' health conditions deteriorate severely, and unfortunately, some patients die waiting for a compatible organ. It is for these patients that imlifidase can make a crucial difference.

How do you look upon your new role, as Medical Director at Hansa Biopharma?
It is very exciting to be able to work with this product. Together with the team at Uppsala University Hospital and Hansa, I have had the opportunity to study it at close range and seen the effect it has, so I really know what it can do for the patients. Moreover, Hansa is a very inspiring company and we work together in a stimulating way, where teamwork is at the center. In this way, it actually is reminiscent of the collaboration that a successful team must have in transplantation.



Transplantation: Quick facts

- Antibodies against a transplanted organ can develop after a transplantation and cause antibody mediated rejection of a transplanted kidney, lung, heart or bone marrow.
- Antibodies towards the cell surface protein HLA or antibodies towards blood-group antigens can form a barrier to become transplanted with a kidney, liver, pancreas, lung, heart or bone marrow.
- Approximately 280,000 patients were on the transplant waitlist in the U.S. and Europe 2015 with approximately 200,000 are waiting for a kidney.
- Approximately 44,000 kidney transplantations were performed 2015 in Europe and the U.S.
- Approximately 30 percent of patients on kidney transplant waitlists are sensitized.

Completed and ongoing clinical studies with imlifidase

Overview

Type of study	ClinicalTrials.gov Identifier	Subjects	Status	Results	Publication
Phase 1 in healthy subjects	NCT01802697	29	Completed	Imlifidase is efficacious and well tolerated with a favorable safety profile.	PLOS ONE (2015) [1]
Phase 2 in sensitized patients	NCT02224820	8	Completed	Imlifidase treatment resulted in HLA levels acceptable for transplantation in all patients.	American Journal of Transplantation (2018) [2]
Phase 2 in sensitized patients	NCT02475551	10	Completed	Imlifidase enabled kidney transplantation for all patients with a favourable safety profile.	The New England Journal of Medicine (2017) [3]
Phase 2 in highly sensitized patients	NCT02426684	17	Completed	The imlifidase treatment enabled life-saving transplants in all 17 patients. Graft survival at study completion, six months post-transplantation, was 94%.	The New England Journal of Medicine (2017) [3]
Multicenter Phase 2 in highly sensitized patients (Highdes)	NCT02790437	18	Completed	The imlifidase treatment enabled life-saving transplants in all 18 patients. Graft survival at study completion, six months post-transplantation, was 89%.	
Phase 2 in Anti-GBM disease (GOOD-IDES)	NCT03157037	Approx. 15	Enrolling		
Phase 2 in AMR	NCT03897205	Approx. 30	Clinical Trial Application approved and clearance from ethical review board		

Anti-GBM antibody disease
An investigator-initiated Phase 2 study evaluating imlifidase in anti-GBM antibody disease[7, 8], an ultra-rare and acute autoimmune kidney disease, is ongoing at several European nephrology clinics with Professor Mårten Segelmark at Lund University Hospital as principal investigator.

There are currently eight patients enrolled in the ongoing study and we are adding additional centers to accelerate recruitment of patients. Although limited follow up data is available from the first seven patients at this point, all seven have responded favorably, and imlifidase appears to be well-tolerated.

In early July, the FDA approved Hansa's application for Orphan Drug Designation for imlifidase for the treatment of anti-GBM. Orphan Drug Designation qualifies the sponsor of the drug for various development incentives, including tax credits, protocol assistance and up to seven years of U.S. marketing exclusivity from time of approval of a BLA.

In October, the Committee for Orphan Medicinal Products of the EMA issued a positive opinion on Orphan Drug Designation for imlifidase in the treatment of anti-GBM antibody disease. Subsequently, the European Commission officially designated imlifidase as an orphan drug in this indication. This designation provides development and commercial incentives, including ten years of market exclusivity, protocol assistance on the development of the drug, including clinical studies, and certain exemptions from or reductions in regulatory fees.

Treatment of acute kidney transplant antibody-mediated rejection (AMR)
There is no effective therapy for the treatment of acute AMR. In heart, lung and kidney transplants, acute AMR occurs in 10–20 percent[9] of patients and remains a significant unmet medical need associated with loss of graft function. Imlifidase is highly effective in inactivating IgG and may have the potential to halt progression of AMR and become an effective treatment in acute cases.

In the first quarter of 2019, Hansa announced that it had initiated enrollment in a Phase 2 study evaluating imlifidase for the treatment of AMR. Approximately 30 patients will be enrolled at eight clinical trial centers in France, Sweden, Austria, Australia and the U.S.

Treatment of Guillain-Barré syndrome (GBS)
GBS is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies. It affects one in 100,000 people annually[10]. While patients are typically treated with either IVIg or plasmapheresis, there remains a significant unmet medical need. In February 2018, imlifidase received Orphan Drug Designation from the FDA for the treatment of GBS.

Hansa expects to initiate enrollment in a Phase 2 study evaluating imlifidase for the treatment of GBS during the second quarter of 2019. Approximately 30 patients will be enrolled in the study.

Interview with Melissa B

Highly sensitized patient from American Association of Kidney Patients, currently on kidney transplant waitlist

Can you tell us about your background as a kidney patient?
I was diagnosed with chronic kidney disease at age 24 and with IgA nephropathy a year later. I never had kidney problems per se before that, but I had plenty of medical problems, certainly a lot of different infections, growing up which in hindsight could have pointed to an autoimmune deficiency.

I was diagnosed with CKD in stage three and received different steroid therapies, fish oil and other treatments but not dialysis.

Once I gave birth to my third child, prematurely, I had lost all functionality of my kidneys. My son was in the neonatal ICU and I passed out on my way to visit him. As both kidneys failed, I was forced to go on dialysis three days a week, and was placed on the kidney transplant waiting list. My pregnancies and the blood transfusions I had received had pushed up my HLA antibodies to a very high level.

When did you start doing dialysis on your own?
With three young children and newly divorced I needed to go back to work in order to support my family . I decided to learn how to dialyse myself and in early 2003, after six weeks of extensive training, I started dialysis on my own at home. So that became the three parts of my life, doing my dialysis, raising my children and working full time. It's all I had mental and physical energy for.

How does it affect you, being on the waiting list with no high hopes?
Being on the waiting list and being highly sensitized means a long wait where nothing really happens. Each year you have to requalify for active placement on the list and that made me reflect on how long it's actually taking for you to get a kidney. I would see other patients who were not overly sensitized receive new kidneys and live a life off of dialysis. I'm asked by friends and colleagues about my r new kidney: "What is taking so long?"they would say. As if I had the answer.

My situation was worse than most others and I didn't even know if I would get a transplant because of my antibodies. In order to cope with the hopelessness, I mentally pushed the chance of getting a transplant to the back of my mind and went into what I call "survival mode". I had to live my best possible life under the circumstances instead of keep hoping for something that is not likely to happen. I started to have a lot of problems related to dialysis. Was hospitalized now and again. I kept doing the yearly testing but I had in my survival mode decided that the idea of getting a transplant was nothing but a myth.

And then after almost ten years something happened?
Just before my ten-year anniversary on dialysis I got a phone call from my transplant coordinator saying that a kidney match had been found. I received a kidney from a deceased donor. While I was grateful for the gift of life, the kidney did not function efficiently from the beginning. I got steroids, chemo treatments, plasmaphereses and more. Finally, my doctor found me healthy enough to discharge and I was back on dialysis.

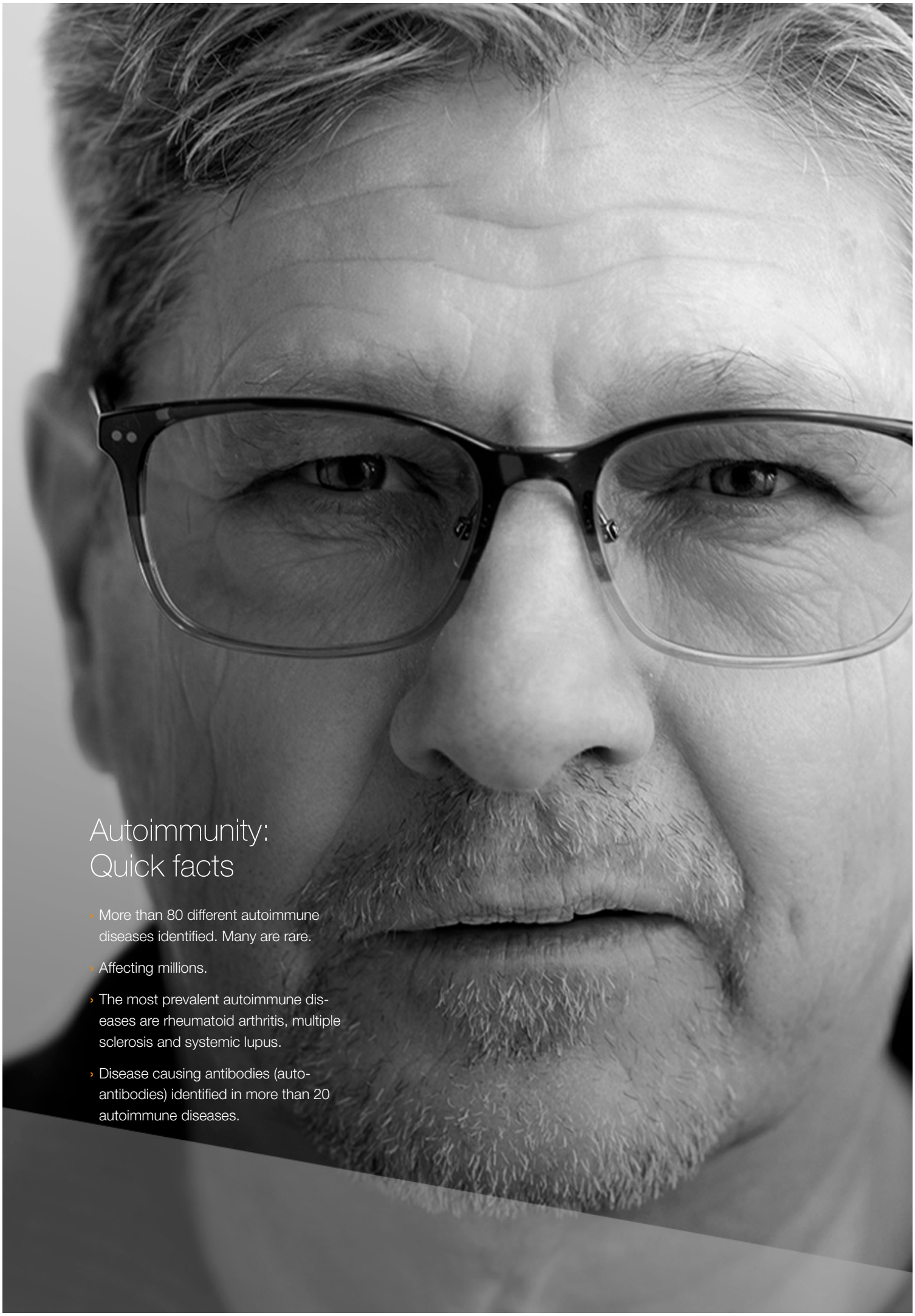
The reoccurring problems made me extremely depressed. After some time, my doctor advised to get me off dialysis and the kidney started to slowly work – not in full, but it started functioning - at about 40%. Again I went into survival mode trying to live my life and not thinking about the likelihood I would resume dialysis in the near future.

Then in late 2016 I got really sick – the kidney had rejected.

And now you are back on the waiting list?
Since then I am back on dialysis and back on the waiting list – but my antibodies are now at the 100% level which means I am one of the absolutely most sensitized patients on that list. It is survival mode again, since my chances of getting transplanted again are very close to zero and zilch.

I do still spend quite a lot of time working with patient advocacy, trying to spread knowledge about the situation for the sensitized patients on the kidney waiting list, trying to promote donor-ship, changing rules, regulations and practices in order to increase the chances for transplantation; practices that will decrease the growing number of highly sensitized patients.

Of course, I have followed the development of imlifidase closely. It will mean a lot to overly sensitized patients when it finally receives approval.



Autoimmunity: Quick facts

- More than 80 different autoimmune diseases identified. Many are rare.
- Affecting millions.
- The most prevalent autoimmune diseases are rheumatoid arthritis, multiple sclerosis and systemic lupus.
- Disease causing antibodies (autoantibodies) identified in more than 20 autoimmune diseases.

Regulatory strategy for imlifidase to enable kidney transplantation in highly sensitized patients

The recently completed Phase 2 studies have enrolled highly sensitized patients who had either failed previous attempts of transplantation or were highly unlikely to receive a compatible kidney transplant. Based on the results from these successfully completed Phase 2 studies, Hansa is seeking a path towards regulatory approval.

In May 2017, the EMA granted imlifidase access to its Priority Medicines (PRIME) scheme for highly sensitized kidney transplant patients. PRIME is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier.

In October 2018 the FDA granted imlifidase Fast Track Designation for the investigation of imlifidase for transplantation. The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs to treat serious or life-threatening conditions that demonstrate the potential to address an unmet medical need. Fast Track designation provides a company more frequent communication with the FDA regarding the investigational drug's development plan and also provides eligibility for priority review if certain criteria are met.

Hansa submitted a Marketing Authorisation Application (MAA) with the EMA on February 5, 2019, and the MAA submission was accepted on February 28, 2019, by EMA for review of IDEFIRIX™ (imlifidase). An opinion of the Committee for Medicinal Products for Human Use (CHMP) is expected within 210 days (plus any clock-stops for the applicant to provide answers to questions which may arise during the review). After the adoption of a CHMP opinion, a final decision regarding the MAA for IDEFIRIX is made by the European Commission.

Hansa's dialogue with the FDA is ongoing and the Company will provide updated guidance regarding the timeline for a potential BLA filing following a meeting with the agency.

Strategy in medical affairs and commercialization

In preparation for approval, Hansa Biopharma's Medical Affairs department is focused on advancing desensitization in the kidney transplantation arena. In the U.S. and Europe, we are building the infrastructure to support the global expansion and development of imlifidase's scientific platform and Phase IV research. We will continue to recruit experienced talent in the areas of Immunology/ Autoimmune Diseases and Transplantation.

Hansa Biopharma aims to obtain market approval for lead candidate imlifidase as pre-treatment of highly sensitized patients prior to kidney transplantation in the U.S. and in the EU. In preparation, a core commercial infrastructure has been established, including senior expertise in Market Access and Patient Advocacy.

Addressable patient population in prioritized indications

The potential indication universe for imlifidase as an effective and safe IgG-eliminating treatment is comprehensive and our long-term goal is to significantly improve the treatment of acute IgG mediated diseases.

We estimate the number of addressable patients within seven major markets (U.S., EU5 and Japan) in the currently prioritized indications, organ transplantation, anti-GBM and GBS, to be between 30,000 to 40,000 patients annually.

How we address our market

Interview with Vincenza Nigro, Vice President Global Medical Affairs

Judging from your contacts with clinicians, surgeons and other key opinion leaders in the kidney transplantation area, how is imlifidase perceived?
Imlifidase has the potential to be a ground-breaking new therapy that would enable kidney transplants for patients who previously had little hope of receiving one. For highly sensitized patients—patients who produce high levels of human leukocyte antigen (HLA) antibodies—the current prognosis is dire. They will spend more time on dialysis and are more likely to die before they can receive a transplant.

About 30,000 of waitlist patients are classified as sensitized, and for the highly sensitized category of patients (approximately half of the sensitized patients), the unmet need is immense. Without desensitization, a sensitized patient on the waiting list may have a very low probability of finding a suitable organ donor for transplantation, as low as 1:300,000[11].

How does imlifidase compare to other treatments?
Currently, the approach to desensitization has involved a few institution-specific approaches using high-dose intravenous immunoglobulin, plasmapheresis and other unapproved combination therapies which require multiple treatments over days or weeks and are not always effective. Because of the unpredictable nature of deceased donor availability, these desensitization therapies would only be feasible if there is a live donor and the transplantation date is known.

What's imlifidase's major advantage when used prior to transplantation?
Imlifidase may "make the impossible possible" by enabling clinicians to rapidly and effectively desensitize patients and inactivate donor-specific antibodies, with a single infusion prior to transplantation.

Once approved, imlifidase can simply be integrated within current practice at the time of transplant when critical decisions, about the organ offer and recipient/donor compatibility, are taking place. Imlifidase is not only a promising therapy for a high-unmetneed patient population for whom a lifesaving transplant is currently out of reach but it may also allow a more standardized approach to desensitization at the time of transplant.

Intellectual property and market exclusivity

Intellectual property

The Hansa Biopharma patent portfolio currently consists of eleven separate patent families plus an exclusive license on one additional patent family. The imlifidase project is protected by seven patent families, which include both granted patents, as well as pending patent applications.

These families cover the use of isolated imlifidase to create antibody fragments, the medical use of imlifidase in IgG-mediated medical conditions including prevention and treatment of transplant rejection and autoimmune disease, dosing regimens in combination with other treatments such as transplantation and oncology as well as new IgG modulating 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.

Orphan drug designation and data exclusivity

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.

In January 2017, the EMA approved our application for orphan drug designation of imlifidase for the prevention of graft rejection following solid organ transplantation. In September 2015, imlifidase was granted orphan drug designation for the prevention of antibody-mediated organ rejection in solid organ transplant patients by the FDA. In February 2018, the FDA granted orphan drug designation to imlifidase for the treatment of Guillain-Barré syndrome. In July 2018 the FDA granted Orphan Drug Designation for imlifidase for the treatment of the rare and acute kidney disease anti-GBM antibody disease, also known as Goodpasture's disease.

In October 2018, the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) issued a positive opinion on Orphan Drug Designation for imlifidase for the treatment of anti-glomerular basement membrane (anti-GBM) antibody disease. Subsequently, the European Commission officially designated imlifidase as an orphan drug in this indication.

Data exclusivity can be granted by regulatory agencies, such as the FDA and EMA, for protection of clinical data submitted in an application for market authorization. Data exclusivity thereby prevents biosimilar manufacturers from referring to this submitted data for the approval of a biosimilar. FDA can grant new biologics 12 years of data exclusivity and EMA can grant innovative new treatments eight years of data exclusivity plus two years of potential additional market protection.

Manufacturing of IDEFIRIX (imlifidase)

Imlifidase manufacturing has been transferred to manufacturers suitable for producing imlifidase for commercialization. The manufacturing process has been optimized, and the product for commercialization is a lyophilized product, which provides the advantages of easy off-the-shelf use and efficient global distribution. The first GMP batch for further clinical studies was produced in late 2017. Full process characterization and validation for commercial supply was completed during 2018.

Preclinical development projects

NiceR – Novel Immunoglobulin Cleaving Enzymes for Repeat dosing

Hansa is developing novel IgG-degrading enzymes with the objective of enabling repeat dosing in autoimmune conditions, transplantation, oncology and within gene therapy, where patients benefit from more than one dose of an IgG-modulating enzyme. The Company has developed and patented several novel immunoglobulin cysteine endopeptidases. Significant progress has been made in the NiceR-project during 2018 and in the first quarter of 2019 a lead candidate was selected from the NiceR program. This is the first IgG-eliminating enzyme from the NiceR program that Hansa intends to advance into clinical development. Development of a GMP-manufacturing process for the lead NiceR candidate has been initiated and preparations for toxicology studies and a clinical Phase 1 study are now ongoing.

EnzE – Enzyme-based antibody Enhancement

Recently published findings[12] demonstrate how pre-treatment with imlifidase in tumor animal models can increase the efficacy of currently available antibody-based cancer therapies. This treatment concept is currently being investigated under the project name EnzE, Enzyme-based antibody Enhancement. Published data demonstrate the potential of an IgG-clearing agent as a pre-treatment for cancer patients. High levels of plasma IgG have been shown to limit the efficacy of therapeutic antibodies, as plasma IgG can saturate the receptors of the patient's immune cells, preventing them from efficiently killing the tumor cells. Removing inhibiting IgG antibodies 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. The EnzE program is in the pre-clinical research phase.

Sustainability, Social responsibility, Employee relations

Interview with Anne Säfström Lanner, Vice President Global Human Resources

You joined Hansa Biopharma in January 2019. What attracted you to Hansa?
Firstly, to be able to work with products that can have an impact on people's lives. For me personally, it is hard to find anything that would be more important and more motivating than to really contribute to changing and improving people's quality of life. Furthermore, Hansa is in an important phase of expansion, with growth and clear goals, which is extremely attractive to me. It provides the exciting challenge to build functions in a new global organizational structure while keeping and developing a healthy organizational culture.

I was also impressed by the Hansa people. Working with people who are passionately devoted to achieve the common goal is very enriching. We are a mixture of different nationalities and backgrounds, who share the vision of being able to change and improve people's lives. I am very inspired by the knowledge, drive and high level of ambition in the company.

How would you describe the Hansa corporate culture?
The culture is built on a sincere wish to improve people's lives. Common traits are a high level of ambition and a strong shared sense of pride in the company's achievements. There is also a sincere and warm spirit of cooperation combined with the courage to break new ground and to test new paths.

Hansa is truly a great workplace where hard and enduring work is performed in an open, transparent, proud and warm atmosphere.

Hansa is now relatively close to having products on the market. What factors are important in this development?
Becoming an international organization with fully developed functions requires strong specialized skills but also a close internal collaboration. To achieve our goals, we will continue working together in projects where we combine diversity and competencies. We have to avoid building silos and keep on proudly sharing our knowledge, insights and discoveries. I see communication, trust and transparency as keywords in our growth journey.

Besides purely professional knowledge and experience, what else is important when Hansa recruits new staff?
First of all, respect for the patients and the important task we face. Equally important is courage to dare to try new ways. We are a company under constant change. That requires a certain personality, a propensity to change, to like it.

Hansa has produced extraordinary results. That requires extraordinary efforts, but most of all an ability to collaborate and communicate, both internally and externally.

Out-licensed royalty-generating programs

HBP – Prediction of severe sepsis

The HBP-assay for measurement of heparin-binding protein (HBP) in plasma is a novel diagnostic method originally developed and patented by Hansa to assist in predicting severe sepsis in patients with infectious disease symptoms at emergency departments[13]. Hundreds of thousands of patients die every year due to severe sepsis as a complication of infections, such as urinary tract infection and pneumonia. Many of these infections can be effectively treated with antibiotics in order to prevent progression to severe sepsis, although early prediction of risk patients is crucial for successful treatment. Severe sepsis affects 300 of 100,000 people annually[14]. The HBP assay has been out-licensed by Hansa to UK-based Axis-Shield Diagnostics, a subsidiary to Abbott, and Hansa holds the right to royalty payments from Axis-Shield. Axis-Shield is engaged in further product development and clinical development with the HBP-assay.

U.S. and European Medical Advisors

Dr. Stanley Jordan
M.D., Ph.D., Director of Kidney Transplantation and Transplant Immunology, Kidney and Pancreas Transplant Center and Director of Division of Pediatric and Adult Nephrology, Cedars-Sinai Medical Center, Los Angeles, California

Dr. Christophe Legendre
M.D., Ph.D. Professor of Nephrology at Paris Descartes University and Head of the Adult Nephrology and Transplantation unit at Necker Hospital in Paris.

Dr. Robert Montgomery
M.D., Ph.D., FACS, Director at NYU Langone Transplant Institute, New York, NY, USA

Dr. Kathryn Wood
Ph.D. Fellow of the Academy of Medical Sciences, Professor of Immunology in the Nuffield Department of Surgical Sciences, University of Oxford, England, runs the Transplantation Research Immunology Group.

Shareholder information

The Hansa Biopharma share is listed on Nasdaq OMX Stockholm, under the ticker HNSA and included in several indexes including:
- OMX Nordic Mid Cap
- OMX Nordic Health Care index
- OMX Stockholm Benchmark Index
- OMX Stockholm Health Care
- OMX Stockholm Pharmaceuticals & Biotechnology
- MSCI Global Small Cap

Brief facts, the Hansa Biopharma-share

Listing	Nasdaq OMX Stockholm
Number of shares	40,681,654 (39,959,890 A-shares and 721,764 C-shares)
Market capitalization (Dec. 31, 2018)	SEK 11,061 m
Ticker	HNSA
ISIN	SE0002148817

According to the shareholder register maintained by Euroclear Sweden AB, as of December 31, 2018, Hansa Biopharma had 12,495 shareholders. On December 31, 2017, Hansa Biopharma had 11,469 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 2018 amounted to 39,959,890 ordinary shares and 721,764 C-shares. At year end the share capital amounted to SEK 40,681,654. 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.

Closing price for the HMED share in 2017 and 2018

	2017		2018	
SEK	High	Low	High	Low
1st quarter	141.3	96.8	290.0	217.0
2nd quarter	66.5	271.5	267.4	196.8
3rd quarter	222.0	158.0	338.4	198.0
4th quarter	260.0	184.5	349.4	260.0

Analyst coverage

SEB
Kempen
RBC Capital Markets
Evercore ISI
ABG Sundal Collier
Redeye
RX Securities

Source: Monitor by Modular Finance AB. Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

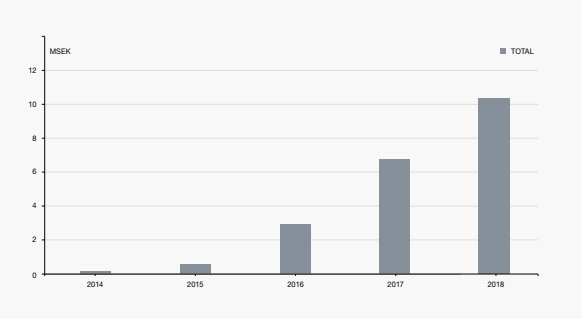
Shareholders by country

Country	Number of shares	Share (%)
Sweden	27,951,638	68.9
United States	3,659,927	9.0
United Kingdom	1,512,316	3.7
Luxembourg	634,542	1.6
Denmark	631,487	1.6
France	285,614	0.7
Germany	157,809	0.4
Bermuda	146,559	0.4
Canada	139,497	0.3
Switzerland	47,271	0.1
Others	106,720	0.3
Anonymous ownership	540,8274	13.1
Total	**40,681,654**	**100.0**

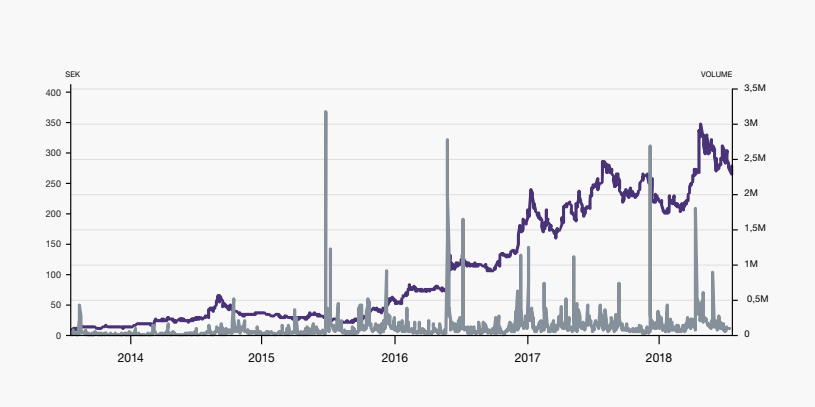
Shareholder categories, December 31, 2018

Owner	Shares	Capital (%)
Other	11,159,930	27.7%
Swedish Private Individuals	9,134,456	22.5%
Swedish Institutional Owners	8,569,747	21.1%
Foreign Institutional Owners	6,409,247	15.8%
Anonymous ownership	5,408,274	13.1%
Total	**40,681,654**	**100.0%**

Turnover of the Hansa share at Nasdaq Stockholm 2014 to 2018



Hansa share price development and trading volume 2014–2018



15 largest shareholders, December 31, 2018

	Number of shares		
Owners	HNSA	HNSA C	Capital (%)
Nexttobe AB	5,755,379	0	14.1
Oppenheimer	2,358,370	0	5.8
Thomas Olausson	1,548,569	0	4.0
Handelsbanken Funds	1,301,766	0	3.2
Gladiator	1,275,000	0	3.1
Avanza Pension	1,170,248	0	2.9
Polar Capital	1,140,691	0	2.8
Norron Funds	988,973	0	2.4
AFA Insurance	959,734	0	2.4
Fourth Swedish National Pension Fund	958,044	0	2.4
Third Swedish National Pension Fund	780,509	0	1.9
Hansa Biopharma AB	0	721,764	1.8
BWG Invest Sàrl (William Gunnarsson)	600,370	0	1.5
Sven Sandberg	494,000	0	1.2
C WorldWide Asset Management	482,291	0	1.2
Total		**721,764**	**100.0**

Source: Monitor by Modular Finance AB. Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

Dividend

The Board proposes no dividend for the financial year 2018. For more information about Hansa Medical's dividend policy, please refer to the Hansa Biopharma Corporate Governance Report available at the company website at http://hansamedical.com/en/investors-me-dia/corporate-governance/corporate-governance-report/

Long-term incentive programs

Hansa Biopharma has three ongoing incentive programs for the company's employees as of April 2019:

- A share warrant program adopted by the Annual General Meeting on June 2, 2015.
- A performance based share program (LTI 2016) adopted by the Extraordinary General Meeting on November 21, 2016.
- A mix of performance based share program and a warrant program (LTI 2018) adopted by the Annual General Meeting on May 29, 2018.

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

Subscription for shares in the share warrant program may take place during the period June 15, 2018 and June 15, 2019. Increase of the company's share capital upon full exercise of the warrants will amount to SEK 355,000, which corresponds to a dilution of 0.9 percent of the total number of ordinary shares and of the total number of votes in the company.

The share rights granted in LTIP 2016 are divided into two vesting periods, the first one ending November 28, 2019 and the second May 18, 2020. 289,750 rights have been allocated in total, of which 78,250 rights previously allocated have been excluded due to accelerated vesting or terminated, so remaining allocated rights as of December 31, 2018 are 211,500. At maximum of 305,000 ordinary shares may be allotted to the participants and 96,000 ordinary shares can be used to cover social security contributions due to the program, which means a dilution effect of 1.0 percent of the total number of ordinary shares and of the total number of votes.

6,701 warrants have been acquired by the participants in LTIP 2018. 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. 178,131 share rights have been totally allocated by the participants in LTIP 2018, of which 580 have been excluded, remaining allocated rights as of December 31, 2018 are 171,756. The rights allocated are divided into two vesting periods, the first of which ends June 15, 2021 and the second November 30, 2021. The number of warrants and share rights allocated to the participants will vary depending on how the participants choose to allocate their Participant Values. Consequently, the dilution, costs and effect on key ratios will vary consequently. The maximum dilution effect of LTIP 2018, which combines two program types, occurs if all of participants choose to solely subscribe for warrants.

Reference list

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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.

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.

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.

IdeS
IdeS, 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.

IgG
IgG, Immunoglobulin G, is the predominant type of antibody in serum.

Imlifidase
imlifidase is the generic name, International Nonproprietary Name (INN), for IdeS.

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.

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.

Sepsis
Diagnosed or suspected infection in combination with the patient being in a systemic inflammatory state (SIRS). Clinical symptoms of systemic inflammation may be a combination of fever, increased heart rate and increased respiratory rate.

Severe sepsis
Sepsis is progressing into severe sepsis when the patient may suffer circulatory effects and reduced functions of vital organs such as the brain, heart, lungs, kidneys or liver.

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.

Five-year summary

KSEK, unless other stated	2014	2015	2016	2017	2018
Net revenue and profit					
Net revenue	1,677	6,675	2,579	3,442	3,358
Operating profit/loss	-24,709	-66 201	-111,135	-176,083	-246,498
Net profit/loss	-29,042	-66,266	-111,129	-176,660	-247,974
Capital					
Total assets	54,311	224,088	310,672	680,415	944,821
Equity	49,804	211,526	283,693	630,661	859,876
Investments (intangible and tangible fixed assets)	1,204	1,317	984	2,409	2,493
Cash and cash equivalents including short term investments	10,152	175,683	253,578	616,061	858,187
Cash flow					
Cash flow from operations before change in working capital	-23,522	-65,078	-106,944	-162,894	-233,264
Cash flow from operating activities	-23,623	-57,799	-94,563	-150,105	-204,560
Cash flow from investing activities	-1,319	-2,796	-45,414	2,693	-387,477
Cash flow from financing activities	-35,004	226,126	177,882	514,902	450,307
Net change in cash	10,062	165,531	37,905	367,490	-141,730
Key ratios					
Equity ratio (%)	92	94	91	93	91
Share overview					
Earnings/loss per share (SEK)	-1.09	-2.12	-3.37	-4.97	-6.47
Shareholders' equity per share (SEK)	1.92	6.53	8.09	16.68	21.52
Dividend (SEK)	–	–	–	–	–

Directors' report

Operations

Hansa Biopharma AB (Hansa Medical AB) is harnessing its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.

The Company's lead product, IDEFIRIX (imlifidase), is a unique antibody-degrading enzyme in late-stage clinical development to enable kidney transplantation in highly sensitized patients, with additional clinical studies in acute autoimmune conditions.

Hansa's research and development program is advancing the Company's technology to develop the next generation of IgG-cleaving enzymes with lower immunogenicity, potentially enabling repeat dosing in relapsing autoimmune diseases, chronic transplant rejection, oncology and repeat dosing of gene therapy.

Hansa Biopharma is headquartered in Lund, Sweden with operations in both Europe and the U.S.

Business review January–December 2018

Positive final top line results from two Phase 2 studies of imlifidase for kidney transplantation
Hansa successfully completed two Phase 2 clinical studies evaluating imlifidase for kidney transplantation in highly sensitized patients. Imlifidase met all primary and secondary endpoints in each study. Treatment with imlifidase enabled transplantation in all 35 highly sensitized patients and at study completion, six months post-transplantation, graft survival was 91%.

The American Journal of Transplantation publishes results from Hansa Biopharma's first Phase 2 study with imlifidase
Clinical results from Hansa's first Phase 2 study of imlifidase were published in the American Journal of Transplantation (AJT). The publication describes the results from Hansa's initial clinical study in sensitized patients, which evaluated the first transplantation enabled by treatment with imlifidase. To date, stable kidney function has been maintained in this very first patient for more than four years.

Initiation of follow up study of patients treated with lead candidate (imlifidase) prior to kidney transplantation
Hansa initiated a long-term observational prospective follow-up study evaluating graft survival in patients who have undergone kidney transplantation after treatment with imlifidase. The objective of the study is to collect long-term outcome data to provide further support to future prescribers, payers and patients.

Imlifidase granted orphan drug designation by the FDA for anti-GBM antibody disease
The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to imlifidase for the treatment of the rare and acute kidney disease anti-GBM antibody disease, also known as Goodpasture's disease.

FDA orphan drug designation for imlifidase and the treatment of Guillain-Barré syndrome
The FDA granted Orphan Drug Designation to imlifidase for the treatment of Guillain-Barré syndrome (GBS).

FDA fast track designation for imlifidase for transplantation
FDA granted imlifidase Fast Track Designation for the investigation of imlifidase for kidney transplantation. The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs to treat serious or life-threatening conditions that demonstrate the potential to address an unmet medical need.

Closing of SEK 453 / $50 million directed share issue
In November, Hansa raised SEK 453 /$50 million in a directed share issue of 1.8 million ordinary shares. The share issue was significantly oversubscribed due to high demand from U.S., UK, Swiss and Swedish institutional investors including Consonance Capital, Redmile Group, Polar Capital and HBM Partners. The funding will enable Hansa to accelerate its commercial preparations for the potential launch of imlifidase and continue advancing the development of Hansa Biopharma's other pipeline projects.

Søren Tulstrup appointed new President and CEO
Søren Tulstrup was appointed President and CEO of Hansa, effective March 20, 2018. The acting CEO Ulf Wiinberg reverts to his former role as Chairman of the board and Birgit Stattin Norinder reverts to her former role as member of the board of directors.

U.S. subsidiary
Hansa formed a U.S. subsidiary. for the continued build-up of a U.S. organization and presence.

Name change
In order to better reflect the Company's development and long-term goals, the Company changed its name from Hansa Medical AB to Hansa Biopharma AB. The new name represents the next stage in the Company's development and emphasizes Hansa's focus on the development and commercialization of biological drugs. This clarification of the Company's profile is particularly important now that it continues to expand its business and investor base internationally.

Risk management

Hansa Biopharma is committed to having an effective risk management process. 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 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 in order 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.

The risk management committee reports quarterly to the executive management team and the board.

Risk factors

Hansa Biopharma's business is influenced by a number of 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, 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 greatest significance for the Company's future development. For natural reasons, not all of the risk factors can be described. Instead, the risks which are specific to the Company or the industry are set forth here. An overall assessment must also include other information contained in the annual report as well as an overall assessment of extraneous factors in general.

Clinical trials and regulatory approvals

All pharmaceuticals which are developed in order to be marketed must undergo an extensive registration procedure before the relevant governmental agency on the particular market, for example the Swedish Medical Products Agency, the U.S. Food and Drug Administration ("FDA") or the European Medicines Agency ("EMA"). The registration procedure includes, for example, where appropriate, requirements regarding preclinical development, clinical testing, registration, approval, marketing, manufacturing and distribution of new pharmaceuticals and medical and biological products. The failure to fulfill such current or future requirements can lead to a need to carry out further clinical studies, the recall of products, stopped import, denial of registration, the withdrawal of previously approved applications, or criminal charges. Even if a pharmaceutical manufactured by Hansa Biopharma, or a third party under an agreement with the Company, were to be registered for commercialization, there is a risk that Hansa Biopharma will not be able to comply with new rules or be able to maintain the registration or receive corresponding authorization for additional pharmaceuticals. There is also a risk that the rules currently applicable to registration, or the interpretation of these rules, will be changed in a way disadvantageous to the Company.

Before a pharmaceutical is approved for marketing, it must be investigated in clinical studies. There is a risk that Hansa Biopharma will not achieve sufficient results in such trials and thus that the necessary approvals will not be obtained.

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.

The Company has an exclusive licensing agreement with Axis-Shield Diagnostics Ltd. and is dependent on this cooperation functioning properly for the sale and further development of HBP-assay. If the Company is unable to maintain this, it might prejudice the Company's business and earnings.

Intellectual property issues

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.

Dependence on key product

The value of the Company is primarily dependent on success in the Company's leading development project, Imlifidase. The market value of the Company, and thus the Company's share price, would be prejudiced by setbacks for Imlifidase.

Market and competition

The products Hansa Biopharma has under development risk being exposed to competition from new pharmaceuticals and 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 which 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.

Manufacturing
The manufacturing process for Imlifidase is made in collaboration with contract manufacturers in Europe. Hansa Biopharma is dependent on the quality of the manufacturing 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 Requirements and consequences for the Company in the event of deficiencies in GMP requirements may lead to delays in clinical trials or to market products.

Purchasing and pricing
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 the pricing of the products by such financiers, this may make it more difficult for the products to reach the market and may prejudice their commercial potential, which may negatively affect the Group'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, this might have a negative effect on the Company's business, financial position and earnings.

Financial risks
Hansa Biopharma carries out capital-intensive and value-generating pharmaceuticals and diagnostics development. Future financing of the operations is expected to take place through new issues of shares, loans, licensing revenues, cooperation with other parties, and the sales of rights 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 revenues from licensing agreements. However, the operations have mostly been financed with shareholders' equity through new issues of shares, primarily rights issues to the shareholders. Debt financing is not considered to be an appropriate form of financing, other than temporarily, until the Company has achieved profitability and positive cash flow. For further description of the Company's financial risks, see note 25.

Substainability, social responsibility and employee relations

Hansa strives to create sustainable values by developing drugs that can give people a better and longer life. Our vision, to significantly improve the lives of people living with rare immuno-pathologies, shows in itself that sustainability is central to the Company.

Social and environmental sustainability are vital aspects of the way we operate, ensuring the long-term success of the Company for the benefit of patients. Our operations are conducted in compliance with regulatory guidelines and industry standards that in a natural way integrates many of the most important sustainability issues. The sustainability work focuses on conducting clinical development in accordance with ethical rules and guidelines, taking into account the environmental impact of both Hansa's own operations and those of our 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, in order to ensure that the resulting drugs are both efficacious and safe. Regulatory approvals are always required for clinical studies, which are then carried out within the framework of the regulatory and ethical regulations of the countries in question. The trials and studies are structured in accordance with applicable standards, guidelines, and directives, e.g. Good Clinical Practice (GCP).

Hansa Biopharma works actively with environmental issues and consistently endeavors 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 we want our employees to be able to attend international conferences and meetings in order to promote development and the exchange of ideas and experiences. We are, however, also keen to reduce the environmental impact caused by unnecessary business trips by encouraging conference calls and online meetings.

Personal development
In addition of having all our employees to operate in the most sustainable way, Hansa Biopharma as an organisation also value the employee with a sustainable approach. We strive to ensure that every employee can make a difference with their extensive experience and highly developed competencies. Our employees play a key role in fulfilling and reaching our vision and are therefore our most valued asset. As an employer, our responsibility is to ensure decent working conditions in a healthy and sustainable work environment. Hansa is responsible for providing personal and professional development opportunities. The model for this is the Hansa P&D (personal development) development process that is reviewed yearly in close collaboration with the employee and the manager. Aligned with this process is also the Hansa salary review process, conducted yearly and serving as a bridge between goal fulfilment and compensation.

Recruitment & gender
Each of our employees has an important role to play and it is essential that we have the right capabilities throughout our business. Its therefore critical that we are successful in our recruitment strategies, using a fair recruitment process free of discrimination

promoting equal treatment of all employees and job applicants. We have actively recruited large numbers of new colleagues and during 2018, we attracted 22 new colleagues to meet the demands as we grow as an organization. This equals a global growth for Hansa of 44% , the turn-over for Hansa was in 2018, 8%.

We promote gender equality, for example, through conducting wage mapping, to ensure that men and women have the same salary for the same work. In December 2018, gender distribution at Hansa was 58% women and 42% men. The Hansa management comprised of 40% women and 60% men.

Hansa's success is based on our ability to collaborate, both internally and externally. We do our utmost to provide a secure and safe workplace and a positive working environment based upon our conviction that a good working climate lays the foundation for job satisfaction and good relationships.

Financial review

Revenue and financial result

Net revenue for the 2018 financial year amounted to SEK 3.4 m (3.4) and comprised of royalty- and license revenue, milestone revenue and patent reimbursement from Axis-Shield Diagnostics.

Other operating income amounted to SEK 0.7 m (1.5) and is comprised mainly of grant from Vinnova. For the previous year, net currency differences are also included. Other operating expense, comprised of net currency differences, amounted to SEK 4.7 m (0) for the full year 2018.

Operating result for the 2018 financial year amounted to SEK -246.5 m (-176.1). During the year, expenses have increased as a result of intensified activities prior to applications for pharmaceutical approval and expansion of the organization in preparation for commercial launch. The result for 2018 includes reported costs for the Company's long-term incentive program (TO 2015, LTIP 2016 and LTIP 2018), which do not affect cash and cash equivalents of SEK 11.7 m (10.1).

Net profit/loss for 2018 amounted to SEK -248.0 m (-176.7).

Cash flow and financial position

Cash flow from operating activities amounted to SEK -204.6 m (-150.1) for the 2018 financial year. The cash flow after financing was positively impacted by the share issue in November. Cash and cash equivalents including short term investments amounted to SEK 858.2 m at the end of the 2018 financial year, as compared with SEK 616.1 m at the year-end 2017.

Investments

Investments during the 2018 financial year amounted to SEK 496.5m (243.3) Investments during 2018 related primarily to:

- Laboratory equipment in the amount of SEK 0.7 m
- Production equipment in the amount of SEK 1.1 m
- Capitalized patent expense of SEK 0.1 m
- Computer equipment in the amount of SEK 0.5 m
- Short term investments of commercial papers of SEK 494.0 m

Shareholders' equity

On December 31, 2018 equity amounted to SEK 859.9 m compared with SEK 630.7 m at the end of the financial year 2017.

Share issue 2018

In the fourth quarter, Hansa Biopharma finalized a directed share issue, which brought the Company SEK 453 m before deduction of costs. The directed issue was comprised of 1,776,765 shares at SEK 255 per share. The number of outstanding ordinary shares amounts to 39,959,890 shares after the share issue. The rights issue will be used to accelerate the preparations for the commercialization of imlifidase in kidney transplantation and for the continued development of the Company's existing development portfolio.

Parent company

The Parent company's net revenue for the 2018 financial year amounted to SEK 3.6 m (3.7). The result after net financial items for the Parent company amounted to SEK -248.3 m (-176.4) for the 2018 financial year. On December 31, 2018, cash and cash equivalents including short-term investments amounted to SEK 852.6 m compared with SEK 613.8 m at the end of 2017.

The Parent company's equity amounted to SEK 833.3 m as per December 31, 2018, as compared with SEK 625.5 m at the end of 2017.

The Group consists of the Parent company Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Immago Biosystems Ltd and Hansa Medical Inc. Hansa Medical Inc was registered in May 2018, and at end of 2018, there were three employees in the Company. Immago Biosystems Ltd is owner of patent rights to the EnzE concept.

Group – Key ratios and other information

	1 January – 31 December	
KSEK, unless other stated	2018	2017
Net revenue and profit		
Net revenue	3,358	3,442
Operating profit/loss	-246,498	-176,083
Net profit/loss	-247,974	-176,660
Per share data		
Earnings/loss per share before and after dilution (SEK)	-6,47	-4.97
Shareholders' equity per share (SEK)	21,52	16.68
Other information		
Shareholders' equity	859,876	630,661
Equity ratio (%)	91	93
Cash flow from operating activities	-204,560	-150,105
Cash and cash equivalents including short term investments	858,187	616,061
Number of employees end of the year	52	33

Organization and employees

At the end of 2018, the Board of Directors was chaired by Ulf Wiinberg and the members were Birgit Stattin Norinder, Stina Gestrelius, Angelica Loskog, Andreas Eggert and Anders Gersel Pedersen. The Board's audit committee consisted of Andreas Eggert (Chairman), Birgit Stattin Norinder and Ulf Wiinberg. The remuneration committee consisted of Birgit Stattin Norinder (chairman), Ulf Wiinberg and Anders Gersel Pedersen and the scientific committee consisted of Anders Gersel Pedersen (chairman), Birgit Stattin Norinder, Stina Gestrelius and Angelica Loskog.

The executive management consisted of CEO Søren Tulstrup; Senior Vice President, Research and Development Christian Kjellman; Vice President, Chief Financial Officer Eva-Maria Joed; Vice President, Business Development and Investor Relations Emanuel Björne; Vice President, Global Medical Affairs Vincenza Nigro; Vice President, Corporate Strategy Max Sakajja; Vice President, Commercial Operations Henk Doude van Troostwijk and Vice President, Regulatory Affairs Karin Aschan. The number of employees at the end of 2018 was 52, compared with 2017 when the number of employees was 33.

Share capital and ownership

Total shares outstanding as of December 31, 2018 comprised of 39,959,890 ordinary shares and 721,764 C-shares. At year end the share capital amounted to SEK 40,681,654. At the general meeting, each ordinary share entitles the holder to one vote and C-shares to one tenth of a vote each and do not entitle 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, 2018, the single largest shareholder in Hansa Biopharma was Nexttobe AB, with a total of 5,755,379 shares, representing 14.4 percent of the voting rights and the capital.

As part of the implementation of ongoing long-term incentive programs, the Company repurchased 401,000 C shares (LTIP 2016) in May 2018 and 391,503 C shares (LTIP 2018) in October 2018 to SEK 1 per share. The quota value for the repurchased shares is SEK 1 per share.

Share warrant program

Hansa Biopharma's Annual General Meeting adopted on June 2, 2015 a share warrant program for the Company's employees. 355,000 warrants were acquired by the Company's employees during 2015 and 2016. Each warrant entitles the holder to subscribe for one new share in Hansa Biopharma. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 15, 2018 to June 15, 2019. The warrants were sold to the Company's employees on market terms at a price established on the basis of an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute. The option program is subsidized by the Company, and the employees, except the former CEO, have been given a one-time bonus as part of the stock option purchase. The options are linked to continued employment with the Company only in the sense that, if the employment would be terminated, the stock option owner shall offer the warrants to the Company and repay the resulting subsidy. The subsidy has affected the Company's results proportionately during the option period in accordance with the same principles as in IFRS 2.

As of December 31, 2018, 305,000 out of 355,000 warrants have been exercised for subscription of shares at the subscription price SEK 44.15-44.85 per share and consequently 305,000 shares have been issued since June 15, 2018.

The increase in the Company's share capital upon full exercise of the share warrants will amount to SEK 355,000, and corresponds to a dilution of 0.9 percent of the total number of shares and the total number of votes in the Company.

Long-term incentive program (LTIP 2016)

The Hansa Biopharma's Extraordinary General Meeting 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 Hansa Biopharma Group, meaning that not more than 30 individuals within the group may participate. The rationale for LTIP 2016 is to create conditions for motivating and retaining competent employees of the Hansa Biopharma Group and for the alignment of the targets of the employees with those of the shareholders and the Company, as well as to increase the motivation of meeting and exceeding the Company's financial targets. A maximum of 305,000 rights may be allotted to participants under LTIP 2016. 289,750 rights have been allocated in total, of which 78,250 rights previously allocated have been excluded due to accelerated vesting or terminated, so remaining allocated rights as of December 31, 2018 are 211,500. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. The rights allocated are divided into two vesting periods, the first of which ends November 28, 2019 and the second May 18, 2020.

The general meeting further resolved, to implement LTIP 2016 cost effectively, to authorize the Board to decide on a directed share issue of a maximum of 401,000 Class C shares to a participating bank, of which a maximum of 96,000 Class C shares to be issued to cover any social costs arising from the program and to authorize the Board to resolve to repurchase all issued C-shares. The directed share issue of the 401,000 Class C-shares and the repurchase were executed in May 2018. After the conversion of C shares to ordinary shares, these shall partly be transferred to participants in LTIP 2016 and partly divested in the market for cash flow purposes to secure certain payments related to LTIP 2016, mainly social security costs. Not more than 305,000 ordinary shares can be transferred to participants under LTIP 2016 and 96,000 ordinary shares can be used to cover any social security contributions due to the LTIP 2016, which means a dilution of 1.0 percent of the ordinary shares and votes in the Company.

LTIP 2016 is reported in accordance with IFRS 2 which means that rights are expensed as a personnel cost over the vesting period. The cost of LTIP 2016, calculated in accordance with IFRS 2, including social security contributions is expected to amount to approximately SEK 28.4 m, of which SEK 13.1 m is included in the

results for the parent Company and the Group for the year 2018. The program is not expected to have any net effect on cash flow provided it is secured fully in the manner described above.

Long-term incentive program (LTIP 2018)

The Hansa Biopharma's Annual General Meeting May 29, 2018 resolved to adopt a long-term incentive program (LTIP 2018). Not more than 52 individuals within the Hansa Biopharma Group may participate in the program and are given the opportunity to acquire warrants at market value and/or receive so called performance-based share awards free of charge which, provided that certain conditions are met, may give the right to acquire shares in the Company. The rationale for LTIP 2018 is to create conditions for motivating and retaining competent employees of the Hansa Biopharma Group and for the alignment of the targets of the employees with those of the shareholders and the Company, as well as to increase the motivation of meeting and exceeding the Company's financial targets. A maximum of 491,419 warrants or 297,902 share rights may be allotted to participants under LTIP 2018.

6,701 warrants have been acquired by the participants in LTIP 2018 as of December 31, 2018. Each warrant entitles the holder to subscribe for one new share in Hansa Biopharma. The warrants were sold to the Company's employees on market terms at a price established based on an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute. For participants who have not yet joined the Hansa Biopharma-Group, acquisitions must be made at the current market value on the day of allocation. 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 subscription price will be the market value of the share at the offer for subscription of the warrants with an annual enumeration of 7 percent. This means that the subscription price after three years will amount to approximately 122.5 percent of the current market value of one ordinary share, and after four years amount to approximately 131.1 percent. Except for the CEO, all participants will be offered a subsidy to partially finance the acquisition of warrants. The subsidy will be equal to 25 percent of the warrant investment (after tax). The options are linked to continued employment with the Company only in the sense that, if the employment would be terminated, the stock option owner shall offer the warrants to the Company and repay the resulting subsidy. The subsidy will affect the Company's results proportionately during the option period in accordance with the same principles as in IFRS 2. At a maximum allocation of warrants, 491,419 warrants will be acquired by the participants, which means a dilution effect of approximately 1.2 percent of the number of shares and votes in the Company.

178,131 share rights have been totally allocated during the year, of which 580 have been excluded, remaining allocated rights as of December 31, 2018 are 171,756. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. A share right may be exercised 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 Hansa Biopharma-Group. The latest start date to receive Share Awards shall be the day prior to the Annual General Meeting 2019. The rights allocated are divided into two vesting periods, the first of which ends June 15, 2021 and the second November 30, 2021.

The general meeting further resolved, to implement LTIP 2018 cost effectively, to authorize the Board to decide on a directed share issue of a maximum of 391,503 Class C shares to a participating bank, of which a maximum of 93,601 Class C shares to be issued to cover any social costs arising from the program and to authorize the Board to resolve to repurchase all issued C-shares. The new share issue of 391,503 Class C shares and the repurchase was performed in October. After the conversion of C shares to ordinary shares, these shall partly be transferred to participants in LTIP 2018 and partly divested in the market for cash flow purposes to secure certain payments related to LTIP 2018, mainly social security costs. Not more than 297,902 ordinary shares can be transferred to participants under LTIP 2018 and 93,601 ordinary shares can be used to cover any social security contributions due to the LTIP 2018, which means a dilution of 1.0 percent of the ordinary shares and votes in the Company.

The cost for the share rights in LTIP 2018 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost calculated in accordance with IFRS 2 including social security contributions (based on social security tax of 31.42 percent), for the share rights allocated as of December 31, 2018, is expected to amount to approximately SEK 23.5 m, of which SEK 2.7 m is included in the results for the parent Company and the Group for the year 2018. The personnel cost for subsidy in connection with the acquisition of warrants amount to SEK 0.2 m for 2018.

The number of warrants and share rights allocated to the participants will vary depending on how the participants choose to allocate their Participant Values. Consequently, the dilution, costs and effect on key ratios will vary consequently. The maximum dilution effect of LTIP 2018, which combines two program types, occurs if all of participants choose to solely subscribe for warrants.

Guidelines for remuneration to senior management

The guidelines proposed by the Board of Directors entail that Executive Management 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 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, non-monetary benefits. The variable salary shall be 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 shall be possible in a total maximum amount of 24 monthly salaries. See Note 5 for information on the most recently adopted guidelines for remuneration to senior management.

Dividend

The Board of Directors proposes no dividend for the fiscal year 2018.

Other information

For additional information, please see the Corporate governance report.

Annual general meeting 2019

The annual general meeting of Hansa Biopharma AB (publ) will take place on May 22, 2019 in the auditorium at the Company's offices on Scheelevägen 22 in Lund. Notice to attend the annual general meeting will be published on Hansa Biopharma's website at www.hansabiopharma.com.

Events after the balance sheet date

European Medicines Agency Accepts Marketing Authorization Application for IDEFIRIX™ (imlifidase), January 2019

The European Medicines Agency (EMA) accepted the Company's Marketing Authorization Application (MAA) for review of IDEFIRIX™ (INN: imlifidase). Hansa is seeking approval of IDEFIRIX as a treatment to enable kidney transplantation in highly sensitized patients.

Regulatory Update for imlifidase in Kidney Transplantation in January, 2019

Hansa provided an update on its interactions with regulatory agencies regarding imlifidase in kidney transplantation. The Company's dialogue with the FDA to determine the path forward for regulatory filing and approval in the U.S. is ongoing and Hansa will provide updated guidance regarding the timeline for a potential Biologic License Application (BLA) following a subsequent meeting with the agency.

Lead candidate selected, NiceR

Lead candidate selected from the NiceR program, Novel IgG Cleaving Enzymes for Repeat dosing. The selected molecule has been developed to enable repeat dosing in several indications with significant unmet medical need in relapsing autoimmune diseases, chronic transplant rejection, oncology and repeat dosing of gene therapy.

Financial calendar

Interim report for January–March 2019	April 29, 2019
Annual General Meeting	May 22, 2019
Interim report for January–June 2019	July 18, 2019
Interim report for January–September 2019	October 31, 2019

Proposal for dividend

Unrestricted shareholders' equity in the Parent company

SEK	
Share premium reserve	1,400,456,077
Own shares	-721,764
Profit carried forward	-358,848,650
Result for the year	-248,296,974
Total	**792,588,689**

The Board of Directors proposes that the profits available for distribution and unrestricted reserves be allocated as follows

SEK	
Share premium reserve	1,400,456,077
Own shares	-721,764
Profit carried forward	-607,145,625
Total	**792,588,689**

The Group's and the Company's results and financial position are shown in the following income statements, balance sheets, 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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Scheelevägen 22, SE-223 63 Lund, Sweden

Postal address

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

Registration number

556734-5359

Financial statements

The Group

Income statement

		1 January – 31 December	
KSEK	Note	2018	2017
Net revenue	2, 3	3,358	3,442
Direct cost of net revenue		-916	-221
Gross profit		**2,442**	**3,221**
Other operating income	4	725	1,479
Sales, general and administration expenses		-90,387	-43,723
Research and development expenses		-154,558	-137,060
Other operating expenses	4	-4,720	
Operating profit/loss	5, 6, 7, 25	**-246,498**	**-176,083**
Financial expenses		-1,516	-616
Net financial income/expenses	8	**-1,516**	**-616**
Result before tax		**-248,014**	**-176,699**
Tax	9	40	39
Result for the year		**-247,974**	**-176,660**
Attributable to			
Parent company shareholders		-247,974	-176,660
		-247,974	**-176,660**
Earnings per share	10		
before dilution (SEK)		-6.47	-4.96
after dilution (SEK)		-6.47	-4.96

Statement of comprehensive income

		1 January – 31 December	
KSEK	Note	2018	2017
Result for the year		-247,974	-176,660
Other comprehensive income			
Items that have been, or may be reclassified to profit or loss for the year			
Translation differences for the year		65	-22
Changes in fair value for the year on available-for-sale financial assets		–	3,535
Items that cannot be reclassified to profit or loss for the year			
Shares valued to fair value as comprehensive income		21,029	–
Other comprehensive income for the year		**21,094**	**3,513**
Comprehensive income for the year		**-226,880**	**-173,147**
Total net comprehensive income attributable to			
The Parent company's owner		-226,880	-173,147
		-226,880	**-173,147**

Balance sheet

KSEK	Note	As of 31 December 2018	2017
ASSETS			
Fixed assets			
Intangible fixed assets	11	33,197	33,749
Tangible fixed assets	12	5,876	3,976
Financial fixed assets	14	39,528	18,508
Total fixed assets		**78,601**	**56,233**
Current assets			
Accounts receivable	17	58	508
Prepaid expenses and accrued income	18	929	320
Other receivables	16	7,046	7,293
Short term investments	25	418,746	34,983
Cash and cash equivalents	19	439,441	581,078
Total currents assets		**866,220**	**624,182**
TOTAL ASSETS		**944,821**	**680,415**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	20		
Share capital		40,682	38,208
Other paid in capital		1,400,512	946,570
Own shares		-722	-401
Reserves		30,895	9,801
Retained earnings including result for the year		-611,491	-363,517
Shareholders' equity attributable to Parent company shareholders		**859,876**	**630,661**
Total shareholders' equity		**859,876**	**630,661**
Long term liabilities			
Deferred tax liabilities	9	511	538
Other provisions	21	10,948	5,017
Long term liabilities, interest bearing	22	1,155	601
Total long-term liabilities		**12,614**	**6,156**
Current liabilities			
Current interest-bearing liabilities	22	101	–
Accounts payable		40,426	3,771
Other liabilities	23	5,562	7,285
Accrued expenses and deferred income	24	26,242	32,542
Total current liabilities		**72,331**	**43,598**
Total liabilities		**84 945**	**49,754**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**944 821**	**680,415**

Information regarding the Group's pledged assets and contingent liabilities, see note 27.

Changes in equity

		Equity attributable to the Parent company's shareholders							
KSEK	Note	Share capital	Additional contributed capital	Own shares	Translation reserve	Fair value reserve	Retained earnings including profit or loss for the year	Total	Total shareholders' equity
Opening shareholders' equity, 1 Jan 2017	20	35,055	429,207	–	-26	6,314	-186,857	283,693	283,693
Net comprehensive income									
Result for the year		–	–	–	–	–	-176,660	-176,660	-176,660
Other comprehensive income for the year		–	–	–	-22	3,535	–	3,513	3,513
Net comprehensive income		**–**	**–**	**–**	**-22**	**3,535**	**-176,660**	**-173,147**	**-173,147**
Transactions with the Group's owner									
New share issue		3,153	542,248	–	–	–	–	545,401	545,401
Expenses attributable to new share issue		–	-30,049	–	–	–	–	-30,049	-30,049
Issued warrants		–	190	–	–	–	–	190	190
Long term incentive program		–	4,974	–	–	–	–	4,974	4,974
Purchase own shares		–	–	-401	–	–	–	-401	-401
Total transactions with the Group's owner		**3 153**	**517 363**	**-401**	**–**	**–**	**–**	**520,115**	**520,115**
Closing shareholders' equity, 31 Dec 2017		**38 208**	**946 570**	**-401**	**-48**	**9 849**	**-363,517**	**630,661**	**630,661**

		Equity attributable to the Parent company's shareholders							
KSEK	Note	Share capital	Additional contributed capital	Own shares	Translation reserve	Fair value reserve	Retained earnings including profit or loss for the year	Total	Total shareholders' equity
Opening shareholders' equity, 1 Jan 2018	20	38,208	946,570	-401	-48	9,849	-363,517	630,661	630,661
Effect on opening balance on the transition to IFRS 9		–	–	–	–	321	-321	–	–
Adjusted shareholders' equity, 1 January 2018		**38,208**	**946,570**	**-401**	**-48**	**10,170**	**-363,838**	**630,661**	**630,661**
Net comprehensive income									
Result for the year		–	–	–	–	–	-247,974	-247,974	-247,974
Other comprehensive income for the year		–	–	–	65	21,029	–	21,094	21,094
Net comprehensive income		**–**	**–**	**–**	**65**	**21,029**	**-247,974**	**-226,880**	**-226,880**
Transactions with the Group's owner									
New share issue		2,169	451,298	–	–	–	–	453,467	453,467
Expenses attributable to new share issue		–	-20,712	–	–	–	–	-20,712	-20,712
Issued warrants		–	354	–	–	–	–	354	354
Long term incentive program		–	5,390	–	–	–	–	5,390	5,390
Purchase own shares		–	–	-392	–	–	–	-392	-392
Disposal own shares		–	4,403	71	–	–	–	4,474	4,474
By employees redeemed stock options		305	13,209	–	–	–	–	13,514	13,514
Total transactions with the group's owner		**2,474**	**453,942**	**-321**	**–**	**–**	**–**	**456,095**	**456,095**
Closing shareholders' equity, 31 Dec 2018		**40,682**	**1,400,512**	**-722**	**17**	**31,199**	**-611,812**	**859,876**	**859,876**

Cash flow statement

		1 January – 31 December	
KSEK	Note	2018	2017
Operating activities			
Operating income		-246,498	-176,083
Adjustment for items not included in cash flow [1]	30	13,444	13,827
Interest paid		-210	-638
Cash flow from operating activities before changes in working capital		**-233,264**	**-162,894**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) of account receivable		450	-434
Increase (-)/Decrease (+) of other operating receivables		-362	-3,835
Increase (+)/Decrease (-) of accounts payable		36,653	-2,711
Increase (+)/Decrease (-) of other operating liabilities		-8,037	19,769
Cash flow from operating activities		**-204,560**	**-150,105**
Investing activities			
Acquisition of intangible fixed assets		-127	-214
Acquisition of tangible fixed assets		-2,366	-2,195
Short term investments		-493,984	-240,898
Divestment short term investments		109,000	246,000
Cash flow from investing activities		**-387,477**	**2,693**
Financing activities			
New share issue [2]		453,075	545,401
Issue expenses		-20,712	-30,050
Purchase of own shares [2]		–	-401
Disposal of own shares [2]		4,473	–
Issued warrants		13,514	–
Repayment of leasing liabilities		-44	-48
Cash flow from financing activities		**450,307**	**514,902**
Net change in cash		-141,730	367,490
Cash and cash equivalents, beginning of year		581,078	213,588
Currency exchange variance, cash and cash equivalents		93	
Cash and cash equivalents, year-end		**439,441**	**581,078**

[1] Values for pertain mainly to costs of share based incentive programs including social contributions.

[2] Values for 2017 refer to directed share issue, repurchase of 401,000 class C shares for financing of the Company's long term incentive program (LTIP 2016) and directed share issue in Q4 2017 of 2,752,526 ordinary shares. In Q1 2018 70,739 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market. Values for 2018 refer to directed share issue in Q4 2018 of 1,776,765 ordinary shares.

Parent company

Income statement

		1 January – 31 December	
KSEK	Note	2018	2017
Net revenue	2, 3	3,603	3 739
Direct cost of net revenue		-916	-221
Gross profit		**2,687**	**3 518**
Other operating income	4	725	1,479
Sales, general and administration expenses		-85,938	-43,740
Research and development expenses		-159,137	-137,015
Other operating expenses	4	-4,720	–
Operating profit/loss	5, 6, 25	**-246,383**	**-175,758**
Result from financial items:			
Other interest income and similar profit/loss items		52	97
Interest expenses and similar profit/loss items		-1,966	-712
Result after financial items	8	**-248,297**	**-176,373**
Result before taxes		**-248,297**	**-176,373**
Tax	9		
Net result		**-248,297**	**-176,373**

Statement of comprehensive income

		1 January – 31 December	
KSEK	Note	2018	2017
Net result		-248,297	-176,373
Other comprehensive income		–	–
Other net comprehensive income		**–**	**–**
Net comprehensive income		**-248,297**	**-176,373**

Balance sheet

KSEK	Note	As of 31 December 2018	2017
ASSETS			
Fixed assets			
Intangible fixed assets	11	30,163	30,709
Tangible fixed assets	12	5,290	3,976
Financial fixed assets			
Interests in group companies	29	5,095	4,818
Other long term holdings of securities	15	12,499	12,499
Total financial fixed assets		17,594	17,317
Total fixed assets		**53,047**	**52,002**
Current assets			
Current receivables			
Accounts receivable	17	58	508
Receivables in group companies	13	2,834	469
Other receivables	16	7,038	7,291
Prepaid expenses and accrued income	18	939	320
Total currents receivables		10,869	8,588
Short term investments	25	418,746	34,992
Cash and cash equivalents	19	433,875	578,795
Total currents assets		**863,490**	**622,375**
TOTAL ASSETS		**916,537**	**674,377**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	20		
Restricted equity			
Share capital		40,682	38,208
Unrestricted shareholders' equity			
Share premium reserve		1,400,456	946,570
Own shares		-722	-401
Retained earnings		-358,849	-182,476
Net result		-248,297	-176,373
Total shareholders' equity		**833,270**	**625,528**
Long-term liabilities			
Other provisions	21	10,948	5,017
Liabilities to group companies		–	98
Long-term liabilities, non interest bearing	22	679	601
Total long-term liabilities		**11,627**	**5,716**
Current liabilities			
Accounts payable		40,333	3,724
Other liabilities	23	5,095	6,882
Accrued expenses and deferred income	24	26,212	32,527
Total current liabilities		**71,640**	**43,133**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**916,537**	**674,377**

Changes in equity

	Restricted equity	Unrestricted equity				
KSEK	Share capital	Share premium reserve	Own shares	Retained earnings	Result for the year	Total shareholders' equity
Opening shareholders' equity, 1 Jan 2017	35,055	429,207	–	-74,083	-108,393	281,786
Net comprehensive income						
Result for the year	–	–	–	–	-176,373	-176,373
Other comprehensive income for the year	–	–	–	–	–	–
Net comprehensive income	**–**	**–**	**–**	**–**	**-176,373**	**-176,373**
Appropriation of profits	–	–	–	-108,393	108,393	–
New share issue	3,153	542,248	–	–	–	545,401
Costs attributable to new share issue	–	-30,049	–	–	–	-30,049
Issued warrants	–	190	–	–	–	190
Long term incentive program	–	4,974	–	–	–	4,974
Purchase own shares	–	–	-401	–	–	-401
Closing shareholders' equity, 31 Dec 2017	**38,208**	**946,570**	**-401**	**-182,476**	**-176,373**	**625,528**

	Restricted equity	Unrestricted equity				
KSEK	Share capital	Share premium reserve	Own shares	Retained earnings	Result for the year	Total shareholders' equity
Opening shareholders' equity, 1 Jan 2018	38,208	946,570	-401	-182, 476	-176,373	625,528
Net comprehensive income						
Result for the year	–	–	–	–	-248,297	-248,297
Other comprehensive income for the year	–	–	–	–	–	–
Net comprehensive income	**–**	**–**	**–**	**–**	**-248,297**	**-248,297**
Appropriation of profits	–	–	–	-176,373	176,373	–
New share issue	2,169	451,298	–	–	–	453,467
Costs attributable to new share issue	–	-20,712	–	–	–	-20,712
Issued warrants	–	354	–	–	–	354
Long term incentive program	–	5,334	–	–	–	5,334
Purchase own shares	–	–	-392	–	–	-392
Disposal own shares	–	4,403	71	–	–	4,474
By employees redeemed stock options	305	13,209	–	–	–	13,514
Closing shareholders' equity, 31 Dec 2018	**40,682**	**1,400,456**	**-722**	**-358,849**	**-248,297**	**833,270**

Cash flow statement

		1 January – 31 December	
KSEK	Note	2018	2017
Operating activities			
Operating income		-246,383	-175,758
Adjustment for items not included in cash flow [1]	30	13,218	13,621
Interest paid		-607	-637
Cash flow from operating activities before changes in working capital		**-233,772**	**-162,774**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) of account receivable		450	-434
Increase (-)/Decrease (+) of other operating receivables		-2,731	-4,201
Increase (+)/Decrease (-) of accounts payable		36,609	-2,736
Increase (+)/Decrease (-) of other operating liabilities		-8,200	19,754
Cash flow from operating activities		**-207,644**	**-150,391**
Investing activities			
Acquisition of tangible fixed assets		-2,366	-2,195
Acquisition of financial assets		-277	–
Short term investments		-493,984	-240,898
Divestment short term investments		109,000	246,000
Cash flow from investing activities		**-387,627**	**2,907**
Financing activities			
New share issue [2]		453,075	545,401
Issue expenses		-20,712	-30,050
Purchase of own shares [2]		–	-401
Disposal of own shares [2]		4,474	–
By employees redeemed stock options		13,514	–
Cash flow from financing activities		**450,351**	**514,950**
Net change in cash		-144,920	367,466
Cash and cash equivalents, beginning of year		578,795	211,329
Cash and cash equivalents, year-end		**433,875**	**578,795**

[1] Values for pertain mainly to costs of share based incentive programs including social contributions.

[2] Values for 2017 refer to directed share issue, repurchase of 401,000 class C shares for financing of the Company's long term incentive program (LTIP 2016) and directed share issue in Q4 2017 of 2,752,526 ordinary shares. In Q1 2018 70,739 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market. Values for 2018 refer to directed share issue in Q4 2018 of 1,776,765 ordinary shares.

Notes

Note 1 Material accounting principles

(a) Compliance with norms and legislation
The consolidated accounts have been prepared in accordance 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 with the exception of those cases set forth below under the section entitled "The Parent company's accounting principles".

The annual report and the consolidated accounts have been approved for issuance by the Board and the Executive President April 11, 2019. Consolidated income statement, statement of other comprehensive income and balance sheet and the Parent company's income statement and balance sheet are subject to approval at the Annual General Meeting on May 22, 2019.

(b) Valuation grounds applied in the preparation of the financial reports
Assets and liabilities are reported at historic acquisition value, with the exception of certain financial assets and liabilities which are valued at net realizble value. Financial assets and liabilities valued at net realizable value consist of shares listed on an exchange, investments in interest-bearing commercial papers and contingent purchase price, 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) Assessments and estimates in the financial reports
Preparing the financial reports in accordance with IFRS requires that corporate management make assessments, estimates and assumptions which impact the application of the accounting principles and the reported amounts of assets, liabilities, revenues and costs. Actual results may deviate from these estimates and assessments.

The estimates and assumptions are reviewed regularly. Changes to estimates are reported in the period in which the changes are made, provided the change only affects this period, or in the period in which the changes were made and future periods, if the change affects both the current period and future periods.

Assessments made by the corporate management in the application of IFRS that have a significant impact on the financial reports and estimates made that may result in significant adjustments in the following financial year's financial statements are described in more detail in Note 33.

(e) Changes in accounting principles
(i) Changes in accounting principles due to new or amended IFRS
The Group applies IFRS 15 and IFRS 9 for the first time as of January 1, 2018. Other amendments to IFRS with effect from January 1, 2018 have not had any significant effect on the Group's accounts.

The transition methods that the Group has chosen to apply to the transition to IFRS 15 and IFRS9 mean that comparative information in the financial reports has not been recalculated to reflect the requirements of the new standards.

The transition effects of the first-time application of these standards are mainly related to:
› classification of accounting of holdings in interest funds

› classification of holdings in commercial papers

IFRS 9 Financial Instruments
IFRS 9 comes into force from January 1, 2018 and replaces IAS 39 Financial Instruments:
Accounting and valuation as the standard for accounting of financial instruments in IFRS. Compared with IAS 39, IFRS 9 changes relating in particular to the classification and valuation of financial assets and financial liabilities, impairment of financial assets and hedge accounting. There are no changes regarding hedge accounting for Hansa Biopharma because the Group does not apply hedge accounting. The effects regarding other parts of IFRS 9 are described below.

Classification and valuation of financial assets and financial liabilities
IFRS 9 has affected how the Group reports holdings in interest funds. Under IAS 39, these have been reported at fair value through other comprehensive income.However, the interest funds do not meet the criteria in IFRS 9 for accounting of changes in value through other comprehensive income as they neither constitute equity instruments nor give rise to payments of capital and interest only. Under IFRS 9, thus, the funds are reported at fair value via the income statement. As a result of the change, accumulated changes in the value of the interest funds summing up to SEK -403 k, has been trasferred from "Fair value reserve" to "Retained earnings" in the Group's opening balance sheet per January 1, 2018.

At the beginning of the year, the Group also had holdings of commercial papers which under IAS 39, were valued at fair value through other comprehensive income. Holdings of commercial papers are under IFRS 9 reported instead at accrued acquisition cost because they are considered to be held in a business model with the goal to collect the contractual cash flows while the commercial

papers only give rise to payment of principal and interest. The accumulated change in the value of the commercial papers of SEK -9k has been rebooked from Fair value reserve against the value of the commercial papers in the balance sheet so that these were reported at an amortized cost of SEK 34,992k in the Group's opening balance sheet as of 1 January 2018.

The Group has chosen to report the holding of the shares in Genovis at fair value through other comprehensive income under IFRS 9. The transition to IFRS 9 had no effect on the accounting of this holding since the shares were previously classified as "available-for-sale financial assets"

IFRS 9 has not affected how the Group classifies and values financial liabilities.

			As of 1 January	
KSEK	Original classification in accordance with IAS 39	New classification in accordance with IFRS 9	Reported value in accordance with IAS 39	Reported value in accordance with IAS 9
Financial assets				
Listed shares	Available-for-sale financial assets	Fair value through other comprehensive income	18,508	18,508
Commercial papers	Available-for-sale financial assets	Accrued acquisition value	34,983	34,992
Holdings in interest funds [1]	Available-for-sale financial assets	Fair value through the income statement	–	–
Cash and cash equivalents, accounts receivable and other receivables	Loan and accounts receivable	Accrued acquisition value	586,679	586,679
Total financial assets	**–**	**–**	**640,170**	**640,179**
Financial liabilities				
Conditional purchase price	Fair value through the income statement	Fair value through the income statement	601	601
Short-term interest-bearing liabilities and accounts payable	Accrued acquisition value	Accrued acquisition value	3,771	3 771
Total financial liabilities	**–**	**–**	**4,372**	**4,372**

[1] No amount is reported for Holdings in interest funds as of January 1, 2018 when the business day for the funds was before the year end, but the settlement date came after the year end. Since Hansa Biopharma applies liquidation accounting, the acquisition of the fixed income funds was only reported after January 1, 2018.

The table below shows valuation categories for financial assets and financial liabilities according to previously accounting principles (IAS 39) and under IFRS 9

The following table summarizes the effect of the transition to IFRS 9 on fair value reserve and retained earnings.

KSEK	Effect on opening balance on the transition to IFRS 9
Fair value reserve	
Accumulated changes in the value of interest funds	403
Accumulated changes in the value of commercial papers	9
Tax	-91
Effect January 1, 2018	**321**
Retained earnings	
Accumulated changes in the value of interest funds	-403
Accumulated changes in the value of commercial papers	-9
Tax	91
Effect January 1, 2018	**-321**

Impairment of financial assets
The Group's exposure to credit risk in accounts receivable is very limited and Hansa Biopharma has not suffered any credit losses in the past five years. The introduction of the new model for Impairment losses in IFRS 9 have thus not had any material impact on impairment testing of receivables. Instead, the Group's exposure to credit risk is mainly attributable to bank balances as well as holdings of funds. Fund units are reported at fair value through profit or loss under IFRS 9, which means that no reserve for expected credit losses is reported for the fund units. For the bank balances there is nor any significant reserve for expected credit losses to be reported since the maturity is very short while the balances exist with banks with high creditworthiness.

IFRS 15 Revenue from contracts with customers
IFRS 15 is a comprehensive standard for determining the size of revenue to be reported and when revenue must be reported. It replaces IAS 18 Revenue.

Hansa Biopharma has developed a method for HBP analysis that is used to predict severe sepsis in emergency clinics. The method has been out-licensed to the partner Axis-Shield Diagnostics. According to the agreement with Axis-Shield, Hansa Biopharma has the right to receive royalties (with a certain minimum level) as compensation for the right Axis-Shield has to use the method developed by

Hansa Biopharma and at the same time the Group has the right to regularly receive compensation for the patents being maintained. In addition, additional compensation may apply when Axis-Shield conducts a sale where the method developed by Hansa Biopharma for HBP analysis is included. According to the agreement Hansa Bipharma is also entitled to receive compensation in cases where Axis-Shield achieves certain milestones in developing. Payment of royalties at a minimum level is received annually and has before the introduction of IFRS 15 been accrued over the period the remuneration refers to, while remuneration for maintenance of the patents has been recognized as revenue as the services has been executed.

The agreement with Axis-Shield entails an out-licensing of the Group's method for HBP analysis. The license gives Axis-Shield's right to access to Hansa Biopharma's intellectual property regarding HBP analysis during the license period within the meaning of IFRS 15.B56, this because the agreement requires Hansa Biopharma to conduct activities that substantially affect the intellectual property rights (such as maintenance of the patents) during the license period, which in turn affects Axis-Shield as a license holder.

According to IFRS 15.B60, a license that entitles the licensee to access the intellectual property during the license period and which meet the criteria in IFRS 15.B58 is reported over time. Hansa Biopharma has done the assessment that the agreement with Axis-Shield fulfills these criteria and that the income in the form of the minimum royalty received will also report over time under IFRS 15. At the same time, the Group has made the assessment that revenues from maintenance of patents also should be credited as the services (performance commitment) are performed. The introduction of IFRS 15 has thus not led to any changes compared with previous accounting principles under IAS 18 regarding reporting of revenue from the agreement with Axis Shield.

(ii) New IFRS that have not yet begun to apply

A number of new or amended standards and interpretations in the IFRS do not enter into force until the next financial year and have not been applied early in conjunction with the preparation of these financial statements. New items or changes with a future application are not planned to be implemented as early application.

IFRS 16 Lease

The Group will apply IFRS 16 Lease from January 1, 2019. IFRS 16 introduces a uniform lease accounting model for lessees. A lessee reports a right-of-use asset the underlying asset and a lease debt that represents an obligation to pay lease charges. There are exceptions for short-term leases and leasing of low-value assets. Accounting for lessor is similar to the current standard, i.e. lessors continue to classify leases as financial or operational leasing.

IFRS 16 Lease replaces from 2019 existing IFRS releated to recognition of lease, such as IAS 17 Lease and IFRIC 4 Determining whether an agreement contains a lease.

The Group will report new assets and liabilities for operational leasing agreements regarding office premises and some technical equipment. The costs of these leases will change, as the Group will account for depreciation for right-of-use assets and interest expenses for leasing liabilities.

Previously, the Group reported operating leasing costs on a straight-line basis over the lease term and reported assets (prepaid leasing fees) and liabilities (accrued leasing fees) only to the extent that there was a difference between actual leasing fees and reported cost.

The Group will apply the modified retroactive method to the transition to IFRS 16. This means that comparative figures for 2018 will not be recalculated. The right-of-use assets will be included in the transition to IFRS 16 to be reported at the value of the liability as of January 1, 2019, with the addition of advance payments reported in the balance sheet as of December 31, 2018.

Based on the information available, the Group calculates that it will report further lease liabilities of SEK 14m and right-of-use assets of SEK 14m. As right-of-use assets are set equal to leasing liabilities, no deferred tax effect or impact on equity arise as of January 1, 2019.

The effect on operating result after tax is expected to be insignificant. Cash flow from operating activities is expected to increase and from financing activities to decrease by SEK 4m due to the fact that the leasing fees' amortization part will be reported as payment in the financing activities.

Leases of low value (assets of less than SEK 50k) – which consists mainly of water dispenser and printers / copiers – will not be included in the lease debt but continuing to be reported with linear expense over the lease term. Furthermore, leases with a lease period of maximum 12 months will not be included in the leasing debt.

Due to the fact that leasing fees for low-value leases and short-term leases are included in the note regarding minimum lease payments for operational leases in the present annual report (see Note 26), the above mentioned lease debt amounts to an amount below the present value of these minimum lease payments of SEK 1m.

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

(f) Classification

Fixed assets and long-term liabilities consist, in all material respects, of amounts expected to be recovered or paid after more than 12 months calculated from the balance sheet date. Current assets and current liabilities consist, in all material respects, of amounts expected to be recovered or paid within 12 months calculated from the balance sheet date.

(g) Operating division reporting

An operating division is a part of the Group which conducts operations from which it can generate revenues and incur costs and for which independent financial information is available. The earnings of an operating division are monitored by the company's most senior executive officer in order to evaluate the earnings and to be able to allocate resources to the operating division. Since the Group's business is organized as a cohesive business with similar risks and opportunities for the goods and services produced, the Group's entire business constitutes a single operating division. The entire business is conducted in Sweden.

(h) Consolidation principles

(i) Subsidiary

Subsidiaries are companies under the controlling influence of Hansa Biopharma AB.

Subsidiaries are accounted for using the purchase method. The method means that acquisition of a subsidiary is regarded as a transaction whereby the Group indirectly acquires the assets and assumes its liabilities. The acquisition analysis determines the fair value at the acquisition date of the identifiable assets acquired and liabilities assumed and any non-controlling interest.

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

(ii) Transactions eliminated during 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 to the functional currency at the currency exchange rate in effect on the transaction date. The functional currency is the currency in the primary financial environments in which the companies conduct their business operations. Monetary assets and liabilities in foreign currency are translated to the functional currency at the currency exchange rate in effect on the balance sheet date. Currency rate differences which arise in the translations are reported in the earnings for the year. Non-monetary assets and liabilities which are reported at their historical acquisition values are translated to the currency exchange rate at the time of the transaction. Non-monetary assets and liabilities which are reported at net realizable values are translated to the functional currency at the exchange rate in effect at the time of the net realizable value valuation.

(ii) Financial statements of foreign operations

Assets and liabilities in foreign operations, including goodwill and other consolidated over- and undervalues, is translated from the functional currency of the foreign operation to the Group's reporting currency, Swedish kronor, to the exchange rate prevailing on the balance sheet date. Revenues and expenses in a foreign operation are translated into Swedish kronor, at an average exchange rate that approximates the exchange rates presented at each transaction time. Translation differences arising from foreign currency translation of foreign operations are reported in other comprehensive income and is accumulated in a separate component of equity, referred to as the translation reserve.

(j) Net sales

(i) Royalty revenues

Hansa Biopharma has developed a method for HBP analysis that is used to predict severe sepsis in emergency clinics. The method has been out-licensed to the partner Axis-Shield Diagnostics. According to the agreement with Axis-Shield, Hansa Biopharma has the right to receive royalties (with a certain minimum level) as compensation for the right Axis-Shield has to use the method developed by Hansa Biopharma. In addition, additional compensation may apply when Axis-Shield sells products where the method developed by Hansa Biopharma for HBP analysis is included.

The agreement with Axis-Shield entails an out-licensing of the Group's method for HBP analysis. The license gives Axis-Shield's right to access to Hansa Biopharma's intellectual property regarding HBP analysis during the license period within the meaning of IFRS 15. This because the agreement requires Hansa Biopharma to conduct activities that substantially affect the intellectual property rights (such as maintenance of the patents) during the license period, which in turn affects Axis-Shield as a license holder. According to IFRS 15, a license means that the licensee has the right to access the intellectual property recognized for income over time. Received payments of minimum royalty is thus accrued and recognized as income during the period to which the royalty refers.

Any sales-based royalties are first recognized when the sale has taken place that gives Hansa Biopharma right to sales-based royalty.

(ii) Milestone revenues

According to the agreement with Axis-Shield, Hansa Bipharma is also entitled to receive compensation in cases where Axis-Shield achieves certain milestones in developing. The Group only recognizes revenue when it is clear that the Group has the right to receive the compensation.

(iii) Patent remuneration

Hansa Biopharma is also entitled to compensation for maintaining the patents connected to HBP analysis. Remuneration for maintenance of the patents has been recognized as revenue as the services are executed.

(iv) Government grants

Government grants are recognized in the balance sheet as accrued income when there is reasonable certainty that the grant will be obtained and that the Group will meet the conditions associated with the grant. Grant are systematically accrued in the profit for the year in the same way and over the same periods as the costs of the contributions intended to compensate for.

(k) Leasing

(i) Operational leasing agreements

Costs regarding operational leasing agreements are reported in the earnings for the year using a straight line method over the leasing term. Benefits obtained in conjunction with the execution of an agreement are reported in the earnings for the year as a reduction in the leasing fees using a straight line method over the term of the leasing agreement. Variable fees are booked as expenses in the periods in which they arise.

(ii) Financial leasing agreements

Minimum leasing fees are allocated between interest expenses and amortization on the outstanding debt. The interest expense is allocated over the leasing term so that an amount is booked in each reporting period which corresponds to a fixed rate of interest for the debt reported in each respective period. Variable fees are booked as expenses in the periods in which they arise.

(l) 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.

(m) Taxes
Income tax consists of current taxes and deferred taxes. Income tax is reported in the earnings for the year with the exception of 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 balance sheet date. 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. In addition, temporary differences related to shares in subsidiaries and affiliated companies which 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 balance sheet date.

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

(n) Financial instruments
Financial instruments which are reported in the statement of financial position include, on the assets side, cash and equivalents, accounts receivable, other financial claims and listed shares. On the liability side, accounts payable, interest-bearing liabilities and other financial liabilities are reported.

(i) Accounting and valuation at the first accounting date
Accounts receivable and debt instruments are reported when they are issued. Spot purchases and spot sales of financial assets are reported 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 profit or loss for which transaction expenses are instead expensed when they arise. Accounts receivable (without a significant financing component) are initially valued at the transaction price as determined in accordance with IFRS 15.

(ii) Classification and valuation of financial assets
At the first accounting date, a financial asset is classified as valued at accrued acquisition value, fair value through other comprehensive income (debt instrument investment), fair value through other comprehensive income (equity investment), or fair value through profit or loss. The following describes how the Group's various holdings of financial assets have been classified:

Holdings of listed shares
The Group holds shares in Genovis which are listed on First North. Since this is a long-term holding, Hansa Biopharma has chosen to report the shares at fair value through other comprehensive income, instead of at fair value through profit or loss.

Holdings of interest funds
The Group's holdings of interest funds are reported at fair value through the income statement. This because the shares (seen from the fund's perspective) constitute debt instruments while the fund shares are not only gives rise to payment of principal and interest.

Other financial assets
All other financial assets are reported at accrued acquisition value. This is because they 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 of payments of principal and interest.

(iii) Classification and valuation of financial liabilities
Financial liabilities are classified as valued at accrued acquisition value or valued at fair value through the income statement. Financial liabilities that are measured at fair value through the income statement consist of conditional purchase prices. Other financial liabilities are valued at accrued acquisition value.

(iv) Classification of financial instruments before January 1, 2018
Prior to January 1, 2018, the Group's holdings of listed shares, funds and holdings of commercial papers were classified as "available-for-sale financial assets" under IAS 39. Other financial assets were classified as "loans and accounts receivables". All financial liabilities were valued under IAS 39 at accrued acquisition value, with the exception of liabilities for contingent purchase price, which was reported at fair value through the income statement.

(v) Removal from the balance sheet
Financial assets
A financial asset is deleted from the balance sheet when the rights to the cash flows from the financial asset cease or if it transfers the right to receive cash flows through a transaction in which substantially all the risks and benefits of ownership have been transferred or in which the Group does not transfer or substantially retain all the risks and benefits of ownership and it does not retains control of the financial asset.

Financial liabilities
The Group deletes a financial liability from the balance sheet when the commitments specified in the agreement are completed, canceled or terminated. The Group also deletes a financial liability 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.

(o) Tangible fixed assets
Tangible fixed assets are reported by the Group at acquisition value after deductions for accumulated depreciation and any write- downs. The acquisition value includes the purchase price and expenses direct attributable to bring it in place and in order in accordance with the purpose of the acquisition. The accounting principles for write-downs are set forth below.

The reported value for a tangible fixed asset is deleted from the balance sheet upon disposal or sale or where no future economic advantages are anticipated from the use or disposal/sale of the asset. Profits or losses which arise upon the sale or disposal of asset consist of the difference between the sales price and the reported value of the asset less any direct sales costs. Profits and losses are reported as other operating income/expenses.

Depreciation is carried out using the straight line method over the anticipated life of the asset. Real property is not depreciated.

Anticipated useful life:

Office equipment, tools and fixtures and fittings	3–10 years

(p) Intangible fixed assets
Acquired intangible assets
Acquired intangible assets held by the Group consists of patents and capitalized development expenses activated at the time of the acquisition. These intangible assets are reported at the acquisition value minus accumulated depreciation and any impairment (see accounting principle (q)). Depreciation is made to allocate the cost of development projects over their estimated useful life and commences when the project starts to generate revenue.

Accrued expenses for internally-generated goodwill and internally-generated trademarks are reported in the profit/loss for the year at the time at which the cost arises.

Anticipated useful life:

Patent expenses	17 years
Capitalized development fees	15 years

Capitalized development expenditures
Costs for research are immediately booked as an expense and there is no capatilized development expense.

Expenses for development projects are reported as intangible assets if the company can show that it is technically possible to pursue and profitable to commercialize the result and only on the expenditure for this project can be measured reliably. This means in practice that expenditure is not capitalized before the pharmaceutical authority FDA in the US or the EU Medicines Agency EMEA has given its approval due to the level of uncertainty connected to the approval process. Similarly, expenses for pharmaceutical substances have been expensed pending approval by the authorities. Once approval is obtained, these type of future expenses for the project will be capitalized. Acquired development projects are capitalized at the time of acquisition.

(q) Impairment
The Group's reported assets are assessed on each balance sheet date in order to determine whether there is an indication of a need for a write-down. IAS 36 is applied regarding impairment of assets other than financial assets which are reported according to IFRS 9.

(i) Impairment of intangible assets
For intangible assets with an indeterminate useful life and intangible assets which are not yet subject to depreciation according to plan, an annual assessment is carried out of the recovery value, which is the net realizable value or the use value, whichever is higher. Upon calculation of the use value, future assessed cash flow is discounted at a rate of interest which takes into consideration the market's assessment of risk-free interest rate and the risk associated with the specific asset.

(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 the longer exists and that there has been a change in the assumptions which formed the basis for the calculation of the recovery value. Impairment of goodwill are never reversed, however. 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 depreciation where relevant, if no write-down had been made.

(iii) Impairment of financial assets
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. Impairment of goodwill are never reversed, however. 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 depreciation where relevant, if no write-down had been made.

(iv) Impairment of financial assets
For financial assets valued at accrued acquisition value, 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 is reported at the present time due to materiality, the amount of accounts receivable is small.

(iv) Principle for impairment before January 1, 2018
Before January 1, 2018, Hansa Biopharma evaluated whether there is objective evidence that a financial asset or group of assets is in need of impairment. Objective evidence consisted partly of observable occured conditions and which had a negative impact on the possibility of recovering the acquisition value, and partly of significant or prolonged reduction in the fair value of an investment in a financial investment classified as a financial asset that can be sold.

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

(s) 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 current financial year and for the comparison years since the company had warrants and share rights as part of the outstanding incentive programs. These shares are not yet dilutive mainly because the result for the year is negative and earnings per share after dilution may not show a lower loss per share than earnings per share before dilution. If the company shows positive results in the future, these options will result in dilution.

(t) Remuneration to employees
(i) Short-term remuneration
Short-term remuneration to employees is calculated without any discounting and reported as an expense when the relevant services are received.

(ii) Defined contribution pension plans
Plans where the company's obligations are limited to the fees 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 fees which the company pays into the plan, or to an insurance company, and the return on capital which the fees 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 statement as they are earned by the employees performing their services on behalf of the company during a given period of time.

(iii) Sharebased payments
A share warrant program was initiated in 2015 enabling employees to acquire shares in the company.The share warrant program is subsidized by Hansa Biopharma and participants (except the former CEO) have received a one-time bonus as part of the purchase option. The value of the subsidy is charged to consolidated earnings over the vesting period.

In 2016 a long-term incentive program (LTIP 2016) was initiated. The participants in the program will be given the oppurtunity to receive ordinary shares if employment during the entire vesting period and a performance condition linked to the share's total return during the period. The fair value of the allotted share rights takes into account the conditions for a certain return on equity during the vesting period. The fair value of allocated share rights is reported as a personnel cost with a corresponding increase in equity. The fair value is calculated at the time of grant and is distributed over the vesting period. The cost reported 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 achieving a certain return during the vesting period. This cost is adjusted in subsequent periods in order to ultimately reflect the actual number of earned share rights. However, adjustment is not made if confiscation is only due to the fact that the return on equity returns is not met. Social costs relating to share-based payments to employees as compensation for services rendered are expensed in the periods in which the services are performed. The charge is based on the fair value of the share-based instruments at the time of the report.

In 2018 a long-term incentive program (LTIP 2018) was initiated. The participants in the program are given the oppurtunity to receive warrants and/or ordinary shares if certain performance conditions are met. The LTIP 2018 consist of two parts; share warrants and share rights.

The share warrant program part is subsidized by Hansa Biopharma and participants (except the CEO) can receive a one-time bonus as part of the purchase option. The value of the subsidy is charged to consolidated earnings over the vesting period.

For the share rights in the program; the participants will be given the oppurtunity to receive ordinary shares if employment during the entire vesting period and a performance condition linked to the share's total return during the period. The fair value of the allotted share rights takes into account the conditions for a certain return on equity during the vesting period. The fair value of allocated share rights s reported as a personnel cost with a corresponding increase in equity. The fair value is calculated at the time of grant and is distributed over the vesting period. The cost reported 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 achieving a certain return during the vesting period. This cost is adjusted in subsequent periods in order to ultimately reflect the actual number of earned share rights. However, adjustment is not made if confiscation is only due to the fact that the return on equity returns is not met. Social costs relating to share-based payments to employees as compensation for services rendered are expensed in the periods in which the services are performed. The charge is based on the fair value of the share-based instruments at the time of the report.

(u) 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 balance sheet 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.

(v) Contingent liabilities
A contingent liability is reported when there is a possible undertaking derived from past events, the existence of which is confirmed only by one or more uncertain future events beyond the control of the Group, or when there is an undertaking which is not reported as a liability or provision on the grounds that it is not probable that an outflow of resources will be required or cannot be calculated with sufficient reliability.

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.

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.

Changed accounting principles
Unless otherwise stated below, the Parent company's accounting principles in 2018 have changed in accordance with what stated above for the Group. Whether the changes in RFR 2 as a result of the introduction of IFRS 9 or the introduction of IFRS 15 has had no significant impact on the Parent company. Implementation of IFRS 16 as of January 1, 2019 will not affect the Parent company because RFR 2 allows IFRS 16 not to be applied in legal personality.

Classification and layout
The differences apparent in the Parent company's income statements and balance sheets as compared with the Group's statements consist primarily of the reporting of financial income and expenses, fixed assets and shareholders'equity.

Financial instruments
The Parent company does not apply IFRS 9 in legal personality. Long-term securities holdings are reported at acquisition value less any impairment losses. Short-term investments valued according to the lowest value principle.

Note 2 Net revenue

Income per significant category of income

	1 January – 31 December	
KSEK	2018	2017
Group		
Net revenue		
Royalty and license revenue	2,071	2,140
Milestone revenue	621	685
Patent reimbursement	666	617
	3,358	**3,442**
Parent company		
Net revenue		
Royalty and license revenue	2,071	2,140
Milestone revenue	621	982
Patent reimbursement	911	617
	3,603	**3,739**

Hansa Biopharma has developed a method for HBP analysis that is used to predict severe sepsis in emergency clinics. The product has been licensed out to the partner Axis-Shield Diagnostics. According to the agreement with Axis-Shield, Hansa Biopharma is entitled to continuously receive mimimum royalty of USD 250k annually until the underlying patent expires. Received payments of minimum royalty is thus accrued and recognized as income during the period to which the royalty refers. In 2018, the company received a total of USD 250k (250) in royalty.

In addition, additional compensation may apply when Axis-Shield conducst a sale where the developed method for HBP analysis is included or in cases where Axis-Shield achieves certain milestones in developing. The Group only recognizes revenue when it is clear that the Group has the right to receive the compensation.

The company has received compensation for maintaining patents. This compensation is called patent reimbursement. Patent reimbursement has been recognized as revenue as the services are executed.

Payment term for the revenue and reimbursement from Axis-Shield Diagnostics is 30 days net.

The Group's and the Parent Company's revenues from agreements with customers coincide with the reported net revenue.

Contract balances
In January 2018, the Group received a minimum royalty amounting to USD 250k. This has been reported as prepaid income during the year and is at year-end recognized as income in its entirety. As of the balance sheet date, there were therefore no outstanding contractual liabilities. The Group has no contractual assets. Accounts receivable are reported on a separate line in the balance sheet.

Note 3 Operating segment

To a significant extent, Hansa Biopharma's business currently consists of research and development for production of pharmaceuticals. The Company is of the opinion that this business, in its entirety, constitutes a single operating segment. Operations are conducted in Sweden and the USA. Income is derived from Sweden and fixed assets are mainly allocated to Sweden.

Note 4 Other operating income and expenses

Group	1 January – 31 December	
KSEK	2018	2017
Other operating income		
Government grant	725	1,439
Profit on sale of fixed assets	–	37
Net currency variances on receivables/liabilities from operating activities	–	3
	725	**1 479**
Other operating expenses		
Net currency variances on receivables/liabilities from operating activities	-4,720	–
	-4,720	**–**

Parent company	1 January – 31 December	
KSEK	2018	2017
Other operating income		
Government grant	725	1,439
Profit on sale of fixed assets	–	37
Net currency variances on receivables/liabilities from operating activities	–	3
	725	**1 479**
Other operating expenses		
Net currency variances on receivables/liabilities from operating activities	-4,720	–
	-4,720	**–**

Government grant

The government grant comes from the Eurostar project "SaferBiopharma" via Vinnova. The project is a collaborative project with Hansa Biopharma, Syddansk Universitetet and Alphalyse A/S in Denmark. Hansa Biopharma's share of the total grant is SEK 2.3 m.

Note 5 Employees and personnel costs

Costs for remuneration to employees

	1 January – 31 December	
KSEK	2018	2017
Group		
Salaries and remuneration, etc.	43,404	32,714
Share-based remuneration	11,675	10,067
Pension costs, contribution plan	4,650	4,682
Social charges	14,875	8,542
	74,604	**56,005**

Average number of employees

	2018		2017	
	Number	of which men	Number	of which men
Parent company				
Sweden	41	41%	32	33%
Total Parent company	41	41%	32	–
Subsidiaries				
US	1	–	–	–
Total subsidiaries	**1**	**–**	**–**	**–**
Total Group	**42**	**41%**	**32**	**33%**

Breakdown of corporate management according to gender

	Share of woman	
	2018-12-31	2017-12-31
Parent company		
Board of Directors	50%	50%
Other senior management	38%	38%
Total group		
Board of Directors	50%	50%
Other senior management	38%	38%

Salaries, other remuneration and employer payroll taxes

KSEK	2018	2017
Parent company		
Salaries and remuneration	40,164	32,714
Share-based remuneration	11,619	10,067
Social charges	19,251	13,224
(of which, pension costs)	[1] (4,630)	[1] (4,682)

[1] Of the Parent company's pension costs, SEK 0 (859) relates to the Board of Directors and CEO.

Salaries and other remuneration broken down between senior management and other employees

	2018		2017	
KSEK	Senior management	Other employees	Senior management	Other employees
Parent company				
Sweden	20,079	20,439	16,321	16,584
(of which commissions and similar remunerations)	(1220)	–	(3 340)	–
Parent company total	20,079	20,439	16,321	16,584
(of which commissions and similar remunerations)	(1 220)	–	(3 340)	–
Group	20,687	–	16,321	–
(of which commissions and similar remunerations)	(1220)	–	(3 340)	–
Group total	**20,687**	**–**	**16,321**	**–**

Benefits for senior management

Remuneration to Board of Directors

Fees are payable to the chairman of the Board of Directors and other directors pursuant to a resolution adapted by the annual general meeting. The 2018 annual general meeting resolved that fees paid to directors for work during 2018 will be SEK 900,000 to the chairman of the Board of Directors and SEK 300,000 to each of the other directors, SEK 40,000 to the chairman and SEK 30,000 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 Committe, however no fee is payable to Angelica Loskog. There are no contracts regarding severance compensation or other benefits for the chairman of the Board of Directors or other directors.

Remuneration to CEO

Remuneration

To the acting CEO, remuneration has been paid in the form of a fixed consultancy fee corresponding to base salary of SEK 510,000, but no pension. The current CEO has received a monthly base salary of SEK 317,000 and SEK 95,000 for pension remuneration. The CEO is responsible for his pension provision, thus the Company has no direct pension cost for the CEO. In 2018 the remuneration paid to the current CEO was SEK 3,912 k, to the acting CEO SEK 1,772 k and to the former CEO SEK 796 k.

Notice of termination periods and severance compensation

Upon termination by the Company or the CEO, a one month notice of termination period has been applied for the acting CEO. Upon termination by the Company the acting CEO has not had any right to severance compensation at the end of his employment. The above-stated also applies upon termination by the CEO where the grounds for termination are gross breach of contract by the Company. Under the current agreement, a mutual notice period of six months applies for the current CEO. In case of termination by the Company the CEO is entitled to severance pay corresponding to six monthly salaries.

Pension remuneration

No pension provision has been done for neither the acting nor the current CEO.

Remuneration paid to other members of group management

Remuneration

Remuneration is determined by the CEO following the approval of the chairman of the Board of Directors. Remuneration in 2018 for members of group management other than CEO amounted to SEK 17 521k. Lena Winstedt and Shmuel Agus are not in the management team at the end of the year.

Notice of termination period and severance compensation

Other members of group management have three or six months' notice of termination upon termination by them or the Company. Where applicable, the Company shall observe the longer notice of termination period set forth in the Employment Protection Act. During their notice period, other members of group management are entitled to full salary and other employment benefits. Four of the other members of group management are entitled to severance compensation of six months.

Pension compensation

Other members of group management are entitled to retire as follows. Emanuel Björne's, Christian Kjellman's, Eva-Maria Joed's, Karin Aschan's and Max Sakajja's employment terminate at the age of 65 without any requirement of notice. However they are entitled to continue working until 67 years of age. Henk Doude van Troostwijk's and Vincenza Nigro's employment terminates without any requirement of notice at the age with right to retirement age according to Dutch Old Age Pension Act (AOW) respective US old-age pension law. Other members of group management, with the exception of Eva-Maria Joed, Karin Aschan, Henk Doude van Troostwijk, Vincenza Nigro and the CEO are entitled to pension benefits in accordance with the Company's insurance and pension policy.

Salary and other remuneration and other benefits paid to senior management, Parent company 2018

KSEK	Base salary Directors' fees	Variable compensation	Share-based payments	Pension cost	Other benefits	Total
Chairman of the Board of Directors Ulf Wiinberg *	2,559	–	–	–	–	2,559
Director Birgit Stattin-Norinder	467	–	–	–	–	467
Director Stina Gestrelius	290	–	–	–	–	290
Director Angelica Loskog	–	–	–	–	–	–
Director Anders Gersel-Pedersen	210	–	–	–	–	210
Director Andreas Eggert	204	–	–	–	–	204
Director Per-Olof Wallström	103	–	–	–	–	103
Director Hans Schikan ***	481	–	–	–	–	481
Current CEO	3,912	–	1,216	–	59	5,187
Acting CEO	796	–	–	–	–	796
Other senior management (7 persons)	9,153	1,220	5,915	1,180	625**	18,093
Total	**18,175**	**1,220**	**7,131**	**1,180**	**684**	**28,390**

*) Of which SEK 1,772 k is fee for acting CEO and SEK 787 k is fee for Chairman of the Board.

**) The amount relates to severance pay to Shmuel Agus.

***) For Hans Schikan paid consulting fees of SEK 270 k is included.

Salary and other remuneration and other benefits paid to senior management, Parent company 2017

KSEK	Base salary Directors' fees	Variable compensation	Share-based payments	Pension cost	Other benefits	Total
Chairman of the Board of Directors Ulf Wiinberg	535	–	–	–	–	535
Director Birgit Stattin-Norinder	276	–	–	–	–	276
Director Stina Gestrelius	155	–	–	–	–	155
Director Per-Olof Wallström	169	–	–	–	–	169
Director Hans Schikan *	364	–	–	–	–	364
Director Angelica Loskog	–	–	–	–	–	–
Acting CEO	884	–	–	–	–	884
Former CEO	2,760	1,942	1,875	859	–	7,436
Other senior management (7 persons)	7,825	1,398	3,579	1,111	–	13,913
Total	**12,968**	**3,340**	**5,454**	**1,970**	**–**	**23,732**

*) For Hans Schikan paid consulting fees of SEK 90 k is included.

Share-based payments

Share warrant program

In 2015 a share warrant program was adopted which gives the Company's employees the right to acquire shares in Hansa Biopharma. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 15, 2018 to June 15, 2019. Each warrant gives the employee 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 36.04) adjusted upwards annually in the amount of seven percent. This entails that the subscription price after three years will be approximately 122.5 percent of the market value of the share (44.15 SEK) as per the annual general meeting 2015 and after four years will amount to approximately 131.1 percent (44.85 SEK).

Should the warrant holder's employment cease before the options are exercised, the Company is entitled to repurchase the options market value less deductions received.

The warrants were sold to the Company's employees 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 (except the former CEO) received a subsidy of maxiumum 60% to acquire warrants. The value of the subsidy will affect the group's results proportionately during the vesting period of the warrants.

Changes in number of share warrants

	2018	2017
Opening balance 1 Jan	355,000	355,000
Exercised	-305,000	–
Closing balance 31 Dec	**50,000**	**355,000**
Obtained amount from exercised options, KSEK	13,514	–
Weighted average share price during exercise period, SEK	221.80	–
Amount to be obtained if all outstanding options are redeemed, KSEK	2,309	15,823
Reported personnel costs (subsidy) during the year, KSEK	58	190
Input for valuation of share warrants according to Black & Scholes at start of the program		
Calculated price, SEK	8.40	–
Grant valuet, SEK	36.04	–
Risk-free interest rate, (%)	-0.043	–
Expected volatility, (%) *	41	
Warrant life, years	4	–
Expected dividend, SEK	–	–

* Based partly on historical volatility of the share price for the Hansa Biopharma share and partly on historical volatility for listed companies with similar business.

Long-term incentive program (LTIP 2016)

The Hansa Biopharma's Extraordinary General Meeting 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 Hansa Biopharma group, meaning that not more than 30 individuals within the group may participate. Participants will, provided continued employment throughout the vesting period, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting periods ending November 28, 2019 and May 18, 2020. Delivery of shares is conditional of continued employment throughout the vesting period. The performance condition is set at a "minimum level" and "maximum level", where the number of Rights which may result in the granting of Performance Shares is increased lineally between the minimum level and maximum level. However, in order for the Rights to entitle to the granting of Performance Shares, the minimum level has to be reached or exceeded. If the specified minimum level of the performance condition is achieved, 25 percent of each participant's Rights will entitle to Performance Shares. If the maximum level is reached, 100 percent of each participant's Rights will entitle to Performance Shares. During the Vesting Period, the minimum level, for each participant, shall be a 25 percent shareholder return condition and the maximum level shall be a 100 percent shareholder return condition. Total share holder return is defined as the return to shareholders through an increased share price and reinvestments of any dividends during the Vesting Period.

Changes in number of rights

	2018	2017
Opening balance 1 January	289,750	234,750
Assigned	–	55,000
Rights expired or redeemed in advance	-78,250	–
Closing balance 31 December	**211,500**	**289,750**
Reported personnel costs during the year, KSEK	13,060	9,877
Allotment date November 29, 2016		
Start value TSR, SEK	112.51	
Input for valuation of share rights according to Monte Carlo-simulation		
Calculated fair value per performance share, SEK	62.01	
Risk-free interest rate, (%)	-0.52	
Expected volatility, (%) *	55	
Expected dividend, SEK	–	
Allotment date May 19, 2017		
Start value TSR, SEK	142.34	
Input for valuation of share rights according to Monte Carlo-simulation	–	
Calculated fair value per performance share, SEK	89.30	
Risk-free interest rate, (%)	-0.51	
Expected volatility, (%) *	55	
Expected dividend, SEK	–	

* Based partly on historical volatility of the share price for the Hansa Biopharma share and partly on historical volatility for listed companies with similar business.

Long-term incentive program (LTIP 2018)

The Hansa Biopharma's Annual General Meeting May 29, 2018 resolved to adopt a long-term incentive program (LTIP 2018). Not more than 52 individuals within the Hansa Biopharma group may participate in the program and are given the opportunity to acquire warrants at market value and/or receive so called performance-based share awards 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 rights may be allotted to participants under LTIP 2018.

Warrants in LTIP 2018

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. Each warrant gives the employee 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 annually in the amount of seven percent. Subscription for shares may take place during the period commencing June 12, 2021 up to and including June 12, 2022. This entails that the subscription price after three years will be approximately 122.5 percent of the market value of the share (273.31 SEK) at the time of the issuance of the warrants and after four years will amount to approximately 131.1 percent (292.44 SEK).

Should the warrant holder's employment cease before the options are exercised, the Company is entitled to repurchase the options market value less deductions received.

The warrants were sold to the Company's employees 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 (except the CEO) received a subsidy of maxiumum 25% to acquire warrants. The value of the subsidy will affect the group's results proportionately during the vesting period of the warrants.

Changes in number of share warrants

	2018
Opening balance 1 Jan	–
Assigned	6,701
Closing balance 31 Dec	**6,701**
Obtained amount from redeemed options, KSEK	–
Amount to be obtained if all outstanding options are redeemed, KSEK	1,495
Reported personnel costs (subsidy) during the year, KSEK	214
Input for valuation of share warrants according to Black & Scholes at start of the program	
Calculated price, SEK	53.41
Grant value, SEK	223.10
Risk-free interest rate, %	-0.178
Expected volatility, % *	43
Warrant life, years	4
Expected dividend, SEK	–

* Based partly on historical volatility of the share price for the Hansa Biopharma share and partly on historical volatility for listed companies with similar business.

Share awards in LTIP 2018

A share right may be exercised 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 Hansa Biopharma-group. The latest start date to receive Share Awards shall be the day prior to the Annual General Meeting 2019. The rights allocated are divided into two vesting periods, the first of which ends June 15, 2021 and the second November 30, 2021. The performance condition is set at a "minimum level" and "maximum level", where the number of Rights which may result in the granting of Performance Shares is increased lineally between the minimum level and maximum level. However, in order for the Rights to entitle to the granting of Performance Shares, the minimum level has to be reached or exceeded. If the specified minimum level of the performance condition is achieved, 25 percent of each participant's Rights will entitle to Performance Shares. If the maximum level is reached, 100 percent of each participant's Rights will entitle to Performance Shares. During the Vesting Period, the minimum level, for each participant, shall be a 25 percent shareholder return condition and the maximum level shall be a 100 percent shareholder return condition. Total share holder return is defined as the return to shareholders through an increased share price and reinvestments of any dividends during the Vesting Period.

The cost for the share rights in LTIP 2018 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period.

Changes in number of rights

	2018
Opening balance 1 Jan	–
Assigned June 15, 2018	105,460
Assigned November 30, 2018	72,671
Rights expired or redeemed in advance	-6,575
Closing balance 31 Dec	**171,556**
Reported personnel costs during the year, KSEK	2,743
Allotment date June 15, 2018	
Start value TSR, SEK	222.10
Input for valuation of share rights according to Monte Carlo-simulation	
Calculated fair value per performance share, SEK	94.08
Risk-free interest rate, (%)	-0.36
Expected volatility, (%) *	43
Expected dividend, SEK	–
Allotment date November 30, 2018	
Start value TSR, SEK	278.70
Input for valuation of share rights according to Monte Carlo-simulation	
Calculated fair value per performance share, SEK	117.43
Risk-free interest rate, (%)	-0.28
Expected volatility, (%) *	43
Expected dividend, SEK	–

* Based partly on historical volatility of the share price for the Hansa Biopharma share and partly on historical volatility for listed companies with similar business.

Note 6 Fees and competition for costs, auditors

KSEK	2018	2017
Group		
KPMG		
Auditing services	500	592
Other services	81	38
Wilkins Kennedy Audit Service		
Auditing services	59	15
Parent company		
KPMG		
Auditing services	500	592
Other services	81	38

Audit services refer to the legally required examination of the annual report and the book-keeping, The Board of Directors' and the Managing Director's management 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 type of cost

Group

KSEK	2018	2017
Other operating income	725	1,479
Personnel costs	-71,674	-56,853
Other external costs	-171,453	-120,151
Depreciation	-1,818	-3,779
Other costs	-4,720	–
	-248,940	**-179,304**

Parent company

KSEK	2018	2017
Other operating income	725	1,479
Personnel costs	-71,861	-56,853
Other external costs	-171,615	-120,326
Depreciation	-1,599	-3,576
Other costs	-4,720	–
	-249,070	**-179,276**

Note 8 Net financial items

Group

KSEK	2018	2017
Other interest income	52	97
Net profit transferred from equity on disposal of available-for sale financial assets	–	-1
Financial income	**52**	**96**
Interest expenses, other	-706	-695
Accumulated changes in the value of interest funds	-851	–
Net exchange rate variances	-11	-17
Financial expenses	**-1,568**	**-712**
Net financial items	**-1,516**	**-616**

Parent company

KSEK	2018	2017
Interest income and similar income statement items		
Interest income, other	52	97
Net profit transferred from equity on disposal of available-for sale financial assets	–	-1
Financial income	**52**	**96**
Interest expenses and similar income statement items		
Interest expenses, other	-712	-711
Accumulated changes in the value of interest funds	-1,254	
Financial expenses	**-1,966**	**-711**

Note 9 Taxes

Deferred tax claims

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

KSEK	2018	2017
Opening balance beginning of the year	538	581
Tax income in the income statement *	-40	-39
Currency differences for the year	13	-4
Closing balance end of the year	**511**	**538**

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

Unreported deferred tax claims

Deferred tax claims have not been reported regarding temporary differences and losses carried forward since it is not probable that such can be set off against future taxable profits.

The group's losses carried forward in 2018 amounted to SEK 714,854 k (480,390). The losses carried forward is, in all material respects, attributable to Swedish companies and therefore has no due date.

Reconciliation effective tax

Group

KSEK	2018 (%)	2018	2017 (%)	2017
Result before tax	–	-248,014	–	-176,699
Tax according to current tax rate for the Parent company	22.0	54,563	22.0	38,874
Effect of other tax rates for foreign subsidiaries	–	–	–	–
Non-deductable expenses	-1.1	-2,831	-1.3	-2,227
Non-taxable income	–	–	–	–
Increase in loss carry-forwards without corresponding capitalization of deferred tax	-20.8	-51,692	-20.7	-36,608
Tax attributable to previous years	–	–	–	–
Effect of changed tax rate on deferred tax liability	–	–	–	–
Other	–	–	–	–
Reported effective tax	–	40	–	39

Parent company

KSEK	2018 (%)	2018	2017 (%)	2017
Result before tax	–	-248,297	–	-176,373
Tax according to current tax rate for the Parent company	22.0	54,625	22.0	38,802
Effect of other tax rates for foreign subsidiaries	–	–	–	–
Non-deductable expenses	-1.1	-2,831	-1.3	-2,227
Non-taxable income	–	–	–	–
Increase in loss carry-forwards without corresponding capitalization of deferred tax	-20.9	-51 794	-20.7	-36,575
Tax attributable to previous years	–	–	–	–
Effect of changed tax rate on deferred tax liability	–	–	–	–
Other	–	–	–	–
Reported effective tax	–	–	–	–

Note 10 Earnings per share

Earnings per share

SEK	2018	2017
Earnings per share prior to and after dilution	-6.47	-4.96

The outstanding potential ordinary shares that existed at the balance sheet date are not yet dilutive. Earnings per share before and after dilution is therefore the same. The outstanding potential stock of ordinary shares may become 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	2018	2017
Profit/loss for the year related to the Parent company's shareholders	-247,974	-176,660
Earnings attributable to the Parent company's shareholders prior to and after dilution	**-247,974**	**-176,660**

Weighted average number of outstanding shares prior to and after dilution

Number of shares	2017	2016
Total number of shares 1 January	37,807,386	35,054,860
Effect of new share issue in December 2017	–	464,169
Effect of conversion from C-shares in January 2018	65,086	–
Effect of new share issue in June 2018	104,724	–
Effect of new share issue in July 2018	21,972	–
Effect of new share issue in October 2018	12,085	–
Effect of new share issue in November 2018	314,845	87,957
Weighted average number of shares during the year prior to and after dilution	**38,326,098**	**35,606,986**

The weighted average number of shares is affected by new share issues carried out in 2017 and 2018. The weighted number of shares for 2017 has been recalculated taking into consideration the new share issue carried out in 2018.

Note 11 Intangible fixed assets

Group

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2017	4,485	3,255	33,515	41,255
Other acquisitions	–	209	–	209
Currency differences for the year	–	-20	–	-20
Closing balance 31 Dec 2017	4,485	3,444	33,515	41,444
Accumulated write-offs and impairment				
Opening balance 1 Jan 2017	-2,243	-214	-2,244	-4,701
Depreciaton for the year	-2,242	-187	-562	-2,991
Currency differences for the year	–	-3	–	-3
Closing balance 31 Dec 2017	-4,485	-404	-2,806	-7,695
Reported values				
As of 1 Jan 2017	2 242	3,041	31,271	36,554
As of 31 Dec 2017	–	3,040	30,709	33,749

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2018	4,485	3,444	33,515	41,444
Other acquisitions	–	124	–	124
Currency differences for the year	–	75	–	75
Closing balance 31 Dec 2018	4,485	3,643	33,515	41,643
Accumulated write-offs and impairment				
Opening balance 1 Jan 2018	4,485	-404	-2,806	-7,695
Depreciaton for the year	–	-199	-546	-745
Currency differences for the year	–	-6	–	-6
Closing balance 31 Dec 2018	4,485	-609	-3,352	-8,446
Reported values				
As of 1 Jan 2018	–	3,040	30,709	33,749
As of 31 Dec 2018	–	3,034	30,163	33,197

Parent company

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2017	4,485	125	33,515	38,125
Closing balance 31 Dec 2017	4,485	125	33,515	38,125
Accumulated write-offs and impairment				
Opening balance 1 Jan 2017	-2,243	-125	-2,244	-4,612
Depreciaton for the year	-2,242	–	-562	-2,804
Closing balance 31 Dec 2017	-4,485	-125	-2,806	-7,416
Reported values				
As of 1 Jan 2017	2,242	–	31,271	33,513
As of 31 Dec 2017	–	–	30,709	30,709

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2017	4,485	125	33,515	38,125
Closing balance 31 Dec 2017	4,485	125	33,515	38,125
Accumulated write-offs and impairment				
Opening balance 1 Jan 2018	4,485	-125	-2,806	-7,416
Depreciaton for the year	–	–	-546	-546
Closing balance 31 Dec 2018	-4,485	-125	-3,352	-7,962
Reported values				
As of 1 Jan 2018	–	–	30,709	30,709
As of 31 Dec 2018	–	–	30,163	30,163

The projects pending in the group a combination of acquired development projects and continued activities in these projects. Of the total fees for the acquired product development, 75% relates to imlifidase and 25% relates to HBP-assay. Capitalized internal development expenses for imlifidase's previous production process were completely amortized during the year.

Project overview	Indication/Purpose	Status
imlifidase	imlifidase is a pharmaceutical candidate the primary goal of which is to make possible transplants by counteracting antibody mediated rejection. Additional goals include treating acute antibody mediated illnesses.	imlifidase has been given Orphan-Drug designation by FDA during 2015 and in January 2017 by European Commission. In September, Hansa announced that the third and fourth phase 2 studies evaluating imlifidase for kidney transplantation in highly sensitized patients were concluded with successful results. The Hansa-sponsored multi-center study Highdes included 18 patients in five clinics in the US, France and Sweden, and the US trial initiated study included 17 patients at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center in Los Angeles. In both studies, imlifidase treatment allowed transplants to be performed for all 35 patients. After completion of studies, six months after transplantation, organ survival was 91%. Thirty-two patients were able to provide good kidney function dialysis treatment with estimated glomerular filtration rate (eGFR) within the expected range. Three patients lost their grafts due to complications not related to imlipidase treatment. The results show a good safety profile after six months of follow-up.
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 receives milestone compensation and additional royalty revenues upon the sale of the sublicensed technology.

Capitalized fees for product development are assessed for possible impairment needs at least on an annual basis. The recovery value is calculated as the Value-In-Use for the intangible asset, the calculated Value-In-Use is then compared to carrying amount.

The Value-In-Use for imlifidase has been calculated based on assumptions of the future potential market for the drug, such assumptions are consistent with external data sources. In addition to this, assumptions on growth, market share and margin has been used, such assumptions are based on the managements estimate of the future business. Due to the inherent uncertainty relating to the development of drug candidates, such assumptions have been adjusted for risk in order to incorporate such uncertainty. The risk-adjusted cash flows have then been discounted to calculate a present value. The methodology used for impairment purposes is consistent with standard operating procedure for valuation of development projects within the biopharmaceutical industry.

The impairment assessment on December 31, 2018 and 2018 demonstrated that there was no need for impairment. The discount rates of interest before tax was 15.0 percent per year.

Capitalized development expenses regarding HBP are written off over the term of the underlying patent in the amount of SEK 546 k 2018 and SEK 562 k 2017.

Note 12 Tangible fixed assets

Group

	Equipment, tools and facilities	
KSEK	2018-12-31	2017-12-31
Accumulated acquisition values		
Opening balance on 1 January	6,816	4,621
Investments during the year	2,365	2,195
Closing balance on 31 December	9,181	6,816
Accumulated depreciation and write-offs		
Opening balance on 1 January	-2,840	-2,051
Depreciaton during the year	-1,052	-789
Closing balance on 31 December	-3,892	-2,840
Reported values		
As of 1 January	3,976	2,570
As of 31 December	5,289	3,976

Financial leasing

KSEK	2018-12-31	2017-12-31
Group		
Reported value for assets under financial leasing agreements	587	–

In 2018, the Group has started leasing of a car under financial leasing agreement.

The leased asset constituted security for the leasing obligations. See also note 22 and note 27.

Parent company

	Equipment, tools and facilities	
KSEK	2018-12-31	2017-12-31
Accumulated acquisition values		
Opening balance on 1 January	6,512	4,317
Investments during the year	2,366	2,195
Closing balance on 31 December	8,878	6,512
Accumulated depreciation and write-offs		
Opening balance on 1 January	-2,536	-1,763
Depreciaton during the year	-1,052	-773
Closing balance on 31 December	-3,588	-2,536
Reported values		
As of 1 January	3,976	2,554
As of 31 December	5,290	3,976

Note 13 Receivables from group companies

Parent company

KSEK	2018-12-31	2017-12-31
Accumulated acquisition values		
Opening balance on 1 January	469	101
Additional receivables	2,436	367
Outgoing receivable	-71	–
Currency differences for the year	–	1
Reported value on 31 December	**2,834**	**469**

Note 14 Financial fixed assets

Group

KSEK	2018-12-31	2017-12-31
Financial investments which are fixed assets		
Realizable financial assets		
Shares and participating interests	39,528	18,508
	39,528	**18,508**

The holdings related to shares in Genovis AB which is listed on First North. These are reported in the Group at market value and in the Parent company at acquisition value less any impairment losses.

Note 15 Other long-term securities holdings

Parent company

KSEK	2018-12-31	2017-12-31
Accumulated acquisition values		
Opening balance on 1 January	12,499	12,499
Purchases	–	–
Closing balance on 31 December	12,499	12,499
Accumulated impairment		
Opening balance on 1 January	–	–
Impairment recovered during the year	–	–
Closing balance on 31 December	–	–
Reported value on 31 December	12,499	12,499

Note 16 Other receivables

Group

KSEK	2018-12-31	2017-12-31
Other receivables which are current assets		
VAT receivables	3,058	1,388
Other receivables	3,988	5,905
	7,046	**7,293**

Parent company

KSEK	2018-12-31	2017-12-31
Other receivables (current)		
VAT receivables	3,058	1,388
Other receivables	3,980	5,903
	7,038	**7,291**

Note 17 Accounts receivable

Accounts receivable are reported after consideration of bad debt losses during the year which amounted to KSEK 0 for the group and Parent company.

Note 18 Prepaid expenses and deferred income

Group

KSEK	2018-12-31	2017-12-31
Prepaid insurance	360	92
Prepaid marketing	114	128
Prepaid software	149	–
Other	306	100
	929	**320**

Parent company

KSEK	2018-12-31	2017-12-31
Prepaid insurance	360	92
Prepaid marketing	114	128
Prepaid software	149	–
Other	316	100
	939	**320**

Note 19 Cash and cash equivalents

Group

KSEK	2018-12-31	2017-12-31
The following subcomponents are included in cash and cash equivalents:		
Cash and bank deposits	439,441	581,078
The total according to balance sheet	439,441	581,078
Total according to cash flow analysis	**439,441**	**581,078**

Parent company

KSEK	2018-12-31	2017-12-31
The following subcomponents are included in cash and cash equivalents:		
Cash and bank deposits	433,875	578,795
The total according to balance sheet	433,875	578,795
Total according to cash flow analysis	**433,875**	**578,795**

Note 20 Shareholders' equity

Group

Share capital and number of shares

Number of shares	2018	2017
Issued as of 1 January	37,807,386	35,054,860
New share issue November 2017	–	2,752,526
Effect of conversion from C-shares in January 2018	70,739	–
Effect of new share issue in June 2018	205,000	–
Effect of new share issue in July 2018	50,000	–
Effect of new share issue in October 2018	50,000	–
Effect of new share issue in December 2018	1,776,765	–
Issued as of 31 December – paid up	**39,959,890**	**37,807,386**

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

Shareholders are entitled to dividends which are determined after they become shareholders and the shareholdings entitle the shareholders to one vote per share at general meetings.

Own shares included in equity

	Number of shares		Reported value	
	2018	2017	2018	2017
Opening balance own shares	401	–	401	–
Purchases during the year	391	401	391	401
Disposals during the year	-70	–	-70	–
Closing balance own shares	**722**	**–**	**722**	**401**

Own shares have a quotient value of SEK 1.

The year's purchase of C shares refers to the new issue and subsequent repurchase of C shares that have taken place in accordance with the LTIP 2018 incentive program. The year's sale refers to the conversion that has taken place to ordinary shares within the framework of the long-term incentive program.

Other contributed capital

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

Reserves

Translation reserve

The translation reserve comprises all foreign exchange differences arising on translation of financial statements from 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 of 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 reserves to retained earnings.

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 22 2019.

No dividend was paid for 2017.

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.

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 rights in the Company's ongoing incentive programs, LTIP 2016 and LTIP 2018. The social contributions are expected to be paid after the vesting period end for different participant groups, which fall November 28, 2019 and May 18, 2020 for LTIP 2016 as well June 15, 2021 and November 30, 2021 respectively for LTIP 2018.

Group

KSEK	2018	2017
Opening balance on 1 January	5,017	114
This year's provision in LTIP 2016	5,096	–
This year's provision in LTIP 2018	835	4 903
Reported value at the end of the year	**10,948**	**5 017**

Parent company

KSEK	2018	2017
Opening balance on 1 January	5,017	114
This year's provision in LTIP 2016	5,096	–
This year's provision in LTIP 2018	835	4 903
Reported value at the end of the year	**10,948**	**5 017**

Note 22 Long term interest-bearing liabilities

This note contains information regarding the Company's contractual terms and conditions regarding interest-bearing liabilities. For more information regarding the Company's exposure to interest risks and the risk of changes in currency exchange rates, reference is made to note 25.

Group

KSEK	2018	2017
Long-term liabilities		
Contingent purchase price, not yet paid	679	601
Financial leasing liabilities	476	–
	1,155	601
Current liabilities		
Current portion of financial leasing liabilities	101	–
	101	**–**

Parent company

KSEK	2018	2017
Long-term liabilities		
Contingent purchase price, not yet paid	679	601
	679	**601**

Contingent purchase price, not yet paid
Contingent purchase price is expected to be paid in 2020. Maximum amount is GBP 70k and the liability is discounted to its present value.

Financial leasing liabilities
On December 31, 2018, there is a financial leasing liability for a leasing car amounting to SEK 578k (0).

Note 23 Other liabilities

Group

KSEK	2018-12-31	2017-12-31
Other current liabilities		
Personnel-related liabilities	5,162	5,424
Fair value interest rate derivatives	–	403
Accumulated development costs government grant	294	1,458
Other liabilities	106	–
	5,562	**7,285**

Parent company

KSEK	2018-12-31	2017-12-31
Personnel-related liabilities	4,801	5,424
Accumulated development costs government grant	294	1,458
	5,095	**6,882**

Note 24 Accrued costs and deferred income

Group

KSEK	2018-12-31	2017-12-31
Holiday pay	4,107	3,538
Social charges	1,263	1,152
Incentive accrual	3,806	1,749
Directors' fee	–	1,111
Project costs	10,924	8,998
Royalties to researchers	201	214
Consulting fees	2,400	1,522
Costs attributable to new share issue	503	10,624
Other	3,038	3,634
	26,242	**32,542**

Parent company

KSEK	2018-12-31	2017-12-31
Holiday pay	4,107	3,538
Social charges	1,263	1,152
Incentive accrual	3,806	1,749
Directors' fee	–	1,111
Project costs	10,924	8,998
Royalties to researchers	201	214
Consulting fees	2,400	1,522
Costs attributable to new share issue	503	10,624
Other	3,008	3,619
	26,212	**32,527**

Note 25 Financial risk management and financial instruments

Through its activities, the group is exposed to the following financial risks. Hansa Biopharma is exposed to a liquidity and refinancing risk, currency risk, interest rate risk, share price risk, and credit risk. The Board of Directors has adopted a policy for managing financial risks within the group. The Board of Directors is responsible for the group's long-term financing strategy as well as any acquisition of capital. The management of financial risks in the day-to-day operations is handled by the CFO together with the CEO.

Liquidity and financing risk
The liquidity and financing risk is the risk that the group will not have access to the financing needed to meet its contractual obligations or can only obtain such financing at significantly increased costs. The Board of Directors is responsible for the long term financing strategy and for the acquisition of capital. All financing must be managed or approved centrally.

In order to secure short-term liquidity, Hansa Biopharma's financial policy prescribes that at least 80% of the anticipated costs for the upcoming month be available in the form of cash and cash equivalents. On the balance sheet date, this goal was fulfilled. Cash and cash equivalents on 31 December 2018 amounted to SEK 439,441 k (581,078).

According to Hansa Biopharma's investment policy, any surplus liquidity can be invested in interest-bearing securities with a maximum of three settlement days in a normal market. Cash and cash equivalents consisted on the balance sheet date of bank deposits. Short term investments in interest-bearing commercial papers amounted to SEK 418,746 k (34,983).

Set forth below is a term-based analysis of the group's financial liabilities

2018

KSEK	Nominal amount	0–3 months	3–12 months	1–5 years
Long-term interest-bearing liabilities	1,155	–	–	1,155
Short term leasing liabilties	101	–	101	–
Accounts payable	40,426	40,426	–	–
Total	**41,682**	**40,426**	**101**	**1,155**

2017

KSEK	Nominal amount	0–3 months	3–12 months	1–5 years
Long-term interest-bearing liabilities	601	–	–	601
Accounts payable	3,771	3,771	–	–
Total	**4,372**	**3,771**	**–**	**601**

Currency risk
Hansa Biopharma 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 revenues which are paid in USD and GBP. A strengthening of the Swedish krona in relation to USD and GBP therefore leads to reduced revenues for the Company expressed in SEK, all else remaining the same.

A strengthening of SEK in relation to EUR by an average of 10% would affect the group's earnings before tax by approximately SEK +6,836 k (+5,953). Correspondingly, a strengthening of SEK in relation to GBP by an average of 10% would affect the group's earnings before tax by approximately SEK +481 k (+679), a strengthening of SEK in relation to DKK by an average of 10 % would affect the group's earnings before tax by approximately SEK +71 k (+94), while a 10 % strengthening of SEK in relation to USD would affect earnings before tax by approximately SEK +2,434 k (+1,061).

The sensitivity analysis has been prepared from the point of departure that revenues and costs in each currency remain unchanged as compared with what is actually reported during each financial year.

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 small since 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-bearing papers.

At the end of December 2017, the Group 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).

In conjunction with investments in interest-bearing securities, Hansa Biopharma shall endeavor to maximize its profits within the scope of the financial policy. Hansa Biopharma endeavors to maintain a sound allocation in a fixed-income portfolio by making investments with varying terms and conditions. However, the underlying principle is that investments shall be made in securities with a low risk.

Share price risk
Hansa Biopharma is exposed to a share price risk through its holdings of shares in Genovis AB which is listed on First North. The share price changes affect the Group's comprehensive income in such a way that if the price rises by 10%, it changes the comprehensive income of SEK +3,953 k and if the price falls by 10%, the total result is affected by SEK-3,953 k.

Credit risk
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.

According to the group's financial policy, Hansa Biopharma 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.

At year-end, SEK 328 million of the Company's short-term investments were invested in a fund for institutional short-term interest rates. Issuers of the investment objects or other guarantors other than states, municipalities or other societies shall the investment date has a credit rating issued by an approved rating agency of at least BBB- orequivalent in the long term. Other SEK 90 million were invested in a housing bond fund where investments in others were made types of securities other than government securities shall, at the time of placement, have the lowest rating rating, BBB- or Baa3 or equivalent for longer placements and lowest A-1, P-1 or K-1 or equivalent for shorter investments according to valuation of approved rating Company.

The net realizable value of financial assets and financial liabilities
The reported values of financial assets and financial liabilities are deemed to be the reasonable estimates of the actual value of each class of financial assets and financial liabilities.

The net realizable value of shareholdings in Genovis has been established based upon the closing price on the balance sheet date.

The fair value of the short term investments is calculated on the basis of the closing price at the balance sheet date.

The fair value of contingent purchase price is calculated at the discounted value of expected future cash flows. A purchase price of GBP 70k enters if a clinical trial is registrated linked to the acquired patent rights.

The reported value 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 in IFRS 9.

Group

	Financial assets valued at accrued acquisition value*		Financial assets valued at fair value through other comprehensive income		Financial assets valued at fair value through income statement	
KSEK	2018	2017	2018	2017	2018	2017
Financial assets valued at net realizable value						
Financial fixed assets						
Listed shares	–	–	39,528	18,508	–	–
Short term investments	–	–	–	34,983	418,746	–
Financial assets not valued at net realizable value						
Accounts receivable	58	508	–	–	–	–
Other receivables	3,988	5,093	–	–	–	–
Cash and cash equivalents	439,441	581,078	–	–	–	–
Total financial assets	**443,487**	**586,679**	**39,528**	**53,491**	**418,746**	**–**

* Financial assets valued at accrued acquisition value belonged 2017 to value category loan- and accounts receivables, while financial assets valued at fair value through other comprehensive income belonged to the valuation category financial available-for-sale assets.

	Financial liabilities valued at accrued acquisition value		Financial liabilities valued at fair value by the income statement	
KSEK	2018	2017	2018	2017
Long-term interest bearing liabilities	–	–	–	–
Contingent purchase price	–	–	1,155	601
Other	–	–	–	–
Current interest-bearing liabilities	–	–	–	–
Accounts payable	40,426	3,771	–	–
Total financial assets	**40,426**	**3,771**	**1,155**	**601**

Levels of financial assets and financial liabilities per valuation hierarchy

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

KSEK	Valuation hierarchy	2018	2017
Financial asset			
Holdings in interest funds	Level 2	418,746	–
Holdings of listed shares	Level 1	39,528	18,507
Commercial papers	Level 1	–	34,983
Contingent purchase price	Level 3	1,155	601

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

	Contingent purchase price	
KSEK	2018	2017
Opening balance	**601**	**548**
Acquisition during the year	–	–
Reported in net result for the year	–	–
Currency differences	12	-3
Interest expense	66	56
Closing balance	**679**	**601**

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

Note 26 Operational leasing

Leasing agreements under which the Company is the lessee.
Future payments for leasing agreements which cannot be terminated amount to:

Group

KSEK	2018-12-31	2017-12-31
Within one year	6,382	1,769
Between one and five years	8,071	1,670
	14,453	**3,439**

Parent company

KSEK	2018-12-31	2017-12-31
Within one year	6,372	1,769
Between one and five years	8,071	1,670
	14,443	**3,439**

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 property is three years from January 1, 2019. The agreement is automatically extended with two years at a time unless cancellation is made no later than nine months before the end of the contract period. There are no variable fees included in the operational leases.

Fees for operational leasing agreements booked as expenses amount to:

Group

KSEK	2018	2017
Minimum leasing fees	4,047	3,324
Total leasing costs	**4,047**	**3,324**

Parent company

KSEK	2018	2017
Minimum leasing fees	4,035	3,359
Total leasing costs	**4,035**	**3,359**

Note 27 Collateral provided, contingent liabilities and contingent assets

Group

KSEK	2018-12-31	2017-12-31
Collateral provided		
In the form of collateral for own liabilities and provisions		
Assets subject to retention of title	587	–
Total collateral provided	**587**	**–**

Note 28 Closely-associated persons

Relationships with closely-associated persons
The group has a closely-associated relationship with Nexttobe AB and key persons in management positions. Nexttobe AB is the Company's largest shareholder with holdings of 14.4%.

The Parent company also has a closely-associated relationship with its subsidiary; see note 29.

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	2018	2017
Cartela R & D AB	Lund / Sweden	100	100
Immago Biosystems Ltd	Cheltenham / United Kingdom	100	100
Hansa Biopharma Inc	Delaware, USA	100	–

Parent company

KSEK	2018-12-31	2017-12-31
Accumulated acquisition values		
Opening balance on 1 January	4,818	4,818
Shareholder contribution Cartela R&D	268	–
Acquisition Immago Biosystems Ltd	9	–
Reported value on 31 December	**5,095**	**4,818**

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

			Reported value	
Subsidiaries / Company reg. no. / Registered office	Number of shares	Share (%)	2018-12-31	2017-12-31
Cartela R & D AB / 556746-0083 / Lund	1,000	100	2,630	2,362
Immago Biosystems Ltd / 08361712 / Cheltemham, United Kingdom	100,000	100	2,456	2,456
Hansa Biopharma Inc, 6846164, Delaware, USA	1,000	100	9	–
			5,095	**4,818**

Note 30 Cash flow analysis

Adjustment for items not included in cash flow
Group

KSEK	2018	2017
Depreciation/writedown	1,837	3,779
Unrealised currency differences	-68	-19
Costs related to incentive program	11,675	10,067
	13,444	**13,827**

Parent company

KSEK	2018	2017
Depreciation/writedown	1,599	3,576
Unrealised currency differences	–	-22
Costs related to incentive program	11,619	10,067
	13,218	**13,621**

Reconciliation of liabilities arising from the financing activities
Group

KSEK	UB 2017	Cash flow	New leasing agreeements*	UB 2018
Leasing payables	–	–	578	578
Total liabilities arising from financing activities	**–**	**–**	**578**	**578**

* Non cash flow changes of debt

The leasing debt relates to a company car.

Note 31 Acquisition of business

Acquisitions 2018
No aquisitions in 2018.

Acquisitions 2017
No aquisitions in 2017.

Note 32 Events after the balance sheet dates

The European Medicines Agency (EMA) accepted the Company's Marketing Authorization Application (MAA) for review of IDEFIRIX™ (INN: imlifidase). Hansa is seeking approval of IDEFIRIX as a treatment to enable kidney transplantation in highly sensitized patients.

Hansa provided an update on its interactions with regulatory agencies regarding imlifidase in kidney transplantation. The Company's dialogue with the FDA to determine the path forward for regulatory filing and approval in the U.S. is ongoing and Hansa will provide updated guidance regarding the timeline for a potential Biologic License Application (BLA) following a subsequent meeting with the agency.

Lead candidate selected from the NiceR program, Novel IgG Cleaving Enzymes for Repeat dosing. The selected molecule has been developed to enable repeat dosing in several indications with significant unmet medical need in relapsing autoimmune diseases, chronic transplant rejection, oncology and repeat dosing of gene therapy.

Note 33 Important estimates and opinions

Certain assumptions regarding the future and certain estimates and opinions on the balance sheet date have particular significance for the valuation of the assets and liabilities set forth in the balance sheet. Set forth below is a discussion of the areas in which the risk of material changes in value, during the subsequent year, are significant

Activation of proprietary development expenditures and pharmaceutical substances
Expenses for development projects are reported as intangible assets if the Company can show that it is technically possible to pursue and profitable to commercialize the result and only on the expenditure for this project can be measured reliably. This means in practice that expenditure is not capitalized before the pharmaceutical authority FDA in the US or the EU Medicines Agency EMEA has given its approval due to the level of uncertainty connected to the approval process. Similarly, expenses for pharmaceutical substances have been expensed pending approval by the authorities. Once approval is obtained, these type of future expenses for the project will be capitalized. Acquired development projects are capitalized at the time of acquisition.

Recovery of the value of development expenses
On at least an annual basis, the group assesses whether there is any impairment need for development projects which have not yet been completed. In the calculation of the beneficial value, future cash flows are discounted at a rate of interest which takes into consideration the market's opinion of risk-free interest and risk (WACC). The group bases these calculations on estimated forecasts and business plans. The estimates and assumptions made by management in the assessment of the need for impairment may have a large effect on the group's reported earnings. Impairment is made if the calculated beneficial value is less than the reported and is charged to the result for the year. The Group's operations are entirely based on the future commercialization of the research projects that are conducted and how these would be assessed and if the assessment of their future potential would change, this would mean a significant negative impact on the Group's operations, earnings and financial position.

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 2018 cover the Parent company and its subsidiaries, jointly referred to as the group.

Note 35 Proposal for dividend

Unrestricted shareholders' equity in the Parent company

KSEK	
Share premium reserve	1,400,456,077
Own shares	-721,764
Profit carried forward	-358,848,650
Result for the year	-248,296,974
Total	**792,588,689**

The Board of Directors proposes that the profits available for distribution and unrestricted reserves be allocated as follows:

KSEK	
Share premium reserve	1,400,456,077
Own shares	-721,764
Profit carried forward	-607,145,624
Total	**792,588,689**

Definitions

Equity ratio
Shareholders' equity as percentage of total balance sheet 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 April 11, 2019

Ulf Wiinberg
Chairman of the Board

Birgit Stattin Norinder
Director

Stina Gestrelius
Director

Andreas Eggert
Director

Angelica Loskog
Director

Anders Gersel Pedersen
Director

Søren Tulstrup
CEO and Executive President

The Board of Directors and CEO approved the annual report for publication on April 11, 2019. The consolidated income statement, report on comprehensive income and balance sheet as well as the Parent company's income statement, report on comprehensive income and balance sheet will be subject to adoption at the annual general meeting to be held on May 29, 2019.

Our auditors' report was submitted on April 11, 2019.
KPMG AB

Jonas Nihlberg
Authorized Public Accountant

Translation from the Swedish original

Auditor's Report

To the general meeting of the shareholders of Hansa Biopharma AB (publ), 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 (publ) for the year 2018. The annual accounts and consolidated accounts of the company are included on pages 33-90 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 2018 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 2018 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.

Going concern

See financial risks on page 36 and accounting principles on pages 51-58 in the annual account and consolidated accounts for detailed information and description of the matter.

Description of key audit matter

The group conducts its own drug development and therefore its going concern assumption depends on the existence of sufficient funds to continue the operations until the results of the research and development can be commercialized.

Group revenue arrives mainly from the agreement with Axis-Shield, who is working to develop a commercial product based on the HBP-analysis method. Hansa Medical receives contractually so-called milestone payments and additional royalties on future sales of products based on the licensed technology.

In the fourth quarter, it was decided at an extraordinary general meeting to conduct a private placement of a maximum of 1,776,765 new shares, the subscription price was set at SEK 255 per share. This issue was then carried out during the financial year and brought the company SEK 453 million.

Cash and cash equivalents amounts to SEK 439 million at December 31, 2018. In addition, the group has short-term investments of SEK 419 million.

Response in the audit

We have in conjunction with the company´s preperation of the annual accounts considered the Board's decision to assume a going concern basis. We have reviewed management's forecasts stating that there is available cash to further operate the business over a period of at least twelve months from the date of the financial statements.

We have considered the reasonableness of and the support for the assessments that form the basis of management's liquidity forecasts, including so-called sensitivity analysis. We have discussed with management how they have made their assumptions and we have considered these in our assessment.

The key areas that we have focused on in the cash flow forecast are:

- Payments based on the agreement with Axis-Shield;

- Expected payouts based on budgeted project costs;

- The availability of future financing such as new share issues.

The agreement with Axis-Shield has among other things been reviewed based on the minimum income that the group contractually is entitled to.

Regarding the budgeted project costs, we have followed up that those are discussed and adopted by the Board. Furthermore, we have with management discussed the actual results compared to prior year and budget and obtained explanations to larger variances.

We have followed the decision of the Extraordinary General Meeting to perform a private placement and verified that payment has been made equivalent to SEK 453 million.

Translation from the Swedish original

Management's assessment of cash at various future dates are essential to base the recognition of the so-called going concern assumption. If this principle can't be applied, it may be relevant to other starting points for the preparation of the accounts, such as the valuation issues. Against this background, the going concern assumption is a key audit matter.

We have also discussed plans and potential sources of financing together with management and assessed them in relation to the available data and past experiences.

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 1-32. 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 disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.

Translation from the Swedish original

- 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, 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 (publ) for the year 2018 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the loss be dealt with in accordance with the proposal in the statutory administration report and that the 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.

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 (publ) by the general meeting of the shareholders on the 29 May 2018. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2014.

Malmö

KPMG AB

Jonas Nihlberg
Authorized Public Accountant

Corporate governance report

Introduction

The Board of Directors of Hansa Biopharma AB (publ), Company reg. no. 556734-5359 ("Hansa Biopharma" or the "Company") hereby submits the 2018 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.bolagsstyrning.se). The Company's shares were admitted for trading on Nasdaq Stockholm in November 2015. The Company's shares were previously, since 2007, listed on Nasdaq First North. The Company's corporate governance is mainly regulated by the provisions of the Company's articles of association, the Swedish Companies Act (2005:551) (Sw. aktiebolagslagen) and other Swedish legislation, the Nasdaq Stockholm Rulebook for issuers 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, Immago Biosystems Ltd and Hansa Medical Inc. Hansa Medical Incorporated was registered in May 2018 and by the end of 2018 there were three employees in the Company. Immago Biosystems Ltd is owner of patent rights to the Enze concept.

On the 20 December 2018, the Company published a press release informing that a name change of the Company had been registered at the Swedish Companies Registration Office. The Company changed name from "Hansa Medical AB" to "Hansa Biopharma AB".

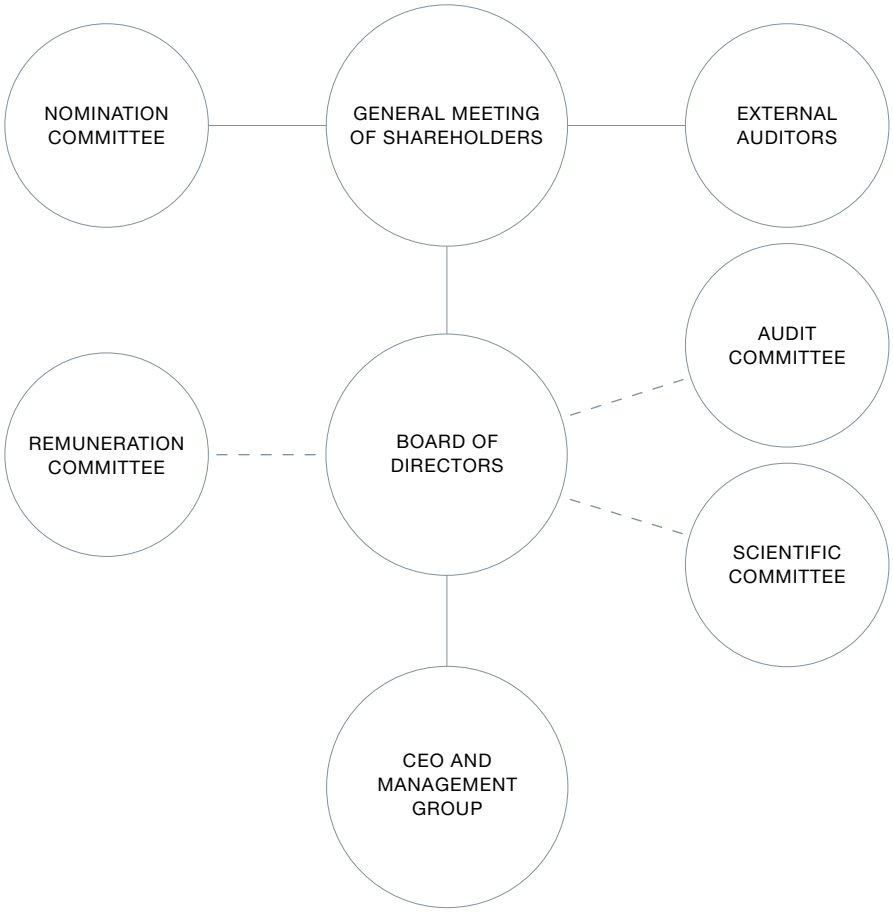
There are no deviations from the Code to report from the financial year of 2018. No infringements of Nasdaq Stockholm's rules and no breach of good practice on the securities market was reported by the stock exchange's disciplinary committee or the Swedish Securities Council during the financial year.

Shareholders

There are no limitations on the transferability of Hansa Biopharma's shares due to legal restrictions or provisions of the articles of association. To Hansa Biopharma's knowledge, no agreement has been entered into between any shareholders which might limit the transferability of the shares. Nexttobe AB is the only shareholder owning more than 10 percent of the Company's shares, by its shareholdings of 14.4 percent.

Hansa Medical's corporate governance model

The diagram set forth below illustrates Hansa Biopharma's corporate governance model and the central corporate bodies during 2018.



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

Significant internal regulations and policies:

- Articles of association
- Rules of procedure for the Board of Directors
- Instruction for the CEO, including the financial reporting instruction
- Disclosure policy
- Insider instruction
- Finance policy
- Risk management policy
- Financial handbook
- Staff handbook

Significant external regulations:

- Swedish Companies Act
- Swedish Accounting Act
- Swedish Annual Accounts Act
- International standards for audits and financial reporting (IFRS)
- Nasdaq Stockholm Rulebook for issuers
- Swedish Code of Corporate Governance

Information regarding Hansa Medical's shares

The shares in the Company are divided into ordinary shares and C-shares. On December 31, 2018, the total number of shares was 40,681,654 with 39,959,890 ordinary shares and 721,764 C-shares, with a quotient value of SEK 1. After the end of the year, additional shares have been issued and there are (March 21, 2019) 40,731,654 total shares in the Company, of which 40,026,107 are ordinary shares and 705,547 are C-shares. 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 share confers the right to an equally large percentage of the Company's distributable profits.

General meeting

The Company's highest decision-making body is the general meeting, where the shareholders' influence over the Company is exercised. Shareholders who wish to participate at a general meeting, personally or through a proxy, must be entered in the share register maintained by Euroclear Sweden AB five business days prior to the general meeting and must give the Company notice of intention to attend as described in the notice to attend the general meeting. Notices to attend general meetings are given through advertisement as well as on the Company's website (www.hansabiopharma.com). The annual general meeting must be held within six months from the close of the financial year. At the annual general meeting, 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 guidelines for remuneration to senior executives.

2018 Annual General Meeting

At the annual general meeting, which was held on May 29, 2018, 104 shareholders representing 44.7 percent of the total number of votes and 44.4 percent of the total number of shares in the Company were represented. The annual general meeting adopted the 2017 annual accounts, adopted a resolution regarding treatment of the Company's loss, and granted the directors and CEO a discharge from liability. The general meeting resolved that no dividend would be paid. In accordance with the proposals of the nomination committee, the general meeting resolved to re-elect Stina Gestrelius, Birgit Stattin Norinder, Angelica Loskog and Ulf Wiinberg as members of the board. Anders Gersel Pedersen and Andreas Eggert were elected as new members of the board. Ulf Wiinberg was elected as chairman of the board. The general meeting adopted resolutions regarding election of an auditor and remuneration to the board and auditors in accordance with the nomination committee's proposal. The general meeting resolved to adopt a long-term incentive programme for the employees (for further information see "Long-term incentive programme 2018"). The general meeting also resolved on guidelines for remuneration to senior management in accordance with the board of directors' proposal.

Minutes from the annual general meeting are available at Hansa Biopharma's website (www.hansabiopharma.com). The annual general meeting 2019 will take place on May 22, May 2019.

Extraordinary general meetings 2018

The Company have held two extraordinary general meeting during 2018.

At the extraordinary general meeting held on October 29, 2018, 89 shareholders representing 32.4 percent of the total number of votes and 31.8 percent of the total number of shares in the Company were represented. The general meeting resolved on an authorization for the board to decide on issues of new ordinary shares until the annual general meeting 2019. Such issues of shares may not in total contain more than ten percent of the number of the outstanding ordinary shares in the Company at the time for the extraordinary general meeting. The Swedish Companies Registration Office has on the November 14, 2018 registered 1,776,765 new ordinary shares through a directed share issue.

At the extraordinary general meeting held on December 11, 2018, 71 shareholders representing 27.9 percent of the total number of votes and 27.4 percent of the total number of shares in the Company were represented. The board resolved on a name change of the Company, from Hansa Medical AB to Hansa Biopharma AB.

2015/2019 incentive programme

The annual general meeting 2015 resolved on an incentive program for all of the employees of the Company as follows.

The employees were offered the opportunity to acquire warrants entitling them 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 36.04) adjusted upwards annually in the amount of seven percent. Subscription for shares may take place during the period commencing June 15, 2018 up to and including June 15, 2019. This entails that the subscription price after three years will be approximately 122.5 percent of the market value of the share as per the annual general meeting 2015 and after four years will amount to approximately 131.1 percent.

Cartela R & D AB, the Company's subsidiary, is entitled to subscribe for warrants. The warrants were issued without payment of any consideration and Cartela R & D AB subsequently transferred the warrants to employees of the Company. The reason that the warrants were issued to Cartela R & D AB is that the Company was able, in this way, to include terms and conditions with a right for the Company to repurchase the warrants in the event the participant's employment with the Company terminates, which would not have been possible if the warrants had been issued directly to the employees. The warrants were transferred to the Company's employees on market terms and conditions at a price established based on a calculated market value for the warrants applying the Black & Scholes valuation model calculated by PricewaterhouseCoopers, a valuation institute independent of the Company. The value was established as SEK 8.40 per warrant based on a share price of SEK 36.04. The total number of warrants issued by the shareholders' meeting on June 2, 2015 was 400,000, which corresponded to a dilution effect of 1.2 percent of the number of shares and votes as per the date of the issue if all of the warrants were to be exercised. All of the warrants were subscribed for by Cartela R & D AB. 355,000 warrants were subsequently transferred to the employees of the Company, which corresponded to a dilution effect of 1.1 percent of

the number of shares and votes as per the date of the transfer if all of the warrants were to be exercised. For all employees, with the exception of the previous CEO, up to 60 percent of the employee's premium was subsidized and the employees have received a one-time bonus as a part of the warrant purchase. The degree of subsidization varies depending on the term of employment with the Company. The bonus payment affected the Company's earnings in the amount of approximately SEK 1,500k. The subsidy in the amount of approximately SEK 800k is booked as a current expense during the term of the warrants. In the event a warrant holder's employment with the Company terminates before the warrants are exercised and the Company elects to buy back the warrants according to the repurchase condition, the buyback must take place at market value less any subsidy received.

During 2018 and 2019 a total number of 355,000 warrants of series 2015/2019 have been exercised for subscription of 355,000 new shares in the Company, resulting in a dilution effect of 0.89 percent of the current number of shares and votes.

Long-term incentive programme 2016

An extraordinary general meeting in Hansa Biopharma was held on November 21, 2016, regarding resolutions to carry out a directed issue of ordinary shares and a proposal to adopt a long-term incentive programme for employees within Hansa Biopharma. At the extraordinary general meeting, it was resolved to adopt a long-term incentive programme in the form of a performance based share programme for employees of the group ("LTIP 2016"). LTIP 2016 has been implemented to motivate and retain competent employees as well as for the alignment of the targets of the employees with those of the shareholders and the Company, as well as to increase the motivation of meeting and exceeding the Company's financial targets.

Participants who, with certain exceptions, are employed by Hansa Biopharma during the entire programme period of three years will, by the end of the period, receive so called performance shares, i.e. listed Hansa Biopharma shares, free of charge, provided that the total shareholder return (the return to shareholders through an increased share price and reinvestments of any dividends during the vesting period) on the Company's ordinary shares exceeds 25 percent (maximum allotment is obtained if the total shareholder return amounts to 100 percent) during the programme period.

289,750 rights have been allocated in total, of which 78,250 rights previously allocated have been excluded due to accelerated vesting or terminated, so remaining allocated rights as of December 31, 2018 are 211,500. Together with a maximum of 96,000 ordinary shares which may be used to secure social charges arising as a result of LTIP 2016, this corresponds to in total 1.0 percent of the existing number of shares and votes in Hansa Biopharma. The costs for LTIP 2016 are reported in accordance with IFRS 2.

Long-term incentive programme 2018

The Annual General Meeting 2018 resolved to adopt a long-term incentive program ("LTIP 2018"). No more than 52 individuals within the Hansa Biopharma group may participate in the program and are given the opportunity to acquire warrants at market value and/or receive so called performance-based share awards ("share awards") free of charge which, provided that certain conditions are met, may give the right to acquire shares in the Company. Each employee has the right to invest in either warrants and/or share awards. The value per employee for investing in either warrants or share awards may reach a maximum value ("Participation value") and a maximum number of warrants or share awards, that is decided by which category the participant belongs to (see the chart below).

As a consequence of the employees' possibility to subscribe for warrants and acquire the remaining participation value in share awards, the outcome of LTIP 2018 will vary concerning costs and dilutions. A maximum number of 491,419 warrants or 297,902 share awards may be allotted to participants under LTIP 2018.

The warrants shall be transferred to the participants on market terms at a price established based on a calculated market value of the warrants. The value per warrant was preliminary calculated to SEK 60.60, based on a share price of SEK 231 per share. Except for the CEO, the Company will offer the participants a one-time bonus to subsidize up to 25 percent of the participant's premium (after tax). The latest date to be alloted share warrants shall be the day prior to the annual general meeting 2019. At a maximum allocation of warrants, 491,419 warrants will be acquired by the participants, corresponding to a dilution effect of approximately 1.3 percent of the number of shares and votes in the Company at the time of the annual general meeting 2018. The costs relating to LTIP 2018 are reported in accordance with IFRS 2.

Warrants and / or share awards may also be acquired by and allocated to new employees in the Hansa Biopharma Group. Such acquisitions and allocations must be made no later than the day before the annual general meeting 2019. 6,701 warrants have been acquired by the participants in LTIP 2018 as of December 31, 2018. 178,131 share awards have been totally allocated during the year, of which 580 have been excluded, remaining allocated share awards as of December 31, 2018 are 171,756.

	Maximum amount for employees	Maximum participation value of each employee (MSEK)	Maximum participation value of each category (MSEK)	Maximum amount of warrants	Maximum amount of share awards
CEO	1	5.1	5.1	84,769	51,385
Managing directors (managing Group)	8	1.5	9.4	154,915	93,907
Middle management	11	0.7	7.7	127,787	77,462
Other employees	32	0.3	7.5	123,984	75,148
Total	**52**	**–**	**29.8**	**491,419**	**297,902**

In connection with the resolution on LTIP 2018, the annual general meeting further resolved to authorize the board to issue class C shares and to authorize the board to resolve to repurchase all issued class C shares. The purpose was to ensure delivery of shares and to secure potential social charges arising from the LTIP 2018. In September, the board resolved, by virtue of the authorization, to issue new class C shares and to immediately thereafter repurchase these class C shares. The class C shares will be converted to ordinary shares before the transfer to the participants of the LTIP 2018.

Nomination committee

Prior to the 2019 annual general meeting, Hansa Biopharma's nomination committee comprises Erika Kjellberg Eriksson (representing Nexttobe AB), Astrid Samuelsson (representing Handelsbanken funds) and Sven Sandberg (representing Thomas Olausson and Gladiator). Erika Kjellberg Eriksson has been elected as chairman of the nomination committee. In addition, the chairman of the board Ulf Wiinberg is 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 annual general meeting 2020. The proposals will be published in connection with the notice to the annual general meeting 2019.

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 2015 annual general meeting. As from the annual general meeting 2018 certified public accountant Jonas Nihlberg is auditor in charge. From the annual general meeting up to and including the annual general meeting 2018, certified public accountant Dan Kjellqvist was auditor in charge. Dan Kjellqvist personally was the Company's auditor commencing at the time of the 2014 annual general meeting up to and including the annual general meeting held in 2015. 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 2018 annual report.

Board of Directors

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. The board of directors 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 of the board of directors. 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 Company's 2018 annual general meeting for a period up to and including the next annual general meeting. The fees for the board of directors' work in 2018 were set as follows. The chairman is paid SEK 900,000, and each other director besides Angelica Loskog is paid SEK 300,000. Further on SEK 40,000 is paid to the chairman and SEK 30,000 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, besides Angelica Loskog. No remuneration other than the above-mentioned fees have been paid to the board of directors except for a consulting fee for Hans Schikan of SEK 90,000 and remuneration for Ulf Wiinberg for his position as deputy CEO during 2018 of SEK 1,772,258. 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 2018 annual report for additional information regarding employment terms and conditions for the board and senior executives.

Directors

Pursuant to the articles of association, Hansa Biopharma's board must comprise not less than three and not more than ten directors. The board currently comprises six individuals, including the chairman. Each director's term continues until the end of the next annual general meeting.

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 March 21, 2019. Holdings in the Company includes one's own holdings as well as those of closely-related persons.

Ulf Wiinberg

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 for the European pharma business and he has also held the position as CEO of H Lundbeck A/S, a pharmaceutical company specialized in psychiatric and neurological disorders, for several years. Ulf is 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, CEO and chairman of the board of Ulf Wiinberg consulting&invest AB as well as CEO for X-Vax Technologies Inc in Jupiter Florida. Born 1958.

Ulf is member of Hansa Biopharma's remuneration committee, and member of the audit committee.

Independent of Hansa Biopharma and its senior management. Independent of major shareholders of Hansa Biopharma.

Holdings: 75,000 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 has extensive experience from international pharmaceutical and biotechnology companies. She has managed several research and development departments, resulting in a number of novel and approved pharmaceuticals. She has held positions such as CEO and chairman of the board at Prolifix Ltd., Senior VP Worldwide Product Development, Pharmacia & Upjohn and Dir. Int. Reg. Affairs Division, Glaxo Group Research Ltd. Birgit has also held a number of board and chairman positions of European biotechnology companies. She is member of the board of AddLife AB och Jettesta AB. Birgit holds a M.Sc. in Pharmacy from Uppsala University. Born 1948.

Birgit is chairman of Hansa Biopharma's remuneration committee and member of the audit committee and the scientific committee.

Independent of Hansa Biopharma and its senior management. Independent of major shareholders of Hansa Biopharma.

Holdings: 39,205 shares

Dr. Stina Gestrelius

Member of the board since 2007.

Stina has 40 years of experience in the pharmaceuticals and biotechnology industries. Entrepreneur and previously Head of Research at Biora AB and Deputy CEO of Medicon Valley Alliance. She is currently working with evaluation of research and innovation project proposals via the consultancy company SigridScience and has held several board positions of Scandinavian biotechnology companies including Biora AB, Biogaia AB (publ), Clavis Pharma ASA (publ), Lipopeptide AB and Gedea AB. Stina holds a M.Sc. and Ph.D. in Applied Biochemistry from Lund University. Born 1949.

Stina is member of the Hansa Biopharma's scientific committee.

Independent of Hansa Biopharma and its senior management. Independent of major shareholders of Hansa Biopharma.

Holdings: 5,833 shares

Anders Gersel Pedersen

Member of the board since 2018

Anders has a long experience from 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 was Executive Vice President of the Research & Development organization during 2008-2018 hence responsible for the discovery and development of the product pipeline from pre-clinical activities to post-launch marketing studies. He serves on the supervisory boards of Bavarian Nordic A/S (deputy chairman) and Genmab A/S. Anders 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. Born in 1951.

Anders is chairman of Hansa Biopharma's scientific committee and member of the remuneration committee.

Independent of Hansa Biopharma and its senior management. Independent of major shareholders of Hansa Biopharma.

Holdings: –

Andreas Eggert

Member of the board since 2018.

Andreas has more than 20 years of cross-functional leadership experience including commercial operations, launch and portfolio management, brand strategy, market access, and strategic consulting. He is COO at X-Vax Technology Inc. in the US. 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 US. 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. He holds an MBA from Azusa Pacific University. Born 1967.

Andreas is the chairman of Hansa Biopharma´s audit committee.

Independent of Hansa Biopharma and its senior management. Independent of major shareholders of Hansa Biopharma.

Holdings: –

Dr. Angelica Loskog

Member of the board since 2016.

Angelica Loskog is Doctor of Philosophy (Faculty of Medicine) and adjunct professor at the Department of Immunology, Genetics and Pathology at Uppsala University. She has a wide experience and is scientific advisor to Nexttobe, CEO of Lokon Pharma AB, and chairman of Vivolux AB as well as Repos Pharma AB and member of the board of Biomics AB. Born 1973.

Angelica is member of Hansa Biopharma's scientific committee.

Independent of Hansa Biopharma and its senior management.

Holdings: –

The Board of Directors' work in 2018

During 2018, the board has held twenty meetings, of which six were held per telephone and one was the inauguration meeting. The board has also made resolutions per capsulam at five occasions during 2018. In 2018, the board primarily worked with the following issues: a resolution to carry out a new share issue, evaluation of appropriate new clinical studies with IdeS and organizational issues.

At the board meetings held during the 2018 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.

The reporting period is 1 January – 31 December 2018

Board member	Elected	Present at meetings of the board	Present at meetings of the remuneration committee	Present at meetings of the audit committee	Independent in relation to the company and corporate management	Independent in relation to the company's largest shareholders
Ulf Wiinberg	2016	20 (20)	4(4)	5 (5)	Yes	Yes
Birgit Stattin Norinder	2012	19 (20)	4(4)	5 (5)	Yes	Yes
Stina Gestrelius	2007	19 (20)	–	–	Yes	Yes
Angelica Loskog	2016	18 (20)	–	–	Yes	No
Anders Gersel Pedersen [1]	2018	9 (20)	3(4)	–	Yes	Yes
Andreas Eggert [2]	2018	11 (20)	–	2 (5)	Yes	Yes
Hans Schikan [3]	2015-2018	8 (20)	1 (4)	1 (5)	Yes	Yes
Per Olof Wallström [4]	2015-2018	8 (20)	–	3 (5)	Yes	Yes

[1] Anders Gersel Pedersen was elected as new member of the board at the annual general meeting on the 29 May 2018

[2] Andreas Eggert was elected as new member of the board at the annual general meeting on the 29 May 2018

[3] Hans Schikan announced at the Annual General Meeting on May 29 2018 that he had declined re-election as a member of the Board.

[4] Per Olof Wallström announced at the Annual General Meeting on May 29 2018 that he had declined re-election as a member of the Board.

Evaluation of the Board of Directors' work

Pursuant to the Code, the board of directors 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, in the end of 2018, interviewing the directors with questions about the work of the board of directors. The result of the responses has been verbally declared to the directors and the members of the nomination committee.

Board committees

Remuneration committee

The remuneration committee has consisted of Ulf Wiinberg, chairman, Birgit Stattin Norinder and Hans Schikan until the annual general meeting 2018, with the exception for the period January 1 until March 20, when Ulf Wiinberg was not a member of the committee and Birgit Stattin Norinder was chairman. After the annual general meeting 2018, the remuneration committee has consisted of Brigit 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 of Directors.

The primary duties of the remuneration committee are to:

- prepare decisions for the Board of Directors regarding remuneration principles, remuneration and other employment terms and conditions for senior management, among other things by proposing to the Board of Directors the guidelines for remuneration to senior management, to be adopted at the annual general meeting of the shareholders;
- monitor and evaluate any programs pending or adopted during the year for variable compensation for senior management; and
- monitor and evaluate the application of the guidelines for remuneration adopted by the annual general meeting, as well as applicable remuneration structures and levels for the Company.

Audit committee

The audit committee has consisted of Per-Olof Wallström, chairman, Birgit Stattin Norinder and Ulf Wiinberg until the annual general meeting 2018 with the exception for the period January 1 until March 20 when Ulf Wiinberg was not a member but instead Hans Schikan was member of the committee. After the annual general meeting 2018 the audit committee has consisted of Andreas Eggert, chairman, Ulf Wiinberg and Birgit Stattin Norinder. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board of Directors. 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 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 the Company;
- assume responsibility for the preparation of the Board of Directors' work by ensuring that the Company's financial reporting maintains high standards;
- assist the nomination committee in the preparation of proposals for resolutions by the shareholders' meeting regarding the choice of auditor and fees for the auditor's work;
- meet with the Company's auditor on a regular basis in order to obtain information regarding the focus and scope of the audit and to discuss the coordination between the external auditor and internal procedures for overview and insight into the Company's risks;
- evaluate the auditor's work and inform the Company's nomination committee or, where applicable, special nomination committee regarding the results of the evaluation; and
- assist the nomination committee in the preparation of proposals for nomination of the external auditor prior to the annual general meeting and proposals for fees for the external auditor's work.

Scientific committee

The scientific committee has consisted of Birgit Stattin Norinder chairman, Stina Gestrelius, Hans Schikan and Angelica Loskog until the annual general meeting 2018. After the annual general meeting 2018 the scientific committee has consisted of Anders Gersel Pedersen, chairman, Stina Gestrelius, Birgit Stattin Norinder and Angelica Loskog. The committee is obligated to keep minutes of its meetings and make the minutes available the Board of Directors.

The primary duties of the scientific committee are to:

- assist the Board of Directors 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 of Directors from time to time.

The scientific committee has not had any separate meetings during 2018, but the duties above were handled at board meetings in February, September and December 2018.

Company management

The board appoints a CEO to manage the Company. In addition to the CEO, there are eight individuals who make up Company management:

- Senior Vice President, Research and Development
- Vice President, Chief Financial Officer
- Vice President Business Development and Investor Relations
- Vice President, Commercial Operations
- Vice President, Regulatory Affairs
- Vice President, Corporate Strategy
- Vice President, Global Medical Affairs
- Vice President, Global HR

The management group holds meetings every month to discuss the Group's earnings and financial position, the status of research and development projects, strategic issues, and follow-up of 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 Nasdaq Stockholm Rulebook for issuers 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 million. 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 annual general meetings 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'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.

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

Senior executives

Hansa Biopharma's senior executives currently comprise ten individuals: the President and the CEO Søren Tulstrup; Senior Vice President, Research and Development Christian Kjellman; Vice President, Chief Financial Officer Eva-Maria Joed; Vice President Business Development and Investor Relations Emanuel Björne; Vice President, Commercial Operations Henk Doude van Troostwijk; Vice President, Regulatory Affairs Karin Aschan; Vice President, Corporate Strategy Max Sakajja; Vice President, Global Medical Affairs Vincenza Nigro and Vice President, Global HR 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 March 21, 2019 are listed below. Holdings in the Company includes both one's own holdings and/or those of closely-related persons

Søren Tulstrup

CEO

Søren Tulstrup is President and CEO of Hansa Biopharma since March 2018. Søren Tulstrup has a broad and extensive background as senior executive in the global biopharma industry. Recently, he served as CEO of Vifor Pharma AG (VTX:VIFN), Switzerland-based global pharmaceutical company with a market-leading position within chronic kidney disease. Prior to joining Vifor Pharma, he served as Senior Vice President, Global Franchise Head, MPS at Shire Pharmaceuticals, CEO of Santaris Pharma A/S, (now part of Roche). Furthermore, Søren has served in several senior commercial roles within Merck & Co., Inc. and Sandoz Pharma AG (Novartis). He holds a M.Sc., Economics and Business Administration from Copenhagen Business School. Born 1965.

Holdings: –
Share rights 51,389

Christian Kjellman

Senior Vice President, Research and Development

Christian joined Hansa Biopharma in 2008 after serving at BioInvent AB as Senior Scientist 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. At Hansa Biopharma, Christian has been leading the development of our lead candidate, imlifidase, from discovery to late stage clinical phase. With his expert knowledge, he currently leads the progression of imlifidase and all other ongoing research projects. Christian holds a M.Sc. in Chemical Biology and a Ph.D. in Tumour Immunology from Lund University. Born 1967.

Holdings: –
Share rights 54,084

Eva-Maria Joed

Vice President, Chief Financial Officer

Eva-Maria joined Hansa Biopharma in 2015 and brings long and wide experience within finance to the company. She has held positions both as Chief Accountant and CFO and worked in international companies such as Kemira Kemi AB, Johns Manville AB within the Berkshire Hathaway group and Procordia Food AB. She has also been responsible for implementing new financial systems and policies, and for IT. Eva-Maria holds a M.Sc. in Business and Economics from Lund University. Born 1969.

Holdings: 8,000
Share rights: 20,000

Emanuel Björne

Vice President, Business Development and Investor Relations

Emanuel joined Hansa Biopharma in 2007 counting more than 10 years of operational experience from Scandinavian Pharma and Biotech industry (Biolin Scientific, Polypeptide Labs and Hansa Biopharma) serving as Business Analyst, Analytical Chemist and CEO. Emanuel holds a M.Sc. in Engineering Physics (biophysics core) from Lund University and the University of California at Santa Barbara. Born 1973.

Holdings: 20,000
Share rights: 20,000

Henk Doude van Troostwijk

Vice President, Commercial Operations

Henk has extensive management experience in sales and marketing in the areas of transplantation and orphan drugs. Before joining Hansa Biopharma in 2016, Henk 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 holds an MBA from Henley Management College at the University of Reading, UK. Born 1965.

Holdings: –
Share rights: 22,100

Karin Aschan

Vice President Regulatory Affairs

Karin joined Hansa Biopharma in 2016. She has a long experience from working within Regulatory Affairs, initially at AstraZeneca, and has worked on EU and US projects in all clinical trial phases through registration up to marketing phase. Karin has held the position as Head of Regulatory Affairs at Active Biotech and at Clinical Data Care. She has also been working as an independent regulatory consultant. Karin holds a M.Sc. in Pharmacy from Uppsala University. Born 1961.

Holdings: –
Share rights: 14,504

Vincenza Nigro

Vice President, Global Medical Affairs

Vincenza holds more than two decades of international, life sciences industry expertise in medical affairs, clinical development and commercial leadership roles, including deep experience in transplantation and orphan diseases. Before joining Hansa Biopharma in 2018, Vincenza built and led the global medical affairs function at Veloxis Pharmaceuticals, a specialty pharmaceutical company focused on transplantation. Previously, she spent over a decade at Hoffmann- La Roche in the US in drug discovery, clinical development and commercial roles within immunology and transplantation. She has also held a commercial leadership role at US specialty pharma company Enzon Pharmaceuticals, which was focused on oncology. Ms. Nigro holds an MBA degree from Massachusetts Institute of Technology (MIT). Born 1963.

Holdings: –
Share rights: 7,042

Anne Säfström Lanner

Vice President, Global HR

Anne joined Hansa Biopharma in January 2019, after having served at European Spallation Source (ESS), a joint 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 growing start-up international companies. Anne holds a Bachelor of Social Science in Human Resource Management, focusing in organizational development & leadership, from Lund University. Born 1969.

Holdings: –
Share rights: –

Max Sakajja

Vice President, Corporate Strategy

Max joined Hansa Medical in 2017. He has a broad background in corporate development, strategy and finance. He has previously worked with corporate finance at Swedish Orphan Biovitrum AB (SOBI) in the position of Director Mergers & Acquisitions. Before joining Hansa Biopharma, Max worked as the Global Product and Service Development Manager at Envirotainer, the world leader in secure cold chain solutions for the life science industry, where he played an active role in building new growth-focused corporate strategy and execution. Max has also worked as an independent management consultant providing advisory services to the Scandinavian life science industry. Max holds an M.Sc. in Molecular Biotechnology from the Royal Institute of Technology. Born 1981.

Holdings: 3,100
Share rights: 20,201

Internal control 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 marketplace 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 management group, 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 must be 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 balance sheet 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 senior 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 includes controls to prevent and detect shortcomings in these 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. 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 of Directors, instructions for the CEO, financial policy, disclosure policy, insider instructions, and risk management policy.

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 must compile 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, must be analysed and commented upon by Company management. Follow-up takes place through regular meetings for review of these reports and analyses with the various managers and project managers. 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, ensuring that there is a properly functioning reporting structure in which the various managers and project managers report pursuant to standardized reporting templates, and that important income statement and balance sheet items are specified 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 marketplace. 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.

Auditor statement on the corporate governance report

To the general meeting of the shareholders in Hansa Biopharma AB (publ), 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 2018 on pages 91 – 105 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 11 April 2019
KPMG AB

Jonas Nihlberg
Authorized public accountant
Lead auditor

www.hansabiopharma.com