Annual Report **2019**

HANSA BIOPHARMA

Annual report 2019

Hansa Biopharma in brief

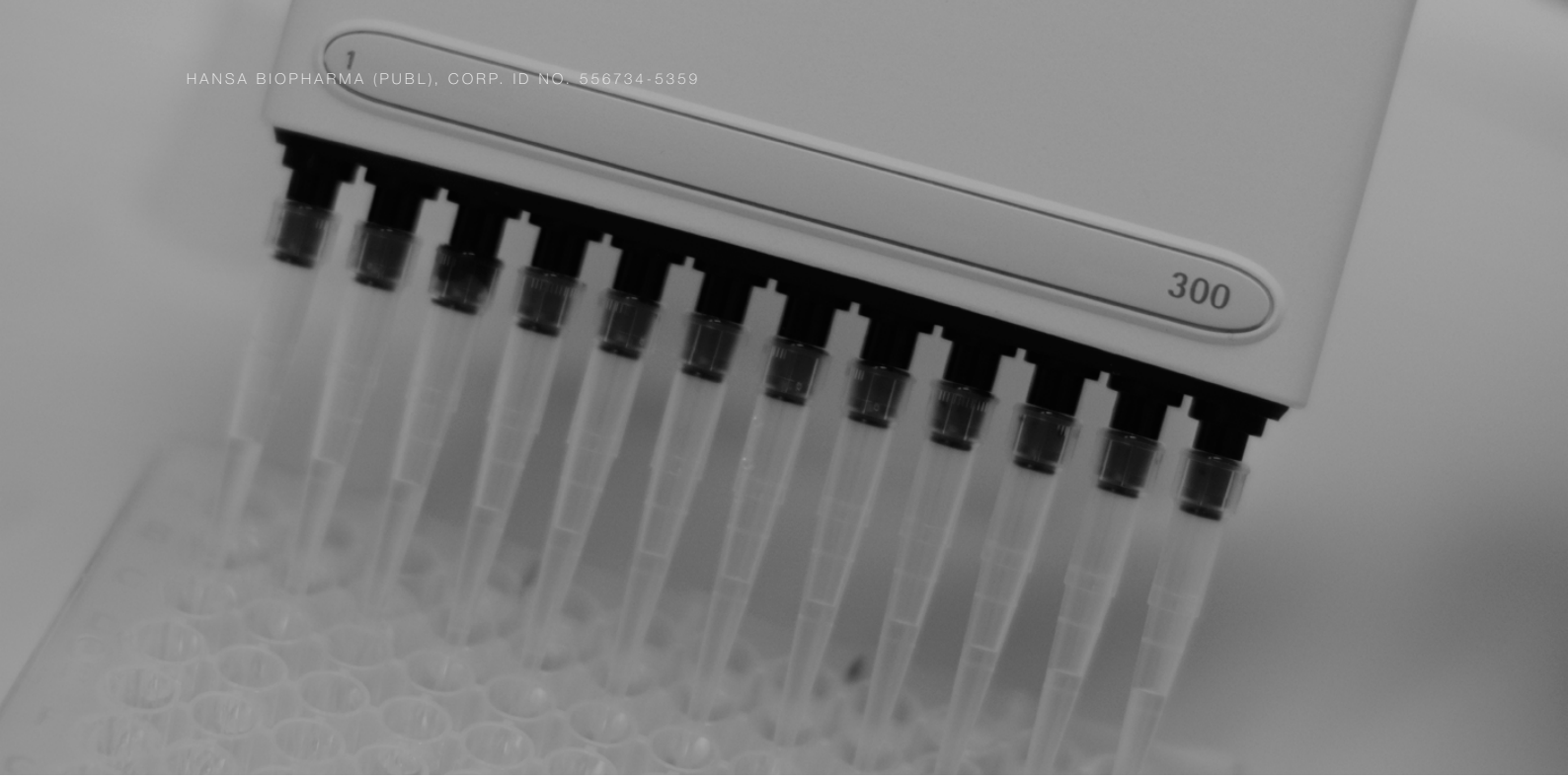
Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.

The Company's lead product candidate, imlifidase, is an antibody-cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. Imlifidase is currently under review for a potential marketing authorization by the European Medicines Agency (EMA).

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

Our vision

At Hansa Biopharma we envision a world where all patients with rare immunologic diseases can lead long and healthy lives.



2019 in brief

Marketing authorization review for imlifidase in EU on track and a regulatory path agreed with FDA in the US. Solid advancement across our pipeline and platform.

January–December 2019 Business Highlights

- The European Medicines Agency (EMA) accepted Hansa's submission of a Marketing Authorization Application (MAA) for review of imlifidase in highly sensitized patients at the end of February 2019. The ongoing review of imlifidase in Europe is on track and responses to the Day 120 questions were submitted on December 20, 2019. An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected in the second quarter of 2020.
- Hansa Biopharma reached agreement with the Food and Drug Administration (FDA) on a regulatory path forward for imlifidase for kidney transplantation in highly sensitized patients in the U.S. The Company will conduct a randomized, controlled clinical study in a well-defined population of highly sensitized patients with the highest unmet medical need in context of the U.S. Kidney Allocation System. Results from this clinical study could support a submission of a Biologics License Application (BLA) in the U.S. under the accelerated approval pathway by 2023.
- The Company advanced its pipeline during 2019 with completion of patient enrolment into the investigator initiated Phase 2 study in anti-GBM in January 2020, the initiation of two new Phase 2 programs in Antibody Mediated Rejection (AMR) and in Guillain Barré Syndrome (GBS). Acute AMR is one of the most challenging adverse events after kidney transplantation, occurring in 10-15% of patients, and is the main cause for graft dysfunction.[1] GBS is a rare, acute inflammatory disease of the peripheral nervous system that affects 1-2 in 100,000 people annually.[2] Lastly a lead candidate from the Company's NiceR program was selected for clinical development.
- In mid-April the Company divested its shareholding in Genovis to a group of Swedish institutional investors. The transaction provided a profitable exit for Hansa Biopharma, and the funds generated will be used to support financing ongoing operations.
- At the 2019 American Transplant Congress (ATC) in June, Dr. Edmund Huang of Cedars-Sinai Medical Center presented data demonstrating a significant reduction in time to transplant for highly sensitized patients treated with imlifidase over matched controls waiting under the Kidney Allocation System (KAS) in the U.S. Dr. Huang's session won ATC's People's Choice Award for the most impactful presentation.
- In September 2019, positive results from a pooled analysis of Phase 2 trials with imlifidase for desensitization in highly sensitized kidney transplant patients were presented for the first time at the European Society of Organ Transplantation's (ESOT) Congress. The data demonstrated that imlifidase enabled kidney transplantation in all 46 sensitized patients.
- Hansa Biopharma has continued to build its organization in preparation to become a fully integrated, commercial-staged biopharmaceutical company. By year-end 2019, the company employed 74 people, which is up from 52 employees a year ago. New employees have been added primarily within R&D, Medical Affairs and Commercial.

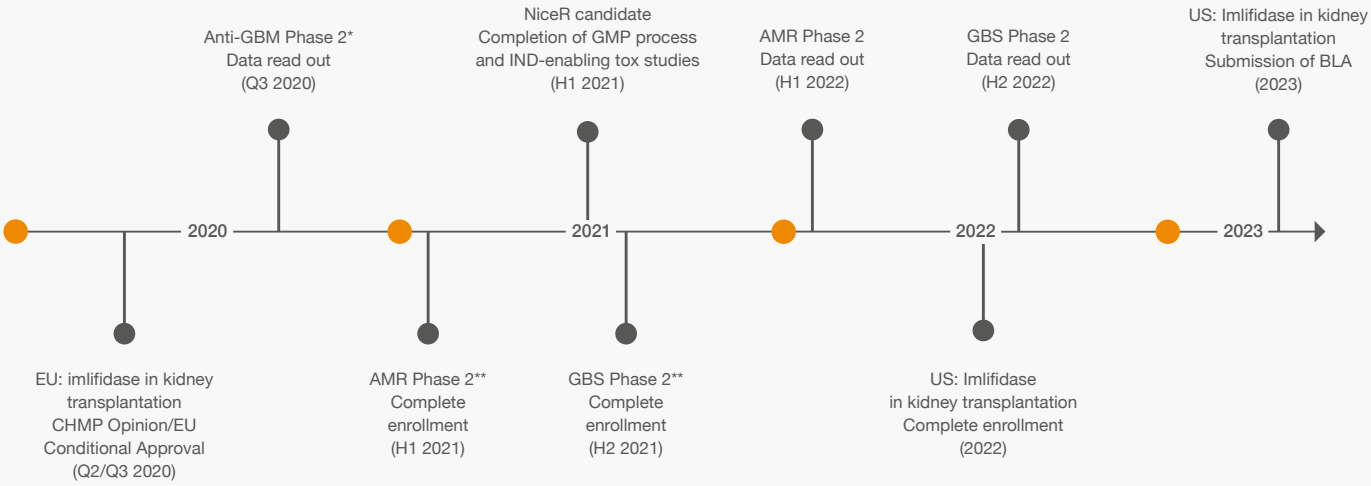
- Two new board members were appointed; Eva Nilsagård and Mats Blom. Eva Nilsagård is currently interim CFO at OptiGroup AB and founder and CEO of Nilsagård Consulting AB. She has served as CFO of Vitrolife and Plastal and Senior Vice President, Strategy & Business Development at Volvo Group. Mats Blom has extensive executive experience and serves as CFO of NorthSea Therapeutics and previously as CFO of Zealand Pharma A/S.

Events after the end of the reporting period

- Hansa Biopharma announced on January 27, 2020 the completion of enrollment in the anti-GBM Phase 2 study. This marks an important milestone for the Company's expansion outside transplantation. The first data read-out from the anti-GBM study is expected to be presented in Q3 2020. Anti-GBM also known as Goodpasture's disease is a rare immunological disease with a significant unmet medical need.
- CSO, Christian Kjellman, assumes an expanded responsibility as CSO and COO effective from February 2020 as the Company prepares to implement a focused launch strategy through leading transplantation clinics and experts upon a conditional approval of imlifidase in the EU.
- At the Cutting Edge of Transplantation summit March 6, 2020, Hansa Biopharma announced long term follow-up data that demonstrates 2-year graft survival of 89% after imlifdase treatment and transplantation.[3] The long term follow up data is in line with best expectations in this group of challenging patients with a very high medical need.
- On March 9, 2020 Hansa Biopharma was notified that Consonance Capman GP, LLC, had reached and exceeded 5% ownership in Hansa Biopharma AB and thus become a major shareholder.
- The COVID-19 virus (Corona): Hansa Biopharma implements measures to protect employees, take social responsibility while attempting to limit negative effects on Hansa's business. Some of the effects resulting from the COVID-19 virus pandemic will potentially impact parts of the Hansa business, namely: recruitment timelines of ongoing clinical studies, start of recruitment into the US phase 3 study, the potential European launch of imlifidase in kidney transplantation, financing strategy.

[1] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.
[2] McGrogan et al., "The Epidemiology of Guillain-Barré Syndrome Worldwide", Neuroepidemiology;2009, 32(2):150-63.
[3] www.myast.org/ceot Abstract no 32 "Long-term Outcomes of Sensitized and Crossmatch-Positive Kidney Transplanted Patients after Desensitization with Imlifidase"

Anticipated future milestones



*Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund.
**An expected delay in the recruitment of patients of 3-6 months in the AMR and GBS studies have been incorporated following the COVID-19 virus (Corona).

CEO statement

2019 was an important and overall successful year for Hansa Biopharma – a year with significant progress across our pipeline and platform development activities and a year in which we achieved the landmark milestone of getting our first Marketing Authorization Application (MAA) accepted for review by a regulatory agency, namely our MAA for imlifidase in kidney transplantation in Europe which was accepted for review by the EMA on Feb 28, 2019. If approved, we have the ability to launch the first in a series of drug candidates in our internal pipeline addressing rare conditions with high unmet medical need and through this transform Hansa Biopharma into a commercial-stage biopharmaceutical company. The review is progressing according to plan, and we submitted the Day 120 responses, within the time window, to EMA in December. Assuming all goes as planned, the opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected during the second quarter, and a formal decision by the European Commission is possible in the third quarter of 2020.

In the US, following a meeting with the FDA on November 20, 2019, we now have a clear path forward toward a BLA submission for imlifidase in kidney transplantation that could support accelerated approval. Given the requirement by the FDA to conduct a randomized, controlled trial prior to submitting a BLA, I am pleased that an agreement was reached with the FDA on a trial design that is limited in scope, includes patients with a high degree of unmet medical need, and is strongly powered to show a significant benefit for the imlifidase arm compared to the control arm.

The study will include approximately 50 highly sensitized kidney patients (≥ 99.9% cPRA). After twelve months the patient's eGFR (estimated Glomerular Filtration Rate) will be measured as a surrogate marker to demonstrate a clinical benefit of imlifidase therapy versus patients in the control arm. We are currently in close interaction with the FDA about the final study protocol. Once the protocol is formally accepted, we will set up the specific trial centers in the US and apply for the necessary ethical approvals. We plan to start recruiting patients towards the end of the year.

Looking beyond the transplantation indication, we see significant potential for imlifidase in the area of acute autoimmune diseases, particularly those for which there is currently no approved therapy, and we have achieved significant progress across our pipeline activities within this disease area during 2019. The completion of enrollment of patients in the investigator initiated anti-GBM antibody disease study was press-released in January 2020 and marks an important milestone for Hansa Biopharma's expansion outside transplantation. We look forward to the next milestone in the third quarter of 2020 when the first data read-out from the anti-GBM study is expected to be presented.

In addition to the ongoing anti-GBM study, we have initiated two new Phase 2 programs during 2019, one in the acute autoimmune disease Guillain Barré Syndrome (GBS) and one in Antibody Mediated Rejection (AMR) in kidney transplant patients. Both studies are now actively recruiting patients.

To summarize, we have made significant progress both in our pipeline building activities and our regulatory interactions in the past year. Another important accomplishment has been our ability to attract the right competences across a range of functional areas from very experienced talent in the industry. A key priority of ours is to build a high-performance medical affairs and commercial organization to ensure a successful potential launch of imlifidase in kidney transplantation.

Our launch strategy involves a sequenced targeting of leading kidney transplantation centers with the potential to become early adopters and centers of reference. We believe imlifidase, as a potentially transformative therapy for highly sensitized patients, has very significant long-term potential. In order to fully realize this potential, however, it will be key to secure early positive treatment experiences by the right centers in the right patients.

Launching a highly innovative drug requires a high-quality internal functional infrastructure with a clear focus on building the necessary external disease awareness and medical intervention preference and associated infrastructure. As said above, we are very encouraged by the talent we have been able to attract and integrate into our organization so far.

If we look outside transplantation and autoimmune indications for imlifidase, we see a very valuable opportunity in the gene therapy space. Most gene therapy programs today use viral vectors originating from Adeno-Associated Viruses (AAV) for gene insertions in vivo. Many patients are not eligible for gene therapy using such vectors due to the existence of neutralizing anti-AAV antibodies that prevent effective transduction. Using imlifidase as preconditioning therapy could potentially improve both efficacy and safety and enable a larger group of patients to benefit from the very promising gene therapies now being investigated and becoming available. This would be a very important value driver and we are currently seeking partnerships in order to develop this area further.

Last but not least, we see significant potential for our next generation enzymes from the NiceR program that we develop for repeat dosing. Drug candidates from this program have the potential to address high unmet medical needs within chronic autoimmune diseases, transplantation, repeat dosing gene therapy and oncology. In 2019, based on encouraging pre-clinical data, we were able to select a lead candidate from the NiceR program and are now focused on preparing this candidate for future clinical studies.

Hansa Biopharma is continuously making progress in transitioning the organization into a fully integrated, commercial-stage global biopharmaceutical company that brings life-saving and life-altering therapies to patients with rare diseases and generates long-term value to our shareholders and society at large.

While an exciting and potentially transformative year lies ahead of us, the COVID-19 virus pandemic imposes additional challenges to us as a company. We have taken measures to protect our employees and take social responsibility while attempting to limit negative effects on Hansa's business. It is still too early to fully understand the potential negative impacts that the pandemic will have on our business – however, the following are key areas we expect an impact:

- The regulatory process (MAA) with EMA is on track with the previously communicated timeline; however, EMA has highlighted a potential risk of staff shortage in the coming period;
- The European launch of imlifidase in kidney transplantation following a potential conditional approval may be impacted by limited access to and reduced decision making ability of market access authorities, potentially delaying pricing and reimbursement approval in early launch countries. In addition, pre-launch communication activities may be impacted negatively by reduced ability to engage with key opinion leaders and clinicians at targeted centers. It remains our aim, however, to launch imlifidase in the first clinics this year;
- We expect a delay in the recruitment of patients in the AMR and GBS studies by 3-6 months;
- We aim to commence the recruitment of the randomized controlled phase 3 study for imlifidase in highly sensitized patients in the US in the 4th quarter of 2020. A reprioritization and cancellation of activities by the FDA as well as operational challenges in initiating trial centers may however impact the timeline;
- Timing of securing financing from the second half of 2021 onwards.

Søren Tulstrup
President and CEO of Hansa Biopharma
Lund, Sweden, April 2, 2020

Our current strategic priorities are:

- Establish a commercial and medical infrastructure in Europe.
- Attain marketing authorization in Europe for imlifidase as a treatment for highly sensitized patients to enable kidney transplantation. Conduct a new randomized, controlled study in the US in the context of KAS to support a BLA filing by 2023.
- Investigate the potential of imlifidase in autoimmune indications and post transplantation.
- Advance a new set of immunomodulatory enzymes designed for repeat dosing in relapsing diseases (NiceR) into clinical development.
- Explore potential combination therapies with imlifidase in oncology and in gene therapy.

We are on a journey to transform Hansa Biopharma into a fully integrated biopharmaceutical company

Targeting rare diseases with a high unmet medical need

- Imlifidase is a unique IgG antibody-cleaving enzyme with a rapid onset of action and high specificity for inactivation of IgG in patients with rare immunologic diseases.

Evolution into a fully integrated biopharmaceutical company

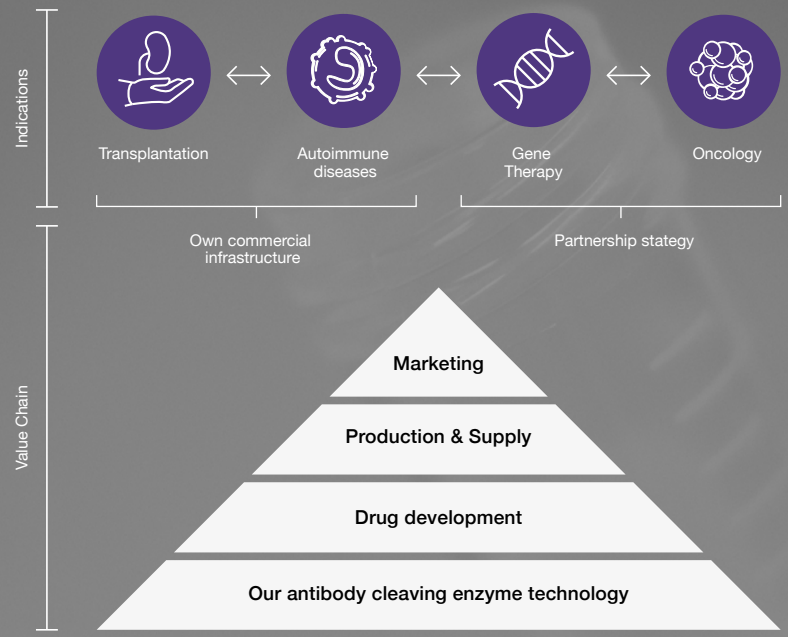
- Controlling the full value chain from early discovery through commercialization to maximize the value creation and capture.

Preparing for commercialization

- Preparing for potential launch of imlifidase under conditional approval in core European markets starting in H2 2020. MAA is currently under review by EMA.
- Imlifidase to be launched through Hansa´s own medical and commercial organization, while the company is expected to pursue a partnership strategy outside core markets.
- In the US a clear regulatory path has been agreed with the FDA that could support potential submission of a BLA in 2023 under the accelerated approval pathway.
- Broad technology protection with patent coverage throughout 2035 in key markets and orphan drug designation in both the US/EU in our lead indications.

Leveraging our proprietary antibody cleaving enzyme technology

- Advancing our pipeline with three phase 2 programs in transplantation and acute autoimmune diseases.
- New set of modified enzymes under development (NiceR program) for repeat dosing; potentially enabling treatment in relapsing diseases and oncology.
- Exploring potential combination therapies in oncology with IgG-modulating enzymes and gene therapy in patients with neutralizing antibodies through potential partnerships.



Chairman letter

Hansa Biopharma is a young company, only thirteen years old. The company started out with innovative academic research in the field of autoimmunity and has, in a cost-efficient, focused and rapid way, used its innovative scientific platform to develop its first drug candidate accepted for regulatory review: imlifidase for kidney transplantation. This landmark achievement could not have been achieved if it wasn't for all the talented and dedicated people in the company. I am truly impressed by their commitment to develop science into medical therapies that can make a real difference for patients suffering from serious rare conditions with no or only limited therapeutic options available to them. After all the diligent efforts by the Hansa team over the past years, we hope to be able to bring imlifidase to highly sensitized patients waiting for a kidney transplant later this year.

Our key short-term priority is to ensure regulatory approval and a subsequent successful launch of imlifidase in kidney transplantation – first in Europe and later in the US and other geographies – and I am very excited by the potential this drug candidate has to transform practice in the transplantation field and significantly improving access to kidney transplantation for highly sensitized patients with currently little hope to benefit from this life-saving and life-altering procedure. I am, however, equally excited by the potential Hansa's platform of immunomodulatory with enzymes may have to generate drug candidates for autoimmune diseases and cancer and as pre-treatment to potentially enable gene therapy in patients with neutralizing antibodies.

In the year just passed, significant progress was made in our efforts to investigate imlifidase as a drug candidate for serious, acute autoimmune diseases. Patient enrollment has now been completed in the ongoing anti-GBM phase 2 study and we are looking forward to the high-level data read-out from this study later this year. A phase 2 study of imlifidase in Guillain Barre Syndrome was also commenced.

We are also investigating the potential that imlifidase could have within gene therapy. Gene therapy is essentially about the prospects of altering the gene setup and accomplish a cure of a rare disease. There is no room for complications in such a therapy because you only have one shot for the goal. That is where imlifidase may have a role. A significant number of potential gene therapy patients have pre-existing antibodies towards the vectors used by the gene therapies, which constitutes a material challenge and a barrier for efficacy and safety. Imlifidase may potentially help these patients qualify for gene therapy by creating the antibody-free environment needed for successful transduction. Enabling a larger share of patients suffering from rare genetic diseases to benefit from breakthrough gene therapy would obviously be of critical value for these patients.

2019 was a landmark year in the history of Hansa Biopharma and 2020 holds the potential to be a transformational year for the Company. The team at Hansa is totally focused on bringing truly innovative therapies from discovery to the patients who need them the most and I feel privileged to be part of the team.

Ulf Wiinberg
Chairman, Hansa Biopharma

The role of immunoglobulin antibodies

An immune response begins with the recognition of a pathogen or foreign molecules followed by a reaction to eliminate it. A wide variety of immune cells and molecules are involved in the development of immune responses. Antibodies, also known as immunoglobulins (Ig), are proteins 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 to which 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.

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

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

In transplantation, by design foreign material is introduced to an individual's immune system. In order to prevent the immune system from fulfilling its duty to recognize and reject the transplanted organ, all transplanted patients are treated with immunosuppressant drugs in order to prevent or mitigate transplant rejection. Also, donors and potential recipients need to be matched with respect to blood type and tissue type prior to transplantation to minimize the risk of transplant rejection.

As part of a natural immune response against the transplanted organ, the immune system can develop antibodies, which then contribute to a rejection. This process is referred to as antibody-mediated rejection (AMR).

Patients in need of a new organ, such as kidney, lung 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.

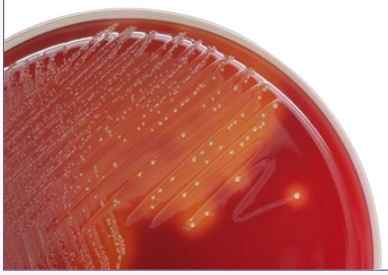
Patients on transplant waitlists are screened with respect to their anti-HLA antibody profiles and carefully tested with respect to donor-specific antibodies (DSA) prior to an actual transplantation. Highly sensitized patients have high levels of anti-HLA antibodies and often DSAs are identified preventing these patients from receiving a transplant since DSAs are likely to target and significantly compromise a transplanted organ. The broader reactivity of the antibodies, the lower the likelihood of finding a donor organ that will be a match. Many of these highly sensitized patients will indefinitely remain in a debilitating disease state on long-term dialysis treatment, which is associated with high cost, a poor quality of life and an increased mortality rate.

Our antibody cleaving enzyme technology

Imlifidase – a novel approach to eliminate pathogenic IgG

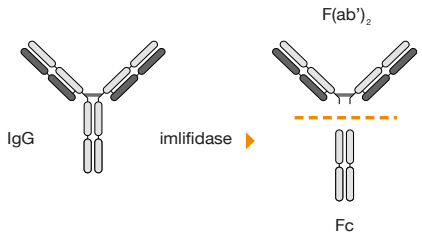
Origins from Streptococcus pyogenes

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



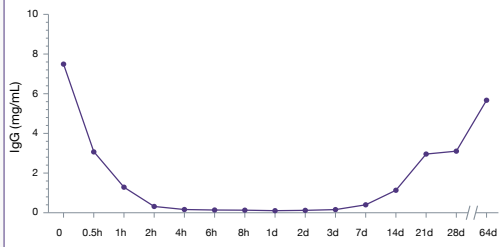
Imlifidase, a unique IgG antibody-cleaving enzyme

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



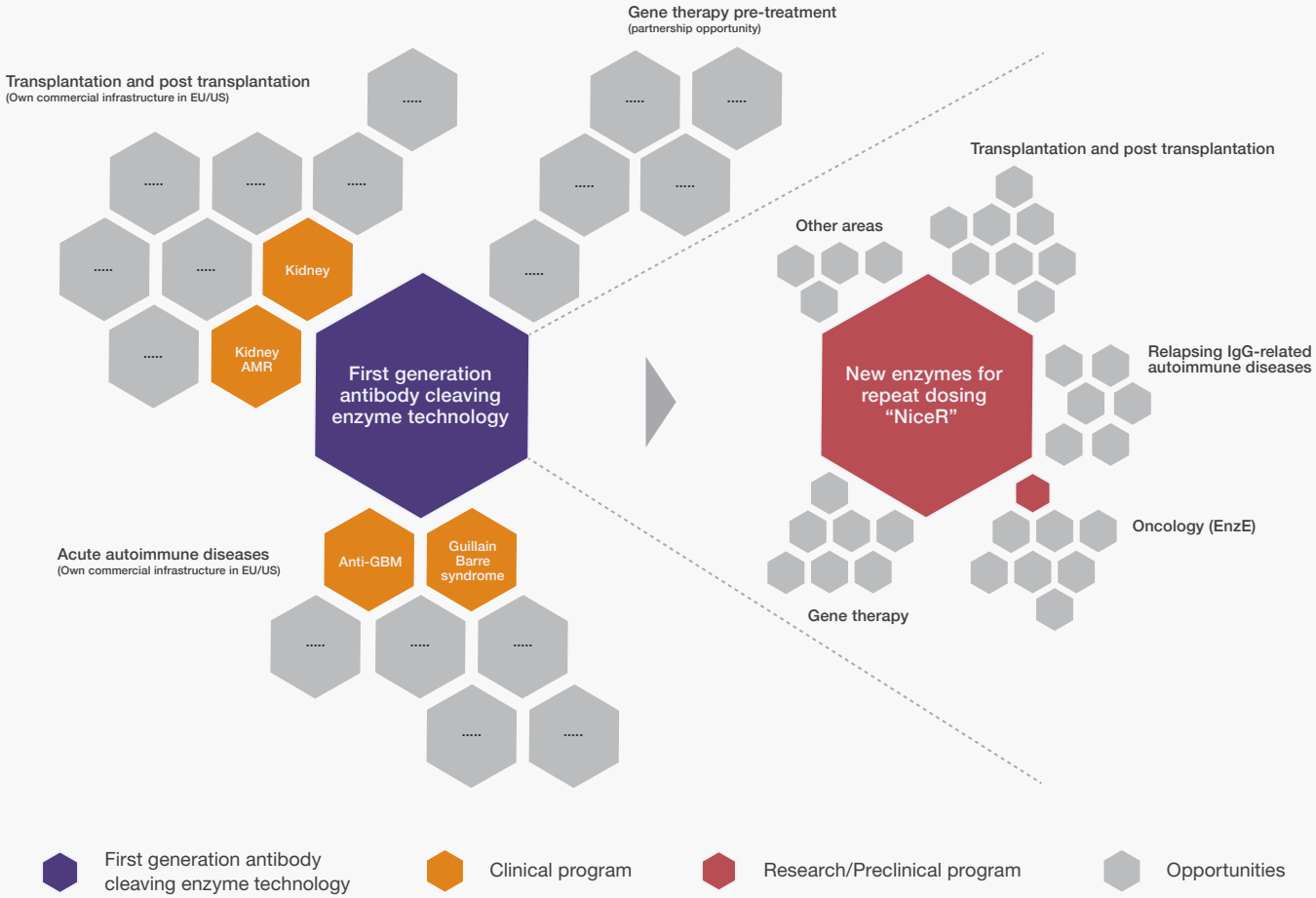
Imlifidase inactivates IgG in 2 hours

- Rapid onset of action that inactivates IgG below detectable level in 2 hours
- IgG antibody-free window for approximately one week



Potential indication universe

Our flexible and versatile enzyme technology platform may potentially provide ample opportunities in transplantation, autoimmune diseases, oncology and gene therapy



Introduction to Hansa Biopharma development programs

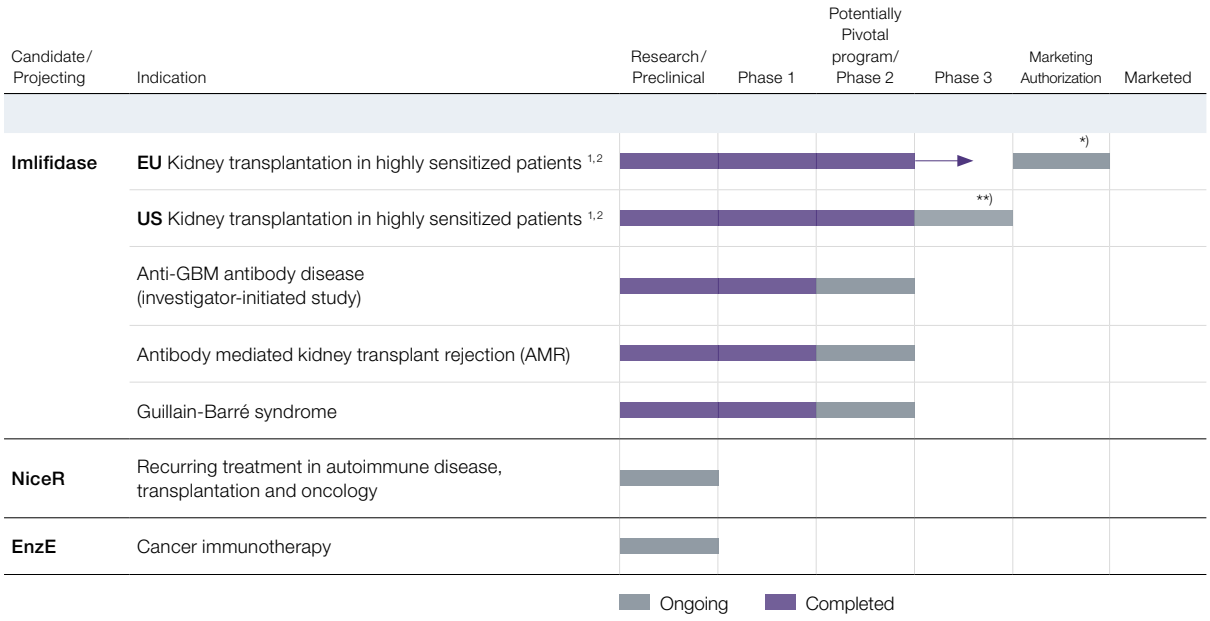
Imlifidase is a unique IgG antibody-cleaving enzyme that specifically and rapidly cleaves immunoglobulin G (IgG), thereby eliminating immunological barriers and potentially enabling treatment of immune-mediated diseases. Imlifidase origins from *Streptococcus pyogenes*, a species of a Gram-positive, spherical bacteria in the genus *Streptococcus*.

Imlifidase is currently under review by EMA for kidney transplantation in highly sensitized patients. A CHMP opinion is expected in the second quarter 2020. Imlifidase is also being evaluated in two Phase 2 programs within autoimmune diseases, namely anti-GBM antibody disease and Guillain Barré syndrome. Lastly, imlifidase is also being evaluated for acute antibody mediated rejection after kidney transplantation. If approved, imlifidase may have the potential to meet a large unmet need and transforming the lives of people with rare disease.

NiceR (Novel immunoglobulin cleaving enzymes for repeat dosing) is a new set of enzymes for repeat dosing; potentially enabling treatment of relapsing diseases. The new IgG-cleaving enzymes have lower immunogenicity in preclinical models, which potentially may enable applications in a broader array of indications, including reoccurring AMR, relapsing autoimmune diseases and oncology. The first selected promising new drug candidate from the NiceR program is an IgG-cleaving enzyme (cysteine peptidase) with characteristics based on a homolog to imlifidase, but with lowered immunogenicity.

EnzE (Enzyme-based antibody Enhancement) is an enzyme-based antibody enhancement that through pre-treatment potentially can improve the therapeutic effect in oncology where the abundance of normal IgG in blood interferes with therapeutic monoclonal antibodies. EnzE is currently being investigated as a pre-clinical development project with proof of concept demonstrated in preclinical models.

Broad pipeline in transplantation and autoimmune diseases



[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7).

[2] Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine).

*) EMA: In imlifidase for kidney transplantation we have filed for conditional approval after completion of phase 2. A post-approval study would need to be executed in case of approval.

**) FDA: Agreement with the FDA on a regulatory path forward in the US. New clinical study could support BLA submission by 2023.

Clinical studies with imlifidase in kidney transplantation

Enabling kidney transplantation for highly sensitized patients
Hansa Biopharma continues to advance imlifidase toward marketing authorization for enabling kidney transplantation in highly sensitized patients in Europe.

The Marketing Authorization Application (MAA) for imlifidase is under review for conditional approval by the European Medicines Agency (EMA). Hansa Biopharma submitted responses to the Day 120 questions on December 20, 2019 and the review process is on track. An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected in the second quarter of 2020, followed by a potential decision by the European Commission during the third quarter 2020.

In the U.S., Hansa Biopharma recently agreed with the FDA on a regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients. Upon agreement with the FDA and following submission of a final study protocol, the Company will conduct a randomized, controlled clinical study in a limited group of highly sensitized kidney patients using a surrogate endpoint.

The new study will target a limited and well-defined population with the highest unmet medical need, consisting of very highly sensitized kidney patients with a cPRA level of ≥99.9% who are waiting for a deceased donor transplantation. These patients have very limited access to transplantation and the only available therapy today is waiting on dialysis for a compatible transplant. In 2019, around 3,000 patients were registered on the waiting list in the US with a cPRA level of 99.9% or above. [4]

The study discussed with the FDA includes approximately 50 patients to be randomized when a donor kidney becomes available to either imlifidase or to a control arm that will continue on the waitlist. A surrogate endpoint measured in the form of eGFR (kidney function) will be used to demonstrate the clinical benefit of imlifidase over the control group after 12 months.

Results from this clinical study could support a future submission of a Biologics License Application (BLA) in the U.S. under the accelerated approval pathway by 2023.

Four succesfully completed Phase 2 studies with imlifidase in highly sensitized patients

Type of study	ClinicalTrials.gov Identifier	Subjects	Country	Design	Main objective	Publication
Study 02 Phase 2	NCT02224820	8	SWE	Single-center, single-arm, open-label.	Efficacy defined as Imlifidase dosing scheme resulting in HLA antibody levels acceptable for transplantation, within 24 hours	Lorant et al (2018) American Journal of Transplantation
Study 03 Phase 2	NCT02475551	10	SWE	Single-center, single-arm, open-label, no prior desensitization.	Safety in the transplantation setting and efficacy defined as HLA antibody levels acceptable for transplantation.	The New England Journal of Medicine (2017)
Study 04 Phase 2	NCT024226684	17	US	Investigator initiated, Single-center, single-arm, open-label. Patients had prior desensitization with IVIG plus rituximab and/or PLEX.	Safety in combination with Cedars Sinai's "standard protocol" for desensitization of highly sensitized patient.	The New England Journal of Medicine (2017)
Study 06 Phase 2	NCT02790437	18	SWE US FR	Multicenter, multinational, single-arm, open-label.	Efficacy in creating a negative cross-match test.	Annals of Surgery (Lonze et al, only New York patients) Montgomery et al ATC abstract (2019)

Beyond the four completed Phase 2 studies in kidney transplantation, Hansa Biopharma is also conducting a prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation to measure long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration.

[4] Organ Procurement and Transplantation Network, 2017

A short introduction to transplantation and sensitization

A short introduction to transplantation

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 2017, approximately 280,000 patients were on transplant waitlists in the U.S. and Europe, with around 200,000 waiting for a kidney. In 2017, approximately 40,000 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. [5]

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. Without a donor organ 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. [6]

[5] Global Observatory on donation & transplant
[6] Orandi et al., "Survival Benefit with Kidney Transplants from HLA-Incompatible Live Donors", N Engl J Med (2016;374:940-50) Data from Global Observatory on Donation and Transplantation, http://www.transplant-observatory.org

Highly sensitized patients are difficult to match. Causes of sensitization includes

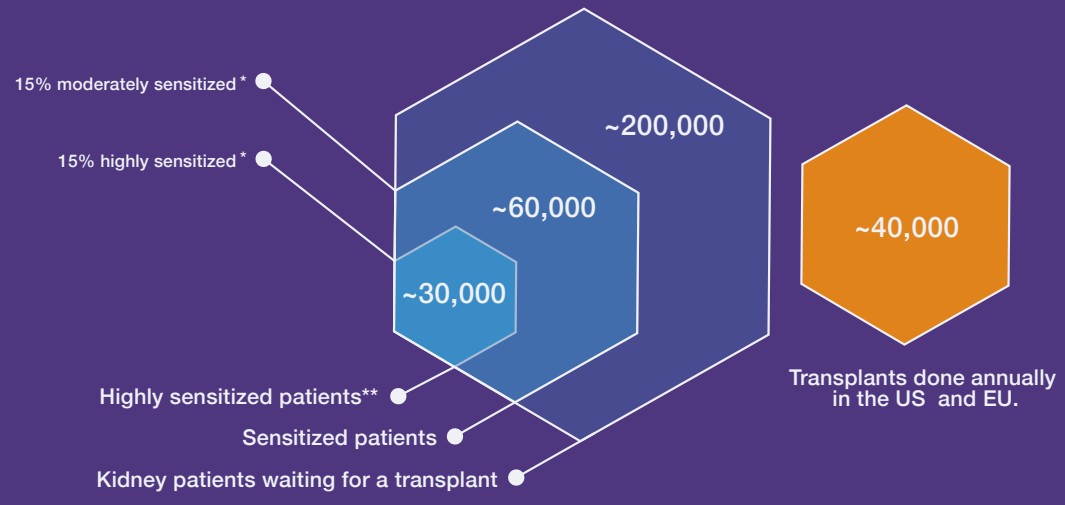
Pregnancy | **Blood transfusion** | **Previous transplantations**

- Panel Reactive Antibodies (PRA) is a measure for HLA-sensitization
- Inability to match or effectively desensitize patients remains a barrier for transplantation in highly sensitized patients
- Allocation Systems such as KAS and Eurotransplant rely on PRA score to characterize patients for transplant

Facts about kidney transplantation

U.S. + EU Kidney Transplant Waitlist Breakdown

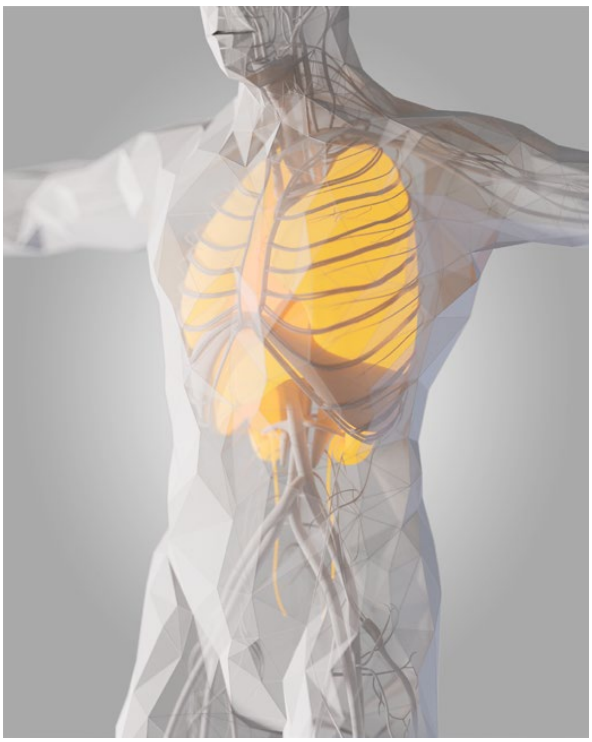
>30% of waitlist patients are sensitized



* Jordan et al. British Medical Bulletin, 2015, 114:113–125 and Orandi et al. N Engl J Med 2016;374:940-50.
** Patients with sensitivity above cPRA 80%.

Anti-GBM antibody disease

Anti-GBM antibody disease, also known as Goodpasture´s disease, is a severe kidney disease where the immune system for unknown reasons develops IgG-antibodies that recognizes a membrane associated antigen in kidney and sometimes lungs. This results in an acute immune attack on these organs. Severe Anti-GBM antibody disease may progress to renal failure or death. Most of the patients are experiencing significant loss of kidney function requiring chronic dialysis and kidney transplantation. Anti-GBM antibody disease affects roughly one to two individuals in a million annually. [7] [8]



An investigator-initiated Phase 2 trial evaluating imlifidase in anti-GBM antibody disease, an ultra-rare and acute autoimmune kidney disease, has been completed at several European nephrology clinics with Professor Mårten Segelmark at Lund and Linköping Universities as Sponsor and Coordinating Principal Investigator.

Enrollment was completed end of January 2020. Recruiting centers across five European countries have been involved in the anti-GBM trial and the first data read-out is expected in Q3 2020. The main objective of the anti-GBM trial is to evaluate safety, tolerability and efficacy of imlifidase in patients with severe Anti-GBM antibody disease.

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

Following the completion of enrollment in January 2020, the Company expect the first data read out in third quarter 2020. More information about the study is available at ClinicalTrials.gov under NCT03157037

[7] Kluth et al. J Am Soc Nephrol. 1999 Nov;10(11):2446-53
[8] Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12

Interview with Professor Mårten Segelmark

Mårten Segelmark, professor at Lunds and Linköpings universities is the sponsor and the coordinating principal investigator for the open label phase 2 investigator initiated trial with imlifidase in anti-GBM.

Can you describe why imlifidase could potentially be an effective therapy for anti-GBM patients?
Anti-GBM is an ultrarare autoimmune disease affecting 1.6 in a million people annually. In anti-GBM disease the antibodies attack an antigen intrinsic to the glomerular basement membrane in lungs and kidneys, leading to bleeding from the lungs and kidney failure. It may quickly result in permanent lung and kidney damage, which untreated could eventually be fatal.

Today anti-GBM is treated with steroids and immunosuppressant drugs, and with plasmapheresis, in which the antibodies are removed from the blood. The inflammatory damage to kidneys and lungs is very severe in the acute stage of the disease and a delayed diagnosis significantly worsen the outcome. Our theory, which has been studied and demonstrated *in vivo*, is that imlifidase not only cleaves IgG in circulation but also degrades IgG bound to the Glomerular Basement Membrane, and thereby potentially halts the process of tissue damage. Time is of absolute essence in the acute stage of the disease and the rapid onset of action by imlifidase creates an IgG -free window much faster than the current standard of care.

So the study focuses on patients in the acute stage of the disease?
Yes, it is designed to evaluate the safety and tolerability of imlifidase and also assess the efficacy based on renal function six months after treatment in patients with severe anti-GBM disease.

How would you describe the symptoms of such a patient?
The anti-GBM disease is caused by the IgG auto antibodies towards basement membrane antigens. You get noticeable symptoms first several months after the antibody production have been established. The first symptoms are usually unspecific malaise that can be present for a few weeks before more, symptoms develop differing depending on if it is the lungs, the kidneys or both organs that are attacked. Some 70-80 percent of the patients with more than 30 percent renal function at diagnosis are possible to treat preventing further deterioration of the kidneys. However, in patients with a kidney function of 10 percent or below, the kidney can hardly ever be saved.

So it is crucial to get early diagnosis once symptoms have established and early treatment?
Early diagnosis and treatment are crucial. Nowadays, there is a diagnostic test that can help determine if a patient has anti-GBM. But since the disease is so rare, the knowledge about the disease


Professor Mårten Segelmark

is not distributed throughout healthcare, nor is the diagnostic test. As the deterioration of kidney function is so rapid in the acute stage, it is of utmost importance to eliminate the antibodies as early as possible. That is how imlifidase could make an important difference. It cleaves and eliminates the antibodies within hours, whereas with plasmapheresis, part of today's standard of care, it would take several days, potentially reaching really low levels first after several weeks. Another important benefit with imlifidase is that it eliminates not only the antibodies in circulation, but also the antibodies bound to the GBM in the kidney tissue, which is not possible using plasmapheresis.

You have enrolled the last patient in the study in Q1 2020. Which inclusion criteria were applied in the study? And when do you expect to be able to present the results?
We targeted fifteen patients that were severely ill, who did not respond to standard treatment or had a kidney function of 15% or less, i.e. patients with very bad prognosis. Our assumption was that in this group, treatment with imlifidase would make a significant impact on the patient's outcome. Fifteen clinics in five European countries participates in the study. The first data read-out from the study is expected in Q3 2020.

The study is an investigator-initiated study. What can you tell us about the collaboration with Hansa Biopharma?
It has been a truly great collaboration. It is an ultra-rare disease. We were able to gather useful input and experience from fellow members of the The European Vasculitis Society (EUVAS), that have performed studies in vasculitis. The members are European clinicians with knowledge and understanding of the disease. Not only has Hansa provided the substance and pharmacological knowledge of the substance. The company has also offered invaluable help when it comes to the documentation and the regulatory applications as well as operational aspects on running the study. It has been a pleasure for me and the investigators in the study to have such a professional and fruitful collaboration. We all hope that we can use what we have learnt in this collaboration going forward with the potential next study.

Expansion of clinical development program in autoimmune diseases, interview Elisabeth Sonesson, Director of Clinical Development

What progress have you made outside transplantation?
During 2019, our clinical development program outside transplantation has made solid advancement . Besides the completion of patient enrollment in the Investigator Initiated Trial in Anti-GBM, we have successfully enrolled the first patients in two new phase 2 studies targeting rare, acute, auto immune conditions in Guillain-Barré Syndrome (GBS) and Antibody Mediated Graft Rejection (AMR).

How will you ensure sufficient statistical power in your clinical trial in GBS?
We are conducting a Phase 2 study targeting 30 patients to evaluate safety, tolerability and efficacy of imlifidase in combination with standard intravenous immunoglobulin treatment (IVIg). The patients will be compared with up to 120 matched controls from an ongoing observational study, The International GBS Outcomes Study, IGOS. The data will be analyzed by Erasmus Medical Centre and provide insights into the final design of a future pivotal Phase 3 trial.

What are the challenges doing clinical trials in GBS?
Entering a new therapeutic area gives us an opportunity to build relationships with leading specialists within a new field . The clinical studies are very different with respect to design and type of data collected compared to a transplantation trial . This trial is the first with imlifidase in GBS and it is designed to gather as much understanding as possible around how imlifidase might impact various GBS disease parameters.

You are also doing a study in AMR; why is that so important?
Antibody Mediated Graft Rejection, AMR, is one of the most challenging adverse events after kidney transplantation, and the main cause for graft dysfunction . There is currently no approved therapy for treatment of AMR and the number of randomized clinical trials in AMR is small.

You are talking about the next steps for imlifidase in anti-GBM. What do you foresee in that respect?
It is too early to say, we will know more when the results are presented later in the year, but of course I have great hopes that the next step will be a pivotal study that could potentially lead to market approval. Being active as a clinician, I am very eager to be able to bring imlifidase to my patients. And in that respect, I truly hope to continue the journey we have embarked on with this phase 2 study.

Elisabeth Sonesson, Director of Clinical Development

"The clinical development program for imlifidase within autoimmune diseases and transplant rejection creates excellent opportunities to break new grounds, build new collaborations, broaden the network with leading experts and most important of all; Make real difference for people with rare diseases", says Elisabeth Sonesson, Director of Clinical Development

Active kidney transplant antibody-mediated rejection (AMR)

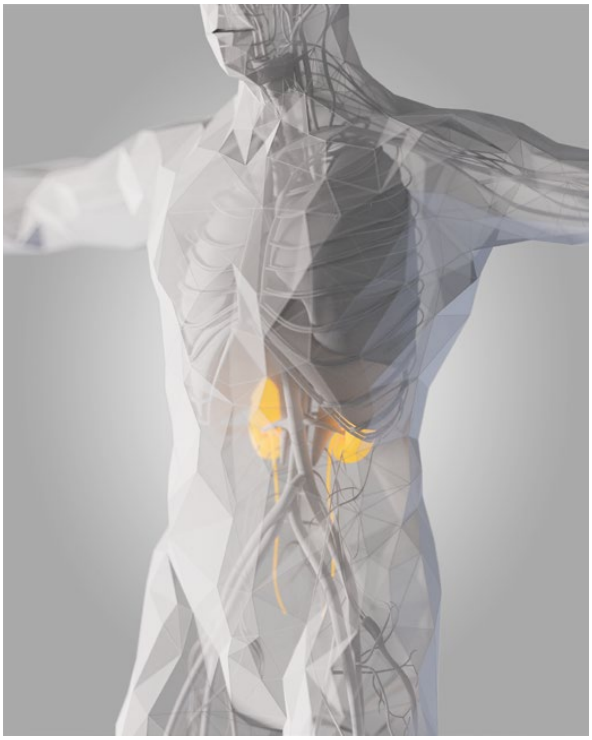
Today graft survival is challenged by antibody mediated rejection (AMR) post transplantation as there is no approved therapy for the treatment of AMR. AMR is one of the most challenging adverse events after kidney transplantation, occurring in 10-15% of patients, and is the main cause for graft dysfunction. In the U.S. and Europe, there are approximately 40,000 patients who receive kidney transplants annually and approximately 400,000 who currently live with a kidney transplant. [9]

Currently used therapies include plasma exchange, and treatment with steroids and IVIg. AMR patients not treated successfully risk graft failure, dialysis and return to the waitlist. [10]

Imlifidase is currently being investigated in a phase 2 trial initiated in 2019. The AMR trial is a randomized, open-label multi-center, active control trial, designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in acute AMR post transplantation.

The new phase 2 trial targets to enroll 30 patients at approximately eight clinical trial centers in France, Austria, Australia and the U.S. 20 subjects will be randomized to receive imlifidase treatment, one intravenous dose of 0.25mg/kg, while 10 subjects in the active control arm will receive 5-10 sessions of plasma exchange. Efficacy and safety will be monitored over a 6-month period post treatment.

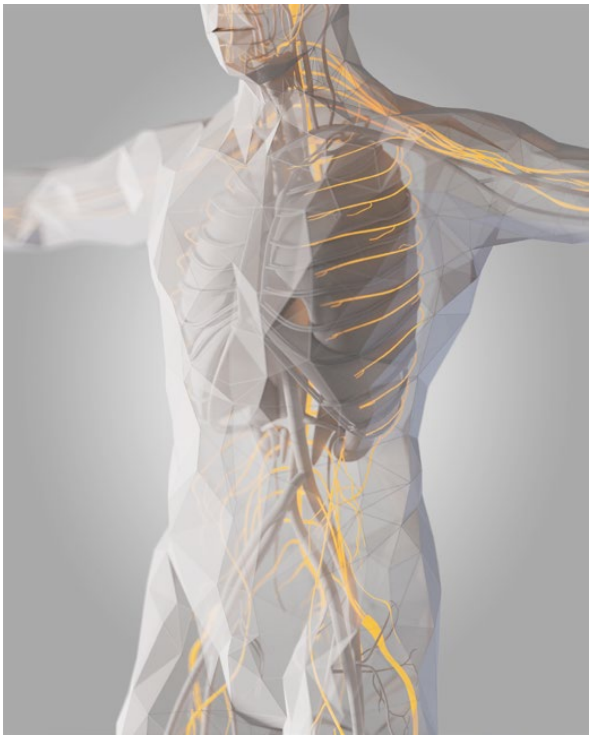
Enrollment is expected to be completed in the first half of 2021 with the first data read out expected in the first half of 2022. As per end of March 2020 4 patients were enrolled. More information about the trial is available at ClinicalTrials.gov under NCT03897205 (2019).



[9] Global Observatory on donation & transplant
[10] Puttarajappa et al., 2012; Jordan et al., 2015

Guillain-Barré syndrome (GBS)

GBS is a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system that affects 1-2 in 100,000 people annually [11] GBS is an aggressive neurological disease, which can affect anyone at any age and with many patients deteriorating despite standard of care treatment. Two thirds of GBS patients have severe symptoms resulting in their inability to walk unaided, and 20-30% require mechanical ventilation for weeks or months. While patients are typically treated with either IVIg or plasmapheresis, a significant unmet medical need remains as only parts of the patients fully recover from GBS. Up to 40% of patients will lose strength and have pain, while mortality is between 3-5%. [12]



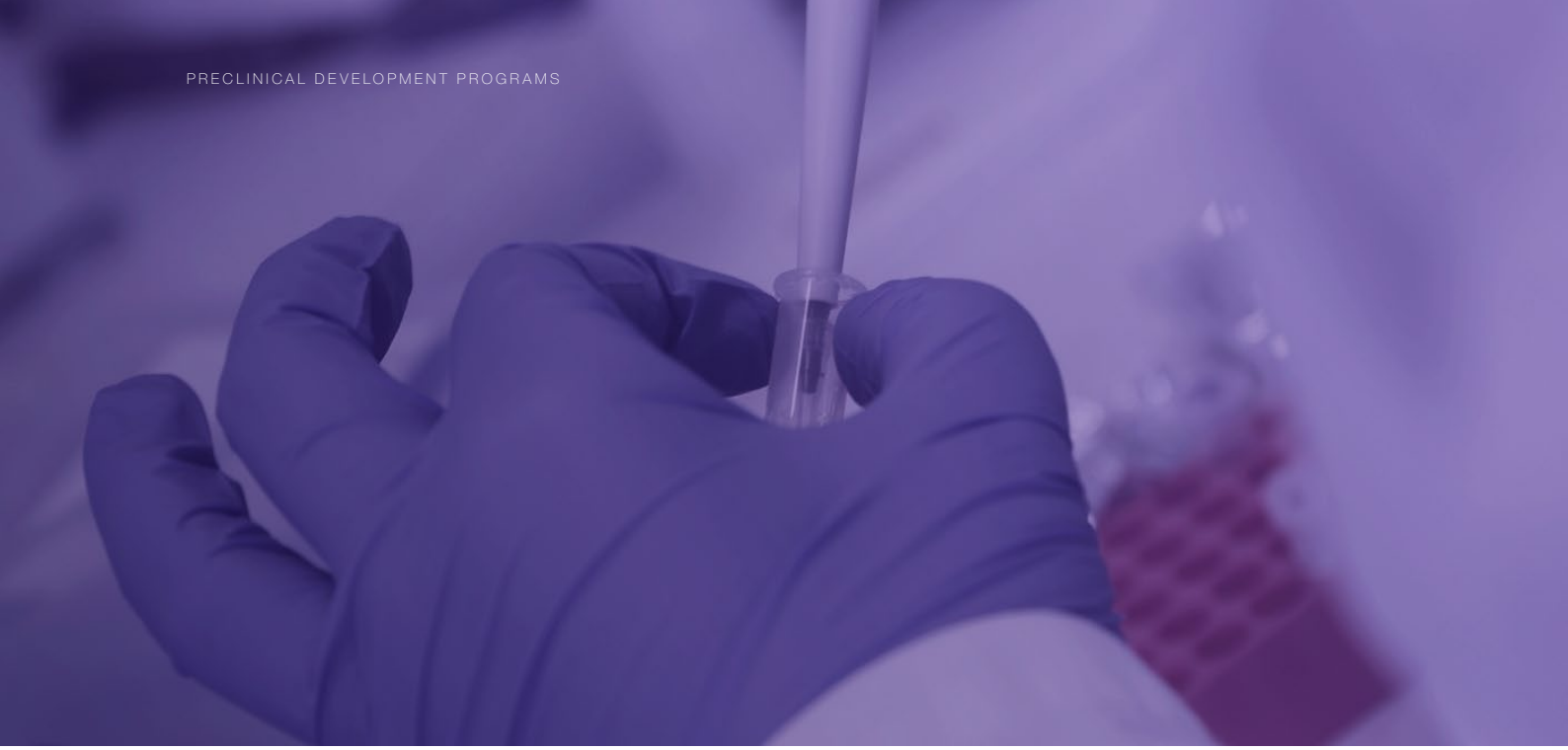
Imlifidase is currently being investigated in a phase 2 trial initiated in 2019 The GBS trial is an open-label, single arm, multi-center study evaluating the safety, tolerability and efficacy of imlifidase in GBS patients in combination with standard of care intravenous immunoglobulin (IVIg).

The GBS trial will target to recruit 30 patients at approximately ten clinics in France, UK and the Netherlands. The GBS patients enrolled in the study will receive a single dose of 0.25 mg/kg of imlifidase. The patients will be compared to a matched control group of GBS patients treated with IVIg from the International Guillain-Barré Syndrome Outcome Study (IGOS) database with a follow up after 6 and 12 months.

Enrollment is expected to be completed in H2 2021 with the first data read out expected in the second half of 2022. As per end of March 2020 4 patients were enrolled. At this point 6 of the targeted 10 clinics were open for recruitment. More information about the study is available at ClinicalTrials.gov under NCT03943589 (2019).

In 2018, the U.S. Food and Drug Administration granted Orphan Drug Designation to imlifidase for the treatment of GBS.

[11] McGrogan et al., "The Epidemiology of Guillain-Barré Syndrome Worldwide", Neuroepidemiology;2009, 32(2):150-63.
[12] van den Berg et al., 2014



Preclinical development projects

NiceR – Novel Immunoglobulin Cleaving Enzymes for Repeat dosing

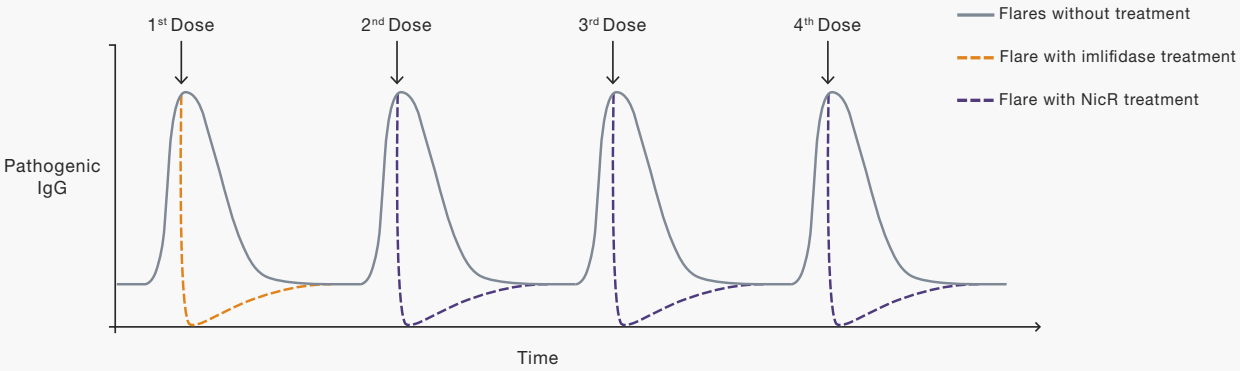
Hansa's NiceR-program is a new set of enzymes for repeat dosing; potentially enabling treatment of relapsing diseases. The new IgG-cleaving enzymes have lower immunogenicity, which potentially may enable applications in a broad array of indications with significant unmet medical need, including reoccurring, relapsing autoimmune diseases and oncology.

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

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

Development of a GMP-manufacturing process for the lead NiceR candidate has been initiated and preparations for IND-enabling toxicology studies are ongoing, expected to be started in early 2021. Preparations for a clinical Phase 1 study will be started in parallel with the toxicology studies.

NiceR can potentially inactivate flares



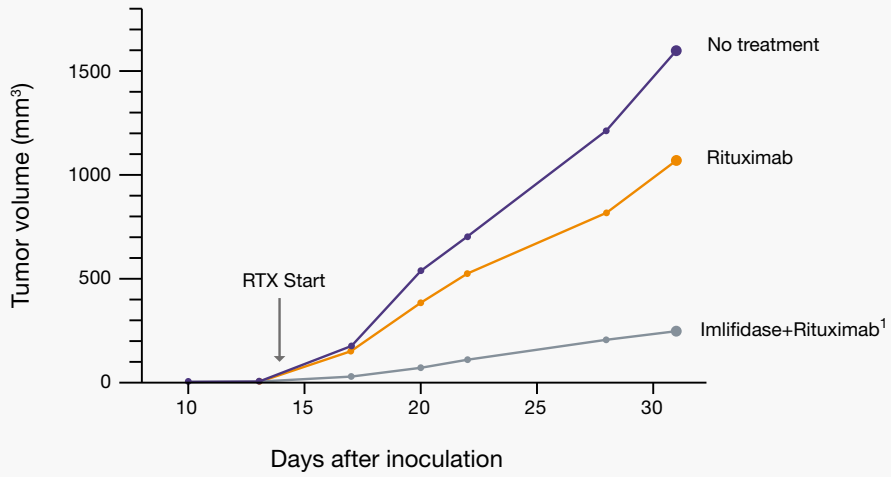
EnzE – Enzyme-based antibody Enhancement

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

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

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

Mice with human IgG (~9mg/mL)



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

Manufacturing & supply chain of imlifidase

Manufacturing is done in close collaboration with two highly experienced and European based third party CMOs. During 2016-2017 the drug substance production process was transferred to Biotechpharma in Vilnius, Lithuania, while the drug product process and upscaling of imlidase was transferred to Baxter in Halle in Westfalen, Germany.

Full process characterization and validation for commercial supply was completed during 2018 and the manufacturing process has gone through optimization for improved product yield.

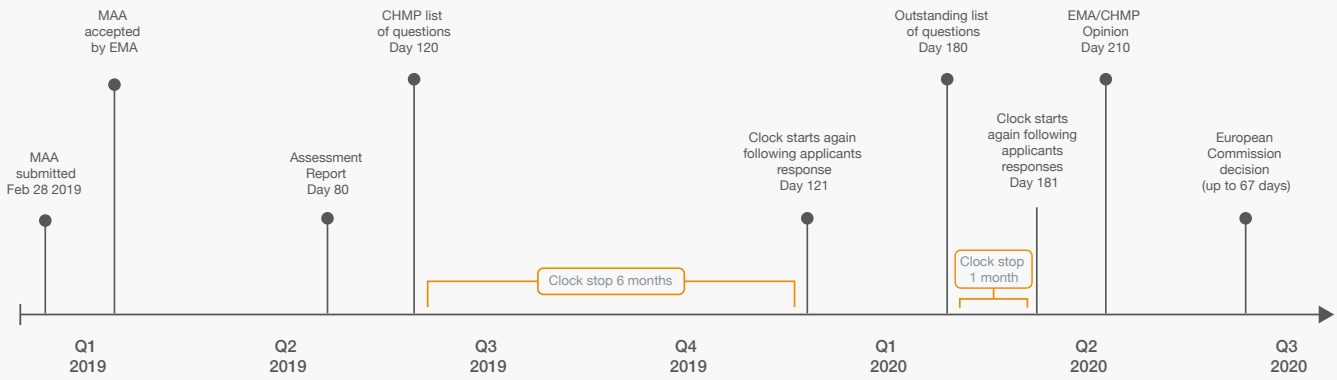
Regulatory path for imlifidase in kidney transplantation

Europe (EMA)

In Europe the European Medicines Agency (EMA) accepted Hansa's Marketing Authorization Application (MAA) for review of imlifidase end of February 2019. The timeline for regulatory review process is 210 working days plus clock stops.

The review process progresses according to plan. The company submitted responses to the Day 120 questions in December 2019, while the list of outstanding questions (Day 180) is being reviewed during the first quarter 2020. An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected in the second quarter of 2020, followed by a decision by the European Commission during the third quarter 2020.

The potential EU approval will be a conditional marketing authorization (CMA) and thus a post-approval study will be initiated following approval.



United States (FDA)

In November 2019 Hansa Biopharma reached an agreement with the FDA on a regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients. Upon agreement with the FDA, following submission of a final study protocol, the Company will conduct a randomized, controlled clinical study in a limited group of highly sensitized kidney patients using kidney function (eGFR) a surrogate endpoint.

The November 2019 meeting was a follow-up to the End-of-Phase 2 meeting the Company had with the FDA in December 2018. At the prior meeting, the FDA provided positive feedback on the data generated on imlifidase from the four completed Phase 2 imlifidase studies and requested additional analyses in the context of the new U.S. Kidney Allocation System (KAS) and the unmet medical need.

Since the prior FDA meeting, Hansa Biopharma has submitted the results from a matched control analysis showing significant shorter time to transplant for highly sensitized patients treated with imlifidase, both under the current and previous KAS. The results from this complementary analysis, together with other additional information that was provided to the FDA in the wake of the End-of-Phase 2 meeting, have further strengthened the evidence of the potential benefit imlifidase could provide to patients in the context of the new KAS and impacted the design of the randomized, controlled study requested by the FDA as part of a BLA submission.

The new study will target a limited and well-defined population with the highest unmet medical need, consisting of very highly sensitized kidney patients with a cPRA level of ≥99.9% who are waiting for a deceased donor transplantation. FDA acknowledged that this represents a patient population with a serious condition. These patients have very limited access to transplantation and the only available therapy today is waiting on dialysis for a compatible transplant. In 2019, around 3,000 patients were registered on the waiting list in the US with a cPRA level of 99.9% or above. [13]

The study discussed with the FDA includes approximately 50 patients to be randomized when a donor kidney becomes available to either imlifidase or to a control arm that will continue on the waitlist. A surrogate endpoint measured in the form of eGFR (kidney function) will be used to demonstrate the clinical benefit of imlifidase over the control group after 12 months.

Results from this clinical study could support a Biologics License Application (BLA) submission in the U.S by 2023 under the accelerated approval pathway.

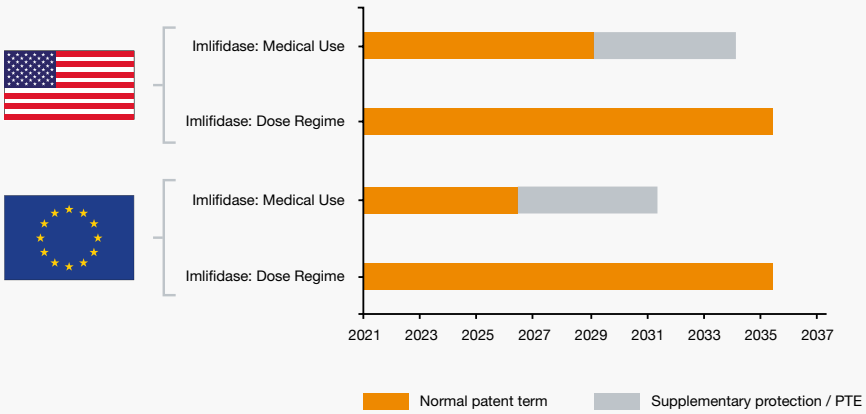
[13] Organ Procurement and Transplantation Network, 2017

Intellectual property rights and orphan drug designation

Hansa Biopharma's technology protection consists of a comprehensive patent portfolio consisting of 11 patent families with patent coverage out to 2035 in key markets. Also, the Company has been granted five orphan drug designations by EMA and the FDA across transplantation, anti-GBM antibody disease and Guillain Barré Syndrome (only FDA).

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

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



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

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

Since 2017, Hansa Biopharma has been granted five exclusive orphans drug designations by EMA and the FDA across transplantation, anti-GBM antibody disease and Guillain Barré Syndrome (only FDA).

EMA
Orphan drug designation

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

FDA
Orphan drug designation

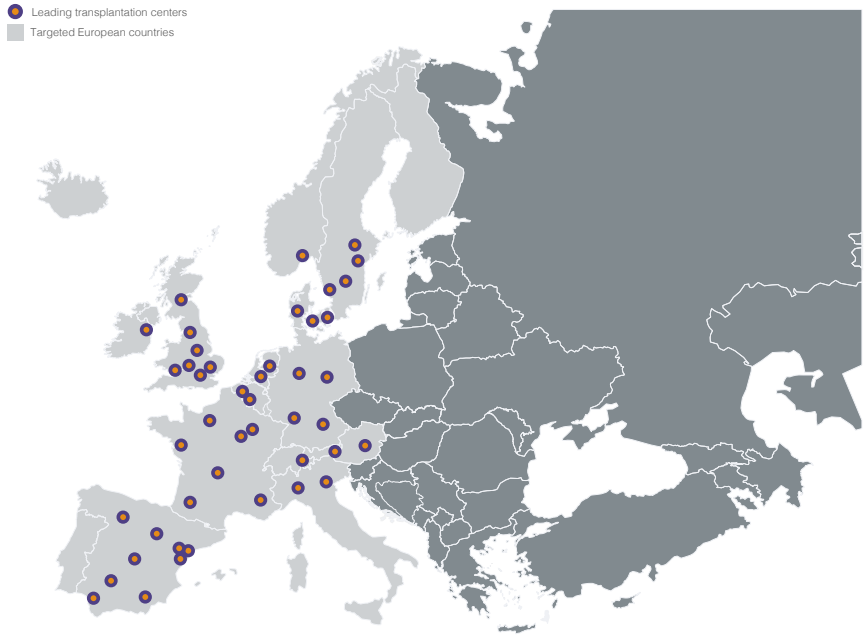
- Imlifidase for the prevention of antibody-mediated organ rejection in solid organ transplantation (2015)
- Imlifidase for the treatment of Guillian-Barré Syndrome (2018)
- Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

Our European launch strategy

In Europe, Hansa Biopharma is preparing for the company's first product launch in the second half of 2020. The potential near-term launch in Europe will be subject to conditional approval and a post approval study will subsequently be conducted.

The initial focus will be on the leading transplantation centers and clinicians across Europe to ensure that they gain a positive experience and knowledge around desensitization with imlifidase. The center focused launch strategy will be sequenced, targeting leading clinics and clinicians that may become early adopters and where there is a positive reimbursement climate. The Post Approval Efficacy Study (PAES) will be key in integrating the commercial and scientific approach to broaden the experience with imlifidase.

As part of the preparations towards the potential commercial launch in Europe, Hansa Biopharma has increased its presence in key markets over the last 12 months through Medical Science Liaison personnel to build awareness around desensitization among Key Opinion Leaders (KOL's) and clinical experts.



European market facts

› Roughly 22,000 transplantation is being done annually in Europe [14]

› In Europe, 70-80% of all kidney transplantations are performed at 5-7 top centers in each countries [15]

[14] European Commission Report, 2016
[15] Biostrategy Market Research, October 2018

Henk Doude van Troostwijk, SVP and CCO

Dr. Christian Kjellman, SVP and CSO/COO

Interview with Dr. Christian Kjellman and Henk Doude van Troostwijk on launch strategy and commercialization

You will potentially gain Marketing Authorization in EU in the third quarter; how would you characterize the European market?

The European market is rather fragmented and complex. There is not one system for the allocation of organs and each of the countries have different approaches to characterize patients who are waiting for a kidney transplantation. However, the countries share the same issue, there are patients who have no or very limited access to transplantation because they have antibodies to HLA. As a consequence, we will implement a sequenced launch throughout Europe. We have a strong MSL team working across Europe, gaining a lot of understanding of procedures, guidelines and allocation systems. They will pave the way for a successful launch.

What are the challenges that you will face when launching imlifidase in Europe?

Highly sensitized patients have a dire need of more options to enable kidney transplantation. There is undoubtedly a very high unmet need for the end-stage renal disease patients who are eligible for transplantation but cannot be offered a compatible organ because they are highly sensitized. It is critical to provide imlifidase to these patients as soon as possible in a safe and controlled way. We will ensure that our knowledge, experience and learnings are passed on to the physicians who are going to treat and transplant these complex patients for the first time.

You will launch imlifidase through leading transplantation clinics, why have you chosen that and how will this impact market penetration?

Imlifdase is a paradigm shift in transplantation and we will therefore initially introduce imlifidase to leading clinics across Europe who are most likely to be early adopters and who are best positioned to successfully introduce a new, highly innovative therapy. Hospitals requesting imlifidase in the early launch stages will be well equipped to ensure that the transplantations using our innovation will be performed in an optimal way. After gaining positive experience with the product, imlifidase is expected to be rolled out more broadly. Sales is therefore expected to initially increase slowly, followed by a phase with more rapid growth as more patients have been treated successfully and more clinics gain positive experience.

You have filed for a conditional approval based on Phase 2 data, how will that influence on your commercial launch?

Since the Marketing Authorization Application is based on limited Phase 2 data from a total of 46 transplanted patients, the potential marketing authorization of imlifidase would be conditional. This means that a post approval study will have to be set up to run in parallel with the commercial launch.

The post approval study will support the introduction of imlifidase in leading clinics by helping to generate experience, guidelines and protocols for how to manage these complex patients.

How do you prepare for a successful launch of imlifidase, and what organizational needs do you need for the launch?

Successfully launching a highly innovative and potentially transformative therapy representing a paradigm shift in the treatment of highly sensitized patients requires a broad range of skills, expertise and resources.

We have therefore established a cross-functional launch team with staff members from R&D, Commercial and Medical Affairs to ensure that all our in-house competences are engaged, aligned and working efficiently to secure a successful launch.

How can we achieve optimum outcomes for highly sensitized kidney transplant candidates?

At the British Transplant Society's Annual Congress held at the ICC Belfast 4th – 6th March, the clinical audience in a packed Hall 2 heard how they should continue to challenge equity to access in kidney allocation systems, particularly for highly sensitized patients.

An internationally-recognized faculty of transplant specialists – Professor David Briggs from NHS Blood and Transplant, Birmingham, Professor Anthony Dorling from King's College, London and chair Professor Nizam Mamode from Guy's and St Thomas' Hospital, London – reminded the audience of recent developments; organ allocation schemes and a new matchability scoring system in the UK giving certain patients improved access to kidney transplantation. However, despite these advances, highly sensitized kidney candidates remain underserved by organ allocation systems and tend to wait longer for a transplant In 2019, the UK national allocation scheme for deceased donors was revised to give priority to the most highly sensitised patients (>99.5% donor panel calculated reaction frequency, CRF). The principles of the scheme are very similar to the 2014 kidney allocation scheme (KAS) in the US. Formal assessment of the impact of the US KAS shows that the most highly sensitized kidney patients (cPRA 99.9+%, ie measured to two decimal places) on the waiting list continues to grow with a low chance of a compatible organ offer.[16] Early indications suggest the same will be seen in the UK.[17] Thus the most sensitised patients have less access to standard risk transplantation. A solution is transplantation against existing or prior HLA-specific antibodies, essentially by reducing the CRF/PRA.

Among such candidates the risk of antibody-mediated rejection (AMR) is high and may be associated with worse long-term graft survival for these patients. Delegates also learnt about identification and treatment strategies to mitigate antibody-mediated rejection in the high-risk highly sensitized patient. Combination therapy is regarded as standard of care for acute onset AMR, whereas data are still maturing on the benefits of specific treatments, including optimized immunosuppression to manage chronic AMR.[18][19] There is evidence that HLA-incompatible transplantation after desensitization may be a valid option as the outcomes for patients are improved.[20] Data on emerging therapies including complement inhibition and IgG cleavage that can prevent or mitigate AMR, allowing transplantation of highly sensitised patients were presented in the symposium.

Speakers left to right: Professor David Briggs, Professor Nizam Mamode and Professor Anthony Dorling.

In conclusion, kidney transplantation is an effective and successful treatment when considering patients who actually receive a transplant. The number of highly sensitized recipients is increasing, especially on the deceased donor waiting list and there is inequality of access to kidneys for highly sensitised patients. Multiple organ allocation schemes and a new matchability scoring system in the UK help the situation, but do not adequately fulfil all patients' needs. New techniques and medicinal products may reduce these problems in the coming years.

References

[16] Stewart et al. Am J Transplant 2016; 16:1834-47.

[17] Data ©2020 University Hospitals Birmingham, UK

[18] Schinstock et al. Transplantation 2020; Jan 8: DOI:10.1097/TP.0000000000003095

[19] Stringer et al. Trials 2019; 20:476.

[20] Manook et al. Lancet 2017;389:727-73

Imlifidase – A unique technology with emerging Business Development opportunities

Hansa Biopharma has a favorable position to attract potential partners due to a proprietary enzyme technology and a very promising clinical safety and efficacy profile.

”Our IgG-modulating technology spearheaded by lead candidate imlifidase, has accomplished clinical validation through four successfully completed phase 2 studies in kidney transplantation and our phase 1 study in healthy subjects. This completely unique IgG-eliminating mode-of-action has potentially broad applicability beyond the indications Hansa is currently pursuing.” says Emanuel Björne, Vice President Business Development

Emanuel, who has been with the company since the start in 2007, now experiences a growing interest among peer biopharma companies for the possibility to combine imlifidase with other treatment modalities in order to reach new patient populations for already approved drugs or drugs in late clinical development.

Emanuel continues: ”Clearly, the growing clinical evidence of the safety and efficacy of our unique therapeutic approach is triggering this increased interest from fellow biopharma companies. At Hansa we are addressing disease-causing IgG antibodies in transplantation and autoimmune diseases, but antibodies may also limit or completely impede the effect of gene therapy and immune-oncology therapies. The existing methods to mitigate IgG antibody interference; e.g. plasmapheresis, steroids and immunosuppressants, are not effective enough. Currently, there is a interest from other biopharmaceutical companies to add imlifidase as a potential treatment protocol, as an IgG-eliminating pre-treatment to approved drugs or to drug candidates evaluated in late clinical development.”

One area of specific interest is gene therapy, where harmless viral components are used to insert healthy genes in patients with genetic diseases such as hemophilia and muscular dystrophies. In gene therapy up to 50% [21] of the potential patients have been exposed to the specific viral components previously in life and have hence developed neutralizing IgG-antibodies against the gene therapy already prior to the treatment with the gene therapy. These patients are today excluded from clinical studies and will not be able to benefit from the approved gene therapy.

Emanuel Björne, VP Business Development

“Collaborations with the gene therapy companies is an obvious target for our business development efforts. Imlifidase could potentially be investigated as a pre-treatment to inactivate the neutralizing antibodies and enabling access to these therapies for more patients.” says Emanuel Björne, VP Business Development

[21] http://www.ijcem.com/files/ijcem0094241.pdf

Shareholder information

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

- OMX Nordic Mid Cap
- OMX Nordic Health Care index
- OMX Stockholm Benchmark Index
- OMX Stockholm Health Care
- OMX Stockholm Pharmaceuticals & Biotechnology
- MSCI Global Small Cap

Brief facts, the Hansa Biopharma-share

Listing	Nasdaq OMX Stockholm
Number of shares	41,447,564 (40,026,107 A-shares and 1,421,457 C-shares)
Market capitalization (Dec. 31, 2019)	SEK ~3.5 bn
Ticker	HNSA
ISIN	SE0002148817

According to the shareholder register maintained by Euroclear Sweden AB, as of December 31, 2019, Hansa Biopharma had 14,125 shareholders. On December 31, 2018, Hansa Biopharma had 12,495 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 2019 amounted to 40,026,107 ordinary shares and 1,421,457 C-shares. At year end the share capital amounted to SEK 41,447,564. 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 HNSA share in 2018 and 2019

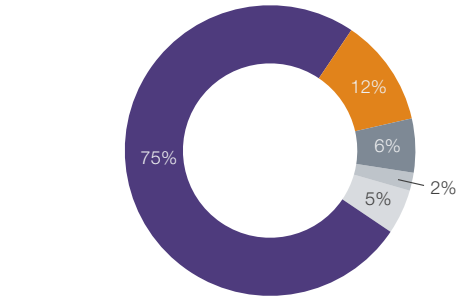
	2018		2019	
SEK	High	Low	High	Low
1st quarter	290.0	217.0	299.0	211.0
2nd quarter	267.4	196.8	230.2	161.3
3rd quarter	338.4	198.0	195.7	129.6
4th quarter	349.4	260.0	159.8	65.1

Analyst coverage

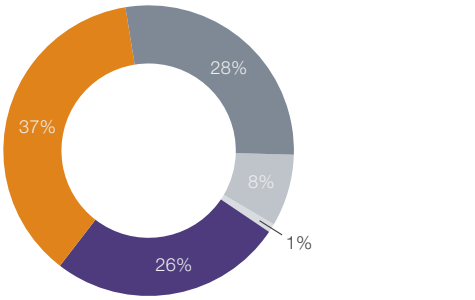
SEB	Christopher Uhde
Kempen	Ingrid Gafanhão
RBC Capital Markets	Zoe Karamanoli
Evercore ISI	Maneka Mirchandaney
ABG Sundal Collier	Viktor Sundberg
Redeye	Arvid Necander
RX Securities	Joseph Hedden
Carnegie	Erik Hultgård

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

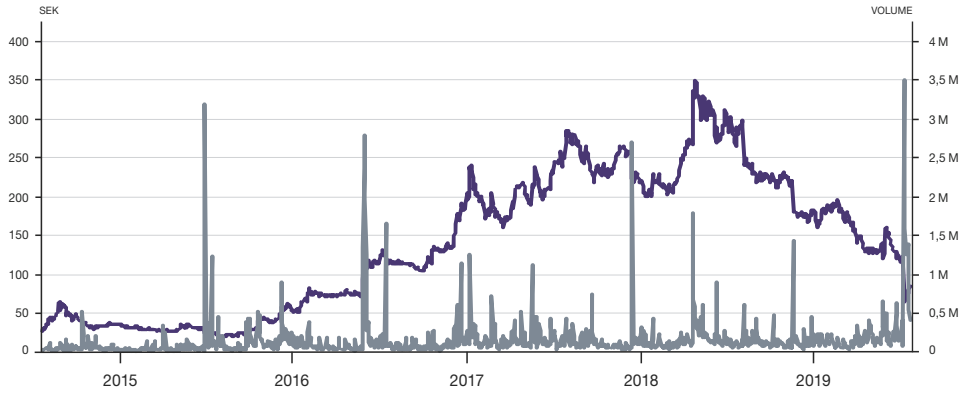
Shareholders by country, December 31, 2019



Shareholder by category, December 31, 2019



Hansa share price development and trading volume 2015–2019



Top 10 largest shareholders, December 31, 2019*

	Number of shares	
Owners	HNSA	Capital (%)
Nexttobe AB	5,755,379	14.4
Invesco	2,166,818	5.3
Thomas Olausson	1,667,654	4.2
Avanza Pension	1,554,486	3.9
Third Swedish National Pension Fund	1,316,470	3.3
Gladiator	1,150,000	2.9
Fourth Swedish National Pension Fund	1,112,044	2.8
Vanguard	930,991	2.3
Swedbank Robur Funds	892,944	2.2
ClearBridge, LLC	691,486	1.7
Other	22,837,835	57.0
Outstanding shares in total	**40,026,107**	**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).

** On March 9, 2020 Hansa Biopharma was notified that Consonance Capman GP, LLC, had reached and exceeded 5% ownership in Hansa Biopharma AB and thus become a major shareholder*

Dividend

The Board proposes no dividend for the financial year 2019. For more information about Hansa Biopharma's dividend policy, please refer to the Hansa Biopharma Corporate Governance Report available at the company website at https://hansabiopharma.com/this-is-hansa/corporate-governance/

Long-term incentive programs

Hansa Biopharma has three ongoing incentive programs for the company's employees as of December 31, 2019:

- A performance based share program (LTIP 2016) adopted by the Extraordinary General Meeting on November 21, 2016.
- A mix of performance based share program and a warrant program (LTIP 2018) adopted by the Annual General Meeting on May 29, 2018.
- A mix of performance based share program, warrant and a option program (LTIP 2019) adopted by the Annual General Meeting on May 22, 2019.

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

Other information

Financial calendar 2020

Annual Report 2019	April 2, 2020
Interim report for January - March 2020	April 28, 2020
Annual General Meeting	June 23, 2020
Interim report for January – June 2020	July 16, 2020
Interim report for January – September 2020	October 22, 2020

Contacts

Klaus Sindahl, Head of Investor Relations
Hansa Biopharma
Mobile: +46 (0) 709–298 269
E-mail: klaus.sindahl@hansabiopharma.com

Glossary

AMR
Antibody mediated transplant rejection.

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

Anti-GBM disease (Goodpasture syndrome)
Anti-GBM antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

Autoimmune disease
Diseases that occur when the body's immune system reacts against the body's own structures.

B-cells
B-cells, also known as B-lymphocytes, are a type of white blood cell of the lymphocyte subtype. They are an important part of the adaptive immune system and secrete antibodies.

Biologics License Application (BLA)
A Biologics License Application (BLA) is submitted to the Food and Drug Administration (FDA) to obtain permission for distribution of a biologic product across the United States.

Biopharmaceutical
A pharmaceutical drug that is manufactured using biotechnology.

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

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

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

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

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

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

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

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

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

FDA
U.S. Food and Drug Administration.

Guillian-Barré syndrome
GBS, Guillian-Barré syndrome, is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies.

HBP
Heparin Binding Protein is a naturally occurring protein that is produced by certain immune cells, i.e. neutrophilic granulocytes, to direct immune cells from the bloodstream into the tissues.

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.

Imlifidase
Imlifidase, is the immunoglobulin G-degrading enzyme of Streptococcus pyogenes, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

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.

Marketing Authorization Application (MAA)
A Marketing Authorization Application (MAA) is an application submitted to the European Medicines Agency (EMA) to market a medicinal product in the EU member states.

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

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

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

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.

2019 Directors' report

Operations

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

The Company's lead product candidate, imlifidase, is an antibody-cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications. Imlifidase is currently under review for a potential marketing authorization by European Medicines Agency (EMA).

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

Business review January – December 2019

- The EMA accepted Hansa Biopharmas submission of a Marketing Authorization Application (MAA) for review of imlifidase in highly sensitized patients end of February 2019. The ongoing review of imlifidase in Europe is on track and responses to the Day 120 questions were submitted on December 20, 2019. An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected in the second quarter of 2020.
- Hansa Biopharma reached agreement with the Food and Drug Administration (FDA) on a regulatory path forward for imlifidase for kidney transplantation in highly sensitized patients in the U.S. The Company will conduct a randomized, controlled clinical study in a well-defined population of highly sensitized patients with the highest unmet medical need in context of the U.S. Kidney Allocation System. Results from this clinical study could support a future submission of a Biologics License Application (BLA) in the U.S. under the accelerated approval pathway by 2023.
- The Company advanced its pipeline during 2019 with completion of patient enrolment into the Investigator Initiated phase 2 study in anti-GBM in January 2020, the initiation of two new Phase 2 programs in Antibody Mediated Rejection (AMR) and in Guillain Barré Syndrome (GBS). Acute AMR is one of the most challenging adverse events after kidney transplantation, occurring in 10-15% of patients, and is the main cause for graft dysfunction. GBS is a rare, acute inflammatory disease of the peripheral nervous system that affects 1-2 in 100,000 people annually. Lastly a lead candidate from the Company's NiceR program was selected for clinical development.
- In Mid-April the Company divested its shareholding in Genovis to a group of Swedish institutional investors. The transaction provided a profitable exit for Hansa Biopharma, and the funds generated will be used to support financing our ongoing operations.
- At the 2019 American Transplant Congress (ATC) in June, Dr. Edmund Huang of Cedars-Sinai Medical Center presented data demonstrating a significant reduction in time to transplant for highly sensitized patients treated with imlifidase over matched controls waiting under the Kidney Allocations System (KAS). Dr. Huang's session won ATC's People's Choice Award for the most impactful presentation.
- In September 2019, positive results from a pooled analysis of Phase 2 trials with imlifidase for desensitization in highly sensitized kidney transplant patients were presented for the first time at the European Society of Organ Transplantation's (ESOT) Congress. The data demonstrated that Imlifidase enabled kidney transplantation in all 46 sensitized patients.
- Hansa Biopharma continued to build its organization in preparation to become a fully integrated, commercial biopharmaceutical company. By year-end, 2019 the company employed 74 people, which is an increase from 52 employees December 31, 2018. New functions and roles have been added during 2019 focusing on R&D functions, Medical Affairs, Market Access and Supply Chain.
- Two new board members were appointed; Eva Nilsagård and Mats Blom. Eva Nilsagård is currently interim CFO at OptiGroup AB and founder and CEO of Nilsagård Consulting AB. She has served as CFO of Vitrolife and Plastal and Senior Vice President, Strategy & Business Development at Volvo Group. Mats Blom has extensive managerial experience and serves as CFO of NorthSea Therapeutics and previously as CFO of Zealand Pharma A/S.
- CSO, Christian Kjellman, assumes an expanded responsibility as CSO and COO effective from February 2020 as the Company prepares to implement a focused launch strategy through leading transplantation clinics and experts upon a conditional approval of imlifidase in the EU.

The COVID-19 virus (Corona): Measures and potential impact

Hansa Biopharma has implemented measures to protect employees and take social responsibility while at the same time attempting to limit any negative effects on Hansa's business. While at the current point in time it is not possible to estimate the extent to which Hansa's business might be affected, the following are key areas where the outbreak potentially will have an impact:

- EMA MAA regulatory review timelines
- Recruitment timelines for the ongoing clinical studies
- Initiation of recruitment into the planned US phase 3 study
- Commercial launch of imlifidase in Europe

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

Risk management

Hansa Biopharma is committed to have 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 to ensure consistent and efficient risk identification, assessment and control.
- Raise awareness of the need for risk management.
- Integrate risk management into the Company culture and processes.
- Establish defined roles, responsibilities and reporting structures for risk management.

Hansa Biopharma's executive management and the board regularly discuss the company's key risks and respective risk management.

Risk factors

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

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

Product development, regulatory approval and commercialization

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

Nevertheless, due to limited resources and access to capital, the Company must and have in the past decided to prioritize development of certain product candidates; these decisions may prove to have been wrong and may adversely affect our business. We are heavily dependent on the success of our product candidate imlifidase. We are also dependent on the success of our other product candidates in the NiceR program. The Company cannot give any assurance that any product candidate will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized. Our business and future success is substantially dependent on our ability to develop successfully, obtain regulatory approval for, and then successfully commercialize our product candidate imlifidase and our other product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, the EMA or any other comparable regulatory authority, and we may never receive such regulatory approval for any of our product candidates. We cannot give any assurances that our clinical trials for imlifidase or our other product candidates will be completed in a timely manner, or at all. If imlifidase or any other product candidate is not approved and commercialized, we will not be able to generate any product revenues for that product candidate.

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

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

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

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following potential marketing approval.Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval, or if approved, market withdrawls, by the FDA, the EMA or other comparable regulatory authorities. The drug-related side effects could affect patient recruit-

ment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Box warnings, labelling restrictions, dose limitations and similar restrictions on use could have a material adverse effect on our ability to commercialize imlifidase in those jurisdictions where such restrictions apply. If the Company is not able to maintain orphan product exclusivity for imlifidase, or obtain such status for other or for future product candidates for which we seek this status, or if our competitors are able to obtain orphan product exclusivity before we do, we may not be able to obtain approval for our competing products for a significant period of time. Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, healthcare payers, patients and the medical community. Coverage and reimbursement decisions by third-party payers may have an adverse effect on pricing and market acceptance. Legislative and regulatory activity may exert downward pressure on potential pricing and reimbursement for any of our product candidates, if approved, that could materially affect the opportunity to commercialize.

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

Reliance on Contract Research Organisations (CROs)
Hansa Biopharma has relied upon and plan to continue to rely upon third-party contract research organizations, or CROs, to conduct, monitor and manage our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable, and the EMA, FDA or other regulatory authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. If any of the relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms.

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

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.

If the Company fail to obtain and/or maintain patent protection and trade secret protection of its product candidates, it could lose its competitive advantage and the competition the Company face would increase, reducing or eliminating any potential revenues and adversely affecting its ability to attain or maintain profitability and the end result could be a significant lower enterprise value of Hansa Biopharma.

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

Market and competition
The product candidates Hansa Biopharma has under development, risk being exposed to competition from new pharmaceuticals and/or diagnostic methods. Developing a new pharmaceutical from invention to finished product requires a long time. Not the least for this reason, when development is underway it is uncertain whether there will be any market for the product when it is finally developed and, in such case, how large this market will be, as well as which competing products the Company's products will encounter when they reach the market. To the extent competition consists of existing preparations or methods, Hansa Biopharma's success is dependent on its ability to induce potential customers to replace known products or methods with those of Hansa Biopharma. Another risk is that competitors, who in many cases have greater resources than the Company, will develop alternative preparations that are more effective, more secure, or cheaper than those offered by Hansa Biopharma. This may lead to the Company not being able to sell its products which may negatively affect the Company's earnings.

Reliance on Contract Manufacturing Organisations (CMOs)
The manufacturing and packaging process for Imlifidase is made in collaboration with contract manufacturers/packagers in Europe. Hansa Biopharma is dependent on the quality of the manufacturing and packaging processes, as well as the availability and maintenance of the production facilities. Regulatory authorities require that all manufacturing processes and methods, as well as all equipment, comply with current requirements of Good Manufacturing Practice (GMP) and consequences for the Company in the event of deficiencies in GMP requirements, and potential withdrawal of approval from the regulatory authorities, in the respective territories, for those facilities providing the services, may lead to delays in or the inability

to supply the product for clinical trials or commercialization which may negatively affect the Company's earnings and future prospects. In addition to the compliance risk of our collaborators, the company is exposed to business continuity risk as our collaborators facilities might be damaged, destroyed or not have sufficient capacity for other reasons. This may lead to the Company not being able to sell its products which may negatively affect the Company's earnings.

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 or impossible 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 harm the Company's business, financial position and earnings.

Financial risks
Hansa Biopharma carries out capital-intensive and value-generating pharmaceuticals development and, potentially, commercialization. Future financing of the operations is expected to take place through new issues of shares, loans, licensing revenue, cooperation with other parties, and the sales of rights or patents. Hansa Biopharma has financed its business operations thus far partially with the help of milestone compensation and one-time compensation amounts from the Company's current and previous cooperating partners and with royalty revenue from licensing agreements. However, the operations have mostly been financed with shareholders' equity through new issues of shares, primarily rights issues to the shareholders. For further description of the Company's financial risks, see note 25.

Sustainability, social responsibility and employee relations

Hansa Biopharma strives to create sustainable values by developing drugs that can give people a better and longer life. Our vision, a world where patients with rare immunologic diseases can lead long and healthy lives , 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 naturally integrates many of the most important sustainability issues. The sustainability work focuses on conducting clinical development in compliance with ethical rules and guidelines, taking into account the environmental impact of both Hansa's operations and those of 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 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 compliance 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 to promote the 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
Besides having all our employees to operate most sustainably, Hansa Biopharma as an organization also values 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. Hansa Biopharma is responsible for providing personal and professional development opportunities. The model for this is the Hansa Biopharma PR (performance review) development process, a process that is designed to continuously review progress in close collaboration with the employee, the line manager and when applicable the project leader. Aligned with this process is also the Hansa Biopharma salary review process, conducted yearly and serving as a bridge between goal fulfillment and compensation.

Flexibility
Hansa Biopharma applies a great deal of flexibility with regard to working hours and planning of tasks. We believe that it is in all our best interests if employees and activities can plan and optimise work efforts to achieve a good balance between working and private life.

At Hansa Biopharma, flexible working hours are applied – this means that, to some extent, the employees have the option to choose his or hers own working hours within a set framework. This framework can include things like meetings or other events which require a physical presence. It is often during such meetings between people that real progress and innovation happen. In addition to this we have invested in digital platforms to enable working

remotely, participating in teams and keeping staff informed and up to date.

Work Environment
As an employer, our responsibility is to ensure decent working conditions in a healthy and sustainable work environment. Hansa Biopharma and the staff of Hansa Biopharma shall together design the work environment, the employee satisfaction is measured through a yearly survey. We as the employer has however the principal responsibility to ensure that necessary measures are taken and followed. Each manager shall thereby ensure that tasks and workplaces is designed and further-developed so that employees are protected. All factors causing accidents, sickness and psychosocial problems must be taken into consideration in preventive and systematic work environment processes. It is the responsibility of the employer to ensure that the work environment is safe, but the employee must participate in the processes to keep them safe. This could for instance include following work instructions, participate in trainings or use the protective equipment provided by the employer.

Hansa Biopharma encourage staff to openly discuss things that affect them in a negative way, so that the immediate supervisor can in turn take responsibility for the work environment and take corrective actions.

Recruitment & gender
Each of our employees has an important role to play and we must have the right capabilities throughout our business. It is therefore critical that we are successful in our recruitment strategies, using a fair and transparent 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 2019, we attracted 21 new colleagues to meet the demands as we grow as an organization. This equals a global growth for Hansa Biopharma of 40%, including all summer workers the turn-over for Hansa Biopharma was in 2019, 6%.

We promote gender equality, for example, through conducting a yearly salary survey, to ensure that men and women have the same salary for the same and equivalent work. The yearly salary survey also serves as a tool for the organization to avoid salary drift and to discover any unconscious discrimination. In December 2019, gender distribution at Hansa Biopharma was 51% women and 49% men. The Companies management, comprised of all people managers globally, was divided in to 54% women and 46% men.

Hansa Biopharma 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. With this in mind we have an ongoing Great Place to Work process with trust as the main ingredient in building a great workplace for all. Establishing a sustainable foundation of trust is the best investment we can do for our organization in order to recruit, retain and develop.

Financial review

Revenue and financial result
Revenue for 2019 amounted to SEK 3.4 m (2018: SEK 3.4 m) and comprised of royalty and license revenue, milestone revenue and patent reimbursement from Axis-Shield Diagnostics Ltd. which was acquired by Abbott Laboratories during 2019.

Other operating income amounted to SEK 0.2 m (2018: SEK 0.7 m) and is comprised mainly of a research grant from Vinnova. Other operating expense, comprised of net currency differences, amounted to SEK -2.1 m (2018: SEK -4.7 m) for the full year 2019.

Operating result for 2019, amounted to SEK -359.7 m (2018: SEK -246.5 m). During the year, expenses have increased as a result of intensified activities related to applications for pharmaceutical approval and expansion of the organization in preparation for a potential commercial launch. The result for 2019 includes non-cash expenses related to the Company's long-term incentive programs amounting to SEK 7.2 m (2018:SEK 11.7 m).

Net profit/loss for 2019 amounted to SEK -360.0 m (2018: SEK -248.0 m).

Cash flow and financial position
Cash flow from operating activities amounted to SEK -334.8 m (2018: -204.6 m) for 2019. The cash flow was positively impacted by the divestment of the equity holding in Genovis in April 2019, which generated gross proceeds of SEK 89.1 m. Cash and cash equivalents including short term investments amounted to SEK 601.1 m at the end of 2019, as compared to SEK 858.2 m at the year-end 2018.

Capital expenditures
Capital expenditures during 2019 amounted to SEK 3.4 m (2018: SEK 2.5 m) Investments during 2019 related primarily to:

- Laboratory equipment, SEK 2.7 m
- Capitalized patent expense, SEK 0.7 m

Shareholders' equity
On December 31, 2019 shareholders equity amounted to SEK 562.8 m compared with SEK 859.9 m at the end of the financial year 2018.

Parent Company
The Parent Company's revenue for 2019 amounted to SEK 3.4 m (2018: SEK 3.6 m). The result after net financial items for the Parent Company amounted to SEK -283.4 m (2018: SEK -248.3 m) for 2019. On December 31, 2019, cash and cash equivalents including short-term investments amounted to SEK 595.9 m compared with SEK 852.6 m at the end of the year 2018.

The Parent Company's shareholders equity amounted to SEK 562.9 m as per December 31, 2019, as compared with SEK 833.3 m at the end of 2018.

The Group consists of the Parent Company Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd and Hansa Biopharma Inc. Hansa Biopharma Inc had four employees at the end of December 2019. Hansa Biopharma Ltd owns patent rights to the EnzE concept and had two employees at the end of 2019.

Five-year summary

KSEK, unless other stated	**2019**	2018	2017	2016	2015
Revenue	3,364	3,358	3,442	2,579	6,675
Sales, general and administration expenses	-167,310	-90,387	-43,723	-29,703	-28,241
Research and development expenses	-192,949	-154,558	-137,060	-82,850	-44,262
Other operating income/expense	-1,907	-3,995	1,479	-944	285
Operating profit/loss	-359,668	-246,498	-176,083	-111,135	-66 201
Net profit/loss	-360,009	-247,974	-176,660	-111,129	-66,266
Cash flow from operating activities	-334,775	-204,560	-150,105	-94,563	-57,799
Cash and cash equivalents, including short-term investments	601,094	858,187	616,061	253,578	175,683
Shareholder's equity	562,815	859,876	630,661	283,693	211,526
Earnings per share before and after the dilution (SEK)	-9.00	-6.47	-4.97	-3.37	-2.12
Number of outstanding shares at the end of the period	40,026,107	39,959,890	37,087,386	35,054,860	32,412,003
Weighted average number of shares before and after dilution	40,020,429	38,326,098	35,519,029	32,773,304	31,208,438
Number of FTE' end of the period	74	52	33	27	19

Share capital and ownership

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

Total shares issued as of 31 December 2019 comprised of 40,026,107 ordinary shares and 1,421,457 C-shares. Each share has a nominal value of SEK 1 resulting in SEK 41,447,564 share capital and SEK 40,026,107 in outstanding share capital as of 31 December 2019.

At the general meeting, each ordinary share entitles the holder to one vote and C-shares to one tenth of a vote each. C shares are not entitled to dividends. Each shareholder may vote the full number of shares held by him or her. The Company's share capital is denominated in Swedish kronor (SEK) and divided amongst the Company's outstanding shares with a quotient value of SEK 1 per share. As per December 31, 2019, 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 issued and repurchased 715,910 C shares in Q3 2019.The quota value for the repurchased shares is SEK 1 per share.

Share-based compensation programs

Hansa Biopharma uses-share based long-term compensation programs to create conditions for motivating and retaining key employees and to align interests and long-term objectives between the shareholders and the Company, as well as to incentivice meeting and exceeding the Company's business and financial targets.
As in certain previous years, and upon the proposal of Hansa Biopharma's Board of Directors, the AGM resolved to adopt a long-term, share-based compensation program in 2019.

2019 Long-term incentive program

Hansa Biopharma's Annual General Meeting (the "AGM") on May 22, 2019 resolved to adopt a long-term incentive program, LTIP 2019. Under the terms of LTIP 2019 key employees may participate in the program and may receive so-called performance-based share awards free-of charge (a "Share Right) which, provided certain pre-defined Performance Conditions (as briefly summarized below) and other criteria are met, give the participants the right to acquire ordinary shares in Hansa Biopharma at no cost. Each share represents the right to acquire one share and shall carry a vesting period of three years commencing on the day of its allotment to a participant (the "Vesting Period").

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

- Condition 1: Obtain market approval in the EU by EMA
- Condition 2: Obtain market approval in the United States by the FDA
- Condition 3: Total shareholder return of at least 25%

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

As of December 31, 2019, 306,303 Share Rights have been allotted to plan participants.

Share option program 2019 (SOP 2019)

The 2019 AGM also resolved to adopt a share option program, SOP 2019. The SOP 2019 consists of two option series: Series 1 – warrants, and Series 2 – employee stock options.

Series 1 consists of not more than 169,848 warrants that can be acquired by senior executives who are taxable in Sweden. The warrants can be exercised after approximately three years, after which the holder is entitled to exercise the warrants to subscribe for ordinary shares during a period of one month. Each warrant entitles the holder to subscribe for one new ordinary share in Hansa Biopharma. The transfer to participants is made at a price corresponding to the fair value of the warrants at the time of transfer. The Company will, pre taxation, subsidize up to 100 per cent of the price for the acquisition of the warrants through a subsidy offered to participants.

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

Each warrant or employee stock option entitles the holder to receive one new ordinary share in Hansa Biopharma at a subscription price corresponding to 110 per cent of the volume weighted average share price during the 10 trading days immediately prior to the offer to subscribe for the warrants or stock options, respectively.

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

As of December 31, 2019, 11,000 warrants have been acquired and 149,148 employee stock options have been allotted to the plan participants in SOP 2019.

Expenses related to the share rights and employee stock options are reported in accordance with IFRS 2. The total expenses including social security contributions (based on social security tax of 31.42 percent) for the share rights and options allotted as of December 31, 2019, is expected to amount to approximately SEK 43.4 m, of which SEK 8.2 m is included in the results for the Parent

Company and the Group for the year 2019. The expenses in connection with subsidizing the acquisition of warrants amount to SEK 0.2 m for 2019.

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

2020 Proposed guidelines for remuneration to senior management

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

The guidelines proposed by the Board of Directors entail that Senior Executives, i.e. the CEO and members of the executive committee, will be offered remuneration which is competitive and on market terms. The level of the remuneration for the individual manager shall be based on factors such as complexity and responsibility of the position, expertise, experience and performance. The remuneration consists of a fixed base salary and pension benefits and, in addition, may consist of a variable cash remuneration, performance-based short-term incentive (STI), share based long-term incentive programs (LTIP) as resolved by a general meeting, severance remuneration, and other benefits. The STI shall be based on the achievement of quantitative and qualitative performance targets and shall not exceed 50 percent of the annual fixed base salary. The variable cash remuneration is intended to support recruitment or retention of key personnel or to reward extraordinary performance beyond the individual's ordinary responsibilities and shall not exceed 30% of the annual fixed base salary. Contributions to pension plans shall not exceed 30% of the annual fixed base salary. Salary during the notice of termination period and severance remuneration shall be possible in a total maximum amount of 18 monthly base salaries.

Ultimate responsibility for the remuneration to senior management as well as setting the respective performance targets lies with the Board of Directors who is supported by the Remuneration Committee and the CEO. Please also visit the Company's web-site at www.hansabiopharma.com for a detailed description on the proposed 2020 guidelines for remuneration to senior management.

Please refer to Note 5 for information on the adopted 2019 guidelines for remuneration to senior management.

Other information

For additional information, please see the Corporate governance report.

Annual general meeting 2020

The annual general meeting of Hansa Biopharma AB (publ) will take place on June 23, 2020 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.

Financial calendar

Annual Report 2019	April 2, 2020
Annual General Meeting	June 23, 2020
Interim report for January–June 2019	July 16, 2020
Interim report for January–September 2019	October 22, 2020

Appropriation of loss carried forward

Unrestricted shareholders' equity in the Parent Company

SEK	
Share premium reserve	1,413,446,572
Treasury shares	-1,421,457
Profit carried forward	-607,145,624
Result for the year	-283,422,500
Total	**521,456,991**

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

SEK	
Share premium reserve	1,413,446,572
Treasury shares	-1,421,457
Profit/loss carried forward	-890,568,124
Total	**521,456,991**

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

Address

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

Postal address

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

Registration number

556734-5359

Financial statements

The Group

Consolidated income statement

		1 January – 31 December	
KSEK	Note	2019	2018
Revenue	2, 3	3,364	3,358
Cost of revenue		-866	-916
Gross profit		**2,498**	**2,442**
Other operating income	4	166	725
Sales, general and administration expenses		-167,310	-90,387
Research and development expenses		-192,949	-154,558
Other operating expenses	4	-2,073	-4,720
Operating profit/loss	5, 6, 7, 25	**-359,668**	**-246,498**
Net financial income/expenses	8	**76**	**-1,516**
Result before tax		**-359,592**	**-248,014**
Tax	9	-417	40
Result for the year		**-360,009**	**-247,974**
Attributable to			
Parent Company shareholders		-360,009	-247,974
		-360,009	**-247,974**
Earnings per share	10		
before dilution (SEK)		-9.00	-6.47
after dilution (SEK)		-9.00	-6.47

Statement of other comprehensive income

		1 January – 31 December	
KSEK	Note	2019	2018
Result for the year		-360,009	-247,974
Other comprehensive income			
Items that have been, or may be reclassified to profit or loss for the year			
Translation differences for the year		143	65
Changes in fair value for the year on available-for-sale financial assets		207	–
Items that cannot be reclassified to profit or loss for the year			
Shares at fair value through other comprehensive income		49,597	21,029
Other comprehensive income for the year		**49,947**	**21,094**
Total comprehensive income for the year		**-310,062**	**-226,880**
Total comprehensive income attributable to:			
The Parent Company's owner		-310,062	-226,880
		-310,062	**-226,880**

Consolidated statement of financial position

		As of 31 December	
KSEK	Note	2019	2018
ASSETS			
Non-current assets			
Intangible assets	11	33,348	33,197
Property, plant and equipment	12	6,035	5,876
Leased assets	26	9,109	-
Financial assets	14	–	39,528
Total non-current assets		**48,493**	**78,601**
Current assets			
Accounts receivable	17	522	58
Prepaid expenses and accrued income	18	2,979	929
Other receivables	16	11,149	7,046
Short term investments	25	419,397	418,746
Cash and cash equivalents	19	181,697	439,441
Total currents assets		**615,743**	**866,220**
TOTAL ASSETS		**664,236**	**944,821**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	20		
Share capital		41,448	40,682
Share premium reserve		1,413,447	1,400,512
Treasury shares		-1,421	-722
Reserves		81,163	31,216
Retained earnings including result for the year		-971,821	-611,812
Shareholders' equity attributable to Parent Company shareholders		**562,815**	**859,876**
Total shareholders' equity		**562,815**	**859,876**
Non-current liabilities			
Deferred tax liabilities	9	507	511
Provisions	21	818	10,948
Lease liabilities	26	4,827	476
Contingent consideration	22	730	679
Total non-current liabilities		**6,881**	**12,614**
Current liabilities			
Lease liabilities	26	4,632	101
Accounts payable		50,573	40,426
Other liabilities	23	6,940	5,562
Accrued expenses and deferred income	24	32,395	26,242
Total current liabilities		**94,540**	**72,331**
Total liabilities		**101,421**	**84,945**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**664,236**	**944,821**

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

Consolidated statements of changes in shareholders' equity

		Equity attributable to the owners of the Parent Company							
KSEK	Note	Share capital	Share premium reserve	Treasury shares reserve	Translation reserve	Fair value reserve	Retained earnings including results for the year	Total	Total shareholders' equity
Balance at 1 January 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**
Total comprehensive income for the year									
Result for the year		–	–	–	–	–	-247,974	-247,974	-247,974
Other comprehensive income for the year		–	–	–	65	21,029	–	21,094	21,094
Total comprehensive income for the year		**–**	**–**	**–**	**65**	**21,029**	**-247,974**	**-226,880**	**-226,880**
Transactions with the owners of the Parent Company									
New share issue		2,169	451,298	–	–	–	–	453,467	453,467
Cost of new share issue		–	-20,712	–	–	–	–	-20,712	-20,712
Issued warrants		–	354	–	–	–	–	354	354
Long term incentive program		–	5,390	–	–	–	–	5,390	5,390
Treasury shares acquired		–	–	-392	–	–	–	-392	-392
Treasury shares sold		–	4,403	71	–	–	–	4,474	4,474
Issuance of ordinary shares upon exercise of stock options		305	13,209	–	–	–	–	13,514	13,514
Total transactions with the owners of the Parent Company		**2,474**	**453,942**	**-321**	**–**	**–**	**–**	**456,095**	**456,095**
Balance at 31 December 2018		**40,682**	**1,400,512**	**-722**	**17**	**31,199**	**-611,812**	**859,876**	**859,876**

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

[1] Values for 2018 refer to directed share issue in Q4 2018 of 1,776,765 ordinary shares. In H1, 2019 50,000 shares where issued due to the TO 2015 program and 16,217 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market due to the LTIP 2016 program.

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

Consolidated statement of cash flow

		1 January – 31 December	
KSEK	Note	2019	2018
Cash flow from operating activities			
Operating profit/loss		-359,668	-246,498
Adjustment for items not included in cash flow	30	14,613	13,444
Interest paid		-337	-210
Income taxes paid		-123	–
Cash flow from operating activities before changes in working capital		**-345,516**	**-233,264**
Changes in working capital			
Increase (-)/Decrease (+) of account receivable		-464	450
Increase (-)/Decrease (+) of other operating receivables		-6,157	-362
Increase (+)/Decrease (-) of accounts payable		10,146	36,653
Increase (+)/Decrease (-) of other operating liabilities		7,215	-8,037
Net cash from operating activities		**-334,775**	**-204,560**
Cash flows from Investing activities			
Acquisition of intangible assets	11	-729	-127
Acquisition of property, plant end equipment's	12	-2,699	-2,366
Proceeds from sale of equipment	12	87	–
Short term investments		–	-493,984
Sale of short term investments		–	109,000
Proceeds from sale of shares in Genovis AB	14	89,125	–
Net cash used in investing activities		**85,784**	**-387,477**
Financing activities			
Issue of shares		–	453,075
Cost of share issue		-7,646	-20,712
Sale of treasury shares		877	4,473
Issue of warrants		2,309	13,514
Repayment of lease liabilities		-4,424	-44
Net cashfrom financing activities		**-8,884**	**450,307**
Net change in cash and cash equivalent		-257,875	-141,730
Cash and cash equivalents, beginning of year		439,441	581,078
Effects of movements in exchange rate on cash held		131	93
Cash and cash equivalents at 31 December		**181,697**	**439,441**

Parent Company

Income statement

		1 January – 31 December	
KSEK	Note	2019	2018
Revenue	2, 3	3,364	3,603
Cost of revenue		-866	-916
Gross profit		**2,498**	**2,687**
Other operating income	4	166	725
Sales, general and administration expenses		-168,520	-85,938
Research and development expenses		-192,570	-159,137
Other operating expenses	4	-2,073	-4,720
Operating profit/loss	5, 6, 26	**-360,501**	**-246,383**
Result from financial items:			
Results from sale of financial assets		76,626	52
Interest expenses and similar profit/loss items	8	452	-1,966
Result after financial items		**-283,423**	**-248,297**
Result before taxes		**-284,423**	**-248,297**
Tax	9	–	–
Result for the year		**-283,423**	**-248,297**

Statement of other comprehensive income

		1 January – 31 December	
KSEK	Note	2019	2018
Result for the year		-283,423	-248,297
Other comprehensive income		–	–
Other net comprehensive income		**–**	**–**
Total comprehensive income		**-283,423**	**-248,297**

Statement of financial position

KSEK	Note	As of 31 December 2019	2018
ASSETS			
Non-current assets			
Intangible assets	11	29,522	30,163
Property, plant and equipment	12	6,035	5,290
Financial assets			
Participation in group companies	29	5,095	5,095
Other long term holdings of securities	15	–	12,499
Receivables, group companies	13	2,244	–
Total financial assets		7,339	17,594
Total non-current assets		**42,896**	**53,047**
Current assets			
Current receivables			
Accounts receivable	17	522	58
Receivables in group companies	13	1,061	2,834
Other receivables	16	11,138	7,038
Prepaid expenses and accrued income	18	2,709	939
Total currents receivables		15,430	10,869
Short term investments	25	419,190	418,746
Cash and cash equivalents	19	176,715	433,875
Total currents assets		**611,334**	**863,490**
TOTAL ASSETS		**654,230**	**916,537**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	20		
Restricted shareholders' equity			
Share capital		41,448	40,682
Unrestricted shareholders' equity			
Share premium reserve		1,413,447	1,400,456
Treasury shares		-1,421	-722
Retained earnings		-607,146	-358,849
Result for the year		-283,423	-248,297
Total shareholders' equity		**562,905**	**833,270**
Non-current liabilities			
Provisions	21	818	10,948
Contingent consideration	22	730	679
Total non-current liabilities		**1,548**	**11,627**
Current liabilities			
Liabilities, group companies		2,793	–
Accounts payable		50,262	40,333
Other liabilities	23	6,621	5,095
Accrued expenses and deferred income	24	30,102	26,212
Total current liabilities		**89,778**	**71,640**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**654,230**	**916,537**

Statement of changes in shareholders' equity

	Restricted shareholders' equity	Unrestricted shareholders' equity				
KSEK	Share capital	Share premium reserve	Treasury shares	Retained earnings	Result for the year	Total shareholders' equity
Balance at 1 January 2018	38,208	946,570	-401	-182, 476	-176,373	625,528
Total 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
Treasury shares acquired	–	–	-392	–	–	-392
Treasury shares sold	–	4,403	71	–	–	4,474
Issuance of ordinary shares upon exercise of stock options	305	13,209	–	–	–	13,514
Balance at 31 December 2018	**40,682**	**1,400,456**	**-722**	**-358,849**	**-248,297**	**833,270**

	Restricted shareholders' equity	Unrestricted shareholders' equity				
KSEK	Share capital	Share premium reserve	Treasury share reserve	Retained earnings	Result for the year	Total shareholders' equity
Balance at 1 January 2019	40,682	1,400,456	-722	-358,849	-248,297	833,270
Net comprehensive income						
Result for the year	–	–	–	–	-283,423	-283,423
Other comprehensive income for the year	–	–	–	–	–	–
Net comprehensive income	**–**	**–**	**–**	**–**	**-283,423**	**-283,423**
Appropriation of profits	–	–	–	-248,297	248,297	–
New share issue	716	–	–	–	–	716
Costs attributable to new share issue	–	-7,646	–	–	–	-7,646
Issued warrants	–	193	–	–	–	193
Long term incentive program	–	17,324	–	–	–	17,324
Treasury shares acquired	–	–	-716	–	–	-716
Sale of treasury shares	–	861	16	–	–	877
Issuance of ordinary shares upon exercise of stock options	50	2,259	–	–	–	2,309
Balance at 31 December 2019	**41,448**	**1,413,447**	**-1,421**	**-607,146**	**-283,423**	**562,905**

Statement of cash flow

		1 January – 31 December	
KSEK	Note	2019	2018
Operating activities			
Operating profit/loss		-360,501	-246,383
Adjustment for items not included in cash flow	30	9,895	13,218
Interest paid		-59	-607
Cash flow from operating activities before changes in working capital		**-350,665**	**-233,772**
Changes in working capital			
Increase (-)/Decrease (+) of account receivable		-464	450
Increase (-)/Decrease (+) of other operating receivables		-6,345	-2,731
Increase (+)/Decrease (-) of accounts payable		9,929	36,609
Increase (+)/Decrease (-) of other operating liabilities		8,332	-8,200
Net cash from operating activities		**-339,213**	**-207,644**
Cash flow from investing activities			
Acquisition of tangible assets	12	-2,699	-2,366
Sale of tangible assets	12	87	–
Sale of Financial Assets	14	89,125	–
Acquisition of financial assets		–	-277
Short term investments		–	-493,984
Sale of short-term investments		–	109,000
Net cash used in investing activities		**86,513**	**-387,627**
Cash flow from financing activities			
Issue of shares		–	453,075
Issue cost of shares		-7,646	-20,712
Sale of treasury shares		877	4,474
Exercise of stock options		2,309	13,514
Net cash from financing activities		**-4,460**	**450,351**
Net change in cash		-257,160	-144,920
Cash and cash equivalents, beginning of year		433,875	578,795
Cash and cash equivalents at 31 December		**176,715**	**433,875**

Notes

Note 1 Significant accounting principles

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

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

The annual report and the consolidated accounts were approved for issuance by the Board and the Chief Executive Officer on April 2, 2020. The consolidated income statement , statement of other comprehensive income and statement of financial position and the Parent Company's income statement and statement of financial position are subject to approval at the Annual General Meeting on June 23, 2020.

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

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

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

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

(e) Changes in accounting principles
(i) Changes in accounting principles due to new or amended IFRS
The Group applies IFRS 16 for the first time as of January 1, 2019. Other amendments to IFRS with effect from January 1, 2019 have not had any significant effect on the Group's accounts.

IFRS 16 Lease Agreement replaces, as of January 1, 2019, existing IFRS related to the recognition of leasing agreements, such as IAS 17 Leasing and IFRIC 4 that determined whether an agreement contained a lease. The introduction of IFRS 16 has affected how the Group accounts for assets under operating leases. Under previous accounting principles, operating leases was recognized in the income statement on a straight-line basis during the lease term. Under IFRS 16, for these agreements, a liability in the statement of financial position corresponding to the obligation to pay leasing fees is recognized at the same time as a corresponding asset that reflects the right to use the leased asset. The depreciation of the asset is recognized in the income statement, as well as interest on the lease liability. However, in accordance with IFRS 16, the Group has decided to exclude leases where the lease term (calculated in accordance with IFRS 16) is less than 12 months as well as leases of low value.

KSEK	
Operational leasing commitments as of December 31, 2018 according to note 26 in the annual report for 2018	**14,453**
Discounted with marginal loan rate as of january 1, 2019	12,814
Additional – financial leasing liabilitites as of December 31, 2018	578
Departs – short-term lease	-38
Leasing debt as of January 1, 2019	**13,354**

Hansa Biopharma has chosen to apply the "modified retrospective approach" at the transition to IFRS 16, which means that comparative figures for 2018 will not be recalculated. Furthermore, as of January 1, 2019, the Group has chosen to recognize leased assets to the same amount as the lease liability, but with the addition of prepaid rents that are reported in the consolidated statement of financial position. Thus, no effect on shareholders' equity is realized on the transition to IFRS 16.

The transition to IFRS 16 has not affected the accounting for existing leases that are recognized as financial leases under the current accounting principles.

IFRS 16 has not been applied in the Parent Company accounts in accordance with the relief rules in RFR 2.

As of January 1, 2019, the transition to IFRS 16 has resulted in an increase of the Group's liabilities by SEK 14.0 million (of which SEK 4.3 million is current liabilities), while at the same time a utilization rights asset of SEK 14.0 million has been recognized. The effect on operating results after tax has been insignificant. Cash flow from operating activities for the full year 2019 has increased and cash flow from financing activities decreased by SEK 4.3 million since the leasing fees' amortization is reported as payment in the financing activities. The discount rate used is 3.4%.

(ii) Voluntarily change in accounting principle
During 2018 the Group presented non-current leasing liabilities and liabilities for contingent consideration under a single line item. During 2019 the Group has chosen to present leasing liabilities and liabilities for contingent consideration as a separate line item. Comparative numbers have been restated accordingly.

(iii) Standards issued but not yet effective
A number of new standards are effective for annual periods beginning after 1 January 2019 and earlier application is permitted; however, the Group has not early adopted the new or amended standards in preparing these consolidated financial statements.

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

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

(g) Operating segment reporting
An operating segment is a component of an entity:

- (a) that engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same entity),
- (b) whose operating results are regularly reviewed by the entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance, and
- (c) for which discrete 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. From the inception of the Group, the financial information available for evaluation by management in deciding how to allocate resources and assess performance is that of the business as a whole. For these reasons the Group had a single reportable segment during the reporting period.

(h) Basis of Consolidation
(i) Subsidiary
Subsidiaries are companies controlled by Hansa Biopharma AB. Subsidiaries are accounted for using the acquisition method. The acquisition method entails that the acquisition of a subsidiary is regarded as a transaction whereby the Group indirectly acquires the subsidiary's assets and assumes its liabilities. The purchase price allocation determines the fair value at the acquisition date of the identifiable assets acquired and liabilities assumed and any non-controlling interest.

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

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

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

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

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

The agreement with Axis-Shield Diagnostics entails an out-licensing of the Group's method for HBP analysis. The license gives Axis-Shield Diagnostics a right to access Hansa Biopharma's AB intellectual property regarding HBP analysis during the license period, since the agreement requires Hansa Biopharma AB 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 Diagnostics as a license holder. According to IFRS 15, a license entails that the licensee has the right to access the intellectual property of an entity and the payment for that right is recognized as revenue over the contract period. Received payments of minimum royalty is thus accrued and recognized as income during the period to which the royalty refers. Any sales-based royalties are recognized when the sale has taken place that gives Hansa Biopharma AB right to sales-based royalty.

(ii) Milestone revenue
According to the agreement with Axis-Shield Diagnostics, Hansa Biopharma AB is entitled to receive milestone payment in cases where Axis-Shield Diagnostics achieves certain development milestones. The Group only recognizes revenue when it is highly probable that the Group has the right to receive the milestone payment.

(iii) Patent remuneration
Hansa Biopharma AB is 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 rendered.

(iv) Government grants
Government grants are recorded in the statement of financial position as accrued income and deferred income when there is reasonable certainty that the grant will be obtained and that the Group will meet the conditions associated with the grant. Grants are systematically recognized in the income statement for the year in the same way and over the same periods as the costs of the contributions is intended to compensate for.

(k) Leasing
Accounting principle applied from 1 January 2019:

(i) IFRS 16
The group leases various offices, laboratory facilities, equipment and vehicles. Rental contracts are typically made for fixed periods of 3 to 4 years but may have extension options as described further in (ii) below.

Contracts may contain both lease and non-lease components. The group allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices. However, for leases of real estate for which the group is a lessee, it has elected not to separate lease and non-lease components and instead accounts for these as a single lease component. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. From 1 January 2019, leases are recognized as a leased asset and a corresponding liability at the date at which the leased asset is available for use by the group. Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the lease payments and they are discounted using the lessee's incremental borrowing rate, estimated to be 3.4%. Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life. Payments associated with short-term leases of equipment and all leases of low-value assets are recognized on a straight-line basis as an expense in the income statement. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise mainly of IT equipment and small items of office furniture.

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

Accounting principles prior to 1 January 2019:

Operational leasing agreements
Costs regarding operational leasing agreements are reported in the profit and loss 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 profit and loss 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.

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

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

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

Deferred tax claims regarding deductible temporary differences and loss carryforwards are reported only to the extent it is probable that these can be utilized. 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 recognized in the statement of financial position include, on the assets side, cash and equivalents, short term investments, other receivables, accounts receivable and listed shares. On the liability side, accounts payable and contingent consideration.

(i) Recognition and initial measurement

Accounts receivable and debt instruments are initially recognized when they are originated. Spot purchases and spot sales of financial assets are recognized on the settlement date. Other financial assets and financial liabilities are recognized when the Group becomes party to the instrument's contractual terms.

Financial instruments are initially recognized at fair value with the addition / deduction for transaction expenses, except for instruments that are continuously measured at fair value through the income statement for which transaction expenses are instead expensed when they arise. Accounts receivable (without a significant financing component) are initially valued at the transaction price as determined in accordance with IFRS 15.

(ii) Classification and subsequent measurement

On initial recognition, a financial asset is classified as measured at: amortized cost, fair value through other comprehensive income (debt instrument investment), fair value through other comprehensive income (equity investment), or fair value through the income statement. The following describes how the Group's various holdings of financial assets have been classified:

Holdings of listed shares

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

The shares in Genovis were sold during 2019.

Holdings of interest funds

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

Other financial assets

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

(iii) Classification and valuation of financial liabilities

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

(iv) Derecognition from the statement of financial position

Financial assets

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

Financial liabilities

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

(o) Property, plant and equipment

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

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

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

Anticipated useful life:

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

(p) Intangible assets

(i) Acquired intangible assets

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

Anticipated useful life:

Patents	17 years
In-process development projects	15 years

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

(ii) Internally generated intangible assets

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

This means in practice that expenditure is not capitalized before the pharmaceutical authorities have given approval due to the level of uncertainty associated with the approval process.

(q) Impairment

At each reporting date, the Group reviews the carrying amounts of its assets to determine whether there is any indication of impairment or write-down. If any such indication exist, then the asset's recoverable amount is estimated and if it is estimated to be lower than the assets carrying amount, an appropriate impairment charge or write-down is recognized in profit or loss. The recoverable amount of an asset or a cash generating unit is the higher of its fair value less costs of disposal and its value in use. The value in use is the present value of the future cash flow expected to be derived from an asset or cash generating unit. The future cash flow is discounted at a rate that takes into consideration the markets assessment of risk-free rate and the risk associated with the specific asset.

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

(ii) Reversal of impairment losses

Impairment of assets included in the area of application for IAS 36 is reversed if there is both an indication that the need for the impairment no longer exists and that there has been a change in the assumptions which formed the basis for the calculation of the recovery value. 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 amortization where relevant, if no write down had been made.

(iii) Impairment of financial assets

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

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

(t) Employee benefits

(i) Short-term employee benefits

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

(ii) Long-term employee benefits

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

(iii) Termination benefits

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

(iv) Defined contribution pension plans

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

(v) Share-based compensation

Share-based compensation pertains to employee benefits, including senior executives in accordance with the long-term share-based compensation schemes that the Company initiated between 2015 and 2019. Costs for employee benefits are recognised in accordance with IFRS 2 as the value of services received, allocated over the vesting periods for the plans, calculated as the fair value of the allotted equity instruments. The fair value is determined on the allotment date. Since the plans are regulated with equity instruments, they are classified as "equity settled" and an amount corresponding to the recognised personnel cost for employee benefits is recognised directly in shareholders' equity.

Share warrant programs 2015, 2018 and 2019; Employee stock option program 2019.

A share warrant program was initiated in 2015, 2018 and 2019. An employee stock option program was initiated in 2019.

Under a share warrant program, participants are given the opportunity to acquire warrants at market value calculated based on the Black-Scholes model. Each warrant entitles the holder to subscribe for one new ordinary share in accordance with the terms of the respective program. Each share warrant program is partly subsidized by the Company and participants (except the CEO) in the share warrant program receive a one-time subsidy when purchasing warrants. The fair value of the subsidy is expensed in accordance with IFRS 2, as described above, over the vesting period under each program, which typically is three (3) years. The 2015 program ended during 2019; 2018 and 2019 programs are ongoing.

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

Long-term incentive programs (LTIP) 2016, 2018 and 2019

Share-based LTIPs were initiated in 2016, 2018 and 2019. Under a LTIP, participants receive share awards free-of-charge which provide for the opportunity to receive ordinary shares subject to certain performance and other criteria being met in accordance with the terms of the respective program.

The fair value of the allotted share rights is calculated at the time of grant based on a Monte-Carlo-Simulation. The fair value of allocated share rights is expensed in accordance with IFRS 2, as described above, over the vesting period under each program, which typically is three (3) years. The expense recognized corresponds to the fair value of an estimate of the number of share rights expected to be earned, taking into account the terms of service and the conditions for earning ordinary shares during the vesting period. This expense is adjusted in subsequent periods in order to ultimately reflect the actual number of earned share rights. However, adjustment is not made if the share rights are forfeited only due to the fact that the performance requirement is not met. Social security 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 statement of financial position when there is a present legal or constructive obligation as a result of a past event, and it is probable that an outflow of resources will be required to settle the obligation and a reliable estimate of the amount can be made.

(v) Contingent liabilities

A contingent liability is:

- (a) a possible obligation that arises from past events and whose existence will be confirmed only by the occurrence or non occurrence of one or more uncertain future events not wholly within the control of the entity; or
- (b) a present obligation that arises from past events but is not recognized because:

  (i) it is not probable that an outflow of resources embodying economic benefits will be required to settle the obligation; or

  (ii) the amount of the obligation cannot be measured with sufficient reliability.

(w) The Parent Company's accounting principles

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

(i) Differences between the Group's and the Parent Company's accounting principles

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

(ii) Change in accounting principles
Unless otherwise stated below, the Parent Company's accounting principles in 2019 have changed in accordance with what is stated above for the Group. Implementation of IFRS 16 as of January 1, 2019 has not affected the Parent Company because RFR 2 allows IFRS 16 not to be applied by the Parent.

(iii) Presentation and classification
The differences in the Parent Company's income statement and statement of financial position as compared with the Group's statements consist primarily of the reporting of financial income and expenses, fixed assets and shareholders' equity.

(iv) Financial instruments
The Parent Company does not apply IFRS 9. Non-current financial assets are measured historical cost less any impairment losses. Short-term investments are measured at the lower of historical cost and net realizable value.

Note 2 Revenue

Disaggregation of revenue

	1 January – 31 December	
KSEK	2019	2018
Group		
Revenue		
Royalty and license revenue	2,265	2,071
Milestone revenue	573	621
Patent reimbursement	526	666
Total revenue	**3,364**	**3,358**
Parent Company		
Revenue		
Royalty and license revenue	2,265	2,071
Milestone revenue	573	621
Patent reimbursement	526	911
Total revenue	**3,364**	**3,603**

According to the agreement with Axis-Shield Diagnostics, Hansa Biopharma AB is entitled to continuously receive minimum royalty of USD 250k annually until the underlying patent expires. Received payments of minimum royalty is thus accrued and recognized as revenue during the period to which the royalty refers. In 2019, the Company received a total of USD 250k (2018: USD 250k) in royalty.

Furthermore, additional compensation may apply when Axis-Shield Diagnostics conduct a sale where the developed method for HBP analysis is included or when Axis-Shield Diagnostics achieves certain development milestones. The Group only recognizes revenue when it is highly probable that the Group has the right to receive the milestone. In 2019 the Company received a milestone payment amounting to USD 60k (2018: USD 75k).

The Company is reimbursed for patent maintainance cost. Patent reimbursement is recognized as revenue as the services are rendered. The Group's and the Parent Company's revenue from contracts with customers coincide with the recognized revenue.

Accrued income
In January 2019, the Group received a minimum royalty payment amounting to USD 250k. The amount was initially recognized as an accrued income and recognized as revenue over the reporting period on a straight line basis. As of the reporting date, there were no accrued income balances.

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

Note 3 Operating segment

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. From the inception of the Group, the financial information available for evaluation by management in deciding how to allocate resources and assess performance is that of the business as a whole. For these reasons, the Group had a single reportable segment during the reporting period.

Note 4 Other operating income and expenses

Group	1 January – 31 December	
KSEK	2019	2018
Other operating income		
Government grant	166	725
Total other operating income	**166**	**725**
Other operating expenses		
Foreign currency gains/losses on receivables/liabilities from operating activities	-2,073	-4,720
Total other operating expenses	**-2,073**	**-4,720**

Parent Company	1 January – 31 December	
KSEK	2019	2018
Other operating income		
Government grant	166	725
Total other operating income	**166**	**725**
Other operating expenses		
Foreign currency gains/losses on receivables/liabilities from operating activities	-2,073	-4,720
Total other operating expenses	**-2,073**	**-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

2019 Guidelines for remuneration to senior management

The 2019 guidelines proposed by the Board of Directors entail that executive management is offered a remuneration which is competitive and on market terms. The level of the remuneration for the individual manager shall be based on factors such as position, expertise, experience and performance. The remuneration consists of a fixed salary and pension benefits and, in addition, may consist of variable salary, share based long-term incentive programs, severance remuneration and non-monetary benefits. The variable salary is based on the achievement of quantitative and qualitative targets and should not exceed 50 percent of the annual fixed salary. Salary during the notice of termination period and severance remuneration can be a maximum amount of 24 months salaries.

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

Group 2019

Personnel expenses in the Group broken down to geographical areas

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

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

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

Parent Company in Sweden 2019

Salaries and other remuneration paid to senior management

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

*Includes 1 226 KSEK, representing 30% of base salary, intended for own pension contribution.

Group 2018

Personnel expenses in the Group broken down to geographical areas

KSEK	Parent in Sweden	Subsidiaries in UK and US	Total Group
Salaries, bonuses* and other benefits	40,164	3,240	43,404
Social charges	14,621	254	14,875
Pension cost, contribution plan	4,630	20	4,650
Share-based compensation	11,619	56	11,675
Total personnel expenses	**71,034**	**3,570**	**74,604**

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

KSEK	Senior management	Other employees	Total Parent company in Sweden
Salaries, bonuses and other benefits	21,701	18,463	40,164
Social charges	6,363	8,258	14,621
Pension cost, contribution plan	1,180	3,450	4,630
Share-based compensation	5,915	5,704	11,619
Total personnel expenses	**35,160**	**35,874**	**71,034**

Parent Company in Sweden 2018

Salaries and other remuneration paid to senior management

KSEK	Base salary Directors' fees	Variable compensation	Other benefits	Total salaries, bonuses and other benefits	Social charges	Pension cost	Share-based payments	Total
Chairman of the Board of Directors Ulf Wiinberg*	2,559	–	–	2,559	804	–	–	3,363
Director Birgit Stattin-Norinder	467	–	–	467	48	–	–	515
Director Stina Gestrelius	290	–	–	290	30	–	–	320
Director Angelica Loskog	–	–	–	–	–	–	–	–
Director Anders Gersel-Pedersen	210	–	–	210	21	–	–	231
Director Andreas Eggert	204	–	–	204	64	–	–	268
Director Per-Olof Wallström	103	–	–	103	32	–	–	135
Director Hans Schikan**	481	–	–	481	151	–	–	632
CEO Søren Tulstrup	3,912	1,179	59	5,150	1,618	–	1,216	7,984
Former CEO	796	–	–	796	–	–	–	796
Other senior management (7 persons)	9,153	1,663	625***	11,441	3,595	1,180	4 699	20,915
Total	**18,175**	**2,842**	**684**	**21,701**	**6,363**	**1,180**	**5 915**	**35,160**

The Company has decided to change its presentation of in the table "Salaries and other remuneration paid to senior management".
The table is presented on accrued basis and now includes a column for social security. Comparative numbers have been updated accordingly.

* Of which SEK 1,772K is fee for acting CEO and SEK 787K is fee for chairman of the board.

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

*** The amount relates to severance pay to Shumel Agus.

Average number of employees

	2019		2018	
	Number	of which men	Number	of which men
Total Group	63	43%	42	41%
Parent Company				
Sweden	58	42%	41	41%
Total Parent Company	58	42%	41	41%
Subsidiaries				
UK	1	100%	–	–
US	4	25%	1	–
Total subsidiaries	**5**	**–**	**1**	**–**

Breakdown of senior management according to gender

	Share of woman	
	2019-12-31	2018-12-31
Total group		
Board of Directors	33%	50%
Other senior management	17%	38%
Parent Company		
Board of Directors	33%	50%
Other senior management	17%	38%

Benefits to senior management

Senior management of the Company includes the Board of Directors, the CEO and the other members of the executive management.

Remuneration to Board of Directors

Fees are payable to the chairman of the Board of Directors and other directors pursuant to a resolution adapted by the annual general meeting. The 2019 annual general meeting resolved that fees paid to directors for work during 2019 will be SEK 900,000 to the chairman of the Board of Directors and SEK 300,000 to each of the other directors, SEK 75,000 to the chairman and SEK 40,000 each to the other directors who are members of the Audit Committee, SEK 40,000 to the chairman and SEK 25,000 each to other directors who are members of the Remuneration Committee and SEK 25,000 each to directors who are members of the Scientific Committee. There are no contracts regarding severance compensation or other benefits for the chairman of the Board of Directors or other directors.

Salaries and other remuneration to the CEO

Salaries, bonuses and other benefits

In 2019, the CEO received a total of SEK 7,014 in salaries, bonuses and other benefits.

Notice of termination periods and severance compensation

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

Pension remuneration

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

Salaries and other remuneration to other members of executive management

Salaries and other remuneration to the other members of the executive management is determined by the CEO and approved by the chairman of the Board of Directors. Following the implementation of a new governance structure during 2019 the number of executive management went from eight people in 2018 to six people in 2019, including the CEO.

Salaries, bonuses and other benefits for the other members of the executive management amounted to SEK 11,671 in 2019.

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

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

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

Share-based compensation
Share warrant program 2015 (LTIP 2015)
In 2015, a share warrant program was adopted which gave the Company's employees the right to acquire shares in Hansa Biopharma AB. In total, 355,000 share warrants were acquired. Subscription for shares in accordance with the terms of the warrants took place during the period from June 15, 2018 to June 15, 2019. Each warrant gave 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 in the amount of seven percent annually during the vesting period of three (3) years. The program ended in 2019.

LTIP 2015: Key figures

	2019	2018
Warrants, Opening balance 1 January	50,000	355,000
Exercised warrants during the period	-50,000	-305,000
Warrants, Closing balance 31 December	**–**	**50,000**
Recorded share-based compensation expenes, KSEK	–	58

Long-term incentive program 2016 (LTIP 2016)
Hansa Biopharma's AB Extraordinary General Meeting on November 21, 2016 resolved to adopt a long-term incentive program (LTIP 2016) in the form of a performance-based share program for all employees of the Group, meaning that not more than 30 individuals within the Group may participate. Participants will, provided that the performance condition is met and provided a continued employment throughout the vesting period of three (3) years (the "Vesting Period"), be granted the right to obtain ordinary shares free of charge (the "Right") after the vesting period. The performance condition is set at a "minimum level" and "maximum level", whereby the number of shares granted under the Rights is increased lineally between the minimum level and maximum level. However, in order for the Rights to entitle to the granting of shares, the minimum level has to be reached or exceeded. If the specified minimum level of the performance condition of 25 percent share-holder return during the Vesting Period is achieved, 25 percent of each participant's Rights will entitle to shares. If the maximum level of 100 percent shareholder return during the Vesting Period is reached , 100 percent of each participant's Rights will entitle to shares. A maximum of 305,000 Rights could be allotted to participants under LTIP 2016 and 289,750 rights were alloted in total.

LTIP 2016: Key figures

	2019	2018
Rights, Opening balance 1 January	211,500	289,750
Allotted Rights during the period	–	–
Rights expired or redeemed in advance during the period	-176,500	-78,250
Rights, Closing balance 31 December	**35,000**	**211,500**
Recorded share-based compensation expenes, KSEK	-5,991	13,060

Long-term incentive program 2018 (LTIP 2018)

Hansa Biopharma's AB Annual General Meeting on May 29, 2018 resolved to adopt a long-term incentive program (LTIP 2018). Not more than 52 individuals within the Hansa Biopharma AB 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 rights free of charge which, provided that certain conditions are met, may give the right to acquire shares in the Company. A maximum of 491,419 warrants or 297,902 share awards may be allotted to participants under LTIP 2018.

Warrants under LTIP 2018

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

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

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

LTIP 2018, Warrants: Key figures

	2019	2018
Warrants, Opening balance 1 January	6,701	–
Warrants acquired by participants	–	6,701
Warrants, Closing balance 31 December	**6,701**	**6,701**
Recorded share-based compensation expenes, KSEK	40	214

Share rights under LTIP 2018

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

LTIP 2018, share rights: Key figures

	2019	2018
Share rights, Opening balance 1 January	171,556	–
Alloted to participants on June 15, 2018	–	105,460
Alloted to participants on November 30, 2018	–	72,671
Alloted to participants on May 14, 2019	82,579	–
Share rights expired or redeemed in advance during the period	-15,767	-6,575
Share rights, Closing balance 31 December	**238,368**	**171,556**
Recorded share-based compensation expenes, KSEK	4,837	2,743

Long-term incentive program 2019 (LTIP 2019)

Hansa Biopharma AB's Annual General Meeting (the "AGM") on May 22, 2019 resolved to adopt a long-term incentive program, LTIP 2019. Under the terms of LTIP 2019 key employees may participate in the program and may receive so-called performance-based share awards free-of charge (a "Share Right") which, provided certain pre-defined Performance Conditions (as briefly summarized below) and other criteria are met, give the participants the right to acquire ordinary shares in Hansa Biopharma AB at no cost. Each Share Right represents the right to acquire one share and shall carry a vesting period of three years commencing on the day of its allotment to a participant (the "Vesting Period").
The final number of shares a participant is entitled to receive is, amongst other terms, conditional upon meeting the following performance conditions during the Vesting Period (the "Performance Conditions"):

- Condition 1: Obtain market approval in the EU by EMA
- Condition 2: Obtain market approval in the United States by the FDA
- Condition 3: Total shareholder return (TSR) of at least 25%

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

LTIP 2019: Key figures

	2019
Share Rights, Opening balance 1 January	–
Allotted to participants 17 June, 2019	288,727
Allotted to participants 24 October, 2019	17,576
Share awards expired or redeemed in advance during the period	–
Share Rights, Closing balance 31 December	**306,303**
Recorded share-based compensation expenes, KSEK	6,981
Allotment date June 17, 2019 – Fair value calculation (Monte Carlo simulation)	
Base line value TSR, SEK	178.40
Calculated average fair value per Share Right, SEK	122.12
Risk-free interest rate, (%)	-0.59
Expected volatility, (%)	43
Expected dividend, SEK	–
Allotment date October 24, 2019 – Fair value calculation (Monte Carlo simulation)	
Base line value TSR, SEK	129.30
Calculated average fair value per Share Right, SEK	89.00
Risk-free interest rate, (%)	-0.41
Expected volatility, (%)	43
Expected dividend, SEK	–

Share option program 2019 (SOP 2019)
The 2019 AGM resolved to adopt a share option program, SOP 2019. The SOP 2019 consists of two option series: Series 1 – Warrants, and Series 2 – Employee stock options.

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

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

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

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

SOP 2019, Warrants: Key figures

	2019
Warrants, Opening balance 1 January	–
Warrants acquired by participants, 17 June	11,000
Rights expired or redeemed in advance	–
Closing balance 31 December	**11,000**
Recorded share-based compensation expenes, KSEK	153
Proceeds from exercise of warrants during the period, KSEK	–
Estimated total proceeds if all outstanding options are exercised, KSEK	2,158
Fair value calculation (Black Scholes model)	
Calculated average fair value per warrant, SEK	45.54
Hansa Biopharma AB base line share price, SEK	178.38
Risk-free interest rate, %	-0.59
Expected volatility, %	43
Warrant life, years	4
Expected dividend, SEK	–

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

	2019
ESO, Opening balance 1 January	–
ESO acquired by participants, 17 June	149,148
ESO expired or redeemed in advance	–
ESO, Closing balance 31 December	**149,148**
Recorded share-based compensation expenes, KSEK	1,226
Proceeds from exercise of warrants during the period, KSEK	–
Estimated total proceeds if all outstanding options are exercised, KSEK	29,265
Fair value calculation (Black Scholes model)	
Calculated average fair value per ESO, SEK	45.19
Hansa Biopharma AB base line share price, SEK	178.38
Risk-free interest rate, %	-0.59
Expected volatility, %	43
Warrant life, years	4
Expected dividend, SEK	–

Note 6 Fees and competition for costs, auditors

	1 January – 31 December	
KSEK	2019	2018
Group		
KPMG		
Auditing services	740	500
Tax services	265	81
Wilkins Kennedy Audit Service		
Auditing services	58	59
Parent Company		
KPMG		
Auditing services	725	500
Tax services	265	81

Audit services refer to the legally required audit 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 nature

Group

KSEK	1 January – 31 December 2019	2018
Other operating income	166	725
Personnel costs	-114,752	-71,674
Other external costs	-243,378	-171,453
Depreciation	-2,063	-1,818
Other costs	-2,139	-4,720
Total operating costs by nature	**-362,166**	**-248,940**

Parent Company

KSEK	1 January – 31 December 2019	2018
Other operating income	166	725
Personnel costs	-101,064	-71,861
Other external costs	-258,162	-171,615
Depreciation	-1,863	-1,599
Other costs	-2,074	-4,720
Total operating costs by nature	**-362,998**	**-249,070**

Note 8 Net financial income/expenses

Group

KSEK	1 January – 31 December 2019	2018
Interest income and similar income statements items		
Interest income, other	118	52
Net profit transferred from shareholders' equity on disposal of available-for sale financial assets	2,719	–
Financial income	**2,837**	**52**
Interest expenses, other	-466	-706
Changes in the fair value of interest funds during the year	-2,274	-851
Net exchange rate gains/losses	-21	-11
Financial expenses	**-2,760**	**-1,568**
Net financial items	**76**	**-1,516**

Parent Company

KSEK	1 January – 31 December 2019	2018
Interest income and similar income statements items		
Interest income, other	118	52
Net profit transferred from shareholders' equity on disposal of available-for sale financial assets	2,719	–
Financial income	**2,837**	**52**
Interest expenses, other	-90	-712
Changes in the fair value of interest funds during the year	-2,274	-1,254
Net exchange rate gains/losses	-21	–
Financial expenses	**-2,384**	**-1,966**
Net financial items	**452**	**-1,914**

Note 9 Taxes

Deferred tax liabilities

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

KSEK	2019	2018
Opening balance 1 January	511	538
Tax income in the income statement*	-42	-40
Currency differences for the year	38	13
Closing balance 31 December	**507**	**511**

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

Unrecognized deferred tax assets

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

The group's losses carried forward in 2019 amounted to SEK 990,873 k (2018: SEK 715,854 k). The losses carried forward is, in all material respects, attributable to Swedish companies and therefore has no due date.

Reconciliation effective tax

Group

KSEK	2019 (%)	2019	2018 (%)	2018
Result before tax	–	-359,592	–	-248,014
Tax according to current tax rate for the Parent Company	21.4	76,953	22.0	54,563
Effect of other tax rates for foreign subsidiaries	–	-62	–	–
Non-deductable expenses	-0.5	-1,701	-1.1	-2,831
Increase in loss carry-forwards without corresponding capitalization of deferred tax	-21.0	-75,606	-20.7	-51,692
Reported effective tax	–0.1	-417	–	40

Parent Company

KSEK	2019 (%)	2019	2018 (%)	2018
Result before tax	–	-283,423	–	-248,297
Tax according to current tax rate for the Parent Company	21.4	60,653	22.0	54,625
Non-deductable expenses	-0,6	-1,658	-1.1	-2,831
Increase in loss carry-forwards without corresponding capitalization of deferred tax	-20.8	-58,995	-20.9	-51 794
Reported effective tax	–	–	–	–

Note 10 Earnings per share

Earnings per share

SEK	2019	2018
Earnings per share prior to and after dilution	-9.00	-6.47

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

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

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

KSEK	2019	2018
Profit/loss for the year related to the Parent Company's shareholders	-360,009	-247,974
Earnings attributable to the Parent Company's shareholders prior to and after dilution	**-360,009**	**-247,974**

Weighted average number of outstanding shares prior to and after dilution

Number of shares	2019	2018
Total number of shares 1 January	39,959,890	37,807,386
Effect of conversion of C to A shares in January 2019	12,062	–
Effect of new share issue in January	45,890	–
Effect of conversion of C to A shares in February 2019	2,586	–
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
Weighted average number of shares during the year prior to and after dilution	**40,020,429**	**38,326,098**

Note 11 Intangible assets

Group

	Developed in-house	Acquired intangible assets		
KSEK	Capitalized development expenditures	Patents	In-process development projects	Total
Cost				
Opening balance 1 January 2019	4,485	3,643	33,515	41,643
Reclassification	–	8,379	-8,379	–
Adjusted opening balance	4,485	12,022	25,136	41,643
Additions	–	729	–	729
Effects of movements in exchange rates	–	-272	–	-272
Closing balance 31 December 2019	4,485	12,479	25,136	42,100
Amortization				
Opening balance 1 January 2019	4,485	-609	-3,352	-8,446
Reclassification	–	-3,352	3,352	–
Adjusted opening balance	4,485	-3,691	–	-8,446
Amortization for the year	–	-812	–	-812
Effects of movements in exchange rates	–	506	–	506
Closing balance 31 December 2019	4,485	-4,267	–	-8,752
Carrying amounts				
At 1 January 2019	–	3,034	30,163	33,197
Reclassification	–	5,027	-5,027	–
Adjusted opening balance at 1 January 2019	–	8,061	25,136	33,197
At 31 December 2019	–	8,212	25,136	33,348

	Developed in-house	Acquired intangible assets		
KSEK	Capitalized development expenditures	Patents	In-process development projects	Total
Cost				
Opening balance 1 January 2018	4,485	3,444	33,515	41,444
Additions	–	124	–	124
Effects of movements in exchange rates	–	75	–	75
Closing balance 31 December 2018	4,485	3,643	33,515	41,643
Amortization				
Opening balance 1 January 2018	-4,485	-404	-2,806	-7,695
Amortization for the year	-	-199	-546	-745
Effects of movements in exchange rates	–	-6	–	-6
Closing balance 31 December 2018	-4,485	-609	-3,352	-8,446
Carrying amounts				
At 1 January 2018	–	3,040	30,709	33,749
At 31 December 2018	–	3,034	30,163	33,197

Parent Company

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

KSEK	Developed in-house: Capitalized development expenditures	Acquired intangible assets: Patents	Acquired intangible assets: In-process development projects	Total
Cost				
Opening balance 1 January 2018	4,485	125	33,515	38,125
Closing balance 31 December 2018	4,485	125	33,515	38,125
Amortization				
Opening balance 1 January 2018	-4,485	-125	-2,806	-7,416
Amortization for the year	–	–	-546	-546
Closing balance 31 December 2018	-4,485	-125	-3,352	-7,962
Carrying amounts				
At 1 January 2018	–	–	30,709	30,709
At 31 December 2018	–	–	30,163	30,163

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

Project overview	Indication/Purpose	Status
imlifidase	Imlifidase is 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 is a unique IgG antibody-cleaving enzyme that specifically and rapidly cleaves immunoglobulin G (IgG), thereby eliminating immunological barriers and potentially enabling treatment of immune-mediated diseases. Imlifidase origins from *Streptococcus pyogenes* a species of a Gram-positive, spherical bacteria in the genus Streptococcus. Imlifidase is currently under review by EMA for kidney transplantation in highly sensitized patients. A CHMP Opinion is expected in the second quarter 2020. Imlifidase is also being evaluated in two Phase 2 programs within autoimmune diseases, namely anti-GBM antibody disease and Guillain Barré syndrome. Lastly, imlifidase is also being evaluated for active antibody mediated rejection after kidney transplantation. If approved, Imlifidase may have the potential to meet a large unmet need and transforming the lives of people with rare disease.
HPB-assay	HBP-assay is a method of analysis used to predict severe sepsis in emergency clinics. A first version has been launched, primarily intended for research purposes and interested specialists.	The product has been licensed to a cooperating partner, Axis-Shield Diagnostics, which is currently developing a fully commercial product. Hansa Biopharma AB receives milestone compensation and additional royalty revenue upon the sale of the sublicensed technology.

Acquired in-process development projects are assessed for possible impairment at least on an annual basis and the impairment assessment on December 31, 2019 and 2018 demonstrated that there was no need for impairment. The estimated recoverable amount supported by external and internal valuation reports by far exceed the assets carrying amount, resulting in no impairment charges for the year 2019 and 2018.

The HBP Patent cost is amortized over the finite useful life of the underlying patent in the amount of SEK 559 k for the 2019 reporting period (2018: 559 k).

Note 12 Property, plant and equipment

Group

	Equipment, tools and facilities	
KSEK	2019	2018
Cost		
Opening balance 1 January	9,181	6,816
Additions during the year	2,699	2,365
Closing balance 31 December	11,880	9,181
Accumulated depreciation and write-offs		
Opening balance 1 January	-3,892	-2,840
Depreciation during the year	-1,315	-1,052
Scrapping during the year	-551	–
Disposals during the year	-87	–
Closing balance 31 December	-5,845	-3,892
Carrying amounts		
At 1 January	5,289	3,976
At 31 December	6,035	5,289

Assets under financial leasing amounting to 587 was presented as part of property, plant and equipment at 31 December 2018.

Financial leasing

KSEK	2019	2018
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 note 27.

Parent Company

	Equipment, tools and facilities	
KSEK	2019	2018
Cost		
Opening balance 1 January	8,878	6,512
Additions during the year	2,699	2,366
Closing balance 31 December	11,577	8,878
Accumulated depreciation and write-offs		
Opening balance 1 January	-3,588	-2,536
Depreciation during the year	-1,315	-1,052
Scrapping during the year	-551	–
Disposals during the year	-87	–
Closing balance 31 December	-5,542	-3,588
Carrying amounts		
At 1 January	5,290	3,976
At 31 December	6,035	5,290

Note 13 Receivables from group companies

Parent Company (Non-current assets)

KSEK	2019	2018
Cost		
Opening balance on 1 January	–	–
Additional receivables	2,244	–
Outgoing receivable	–	–
Effects of movements in exchange rates	–	–
Closing balance 31 December	**2,244**	–

Parent Company (Current assets)

KSEK	2019	2018
Cost		
Opening balance on 1 January	2,834	469
Additional receivables	1,949	2,436
Outgoing receivable	-3,723	-71
Effects of movements in exchange rates	–	–
Closing balance 31 December	**1,061**	**2,834**

Note 14 Financial assets

Group

KSEK	2019	2018
Shares in Genovis AB	–	39,528
Balance 31 December	**–**	**39,528**

The investment in the First North listed company Genovis AB was sold during 2019 for SEK 89,125 k.

The investment was reported in the Group at fair value and in the Parent Company at cost less any impairment losses.

Note 15 Other long term holdings of securities

Parent Company

KSEK	2019	2018
Cost		
Opening balance 1 January	12,499	12,499
Sale of securities	-12,499	–
Closing balance 31 December	–	12,499
Amortization		
Opening balance 1 January	–	–
Impairment recovered during the year	–	–
Closing balance on 31 December	–	–
Carrying amounts		
At 31 December	–	12,499

Note 16 Other receivables

Group

KSEK	2019	2018
Other receivables (current)		
VAT receivables	2,058	3,058
Advanced payment to suppliers	6,414	–
Other receivables	2,676	3,988
Balance 31 December	**11,149**	**7,046**

Parent Company

KSEK	2019	2018
Other receivables (current)		
VAT receivables	2,054	3,058
Advanced payment to suppliers	6,414	–
Other receivables	2,670	3,980
Balance 31 December	**11,138**	**7,038**

Note 17 Accounts receivable

Accounts receivable amounting to SEK 522 k (2018: 58 k) are reported after consideration of bad debt losses during the year which amounted to SEK 0 (2018: SEK 0) for the group and Parent Company.

Note 18 Prepaid expenses and accrued income

Group

KSEK	2019	2018
Prepaid insurance	1,384	360
Prepaid marketing	579	114
Prepaid software	320	149
Other	696	306
Balance 31 December	**2,979**	**929**

Parent Company

KSEK	2019	2018
Prepaid insurance	1,384	360
Prepaid marketing	579	114
Prepaid software	320	149
Other	426	316
Balance 31 December	**2,709**	**939**

Note 19 Cash and cash equivalents

Group

KSEK	2019	2018
The following subcomponents are included in cash and cash equivalents:		
Cash and bank deposits	181,697	439,441
The total according to statement of financial position	181,697	439,441
Total according to cash flow analysis	**181,697**	**439,441**

Parent Company

KSEK	2019	2018
The following subcomponents are included in cash and cash equivalents:		
Cash and bank deposits	176,715	433,875
The total according to statement of financial position	176,715	433,875
Total according to cash flow analysis	**176,715**	**433,875**

Note 20 Shareholders' equity

Group

Share capital and number of shares

Number of shares	2019	2018
Issued as of 1 January	39,959,890	37,807,386
Effect of conversion of C to A shares in January 2019	13,142	–
Effect of new share issue in January	50,000	–
Effect of conversion of C to A shares in February 2019	3,075	–
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	**40,026,107**	**39,959,890**

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.

Treasury shares included in equity

	Number of shares		Reported value SEK '000	
	2019	2018	2019	2018
Opening balance of Treasury shares	721,764	401,000	722	401
Additions during the year	715,910	391,503	716	391
Disposals during the year	-16,217	-70,739	-16	-70
Closing balance of Treasury shares	**1,421,457**	**721,764**	**1,421**	**722**

Treasury shares have a quotient value of SEK 1.

The year's additions of C shares refers to the new issue and subsequent repurchase of C shares that have taken place in accordance with the respective LTIP program. The sale refers to the conversion that has taken place to ordinary shares within the framework of the respective LTIP program.

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

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

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

Translation reserve
The translation reserve comprises all foreign exchange differences arising on translation of financial statements from foreign business prepared in currency other than the reporting currency for the financial statements of the group. The Parent Company and the group present their financial statements in Swedish kronor.

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

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 June 23, 2020.

No dividend was paid for 2018.

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, LTIP 2018 and LTIP 2019. The social contributions are expected to be paid after the vesting period end for different participant groups, which fall between November 28, 2019 and May 18, 2020 for LTIP 2016, as well June 15, 2021 and November 30, 2021 for LTIP 2018, and June 17,2022 and October 24, 2022, respectively for LTIP 2019.

Group

KSEK	2019	2018
Opening balance 1 January	10,948	5,017
Provision related to LTIP 2016	-10,112	5,096
Provision related to LTIP 2018	-791	835
Provision related to LTIP 2019	688	–
Pension provision	85	–
Closing balance 31 December	**818**	**10,948**

Parent Company

KSEK	2019	2018
Opening balance 1 January	10,948	5,017
Provision related to LTIP 2016	-10,112	5,096
Provision related to LTIP 2018	-791	835
Provision related to LTIP 2019	688	–
Pension provision	85	–
Closing balance 31 December	**818**	**10,948**

Note 22 Contingent consideration

The company acquired Immago Ltd on 19 July 2016. The agreed upon purchase price was GBP 170k and additional GBP 70k milestone payment is to be paid if certain milestones were achieved. The estimated payment date is 19 July 2021, resulting in fair value of contingent liability at 31 December 2019 amounting to SEK 730k (2018: SEK 679k).

Note 23 Other liabilities

Group

KSEK	2019	2018
Other current liabilities		
Personnel-related liabilities	6,621	5,162
Accumulated development costs government grant	–	294
Current tax	319	–
Other liabilities	–	106
Balance 31 December	**6,940**	**5,562**

Parent Company

KSEK	2019	2018
Personnel-related liabilities	6,621	4,801
Accumulated development costs government grant	–	294
Balance 31 December	**6,621**	**5,095**

Note 24 Accrued costs and deferred income

Group

KSEK	2019	2018
Holiday pay	7,317	4,107
Social charges	2,020	1,263
Incentive accrual	9,683	3,806
Project costs	7,328	10,924
Royalties to researchers	284	201
Consulting fees	555	2,400
Costs attributable to new share issue	–	503
Other	5,208	3,008
Balance 31 December	**32,395**	**26,212**

Parent Company

KSEK	2019	2018
Holiday pay	7,317	4,107
Social charges	2,020	1,263
Incentive accrual	9,683	3,806
Directors' fee	–	–
Project costs	7,328	10,924
Royalties to researchers	284	201
Consulting fees	555	2,400
Costs attributable to new share issue	–	503
Other	2,915	3,038
Balance 31 December	**30,102**	**26,242**

Note 25 Financial risk management and financial instruments

Financial risk management

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

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

Risk management framework

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

A. Liquidity risk

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

In order to secure short-term liquidity, Hansa Biopharma's AB treasury policy prescribes that an appropriate level of liquidity in the form of cash and cash equivalents shall be held in an amount sufficient to cover the expected Company financial obligations over the next 12 months period. This principle shall be checked and assured every time a new investment decision is taken.
On the reporting date, this goal was fulfilled. Cash and cash equivalents on 31 December 2019 amounted to SEK 181,697 k (2018: SEK 439,441 k).

Cash and cash equivalents consisted on the reporting date of bank deposits. Short term investments in interest funds amounted to SEK 419,397 k (2018: 418,746 k).

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

2019

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

2018

KSEK	Nominal amount	0–3 months	3–12 months	1–5 years
Contingent consideration	679	–	–	679
Non-current leasing liabilities	476	–	–	476
Current leasing liabilities	101	26	75	–
Accounts payable	40,426	40,426	–	–
Total	**41,682**	**40,452**	**75**	**1,155**

B. Market Risk

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

Currency risk

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

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

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

As an exception to the above, the Company may hold Cash in foreign currency in the normal course of business to pay any accounts payable in foreign currencies. Subsidiaries will hold Cash in their local currency within their normal course of business.

Sensitivity analysis

Hansa Biopharma AB purchases research-related services in USD, GBP, DKK and EUR. A weakening of the Swedish krona in relation to these currencies therefore leads to increased costs for the group, all else remaining the same. In addition, the group receives licensing revenue which are paid in USD and GBP. A strengthening of the Swedish krona in relation to USD and GBP therefore leads to reduced revenue for the Company expressed in SEK, all else remaining the same.

A change in SEK in relation to EUR by an average of 10% would affect the group's earnings before tax by approximately SEK +/-8,742k (2018: SEK +/-6,836). Correspondingly, a 10% strengthening of SEK in relation to USD would affect earnings before tax by approximately SEK +/-6,201k (2018: SEK +/-2,434), a strengthening of SEK in relation to GBP by an average of 10% would affect the group's earnings before tax by approximately SEK +/-2,476k (2018: SEK +/-481) and a strengthening of SEK in relation to DKK by an average of 10% would affect the group's earnings before tax by approximately SEK +/-125k (2018: SEK +/-71). This analysis assumes that all other variables, in particular interest rates, remain constant and ignores any impact of forecast sales and purchases.

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

Interest rate risk

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

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). This would lead to impact on profit or loss of SEK +/-1,048k to SEK +/-2,096k, before tax (2018: SEK +/-1,047 k to SEK +/-2094k).

Share price risk

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

C. Credit risk

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Group's receivables from customers and investments in debt securities.

The group's credit risk is primarily related to bank deposits. However, this risk is considered to be low since the bank deposits are held in Swedish banks with good credit ratings. See further discussions in note 17. According to the group's treasury policy, Hansa Biopharma AB may only hold bank deposits with, or initiate payments through, Swedish and foreign banks under the supervision of the Swedish Financial Supervisory Authority or similar foreign agency.

Investment policy
The Company may invest a portion of its funds in bank deposits, bonds, investment funds and the like with maturity of more than 35 days, while managing the interest rate risk exposure, credit risk exposure as well as the cluster risk. As a general principle, the Company may only invest in investment grade issuers, measured at the day of the investment.

Therefore, the following applies:
› Minimum credit rating of one of the following rating agencies (or comparable):

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

› The maximum amount invested with one counterparty or issuer is limited to 30% of total funds at the time a new investment decision is taken. This limit might be increased to up to 50% upon prior approval of the Audit Committee.

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

At year-end, SEK 329 million of the Company's short-term investments were invested in an investment grade fixed income fund denominated in SEK that invests primarily in Swedish interest-bearing securities with a remaining duration of maximum 360 days. Other SEK 90 million were invested in a housing bond fund which invests in investment grade assets denominated in SEK.

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

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

The fair value of contingent consideration is calculated at the discounted value of expected future cash flows. The purchase price will increase by GBP 70 k if a clinical trial is registered and linked to the acquired patent rights. Contingent purchase price is expected to be paid in 2021.

The carrying amounts of financial assets and financial liabilities per valuation category
The table below shows the reported value for financial assets and financial liabilities broken down by valuation category in IFRS 9.

Group

	Financial assets valued at amortized cost		Financial assets valued at fair value through other comprehensive income		Financial assets valued at fair value through income statement	
KSEK	2019	2018	2019	2018	2019	2018
Financial assets at fair value						
Financial fixed assets						
Listed shares	–	–		39,528	–	–
Short term investments	–	–	–	–	419,397	418,746
Financial assets at amortized cost						
Accounts receivable	522	58	–	–	–	–
Other receivables	2,676	3,988	–	–	–	–
Cash and cash equivalents	181,697	439,441	–	–	–	–
Total financial assets	**184,895**	**443,487**	–	**39,528**	**419,397**	**418,746**

	Financial liabilities valued at amortized cost		Financial liabilities valued at fair value by the income statement	
KSEK	2019	2018	2019	2018
Financial liabilities at fair value				
Contingent consideration	–	–	730	679
Financial liabilities at amortized cost				
Accounts payable	50,573	40,426	–	–
Total financial liabilities	**50,573**	**40,426**	**730**	**679**

Levels of financial assets and financial liabilities per valuation hierarchy

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

KSEK	Valuation hierarchy	2019	2018
Financial asset			
Holdings of short term investments	Level 2	419,397	418,746
Holdings of listed shares	Level 1	–	39,528
Contingent consideration	Level 3	730	679

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

	Contingent purchase price	
KSEK	2019	2018
Opening balance	**679**	**601**
Currency differences	51	12
Interest expense	–	66
Closing balance 31 December	**730**	**679**

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

Management best estimate at 31 December 2019 is that the contingent consideration will be paid in 2021. Previous estimate made at 31 December 2018 was the contingent consideration would be paid in 2020.

Note 26 Leases

This note provides information for leases where the group is lessee.
The statement of financial position shows the following amounts related to leases:

Group

KSEK	2019	1 January, 2019
Leased assets		
Buildings	8,124	12,674
Equipment	345	102
Vehicles	640	578
	9,109	13,354
Lease liabilities		
Non-current	4,827	9,015
Current	4,632	4,340
	9,459	**13,354**

In 2018 non-current lease liabilities amounting to SEK 679k and current lease liabilities amounting to 101K was presented under non-current liabilities, interest bearing and current other interest-bearing liabilities, respectively.

Depreciation charge of Leased assets

KSEK	2019	2018
Buildings	-4,550	–
Equipment	-116	–
Vehicles	-118	–
	-4,784	**–**

Interest expense (including in finance cost) amounted to SEK 392k. Expenses related to low-value leases and short-term leases amounted to SEK 852 k. Total cash outflow of leases amounted to SEK 5,677k.

Parent Company
IFRS 16 has not been applied in the Parent Company in accordance with the relief rules in RFR 2.

Leasing agreements under which the Group is the lessee

Future payments for leasing agreements which cannot be terminated amounts to:

Group

KSEK	2019-12-31	2018-12-31
Within one year	6,036	6,382
Between one and five years	6,680	8,071
	12,716	**14,453**

Parent Company

KSEK	2019-12-31	2018-12-31
Within one year	6,024	6,372
Between one and five years	6,680	8,071
	12,704	**14,443**

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

Fees for operational leasing agreements booked as expenses amount to:

Group

KSEK	2019	2018
Minimum leasing fees	6,047	4,047
Total leasing costs	**6,047**	**4,047**

Parent Company

KSEK	2019	2018
Minimum leasing fees	6,024	4,035
Total leasing costs	**6,024**	**4,035**

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

Note 27 Collateral provided, contingent liabilities and contingent assets

Group

KSEK	2019-12-31	2018-12-31
Assets under finance lease that are subject to retention of title	–	587
Total collateral provided	**–**	**587**

Note 28 Related party transactions

Subsidiaries
Interest in subsidiaries are set out in note 29.
See further note 13 - Receivables from group companies.

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

Note 29 Group companies

Holdings in subsidiaries

		Share ownership percentage (%)	
Subsidiaries	Registered office / Country	2019	2018
Cartela R & D AB	Lund / Sweden	100	100
Immago Biosystems Ltd	Cheltenham / United Kingdom	100	100
Hansa Biopharma Inc	Delaware, USA	100	100

Parent Company

KSEK	2019	2018
Cost		
Opening balance on 1 January	5,095	4,818
Shareholder contribution Cartela R&D	–	268
Acquisition of Immago Biosystems Ltd	–	9
Closing balance 31 December	**5,095**	**5,095**

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

Subsidiaries / Company reg. no. / Registered office	Number of shares	Share (%)	2019	2018
Cartela R & D AB / 556746-0083 / Lund	1,000	100	2,630	2,630
Immago Biosystems Ltd / 08361712 / Cheltemham, United Kingdom	100,000	100	2,456	2,456
Hansa Biopharma Inc, 6846164, Delaware, USA	1,000	100	9	9
Closing balance 31 December			**5,095**	**5,095**

Note 30 Cash flow analysis

Adjustment for items not included in cash flow

Group

	1 January – 31 December	
KSEK	2019	2018
Depreciation/amortization/impairment/write-offs	7,463	1,837
Costs related to incentive program	7,246	11,675
Costs related to pension plan	85	–
Unrealized currency differences	-181	-68
Total adjustment for items not included in cash flow	**14,613**	**13,444**

Parent Company

	1 January – 31 December	
KSEK	2019	2018
Depreciation/writedown	2,508	1,599
Costs related to incentive program	7,302	11,619
Costs related to pension plan	85	–
Total adjustment for items not included in cash flow	**9,895**	**13,218**

Reconciliation of liabilities arising from the financing activities

Group – IFRS 16

KSEK	Balance at 31 December 2018 as previously reported	Effect of IFRS 16	Restated balance at 1st January 2019	New leasing agreements*	Payment of lease liabilities	Balance at 31 December 2019
Lease liabilities	578	12,776	13,354	528	-4,424	9,458

KSEK	Balance at 1 January 2018	New leasing agreements*	Payment of lease liabilities	Balance at 31 December 2018
Lease liabilities	–	622	-44	578

* Non cash flow changes of debt

Note 31 Royalty-bearing agreements

In the past, the Company has entered into several royalty agreements (the "Royalty Agreements") with researchers and institutions (the "Counterparties") related to IdeS or imlifidase pursuant to which the Counterparties assign certain IP, patent and other rights (the "Rights") to the Company. As a compensation for the assignment of the Rights to the Company, the Counterparties are granted rights to receive royalties on net income and / or other compensation related to other payments the Company may receive related to IdeS or imlifidase in accordance with the terms of the Royalty Agreements. As the Company has filed for an MAA in Europe beginning of 2019 and the MAA is currently under review with a potential CHMP decision in Q2-2020 and a potential adoption of such decision by the EMA in Q3-2020, above mentioned compensation obligations under the Royalty Agreements may become effective during 2020.

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

The COVID-19 virus (Corona): Measures and potential impact
Hansa Biopharma has implemented measures to protect employees and take social responsibility while at the same time attempting to limit any negative effects on Hansa's business. While at the current point in time it is not possible to estimate the extent to which Hansa's business might be affected, the following are key areas where Hansa expects a potential impact:

- The regulatory process (MAA) with EMA is on track with the previously communicated timeline; however, EMA has highlighted a potential risk of staff shortage in the coming period;
- The European launch of imlifidase in kidney transplantation following a potential conditional approval may be impacted by limited access to and lower decision making ability of market access authorities, potentially delaying pricing and reimbursement approval in early launch countries. In addition, pre-launch communication activities may be impacted negatively by reduced ability to engage with key opinion leaders and clinicians at targeted centers. It remains our aim, however, to launch imlifidase in the first clinics this year;
- We expect a delay in the recruitment of patients in the AMR and GBS studies by 3-6 months;
- We aim to commence the recruitment of the randomized controlled phase 3 study for imlifidase in highly sensitized patients in the US in the 4th quarter of 2020. A reprioritization and cancellation of activities by the FDA as well as operational challenges in initiating trial centers may however impact the timeline;
- Timing of securing financing from the second half of 2021 onwards.

Note 33 Key judgement, estimates and assumptions

Certain assumptions regarding the future and certain estimates and judgements appliedas of 31 December 2019 do have the most significant effect on the valuation of the assets and liabilities set forth in the statement of financial position. Set forth below is a discussion of the areas in which the risk of material changes in value, during the subsequent year, are significant:

Internally generated intangible assets
Expenditure on research activities is recognized in the income statement as incurred. Development expenditure is capitalized only if the expenditure can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Group intends to and has sufficient resources to complete development and to use or sell the asset. Otherwise, it is recognized in the income statement as incurred. Subsequent to initial recognition, development expenditure is measured at cost less accumulated amortization and any accumulated impairment losses.
This means in practice that expenditure is not capitalized before the pharmaceutical authorities have given approval due to the level of uncertainty associated with the approval process.

Impairment
At each reporting date, the Group reviews the carrying amounts of its assets to determine whether there is any indication of impairment or write-down. If any such indication exists, then the asset's recoverable amount is estimated and if it is estimated to be lower than the assets carrying amount, an appropriate impairment charge or write-down is recognized in profit or loss. The recoverable amount of an asset or a cash generating unit is the higher of its fair value less costs of disposal and its value in use. The value in use is the present value of the future cash flow expected to be derived from an asset or cash generating unit. The future cash flow is discounted at a rate that takes into consideration the markets assessment of risk-free rate and the risk associated with the specific asset.

IAS 36 is applied regarding impairment of assets other than financial assets which are reported according to IFRS 9.

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

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 2019 cover the Parent Company and its subsidiaries, jointly referred to as the group.

Note 35 Appropriation of loss carried forward

Unrestricted shareholders' equity in the Parent Company:

KSEK	
Share premium reserve	1,413,446,572
Treasury shares	-1,421,457
Profit carried forward	-607,145,624
Result for the year	-283,422,500
Total	**521,456,991**

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

KSEK	
Share premium reserve	1,413,446,572
Treasury shares	-1,421,457
Loss carried forward	-890,568,124
Total	**521,456,991**

Definitions

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

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

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

Signatures

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

Lund 2 April 2020

Ulf Wiinberg
Chairman of the Board

Birgit Stattin Norinder
Director

Mats Blom
Director

Andreas Eggert
Director

Eva Nilsagård
Director

Anders Gersel Pedersen
Director

Søren Tulstrup
CEO and Executive President

The Board of Directors and CEO approved the annual report for publication on 2 April 2020. The consolidated income statement, report on comprehensive income and statement of financial position as well as the Parent Company's income statement, report on comprehensive income and statement of financial position will be subject to adoption at the annual general meeting to be held on June 23, 2020.

Our auditors' report was submitted on 2 April 2020.

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, corp. id 556734-5359

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of Hansa Biopharma AB for the year 2019. The annual accounts and consolidated accounts of the company are included on pages 34-92 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 2019 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 2019 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.

Financing

See page 37 and note 25 about financial risks and accounting principles on pages 51-57 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 Biopharma receives contractually so-called milestone payments and additional royalties on future sales of products based on the licensed technology.

Cash and cash equivalents amounts to SEK 182 million at December 31, 2019. In addition, the group has per balance sheet day short-term investments of SEK 419 million.

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 financing of the group is a key audit matter.

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

Translation from the Swedish original

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-33. 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.
- 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.

Translation from the Swedish original

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Hansa Biopharma AB for the year 2019 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.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

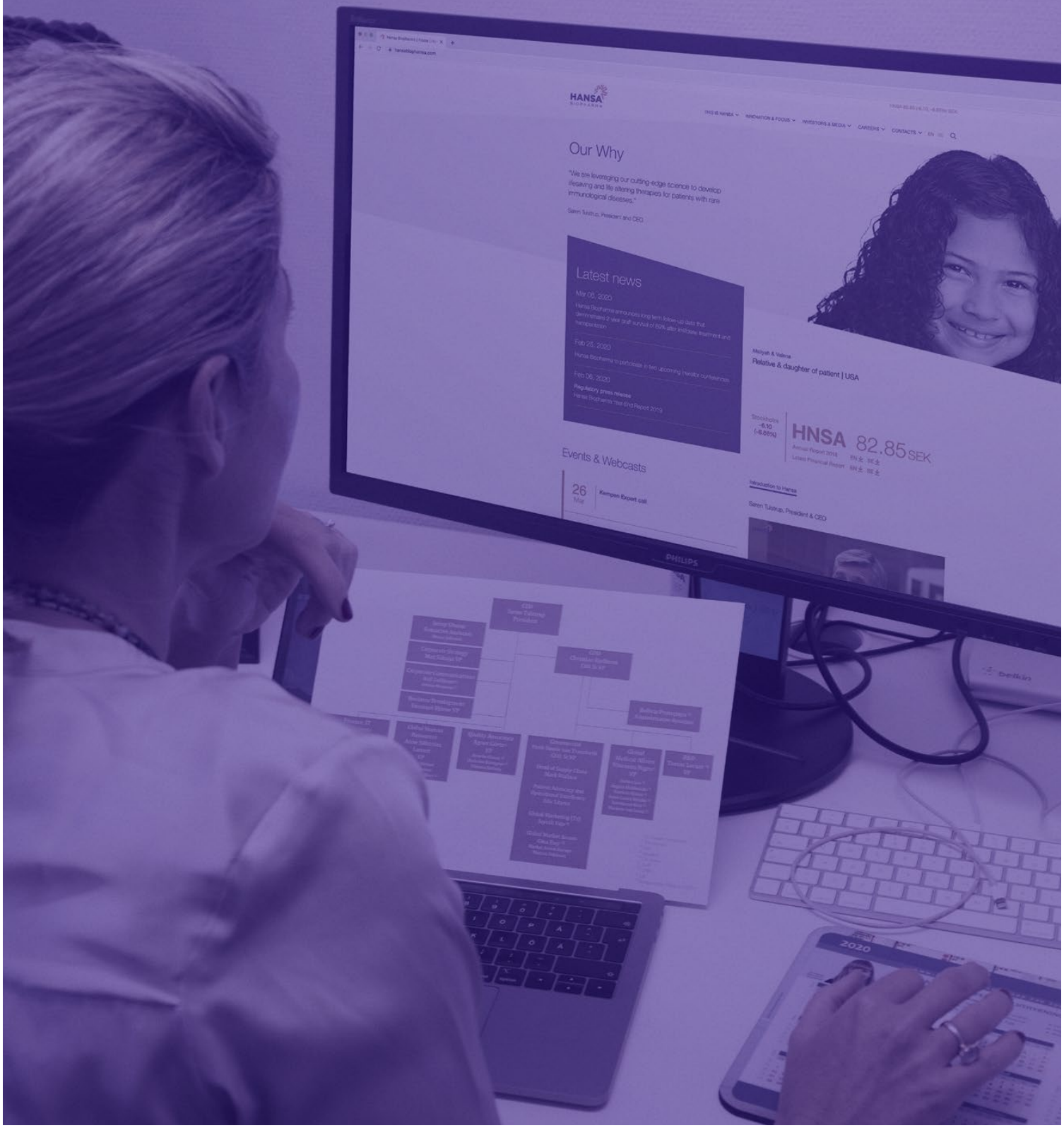
KPMG AB, Box 227, 201 22 , Malmö, was appointed auditor of Hansa Biopharma AB by the general meeting of the shareholders on the 22 of May 2019. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2014.

Malmö

KPMG AB

Jonas Nihlberg
Authorized Public Accountant

Corporate governance report



Introduction

The Board of Directors of Hansa Biopharma AB (publ) (the "Board"), Company reg. no. 556734-5359 ("Hansa Biopharma" or the "Company") hereby submits the 2019 corporate governance report in accordance with the requirements of the Swedish Annual Accounts Act (1995:1554) (Sw. årsredovisningslagen) and the Swedish Code of Corporate Governance (the "Code"; see the Swedish Corporate Governance Board website at www.corporategovernanceboard.se). The Company's shares were admitted for trading on Nasdaq Stockholm in November 2015. The Company's shares were previously, since 2007, listed on Nasdaq First North. The Company's corporate governance is mainly regulated by the provisions of the Company's articles of association, the Swedish Companies Act (2005:551) (Sw. aktiebolagslagen) and other Swedish legislation, the 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, Hansa Biopharma Ltd and Hansa Biopharma Inc. Hansa Biopharma Ltd is owner of patent rights to the EnzE concept.

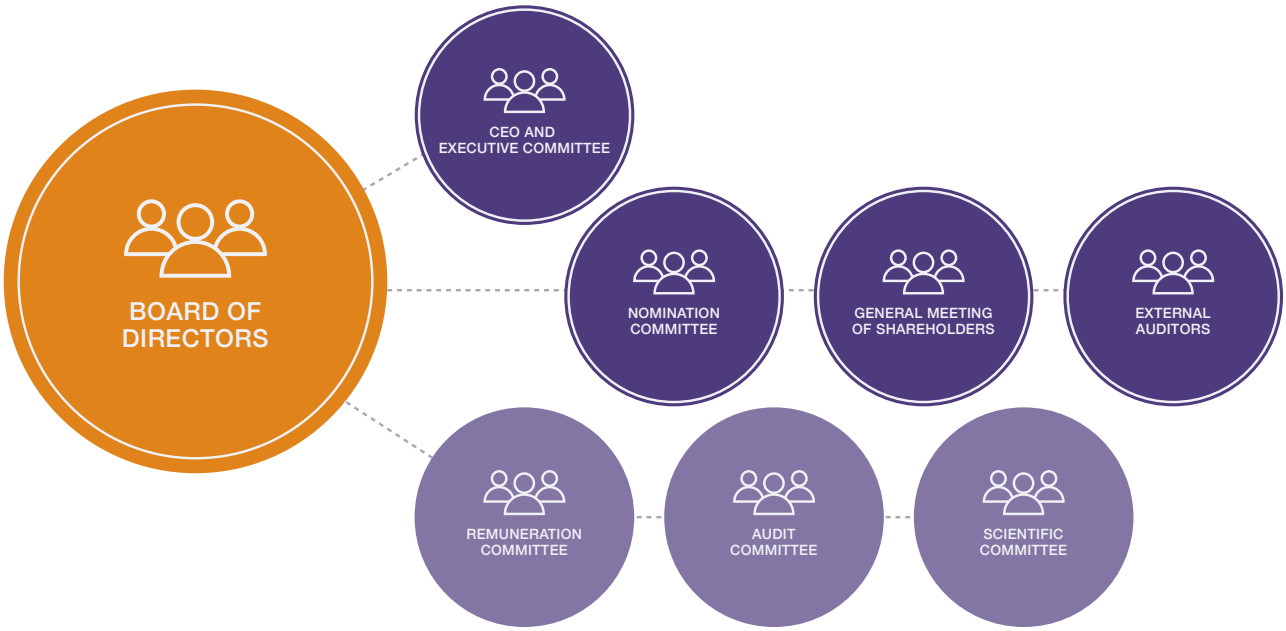
There are no deviations from the Code to report for the financial year 2019. No infringements of Nasdaq Stockholm's rules and no breach of good practice on the securities market was reported by the stock exchange's disciplinary committee or the Swedish Securities Council during the financial year 2019.

Shareholders

There are no limitations on the transferability of Hansa Biopharma's shares due to legal restrictions or provisions of the articles of association. To Hansa Biopharma's knowledge, no agreement has been entered between any shareholders which might limit the transferability of the shares. As of December 31, 2019 Nexttobe AB is the only shareholder owning more than 10 percent of the Company's shares, by its shareholdings of 14.4 percent.

Hansa Biopharma corporate governance model

The diagram set forth below illustrates Hansa Biopharma's corporate governance model and the central corporate bodies during 2019.



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

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 Biopharma AB shares

The shares in the Company are divided into ordinary shares and C-shares. On December 31, 2019, the total number of shares was 41,447,564 with 40,026,107 ordinary shares and 1,421,457 C-shares, with a quotient value of SEK 1. Each ordinary share carries one vote and each C-share carries one tenth. All C-shares are owned by the Company. Each person entitled to vote may vote for his or her full number of shares. Each 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 ("AGM") must be held within six months from the close of the financial year. At the AGM, the shareholders adopt resolutions regarding, among other things: the Board and auditors; the procedure for appointing the nomination committee; and discharge from liability for the Board and the CEO in respect of the preceding year. Resolutions are also adopted regarding: adoption of the annual report; disposition of profits or treatment of losses; fees for the directors and auditors; and guidelines for remuneration to senior executives.

2019 Annual General Meeting

At the 2019 AGM, which was held on May 22, 92 shareholders representing 36.6 percent of the total number of votes and 36 percent of the total number of shares in the Company were represented. The AGM adopted the 2018 annual accounts, adopted a resolution regarding that the members of the Board shall be six with no deputy members, and granted the directors and CEO a discharge from liability. The general meeting resolved that no dividend would be paid. The AGM resolved that Ulf Wiinberg, Birgit Stattin Norinder, Anders Gersel Pedersen and Andreas Eggert are re-elected as members of the Board and that Eva Nilsagård and Mats Blom would be elected as new members of the Board, for the period until the end of the next AGM. The AGM further resolved to re-elect Ulf Wiinberg as chairman of the Board for the period until the end of the next AGM. The AGM resolved to re-elect KPMG AB as auditor, with Jonas Nihlberg as the auditor in charge, for the period until the end of the next AGM.

The AGM resolved that the fees for the Board, for the period until the end of the next AGM, shall be SEK 900,000 to the chairman of the Board and SEK 300,000 each to the other Board members. It was further resolved that the remuneration to the chairman of the Audit Committee should be SEK 75,000 and SEK 40,000 to each other member in the Audit Committee, SEK 40,000 to the chairman of the Remuneration Committee and SEK 25,000 to each other member in the Remuneration Committee, and SEK 25,000 to each board member in the Scientific Committee. It was further resolved that the remuneration to the auditor shall be paid as per approved current account.

The AGM further resolved, in accordance with the Boards' proposal, to authorize the Board, for the period up to the next AGM, to adopt decisions, whether on one or several occasions and whether with or without pre-emptive rights for the shareholders, to issue new ordinary shares; provided however that such issues, in aggregate, must not exceed ten percent of the total number of outstanding ordinary shares in the company as of the date of the AGM. It should also be possible to make such an issue resolution stipulating in-kind payment, the right to offset debt or other conditions. The purpose of the authorization is to increase the financial flexibility of the company and the acting scope of the Board as well as to potentially broaden the shareholder base.

Minutes from the AGM are available at Hansa Biopharma's website (www.hansabiopharma.com). The 2020 AGM will take place on June 23, 2020.

Remuneration to Executive Management

The remuneration guidelines for Executive Management adopted by the 2019 AGM entail that Executive Management is offered remuneration which is competitive and on market terms. The level of the remuneration for the individual manager shall be based on factors such as position, expertise, experience and performance. The remuneration consists of a fixed salary and pension benefits and, in addition, may consist of variable salary, share based long term incentive programmes, severance remuneration, non-monetary benefits. The variable salary shall be based on the achievement of quantitative and qualitative targets and should not exceed 50 per cent 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 base salaries.

Share and share based long term incentive programmes shall, if applicable, be decided by the Annual General Meeting. For information regarding the adopted long term incentive programs, please refer to the Directors Report on page 34–41 and Note 1 and Note 5 to the Consolidated Financial Statements on page 51–57 and 59–66 respectively.

Where special cause exists in an individual case the Board of Directors is authorised to deviate from the guidelines.

Nomination committee

Prior to the 2020 AGM, Hansa Biopharma's nomination committee comprises Erika Kjellberg Eriksson (representing Nexttobe AB), Anna Sundberg (representing Handelsbanken funds), Sven Sandberg (representing Thomas Olausson and Gladiator) and Ulf Wiinberg (chairman of the Board). Erika Kjellberg Eriksson has been elected as chairman of the nomination committee. Ulf Wiinberg is the convener of the committee.

The nomination committee prepares a proposal regarding the number of directors and persons to be elected as directors, including the chairman, and a proposal for remuneration to the chairman and the other Board members, as well as a proposal for remuneration for the Board members' committee work. The nomination committee also proposes election of auditors including remuneration to the auditor. Finally, the nomination committee proposes principles for the nomination committee prior to the AGM 2021. The proposals will be published in connection with the notice to the 2020 AGM.

External auditors

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

Pursuant to the articles of association, Hansa Biopharma must have a registered accounting firm as its external auditor. The accounting firm KPMG AB has been the auditor of the Company since the 2015 AGM. As from the 2018 AGM certified public accountant Jonas Nihlberg is auditor in charge. From the 2016 AGM up to and including the 2018 AGM, certified public accountant Dan Kjellqvist was auditor in charge. Dan Kjellqvist personally was the Company's auditor commencing at the time of the 2014 AGM up to and including the 2015 AGM. Jonas Nihlberg and Dan Kjellqvist are members of the Swedish Institute of Authorized Public Accountants. For information regarding fees paid to the auditors, please refer to note 6 in the 2019 annual report.

The Board

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

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

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

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

Pursuant to the articles of association, the Board must comprise not less than three and not more than ten directors elected by the general meeting. The Board is quorate when more than half of the directors are present. The articles of association do not contain any provisions regarding appointment or dismissal of directors or regarding amendment of the articles of association.
Directors' fees were set at the 2019 AGM for a period up to and including the next AGM. The fees for the Board's work in 2019 were set as follows. The chairman is paid SEK 900,000, and each other director is paid SEK 300,000. Further on SEK 75,000 is paid to the chairman and SEK 40,000 is paid to each other board member in the audit committee, SEK 40,000 is paid to the chairman and SEK 25,000 is paid to each other board member in the remuneration committee and SEK 25,000 is paid to each board member in the scientific committee. No remuneration other than the above-mentioned fees have been paid to the Board except for travel costs. 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 2019 annual report for additional information regarding employment terms and conditions for the Board and senior executives.

Directors

The Board currently comprises six individuals, including the chairman. Each director's term continues until the end of the next AGM.

The following is a list of the directors, containing information regarding their years of birth and election to the Board, education, work experience, engagement in the Company and other significant engagements and holdings in the Company as of 31 December 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 of the European pharma business. He also held the position of CEO of H Lundbeck A/S, a pharmaceutical company specialized in psychiatric and neurological disorders, for several years. Ulf is 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 as well as CEO and chairman of the board of Ulf Wiinberg Consulting & Invest AB. He was born in 1958.

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

Shareholding: 114,900 shares

Birgit Stattin Norinder

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

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

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

Shareholding: 42,205 shares

Anders Gersel Pedersen

Member of the Board since 2018.

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

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

Shareholding: 2,500 shares

Andreas Eggert

Member of the Board since 2018.

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

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

Shareholding: 5,500 shares

Eva Nilsagård

Member of the Board since 2019.

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

Eva is Chairman of Hansa Biopharma's Audit Committee. Independent of Hansa Biopharma and its senior management. Independent of major shareholders of Hansa Biopharma. She was born in 1964.

Shareholding: 3,000 shares

Mats Blom

Member of the Board since 2019.

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

Mats is member of Hansa Biopharma's Audit Committee. Independent of Hansa Biopharma and its senior management. Independent of major shareholders of Hansa Biopharma. He was born in 1965.

Shareholding: 1,000 shares

The Board of Directors' work in 2019

During 2019, the Board has held eleven meetings, of which four were held per telephone and one was the inauguration meeting. The Board has also made resolutions per capsulam at one occasion. In 2019, the Board primarily worked with the approval of imlifidase in the EU and USA, including the development of the organization from both a medicinal and commercial standpoint.

At the Board meetings held during the 2019 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	Present at meetings of the scientific committee	Independent in relation to the company and corporate management	Independent in relation to the company's largest shareholders
Ulf Wiinberg	2016	11(11)	4(4)	3(6)	2(2)	Yes	Yes
Birgit Stattin Norinder	2012	11(11)	4(4)	3(6)	2(2)	Yes	Yes
Anders Gersel Pedersen	2018	7(11)	3(4)	–	1(2)	Yes	Yes
Andreas Eggert	2018	11(11)	–	6(6)	2(2)	Yes	Yes
Eva Nilsagård [1]	2019	7(11)	–	3(6)	–	Yes	Yes
Mats Blom [2]	2019	7(11)	–	3(6)	–	Yes	Yes
Stina Gestrelius [3]	2007-2019	3(11)	–	–	–	Yes	Yes
Angelica Loskog [4]	2016-2019	3(11)	–	–	–	Yes	No

[1] Eva Nilsagård was elected as new member of the Board at the 2019 AGM.

[2] Mats Blom was elected as new member of the Board at the 2019 AGM.

[3] Stina Gestrelius declined re-election as a member of the Board in connection with the 2019 AGM.

[4] Angelica Loskog declined re-election as a member of the Board in connection with the 2019 AGM.

Evaluation of the Board of Directors' work

Pursuant to the Code, the Board is to evaluate its work annually, using a systematic and structured process, with the aim of developing the Board's working methods and efficiency. The evaluation has been carried out by the chairman of the Board by, in the end of 2019, interviewing the directors with questions about the work of the Board. The result of the responses has been verbally declared to the directors and the members of the nomination committee.

Board committees

Remuneration committee

After the 2019 AGM, the remuneration committee has consisted of Birgit Stattin Norinder, chairman, Ulf Wiinberg and Anders Gersel Pedersen. The remuneration committee is charged with performing the duties set forth in the Swedish Corporate Governance Code. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board.

The primary duties of the remuneration committee are to:

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

Audit committee

After the 2019 AGM, the Audit Committee consisted of Eva Nilsagård, chairman, Mats Blom and Andreas Eggert. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board. The Audit Committee shall perform the duties incumbent upon audit committees as required by law and the Swedish Code of Corporate Governance.

The primary duties of the audit committee are to:

- monitor the Company's financial reporting;
- with respect to the financial reporting, monitor the effectiveness of the Company's internal controls, internal audit and risk management;
- inform itself of the audit of the annual reports and group accounts;
- review and monitor the auditor's impartiality and independence, and, in this context, particularly monitor whether the auditor is providing the Company with services other than auditing services;
- take decisions regarding guidelines for services other than the auditing services which the external auditor can provide.

Scientific committee

After the 2019 AGM, the Scientific Committee consists of Anders Gersel Pedersen, chairman, Birgit Stattin Norinder and Andreas Eggert. The committee is obligated to keep minutes of its meetings and make the minutes available the Board.

The primary duties of the scientific committee are to:

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

Executive management

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

- Senior Vice President, Chief Financial Officer
- Senior Vice President, Chief Commercial Officer
- Senior Vice President, Chief Scientific Officer
- Vice President, Global HR
- Vice President, Corporate Strategy

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 AGM:s and extraordinary general meetings. The CEO may not have any engagements outside of the Company without the Board's approval.

The CEO is also responsible for implementing the strategy approved by the Board and to propose such other strategies and operational measures to the Board which he deems appropriate. The CEO is responsible for the Company's internal organization, but must obtain the Board's approval prior to major organizational changes. The CEO is responsible for issuing and maintaining instructions for delegation to senior executives of the Company. He is also responsible for entering into or terminating employment agreements and for other employment terms and conditions; however the chairman'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 six individuals: the President and the CEO Søren Tulstrup; Senior Vice President, Research and Development, Chief Scientific Officer and Chief Operating Officer Christian Kjellman; Senior Vice President, Chief Financial Officer Donato Spota; Senior Vice President, Chief Commercial Officer Henk Doude van Troostwijk; Vice President, Corporate Strategy Max Sakajja 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 31 December 2019 are listed below. Holdings in the Company includes both one's own holdings and/or those of closely-related persons.

The number of share rights refers to the possible entitlement of share rights through the incentive program LTIP 2016, LTIP 2018 & 2019 is the potential maximum number. Share right allocation could be lower or zero depending on the share price development.

Søren Tulstrup

CEO

Søren Tulstrup has broad and extensive experience as senior executive in the global biopharma industry. Recently, he served as CEO of Vifor Pharma AG (VTX:VIFN), a Glattbrugg, Switzerland-based global pharmaceutical company. Søren Tulstrup has also served as CEO of Santaris Pharma A/S, now part of Roche, a leading clinical stage biopharmaceutical company developing RNA-targeted drugs for various therapeutic areas including rare genetic diseases. Furthermore, Søren Tulstrup has served in several senior general management and commercial roles within Shire Pharmaceuticals (now Takeda), Merck & Co., Inc. and Sandoz Pharma AG (now Novartis) in both Europe and the United States and he holds a Master of Science, Economics and Business Administration from Copenhagen Business School. He was born in 1965.

Shareholding: 10,000
Share rights: 86,540
ESOPs: 66,347

Christian Kjellman

Senior Vice President, Research and Development, Chief Scientific Officer and Chief Operating Officer

Christian Kjellman is an experienced researcher and senior executive that joined Hansa Biopharma in 2008. This year Christian expanded his duties within Hansa Biopharma, serving as Chief Operating Officer as well as continuing to serve as Chief Scientific Officer. Christian has previously served as Senior Scientist at BioInvent AB focusing on novel target evaluation and antibody technology. Prior to that, he functioned as Head of Research at the biopharmaceutical development company Cartela AB, mainly focusing on novel drug target evaluation. He has extensive research experience in cell- and molecular biology and as an Assistant Professor in Molecular Genetics at Lund University. Christian Kjellman holds a M.Sc. in Chemical Biology and a Ph.D. in Tumour Immunology from Lund University. He was born in 1967.

Shareholding: –
Share rights: 69,801
ESOPs: –

Donato Spota

Senior Vice President, Chief Financial Officer

Donato Spota joined Hansa Biopharma in 2019, and brings more than 20 years of pharmaceutical industry experience in international environments, including strategic finance, business development, investor relations and international capital markets transactions to the company. Prior to joining Hansa, Donato Spota served as Chief Financial Officer at Basilea Pharmaceutica AG. He holds a degree in Information Technology from the Swiss BBT (Bundesamt für Berufsbildung und Technologie) and a master's degree in business administration from the Hochschule für Wirtschaft und Umwelt Nürtingen-Geislingen. He was born 1971.

Shareholding: –
Share rights: 23,434
ESOP's: 42,642

Henk Doude van Troostwijk

Vice President, Chief Commercial Officer

Henk Doude van Troostwijk has extensive management experience in sales and marketing in the areas of transplantation and orphan drugs. Before joining Hansa Biopharma in 2016, Henk Doude van Troostwijk served as General Manager of European Commercial Operations and Emerging Markets at Raptor Pharmaceuticals, an orphan disease focused global biopharma company based in the US. Prior to that, he held the position of Business Unit Director Oncology and Transplantation at Genzyme Europe BV. Henk Doude van Troostwijk holds an MBA from Henley Management College at the University of Reading, UK. He was born in 1965.

Shareholding: –
Share rights: 33,817
ESOPs: 21,231

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. She was born in 1969.

Shareholding: 610
Share rights: 29,618
ESOPs: 2,000

Max Sakajja

Vice President, Corporate Strategy

Max joined Hansa Biopharma in 2017. He has a broad background in corporate development, strategy and finance. He has previously worked with corporate finance at Swedish Orphan Biovitrum (SOBI) as Director Mergers & Acquisitions and was actively involved in all major transactions such as the acquisition and merger of Swedish Orphan International. Before joining Hansa, Max worked as 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 launched a number of industry-first global commercial offerings. 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. He was born in 1981.

Shareholding: 7,000
Share rights: 30,746
ESOPs: 5,000

The possible entitlement of share rights through the incentive program LTIP2016, LTIP2018 & 2019 is the potential maximum number. Share right allocation could be lower or zero depending on the share price development.

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 market in Sweden. The important prerequisites for achieving this are: (i) the existence of a satisfactory control environment; (ii) the execution of reliable risk assessments; (iii) the existence of established control structures and control activities; and (iv) satisfactory information, communications and follow-up.

Internal audit

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

Control environment

Internal control is based on Hansa Biopharma's control environment, which comprises the values and ethics from which the board, the audit committee, the CEO, the 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 statement of financial position entailing a great risk of significant error are identified. For Hansa Biopharma, accrued project costs in the Company's clinical projects have, at various times, involved significant amounts. The size of these is based, to great extent, on 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, 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 statement of financial position 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 market. The policy applies to all employees and directors of Hansa Biopharma and applies to both oral and written information.

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

Follow-up

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

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

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

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 who is responsible for the corporate governance statement for the year 2019 on pages 93–105 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 2 April 2020
KPMG AB

Jonas Nihlberg
Authorized public accountant
Lead auditor

www.hansabiopharma.com