Year-End Report **2018**

HANSA BIOPHARMA

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

October–December 2018 in brief

- To better reflect its evolution and long-term aspirations, Hansa Medical AB changed its name to Hansa Biopharma AB. The new name represents the next stage in the Company's lifecycle and emphasizes Hansa's focus on the development and commercialization of biopharmaceuticals. This refinement of Hansa's profile is particularly salient as the Company continues the international expansion of its business and investor base.
- In November, Hansa raised SEK 453 /$50 million in a directed share issue of 1.8 million ordinary shares. The share issue was significantly oversubscribed due to high demand from U.S., UK, Swiss and Swedish institutional investors including Consonance Capital, Redmile Group, Polar Capital and HBM Partners. This funding will enable the Company to accelerate commercial preparations for launch of imlifidase in kidney transplantation and to continue advancing the development of its other pipeline projects.
- The U.S. Food and Drug Administration (FDA) granted imlifidase Fast Track Designation for the investigation of imlifidase for kidney transplantation. The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs which demonstrate the potential to address an unmet medical need, in treating serious or life-threatening conditions.
- The Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) issued a positive opinion on Orphan Drug Designation for imlifidase for the treatment of anti-glomerular basement membrane (anti-GBM) antibody disease. Subsequently, the European Commission officially designated imlifidase as an orphan drug in this indication.

Significant events after the end of the reporting period

- The Company provided an update on its interactions with regulatory agencies regarding imlifidase in kidney transplantation. Hansa expects to file a Marketing Authorisation Application with the EMA in the first quarter of 2019. The Company's dialogue with the FDA to determine the path forward for regulatory filing and approval in the U.S. is ongoing and Hansa will provide updated guidance regarding the timeline for a potential Biologic License Application (BLA) following a subsequent meeting with the agency in the coming months.
- Anne Säfström Lanner joined Hansa as Vice President, Global Human Resources. Mrs. Lanner has over 15 years of broad human resources experience in international growth companies, including developing and implementing strategies for talent acquisition and management, organizational culture and employer branding, compensation and benefits, and employee training and development.
- Donato Spota appointed new Chief Financial Officer. Mr. Spota is a senior executive with more than 20 years of international pharmaceutical industry experience, including strategic finance, investor relations and international capital markets transactions. Prior to joining Hansa, Mr. Spota was with Basilea Pharmaceutica AG, a Swiss listed biopharmaceutical company, for 16 years where he served as CFO for the past five years.

January–September 2018 in brief

- Hansa successfully completed two Phase 2 clinical studies evaluating imlifidase for kidney transplantation in highly sensitized patients. Imlifidase met all primary and secondary endpoints in each study. Treatment with imlifidase enabled transplantation in all 35 highly sensitized patients and at study completion, six months post-transplantation, graft survival was 91%.
- Hansa initiated a long-term observational prospective follow-up study evaluating graft survival in patients who have undergone kidney transplantation after treatment with imlifidase. The objective of the study is to collect long-term outcome data to provide further support to future prescribers, payers and patients.
- The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to imlifidase for the treatment of the rare and acute kidney disease anti-GBM antibody disease, also known as Goodpasture's disease.
- Vincenza Nigro was appointed as Vice President, Global Medical Affairs. Ms. Nigro has more than two decades of international life sciences industry experience in medical affairs, clinical development and commercial leadership roles, including significant expertise in transplantation and orphan diseases.
- The board of directors strengthened its expertise in biopharma commercialization and R&D through the appointments of Anders Gersel Pedersen and Andreas Eggert.
  - Anders Gersel Pedersen, MD, Ph.D, previously served as Executive Vice President, Research & Development at H. Lundbeck A/S and is a member of the boards of Genmab A/S and Bavarian Nordic A/S.
  - Andreas Eggert, MBA has more than 20 years of cross-functional leadership experience in biopharma commercialization, including Senior Group Vice President, Global Product Strategy & Portfolio Development at H. Lundbeck A/S and Vice President & Global Business Manager at Wyeth/Pfizer in the U.S.
- Hansa formed a U.S. subsidiary. for the continued build-up of a U.S. organization and presence.
- Søren Tulstrup was appointed President and CEO of Hansa, effective March 20, 2018. He has over 25 years of broad senior leadership experience in the life sciences industry, including as a CEO of a high-growth, global biopharma company.
- The FDA granted Orphan Drug Designation to imlifidase for the treatment of Guillain-Barré syndrome (GBS).
- Clinical results from Hansa's first Phase 2 study of imlifidase were published in the American Journal of Transplantation (AJT), the monthly peer reviewed medical journal published by the American Society of Transplant Surgeons and the American Society of Transplantation. The publication describes the results from Hansa's initial clinical study in sensitized patients, which evaluated the first transplantation enabled by treatment with imlifidase. To date, stable kidney function has been maintained in this very first patient for more than four years.

Financial summary for the Group (KSEK)

	October–December		Year	
KSEK, unless otherwise stated	2018	2017	2018	2017
Net revenue	1,386	1,013	3,358	3,442
Operating profit/loss	-80,605	-48,921	-246,498	-176,083
Net profit/loss	-81,229	-48,988	-247,974	-176,660
Earnings per share before and after dilution (SEK)	-2.07	-1.35	-6.47	-4.96
Shareholders' equity	859,876	630,661	859,876	630,661
Cash flow from operating activities	-57,466	-29,142	-204,560	-150,105
Cash and cash equivalents including short term investments	858,187	616,061	858,187	616,061

CEO statement

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

Imlifidase in kidney transplantation

Imlifidase is a novel enzyme that specifically and rapidly degrades immunoglobulin G (IgG) antibodies, thereby eliminating immunological barriers and enabling treatment of immune-mediated diseases. Our lead clinical program is developing imlifidase as a treatment to enable kidney transplantation in highly sensitized patients. These patients carry high levels of anti-HLA antibodies, which can target and significantly compromise a transplanted organ. The more anti-HLA antibodies, the lower the likelihood of finding a donor organ that will be a match. The unmet medical need in sensitized patients is high with many patients indefinitely remaining 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.

We further advanced the clinical development of our lead program in 2018, most notably in the third quarter, when we announced six-month follow up data from two Phase 2 clinical studies of imlifidase for kidney transplantation in highly sensitized patients. These results demonstrated that treatment with imlifidase enabled transplantation in all 35 highly sensitized patients and at study completion, six months post-transplantation, graft survival was 91%. Imlifidase has the potential to create equality on the organ donor waiting list by improving access to organs for highly sensitized patients. The outcomes of the Phase 2 studies are described in greater detail on pages 7–8 in this report.

In 2018, imlifidase also continued to receive further validation from the scientific community. In May, clinical results from our first Phase 2 study of imlifidase were published in the American Journal of Transplantation, the peer-reviewed medical journal of the American Society of Transplant Surgeons and the American Society of Transplantation. In June, at the prestigious American Transplant Congress, Stanley Jordan, M.D., Director of Kidney Transplantation and Transplant Immunology at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center, Los Angeles, USA, presented additional data and conclusions from his investigator-initiated Phase 2 study of imlifidase. In October at the American Society of Nephrology's Kidney Week, Dr. Jordan highlighted graft survival and stable renal function at up to 24 months following transplantation enabled by imlifidase.

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

We are actively engaged with the European and U.S. regulatory agencies regarding the path to approval for imlifidase in kidney transplantation. We expect to file a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA) in the first quarter of 2019. In addition to the six-month follow-up data announced in September, the filing will include positive data collected across all four Phase 2 clinical studies demonstrating the efficacy and safety of imlifidase to enable kidney transplantations; the validation of the manufacturing process for imlifidase; and evidence of the significant medical need for these highly sensitized patients who today have very limited opportunity for transplantation. Our dialogue with the FDA to determine the path forward for regulatory filing and approval in the U.S. is ongoing and we will provide updated guidance regarding the timeline for a potential Biologic License Application following a subsequent meeting with the agency in the coming months. We are determined to bring imlifidase to market in kidney transplantation as soon as possible.

Imlifidase in additional indications

Imlifidase also has potential applications in other solid organ transplantation and an array of acute autoimmune indications.

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

In early July, the FDA granted Orphan Drug Designation to imlifidase for the treatment of anti-GBM disease. In November, following the EMA's Committee for Orphan Medicinal Products (COMP) positive opinion, the European Commission also officially designated imlifidase as an orphan drug for the treatment of anti-GBM. These designations both confirm the high unmet medical need of patients with this devastating disease, and recognize the potential for imlifidase to help prevent acute kidney damage and the progression to kidney failure and dialysis.

We have currently enrolled seven of the targeted 15 patients with this ultra-rare disease in the Phase 2 study, which aims to evaluate the safety and tolerability of imlifidase, and assess efficacy based on renal function at six months after treatment. Thus far, all seven patients have responded favorably and imlifidase seems to be well tolerated. We anticipate completing enrollment in this study during 2019.

The next two indications in which we will evaluate imlifidase are Guillain-Barré syndrome (GBS) and Acute Kidney Antibody Mediated Rejection (AMR) post transplantation. Guillain-Barré syndrome (GBS) is a rare, acute neurological disease in which the peripheral nervous system is attacked by the immune system and IgG-antibodies. Last year, the FDA granted Orphan Drug Designation for imlifidase for the treatment of GBS. During the first quarter of 2019, we expect to begin enrollment in a Phase 2 study in GBS and a separate Phase 2 study in AMR, each of which is designed to enroll approximately 30 patients. To support imlifidase's clinical development across these indications, we have continued to expand Hansa's research and development team.

Next generation of immunomodulatory enzymes

We believe that our unique and proprietary capabilities in immunomodulatory enzymes extend beyond imlifidase to other novel IgG-cleaving enzymes. In our next generation program, NiceR, we are developing candidates with lower immunogenicity that potentially will enable repeat dosing. This program has the potential to apply to a broad array of indications, including relapsing autoimmune diseases and oncology. In 2018, we made significant advancements in our research and development work and we expect to select a candidate for clinical development in 2019.

Looking ahead

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

As part of the expansion of our commercial organization, in September, we were fortunate to appoint Vincenza Nigro as Vice President, Global Medical Affairs. Vincenza brings more than two decades of international life sciences industry expertise in medical affairs, clinical development and commercial leadership roles, including deep experience in transplantation and orphan diseases. With her extensive background building and leading high-performance medical affairs teams, and in lifecycle management for innovative transplant-related and immunology products, she is a valuable asset to our team as we transform Hansa into a global, commercial-stage biopharma company.

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

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

Søren Tulstrup
President and CEO of Hansa Biopharma
Lund, Sweden, February 8, 2019


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Hansa Biopharma in brief

Hansa Biopharma AB is harnessing its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulinG (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product imlifidase is a unique antibody-degrading enzyme in late-stage clinical development to enable kidney transplantation in highly sensitized patients, with additional clinical studies in acute autoimmune indications. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and its shares are listed on NASDAQ Stockholm (HNSA).

Business overview

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

NiceR is a program developing novel IgG-inactivating drug candidates for repeat dosing, which may enable broader usage in relapsing autoimmune diseases and oncology.

EnzE is a preclinical research and development program under which the combination use of approved antibody-based cancer treatments with IgG-modulating enzymes is explored in order to potentiate presently available antibody-based cancer therapies.

Pipeline

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

In planning Ongoing Completed

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

Imlifidase

Imlifidase – A novel therapeutic approach

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

Overview of imlifidase clinical program

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

Imlifidase has been evaluated in a Phase 1 study[1] in healthy subjects and in four Phase 2 studies in sensitized patients awaiting kidney transplantation[2, 3]. The results from these studies demonstrate that imlifidase is highly effective in reducing donor-specific antibodies (DSAs) to levels that enable transplantation, and that imlifidase is well-tolerated. Based on the successful outcome from these five clinical studies, Hansa is seeking a path towards regulatory approval in Europe and the U.S. The Company expects to file a Marketing Authorisation Application (MAA) with the EMA in the first quarter of 2019. Hansa's dialogue with the FDA is ongoing and the Company will provide updated guidance regarding the timeline for filing of a potential BLA filing following a meeting with the agency in the coming months.

An investigator-initiated Phase 2 study evaluating imlifidase in anti-GBM antibody disease, an ultra-rare and acute autoimmune kidney disease, is ongoing at several European nephrology clinics with Professor Mårten Segelmark at Lund University and Skåne University Hospital as principal investigator. Imlifidase will be evaluated in Phase 2 studies for two additional indications: acute kidney transplant antibody mediated rejection (AMR); and Guillain-Barré syndrome (GBS), which is a rare, acute neurological disease. Patient enrollment in these studies is expected to begin during the first quarter of 2019.

Imlifidase – enabling kidney transplantation for highly sensitized patients

Highly sensitized patients have high levels of anti-HLA antibodies, which are likely to target and significantly compromise a transplanted organ. The more antibodies, the lower the likelihood of finding a donor organ that will be a match. Many highly sensitized patients will indefinitely remain in a debilitating disease state on long-term dialysis treatment, which is associated with high cost, a poor quality of life and an increased mortality rate.

Latest developments

In September, Hansa announced the successful completion of the third and fourth Phase 2 studies evaluating imlifidase in kidney transplantation for highly sensitized patients. The Hansa sponsored, multi-center Highdes study enrolled 18 patients at five sites in the U.S., France and Sweden; the U.S. investigator-initiated study enrolled 17 patients at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center, Los Angeles.

Across both studies, treatment with imlifidase successfully enabled transplantation for all 35 patients. At study completion, six months post-transplantation, graft survival was 91%. Thirty-two

patients were off dialysis with good kidney function with estimated glomerular filtration rates (eGFR) within the expected range. Three patients experienced graft loss unrelated to the treatment with imlifidase. Results demonstrate favorable safety profile after six-month follow-up.

The trials were single-arm, open-label studies designed to assess the safety and efficacy of imlifidase for patients transplanted with either a deceased or living donor kidney. The 35 highly sensitized patients had either failed previous attempts of desensitization or were highly unlikely to receive a compatible kidney transplant.

Concurrently, Hansa initiated a long-term observational prospective follow up study, which will evaluate graft survival across a five-year time frame in patients who have undergone kidney transplantation after treatment with imlifidase. The study aims to encompass all patients from the four Phase 2 studies of imlifidase in sensitized kidney transplantation patients. Interim results will be available on a regular basis. The objective of the study is to collect long-term outcome data to provide further support to future prescribers, payers and patients.

Imlifidase – Treatment of anti-GBM antibody disease

Anti-GBM antibody disease, also known as Goodpasture's disease, is a rare, acute autoimmune disease where autoantibodies directed against type IV collagen cause acute inflammation of the kidney and/or the lungs. In severe anti-GBM, the disease may progress to renal failure or death. Anti-GBM antibody disease affects one in a million patients annually[4], and less than one third of the patients survive with preserved kidney function after six-months follow-up[5].

An open-label, investigator-initiated Phase 2 study in severe anti-GBM antibody disease with imlifidase is ongoing. Approximately 15 patients will be recruited to the study at up to 15 clinics in Europe. The primary objective of the study is to evaluate the safety and tolerability of imlifidase in patients with severe anti-GBM anti- body disease in addition to standard-of-care. The efficacy of imlifidase will be assessed by evaluating renal function at six months after imlifidase treatment.

Latest developments

There are currently seven patients enrolled in the ongoing study. Although limited follow up data is available at this point, all of the patients have responded favorably, and imlifidase appears to be well-tolerated.

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

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

Completed and ongoing clinical studies with imlifidase

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

Manufacturing of imlifidase

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

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

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

In May 2017, the EMA granted imlifidase access to its Priority Medicines (PRIME) scheme for highly sensitized kidney transplant patients. Through PRIME, EMA offers early and proactive scientific advice meeting support. A product that benefits from PRIME can be expected to be eligible for accelerated assessment of the MAA once submitted.

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

Hansa expects to file a Marketing Authorisation Application (MAA) with the EMA in the first quarter of 2019. Hansa's dialogue with the FDA is ongoing and the Company will provide updated guidance regarding the timeline for filing of a potential BLA filing following a meeting with the agency in the coming months.

Clinical studies of imlifidase in additional indications

Treatment of acute kidney transplant antibody-mediated rejection (AMR)

There is no effective therapy for the treatment of acute AMR. In heart, lung and kidney transplants, acute AMR occurs in 10–20 percent[6] of patients and remains a significant unmet medical need associated with loss of graft function. Imlifidase is highly effective in inactivating IgG and has the potential to halt progression of AMR and be an effective treatment in acute cases.

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

Treatment of Guillain-Barré syndrome (GBS)

GBS is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG-antibodies. It affects one in 100,000 people annually[7]. While patients are typically treated with either IVIG or plasmapheresis, there remains a significant unmet medical need. In February 2018, imlifidase received Orphan Drug Designation from the FDA for the treatment of GBS.

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

Preclinical development projects

NiceR – Novel Immunoglobulin Cleaving Enzymes for Repeat dosing

Hansa is developing novel IgG-degrading enzymes with the objective of enabling repeat dosing in autoimmune conditions, oncology and transplantation where patients benefit from more than one dose of an IgG-modulating enzyme. The Company has developed and patented several novel immunoglobulin cysteine endopeptidases. These novel enzymes have potential applicability in a broad array of indications, including relapsing autoimmune diseases and oncology. Significant progress has been made in the NiceR-project during 2018 and it is anticipated that a lead candidate will be selected in 2019. When selected, the program will enter pre-clinical development, including chemistry, manufacturing and controls (CMC) development and toxicology studies.

EnzE – Enzyme-based antibody Enhancement

Recently published findings[8] demonstrate how pre-treatment with imlifidase in tumor animal models can increase the efficacy of currently available antibody-based cancer therapies. This treatment concept is currently being investigated under the project name EnzE, Enzyme-based antibody Enhancement. Published data demonstrate the potential of an IgG-clearing agent as a pre-treatment for cancer patients. High levels of plasma IgG have been shown to limit the efficacy of therapeutic antibodies, as plasma IgG can saturate the receptors of the patient's immune cells, preventing them from efficiently killing the tumor cells. Removing inhibiting IgG antibodies with imlifidase or novel IgG-clearing enzymes prior to dosing the patient with a therapeutic antibody can potentially increase the efficacy of the given cancer therapy. The EnzE-program is in the pre-clinical research phase.

Out-licensed royalty generating programs

HBP – Prediction of severe sepsis

The HBP-assay for measurement of heparin-binding protein (HBP) in plasma is a novel diagnostic method originally developed and patented by Hansa to assist in predicting severe sepsis in patients with infectious disease symptoms at emergency departments[9]. Hundreds of thousands of patients die every year due to severe sepsis as a complication of infections, e.g. urinary tract infection and pneumonia. Many of these infections can be effectively treated with antibiotics in order to prevent progression to severe sepsis, although early prediction of risk patients is crucial for successful treatment. Severe sepsis affects 300 of 100,000 people annually[10]. The HBP-assay has been out-licensed by Hansa to UK-based Axis-Shield Diagnostics, a subsidiary to Abbott, and Hansa holds the right to royalty payments from Axis-Shield. Axis-Shield is engaged in further product development and clinical development with the HBP-assay.

Financial review January–December 2018

In order to better reflect the company's development and long-term goals, the company changed its name from Hansa Medical AB to Hansa Biopharma AB.

Net revenue

Net revenue for the fourth quarter 2018 amounted to SEK 1.4 m (1.0) and to SEK 3.4 m (3.4) for the full year 2018 and is comprised of royalty income from Axis-Shield Diagnostics.

Other operating income and expenses

Other operating income amounted to SEK 0.1 m (0.1) for the fourth quarter 2018 and to SEK 0.7 m (1.5) for the full year 2018 and is comprised of a grant from Vinnova. For the previous year, net currency differences are also included. Other operating expense, comprised of net currency differences, amounted to SEK 2.4 m (0.6) for the fourth quarter 2018 and to SEK 4.7 m (0) for the full year 2018.

Sales, general and administration expenses

Sales, general and administration expenses for the fourth quarter 2018 amounted to SEK 36.3 m (13.6) and to SEK 90.4 m (43.7) for the full year 2018. The expenses reflect the continued activities and build-up of the organization to prepare for commercial launch and include recorded non-cash costs for the company's employee long-term incentive programs (LTIP 2016 and LTIP 2018) amounting to SEK 10.9 m (4.5).

Research and development expenses

Research and development expenses amounted to SEK 42.6 m (35.8) for the fourth quarter 2018 and to SEK 154.6 m (137.1) for the full year 2018 and include non-cash costs for the company's long-term incentive programs amounting to SEK 4.9 m (5.4). Compared with the previous year, the higher expenses are due to intensified activities to prepare for filing together with an expansion of the organization.

Financial result

Operating result for the fourth quarter 2018 amounted to SEK -80.6 m (-48.9) and SEK -246.5 m (-176.1) for the full year 2018.

Profit/loss for the fourth quarter 2018 amounted to SEK -81.2 m (-49.0) and to SEK -248.0 m (-176.7) for the full year 2018.

Cash flow and investments

Cash flow from operating activities amounted to SEK -57.5 m (-29.1) for the fourth quarter 2018 and to SEK -204.6 m (-150.1) for the full year 2018. Cash and cash equivalents including short term investments amounted to SEK 858.2 m on December 31, 2018, as compared with SEK 483.4 m at the end of third quarter 2018.

Investments for the fourth quarter 2018 amounted to SEK 0.7 m (0.7) and to SEK 2.5 m (2.4) for the full year 2018. Cash flow from financing activities amounted to SEK 433.5 m (515.0) for the fourth quarter 2018 and to SEK 450.3 m (514.9) for the full year 2018.

Shareholders' equity

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

Share issue 2018

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

Parent company

The parent company's net revenue for the fourth quarter 2018 amounted to SEK 1.4 m (1.3) and to SEK 3.6 m (3.7) for the full year 2018. Profit/loss for the parent company amounted to SEK -81.3 m (-48.8) for the fourth quarter and to SEK -248.3 m (-176.4) for the full year 2018. On December 31, 2018, cash and cash equivalents including short term investments amounted to SEK 852.6 m compared with SEK 477.7 m at the end of third quarter 2018.

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

The Group consists of the parent company Hansa Biopharma AB and the subsidiaries Cartela R&D AB, Immago Biosystems Ltd and Hansa Medical Inc. Hansa Medical Inc was registered in May 2018, and at end of 2018 the company employed 3 persons. Immago Biosystems Ltd is owner of patent rights to the EnzE concept.

Financial summary for the Group (KSEK)

	October–December		Year	
KSEK, unless otherwise stated	2018	2017	2018	2017
Net revenue	1,386	1,013	3,358	3,442
Operating profit/loss	-80,605	-48,921	-246,498	-176,083
Net profit/loss	-81,229	-48,988	-247,974	-176,660
Earnings per share before and after dilution (SEK)	-2.07	-1.35	-6.47	-4.96
Shareholders' equity	859,876	630,661	859,876	630,661
Cash flow from operating activities	-57,466	-29,142	-204,560	-150,105
Cash and cash equivalents including short term investments	858,187	616,061	858,187	616,061

Shareholder information

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

According to the shareholder register maintained by Euroclear Sweden AB, as of December 31, 2018, Hansa Biopharma had 12,495 shareholders. On December 31, 2017, Hansa Biopharma had 11,469 shareholders. Information regarding shareholders and shareholdings is updated each quarter on the company's website, www.hansabiopharma.com.

Hansa Biopharma - shares in brief

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

15 largest shareholders, December 31, 2018

Name	Number of shares	Share (%)
Nexttobe AB	5,755,379	14.4
Oppenheimer	2,358,370	5.9
Thomas Olausson (private and via company)	1,613,474	4.0
Handelsbanken funds	1,301,766	3.3
Gladiator	1,275,000	3.2
Avanza Pension	1,170,248	2.9
Polar Capital Funds PLC	1,140,691	2.9
Norron Funds	988,973	2.5
AFA Insurance	959,734	2.4
Fourth Swedish National Pension Fund	958,044	2.4
Third Swedish National Pension Fund	780,509	2.0
BWG Invest Sarl.	600,370	1.5
Sven Sandberg	494,000	1.2
C WorldWide Asset management	482,291	1.2
Oberweis Funds	385,269	1.0
Other	19,695,772	49.2
In total	**39,959,890**	**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).

Other information

Employees and organization

The number of employees at the end of the fourth quarter 2018 was 52, compared to 33 at the end of corresponding period 2017.

Share warrant program

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

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

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

Long-term incentive program (LTIP 2016)

The Hansa Biopharma's Extraordinary General Meeting November 21, 2016 resolved to adopt a long-term incentive program (LTIP 2016) in the form of a performance-based share program for all employees of the Hansa Biopharma Group, meaning that not more than 30 individuals within the group may participate. The rationale for LTIP 2016 is to create conditions for motivating and retaining competent employees of the Hansa Biopharma group and for the alignment of the targets of the employees with those of the shareholders and the company, as well as to increase the motivation of meeting and exceeding the company's financial targets. A maximum of 305,000 rights may be allotted to participants under LTIP 2016. 289,750 rights have been allocated in total, of which 78,250 rights previously allocated have been excluded due to accelerated vesting or terminated, so remaining allocated rights as of December 31, 2018 are 211,500. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. The rights allocated are divided into two vesting periods, the first of which ends November 28, 2019 and the second May 18, 2020.

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

LTIP 2016 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost of LTIP 2016, calculated in accordance with IFRS 2, including social security contributions is expected to amount to approximately SEK 28.4 m, of which SEK 13.1 m is included in the results for the parent company and the group for the year 2018. The program is not expected to have any net effect on cash flow provided it is secured fully in the manner described above.

Long-term incentive program (LTIP 2018)

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

6,701 warrants have been acquired by the the participants in LTIP 2018 as of December 31, 2018. Each warrant entitles the holder to subscribe for one new share in Hansa Biopharma. The warrants were sold to the company's employees on market terms at a price established based on an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute. For participants who have not yet joined the Hansa Biopharma-group, acquisitions must be made at the current market value on the day of allocation. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 12, 2021 through June 12, 2022. The subscription price will be the market value of the share at the offer

for subscription of the warrants with an annual enumeration of 7 percent. This means that the subscription price after three years will amount to approximately 122.5 percent of the current market value of one ordinary share, and after four years amount to approximately 131.1 percent. Except for the CEO, all participants will be offered a subsidy to partially finance the acquisition of warrants. The subsidy will be equal to 25 percent of the warrant investment (after tax). The options are linked to continued employment with the company only in the sense that, if the employment would be terminated, the stock option owner shall offer the warrants to the company and repay the resulting subsidy. The subsidy will affect the company's results proportionately during the option period in accordance with the same principles as in IFRS 2. At a maximum allocation of warrants, 491,419 warrants will be acquired by the participants, which means a dilution effect of approximately 1.2 percent of the number of shares and votes in the company.

178,131 share rights have been totally allocated during the year, of which 580 have been excluded, remaining allocated rights as of December 31, 2018 are 171,756. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. A share right may be exercised provided that the participant, with certain exceptions, from the date of the start of LTIP 2018 for each participant, up until and including the date three years thereafter (the "Vesting Period"), maintains his or her employment within the Hansa Biopharma-group. The latest start date to receive Share Awards shall be the day prior to the Annual General Meeting 2019. The rights allocated are divided into two vesting periods, the first of which ends June 15, 2021 and the second November 30, 2021.

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

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

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

Dividend

The Board of Directors proposes that no dividend be paid for the 2018 financial year.

Committee for the 2019 Annual General Meeting

Hansa Biopharma AB's Nomination Committee for the AGM 2019 will consist of Erika Kjellberg Eriksson representing Nexttobe AB, Astrid Samuelsson representing Handelsbanken Funds and Sven Sandberg representing himself, Thomas Olausson and Gladiator. It also includes the chairman of the board Ulf Wiinberg as convener.

Financial calendar

Annual report 2018	April 15, 2019
Interim report January–March 2019	April 29, 2019
Annual General Meeting	May 22, 2019
Interim report January–June 2019	July 18, 2019
Interim report January–September 2019	October 31, 2019

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 third party's intellectual property rights, technological development, exchange rate and interest rate fluctuations and political risks.

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This report has not been subject to auditors' review.

Condensed financial statements

Consolidated statement of comprehensive income

	October–December		Year	
KSEK	2018	2017	2018	2017
Net revenue	1,386	1,013	3,358	3,442
Direct cost of net revenue	-765	-53	-916	-221
Gross profit	**621**	**960**	**2,442**	**3,221**
Other operating income	54	115	725	1,479
Sales, general and administration expense	-36,285	-13,620	-90,387	-43,723
Research and development expenses	-42,635	-35,768	-154,558	-137,060
Other operating expenses	-2,360	-608	-4,720	–
Operating profit/loss	**-80,605**	**-48,921**	**-246,498**	**-176,083**
Financial income/expenses	-634	-77	-1,516	-616
Profit/loss for the period before tax	**-81,239**	**-48,998**	**-248,014**	**-176,699**
Tax	10	10	40	39
Net profit/loss for the period	**-81,229**	**-49,988**	**-247,974**	**-176,660**
Attributable to				
Parent company shareholders	-81,229	-48,988	-247,974	-176,660
Earnings per share				
Before dilution (SEK)	-2.07	-1.35	6.47	-4.96
After dilution (SEK)	-2.07	-1.35	6.47	-4.96
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	-27	44	65	-22
Changes in fair value on available-for-sale financial assets	–	-4,754	–	3,535
Shares valued at fair value through other comprehensive income	-799	–	21,029	–
Other comprehensive income for the period	**-826**	**-4,710**	**21,094**	**3,513**
Total net comprehensive income	**-82,055**	**-53,698**	**-226,880**	**-173,147**

Consolidated balance sheet

KSEK	December 31 2018	2017
ASSETS		
Non-current assets		
Intangible fixed assets	33,197	33,749
Tangible fixed assets	5,876	3,976
Financial fixed assets	39,528	18,508
Total non-current assets	**78,601**	**56,233**
Current assets		
Current receivables, non-interest bearing	8,033	8,121
Short term investments	418,746	34,983
Cash and cash equivalents	439,441	581,078
Total current assets	**866,220**	**624,182**
TOTAL ASSETS	**944,821**	**680,415**
EQUITY AND LIABILITIES		
Shareholders' equity	**859,876**	**630,661**
Long term liabilities		
Deferred tax liabilities	511	538
Other provisions	10,948	5,017
Long term liabilities, interest bearing	1,155	601
Total long term liabilities	**12,614**	**6,156**
Current liabilities		
Current liabilities, non-interest bearing	46,089	11,056
Accrued expenses and deferred income	26,242	32,542
Total current liabilities	**72,387**	**43,598**
TOTAL EQUITY AND LIABILITIES	**944,821**	**680,415**

Consolidated changes in equity

	Year	
KSEK	2018	2017
Opening shareholders' equity	**630,661**	**283,693**
Result for the period	-247,974	-176,660
Other comprehensive income for the period	21,094	3,513
Net comprehensive income	**-226,880**	**-173,147**
Transactions with the group's owner		
New share issue [1]	453,075	545,401
Expenses attributable to new share issue	-20,711	-30,049
Repurchase/Sales own shares [1]	4,473	-401
Issued warrants	354	190
Long term incentive program	5,390	4,974
By employees redeemed stock options	13,514	–
Total transactions with the group's owner	**456,095**	**520,115**
Closing shareholders' equity	**859,876**	**630,661**

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

Consolidated cash flow statement

	October–December		Year	
KSEK	2018	2017	2018	2017
Operating activities				
Operating profit/loss	-80,605	-48,921	-246,498	-176,083
Adjustment for items not included in cash flow [1]	1,239	4,360	13,444	13,827
Interest received and paid, net	372	-57	-210	-638
Cash flow from operations before change in working capital	**-78,944**	**-44,618**	**-233,264**	**-162,894**
Change in working capital	21,528	15,476	28,704	12,789
Cash flow from operating activities	**-57,466**	**-29,142**	**-204,560**	**-150,105**
Investing activities				
Investments in intangible fixed assets	-103	-214	-127	-214
Investments in tangible fixed assets	-613	-518	-2,366	-2,195
Short term investments	–	-34,989	-493,984	-240,898
Divestment short term investments	10,000	105,000	109,000	246,000
Cash flow from investing activities	**9,284**	**69,279**	**-387,477**	**2,693**
Financing activities				
New share issue [2]	453,075	545,000	453,075	545,401
Issue expenses	-19,561	-29,940	-20,711	-30,050
Repurchase/Sales own shares [2]	–	–	4,473	-401
By employees redeemed stock options	–	–	13,514	–
Repayment of leasing liabilities	-44	-15	-44	-48
Cash flow from financing activities	**433,470**	**515,045**	**450,307**	**514,902**
Net change in cash	**385,288**	**555,182**	**-141,730**	**367,490**
Cash and cash equivalents, beginning of period	54,060	25,896	581,078	213,588
Exchange differences in cash and cash equivalents	93	–	93	–
Cash and cash equivalents, end of period	**439,441**	**581,078**	**439,441**	**581,078**

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

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

Consolidated key ratios and other information

	October–December		Year	
KSEK, unless otherwise stated	2018	2017	2018	2017
Profit numbers				
Net revenue	1,386	1,013	3,358	3,442
Operating profit/loss	-80,605	-48,921	-246,498	-176,083
Net profit/loss	-81,229	-48,988	-247,974	-176,660
Per share data				
Earnings/loss per share before and after dilution (SEK)	-2.07	-1.35	6.47	-4.96
Shareholders' equity per share (SEK)	21.52	16.68	21.52	16.68
Other information				
Equity ratio (%) [1]	91	93	91	93
Cash and cash equivalents including short term investments	858,187	616,061	858,187	616,061
Number of outstanding shares at the end of the period	39,959,890	37,807,386	39,959,890	37,807,386
Weighted average number of shares before and after dilution	39,153,175	36,238,797	38,326,098	35,606,986

1) Equity ratio is a financial key figure that indicates the proportion of assets financed by equity and is calculated as equity in relation to the balance sheet total at the end of the period.

Parent company – Statement of comprehensive income

	October–December		Year	
KSEK	2018	2017	2018	2017
Net revenue	1,424	1,310	3,603	3,739
Direct cost of net revenue	-765	-53	-916	-221
Gross profit	**659**	**1,257**	**2,687**	**3,518**
Other operating income	54	115	725	1,479
Sales, general and administration expenses	-33,359	-13,621	-85,938	-43,740
Research and development expenses	-45,628	-35,910	-159,137	-137,015
Other operating expenses	-2,360	-608	-4,720	–
Operating profit/loss	**-80,634**	**-48,767**	**-246,383**	**-175,758**
Result from short term financial receivables	28	28	52	97
Other financial expenses	-654	-105	-1,966	-712
Profit/loss for the period (before and after taxes)	**-81,260**	**-48,844**	**-248,297**	**-176,373**
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total net comprehensive income	**-81,260**	**-48,844**	**-248,297**	**-176,373**

Parent company – Balance sheet

KSEK	December 31 2018	2017
ASSETS		
Non-current assets		
Intangible fixed assets	30,163	30,709
Tangible fixed assets	5,290	3,976
Financial fixed assets	17,594	17,317
Total non-current assets	**53,047**	**52,002**
Current assets		
Receivables group-companies	2,834	–
Current receivables, non-interest bearing	8,035	8,588
Short term investments	418,746	34,992
Cash and cash equivalents	433,875	578,795
Total current assets	**863,490**	**622,375**
TOTAL ASSETS	**916,537**	**674,377**
EQUITY AND LIABILITIES		
Shareholders' equity	**833,270**	**625,528**
Long term liabilities		
Other provisions	10,948	5,017
Liabilities to group companies	–	98
Long term liabilities, non-interest bearing	679	601
Total long term liabilities	**11,627**	**5,716**
Current liabilities		
Current liabilities, non-interest bearing	45,428	10,606
Accrued expenses and deferred income	26,212	32,527
Total current liabilities	**71,640**	**43,133**
TOTAL EQUITY AND LIABILITIES	**916,537**	**674,377**

Parent company – Changes in equity

	Year	
KSEK	2018	2017
Opening shareholders' equity	**625,528**	**281,786**
Result for the period	-248,297	-176,373
New share issue [1]	453,075	545,401
Expenses attributable to new share issue	-20,711	-30,049
Repurchase/Sales own shares [1]	4,473	-401
Issued warrants	354	190
Long term incentive program	5,334	4,974
By employees redeemed stock options	13,514	–
Total transactions with the group's owner	**456,039**	**520,115**
Closing shareholders' equity	**833,270**	**625,528**

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

Financial notes

Note 1 Basis of Preparation and Accounting policies

This consolidated interim report has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act. The interim report for the parent Company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting. A full description of the accounting principles applied in this interim report can be found in the Annual Report 2017. The same accounting principles have been used as in the latest annual report except for what is stated below. The Annual report 2017 was published on April 11, 2018 and is available on www.hansabiopharma.com. Disclosures in accordance with IAS 32.16A are as applicable in the notes or on the pages before the consolidated income statement.

Effects of IFRS 15 Revenue from contracts with customers
IFRS 15 came into effect as of January 1, 2018. The Group's revenue from contracts with customers currently consists mainly of royalty revenue from the agreement with Axis-Shield Diagnostics (ASD). The transition to IFRS 15 has not affected how Hansa Biopharma recognises revenue from the agreement with ASD.

Effects of IFRS 9 Financial instruments
IFRS 9 came into effect as of January 1, 2018 and replaces IAS 39 Financial Instruments: Recognition and Measurement as the standard on recognition and measurement of financial instruments in IFRS. Compared with IAS 39, IFRS 9 primarily brings changes regarding classification and measurement of financial assets and financial liabilities, impairment of financial assets and hedge accounting. IFRS 9 has affected how the Group accounts for investments in interest rate funds. Under IAS 39 the funds have been measured at fair value through other comprehensive income. However, the funds do not meet the criteria in IFRS 9 for changes in fair values to be recognized in other comprehensive income. Instead, under IFRS 9 the changes in the fair values of the funds has been reported in profit or loss. Therefore, accumulated changes in fair values of the funds of SEK -403 k has been transferred from the "Fair value reserve" to "Retained earnings" in the opening balance as per January 1, 2018.

The Group also has investments in commercial papers, which under IAS 39 has been measured at fair value through other comprehensive income. Under IFRS 9, investments in commercial papers has instead been measured at amortized cost. The accumulated change in the fair values of the commercial papers of SEK -9 k has been removed from the "Fair value reserve" and booked against the carrying amount of the commercial papers in the balance sheet. The commercial papers have therefore been reported at a carrying amount of SEK 34,992 k in the opening balance for the Group as per January 1, 2018.

The transition to IFRS 9 has not had any other material effects for the Group.

New IFRS which have not yet begun to be applied
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 Determining whether an agreement contains a lease. The introduction of IFRS 16 will affect how the Group reports agreements on renting premises. Under current accounting principles, these are reported as operating leases, which means that the rental cost is recognized in the income statement on a straight-line basis during the lease term. Under IFRS 16, for these agreements, a liability in the balance sheet corresponding to the obligation to pay leasing fees will be reported at the same time as a corresponding asset that reflects the right to use the premises is reported. In the income statement, the depreciation of the asset will be reported 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.

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 report access rights asset to the same amount as the lease liability, but with the addition of prepaid rents that are reported in the consolidated balance sheet as of December 31, 2018. Thus, no effect on equity is realized on the transition to IFRS 16.

The transition to IFRS 16 will not affect the accounting of existing leases that are reported as financial leases under the current accounting principles.

IFRS 16 will not be applied in the Parent Company in accordance with the relief rules in RFR 2.

The transition to IFRS 16 is expected to result in an increase of the Group's liabilities by approximately SEK 13.7 million (of which approximately SEK 6.0 million is short-term liabilities), while at the same time a utilization rights asset of approximately SEK 13.7 million will be reported.

Note 2 Fair value of financial instruments

The reported value is assessed as being a fair approximation of the fair value for all of the Group's financial instruments except investments in short term commercial papers, which have been measured at amortized cost. The financial instruments reported at fair value in the balance sheet are comprised partly of holdings of interest rate funds consisting of investments in interest-bearing securities and other interest-rate instruments of high-rating and partly of the Group's holding of shares in Genovis, which are listed on Nasdaq First North.

The fair value of the holdings based on the closing price at the balance sheet date in k SEK:

Financial instrument	Valuation hierarchy	Dec 31, 2018	Dec 31, 2017
Interest funds	Level 2	418,746	–
Shares	Level 1	39,528	18,507
Commercial papers	Level 1	–	34,983

Reference list

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Glossary

AMR
Antibody mediated transplant rejection.

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

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

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

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

Biopharmaceutical
A pharmaceutical drug that is manufactured using biotechnology.

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 Phase 1
The first time a drug under development is administered to humans. Phase 1 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.

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

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.

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

Imlifidase
imlifidase (INN), also known as IdeS, Immunoglobulin G-degrading enzyme of Streptococcus pyogenes, is a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

INN
International Nonproprietary Name (INN) is a generic and non-proprietary name to facilitate the identification of a pharmaceutical substances or active pharmaceutical ingredient. Each INN is a unique name that is globally recognized and is public property. The INN system has been coordinated by the World Health Organization (WHO) since 1953.

In vitro
Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

In vivo
Term within biomedical science to indicate that experiments or observations are made on 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.

Milestones
Payments a company receives in accordance with a cooperation agreement after the company reaches a pre-set target, such as "proof-of-concept".

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.

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