
Hansa Medical
Annual Report for 2015

Hansa Medical in brief

Hansa Medical is a biopharmaceutical company focusing on novel immunomodulatory enzymes. The lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Additional projects focus on development of new antibody modulating enzymes, as well as HBP, a diagnostic biomarker for prediction of severe sepsis at emergency departments that is already introduced on the market.

The company is based in Lund, Sweden. Hansa Medical's share (ticker: HMED) is listed on Nasdaq OMX Stockholm.

Several significant milestones reached in 2015

January–December 2015 in summary

- Phase II clinical study of IdeS in highly sensitized patients awaiting kidney transplantation successfully completed
- Development of new generation of IdeS molecules for repeat dosing announced
- US medical advisory board established
- First patient in second IdeS Phase II study at Uppsala University Hospital transplanted
- Positive data on IdeS Phase I study published in scientific journal *PLOS ONE*
- First patient treated and transplanted with IdeS in investigator sponsored US Phase II study at Cedars-Sinai Medical Center, Los Angeles. Data showed that one dose of IdeS effectively inactivates donor specific antibodies.
- FDA Orphan Drug Designation for IdeS in solid organ transplant patients received
- First Phase II study of IdeS in sensitized kidney transplantation patients presented at *ESOT 2015*
- Data published in *Journal of Immunology* shows that IdeS temporarily can silence B-cells, preventing B-cells from developing into antibody producing cells
- Results from a clinical multicenter trial with HBP-assay published in *Critical Care Medicine*
- Hansa Medical secured MSEK 246 in funding through a fully subscribed rights issue
- Göran Arvidson appointed new President and CEO of Hansa Medical
- Hansa Medical's shares began trading on Nasdaq OMX Stockholm on November 2, 2015

Financial summary

- Net revenue for the group amounted to MSEK 5.4 (1.6)
- Operating result was MSEK -66.2 (-24.7)
- Consolidated net result was MSEK -66.3 (-29.0)
- Earnings per share before and after dilution were SEK -2.13 (-1.09)
- Cash position on December 31, 2015, of MSEK 175.7 (10.2)

"2015 was, in many ways, a truly remarkable year for Hansa Medical. We reached a number of important milestones and continued to pave the way to build a biopharmaceutical company with a product candidate that has the potential to significantly improve health outcomes in patients."

Göran Arvidson, President and CEO of Hansa Medical

Group – Key ratios and other information

	1 January – 31 December	
KSEK, unless otherwise stated	2015	2014
Profit numbers		
Total operating income	7,155	4,775
Operating profit/loss	-66,201	-24,709
Net profit/loss	-66,266	-29,042
Per share data		
Earnings/loss per share before and after dilution (SEK)	-2.13	-1.09
Shareholders' equity per share (SEK)	6.53	1.92
Other information		
Shareholders' equity	211,526	49,804
Equity ratio (%)	94	92
Cash flow from operating activities	-57,799	-23,623
Cash and cash equivalents	175,683	10,152
Number of employees end of the year	19	14

CEO statement

2015 was, in many ways, a truly remarkable year for Hansa Medical. We reached a number of important milestones and continued to pave the way to build a biopharmaceutical company with a product candidate that has the potential to significantly improve health outcomes in patients.

Much of our work centered on our lead project IdeS, which continues to attract attention in the international scientific community. In July, results from the clinical Phase I study were published in the scientific journal PLOS ONE [1]. Later, in the autumn, data from the subsequent successful Phase II study in sensitized kidney transplantation patients were presented at the 17th Congress of the European Society for Organ Transplantation.

The study results showed that a single dose of IdeS rapidly and efficiently inactivates IgG in humans. This makes it an attractive therapeutic approach for acute IgG-mediated conditions. The data clearly support further development in the area of transplantation and supports our decision to keep this as our main focus right now. IdeS' ability to reduce anti-HLA antibodies to levels acceptable for transplantation strengthens our belief in and commitment to this exciting project.

Also during the year, we initiated two additional clinical Phase II studies; one at Uppsala University Hospital and one investigator-sponsored study at Cedars-Sinai Medical Center in Los Angeles, led by the renowned transplantation expert Professor Stanley Jordan. Professor Jordan also participated as one of several keynote speakers at our Capital Markets Day in Stockholm last November. All in all, we are very pleased with the progress and preliminary results of the two ongoing clinical studies and expect patient enrollment to be completed in the first half-year of 2016. In mid February 2016, 11 sensitized patients had been treated with IdeS and then transplanted.

In May, we announced the inception of a US medical advisory board for IdeS in kidney transplantation. The board will assist the company in developing IdeS within transplantation in sensitized patients. Apart from Professor Jordan as chairman, the board consists of Professor Robert Montgomery from Johns Hopkins Medicine in Baltimore, and Professor Kathryn Wood from University of Oxford. Professor Wood is also on the previously initiated European advisory board with the European transplantation experts Professor Gunnar Tufveson, Uppsala University Hospital and Professor Christophe Legendre at Necker Hospital in Paris.

Together with these experts, and our highly motivated team of scientists in Lund, we intend to build upon current success and continue with the development of IdeS in the field of transplantation. This strategy was further bolstered by being awarded Orphan Drug Designation for IdeS for the prevention of antibody-mediated organ rejection in patients undergoing all types of solid organ transplants. Human Leukocyte Antigen (HLA) sensitization constitutes a significant barrier for transplantation for thousands of patients annually. Approximately 30 percent [2] of the patients on the waiting lists for kidney, heart, lung and pancreas transplantation, equivalent to approximately 35,000 patients in the US alone, are sensitized to HLA. Gaining Orphan Drug Status is an important step closer to helping those with HLA sensitization.

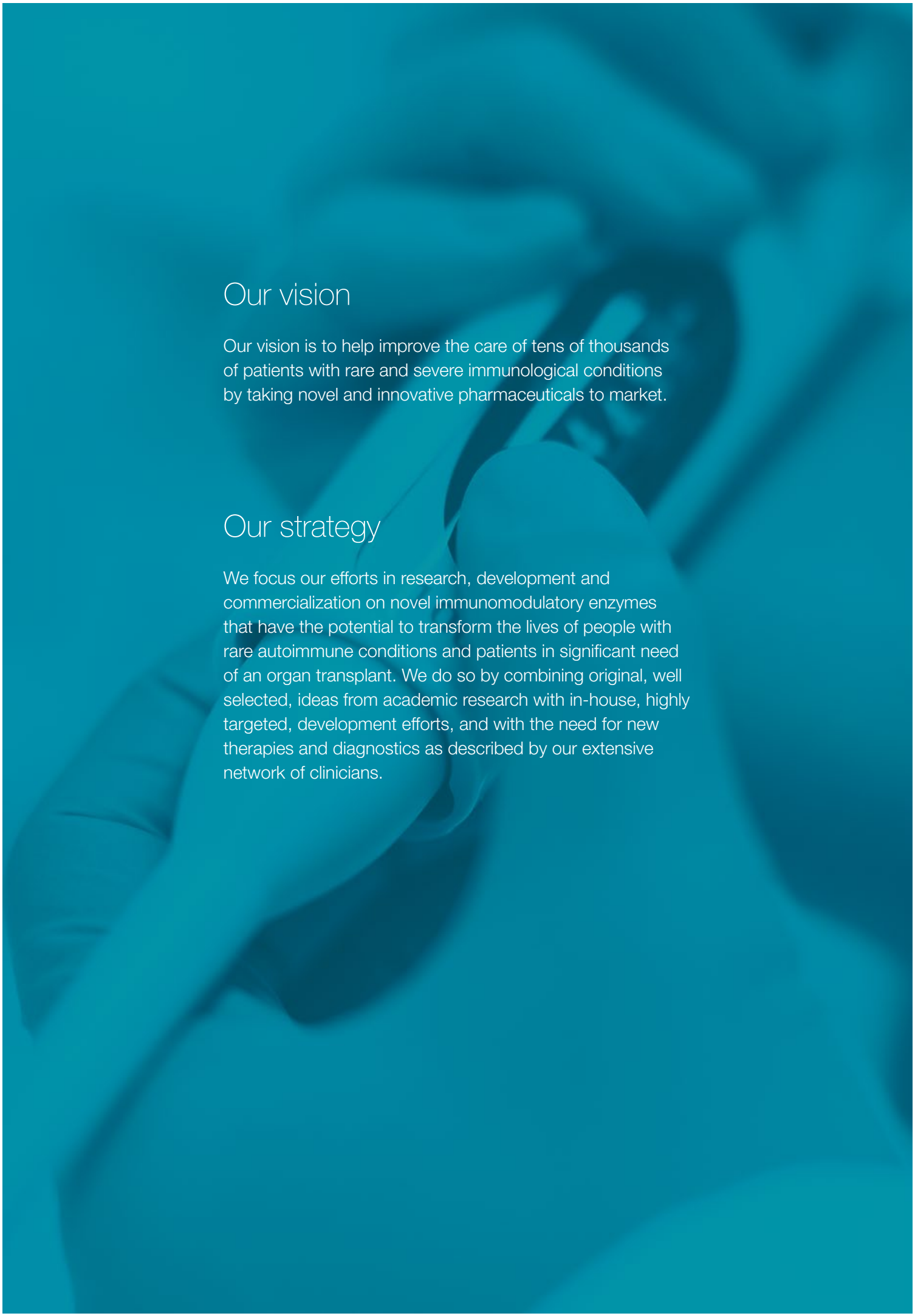
There is a defined group of patients with very high levels of broad HLA antibodies and who have been on dialysis for very long and are therefore in urgent need of transplantation. These patients have highest priority for transplantation and are referred to specialized clinics. However, they have a negligible chance of being transplanted using the current protocols. We believe that IdeS can be a life-saving treatment by making renal transplantation possible in these patients. We are planning to initiate a clinical trial in this category of patients in the US shortly. We are hopeful that successful results from this planned study, in combination with the results from the finalized Phase I/II and the two ongoing Phase II trials will bring us closer to market approval for IdeS in this patient group.

On March 10, 2016, study results presented in the New England Journal of Medicine further strengthen Hansa Medical's belief in the potential of IdeS. The study demonstrated a significant survival benefit in 1,025 patients undergoing HLA-incompatible kidney transplantation following desensitization with currently available methods, when compared to non-transplanted patients on the transplant wait list. Although IdeS was not subject of this study, it highlights the need for and benefit from desensitization in kidney transplantation and further strengthens our belief that IdeS has the potential to play a very important role in kidney transplantation going forward. Our vision for IdeS is to make desensitization possible for highly and moderately HLA-sensitized patients relying on donation from either deceased or living donors.

In addition to transplantation, we plan to further broaden the potential disease indications that can be treated with IdeS, including rare and serious acute autoimmune diseases within neurology, nephrology and hematology. We aim to initiate company or investigator sponsored studies to be able to show Proof of Concept in these patient groups.

Besides the scientific milestones in 2015, we also secured the necessary capital to ensure that our operations and our R&D efforts are well funded. The rights issue in 2015 gave us the financial strength and flexibility to continue this focused drive to achieve our objectives to take a product to market as soon as possible and to affect better health in patients quickly and efficiently. In 2016, we intend to build on the successes we had in 2015 and follow the path that we have carefully and strategically laid out in order to provide greater value to our shareholders and better health outcomes for all those who can benefit from our work.

Göran Arvidson
President and CEO



Our vision

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

Our strategy

We focus our efforts in research, development and commercialization on novel immunomodulatory enzymes that have the potential to transform the lives of people with rare autoimmune conditions and patients in significant need of an organ transplant. We do so by combining original, well selected, ideas from academic research with in-house, highly targeted, development efforts, and with the need for new therapies and diagnostics as described by our extensive network of clinicians.

Project overview

Pipeline

Candidate/Method	Indication	Research/ Preclinical	Phase I [1]	Phase I/II	Phase II	Phase II/III	Registration
IdeS	Kidney transplantation in sensitized patients [2]						
	Acute autoimmune disease [3]						
	Antibody medicated kidney transplant rejection						
IdeS 2nd gen.	Recurring treatment in autoimmune disease						
EndoS	Acute autoimmune disease						
HBP-assay (IVD)	Prediction of severe sepsis [4]						

Planned Ongoing Completed

[1] Present and future IdeS Phase II and Phase II/III studies to be based on the same Phase I study.

[2] Two Phase II trials are currently ongoing in Sweden (Uppsala/Huddinge) and the US (Cedars-Sinai Medical Center, Los Angeles). An additional trial in highly sentisized patients is being planned.

[3] Pilot Phase II trials in rare autoimmune conditions like GBS, TTP and anti-GBM are being planned.

[4] Outlicensed to Axis-Shield Diagnostics Ltd.

Antibodies for good and for bad

An immune response starts with the recognition of a pathogen or other foreign material followed by a reaction in order to eliminate it. A wide variety of immune cells and molecules are involved in the development of immune responses. Antibodies, also called immunoglobulins (Ig), are proteins used by the immune system to identify pathogens or other foreign material. Each antibody molecule binds to one of many molecules on the microorganism's surface and hence there may be several different antibodies for a given pathogen.

The molecule that the antibody binds to is called an antigen. Through this binding mechanism, one or several antibodies can tag a pathogen or infected cell. This tagging results in one or several different so called effector functions in which other parts of the immune system is activated in order to inhibit and/or eliminate the pathogen or foreign material. The human immune system uses different classes of antibodies, of which the most common type is IgG.

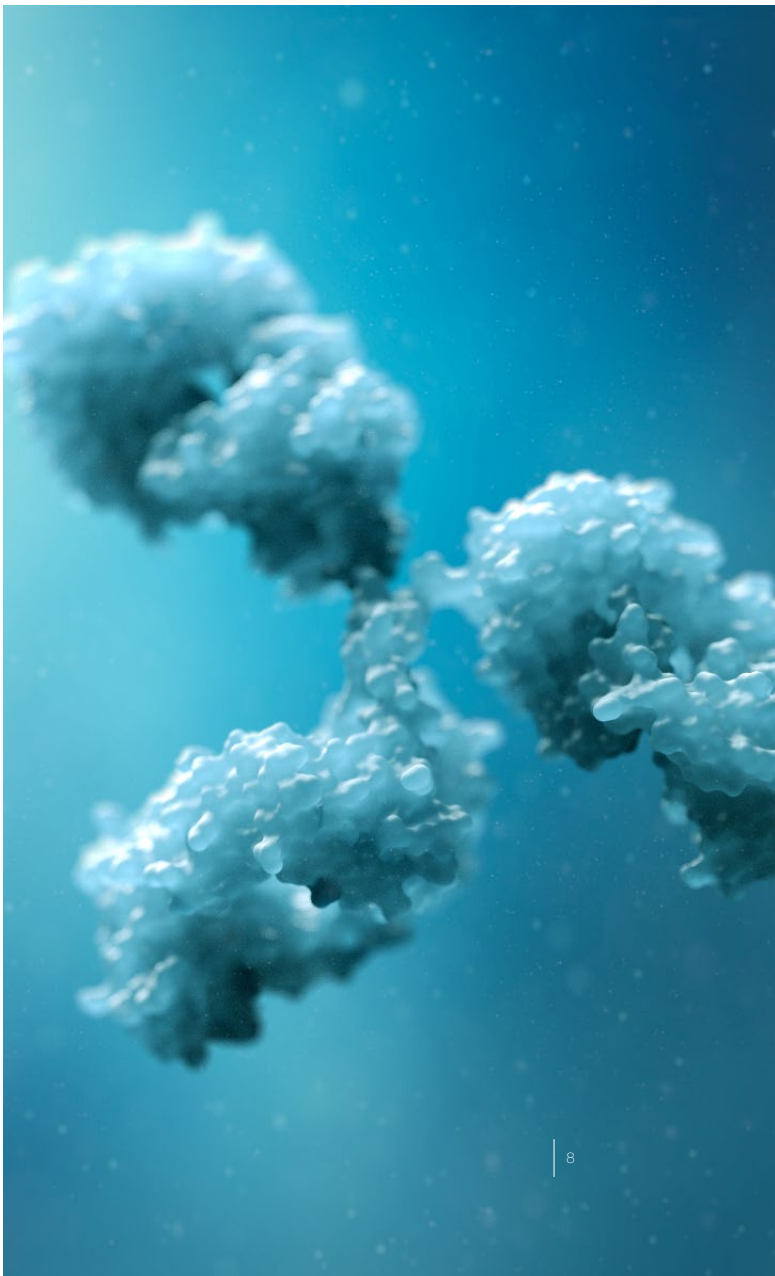
In various autoimmune diseases, the immune system mistakenly mounts an immune response towards the body's own cells and tissues. This misguided attack then results in different clinical symptoms depending on what cells or tissues are subject of the immune attack. In several autoimmune diseases, antibodies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

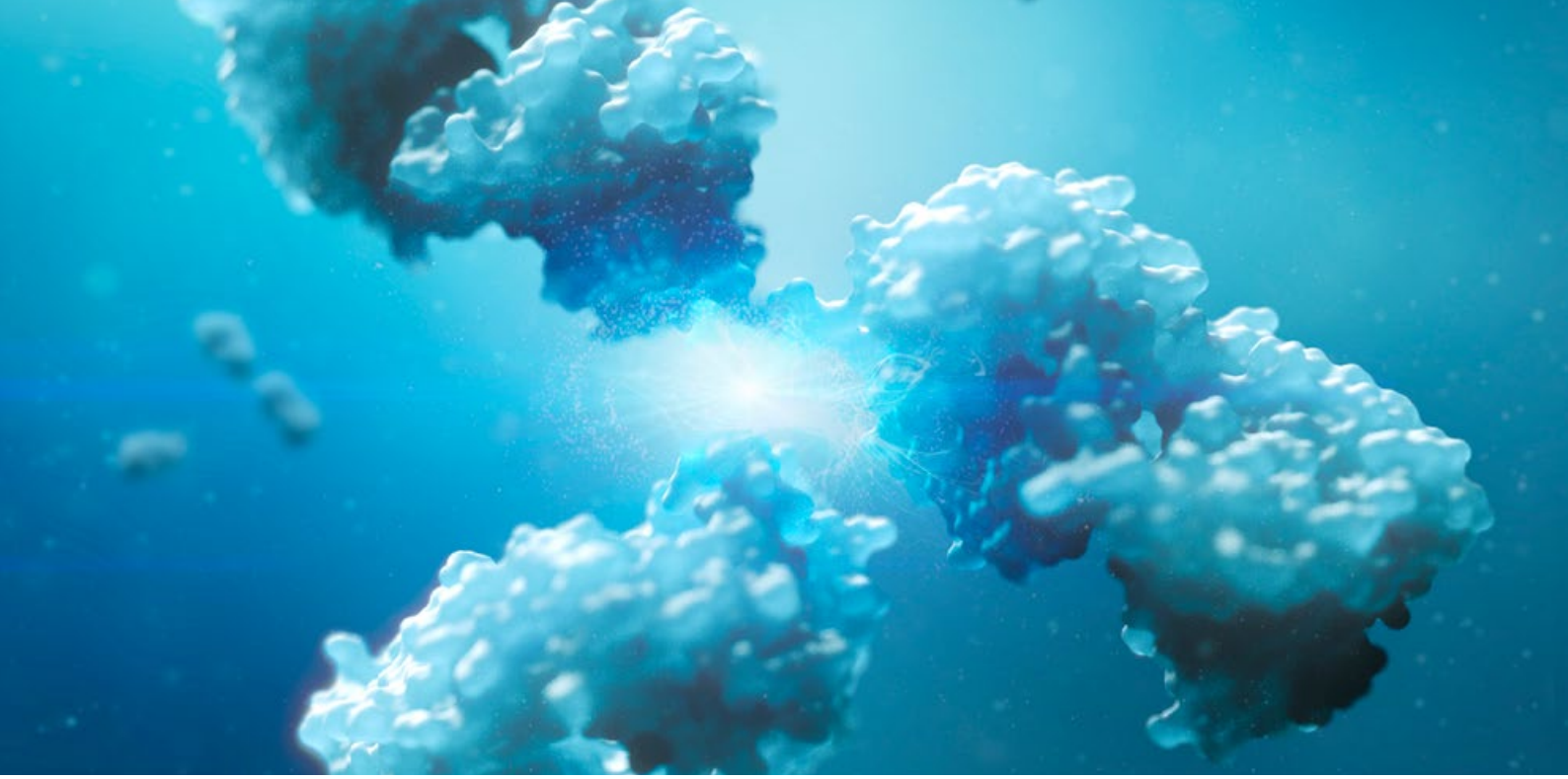
In transplantation, foreign material is by design introduced to an individual's immune system. In order to prevent the immune system from fulfilling its duty to recognize and eliminate the transplanted organ, all transplanted patients are treated with immunosuppressant drugs in order to prevent or mitigate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

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

Patients in need of a new organ, such as kidney or heart, can also have so called pre-formed anti-HLA antibodies prior to a performed transplantation. These pre-formed anti-HLA antibodies were developed earlier in life due to pregnancies, blood transfusions or previous transplantations when exposed to foreign HLA (Human Leukocyte Antigen). These individuals are referred to as HLA-sensitized or HLA-immunized patients. In general, it is more difficult 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 prior to an actual transplantation.

Antibodies are complex proteins that play an important role in the immune system. However, in autoimmune diseases and transplantation, antibodies can become a problem and be part of disease progression.





Lead candidate IdeS

IdeS – a novel therapeutic principle

Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes* (IdeS) is an enzyme that specifically cleaves immunoglobulin G (IgG). Our strategy takes advantage of the ability of IdeS to specifically and efficiently inactivate IgG, to prevent and treat patients who have developed pathogenic IgG. IdeS-mediated IgG degradation constitutes a novel therapeutic principle for the treatment of IgG-mediated human diseases. Our clinical studies are focused on desensitization of HLA-immunized patients before kidney transplantation, also referred to as sensitized patients. In addition, several additional indications are planned for clinical trials including antibody mediated graft rejection as well as several autoimmune indications within the areas of neurology, nephrology and hematology.

Transplantation of sensitized patients

Approximately one third of the kidney patients that require dialysis are sensitized to human leukocyte antigens (HLA)[2]. The presence of antibodies that react with a potential donor organ – i.e. donor specific HLA antibodies (DSA) – is a significant barrier to transplantation due to the risk of acute antibody mediated rejection (AMR) and hyper acute graft failure. Sensitized patients in general have an increased waiting time for transplantation. Depending on level of HLA-immunization, some sensitized patients can be transplanted with treatment procedures using plasmapheresis or intravenous gamma globulin at some specialized clinics. The most highly sensitized patients are today very difficult to desensitize and transplant despite highest priority and the engagement of various strategies to increase the donor pool. Patients who are not possible to transplant are maintained on dialysis at a high cost, with a poor quality of life and an increased mortality.

The long-term survival rate in patients that are transplanted following desensitization is significantly better compared to patients remaining on dialysis[3]. More than 32,000 patients awaiting kidney transplantation in the US are sensitized. The presence of anti-HLA antibodies makes it very difficult to find a match with a compatible donor. Sensitized patients can remain on the waiting list for a kidney transplant for years without a suitable donor ever being identified. Remaining on the wait list is associated with a high mortality rate.

The problems with kidney disease are taking a growing toll on patients. Death rates are very high, dialysis has very poor outcome, and it's very expensive. People die and languish for years on dialysis without hope for transplantation, especially if they have antibodies.

Antibody mediated injury to allografts represents one of the most important unmet needs in transplantation today. Currently, there are no FDA approved drugs for prevention and treatment of antibody-mediated injury to allografts.

The types of therapies that we have for treating rejection are not very good. We have a big unmet need in transplantation medicine.

Professor Stanley Jordan (MD, PhD)

Director of Kidney Transplantation and Transplant Immunology, Kidney and Pancreas Transplant Center and Director of Division of Pediatric and Adult Nephrology at Cedars Sinai Medical Center, Los Angeles, USA.

A recently published[3] study concludes that sensitized patients receiving an incompatible kidney transplant have a higher survival rate than sensitized patients remaining on the transplant waitlist. The eight-year survival rate for transplanted sensitized patients is estimated to be 76.5 percent. The study compared this survival rate with two control groups: wait-list-or-transplant or wait-list only. The eight-year survival rate for the wait-list-or-transplant group was 62.9 percent and the eight-year survival rate for wait-list only was 43.9 percent. This study clearly demonstrates the benefit for sensitized patients to become transplanted as opposed to long-term dialysis treatment.

However, currently available desensitization protocols using plasmapheresis or intravenous gamma globulin are not always effective, and are time consuming, expensive, associated with serious side effects and have a significant impact on patient well being.

Desensitization with IdeS

Hansa Medical's primary development goal is to make transplantation possible for sensitized kidney transplantation patients through one 15 minute infusion dose of IdeS. IdeS inactivates both circulating and extravascular IgG very effectively and very fast. Within a couple of hours, basically all IgG antibodies are inactivated.

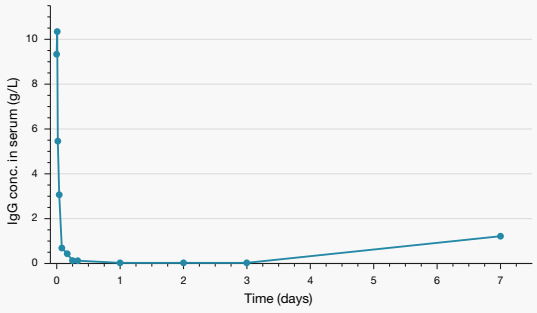


Figure A. Serum IgG after one dose of IdeS

Current protocols for desensitization, primarily involving plasmapheresis, intravenous gammaglobulin and rituximab, require meticulous planning and timing and these are not feasible in most cases for deceased donor kidney transplantation. In many cases these currently available protocols are also not effective enough for living donor transplantation.

IdeS with its rapid and powerful pharmacological effect is currently in clinical development. It is administered just prior to transplantation and has the potential to increase the number of sensitized patients receiving kidney transplants.

Clinical Phase I study with IdeS

During 2013 and 2014, Hansa Medical conducted a clinical first-in-human Phase I study with IdeS. The study was a randomized placebo controlled dose-escalation study with 29 healthy subjects. The primary objective was to assess the safety and tolerability of IdeS following intravenous administration. Secondary objectives were efficacy in IgG cleavage, the pharmacokinetics and the immunogenicity of IdeS. IdeS was considered safe; no adverse events were reported as serious. In July 2015, the results from the Phase I study were published in PLOS ONE[1].

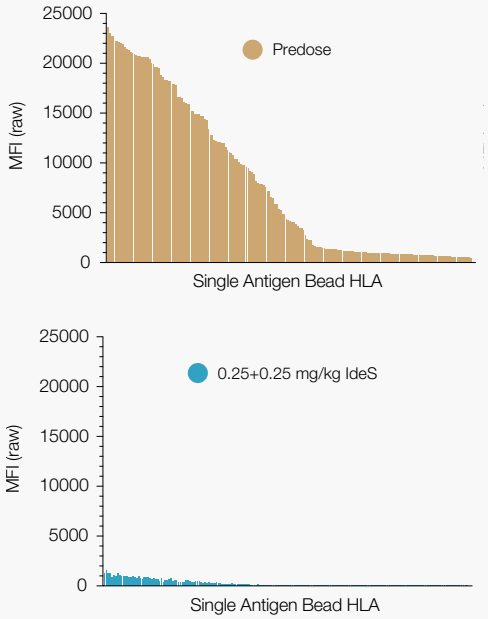


Figure B. IdeS effectively reduces anti-HLA antibodies. Single Antigen Bead analyses before (gold) and 24 hours after IdeS treatment (blue)

First clinical Phase I/II in sensitized patients with IdeS successfully completed

During 2014 and 2015, the first clinical Phase I/II study with IdeS in sensitized patients was conducted and completed. The study was a dose-finding study in eight dialysis patients, ranging from very highly and broadly sensitized to more moderately sensitized patients.

The results from the study show that IdeS can effectively reduce anti-HLA antibodies to levels acceptable for transplantation. Both the primary and secondary objectives of the study were met and IdeS had an acceptable safety profile in the study. Even though it was not an objective of the study, one sensitized patient with donor specific antibodies who was on a waiting list for kidney transplant was subsequently successfully transplanted after having received two doses of IdeS. Stable graft function has been maintained to date (19 months) with normal creatinine and no rejection episodes.

Ongoing Phase II trials in sensitized patients in Sweden and the US

In July 2015, a Phase II study in sensitized patients was initiated in Sweden. The study aims to include up to ten sensitized patients on the waiting list for transplantation and the study allows dose escalation. The objectives are to investigate both effect on HLA-antibodies and the safety of IdeS in the transplantation setting. The patients will receive a single dose of IdeS and if the patients become cross-match negative, they will be transplanted with a kidney from either a living or deceased donor. Each patient will be followed for six months and results are expected in 2016.

In August 2015, an investigator sponsored study using IdeS was initiated and run by Professor Stanley Jordan at Cedars-Sinai Medical Center in Los Angeles. Professor Jordan has developed a desensitization protocol that allows transplantation of highly sensitized patients using kidneys from deceased donors, a procedure that is very difficult using other protocols based on plasmapheresis. The protocol is based on the use of alternating high dose intravenous gamma globulin and anti-CD20 treatments in order to lower the levels of anti-HLA antibodies and to prevent rebound of antibodies after incompatible transplantation. The patients are kept in the program for many months waiting for an organ offer from a deceased donor.

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As I get older, it’s harder for me to get excited about anything. But truly, this is the most exciting thing that happened to this field. I am very optimistic about IdeS.

The survival benefit of getting desensitized and getting a transplant is of the magnitude of the best cancer therapies that we have. Being on dialysis for ten years is worse than a lot of cancers and desensitization brings their survival up to a level that, really, for very few types of cancer can be achieved.

Professor Robert A. Montgomery (MD, DPhil, FACS)

Chief of the Division of Transplantation, Professor of Surgery, and the Director Comprehensive Transplant Center at Johns Hopkins, Baltimore, USA.

IdeS is investigated in combination with the high dose intravenous gamma globulin and anti-CD20 procedure. The study will include 10–20 patients and the patients will be followed for six months. The objectives are to investigate both efficacy (i.e. decrease in PRA, reduction in HLA antibody levels and reduction in AMR frequency) and safety of IdeS.

Planned pivotal studies in highly sensitized patients

The first Phase I/II study completed with IdeS clearly demonstrated that IdeS effectively inactivates antibodies also in the very highly/broadly sensitized patients. There is a defined group of patients with very high levels of broad HLA-antibodies and who have been on dialysis for very long and are therefore in urgent need of transplantation. These patients have highest priority for transplantation and are referred to specialized clinics in the US. However, they have a negligible chance of being transplanted using the current protocols. Considering the effect and rapid onset of action of IdeS, we believe that IdeS can be a life-saving treatment to allow transplantation of these patients with kidneys from both living and deceased donors. We are currently planning a clinical trial in this category of patients.

IdeS in other indications

IdeS can potentially be used in many different acute and rare autoimmune conditions in which IgG antibodies are proven or suspected to play a significant role for disease progression. Hansa Medicals long-term vision is to make IdeS available for as many of these conditions as possible. In several of these indications, IgG removal through plasmapheresis has proven to be somewhat effective which further strengthens the rational for considering further clinical development with IdeS in these indications. IdeS with its rapid and powerful pharmacological effect could potentially make a significant therapeutic difference in several of these acute indications. (See Table A.)

Some of these indications have been identified as especially interesting to evaluate further in pilot Phase II trials. These indications are antibody mediated graft rejection (AMR) and the rare and acute autoimmune conditions Thrombotic Thrombocytopenic Purpura (TTP), anti-GBM disease and Guillain-Barré syndrome (GBS).

Approximately ten percent[4] of all transplanted patients experience antibody mediated rejection post transplant. In severe AMR, plasmapheresis is not sufficient to rescue the kidney since the magnitude of the antibody response exceeds the capacity of plasmapheresis to clear antibodies. The completed Phase I and II studies demonstrated that IdeS cleaves and inactivates IgG very rapidly and effectively with no reflux of IgG from the tissues. This makes IdeS very interesting to investigate as a treatment for AMR and particularly severe AMR.

TTP is a rare thrombotic disorder. In the majority of patients, TTP is a result of autoantibody-mediated inhibition of an enzyme (ADAMTS13) that is vital in controlling clotting. 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. GBS is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies.

Hansa Medical has initiated a collaboration with Professor Shahram Attarian at Hôpital de la Timone in Marseille, France. The ambition of the collaboration is to investigate the design of a possible

Table A. Potential IdeS indications*

Transplantation	Neurology	Hematology	Nephrology	Other
Kidney transplantation in sensitized patients	Guillain-Barré syndrome	Thrombotic thrombocytopenic purpura (TTP)	Anti-GBM disease	Flares in Systemic Lupus Erthematosus (Rheumatology)
Kidney transplantation in highly sensitized patients	Anti-NMDA receptor encephalitis	Catastrophic Anti-Phospholipid Syndrome (CAPS)	ANCA associated vasculitis	Flares in Pemphigus (Dermatology)
Kidney transplant AMR	Myasthenic crisis	Life threatening ITP	Lupus nephritis	Life threatening Anti Drug Antibodies (ADA)
Sensitized heart transplant patients	Relapsing Neuromyelitis optica	Hemolytic disease of newborn		
Heart transplant AMR	Steroid refractory multiple sclerosis relapse	Neonatal alloimmune thrombocytopenia		
ABOi kidney transplantation	Acute CIDP	Refractory autoimmune hemolytic anemia		
	Lambert-Eaton Syndrome			

*The table lists indications in which IdeS potentially could make a significant therapeutic difference but the table should not be regarded as complete. To date, Hansa Medical have conducted Phase II trials in sensitized patients with promising initial results. Additional clinical trials are necessary to demonstrate IdeS’ efficacy and safety in additional indications.

pilot Phase II trial with IdeS in GBS in collaboration with Professor Attarian and Hôpital de la Timone.

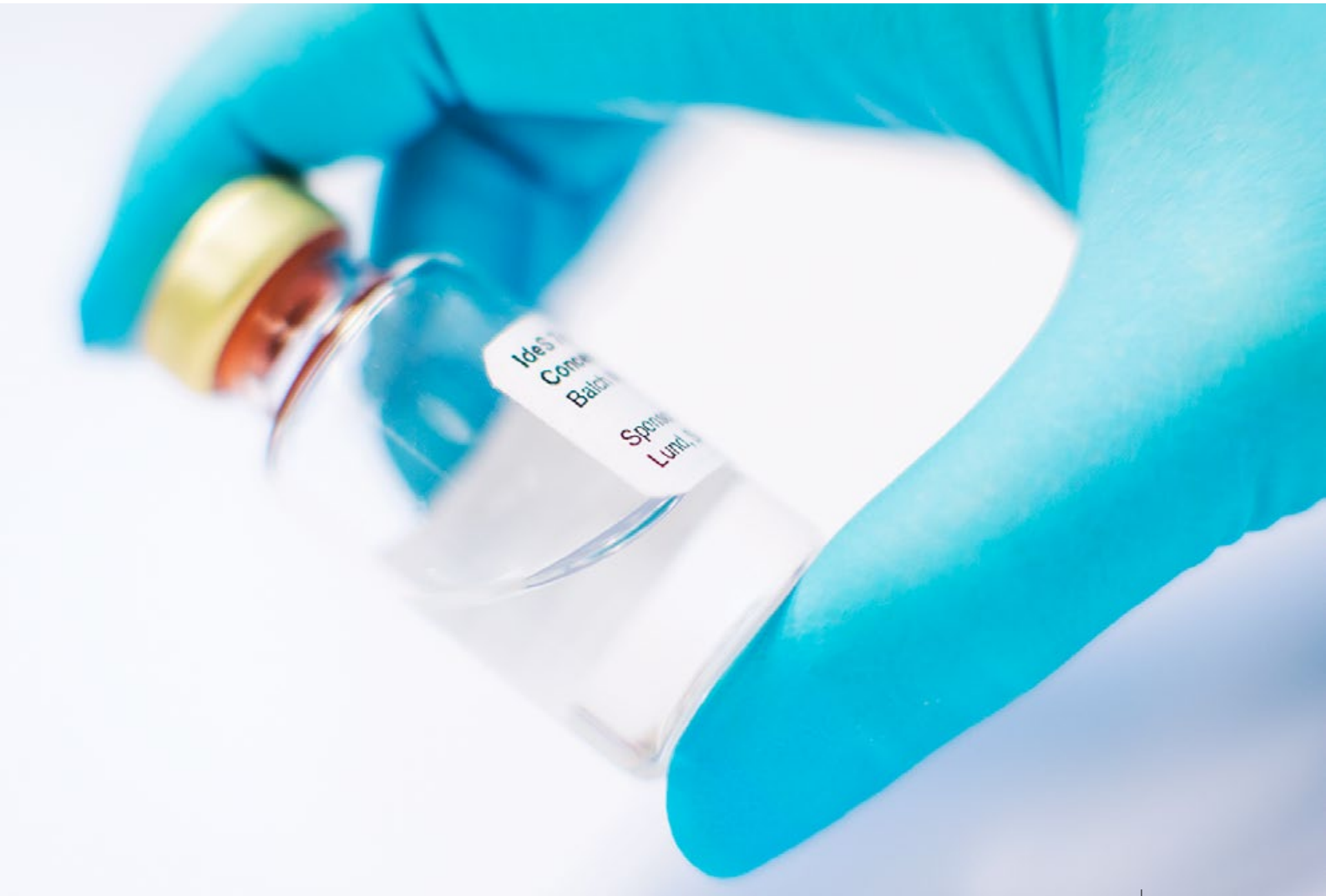
Production

The production of IdeS is a complex process which involves microbial fermentation with recombinant *E.Coli* involving several steps of purification and characterization. For preclinical experiments, production takes place on a small and experimental scale in-house or by academic research partners. Production for toxicological studies and for clinical phase I and phase II studies normally takes place on a limited scale and with preliminary quality-assurance by a contract manufacturer. Production for further clinical studies and for subsequent marketing and sales takes place on a larger and ultimately quality-assured scale by contract manufacturers. This production can involve several different contract manufacturers. Process development and process validation for Phase II/III clinical trials and marketing is currently ongoing.

> IdeS has so far proved to be even more effective than we expected. I am very convinced by IdeS efficacy. One hour after dosing the complement fixating antibodies completely disappeared.
>
> **Professor Gunnar Tufveson (MD, PhD)**
> Professor emeritus of Transplant Surgery at Uppsala University at Uppsala University Hospital.

IdeS 2nd generation

Hansa Medical is also developing new drug candidates related to IdeS with the ambition to create an IgG inactivating drug that can be used for repeated dosing. Repeated dosing is relevant in several IgG mediated autoimmune conditions. Hansa Medical has filed patent applications covering these molecules.



EndoS

EndoS is a secreted enzyme from *Streptococcus pyogenes* that specifically hydrolyzes the functionally important glycan in IgG. EndoS has proven effective in a range of autoimmune models including rheumatoid arthritis (RA), immune thrombocytopenic purpura (ITP), autoimmune hemolysis, multiple sclerosis (MS) and autoimmune blistering skin disorder. Given the importance of the IgG glycans in orchestrating the IgG's effector functions and the unique specificity of EndoS for these glycans, we believe that EndoS has potential as a novel therapy for antibody-mediated autoimmune diseases.

HBP-assay

The HBP-assay is a novel diagnostic method developed and patented by Hansa Medical to help predict severe sepsis in patients with infectious disease symptoms. Hundreds of thousands of patients die every year due to severe sepsis as a complication to infections like urinary tract infection and pneumonia. 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. A seemingly stable patient with an infectious disease can within hours develop severe sepsis as manifested through clinical symptoms like organ failure and circulatory failure. Early prediction and treatment of risk patients is key to prevent death from severe sepsis.

Results from the IMPRESSED study [5]

IMPRESSED, *IMproved PREdiction of Severe Sepsis in the Emergency Department*, is a completed prospective clinical multicenter trial involving 759 patients admitted to emergency departments in Sweden and the US with infectious disease symptoms. In the study, 674 patients were diagnosed with an infection, of which 487 did not have organ dysfunction at enrollment. Of these 487 patients, 141 (29 %) developed severe sepsis within 72 hours. 78 % of these patients had elevated levels plasma-HBP prior to developing severe sepsis.

HBP outperformed those biomarkers available today for predicting severe sepsis including Procalcitonin, White blood cell count (WBC), CRP, Lactate. Samples from a Canadian validation cohort of 104 patients confirmed the results of the combined Sweden/US study. The diagnostic accuracy for HBP in predicting severe sepsis in the Canadian cohort was even higher than in the Sweden/US cohort. The sensitivity was 78 % and the specificity was 95 % in predicting severe sepsis among infected patients in the Canadian cohort.

Commercial development of HBP-assay

Hansa Medical's development partner Axis-Shield Diagnostics is the global developer of the HBP testing market. In order to further strengthen the clinical validity of HBP-assay, Axis-Shield is currently coordinating additional clinical trials with HBP-assay in the US, Europe, China, South Korea and India. In addition, Axis-Shield is also developing upgraded versions of the HBP-assay for improved routine clinical applicability. Hansa Medical carries rights to royalties from Axis-Shield derived from sales and sublicensing of the HBP-assay as well as milestones payments.

The importance of transplantation – a personal perspective

I have first-hand knowledge of what it is like to live for a long period of time waiting for a new kidney. Therefore, also on a personal level, I feel strongly for what we try to achieve at Hansa Medical.

In November 2009, I was told I needed a new kidney. I was put on the strict, tiresome and time-consuming regime of renal care. It then took another four years to find the right donor and for me to be able to have a transplantation. Renal care affects your daily life in many ways; it limits your movements, it requires five-six hours at the hospital every other day, and it has many physical and psychological consequences.

Two years ago, I was successfully transplanted and feel like a whole human being again.

Consequently, I believe that our research around IdeS is so important. Ultimately, when we hopefully have a product on the market, this development has the potential to be of tremendous importance to hundreds of thousands of people around the world who are in the same precarious position as I was.

Göran Arvidson, President and CEO

Intellectual property

The Hansa Medical patent portfolio currently consists of eleven separate patent families plus an exclusive license on one additional patent family.

The IdeS project is protected by six patent families, which include both granted patents, as well as pending patent applications. These families cover the use of isolated IdeS to create antibody fragments, the medical use of IdeS in IgG mediated medical conditions including prevention and treatment of transplant rejection and autoimmune disease, dosing regimens in combination with other treatments such as transplantation as well as of new versions of IdeS. Geographically, these patent families cover a large number of jurisdictions including the United States, Europe and Japan. The various IdeS patent families expire between 2021 and 2035, with the possibility for up to 5 years of supplemental protection.

HBP-assay is protected by three different patent families, which are including both granted, and pending patents. These families cover the prediction of severe sepsis, the diagnosis of bacterial meningitis and diagnosis of urinary tract infections. Geographically, these patent families cover a large number of countries and they expire between 2027 and 2031, with the possibility for up to 5 years of supplemental protection.

Various applications for EndoS are protected by three different patent families that include both granted patents and pending patent applications. Geographically, these patent families cover a large number of countries and they expire between 2027 and 2031, with the possibility for up to 5 years of supplemental protection.

Shareholder information

The Hansa Medical share is listed on Nasdaq OMX Stockholm, under the ticker HMED and included in both the OMX Nordic Small Cap and Health Care sector index.

Brief facts, the HMED share

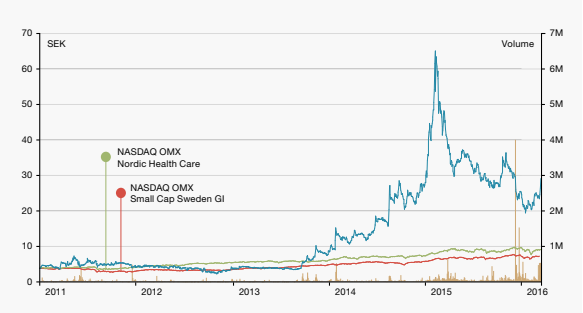
Listing	Nasdaq OMX Stockholm
Number of shares	32,412,003
Market capitalization (160329)	MSEK 972
Ticker	HMED
ISIN	SE0002148817

Share capital

Total shares outstanding as of 31 December 2015 amounted to 32,412,003 ordinary shares. At year end the share capital amouted to SEK 32,412,003. 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.

In 2015, the company's employees acquired a total of 296,000 warrants and each warrant entitles the holder to subscribe for one new share in Hansa Medical. Subscription for shares may take place during the period from June 15, 2018, to June 15, 2019. Upon full exercise of the share warrants, the share capital will increase with SEK 296,000, corresponding to a dilution of approximately 0.9 percent.

HMED share price and trading volume 2011–March 2016



Closing price for the HMED share in 2014 and 2015

	2014		2015	
SEK	High	Low	High	Low
1st quarter	16.3	9.3	66.8	29.5
2nd quarter	19.5	12.2	38.3	29.7
3rd quarter	30.0	16.5	33.5	26.4
4th quarter	29.0	22.1	36.3	23.1

Shareholder categories, December 31, 2015

	Percentage of shares
Swedish legal entities	51.4
Swedish private persons	22.4
Foreign shareholders	14.0
Financial institutions	12.3

Shareholders

The number of shareholders at year-end totalled 3,050 (1,198). The holding of the largest shareholder, Nexttobe AB, remained unchanged at 29.1 percent. Swedish legal entities, including institutions and funds, owned 63.7 percent of the shares at year-end. There were several additions to the list of the 15 largest shareholders as of March 11, 2016 including Gladiator, Tredje AP-fonden, Handelsbanken Fonder, Catella and Rhenman Healthcare Equity L/S.

Largest shareholders, December 31, 2015

Name	Number of shares	Percentage (%)
Nexttobe AB	9,443,761	29.1
Fam Håkansson, incl. Farstorps Gård AB	5,350,182	16.5
Försäkringsaktiebolaget, Avanza Pension	2,271,847	7.0
Handelsbanken Fonder AB	1,114,913	3.4
Rhenman Healthcare Equity L/S	822,367	2.5
JP Morgan Bank Luxembourg	560,631	1.7
Shaps Capital AB	557,000	1.7
Banque Carnegie Luxembourg SA	505,000	1.6
SEB Enskilda	485,969	1.5
Sandberg, Sven	476,278	1.5
Nordnet Pensionsförsäkring AB	398,862	1.2
Gladiator	340,000	1.1
Ellesson Ljunggren, Anja	325,228	1.0
Aktiebolaget Protiga	250,000	0.8
SSE Opportunities Ltd.	246,904	0.8
Other	9,263,061	28.6
Total	**32,412,003**	**100.0**

Largest shareholders, March 11, 2016

Name	Number of shares	Percentage (%)
Nexttobe AB	9,443,761	29.1
Gladiator	2,490,000	7.7
Tredje AP-fonden	1,400,000	4.3
Försäkringsaktiebolaget, Avanza Pension	1,112,777	3.4
Fam Håkansson, incl. Farstorps Gård AB	1,084,070	3.3
Handelsbanken Fonder AB	1,062,316	3.3
Catella Småbolagsfond	1,000,000	3.1
Rhenman Healthcare Equity L/S	822,367	2.5
Skandinaviska Enskilda Banken S.A.	628,578	1.9
JP Morgan Bank Luxembourg	560,631	1.7
Banque Carnegie Luxembourg SA	505,000	1.6
SEB Life International	500,000	1.5
Sandberg, Sven	488,278	1.5
Nordnet Pensionsförsäkring AB	435,018	1.3
Tamt AB	400,000	1.2
Ellesson Ljunggren, Anja	325,228	1.0
Shaps Capital AB	293,990	0.9
Other	9,859,989	30.4
Total	**32,412,003**	**100.0**

Market maker

Hansa Medical has a market maker agreement with Erik Penser Bankaktiebolag since March 25, 2013 for promoting liquidity and reduce spread between ask and bid prices in the HMED share.

Four-year summary

KSEK, unless otherwise stated	2012	2013	2014	2015
Profit number				
Total operating income	2,619	1,727	4,775	7,155
Operating profit/loss	-16,798	-17,629	-24,709	-66,201
Net profit/loss	-16,468	-17,562	-29,042	-66,266
Capital				
Total assets	63,345	50,614	54,311	224,088
Capital employed	60,789	46,036	49,934	211,617
Equity	60,585	45,349	49,804	211,526
Investments (intangible and tangible fixed assets)	2,707	64	1,204	1,317
Cash and cash equivalents	18,966	90	10,152	175,683
Cash flow				
Cash flow from operations before change in working capital	-16,278	-17,520	-23,522	-64,894
Cash flow from operating activities	-17,899	-14,830	-23,623	-57,799
Cash flow from investing activities	-6,559	-4,529	-1,319	-2,796
Cash flow from financing activities	42,267	483	35,004	226,126
Net change in cash	17,809	-18,876	10,062	165,531
Key ratios				
Return on capital employed (%)	-28	-38	-49	-31
Return on equity (%)	-35	-33	-61	-51
Equity ratio (%)	96	90	92	94
Debt/Equity ratio (%)	5	12	9	6
Share overview				
Earnings/loss per share (SEK)	-0.75	-0.75	-1.09	-2.13
Shareholders' equity per share (SEK)	2.73	2.04	1.92	6.53
Dividend (SEK)	0	0	0	0

Directors' report

Operations

Hansa Medical is a biopharmaceutical company focusing on novel immunomodulatory enzymes. The lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. IdeS is currently in clinical Phase II studies in Sweden and the US.

Additional projects focus on development of new antibody modulating enzymes, as well as HBP, a diagnostic biomarker for prediction of severe sepsis at emergency departments that is already introduced on the market. Hansa Medical had 19 employees at the end of the year and is based in Lund, Sweden. Hansa Medical's share (ticker: HMED) is listed on Nasdaq OMX Stockholm.

Business Review January – December 2015

Data from Hansa Medical's first Phase II study of IdeS in sensitized kidney transplantation patients presented in oral session at ESOT 2015

Principal investigator, Dr. Tomas Lorant from Uppsala University Hospital, presented data from the first completed Phase II study of IdeS in sensitized patients at the 17th Congress of the European Society for Organ Transplantation (ESOT) in Brussels. Data from the Hansa Medical sponsored study showed that IdeS can effectively reduce anti-HLA antibodies to levels acceptable for transplantation. Both the primary and secondary objectives of the study were met, and IdeS has an acceptable safety profile. Even though it was not an objective of the study, one patient with donor specific antibodies who was on a waiting list for kidney transplant was subsequently successfully transplanted after having received two doses of IdeS. Stable graft function has been maintained to date (19 months) with normal creatinine and no rejection episodes.

Development of a new generation of IdeS molecules for repeat dosing announced

In 2015, Hansa Medical announced the ongoing development of a new generation of molecules based on IdeS that will have the potential of repeat dosing and thereby broadening the therapeutic opportunities into more chronic disease areas. The new generation IdeS molecules reduces anti-drug antibody binding and has reduced immunogenicity as well as increased specific activity.

Hansa Medical established a US medical advisory board

Hansa Medical established a US medical advisory board for IdeS in kidney transplantation with world leading experts in desensitization and transplantation. The board will assist the company in developing IdeS within transplantation in sensitized patients. The US medical advisory board consists of Professor Stanley Jordan (chairman) at Cedars-Sinai Medical Center, Los Angeles, Professor Robert Montgomery, Johns Hopkins Medicine, Baltimore and Professor Kathryn Wood, University of Oxford.

IdeS Phase II study initiated at Uppsala University Hospital and Karolinska University Hospital

A second Phase II study with IdeS was initiated at Uppsala University Hospital and Karolinska University Hospital in Huddinge. The study will evaluate the safety, tolerability and efficacy of IdeS in kidney transplantation of sensitized patients. Up to 10 patients will be included in the study. All patients will undergo kidney transplantation and it is expected that all patients will be included in the study by the first half of 2016.

Positive IdeS Phase I data published in scientific journal PLOS ONE [1]

The Phase I trial was a first-in-man, double blind, randomized study with single-ascending doses of IdeS in 29 healthy subjects who were given intravenous doses of placebo or IdeS. Treatment with IdeS was considered safe with no serious adverse events. Full or close to full effect on IgG was seen in all subjects in the two highest dose groups.

First patient treated and transplanted with IdeS in US Phase II study at Cedars-Sinai Medical Center, Los Angeles

The first patient in an investigator-sponsored Phase II clinical study at Cedars-Sinai Medical Center in Los Angeles, California, was treated with IdeS and subsequently transplanted. The study is an open-label study to assess the safety and efficacy of IdeS in eliminating donor specific antibodies in highly sensitized patients. The study will include 10-20 highly sensitized patients. At Hansa Medical's Capital Markets Day in Stockholm on November 13, 2015, principle investigator Professor Stanley Jordan, presented data regarding the first patient included in the study. The data showed that the patient had been successfully desensitized with IdeS and subsequently transplanted.

Hansa Medical received FDA Orphan Drug Designation for IdeS

The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to IdeS for the prevention of antibody mediated organ rejection in patients undergoing solid organ transplant patients. Approximately 30 percent of the patients on the waiting lists for kidney, heart, lung and pancreas, equivalent to approximately 35,000 patients in the US, are sensitized to Human Leukocyte Antigen (HLA).

Data published in Journal of Immunology showed that IdeS can silence memory B-cells [6]

The scientific article entitled "The bacterial enzyme IdeS cleaves the IgG-type of B-cell receptor, abolishes BCR-mediated cell signaling and inhibits memory B-cell activation", by Järnum et al., shows that IdeS not only inactivates plasma IgG but also cleaves IgG present on B-cells. The IdeS-treated cells are temporarily silenced and prevented from developing into antibody producing cells. In transplantation, a delay in the activation of memory B-cells and production of IgG could help the organ to accommodate in its new host. Furthermore, the concept indicates therapeutic possibilities not only in transplantation but also in other situations where a memory B-cell response must be prevented or delayed.

Results from a clinical multicenter trial with HBP-assay published in Critical Care Medicine [5]

Results from a clinical multicenter trial with samples from Emergency Departments in Sweden, the US and Canada collected

during 2011-2014 was published by the scientific journal Critical Care Medicine. The study results showed that the diagnostic method for assessing Heparin Binding Protein (HBP) predicts severe sepsis with significantly higher accuracy than other biomarkers available today. The study demonstrates that the HBP-assay has the potential to become a significant tool in helping predicting severe sepsis at emergency departments and infectious disease clinics.

Hansa Medical secured MSEK 246 in funding through a fully subscribed rights issue
Hansa Medical raised MSEK 246 before emission costs, through a fully subscribed rights issue with preferential rights. The rights issue comprised of 6,482,400 shares at SEK 38 per share. The proceeds will enable Hansa Medical to bring the candidate drug IdeS into several clinical Phase II trials as well as preparing the IdeS production process for clinical pivotal studies and product launch.

Göran Arvidson appointed new President and CEO of Hansa Medical
Göran Arvidson was appointed President and CEO of the company, effective from April 30, 2015. Göran Arvidson has significant experience from the life science industry. Göran's previous positions include Executive Vice President and CFO of Swedish Orphan Biovitrum AB (publ), co-founder and CFO of Biovitrum, as well as several senior positions in corporate development and finance with Pharmacia AB and Procordia AB.

Risk management

Hansa Medical is committed to having an effective Risk management process. Risk management is recognized as an integral part of good management practice and is a basis for the company to achieve its objectives and strategies. Hansa Medical´s risk management policy was launched in 2015 and provides Management with a facilitating framework providing guidance when dealing with risks inherent in achieving the organization's objectives and to:

- Establish a common organizational approach to Risk management in order to ensure consistent and efficient risk identification, assessment and control.
- Raise awareness of the need for Risk management.
- Integrate Risk management into the company culture and processes.
- Establish defined roles, responsibilities and reporting structures for Risk management.
- The Risk Management Committee reports quarterly to the Executive Management Team and the Board.

Risk factors

Hansa Medical's business is influenced by a number of factors, the effects of which on the company's earnings and financial position, in certain respects, cannot be controlled by the company at all or in part. In an assessment of the company's future development, it is important, alongside the possibilities for growth in earnings, to also consider these risks. Set forth below is a description, without any internal order of priority, of the risks which are considered to have greatest significance for the company's future development. For natural reasons, not all of the risk factors can be described. Instead, the risks which are specific to the company or the industry are set forth here. An overall assessment must also include other information contained in the annual report as well as an overall assessment of extraneous factors in general.

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

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

Collaboration and partnerships
Hansa Medical is involved in the research and development of pharmaceuticals and, for many years, has cooperated with well-established researchers with whom the company has had long-term relationships. However, some of these cooperation projects are governed by agreements with terms of only one year each time. Were these agreements to terminate or not be renewed, it might have negative consequences both for the company's business operations as well as its earnings and financial position.
The company has an exclusive licensing agreement with Axis-Shield Diagnostics Ltd. and is dependent on this cooperation functioning properly for the sale and further development of HBP-assay. If the company is unable to maintain this, it might prejudice the company's business and earnings.

Intellectual property issues
The value of Hansa Medical 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.

Concentration of products
The value of the company is primarily dependent on success in the company's leading development project, IdeS, but also to a certain extent on the future sales of HBP-assay under the management of the licensee Axis-Shield. The market value of the company, and thus the company's share price, would be prejudiced by setbacks for IdeS and HBP-assay.

Market and competition
The industry for the development of new pharmaceuticals and diagnostic methods is heavily exposed to competition. Developing a new pharmaceutical from invention to finished product requires a great deal of 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 Medical's success is dependent on its ability to induce potential customers to replace known products or methods with those of Hansa Medical. Another risk is that competitors, who in many cases have greater resources than the company, will develop alternative preparations which are more effective, more secure, or cheaper than those offered by Hansa Medical. 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 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 Medical is, to a high degree, dependent on key persons, both employees as well as directors. The company's future earnings are affected by its ability to attract and retain qualified key persons. In cases where one or more key persons leave the company and the company is not successful in replacing such person, this might have a negative effect on the company's business, financial position and earnings.

Financial risks
Hansa Medical carries out capital-intensive and value-generating pharmaceuticals and diagnostics development. Future financing of the operations is expected to take place through new issues of shares, loans, licensing revenues, cooperation with other parties, and the sales of rights or patents. Hansa Medical has financed its business operations thus far partially with the help of milestone compensation and one-time compensation amounts from the company's current and previous cooperating partners and with royalty revenues from licensing agreements. However, the operations have mostly been financed with shareholders' equity through new issues of shares, primarily rights issues to the shareholders. Debt financing is not considered to be an appropriate form of financing, other than temporarily, until the company has achieved profitability and positive cash flow. For further description of the company's financial risks, see note 23.

Environmental work
Hansa Medical 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 Medical uses genetically modified micro-organisms (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.

Financial Review

Net revenue
Net revenue during the 2015 financial year amounted to MSEK 5.4 (1.6) and comprised of licensing and royalty income from Axis-Shield Diagnostics.

Operating result for the 2015 financial year amounted to MSEK -66.2 (-24.7). The 2015 result was negatively impacted by increased activity level with the start of clinical studies and CMC development together with the continued expansion of the organization, but also non-recurring costs amounting to approx. MSEK 10.8. The non-recurring costs are mainly classified as administrative expenses and include costs for the listing on Nasdaq OMX, bonus to the former CEO and one-time cash bonus when warrants were acquired by the company´s employees.

Net profit/loss for 2015 amounted to MSEK -66.3 (-29.0).

Cash flow and financial position
Cash flow from operating activities amounted to MSEK -57.8 (-23.6) for the 2015 financial year. The cash flow after financing was positively impacted by the rights issue in April and the proceeds from the sale of warrants to employees. Cash and cash equivalents amounted to MSEK 175.7 at the end of the 2015 financial year, as compared with MSEK 10.2 at the corresponding time in 2014.

Investments
Investments during the 2015 financial year amounted to MSEK 2.8 (1.3) Investments during 2015 related primarily to laboratory equipment and office fixtures in the amount of MSEK 1.3 and the acquisition of 1,464,376 shares in Genovis AB with an acquisition value of MSEK 1.5. In total, the company's holdings in Genovis AB amount

to 3,641,441 shares with an acquisition value of MSEK 9.9. Genovis AB is a biotechnology company focused on antibody modification with the help of the IdeS and EndoS enzymes. Genovis AB's applications of IdeS and EndoS are marketed under the trademarks FabRICATOR and IgGZERO. These products simplify the development and quality control of pharmaceuticals products. Hansa Medical and Genovis entered into a licensing agreement in 2007 which grants Genovis the right to commercialize the IdeS enzyme as a non-therapeutic research tool. Hansa Medical's investment in Genovis is a strategic investment in a biotechnology company which develops new and promising non-therapeutical applications of assets which are central to Hansa Medical's operations: the IdeS and EndoS enzymes.

Equity
On December 31, 2015, equity amounted to MSEK 211.5 compared with MSEK 49.8 at the end of the financial year 2014.

Rights issue 2015
In the second quarter, Hansa Medical finalized a fully subscribed rights issue with preferential rights for existing shareholders. The rights issue raised MSEK 246.3 before deduction of costs. The rights issue comprised of 6,482,400 at SEK 38 per share. The number of outstanding shares amounts to 32,412,003 shares after the rights issue. The proceeds will enable Hansa Medical to bring the candidate drug IdeS into several clinical Phase II trials as well as to prepare the IdeS production process for clinical pivotal studies.

Parent company
The Parent company's net revenue for the 2015 financial year amounted to MSEK 5.4 (1.6). Result after net financial items for the Parent company amounted to MSEK -64.6 (-31.4) for the 2015 financial year. On December 31, 2015, cash and cash equivalents amounted to MSEK 173.8 compared with MSEK 10.2 at the end of 2014.

The Parent company's equity amounted to MSEK 211.5 as per December 31, 2015, as compared with MSEK 49.8 at the end of 2014.

The Group consists of the parent company Hansa Medical AB and the subsidiary Cartela R&D AB, in which no business is currently conducted.

Group – Key ratios and other information

	1 January – 31 December	
KSEK, unless otherwise stated	2015	2014
Profit numbers		
Total operating income	7,155	4,775
Operating profit/loss	-66,201	-24,709
Net profit/loss	-66,266	-29,042
Per share data		
Earnings/loss per share before and after dilution (SEK)	-2.13	-1.09
Shareholders' equity per share (SEK)	6.53	1.92
Other information		
Shareholders' equity	211,526	49,804
Equity ratio (%)	94	92
Cash flow from operating activities	-57,799	-23,623
Cash and cash equivalents	175,683	10,152
Number of employees end of the year	19	14

Organization and employees

At the close of 2015, the Board of Directors consisted of the chairman Birgit Stattin Norinder and directors Anders Blom, Stina Gestrelius, Per Olof Wallström, Cindy Wong and Hans Schikan. The board's audit committee consisted of Anders Blom (chairman), Birgit Stattin Norinder and Per-Olof Wallström. The remuneration committee consisted of Birgit Stattin Norinder (chairman), Stina Gestrelius and Per-Olof Wallström and the scientific committee consisted of Lars Björck (chairman), Hans Wigzell, Stina Gestrelius, Birgit Stattin Norinder and Cindy Wong.

Corporate management consists of the CEO Göran Arvidson, CFO Eva-Maria Joed, CSO Christian Kjellman, CRD Lena Winstedt, Director, Corporate Development and Investor Relations Emanuel Björne and CMO Steven Glazer. There were 19 employees at the end of 2015 as compared with 14 employees at the end of 2014.

Share warrant program

A total of 296,000 warrants were acquired by the company's employees under the warrant program that Hansa Medical's Annual General Meeting adopted on June 2, 2015. Each warrant entitles the holder to subscribe for one new share in Hansa Medical. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 15, 2018, and 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 value has been set at SEK 8.40 per option based on a share price of SEK 36.04 with a future annual increase of 7 percent. The increase in the company's share capital upon full exercise of the share warrants will amount to SEK 296,000, and corresponds to a dilution of approximately 0.9 percent of the total number of shares and the total number of votes in the company.

The option program is subsidized by the company, and the employees, except the 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.

Other information

For additional information, please see the Corporate governance report.

Annual general meeting 2016

The annual general meeting of Hansa Medical AB (publ) will take place on 11 May 2016 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 Medical's website at www.hansamedical.com.

Events after the balance sheet date

There were no significant events after the balance date.

Financial calendar

Interim report for January–March 2016	April 27, 2016
Annual General Meeting	May 11, 2016
Interim report for January–June 2016	July 21, 2016
Interim report for January–September 2016	November 10, 2016

Proposal for dividend

Unrestricted shareholders' equity in the parent company

SEK	
Share premium reserve	253,218,480
Profit carried forward	-9,459,840
Result for the year	-64,623,101
Total	**179,135,539**

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

SEK	
Share premium reserve	179,135,539
Profit carried forward	–
Total	**179,135,539**

The group's and the company's results and financial position are shown in the following income statements, balance sheets, cash flow statements and statements of shareholders' equity and accompanying notes and supplementary information, which are an integral part of these financial statements.

Address

Hansa Medical 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

Income statement

		1 January – 31 December	
KSEK	Note	2015	2014
Net revenue	2, 3	5,434	1,618
Other operating income		1,721	3,157
Total operating income		**7,155**	**4,775**
Direct cost of net revenue		-658	–
Gross profit		**6,497**	**4,775**
Sales, general and administration expense		-28,241	-7,609
Research and development expenses		-44,262	-21,742
Other operating expenses		-195	-133
Operating profit/loss	4, 5, 6, 24	**-66,201**	**-24,709**
Financial income		–	42
Financial expenses		-65	-4,375
Net financial income/expenses	7	**-65**	**-4,333**
Result before tax		**-66,266**	**-29,042**
Tax	8		
Result for the year		**-66,266**	**-29,042**
Attributable to			
Parent company shareholders		-66,266	-29,042
Earnings per share	9		
Before dilution (SEK)		-2.13	-1.09
After dilution (SEK)		-2.13	-1.09

Statement of comprehensive income

		1 January – 31 December	
KSEK	Note	2015	2014
Result for the year		-66,266	-29,042
Other comprehensive income			
Items that have been, or may be reclassified to profit or loss for the year			
Fair value changes for the year on financial assets which can be sold		1,624	-2,064
Other comprehensive income for the year		**1,624**	**-2,064**
Comprehensive income for the year		**-64,642**	**-31,106**
Total net comprehensive income attributable to			
The parent company's owners		-64,642	-31,106
		-64,642	**-31,106**

Balance sheet

KSEK	Note	As of 31 December 2015	2014
ASSETS			
Fixed assets			
Intangible fixed assets	10	36,327	36,898
Tangible fixed assets	11	2,182	1,283
Financial fixed assets	13	7,283	4,180
Total fixed assets		**45,792**	**42,361**
Current assets			
Tax receivable		108	292
Accounts receivable	16	625	59
Prepaid expenses and accrued income	17	368	373
Other receivables	15	1,512	1,074
Cash and cash equivalents	18	175,683	10,152
Total current assets		**178,296**	**11,950**
TOTAL ASSETS		**224,088**	**54,311**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	19		
Share capital		32,412	25,930
Other paid in capital		253,218	33,336
Reserves		1,624	–
Retained earnings including result for the year		-75,728	-9,462
Shareholders' equity attributable to parent company shareholders		**211,526**	**49,804**
Total shareholders' equity		**211,526**	**49,804**
Liabilities			
Long-term interest bearing liabilities	20	49	91
Total long-term liabilities		**49**	**91**
Current interest-bearing liabilities	20	42	39
Accounts payable		1,000	1,795
Other liabilities	21	1,294	1,039
Accrued expenses and deferred income	22	10,177	1,543
Total current liabilities		**12,513**	**4,416**
Total liabilities		**12,562**	**4,507**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**224,088**	**54,311**

Information regarding the group's pledged assets and contingent liabilities, see note 25.

Changes in equity

		Equity attributable to the parent company's shareholders					
KSEK	Note	Share capital	Additional paid in capital	Fair value reserve	Retained earnings incl. profit or loss for the year	Total	Total shareholders' equity
Opening shareholders' equity, 1 Jan 2014	19	22,225	1,480	2,064	19,580	45,349	45,349
Net comprehensive income							
Result for the year					-29,042	-29,042	-29,042
Other comprehensive income for the year				-2,064		-2,064	-2,064
Net comprehensive income		**0**	**0**	**-2,064**	**-29,042**	**-31,106**	**-31,106**
Transactions with the group's owner							
New share issue		3,705	33,337			37,042	37,042
Expenses attributable to new share issue			-1,481			-1,481	-1,481
Total transactions with the group's owner		**3,705**	**31,856**	**0**	**0**	**35,561**	**35,561**
Closing shareholders' equity, 31 Dec 2014		**25,930**	**33,336**	**0**	**-9,462**	**49,804**	**49,804**

		Equity attributable to the parent company's shareholders					
KSEK	Note	Share capital	Additional paid in capital	Fair value reserve	Retained earnings incl. profit or loss for the year	Total	Total shareholders' equity
Opening shareholders' equity, 1 Jan 2015	19	25,930	33,336		-9,462	49,804	49,804
Net comprehensive income							
Result for the year					-66,266	-66,266	-66,266
Other comprehensive income for the year				1,624		1,624	1,624
Net comprehensive income				**1,624**	**-66,266**	**-64,642**	**-64,642**
Transactions with the group's owner							
New share issue		6,482	239,849			246,331	246,331
Expenses attributable to new share issue			-21,999			-21,999	-21,999
Issued warrants			2,032			2,032	2,032
Total transactions with the group's owner		**6,482**	**219,882**	**0**	**0**	**226,364**	**226,364**
Closing shareholders' equity, 31 Dec 2015		**32,412**	**253,218**	**1,624**	**-75,728**	**211,526**	**211,526**

Cash flow statement

		1 January – 31 December	
KSEK	Note	2015	2014
Operating activities	28		
Operating income		-66,201	-24,709
Adjustment for items not included in cash flow		1,188	1,349
Interest received		–	42
Interest paid		-65	-123
Income tax paid		184	-81
Cash flow from operating activities before changes in working capital		**-64,894**	**-23,522**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) of accounts receivable		-566	-59
Increase (-)/Decrease (+) of other operating receivables		-433	159
Increase (+)/Decrease (-) of accounts payable		-795	1,085
Increase (+)/Decrease (-) of other operating liabilities		8,889	-1,286
Cash flow from operating activities		**-57,799**	**-23,623**
Investing activities			
Acquisition of tangible fixed assets		-1,317	-1,204
Acquisition of financial assets		-1,479	-115
Cash flow from investing activities		**-2,796**	**-1,319**
Financing activities			
New share issue		246,331	37,042
Issue expenses		-21,999	-1,481
Issued warrants		1,833	–
Repayment of loans		–	-519
Repayment of leasing liabilities		-39	-38
Cash flow from financing activities		**226,126**	**35,004**
Net change in cash		165,531	10,062
Cash and cash equivalents, beginning of year		10,152	90
Cash and cash equivalents, year-end		**175,683**	**10,152**

The parent company

Income statement

		1 January – 31 December	
KSEK	Note	2015	2014
Net revenue	2, 3	5,434	1,618
Other operating income		1,721	3,157
Total operating income		**7,155**	**4,775**
Direct cost of net revenue		-658	–
Gross profit		6,497	4,775
Sales, general and administration expenses		-28,228	-7,615
Research and development expenses		-44,262	-21,742
Other operating expenses		-195	-133
Operating profit/loss	4, 5, 24	**-66,188**	**-24,715**
Result from financial items:			
Result from participating interests in group companies		–	-2,398
Result from other securities and receivables which are fixed assets		1,624	-4,252
Other interest income and similar profit/loss items		–	42
Interest expenses and similar profit/loss items		-59	-115
Result after financial items	7	**-64,623**	**-31,438**
Result before tax		-64,623	-31,438
Tax	8	–	–
Net result		**-64,623**	**-31,438**

Statement of comprehensive income

		1 January – 31 December	
KSEK	Note	2015	2014
Net result		-64,623	-31,438
Other comprehensive income		–	–
Other net comprehensive income		**–**	**–**
Net comprehensive income		**-64,623**	**-31,438**

Balance sheet

KSEK	Note	As of 31 December 2015	2014
ASSETS			
Fixed assets			
Intangible fixed assets	10	36,327	36,898
Tangible fixed assets	11	2,110	1,155
Financial fixed assets			
Interests in group companies	27	1,933	100
Other long-term holdings of securities	14	7,283	4,180
Total financial fixed assets		9,216	4,280
Total fixed assets		**47,653**	**42,333**
Current assets			
Current receivables			
Accounts receivable	16	625	59
Tax receivable		107	292
Other receivables	15	1,512	1,074
Prepaid expenses and accrued income	17	368	373
Total current receivables		2,612	1,798
Cash and cash equivalents		173,850	10,152
Total current assets		**176,462**	**11,950**
TOTAL ASSETS		**224,115**	**54,283**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	19		
Restricted equity			
Share capital		32,412	25,930
Unrestricted shareholders' equity			
Share premium reserve		253,218	33,336
Retained earnings		-9,460	21,978
Net result		-64,623	-31,438
Total shareholders' equity		**211,547**	**49,806**
Current liabilities			
Accounts payable		1,000	1,795
Liabilities to group companies		98	100
Other liabilities	21	1,293	1,039
Accrued expenses and deferred income	22	10,177	1,543
Total current liabilities		**12,568**	**4,477**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**224,115**	**54,283**

Pledged assets and contingent liabilities of the parent company

KSEK	Note	As of 31 December 2015	2014
Pledged assets		None	None
Contingent liabilities		None	None

Changes in equity

	Restricted equity	Unrestricted equity			
KSEK	Share capital	Share premium reserve	Retained earnings	Result for the year	Total share-holders' equity
Opening shareholders' equity, 1 Jan 2014	22,225	1,480	39,538	-17,560	45,683
Net comprehensive income					
Result for the year				-31,438	-31,438
Other comprehensive income for the year					0
Net comprehensive income	**0**	**0**	**0**	**-31,438**	**-31,438**
Appropriation of profits			-17,560	17,560	0
New share issue	3,705	33,337			37,042
Costs attributable to new share issue		-1,481			-1,481
Closing shareholders' equity, 31 Dec 2014	**25,930**	**33,336**	**21,978**	**-31,438**	**49,806**

	Restricted equity	Unrestricted equity			
KSEK	Share capital	Share premium reserve	Retained earnings	Result for the year	Total share-holders' equity
Opening shareholders' equity, 1 Jan 2015	25,930	33,336	21,978	-31,438	49,806
Net comprehensive income					0
Result for the year				-64,623	-64,623
Other comprehensive income for the year					0
Net comprehensive income	**0**	**0**	**0**	**-64,623**	**-64,623**
Appropriation of profits			-31,438	31,438	0
New share issue	6,482	239,849			246,331
Costs attributable to new share issue		-21,999			-21,999
Issued warrants		2,032			2,032
Closing shareholders' equity, 31 Dec 2015	**32,412**	**253,218**	**-9,460**	**-64,623**	**211,547**

Cash flow statement

		1 January – 31 December	
KSEK	Note	2015	2014
Operating activities	28		
Operating income		-66,188	-24,715
Adjustment for items not included in cash flow		1,132	1,294
Interest received		–	42
Interest paid		-59	-115
Income taxes paid		185	-81
Cash flow from operating activities before changes in working capital		**-64,930**	**-23,575**
Cash flow from changes to working capital			
Increase (-)/Decrease (+) of accounts receivable		-566	-59
Increase (-)/Decrease (+) of other operating receivables		-433	176
Increase (+)/Decrease (-) of accounts payable		-795	1,085
Increase (+)/Decrease (-) of other operating liabilities		8,888	-1,286
Cash flow from operating activities		**-57,836**	**-23,659**
Investing activities			
Acquisition of tangible fixed assets		-1,317	-1,204
Acquisition of financial assets		-1,479	-117
Cash flow from investing activities		**-2,796**	**-1,321**
Financing activities			
New share issue		246,331	37,042
Issue expenses		-21,999	-1,481
Repayment of loans		-2	-519
Cash flow from financing activities		**224,330**	**35,042**
Net change in cash		163,698	10,062
Cash and cash equivalents, beginning of year		10,152	90
Cash and cash equivalents, year-end		**173,850**	**10,152**

Notes

Note 1 Material accounting principles

(a) Compliance with norms and legislation
The consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) as adopted by the EU. In addition, recommendation RFR 1 issued by the Swedish Financial Reporting Board (Supplemental Accounting Rules for Corporate Groups) has been applied. The parent company applies the same accounting principles as the group with the exception of those cases set forth below under the section entitled "The parent company's accounting principles".

(b) Valuation grounds applied in the preparation of the financial reports
Assets and liabilities are reported at the historical acquisition values, with the exception of certain financial assets and liabilities which are valued at net realizable value. Financial assets and liabilities valued at net realizable value consist of shares listed on an exchange.

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

(d) Assessments and estimates in the financial reports
Preparing the financial reports in accordance with IFRS requires that corporate management make assessments, estimates and assumptions which impact the application of the accounting principles and the reported amounts of assets, liabilities, revenues and costs. Actual results may deviate from these estimates and assessments.

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

(e) Changes in accounting principles
(i) Changes in accounting principles due to new or amended IFRS
The amendments to IFRS applicable with effect from from January 1, 2015 have no material effect on the consolidated accounts.

(ii) New IFRS which have not yet begun to be applied
A number of new or amended standards and interpretations in the IFRS do not enter into force until the next financial year and have not been applied prematurely in conjunction with the preparation of these financial statements. New items or changes with a future application are not planned to be implemented prematurely. No changes in the IFRS with a future application are considered to have any material effect on the group's reporting.

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

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

(h) Consolidation principles
Subsidiaries are companies under the controlling influence of Hansa Medical AB. Intra-group receivables and liabilities, revenues or costs and unrealized profits or losses which arise from intra-group transactions between group companies are eliminated in their entirety in the preparation of the consolidated financial statements.

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

(j) Net sales
The group's reported net sales derive primarily from licensing and royalty revenues. Revenues are reported at the net realizable value of what has been, or will be, received. Revenues are reported to the extent it is probable that the economic advantages will be realized by the company and the revenues can be calculated in a reliable manner. Licensing compensation is reported as revenue when all contractual undertakings incumbent upon the group have been fulfilled.

(k) Leasing

(i) Operational leasing agreements

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

(ii) Financial leasing agreements

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

(l) Financial income and expenses

Financial income consists of interest income and other financial income. Financial expenses consist of interest expenses on loans, write-downs of financial assets, and other financial expenses.

(m) Taxes

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

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

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

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

(n) Financial instruments

Financial instruments which are reported in the balance sheet include, on the assets side, cash and equivalents, accounts receivable, other financial claims and listed shares. On the liability side, accounts payable, interest-bearing liabilities and other financial liabilities are reported.

(i) Reporting in, and deletion from, the balance sheet

A financial asset or financial liability is reported in financial statement when the company becomes a party according to the contract terms and conditions of the instrument. A receivable is reported when the company has performed and a contractual obligation exists for the counterparty to make payment, notwithstanding that an invoice has not yet been issued. Accounts receivable are reported in the balance sheet when an invoice has been issued. Liabilities are reported when the counterparty has performed and a contractual obligation exists to make payment, notwithstanding that an invoice has not yet been received. Accounts payable are reported when an invoice has been received.

A financial asset is deleted from the balance sheet when the rights in the agreement have been realized, lapsed, or the company loses control over them. This also applies for part of a financial asset. A financial liability is deleted from the balance sheet when the obligation set forth in the agreement has been performed or otherwise extinguished. This also applies to a part of a financial liability.

A financial asset and a financial liability are set off and reported at a net amount in the balance sheet only when there is a legal right to set off the sums and there is an intent to settle the items with a net amount, or to simultaneously realize the asset and settle the liability.

Acquisitions and sales of financial assets are reported on the transaction date. The transaction date is the date on which the company undertakes to acquire or sell the asset.

(ii) Classification and valuation

Financial instruments are initially reported at an acquisition value corresponding to the instrument's net realizable value plus any transaction costs for all financial instruments. A financial instrument is classified in the first reporting on the basis, among other things, of the purpose behind the acquisition of the instrument. The classification determines how the financial instrument is valued after the first reporting occasion as described below.

Cash and equivalents consist of cash and immediately available funds deposited with banks and corresponding institutions as well as short-term liquid investments with terms from the date of acquisition of less than three months which are only exposed to an insignificant risk of fluctuation in value.

Loan claims and accounts receivable

Loan claims and accounts receivable are financial assets which are not derivatives, and which have fixed or fixable payments, and are not listed on an active market. These assets are valued at the accrued acquisition value. The accrued acquisition value is determined based on the effective rate of interest which is calculated at the time of acquisition. Accounts receivable are reported at the sums at which they are anticipated to be collected, i.e. after deductions for doubtful receivables.

Realizable financial assets
The category "realizable financial assets" includes financial instruments which have not been classified in any other category or financial assets which the company initially chose to classify in this category. Only the group's holdings of listed shares are reported in this category.

Financial liabilities valued at accrued acquisition value
Loans as well as other financial liabilities, for example accounts payable, are included in this category. The liabilities are valued at the accrued acquisition value.

(o) Tangible fixed assets
Tangible fixed assets are reported by the group at acquisition value after deductions for accumulated depreciation and any write-downs. The acquisition value includes the purchase price and is utilized in accordance with the purpose of the acquisition. The accounting principles for write-downs are set forth below.

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

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

Anticipated useful life:

Office equipment, tools and fixtures and fittings	5 years

(p) Intangible fixed assets
Acquired intangible assets
Acquired intangible assets held by the group consists of patents and capitalized development expenses. These intangible assets are reported at the acquisition value minus accumulated depreciation and any impairment (see accounting principle (q)).

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

Capitalized development expenditures
Costs for research are immediately booked as an expense. Development costs directly related to the development of production processes which will probably be used for production of a pharmaceutical candidate for clinical studies and for market introduction of an approved pharmaceutical are booked as an asset. Costs regarding development projects (related to the design and testing of new or improved products) are booked as an intangible asset of the group to the extent these costs are anticipated to a high degree of certainty to generate future economic advantages. Other development costs are booked as expenses as they arise. Development costs which were previously booked as expenses are not booked as assets in subsequent periods.

Depreciation of capitalized development costs begins when the project is deemed completed, which either takes place by the group in-house or in conjunction with the licensing of patents or preparations in exchange for compensation, where continued development work is carried out by an independent party. Depreciation is carried out using the straight line method over the anticipated economic life cycle; however, for patents not longer than the remaining patent protection.

(q) Impairment
The group's reported assets are assessed on each balance sheet date in order to determine whether there is an indication of a need for a write-down. IAS 36 is applied regarding impairment of assets other than financial assets which are reported according to IAS 39.

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

(ii) Impairment of financial assets
On each reporting occasion, the company evaluates whether there is objective evidence that a financial asset or group of assets should be written down. Objective evidence consists of observable circumstances which have occurred and which have a negative impact on the possibility of recovering the acquisition value, as well as significant or extended reductions in the net realizable value of an investment in a financial investment classified as a realizable financial asset.

(iii) Reversal of impairment losses
Impairment of assets included in the area of application for IAS 36 is reversed if there is both an indication that the need for the impairment the longer exists and that there has been a change in the assumptions which formed the basis for the calculation of the recovery value. Impairment of goodwill are never reversed, however. A reversal is only made to the extent the reported value of the asset after reversal does not exceed the reported value which would have been reported, following a deduction for depreciation where relevant, if no write-down had been made. Impairment of loan claims and accounts receivable which are reported at the accrued acquisition value are reversed if the earlier reasons for the impairment no longer exist and where full payment by the customer is expected.

Impairment of the company's own capital instruments which are classified as realizable financial assets, and which were previously reported in the income statement, are not reversed in the income statement but in other comprehensive income instead. The written down value is the value from which subsequent re-evaluations are made, which is reported in other comprehensive income.

(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 no potential diluting common shares either for the current financial year for the comparison years. There is thus no dilution effect.

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

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

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

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

Differences between the group's and the parent company's accounting principles
The differences between the group's and the parent company's accounting principles are set forth below. The accounting principles set forth below for the parent company have been applied consistently to all periods presented in the parent company's financial statements.

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

Financial instruments
Due to the connection between reporting and taxation, the rules governing financial instruments and hedge reporting set forth in IAS 39 are not applied in the parent company as a legal entity.

Note 2 Breakdown of income

Income per significant category of income

	1 January – 31 December	
KSEK	2015	2014
Group		
Net revenue		
Royalty and licensing revenue	5,434	1,618
	5,434	**1,618**
Parent company		
Net revenue		
Royalty and licensing revenue	5,434	1,618
	5,434	**1,618**

Note 3 Operating segments

To a significant extent, Hansa Medical's business currently consists of research and development for production of pharmaceuticals. The company is of the opinion that this business, in its entirety, constitutes a single operating segment. All operations are conducted in Sweden and income is derived from Sweden and fixed assets are allocated to Sweden.

Note 4 Employees and personnel costs

Costs for employee remuneration

	1 January – 31 December	
KSEK	2015	2014
Group		
Salaries and remuneration, etc.	17,982	7,232
Pension costs, contribution plan	2,202	1,025
Social charges	5,248	1,518
	25,432	**9,775**

Average number of employees

	2015		2014	
	Number	of whom men	Number	of whom men
Parent company				
Sweden	16	40%	10	50%
Parent company total	16		10	
Group total	16	40%	10	50%

Breakdown of corporate management according to gender

	Share of women	
	2015-12-31	2014-12-31
Parent company		
Board of Directors	50%	60%
Other senior management	33%	33%
Total group		
Board of Directors	50%	60%
Other senior management	33%	33%

Salaries, other remuneration and employer payroll taxes

KSEK	2015	2014
Parent company		
Salaries and remuneration	17,982	7,232
Social charges	7,450	2,543
(of which, pension costs)	[1] (2,202)	[1] (1,025)

[1] Of the parent company's pension costs, KSEK 668 (484) relates to the Board of Directors and CEO. There is an outstanding pension obligation to the CEO of 480 KSEK.

Salaries and other remuneration broken down between directors, etc. and other employees

	2015		2014	
KSEK	Senior management	Other employees	Senior management	Other employees
Parent company				
Sweden	10,912	7,070	3,534	3,698
(of which commissions and similar remuneration)	(0)	(0)	(0)	(0)
Parent company total	10,912	7,070	3,534	3,698
(of which commissions and similar remuneration)	(0)	(0)	(0)	(0)
Group total	10,912		3,534	
(of which commissions and similar remuneration)	(0)		(0)	

Benefits for senior management

Remuneration to Board of Directors
Fees are payable to the chairman of the Board of Directors and other directors pursuant to a resolution adapted by the annual general meeting. The 2015 annual general meeting resolved that fees paid to directors for work during 2015 will be SEK 300,000 to the chairman of the Board of Directors and SEK 100,000 to each of the other directors, SEK 40,000 to the chairman and SEK 30,000 each to the other directors who are members of the Audit Committee, SEK 40,000 to the chairman and SEK 25,000 each to other directors who are members of the Remuneration Committee and with SEK 25,000 each to directors who are members of the Scientific Committe, however no fee is payable to Anders Blom. There are no contracts regarding severance compensation or other benefits for the chairman of the Board of Directors or other directors.

Remuneration to CEO
Remuneration
Remuneration is payable to the CEO in the form of a fixed salary and pension. The current CEO assumed office on 30 of April 2015. During 2015, the basic salary per month was SEK 200,000 for the current CEO and SEK 150,000 for the previous CEO. In addition to this, remuneration may be paid in the form of variable salary, severance compensation and non-monetary benefits. The variable salary shall be based on the achievement of quanitative and qualitative goals. In 2015 the remuneration paid to the current CEO was KSEK 1,600 and KSEK 3,750 to the previous CEO.

Notice of termination periods and severance compensation
Upon termination by the company or the CEO, a six month notice of termination period applies. Upon termination by the company the CEO shall be entitled to severance compensation corresponding to 12 times his/her monthly salary at the end of his/her employment. The above-stated also applies upon termination by the CEO where the grounds for termination are gross breach of contract by the company.

Pension remuneration
The employment contract for the CEO terminates without prior notice of termination at the time of the CEO's age of retirement. The company sets aside 30 % of the CEO's monthly salary on a monthly basis for the occupational pension insurance indicated by the CEO. In 2015, the cost premiums for the CEO was KSEK 668.

Remuneration paid to other members of group management
Remuneration
Remuneration is determined by the CEO following the approval of the chairman of the Board of Directors. Remuneration in 2015 members of group management other than CEO amounted to KSEK 4,745.

Notice of termination period and severance compensation
Other members of group management have three or six months' notice of termination upon termination by them or the company. Where applicable, the company shall observe the longer notice of termination period set forth in the Employment Protection Act. During their notice period, other members of group management are entitled to full salary and othere employment benefits. None of the other members of group managment are entitled to severance compensation.

Pension compensation
Other members of group management are entitled to retire as follows. Lena Winstedt's employment terminate at the age of 67 without any requirement of notice. Emanuel Björne's, Christian Kjellman's och Eva-Maria Joed's employments terminates at the age of 65 without any requirement of notice. However they are entitled to continue working until 67 years of age. Other members of group management, with the exception of CEO and Steven Glazer, are entitled to pension benefits in accordance with the company's insurance and pension policy.

Salaries and other remuneration, and other benefits paid to senior management, parent company 2015

KSEK	Base salary Directors' fees	Variable compensation	Other benefits	Pension costs	Total
Chairman of the Board of Directors Birgit Stattin-Norinder	365				365
Director Stina Gestrelius	130				130
Director Per-Olof Wallström	133				133
Director Hans Schikan	73				73
Director Cindy Wong	116				116
CEO current	1,600			480	2,080
CEO previous	1,050	2,700		188	3,938
Other senior management (5 persons)	3,687	1,020	38	578	5,323
Total	**7,154**	**3,720**	**38**	**1,246**	**12,158**

Salaries and other remuneration paid to senior management, parent company 2014

KSEK	Base salary Directors' fees	Variable compensation	Other benefits	Pension costs	Total
Chairman of the Board of Directors Bo Håkansson	168				168
Director Stina Gestrelius	94				94
Director Per-Olof Wallström	115				115
Director Fredrik Lindgren	113				113
Director Cindy Wong	94				94
Director Birgit Stattin Norinder	144				144
CEO	1,069			168	1,237
Other senior management (3 persons)	1,737			316	2,053
Total	**3,534**	**0**	**0**	**484**	**4,018**

Note 5 Fees and competition for costs, auditors

KSEK	2015	2014
Group		
KPMG		
Auditing services	2,401	145
Other services	214	–
Grant Thornton Sweden AB		
Auditing services	–	168
Other services	–	17
Parent company		
KPMG		
Auditing services	2,401	145
Other services	214	–
Grant Thornton Sweden AB		
Auditing services	–	168
Other services	–	17

Auditing services means statutory audit of the annual report and group accounts and bookkeeping, and the management by the Board of Directors and CEO, as well as the audit and other reviews carried out as agreed. This includes the 2015 audit of the IFRS conversion, audit of historical financial information and other auditing assignments in connection with the prospectus and the listing process. The above-stated includes other duties incumbent upon the company's auditor as well as advice or other assistance necessitated by observations in conjunction with such reviews or the performance of such other duties.

Note 6 Operating costs by type of cost

	Group	
KSEK	2015	2014
Personnel costs	-25,839	-10,468
Other external costs	-45,675	-17,534
Depreciation	-989	-790
Write-down	–	-559
Other costs	-195	-133
	-72,698	**-29,484**

Note 7 Net financial items

Group

KSEK	2015	2014
Interest income on bank deposits	–	42
Financial income	**–**	**42**
Interest expenses, credit institutions	–	-75
Interest expenses, other	-65	-48
Impairment of realizable financial assets [1]	–	-4,252
Financial expenses	**-65**	**-4,375**
Net financial items	**-65**	**-4,333**

[1] Relates to impairment of shares in Genovis AB due to significant decrease in value.

Parent company

KSEK	2015	2014
Profit/loss from shares in group companies		
Impairment of shareholder contribution	–	-2,398
	–	**-2,398**
Results from other securities and claims which are fixed assets		
Impairment of shares in Genovis AB	1,624	-4,252
	1,624	**-4,252**
Interest income and similar income statement items		
Interest income on bank deposits	–	42
	–	**42**
Interest expenses and similar income statement items		
Interest expenses, credit institutions	–	-75
Interest expenses, other	-59	-40
	-59	**-115**

Note 8 Taxes

Unreported deferred tax claims

Deferred tax claims have not been reported regarding temporary differences and losses carried forward since it is not probable that such can be set off against future taxable profits.
The group's losses carried forward in 2015 amounted to KSEK 203,689 (137,530).

Note 9 Earnings per share

Earnings per share

SEK	2015	2014
Earnings per share prior to and after dilution	-2.13	-1.09

There were no outstanding potential shares on the balance sheet date which might give rise to a dilution effect. The earnings per share prior to, and after, dilution are therefore the same.

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	2015	2014
Profit/loss for the year related to the parent company's shareholders	-66,266	-29,042
Earnings attributable to the parent company's shareholders prior to and after dilution	**-66,266**	**-29,042**

Weighted average number of outstanding shares prior to and after dilution

Number of shares	2015	2014
Total number of shares on 1 January	25,929,603	22,225,374
Effect of new share issues in April 2014	–	2,985,201
Effect of new share issues in April 2015	5,208,249	1,333,754
Weighted average number of shares during the year prior to and after dilution	**31,137,852**	**26,544,329**

The weighted average number of shares is affected by new share issues carried out in 2014 and 2015. The weighted number of shares for 2014 has been recalculated taking into consideration the new share issue carried out in 2015.

Note 10 Intangible fixed assets

Group

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2014	4,485	125	33,515	38,125
Closing balance 31 Dec 2014	4,485	125	33,515	38,125
Accumulated write-offs and impairment				
Opening balance 1 Jan 2014	–	-97	–	-97
Impairment for the year	–	–	-559	-559
Depreciaton for the year	–	-12	-559	-571
Closing balance 31 Dec 2014	–	-109	-1,118	-1,227
Reported values				
As of 1 Jan 2014	4,485	28	33,515	38,028
As of 31 Dec 2014	4,485	16	32,397	36,898

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2015	4,485	125	33,515	38,125
Closing balance 31 Dec 2015	4,485	125	33,515	38,125
Accumulated write-offs and impairment				
Opening balance 1 Jan 2015	–	-109	-1,118	-1,227
Depreciaton for the year	–	-12	-559	-571
Closing balance 31 Dec 2015	–	-121	-1,677	-1,798
Reported values				
As of 1 Jan 2015	4,485	16	32,397	36,898
As of 31 Dec 2015	4,485	4	31,838	36,327

Parent company

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2014	4,485	125	33,515	38,125
Closing balance 31 Dec 2014	4,485	125	33,515	38,125
Accumulated write-offs and impairment				
Opening balance 1 Jan 2014	–	-97	–	-97
Impairment for the year	–	–	-559	-559
Write-offs for the year	–	-12	-559	-571
Closing balance 31 Dec 2014	–	-109	-1,118	-1,227
Reported values				
As of 1 Jan 2014	4,485	28	33,515	38,028
As of 31 Dec 2014	4,485	16	32,397	36,898

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2015	4,485	125	33,515	38,125
Closing balance 31 Dec 2015	4,485	125	33,515	38,125
Accumulated write-offs and impairment				
Opening balance 1 Jan 2015	–	-109	-1,118	-1,227
Depreciaton for the year	–	-12	-559	-571
Closing balance 31 Dec 2015	–	-121	-1,677	-1,798
Reported values				
As of 1 Jan 2015	4,485	16	32,397	36,898
As of 31 Dec 2015	4,485	4	31,838	36,327

The projects pending in the group are combination of acquired development projects and continued activities in these projects. Of the total fees for product development, 75 % relates to IdeS and 25 % relates to HBP-assay.

Project overview	Indication/Purpose	Status
IdeS	IdeS 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.	IdeS has been given Orphan-Drug approval by FDA during 2015. Positive results of phase I studies executed during 2014 have been reported in Scientific Journals. Results from phase II studies conducted on kidney patients with positive results have been presented at ESOT 2015. Further phase II studies have started in 2015 at Akademiska Sjukhuset i Uppsala, Karolinska Institutet and Cedars-Sinai Medical Center in Los Angelse. Partial results based on the observation of a single patient in this latter study were presented in November 2015. The study is currently ongoing with further trials.
HBP-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 Medical receives milestone compensation and additional royalty revenues upon the sale of the sublicensed technology.

Write-offs of capitalized costs for product development of IdeS have not yet commenced since the intangible asset cannot be used yet as intended by corporate management, i.e. it has not yet begin to generate revenues. The company will begin to write off the capitalized costs for product development of IdeS when these begin to generate revenues.

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

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

The impairment assesment on 31 December 2015 and 2014 demonstrated that there was no need for impairment. The discount rates of interest before tax were 17.8 percent and 19.4 percent respectively.

Capitalized development expenses regarding HBP are written off over the term of the underlying patent in the amount of KSEK 559 per year.

Note 11 Tangible fixed assets

Group

	Equipment, tools and facilities	
KSEK	2015-12-31	2014-12-31
Accumulated acquisition values		
Opening balance on 1 January	2,377	1,173
Investments during the year	1,317	1,204
Closing balance on 31 December	3,694	2,377
Accumulated depreciation and write-offs		
Opening balance on 1 January	-1,094	-875
Depreciaton during the year	-418	-219
Closing balance on 31 December	-1,512	-1,094
Reported values		
As of 1 January	1,283	298
As of 31 December	2,182	1,283

Financial leasing – the group

KSEK	2015-12-31	2014-12-31
Group		
Reported value for assets in financial leasing agreements	72	128

The group leases automobiles under financial leasing agreements. The leased asset constitutes security for the leasing obligations.

See also note 20 and note 25.

Parent company

	Equipment, tools and facilities	
KSEK	2015-12-31	2014-12-31
Accumulated acquisition values		
Opening balance on 1 January	2,073	869
Investments during the year	1,317	1,204
Closing balance on 31 December	3,390	2,073
Accumulated depreciation and write-offs		
Opening balance on 1 January	-918	-754
Depreciaton during the year	-362	-164
Closing balance on 31 December	-1,280	-918
Reported values		
As of 1 January	1,155	115
As of 31 December	2,110	1,155

Note 12 Receivables from group companies

Parent company

KSEK	2015-12-31	2014-12-31
Accumulated acquisition values		
1 January	–	2,296
Additional receivables	–	2
Settled through shareholder contribution	–	-2,298
Reported value on 31 December	**–**	**–**

Note 13 Financial fixed assets

Group

KSEK	2015-12-31	2014-12-31
Financial investments which are fixed assets		
Realizable financial assets		
Shares and participating interests	7,283	4,180
	7,283	**4,180**

The holdings related to shares in Genovis AB which is listed on First North. These are valued at market value.

Not 14 Other long-term securities holdings

Parent company

KSEK	2015-12-31	2014-12-31
Accumulated acquisition values		
1 January	8,432	8,317
Purchases	1,479	115
Closing balance 31 December	9,911	8,432
Accumulated impairment		
1 January	-4,252	–
Impairment recovered during the year	1,624	–
Impairment during the year	–	-4,252
Closing balance on 31 December	-2,628	-4,252
Reported value on 31 December	7,283	4,180

Note 15 Other receivables

Group

KSEK	2015-12-31	2014-12-31
Other receivables which are current assets		
VAT receivables	724	796
Other receivables	788	278
	1,512	**1,074**

Parent company

KSEK	2015-12-31	2014-12-31
Other receivables (current)		
VAT receivables	724	796
Other receivables	788	278
	1,512	**1,074**

Note 16 Accounts Receivable

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

Note 17 Prepaid expenses and accrued income

Group

KSEK	2015-12-31	2014-12-31
Interest	–	41
Accrued royalties and licensing revenues	–	170
Prepaid insurance	78	–
Prepaid pension premiums	258	–
Other	32	162
	368	**373**

Parent company

KSEK	2015-12-31	2014-12-31
Interest	–	41
Accrued royalties and licensing revenues	–	170
Prepaid insurance	78	–
Prepaid pension premiums	258	–
Other	32	162
	368	**373**

Note 18 Cash and cash equivalents

Group

KSEK	2015-12-31	2014-12-31
The following subcomponents are included in cash and cash equivalents		
Cash and bank deposits	175,683	10,152
Total according to balance sheet	175,683	10,152
Total according to cash flow analysis	**175,683**	**10,152**

Note 19 Shareholders' equity

Share capital and number of shares

Number of shares	2015	2014
Issued as of 1 January	25,929,603	22,225,374
New share issue April 2014	–	3,704,229
New share issue April 2015	6,482,400	–
Issued as of 31 December – paid up	**32,412,003**	**25,929,603**

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.

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

Reserves
Fair value of reserves
The reserve for the net realizable value includes the accumulated net change in the net realizable value of realizable financial assets until the asset can be deleted from the balance sheet.

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

Dividends
The dividend proposal will be submitted to the annual general meeting on May 11 2016.

No dividend was paid for 2014.

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 20 Long term interest-bearing liabilities

This note contains information regarding the company's contractual terms and conditions regarding interest-bearing liabilities. For more information regarding the company's exposure to interest risks and the risk of changes in currency exchange rates, reference is made to note 23.

Group

KSEK	2015	2014
Long-term liabilities		
Financial leasing liabilities	49	91
	49	**91**
Current liabilities		
Current portion of financial leasing liabilities	42	39
	42	**39**

Financial leasing liabilities
Financial leasing liabilities due and payable as follows:

Group
2015

KSEK	Minimum leasing fees	Interest	Principal amount
Within one year	46	4	42
Between one and five years	50	1	49
Later than five years	–	–	–
	96	**5**	**91**

2014

KSEK	Minimum leasing fees	Interest	Principal amount
Within one year	46	7	39
Between one and five years	96	5	91
Later than five years	–	–	–
	142	**12**	**130**

Note 21 Other liabilities

Group

KSEK	2015-12-31	2014-12-31
Other current liabilities		
Personnel-related liabilities	1,294	1,039
	1,294	**1,039**

Parent company

KSEK	2015-12-31	2014-12-31
Personnel-related liabilities	1,293	1,039
	1,293	**1,039**

Note 22 Accrued costs and deferred income

Group

KSEK	2015-12-31	2014-12-31
Holiday pay	1,445	812
Social charges	445	255
Pension premium	480	–
Directors' fee	689	181
Project cost IdeS	3,707	–
Royalties to researchers	658	–
Consulting fees	1,761	–
Other	992	295
	10,177	**1,543**

Parent company

KSEK	2015-12-31	2014-12-31
Holiday pay	1,445	812
Social charges	445	255
Pension premium	480	–
Directors' fee	689	181
Project cost IdeS	3,707	–
Royalties to researchers	658	–
Consulting fees	1,761	–
Other	992	295
	10,177	**1,543**

Note 23 Financial risk management and financial instruments

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

Liquidity and financing risk

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

In order to secure short-term liquidity, Hansa Medical's financial policy prescribes that at least 80 % of the anticipated costs for the upcoming month be available in the form of cash and cash equivalents.
On the balance sheet date, this goal was fulfilled. Cash and cash equivalents on 31 December 2015 amounted to KSEK 175,683 (10,152).

According to Hansa Medical's investment policy, any surplus liquidity can be invested in interest-bearing securities with a maximum of three settlement days in a normal market. However, cash and cash equivalents consisted on the balance sheet date only of bank deposits.

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

2015

KSEK	Nominal amount	0–3 months	3–12 months	1–5 years
Long-term interest-bearing liabilities	49	–	–	49
Current interest-bearing liabilities	42	11	31	–
Accounts payable	1,000	1,000	–	–
Total	**1,091**	**1,011**	**31**	**49**

2014

KSEK	Nominal amount	0–3 months	3–12 months	1–5 years
Long-term interest-bearing liabilities	91	–	–	91
Current interest-bearing liabilities	39	10	29	–
Accounts payable	1,795	1,795	–	–
Total	**1,925**	**1,805**	**29**	**91**

Currency risk

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

A strengthening of SEK in relation to EUR by an average of 10 % would affect the group's earnings before tax by approximately KSEK +363 (+162) KSEK. Correspondingly, a strengthening of SEK in relation to GBP by an average of 10 % would affect the group's earnings before tax by approximately KSEK +141 (+87), while a 10 % strengthening of SEK in relation to USD would affect earnings before tax by approximately KSEK -232 (-46). The sensitivity analysis has been prepared from the point of departure that revenues and costs in each currency remain unchanged as compared with what is actually reported during each financial year.

Interest rate risk

The interest rate risk consists of the risk that a change in market interest rates will have a negative effect on earnings. The group's exposure to interest rate risks is considered to be small since the group only has very limited interest-bearing liabilities. There is certain exposure to interest rate risks in cash and cash equivalents in the form of bank deposits. However, this risk is also considered to be small.

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

Share price risk
Hansa Medical is exposed to a share price risk through its holdings of shares in Genovis AB which is listed on First North. In 2015, the group did not do any impairment of the holdings (2014: KSEK -4,252).

Credit risk
The group's credit risk is primarily related to bank deposits. However, this risk is considered to be low since the bank deposits are held in Swedish banks with good credit ratings.

According to the group's financial policy, Hansa Medical may only hold bank deposits with, or initiate payments through, Swedish and foreign banks under the supervision of the Swedish Financial Supervisory Authority or similar foreign agency.

The net realizable value of financial assets and financial liabilities
The reported values of financial assets and financial liabilities are deemed to be the reasonable estimates of the actual value of each class of financial assets and financial liabilities. The net realizable value of shareholdings in Genovis has been established based upon the closing price on the balance sheet date. The valuation of the holdings in Genovis is thus at Level I in the evaluation hierarchy.

The reported value for 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 IAS 39.

Group

	Loan claims and accounts receivable		Realizable financial assets	
KSEK	2015	2014	2015	2014
Financial assets valued at net realizable value				
Financial fixed assets				
Listed shares			7,283	4,180
Financial assets not valued at net realizable value				
Accounts receivable	625	59		
Accrued income	–	211		
Other receivables	788	278		
Cash and cash equivalents	175,683	10,152		
Total financial assets	**177,096**	**10,700**	**7,283**	**4,180**

	Financial liabilities valued at accrued acquisition value	
KSEK	2015	2014
Long-term interest-bearing liabilities	49	91
Current interest-bearing liabilities	42	39
Accounts payable	1,000	1,795
Total financial liabilities	**1,091**	**1,925**

Note 24 Operational leasing

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

Group

KSEK	2015-12-31	2014-12-31
Within one year	1,779	1,065
Between one and five years	1,680	2,133
Later than five years	–	–
	3,459	**3,198**

Parent company

KSEK	2015-12-31	2014-12-31
Within one year	1,817	1,111
Between one and five years	1,680	2,133
Later than five years	–	–
	3,497	**3,244**

Most of the group's operational leasing agreements involve leases of real property and premises on which the business operations are conducted.

Fees for operational leasing agreements booked as expenses amount to:

Group

KSEK	2015	2014
Total leasing costs	**1,624**	**1,087**

Parent company

KSEK	2015	2014
Total leasing costs	**1,673**	**1,151**

Note 25 Collateral provided, contingent liabilities and contingent assets

Group

KSEK	2015-12-31	2014-12-31
Collateral provided		
In the form of collateral for own liabilities and provisions		
Assets subject to retention of title	72	128
Total collateral provided	**72**	**128**

Note 26 Closely-associated persons

Relationships with closely-associated persons

The group has a closely-associated relationship with Farstorps Gård AB, the decedent's es-tate of Bo Håkansson, Nexttobe AB, and key persons in management positions. Farstorps Gård AB was wholly-owned by the former chairman of the Board of Directors Bo Håkansson. Nexttobe AB was previously the company's second largest shareholder with holdings of 29.1 %.

The parent company also has a closely-associated relationship with its subsidiary; see note 27.

Transactions with closely-associated persons

KSEK	2015	2014
Bo Håkansson		
Remuneration for underwriting guarantee	–	418
Nexttobe AB		
Remuneration for underwriting guarantee	–	418
Interest	29	–

Transactions with key persons in a senior management position

Transactions with key persons in a senior management position are set forth in note 4.

Note 27 Group companies

Holdings in subsidiaries

		Share ownership percentage (%)	
Subsidiary	Registered office / Country	2015	2014
Cartela R & D AB	Lund / Sweden	100.0	100.0

Parent company

KSEK	2015-12-31	2014-12-31
Accumulated acquisition values		
On 1 January	100	100
Shareholder contribution	1,833	–
Reported value on 31 December	**1,933**	**100**

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

			Reported value	
Subsidiaries / Corp. ID no. / Registered office	Number of shares	Percentage (%)	2015	2014
Cartela R & D AB / 556746-0083 / Lund	1000	100	1,933	100
			1,933	**100**

Note 28 Cash flow analysis

Adjustment for items not included in cash flow

Group

KSEK	2015	2014
Depreciation/writedown	989	1,349
Share warrants	199	–
	1,188	**1,349**

Parent company

KSEK	2015	2014
Depreciation/writedown	933	1,294
Share warrants	199	–
	1,132	**1,294**

Note 29 Events after the balance sheet date

There were no significant events after the balance date.

Note 30 Important estimates and opinions

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

Recovery of the value of development expenses
On at least an annual basis, the group assesses whether there is any impairment need for development projects which have not yet been completed. In the calculation of the beneficial value, future cash flows are discounted at a rate of interest which takes into consideration the market's opinion of risk-free interest and risk (WACC). The group bases these calculations on estimated forecasts and business plans. The estimates and assumptions made by management in the assessment of the need for impairment may have a large effect on the group's reported earnings. Impairment is made if the calculated beneficial value is less than the reported.

Note 31 Information regarding the parent company

Hansa Medical AB (publ) is a Swedish registered public company (corp. ID no. 556734-5359). The registered office is located in Lund.

The parent company's shares are registered on Nasdaq OMX, Stockholm. The address of the headquarters is Scheelevägen 22, 223 63 Lund. The consolidated accounts for 2015 cover the parent company and its subsidiaries, jointly referred to as the group.

Definitions

Earnings per share prior to dilution
Profit/loss for the period divided by the weighted average number of shares during the period prior to dilution.

Earnings per share after dilution
Profit/loss divided by the weighted average number of shares during the period after dilution.

Capital employed
Total assets less non-interest-bearing responsibilities

Return on capital employed
Operating profit/loss as percentage of capital employed

Return on equity
Net profit/loss as percentage of average shareholders' equity

Equity ratio
Shareholders' equity as percentage of total balance sheet assets at theend of the period.

Debt/Equity ratio
Relative proportion of shareholders' equity and debt used to finance the company's assets

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, 30 March 2016

Birgit Stattin Norinder
Chairman of the Board

Anders Blom
Director

Stina Gestrelius
Director

Per-Olof Wallström
Director

Cindy Wong
Director

Hans Schikan
Director

Göran Arvidson
CEO and Executive President

The Board of Directors and CEO approved the annual report for publication on 30 March 2016. The consolidated income statement, report on comprehensive income and balance sheet as well as the parent company's income statement, report on comprehensive income and balance sheet will be subject to adoption at the annual general meeting to be held on 11 May 2016.

Our auditors' report was submitted on 30 March 2016.
KPMG AB

Dan Kjellqvist
Authorized public accountant
Lead auditor

Jonas Nihlberg
Authorized public accountant

Auditors' report

To the annual meeting of the shareholders of Hansa Medical AB (publ), corp. ID no. 556734-5359

Report on the annual accounts and consolidated accounts

We have audited the annual accounts and consolidated accounts of Hansa Medical AB (publ) for the year 2015. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 19–56.

Responsibilities of the Board of Directors and the Managing Director for the annual accounts and consolidated accounts

The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of these annual accounts in accordance with the Annual Accounts Act and of the consolidated accounts in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the Managing Director 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.

Auditor's responsibility

Our responsibility is to express an opinion on these annual accounts and consolidated accounts based on our audit. We conducted our audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and consolidated accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and consolidated accounts 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. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the annual accounts and consolidated accounts.

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

Opinions

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 2015 and of their financial performance and cash flows 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 2015 and of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards, as adopted by the EU, and in accordance with 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 annual meeting of shareholders adopt the income statement and balance sheet for the parent company and the group.

Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the Managing Director of Hansa Medical AB (publ) for the year 2015.

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, and the Board of Directors and the Managing Director are responsible for administration under the Companies Act.

Auditor's responsibility

Our responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on our audit. We conducted the audit in accordance with generally accepted auditing standards in Sweden.

As 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.

As basis for our opinion concerning discharge from liability, in addition to our audit of the annual accounts and consolidated accounts, we examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the Managing Director is liable to the company. We also examined whether any member of the Board of Directors or the Managing Director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

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

Opinions

We recommend to the annual meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Malmö, 30 March 2016
KPMG AB

Dan Kjellqvist
Authorized Public Accountant
Lead auditor

Jonas Nihlberg
Authorized Public Accountant

Corporate governance report

Introduction

The Board of Directors of Hansa Medical AB (publ), corp. ID no. 556734-5359 (the "**company**") hereby submits the 2015 corporate governance report in accordance with the requirements of the Swedish Annual Accounts Act (1995:1554) ((Sw. årsredovisningslagen) and the Swedish Code of Corporate Governance (the "Code"; see the Swedish Corporate Governance Board website at www.bolagsstyrning.se). The company's shares were admitted for trading on Nasdaq OMX 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 OMX 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 Medical AB, and its wholly-owned subsidiary Cartela R & D AB. The subsidiary does not currently conduct any operations.

Deviations from the Code

The company deviates from the Code on one point. According to the Code, a member of the board shall not be chairman of the nomination committee. In the company, board member Anders Blom is also chairman of the nomination committee. According to the principles for appointing the nomination committee adopted by the annual general meeting 2015, the shareholder representative who represents the largest shareholder shall be appointed chairman of the nomination committee, unless the nomination committee decides otherwise. Anders Blom, acting as representative for the company's largest shareholder, Nexttobe AB, was appointed chairman of the nomination committee.

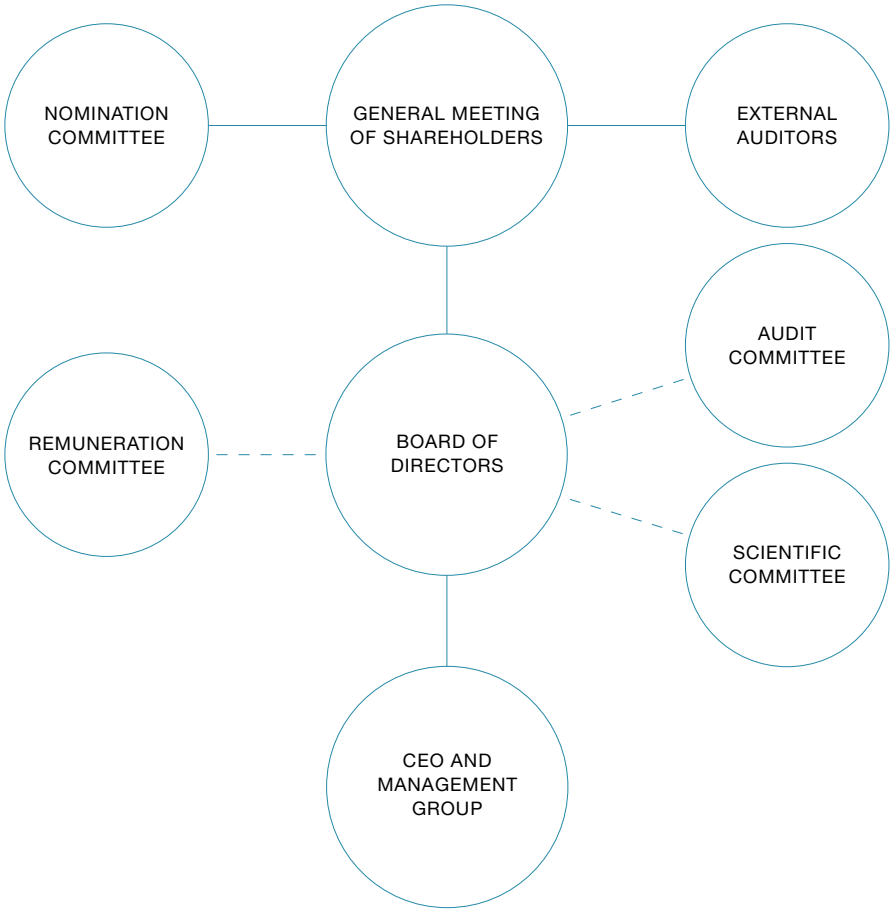
Shareholders

There are no limitations on the transferability of Hansa Medical's shares due to legal restrictions or provisions of the articles of association. To Hansa Medical's knowledge, no agreement has been entered into between any shareholders which might limit the transferability of the shares. Nexttobe AB is the only shareholder owning more than 10 percent of the company's shares, by its shareholdings of 29.1 %, As per 31 December 2015, Farstorps Gård AB owned 16.5 % of the company's shares, but has in the beginning of March 2016 reduced its shareholdings to circa 3 %. Farstorps Gård AB has committed not to divest any further shares within the next 12 months (a so called 12 month lock-up period).

There was no infringement of Nasdaq OMX Stockholms rules and no breach of good practice on the securities market reported by the stock exchange's disciplinary committee or the Swedish Securities Council during the financial year.

Hansa Medical's corporate governance model

The diagram set forth below illustrates Hansa Medical's corporate governance model and the central corporate bodies during 2015.



Significant external and internal regulations and policies which affect corporate governance

Significant internal regulations and policies:

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

Significant external regulations:

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

Information regarding Hansa Medical's shares

On 31 December 2015, the total number of shares was 32,412,003, with a quotient value of SEK 1. Each share carries one vote, and 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.

On 2 June 2015, the annual general meeting resolved to authorize the board, on one or more occasions before the next annual general meeting, applying or not applying shareholders' pre-emptive rights, to resolve upon a new issue of shares or issue of convertible instruments or warrants, see Annual General Meeting 2015.

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.hansamedical.com). The annual general meeting must be held within six months from the close of the financial year. At the annual general meeting, the shareholders adopt resolutions regarding, among other things: the board and auditors; the procedure for appointing the nomination committee; and discharge from liability for the board and the CEO in respect of the preceding year. Resolutions are also adopted regarding: adoption of the annual report; disposition of profits or treatment of losses; fees for the directors and auditors; and guidelines for remuneration to senior executives.

2015 Annual General Meeting

At the annual general meeting which was held on 2 June 2015, 16 shareholders representing 52 percent of the total number of votes in the company were represented. The annual general meeting adopted the 2014 annual accounts, adopted a resolution regarding treatment of the company's loss, and granted the directors and CEO a discharge from liability. The general meeting resolved that no dividend would be paid. In accordance with the proposals of the nomination committee, the general meeting resolved to re-elect Birgit Stattin Norinder as chairman of the board, and Anders Blom, Stina Gestrelius, Per Olof Wallström and Cindy Wong as board members. Hans Schikan was elected as board member. The general meeting adopted resolutions regarding election of an auditor and remuneration to the board and auditors in accordance with the nominations committee's proposal. The general meeting also resolved on guidelines for remuneration to senior management in accordance with the board of directors' proposal.

The annual general meeting resolved that the board of directors shall be authorized to issue new shares, warrants or convertible instruments on one or more occasions prior to the next AGM, with or without regard to shareholders' pre-emption rights. The payment of issued shares may be in cash, by non-cash consideration, by set-off or otherwise subject to terms and conditions stated in The Swedish Companies Act, chapter 2 section 5, second paragraph, points 1-3 and 5. The number of shares, warrants or convertible instruments to be issued pursuant to the authorization shall be limited to 10 percent of the shares from time to time outstanding. If the board of directors decides on an issue without regard to shareholders' pre-emption rights, the reason for deviation from the shareholders' pre-emption rights shall be for the purpose of expanding the circle of owners, acquire or render possible the acquisition of working capital, increase liquidity in the share, carry out corporate acquisitions, or acquire or render possible the acquisition of capital for corporate acquisitions. In conjunction with resolutions regarding share issues with a deviation from the shareholders' pre-emption rights, the subscription price shall be on market terms at the time of the adoption of the issue resolution.

In addition, the annual general meeting resolved on an incentive program as described below. Minutes from the annual general meeting are available at Hansa Medical's website www.hansamedical.com. The annual general meeting 2016 will take place on 11 May 2016.

2015/2019 incentive program

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

The employees were offered the opportunity to acquire warrants entitling them to exercise the warrants for subscription of shares in the company at a price equal to the market value of the share at the time of the issuance of the warrants (SEK 36.04) adjusted upwards annually in the amount of seven percent. Subscription for shares may take place during the period commencing 15 June 2018 up to and including 15 June 2019. This entails that the subscription price after three years will be approximately 122.5 percent of the current market value of the share and after four years will amount to approximately 131.1 percent.

Cartela R & D AB, the company's subsidiary, is entitled to subscribe for warrants. The warrants were issued without payment of any consideration and Cartela R & D AB subsequently transferred the warrants to employees of the company. The reason that the warrants were issued to Cartela R & D AB is that the company was able, in this way, to include terms and conditions with a right for the company to repurchase the warrants in the event the participant's employment with the company terminates, which would not have been possible if the warrants had been issued directly to the employees. The warrants were transferred to the company's employees on market terms and conditions at a price established based on a calculated market value for the warrants applying the Black & Scholes valuation model calculated by PricewaterhouseCoopers, a valuation institute independent of the company. The value was established as SEK 8.40 per warrant based on a share price of SEK 36.04. The total number of warrants issued by the shareholders' meeting on 2 June 2015 was 400,000, which corresponds to a dilution effect of 1.2 percent of the number of shares and votes if all of the warrants are exercised. All of the warrants were subscribed for by Cartela R & D AB. 296,000 warrants were subsequently transferred to the employees of the company, corresponding to a dilution effect of 0.9 percent of the number of shares and votes if

all of the warrants are exercised. For all employees, with the exception of the CEO, up to 60 percent of the employee's premium is subsidized and the employees have received a one-time bonus as a part of the warrant purchase. The degree of subsidization varies depending on the term of employment with the company. The bonus payment affected the company's earnings in the amount of approximately MSEK 1.40. The subsidy in the amount of approximately SEK 600,000 is booked as a current expense during the term of the warrants. In the event a warrant holder's employment with the company terminates before the warrants are exercised and the company elects to buy back the warrants according to the repurchase condition, the buyback must take place at market value less any subsidy received.

Nominating committee

Prior to the 2016 annual general meeting, Hansa Medical:s nomination committee comprises Anders Blom (representing Nexttobe AB), Fredrik Bogren (representing Farstorps Gård AB) and Astrid Samuelsson (representing Handelsbanken Fonder). It also includes the chairman of the board Birgit Stattin Norinder as convener. Anders Blom has been elected chairman of the nomination 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. The proposals will be published in connection with the notice to the annual general meeting 2016.

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 Medical must have a registered accounting firm as its external auditor.
The accounting firm KPMG AB has been the auditor of the company since the 2015 annual general meeting, with certified public accountant Dan Kjellqvist as the auditor in charge. Dan Kjellqvist is a member of the Swedish Institute of Authorized Public Accountants. Dan Kjellqvist at KPMG AB was the company's auditor commencing at the time of the 2014 annual general meeting up to and including the annual general meeting held in 2015. Prior to this, Ann Theander, who is a member of the Swedish Institute of Authorized Public Accountants and who works at Grant Thornton Sweden AB, was the company's auditor. For information regarding fees paid to the auditors, please refer to note 5 in the 2015 annual report.

Board of directors

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

The chairman must keep herself 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 directors regularly update their knowledge about the company and that new directors receive necessary introductory training.

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

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

Pursuant to the articles of association, the board must comprise not less than three and not more than ten directors elected by the general meeting, with no alternate directors. The board is quorate when more than half of the directors are present. The articles of association do not contain any provisions regarding appointment or dismissal of directors or regarding amendment of the articles of association.

Directors' fees were set at the company's 2015 annual general meeting for a period up to and including the next annual general meeting. The fees for the board of directors' work in 2015 were set as follows. The chairman is paid SEK 300,000, and each other director is paid SEK 100,000, SEK 40,000 is paid to the chairman and SEK 30,000 is paid to each other board member in the audit committee, SEK 40,000 is paid to the chairman and SEK 25,000 is paid to each other board member in the remuneration committee and SEK 25,000 is paid to each board member in the scientific committee, however, that no fees were to be paid to Anders Blom. No remuneration other than the above mentioned fees have been paid to the board of directors for their duty as directors. 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 4 in the 2015 annual report for additional information regarding employment terms and conditions for the board and senior executives.

Directors

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

The following is a list of the directors, containing information regarding their years of birth and election to the board, education, work experience, engagement in the company and other significant engagements and holdings in the company as of 4 February 2016. Holdings in the company includes one's own holdings as well as those of closely-related persons.

Birgit Stattin Norinder

Chairman of the board since 2014

Birgit has extensive experience from international pharmaceutical and biotechnology companies. She has managed several research and development departments, resulting in a number of novel pharmaceuticals. She has held positions such as CEO and Chairman at Prolifix Ltd., Sr VP Worldwide Product Development, Pharmacia & Upjohn and Dir. Int. Reg. Affairs Division, Glaxo Group Research Ltd. Birgit has also held a number of board and chairman positions of European biotechnology companies. She is director of the board at Jettesta AB, Nicox S.A. and AddLife AB. Director of the Board of Hansa Medical since 2012. Birgit holds an M.Sc. in Pharmacy from Uppsala University. Born 1948.

Birgit is Chairman of Hansa Medical´s Remuneration Committee, and member of the Audit Committee and Scientific Committee

Independent of Hansa Medical and senior management. Independent of major shareholders of Hansa Medical.

Shareholding: 29,205

Stina Gestrelius

Member of the board since 2007

Stina has 30 years of experience in the pharmaceutical and biotech industries. Entrepreneur and previously Head of Research at Biora AB and Deputy CEO of Medicon Valley Alliance. She is currently member of the board in BioActive Polymers in Lund AB and Hansa Medical AB and has held several board positions of Scandinavian biotechnology companies including Biogaia AB (publ.), Clavis Pharma ASA (publ.) and Lipopeptide AB. Stina holds an M.Sc. and a Ph.D. in Applied Biochemistry from Lund University. Born 1949.

Stina is member of the Hansa Medical Scientific Committee and of the Remuneration Committee

Independent of Hansa Medical and senior management. Independent of major shareholders of Hansa Medical.

Shareholding: 5,833

Hans Schikan

Member of the board since 2015

Hans has more than 25 years' international (bio) pharma company experience. He is currently Chairman of the Board of Directors of Asceneuron (Switzerland), Complix (Belgium) and InteRNA Technologies (The Netherlands) and member of the Board of Directors of Sobi and Wilson Therapeutics (Sweden). He is also Member of the Core Team of the Dutch Top Sector Life Sciences & Health and adviser to several biotech companies. His past experience includes inter alia CEO of Prosensa (The Netherlands).

Hans holds a Pharm.D. degree from the University of Utrecht, The Netherlands. Born 1958.

Hans is member of the Hansa Medical Scientific Committee.

Independent of Hansa Medical and senior management. Independent of major shareholders of Hansa Medical.

Shareholding: 10,000

Dr. Cindy Wong

Member of the board since 2012

Cindy has extensive experience from clinical medicine, clinical research, and regulatory requirements for registration of new medicinal products and biotechnology products. She has held senior positions in the Department of Health in Australia and at the Swedish Medical Products Agency. She is currently the Chief Medical Officer and Head of Medical Affairs at Q-Med, a Galderma division, in Uppsala, Sweden. In this position she has overseen the clinical development of a number of biotechnology products for registration in Europe, the USA, China and in Japan. Cindy holds a M.D. from the University of Adelaide and is a medical specialist in both internal medicine and immunopathology qualified in Australia. Cindy is a Fellow of the Royal Australasian College of Physicians and a Fellow of the Royal College of Pathologists of Australasia. Born 1959.

Cindy is member of the Hansa Medical Scientific Committee.

Independent of Hansa Medical and senior management. Independent of major shareholders of Hansa Medical.

Shareholding: 12,503

Per-Olof Wallström

Member of the board since 2011

Per Olof has extensive experience from various positions in the international pharmaceutical and biotechnology industry, including Senior Management positions at Merck, Astra, Pharmacia and Bristol-Myers Squibb. In addition, he has served as CEO of Q-Med AB, Melacure Therapeutics AB and Karo Bio AB. Per-Olof is also director of the boards at Camurus AB (Chairman), MB Eriksson Bygg och Fastighet AB (Chairman), Arosia Communication AB (Chairman), Patients Pending Ltd. (Chairman) and NeoDynamics AB" (Director). Per Olof holds an M.Sc. in Pharmacy from Uppsala University. Born 1949.

Per Olof is member of the Hansa Medical Audit committee and of the Remuneration Committee

Independent of Hansa Medical and senior management. Independent of major shareholders of Hansa Medical.

Shareholding: 23,000

Anders Blom

Member of the board since 2014

Anders is Executive Vice President at Oasmia Pharmaceutical AB. Prior to that, Anders worked as CEO and partner at Nexttobe AB, the main owner of Hansa Medical. Prior to that he spent ten years at Q-Med in finance and heading the business- and corporate development departments. In addition, Anders has served as Business Controller in the EMEA region for Pharmacia Corp. and as auditor at the Swedish Tax Agency (Skatteverket). Anders has been board member, chairman and CEO in several companies, including EQUIDx AB, Svenska Elitskon AB, Vivalavida AB, Delta Projects AB, BioLamina AB and Selego AB. Anders holds a Bachelor of Science in Business Administration from Uppsala University. Born 1969.

Anders Blom is Chairman of Hansa Medical´s Audit Committee.

Independent of Hansa Medical and senior management.

Shareholding: –

The Board of Director's work in 2015

During 2015, the board held twelve meetings, of which six were held per telephone and one was the constituent meeting. During 2015, the board primarily worked with the following issues: stock market adaptation through the adoption of management documents and the formation of board committees, a resolution to carry out a new share issue, the appointment of a new CEO, evaluation of indication area for IdeS, a decision to initiate part two of a phase II study at the Uppsala University Hospital and the Karolinska University Hospital in Huddinge, the decision to commence clinical studies at Cedars-Sinai Medical Center with Dr. Stanley Jordan, and questions regarding CMC development.

At the board meetings held during the 2015 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, given that one of the directors was newly elected during the financial year.

The reporting period is 1 January – 31 December 2015

Director	Elected	Present at board meetings	Present at remuneration committee meetings	Present at audit committee meetings	Independent in relation to the company and corporate management	Independent in relation to the company's largest shareholders
Birgit Stattin Norinder	2012	12 (12)	4 (4)	5 (5)	Yes	Yes
Stina Gestrelius	2007	12 (12)	4 (4)	-	Yes	Yes
Per-Olof Wallström	2011	12 (12)	4 (4)	5 (5)	Yes	Yes
Cindy Wong	2012	11 (12)	-	-	Yes	Yes
Anders Blom	2014	12 (12)	-	5 (5)	Yes	No
Hans Schikan[1]	2015	4 (4)	-	-	Yes	Yes

[1)] Joined the board in June 2015

Evaluation of the Board of Director's work

Pursuant to the Code, the board of directors is to evaluate its work annually, using a systematic and structured process, with the aim of developing the board's working methods and efficiency. The evaluation has been carried out by asking the directors to, in the end of 2015, fill out a questionnaire with questions about the work of the board of directors. The directors were to rate how well a number of statements corresponded with their opinion, but have also been invited to provide comments on their answers. The result of the responses have been compiled. The compilation has been reported to the directors and to the members of the nomination committee.

Board committees

The Board of Directors did not have any committees in 2014. In January 2015, the Board of Directors formed an audit committee, a remuneration committee and a scientific committee.

Remuneration committee

The remuneration committee which the company formed in January 2015 consists of Birgit Stattin Norinder, chairman, Stina Gestrelius and Per-Olof Wallström. The remuneration committee is charged with performing the duties set forth in the Swedish Corporate Governance Code. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board of Directors.

The primary duties of the remuneration committee are to:

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

Audit committee

The audit committee established by the company in January 2015 consists of Anders Blom, chairman, Birgit Stattin Norinder and Per-Olof Wallström. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board of Directors. The audit committee shall perform the duties incumbent upon audit committees as required by law and the Swedish Code of Corporate Governance.

The primary duties of the audit committee are to:

- monitor the company's financial reporting;
- with respect to the financial reporting, monitor the effectiveness of the company's internal controls, internal audit and risk management;
- inform itself of the audit of the annual reports and group accounts;
- review and monitor the auditor's impartiality and independence and, in this context, particularly monitor whether the auditor is providing the company with services other than auditing services;
- take decisions regarding guidelines for services other than the auditing services which the external auditor can provide the company;
- assume responsibility for the preparation of the Board of Directors' work by ensuring that the company's financial reporting maintains high standards;
- assist the nomination committee in the preparation of proposals for resolutions by the shareholders' meeting regarding the choice of auditor and fees for the auditor's work;
- meet with the company's auditor on a regular basis in order to obtain information regarding the focus and scope of the audit and to discuss the coordination between the external auditor and internal procedures for overview and insight into the company's risks;
- evaluate the auditor's work and inform the company's nomination committee or, where applicable, special nomination committee regarding the results of the evaluation; and
- assist the nomination committee in the preparation of proposals for nomination of the external auditor prior to the annual general meeting and proposals for fees for the external auditor's work.

Scientific committee

The scientific committee which the company established in January 2015 consists of Lars Björck, chairman, Hans Wigzell, Stina Gestrelius, Birgit Stattin Norinder and Cindy Wong. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board of Directors.

The primary duties of the scientific committee are to:

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

Company management

The board appoints a CEO to manage the company. In addition to the CEO, there are five individuals who make up company management: the Chief Financial Officer; the Chief Scientific Officer; the Clinical Research Director; Director, Corporate Development and Investor Relations and the Chief Medical Officer. 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 CEOs 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 OMX 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 attend. The CEO must also attend all general meetings of the company, including both annual general meetings and extraordinary general meetings. The CEO may not have any engagements outside of the company without the board's approval.

The CEO is also responsible for implementing the strategy approved by the board and to propose such other strategies and operational measures to the board which he deems appropriate. The CEO is responsible for the company's internal organization, but must obtain the board's approval prior to major organizational changes. The CEO is responsible for issuing and maintaining instructions for delegation to senior executives of the company. He is also responsible for entering into or terminating employment agreements and for other employment terms and conditions; however the chairman's approval is necessary for such issues in respect of senior executives. In a serious crisis situation, it is the CEO's responsibility to inform the board immediately and, if necessary, to form and instruct a crisis committee and to prepare a contingency plan for the business. The CEO must immediately report any event or procedure which he suspects may be significantly adverse to the business or the company's financial position, e.g. a liquidity crisis, to the chairman.

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

Senior executives

Hansa Medical's senior executives currently comprise six individuals: the CEO Göran Arvidson, the Chief Financial Officer Eva-Maria Joed, the Chief Scientific Officer Christian Kjellman, Chief Research Director Lena Winstedt, Director, Corporate Development and Investor Relations Emanuel Björne and the Chief Medical Officer Steven Glazer.

Hansa Medical'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 Medical as of 4 February 2016 are listed below. Holdings in the company includes both one's own holdings and/or those of closely-related persons.

Göran Arvidson

President and CEO

Göran Arvidson is CEO of Hansa Medical since April, 2015. Göran Arvidson has significant experience from the life science sector. He has been Executive Vice President and CFO of Swedish Orphan Biovitrum AB (publ), Co-founder of Biovitrum and has held senior positions with Procordia AB and Pharmacia AB. Göran holds B.Sc. in Business Administration from Stockholm School of Economics. Born 1960.

Shareholding: 63,000
Share warrants: 150,000

Emanuel Björne

Director, Corporate Development and Investor Relations

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

Shareholding: 21,300
Share warrants: 15,000

Dr. Steven Glazer

Chief Medical Officer

Steven Glazer joined Hansa Medical in August 2015. He has extensive experience in drug development from pharmaceutical and biotechnology companies. He served as Senior Vice President Development at BioInvent AB, Vice President Development at Zealand Pharma and Medical Director at NovoNordisk. Steven holds a Doctor of Medicine from the University of Copenhagen and trained in Internal Medicine.

Shareholding: -
Share warrants: -

Eva-Maria Joed

Chief Financial Officer

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

Shareholding: 1,000
Share warrants: -

Dr. Christian Kjellman

Chief Scientific Officer

Christian joined Hansa Medical in 2008 after serving at BioInvent AB as Senior Scientist focusing on novel target evaluation and antibody technology. Prior to that, he functioned as Head of Research at the biopharmaceutical development company Cartela AB, mainly focusing on novel drug target evaluation. He has extensive research experience in cell- and molecular biology and as an Assistant Professor in Molecular Genetics at Lund University. Christian holds a M.Sc. in Chemical Biology and a Ph.D. in Tumour Immunology from Lund University.

Shareholding: -
Share warrants: 40,000

Dr. Lena Winstedt

Clinical Research Director

Lena carries extensive experience from clinical development of biopharmaceuticals and small molecules. Before joining Hansa Medical in 2011, she served as Clinical Project Manager at BioInvent International AB focusing on Phase I clinical trials for biopharmaceuticals in Europe and in the United States. Prior to that she functioned as International Clinical Project Manager at Genmab A/S and Clinical Research Associate at H. Lundbeck AB. Lena holds an M.Sc. in Molecular Biology from Lund University and the University of Glasgow and a Ph.D. in Microbiology from Lund University.

Shareholding: 665
Share warrants: 30,000

Internal control and risk management in respect of the financial reporting

Introduction

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

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

Internal audit

The board has evaluated the need for an internal audit function and has concluded that it is not warranted for Hansa Medical 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 Medical's control environment, which comprises the values and ethics from which the board, the audit committee, the CEO, the management group, and other employees communicate and operate. The control environment also includes the company's organizational structure, leadership, decisional structure, decision-making authority, responsibility, and employee proficiency.

Risk assessment

Risk identification and evaluation must be carried out in the manner described above including regarding risks in respect of the financial reporting. As part of this procedure, items in the income statement and balance sheet entailing a great risk of significant error are identified. For Hansa Medical, 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 Medical, 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 Medical'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 Medicals Financial Handbook. Routines and activities have been designed to manage and rectify significant risks which are related to the financial reporting and which are identified in the risk analysis. The most significant, overall, group-wide corporate governance documents are the work procedures for the Board of Directors, instructions for the CEO, financial policy, disclosure policy, insider instructions, and risk management policy.

The primary purpose of control activities is the prevention and early-stage detection of errors in the financial reporting so that they can be addressed and corrected. There are both 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 analyzed and commented upon by company management. Follow-up takes place through regular meetings for review of these reports and analyses with the various managers and project managers. In this way, significant fluctuations and deviations are followed-up, minimizing the risk of errors in the financial reporting. The work involved with annual accounts and annual reports are processes which pose additional risks for errors in the financial reports. This work is of a less repetitive nature and contains more evaluative elements. Important control activities include, among other things, ensuring that there is a properly functioning reporting structure in which the various managers and project managers report pursuant to standardized reporting templates, and that important income statement and balance sheet items are specified and commented upon.

Information and communication

The informational activities are governed by an information policy. There are guidelines for external communications which ensure that the company meets high standards for providing correct information to the shareholders and the financial market. Hansa Medical'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 OMX Stockholm's Issuer Rules, the Swedish Code of Corporate Governance, and the laws and requirements imposed on Swedish

companies whose shares are admitted for trading on a regulated marketplace. The policy applies to all employees and directors of Hansa Medical and applies to both oral and written information.

The board adopts annual reports, financial statements and interim reports. All financial reports are published on the website www.hansamedical.com after having first been published pursuant to Nasdaq OMX 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 Medical'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.

Auditors' statement on the corporate governance report

To the Annual General Meeting of Hansa Medical AB (publ), corp. ID no. 556734-5359.

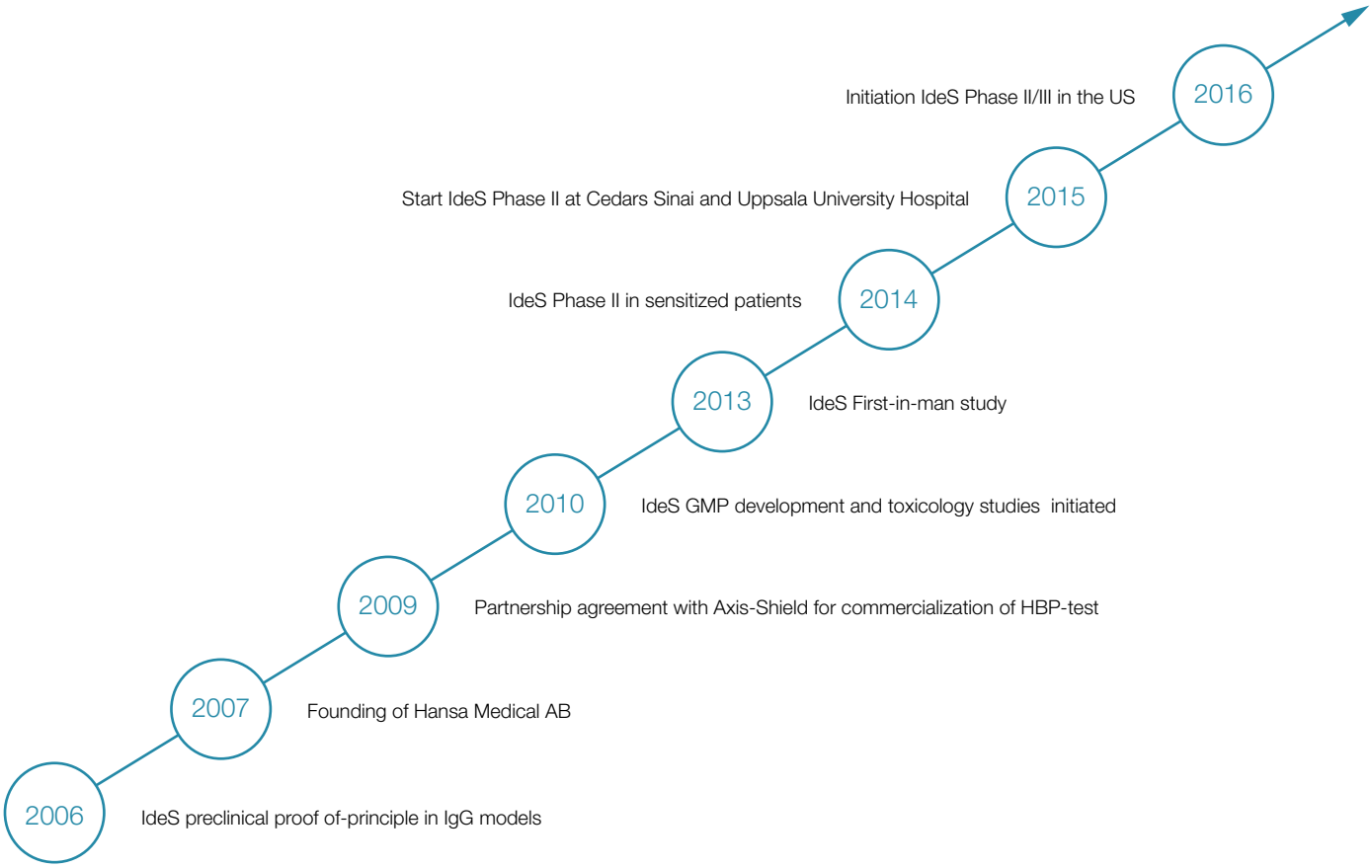
The Board of Directors is responsible for the corporate governance report for 2015 set forth on pages 57–69 and for ensuring that it is prepared in accordance with the Annual Accounts Act. We have read the corporate governance report and evaluated its statutorily-required content based on our knowledge of the company in order to form our opinion regarding whether the corporate governance report has been prepared and is consistent with the Annual Accounts Act and the consolidated accounts. We believe that a corporate governance report has been prepared and that its statutorily-required information is consistent with the Annual Accounts Act and the consolidated accounts.

Malmö, 30 March 2016
KPMG AB

Dan Kjellqvist
Authorized Public Accountant
Lead auditor

Jonas Nihlberg
Authorized Public Accountant

History


2006
IdeS preclinical proof of-principle in IgG models
2007
Founding of Hansa Medical AB
2009
Partnership agreement with Axis-Shield for commercialization of HBP-test
2010
IdeS GMP development and toxicology studies initiated
2013
IdeS First-in-man study
2014
IdeS Phase II in sensitized patients
2015
Start IdeS Phase II at Cedars Sinai and Uppsala University Hospital
2016
Initiation IdeS Phase II/III in the US

Reference list

1. Winstedt el al., (2015) PLOS ONE 10(7)

2. Jordan et al., British Medical Bulletin, 2015, 114:113–125

3. Orandi et al., New England Journal of Medicine (2016;374:940-50)

4. Puttarajappa et al., J. Transplant.Volume 2012 (2012), Article ID 193724

5. Linder et al., Critical Care Medicine. 43(11):2378-2386, Nov 2015

6. Järnum et al., The Journal of Immunology, December 15, 2015, vol. 195 no. 12, 5592-5601

Glossary

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.

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

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

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 I
The first time that 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 II
Refers to the first time that 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 III
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.

EndoS
A bacterial endoglycosidase of *Streptococcus pyogenes*. An enzyme with the unique ability to modify a specific carbohydrate chain of immunoglobulins.

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

FDA
US Food and Drug Administration.

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

HLA
Human Leukocyte Antigen is a protein complex found on the surface of all cells in a human. The immune system uses HLA to distinguish between endogenous and foreign.

IdeS
IdeS, immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies.

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

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.

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.

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

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 II studies can be used as pivotal studies if the drug is intended to treat life-threatening or severely debilitating conditions.

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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