Hansa Medical

Annual report 2017

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Hansa Medical in brief

Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for transplantation and acute autoimmune diseases.

The lead project IdeS is a proprietary antibody-degrading enzyme currently in late-stage clinical development for kidney transplant patients, with significant potential for further development in other solid organ transplants and a wide range of acute autoimmune indications.

The company also has a strong pipeline of preclinical assets that may provide a second wave of potential drugs. Under the project name NiceR, novel immunoglobulin cleaving enzymes are developed for repeat dosing translating the Hansa Medical technology into relapsing autoimmune diseases and oncology.

Hansa Medical is based in Lund, Sweden, its shares (ticker: HMED) are listed on Nasdaq Stockholm.

www.hansamedical.com

IdeS consistently demonstrates strong efficacy and safety in highly sensitized patients awaiting lifesaving kidney transplant

January–December 2017 Business Highlights

- Combined data from three independent clinical Phase II studies with Hansa Medical's lead candidate IdeS was published in *The New England Journal of Medicine*;377:442-53, August 3, 2017 issue. The published results demonstrate that treatment with IdeS is effective in reducing donor-specific antibodies (DSAs) to levels allowing lifesaving kidney transplantation of highly sensitized patients.
- The European Medicines Agency (EMA) granted Hansa Medical access to its Priority Medicines (PRIME) scheme for IdeS in enabling kidney transplantation for highly sensitized patients. PRIME is a scheme launched by the EMA to enhance support for the development of medicines that target an unmet medical need.
- Hansa Medical successfully raised SEK 545 million (USD 65 million), gross, through a directed share issue to a number of US, UK and Swedish specialist healthcare investors. The proceeds will enable the timely completion of ongoing clinical studies with IdeS evaluating the efficacy of this drug candidate to enable kidney transplantation in highly sensitized patients. The proceeds are also being used to expand the company's commercial and medical affairs' capabilities. Hansa Medical will also carry out several clinical studies in related transplant indications and in selected acute autoimmune diseases, including GBS and anti-GBM disease.
- Continued patient enrollment in the investigator-initiated Phase II study with IdeS in anti-GBM. The study began in June 2017, and as of March 21, seven patients have been recruited and treated with IdeS. Limited follow-up data is currently available from five of these seven patients who have all responded favorably and IdeS appears to be well tolerated. Patients enrolled in the study will be monitored for six months.
- Ulf Wiinberg, the company's Non-Executive Chairman, was appointed Acting CEO, following the tragic and unexpected death of the company's CEO, Göran Arvidson. Board member Birgit Stattin Norinder was appointed Chairman.

Significant events after the end of the reporting period

- Søren Tulstrup appointed new President and CEO of Hansa Medical effective March 20, 2018. Hansa Medical's acting CEO Ulf Wiinberg reverts to his former role as Chairman of Hansa Medical and Birgit Stattin Norinder reverts to her former role as member of the board of directors. Søren Tulstrup has a broad and extensive background as senior executive in the global biopharma industry. Recently, he served as CEO of Vifor Pharma AG (VTX:VIFN), a Swiss-based global pharmaceutical company with a market-leading position within chronic kidney disease, annual sales of approximately USD 1 billion and 2,000 employees.
- Completed enrollment in Hansa Medical's international multicenter Phase II study Highdes. The primary objective of the study – to turn a positive crossmatch test into a negative and thereby enable kidney transplantation - was accomplished in all 18 treated patients. All patients will be monitored for six months.
- Finalized enrollment in US investigator-initiated Phase II study with IdeS in highly sensitized patients. IdeS effectively reduced the level of DSAs in all 17 treated patients and turned the crossmatch tests from positive to negative, thereby enabling transplantation for all patients. All patients will be followed for six months to monitor safety, kidney function and DSA levels.
- The FDA granted orphan drug designation to IdeS (INN: imlifidase) for the treatment of Guillain-Barré syndrome. The FDA Orphan Drug Act (ODA) provides for granting special status to a drug or biological product to treat a rare disease that affect fewer than 200,000 people in the US. Orphan drug designation qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits, protocol assistance and up to seven years of orphan drug exclusivity.

Financial summary for the Group

	1 January – 31 December	
KSEK, unless other stated	2017	2016
Profit/loss		
Net revenue	3,442	2,579
Operating profit/loss	-176,083	-111,135
Net profit/loss	-176,660	-111,129
Per share data		
Earnings/loss per share before and after dilution (SEK)	-4.97	-3.37
Shareholders' equity per share (SEK)	16.68	8.09
Other information		
Shareholders' equity	630,661	283,693
Equity ratio (%)	93	91
Cash flow from operating activities	-150,105	-94,563
Cash and cash equivalents including short term investments	616,061	253,578
Number of employees end of the year	33	27

Chairman statement

2017 was a successful year for Hansa Medical, during which we reached several important milestones with our clinical studies and broadened our long-term investor base to include specialist international healthcare funds. We also gained increased attention from the medical research community following the publication of clinical IdeS data in *The New England Journal of Medicine*.

A lot of the progress achieved during the year should be attributed to the groundwork of our late CEO Göran Arvidson, who unexpectedly passed away in November. Through his inspirational leadership and dedication, he evolved Hansa Medical into a strong, emerging biopharmaceutical company with a clear, ambitious strategy and a dedicated organization capable of executing and delivering on milestone targets.

We are pleased to welcome Søren Tulstrup as new President and CEO of Hansa Medical as of March 20, 2018. Søren is an accomplished life science industry executive, who brings diverse and extensive industry experience having built and led high-performance biopharma companies, country operations and teams both in Europe and the US. Søren's strong track record of managing the development, launch and growth of biopharmaceuticals globally for the treatment of rare diseases and kidney diseases greatly matches Hansa Medical's promising position.

During the year, we received further evidence of the potential of our lead compound IdeS as a new and innovative treatment to enable life-saving kidney transplantation. Our two ongoing clinical Phase II studies in Europe and the US completed enrollment in January 2018, and a total of 35 patients were treated with IdeS prior to kidney transplantation. IdeS effectively reduced the level of donor-specific antibodies (DSAs) in all patients and turned the crossmatch tests from positive to negative, thereby enabling transplantation for all patients. Safety, kidney function and DSA levels will be monitored for all patients during a six-month follow-up period.

We received further validation of the increasing medical need for IdeS as a new treatment option to enable kidney transplantation in highly sensitized patients when the European Medicines Agency (EMA) granted our IdeS development program access to its Priority Medicines (PRIME) scheme. The PRIME scheme is based on enhanced interaction and dialogue, to optimize development plans and speed up evaluation so that medicines that target an unmet medical need can reach patients earlier. Access to the PRIME scheme was granted on the basis of data from both our finalized and ongoing Phase II studies in sensitized patients.

In line with the clinical progress, we also gained increased attention from the medical research community. In August, data from two of our clinical Phase II studies with IdeS was published in one of the leading medical journals, *The New England Journal of Medicine*. The article, titled *IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation*, concluded that treatment with IdeS effectively reduces DSA and thus enables lifesaving transplantation for highly sensitized kidney transplant patients. The publication is an important peer review of our novel treatment concept and now also forms the basis for interactions with global key opinion leaders, both in transplantation and within several autoimmune indications.

In parallel with our work in organ transplantation, we have taken the first important clinical steps to broaden the use of IdeS for both transplant-related indications and acute autoimmune diseases.

A Phase II study is ongoing in anti-GBM antibody disease, a rare and acute autoimmune kidney disease, where approximately two-thirds of the patients lose their kidney function, resulting in the need of chronic dialysis. As of March 21, 2018 seven patients had been included in the investigator-initiated Phase II study in severe anti-GBM. Limited follow-up data is currently available from five of these seven patients who have all responded favorably. IdeS appears to be well tolerated. The study aims to enroll approximately 15 patients at clinics across Europe. Prior to site initiation of this study, three additional patients were treated on a so called named patient basis in Sweden.

Guillain-Barré syndrome (GBS), a rare acute autoimmune neurological disease, is another indication in which the mode of action of IdeS has a promising potential to make significant treatment improvements. In February 2018, we received orphan drug designation for IdeS in the US for the treatment of GBS, and we are currently planning a Phase II study in this disease.

We are developing completely new IgG-degrading enzymes under the umbrella project annotation NiceR – Novel immunoglobulin cleaving enzymes for Repeat dosing. The aim of the development is to create novel IgG-inactivating drugs that can be used for repeated dosing in autoimmune conditions, oncology and transplantation where patients would benefit from more than one dose of an IgG-modulating enzyme. The research and development is progressing nicely, and we have decided to direct our preclinical research efforts in this direction. Several novel IgG-degrading enzymes have been designed and are further evaluated towards lead candidate selection and clinical development. We have decided to deprioritize EndoS and put further work on hold.

We made significant investments in the IdeS manufacturing process during 2017. The process has been transferred to manufacturers in Europe suitable for commercialization. The IdeS product intended for launch is lyophilized for convenient and effective world-wide distribution.

Financially, we are in a strong position. In November, the Board resolved the company to undertake a directed share issue that raised SEK 545 million. The proceeds from this offering are being used to fund the continued development of our existing product portfolio and to expand our medical affairs and commercial capabilities, ahead of a potential US and European approval and subsequent launch of IdeS. We received strong interest from several reputable US, UK and Swedish institutional investors and the share issue was fully completed by December 29, 2017.

During 2017, we continued to build a strong and experienced team expanding our capabilities in R&D, medical affairs and marketing, and we now have a dedicated team of approximately 40 co-workers. We will continue to add more expertise to the organization, particularly within regulatory affairs, medical affairs and commercial competencies.

It has been a privilege to serve as acting CEO for four months with our highly committed management team and co-workers in Lund and the US and I look forward to continuing my engagement in the company by reverting to my previous role as chairman of the board of directors.

Ulf Wiinberg
Chairman of the board of directors
Acting CEO November 9, 2017 to March 20, 2018
Hansa Medical AB

CEO comment

”It is a privilege and an honor to join a company that over the last couple of years, has step by step created an exciting platform within IgG-modulating enzymes for transplantation and acute autoimmune diseases. The team at Hansa Medical has successfully designed and carried out a series of clinical studies with its lead compound IdeS, and at the same time created a strong pipeline in a drug based on IdeS.”

I am very impressed with the science and the development strategy along with the quality and ambition of the team, and I look forward working with them as we continue to build on the significant achievements accomplished to date.

Our focus will be on completing the development of IdeS in highly sensitized patients and the ongoing Phase II study in anti-GBM, as well as initiating additional Phase II studies in closely related transplant indications and in autoimmune disease. In addition, we will continue the development of our novel IgG-eliminating enzymes, as well as explore development of potential applications in oncology of these enzymes.

We still have a number of milestones to reach before IdeS is available on the market. During 2018 we plan to continue discussions with both the FDA and EMA, regarding the regulatory path to approval for IdeS in transplantation. In addition to the convincing data demonstrating the efficacy and safety of IdeS in enabling kidney transplantation, important items for these discussions will be six-month follow-up data from our Highdes-study, further optimization of the manufacturing process, and the significant medical need for these highly sensitized patients who today have very limited chances, if any, to be transplanted.

We are in a strong and unique position in the development of our novel immunomodulatory enzymes. Our vision is to become a world-leading IgG-modulating company and bring our products to patients across a range of conditions where IgG plays a key role in disease. I look forward to informing you in more detail on the progress in our development programs. Very interesting times lie ahead.

Søren Tulstrup
President and CEO since March 20, 2018
Hansa Medical AB

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

Our strategy

We are focused on the research, development and commercialization of novel immunomodulatory enzymes that eliminate harmful IgG antibodies from the body and have the potential to transform the lives of people in significant need of an organ transplant or patients with autoimmune conditions.

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

Our short term strategic priorities are:

- to quickly attain market approval for lead candidate IdeS as pre-treatment of sensitized patients prior to kidney transplantation, and start building a commercial infrastructure
- to expand knowledge and awareness of the potential of lead candidate IdeS in additional transplant and autoimmune indications
- to follow up with clinical studies in additional indications with significant unmet medical need where IdeS has apparent potential to effectively treat, or prevent, IgG-mediated pathophysiology

IdeS can potentially be used in several different transplant-related indications and acute autoimmune conditions in which IgG antibodies are proven, or suspected, to play a significant role for disease progression. In addition, IdeS has the potential to effectively inactivate anti-drug antibodies developed against other lifesaving biological drugs and gene therapies. Hansa Medical's long-term vision is to make IdeS and Novel immunoglobulin cleaving enzymes for Repeat dosing (NiceR) available for as many of these IgG-mediated conditions as possible.

Antibodies for better or worse

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

The molecule that the antibody binds to is called an antigen. Through this binding mechanism, one or several antibodies can tag a pathogen or infected cell. This tagging results in one or several different so-called effector functions in which other parts of the immune system are activated in order to inhibit and/or eliminate the pathogen or foreign material. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM. The different isotypes have slightly different structures and they play different roles in the immune system. Immunoglobulin G, IgG, is the most common type in the blood and tissue and provides the majority of antibody-based immunity against invading pathogens. IgA is found mainly in mucosal areas and prevents colonization by pathogens. IgD mainly functions as receptor on B-cells that have not yet been activated. IgE binds to allergens and is involved in allergy. IgM is mainly found in the blood and is part of the first response against an infection.

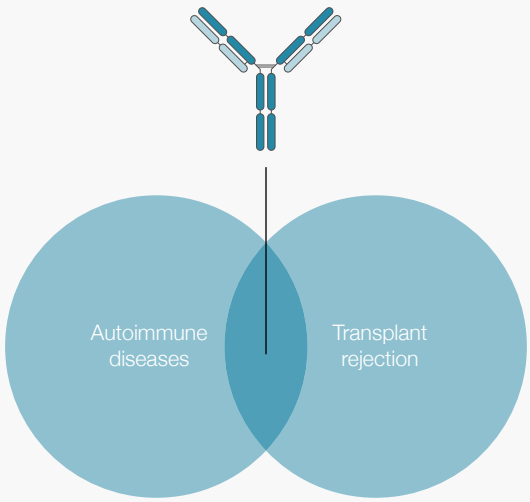


Figure A. In IgG-mediated acute conditions, pathogenic IgG-antibodies are at the center of disease progression. In several autoimmune diseases, autoantibodies engage the immune system to attack self-antigens. In organ and tissue transplantation, donor-specific antibodies can form a barrier for transplantation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

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

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 need to be matched with respect to blood type and tissue type prior to transplantation to minimize the risk of transplant rejection.

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

Patients in need of a new organ, such as kidney or heart, can also develop pre-formed anti-HLA (Human Leukocyte Antigen) antibodies prior to the transplantation. These pre-formed anti-HLA antibodies have been developed earlier in life due to pregnancies, blood transfusions or previous transplantations when exposed to foreign HLA. These individuals are referred to as HLA-sensitized or HLA-immunized patients. In general, it is more difficult to allocate donor organs to HLA–sensitized patients. Patients on transplant waitlists are screened with respect to their anti-HLA antibody profiles and carefully tested with respect to donor-specific antibodies prior to an actual transplantation.

Introduction to Hansa Medical development programs

IdeS is an enzyme, currently in late stage clinical development, 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 elimination constitutes a novel therapeutic principle for the treatment of IgG-mediated acute human diseases.

NiceR (Novel immunoglobulin cleaving enzymes for Repeat dosing) is a preclinical research and development program under which IgG-cleaving enzymes with novel properties are developed. The aim of the development is to create novel IgG-inactivating drugs that can be used for repeated dosing in autoimmune conditions, oncology and transplantation where patients benefit from more than one dose of an IgG-modulating enzyme. The development program is currently in the lead optimization phase with the intention to select a lead candidate suitable for clinical development.

EnzE (Enzyme-based antibody Enhancement) is a preclinical research and development program under which the combination use of approved antibody based cancer treatments with IgG-modulating enzymes is examined. Recent findings demonstrate that pre-treatment with IgG-degrading or modulating enzymes has the potential to potentiate presently available antibody-based cancer therapies.

HBP-assay (serum quantification of Heparin-Binding Protein) is a novel diagnostic method developed by Hansa Medical to help predict severe sepsis in patients with infectious disease symptoms. Early prediction and treatment of risk patients is key to prevent death from severe sepsis. A first version of HBP-assay has been launched on the European market and has been evaluated in two finalized clinical studies in approximately 1,000 patients demonstrating superior performance in predicting severe sepsis. HBP-assay has been out-licensed to Axis-Shield Diagnostics who is now running additional clinical trials in Europe, the US and China, and the agreement includes rights to royalties from Axis-Shield to Hansa Medical.

Pipeline

Candidate/ Method/Project[1]	Indication	Research/ Preclinical	Phase I[2]	Phase I/II	Phase II	Pivotal	Registration
THERAPEUTICS							
IdeS	Kidney transplantation in highly sensitized patients[3]						
	Anti-GBM antibody disease						
	Antibody mediated kidney transplant rejection (AMR)						
	Guillain-Barré syndrome						
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology						
EnzE	Cancer immunotherapy						
DIAGNOSTICS							
HBP-assay (IVD)[4]	Prediction of severe sepsis						

[1] The EndoS project has been deprioritized and is put on hold.

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

[3] Two separate Phase II studies with IdeS in highly sensitized patients are currently ongoing.

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

Hansa Medical's lead drug candidate IdeS

IdeS – a novel therapeutic principle

Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes* (IdeS, INN: imlifidase) 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 elimination constitutes a novel therapeutic principle for the treatment of IgG-mediated human diseases. Our clinical studies are initially focused on desensitization of HLA-immunized patients prior to kidney transplantation, also referred to as sensitized patients. Our long-term vision is that IdeS will become the treatment of choice in several acute IgG-mediated conditions within autoimmunity and transplantation.

Development status for IdeS

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

IdeS has been evaluated in a Phase I study[1] in healthy subjects and in two finalized Phase II studies in sensitized patients awaiting kidney transplantation[2,3]. The results from these studies demonstrate that IdeS is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation and is well tolerated.

The efficacy and safety of IdeS is currently being investigated in two ongoing Phase II studies in highly sensitized kidney transplantation patients. Patient recruitment was completed in early January 2018 to these two Phase II studies and the patients will be monitored for six months with respect to safety, kidney function and levels of donor-specific antibodies (DSA). Results from these two studies are expected by Q3 2018.

An investigator-initiated Phase II study with IdeS in the rare and acute autoimmune kidney disease anti-GBM antibody disease is ongoing in collaboration with several European nephrology clinics. Additional Phase II studies with IdeS are being planned within acute antibody-mediated rejection (AMR) and treatment of the acute autoimmune neurological disease Guillain-Barré syndrome (GBS).

A short introduction to transplantation[4]

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

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

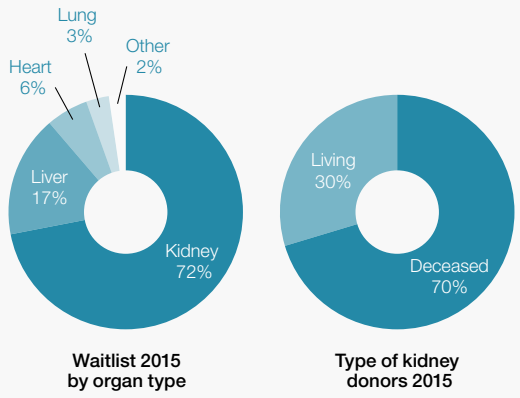


Figure B. Waitlist 2015 in the US and Europe by organ type and type of kidney transplantation (deceased donation vs living donation)[4]

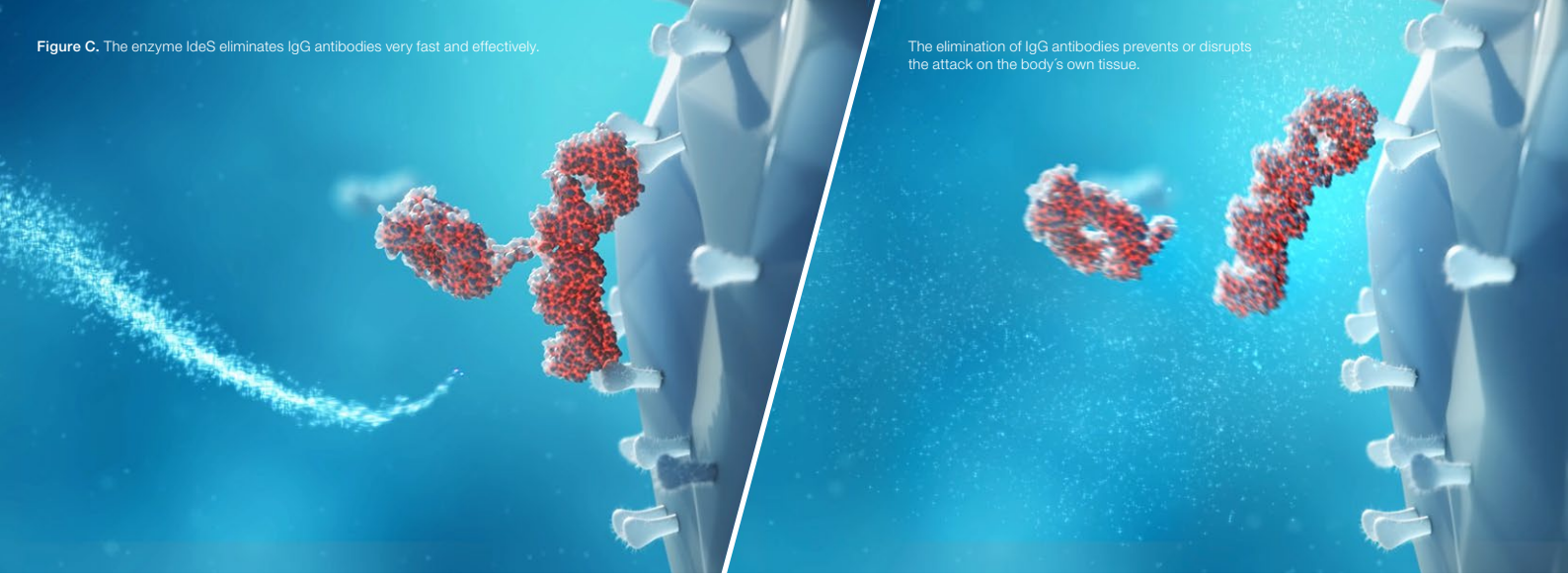


Figure C. The enzyme IdeS eliminates IgG antibodies very fast and effectively.

The elimination of IgG antibodies prevents or disrupts the attack on the body's own tissue.

HLA-sensitized patients

Approximately one third[5] of the patients on kidney transplant waitlists have developed antibodies to the cell surface protein HLA (Human leukocyte Antigen). These antibodies make it more difficult to find a suitable donor in the transplantation of kidney, heart, lung and bone marrow which results in longer waiting times for patients which have notable levels of anti-HLA antibodies.

Moderately sensitized patients can in many cases be transplanted following extended time on the transplant waitlist. If the patient has an identified potential living donor but has donor specific antibodies, desensitization with plasmapheresis and intravenous gamma globulin can be considered. For highly sensitized patients it can be difficult to find a suitable deceased or living donor, which results in significantly longer waiting times and extended treatment in dialysis.

Pre-treatment with IdeS to enable transplantation

Hansa Medical's primary indication for the drug candidate IdeS is to enable kidney transplantation for sensitized patients on transplant waitlists around the world. Through one 15-minute infusion of IdeS, both circulating and extravascular IgG is inactivated within two-four hours[1,2,3]. This effectiveness and fast onset makes IdeS highly suitable as an IgG-eliminating treatment hours prior to kidney transplantation independent of whether the kidney is donated from a living or deceased donor.

The IgG-eliminating effectiveness and fast onset of IdeS is unprecedented and can potentially enable shorter waiting-time on transplant waitlists for all sensitized patients and enable organ transplantation for patients that today are not possible to transplant due to sensitization. Hansa Medical is focused on desensitization prior to kidney transplantation but desensitization prior to transplantation of heart, lung, and bone marrow may constitute equally promising opportunities.

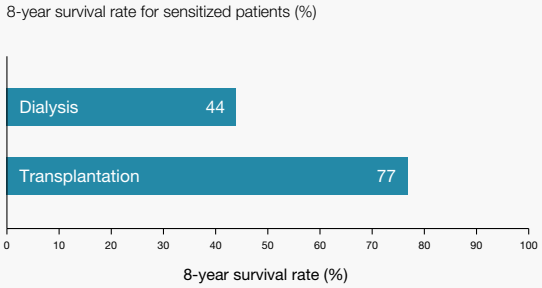


Figure D. In a recently published study[5] based on 1026 sensitized patients, it is concluded that the 8-year survival rate for sensitized (moderately and highly) patients undergoing desensitization followed by kidney transplantation is 77 percent. The 8-year survival rate for sensitized patients treated with dialysis only, was 44 percent.

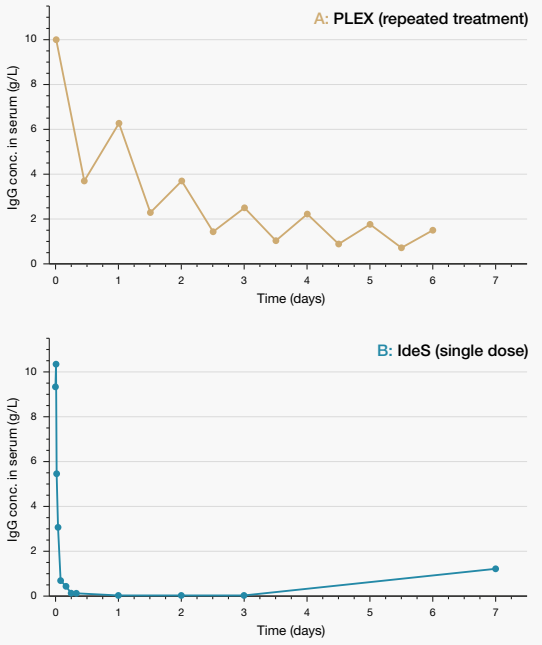


Figure E. A: The IgG levels in a patient that is treated with plasmapheresis for IgG elimination[7]. IgG elimination requires several rounds of plasmapheresis over several days or weeks. It is difficult to reach zero or close to zero levels of IgG. B: One dose of IdeS eliminates circulating and extravascular IgG with unprecedented efficacy and fast onset. After one dose of IdeS, circulating and extravascular IgG is eliminated in two-four hours.

Interview with Dr. Tomas Lorant

Consultant Transplant Surgeon at Uppsala University Hospital, Uppsala, Sweden

What are the most significant challenges for people waiting for a new kidney?
One of the biggest challenges for many patients waiting for a new kidney is the strenuous long waiting time until a suitable transplant has been identified. This long uncertain wait is difficult for a lot of patients. Further, many of the patients on the transplant waiting lists have so-called donor-specific antibodies in the blood. The patients are not born with these antibodies but antibodies can develop through pregnancies, an earlier transplant or if the patient has received a blood transfusion. For these patients, the time on the transplant waitlist is even longer than for others, and some will not get transplanted before they have to be removed from the transplant waitlist because they become too sick to undergo surgery.

It is also challenging to stay healthy while waiting for transplantation. Renal disease patients have an increased risk of suffering from a number of co-morbidities including heart failure, infections, type 2 diabetes and other metabolic disorders.

How many Swedish patients are on dialysis today waiting for a new kidney and how does it look globally?
By the end of last year, nearly 700 kidney disease patients in Sweden were waiting for kidney transplantation, and the majority of these patients are currently undergoing dialysis. In Europe, about 50,000 patients are currently waiting for a kidney transplant. Waiting times can range from a few months to several years. In some cases patients never get transplanted because of the presence of donor-specific antibodies, or because they are too sick.

What makes it more difficult for some patients to find a suitable kidney?
When a kidney becomes available for transplant, the organ coordinator needs to look for a suitable recipient based on, for example waiting time and blood group. In addition, a so-called cross match test must be performed. In these *in vitro* tests (in the laboratory), you can see if the intended recipient has donor-specific antibodies. In order for the transplantation to take place, the patient should not have antibodies with the ability to bind to the transplanted kidney and cause irreversible damage. This means that the waiting time cannot strictly be used as a selection criterion, but it is also essential to map the recipient's immune system so that the kidney has the best chance of being healthy and well-functioning for a long time.

What does it mean to be HLA-sensitized?
HLA-sensitized simply means that there are circulating antibodies in the patient's blood which make it difficult to find a matching kidney and this leads to considerably longer waiting times.

How do you manage HLA-sensitization?
Today, HLA sensitization is primarily handled through exclusion of patients who have antibodies that potentially can react with the kidney to be transplanted. Another way is to pre-treat patients on the waiting list with a treatment which inhibits the white blood cells that produce antibodies as well as to give intravenous gamma globulin (IVIG) in large doses. In some patients these methods have a moderate effect on the antibodies, but they do not work for all patients. Another treatment is to wash out the antibodies through so-called plasmapheresis. This method is too tedious and not

effective enough to enable transplantation when an organ is offered from a deceased donor, where the time from donor death to transplantation is crucial.

What are the most important conclusions from your clinical study with IdeS published in The New England Journal of Medicine (NEJM)?

In the work published in NEJM, two separate studies were conducted, one of which was conducted in Los Angeles, and one was performed in Uppsala and Stockholm here in Sweden. The most important lesson from that study was that the investigational drug candidate IdeS has a very strong ability to cleave and inactivate antibodies with a favourable safety profile. The most common adverse events were temporary infections that all resolved. If you specifically study the effect on the malignant transplant antibodies they are inactivated, or completely eliminated, as fast as one hour after the study drug has been administered and the effect lasts for up to two weeks to allow the patients in the two separate studies to be transplanted. The effect is extremely strong and it has worked well in all patients to whom it has been given in the two studies. Several of the patients have had very large amounts of antibodies that would otherwise make transplantation impossible. Receiving this treatment has given them a chance of a new life.

How problematic is the shortage of organs? What can we do as individuals and as a society to increase the availability of transplantable organs?

The shortage of organs is a significant problem worldwide. Every year patients die whilst waiting for a new organ because it just isn't available fast enough. Even though we in Sweden have a very positive attitude towards donation, there is a lot of work left to be done. There is a continuous effort at different hospitals to more effectively identify possible deceased donor organs. This is important both for those on the waiting lists, but also in order to meet the will of deceased persons to donate. The number of donations varies greatly between different countries. Spain is a good example of a country with successfully implemented active work on organ donation. Another way to increase the availability of organs is to carry out more transplantations with living donors. In many cases, live donor transplantation cannot be performed because the recipient has transplant antibodies to the donor. Within the aforementioned study, two patients obtained kidneys from living donors that would otherwise have been impossible to transplant due to these problematic antibodies.

Transplantation: Quick facts

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

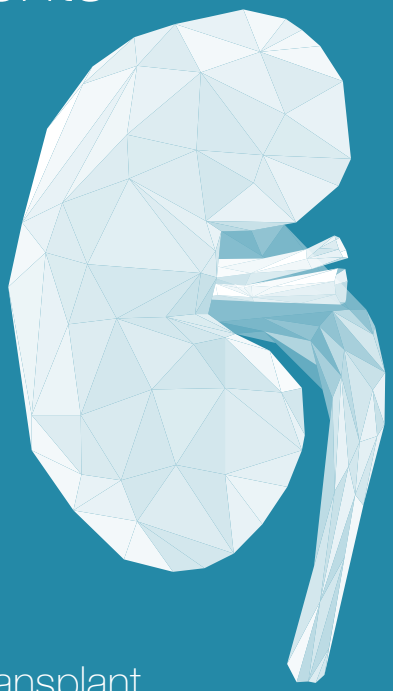
IdeS enables lifesaving kidney transplant in sensitized patients

Results from *The New England Journal of Medicine*

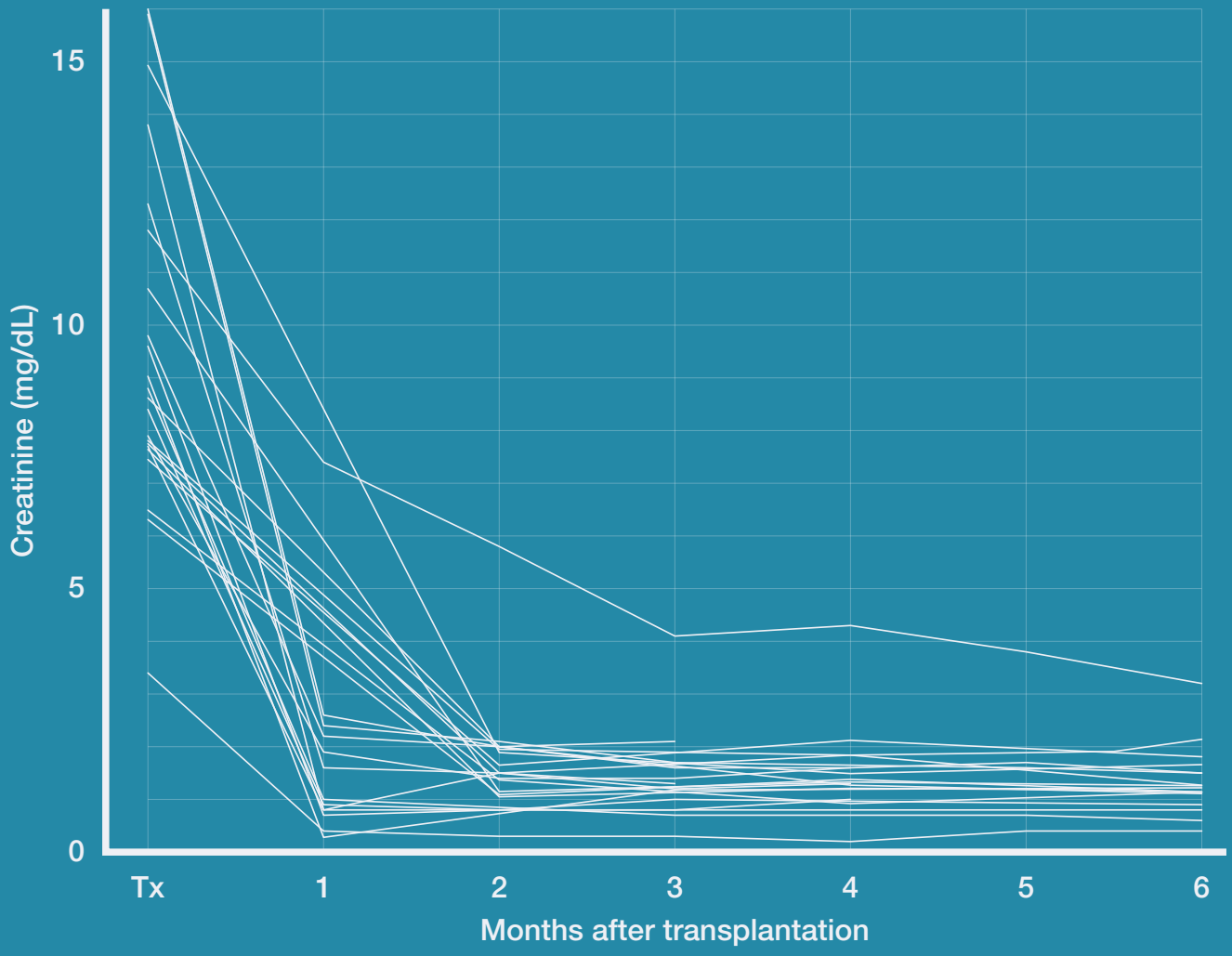
24/25

Patients successfully transplanted with normalised kidney function six months post-transplant*

*Jordan et al. *The New England Journal of Medicine* 2017;377:442-53
*"IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation".



Normalized kidney function 6 months post transplant



Clinical studies with IdeS as pre-transplant treatment – Results and ongoing studies

Clinical Phase I study with IdeS – Successfully completed 2014
During 2013 and 2014, Hansa Medical conducted a clinical first-in-human Phase I study (ClinicalTrials.gov Identifier NCT01802697) 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].

First clinical Phase II in sensitized patients with IdeS – Successfully completed 2015
During 2014 and 2015, the first clinical Phase I/II study (ClinicalTrials.gov Identifier NCT02224820) with IdeS in sensitized patients was conducted and completed. The study was a single center, open label ascending dose study in sensitized chronic kidney disease patients assessing the safety, immunogenicity, pharmacokinetics and efficacy of IdeS. The study was conducted at Uppsala University Hospital in Sweden and eight patients with cytotoxic panel-reactive antibodies (median cytotoxic PRA 64%) received one or two intravenous infusions of IdeS.

In the study, IdeS eliminated IgG in sensitized patients with unprecedented efficacy and no intact IgG could be detected less than one hour following IdeS treatment. Anti-HLA IgG antibody reactivity was substantially reduced in all patients and C1q binding to anti-HLA IgG was abolished. IdeS also cleaved the IgG-type B cell receptor on CD19+ memory B cells. Three cases of infection and one case of myalgia were reported as serious adverse events potentially related to IdeS. These events were effectively treated or resolved.

It was a dose finding study, but transplantation was allowed if a kidney was offered during the study period. An HLA-incompatible kidney from a deceased donor was offered to one of the patients. This sensitized patient had 13 different anti-HLA IgG antibodies, a 69 % PRA as well as a positive CDC crossmatch to the offered kidney at enrollment. The IdeS treatment effectively reduced donor-specific antibodies and shifted the crossmatch test from positive to negative, thereby enabling the first kidney transplantation through IdeS-based desensitization. Stable kidney function has been maintained in this patient for more than three years.

The results from the study were published in March 2018 in the *American Journal of Transplantation (AJT)*[2], the monthly peer reviewed medical journal published by the *American Society of Transplant Surgeons* and the *American Society of Transplantation*.

Second clinical Phase II in sensitized patients with IdeS – Successfully completed 2016
In December 2016, a Phase II study (ClinicalTrials.gov Identifier NCT02475551) to evaluate the safety, tolerability, efficacy and pharmacokinetics of intravenous ascending doses of IdeS in kidney transplantation was successfully completed, and the primary and secondary objectives were met. The study was conducted in Sweden at Uppsala University Hospital and Karolinska University Hospital in Huddinge.

In the study, ten sensitized kidney patients were given IdeS, which enabled all of them to have a kidney transplantation thereafter. Results from the study were published in *The New England Journal of Medicine* in August 2017[3].

US investigator-initiated Phase II study in highly sensitized patients – Enrollment completed in January 2018
In August 2015, an investigator sponsored study (ClinicalTrials.gov Identifier NCT02426684) using IdeS was initiated by Professor Stanley Jordan at Cedars-Sinai Medical Center in Los Angeles. IdeS is investigated in combination with high dose intravenous gamma globulin and anti-CD20 treatment.

The ongoing US investigator-initiated Phase II study has enrolled and transplanted a total of 17 patients. Included patients had donor-specific antibodies (DSAs) and a positive cross-match test prior to IdeS treatment. Attempts to desensitize these patients using currently available methods had been made prior to inclusion in the IdeS study. IdeS effectively reduced the level of DSAs in all patients and turned the crossmatch tests from positive to negative, thereby enabling transplantation for all patients. All patients will be followed for six months to monitor safety, kidney function and DSA levels. Results from the study were published in *The New England Journal of Medicine* in August 2017[3].

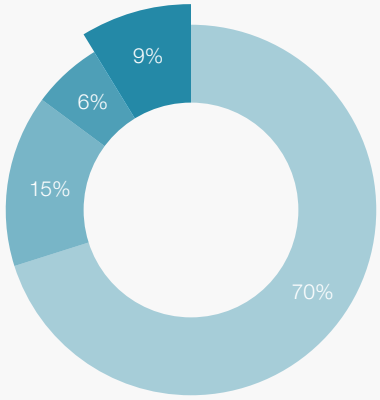


Figure G. Approximately 30 percent of the patients on transplant wait-lists are sensitized. Approximately half of these patients are highly sensitized and half are moderately sensitized. Approximately nine percent of the patients on the US kidney transplant waitlist are refractory HLA-sensitized patients. This share is equivalent to 9000 patients[4].

The multi-center study Highdes in highly sensitized patients – Enrollment completed in January 2018

The ongoing Highdes study (ClinicalTrials.gov Identifier: NCT02790437) has enrolled and transplanted a total of 18 patients at NYU Langone Medical Center in New York, Cedars-Sinai Medical Center in Los Angeles, The Johns Hopkins Hospital in Baltimore, Necker Hospital in Paris and Uppsala University Hospital in Uppsala, Sweden. The primary objective of the study is to evaluate the efficacy of IdeS in patients who are on the waiting list for kidney transplant and have previously undergone desensitization unsuccessfully or in whom effective desensitization with currently available methods will be highly unlikely.

At study entry, the patients had an available deceased or live donor with a positive crossmatch test. The study assesses the efficacy and safety of IdeS in removing donor-specific antibodies (DSAs) and thereby converting a positive crossmatch test to negative. All treated and transplanted patients will be followed up for six months. The primary objective of the study – to turn a positive crossmatch test into a negative and thereby enable kidney transplantation - has been accomplished in all 18 treated patients.

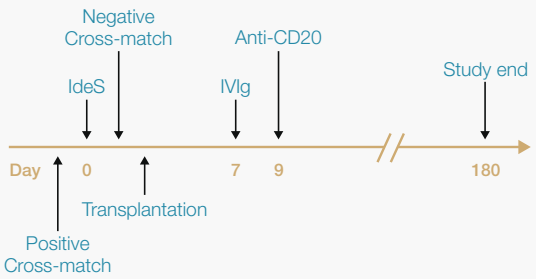


Figure H. The Highdes study protocol. IdeS turns a positive cross match into a negative crossmatch test and thereby enables kidney transplantation for a highly sensitized patient. Seven days after the transplantation the patient is given one dose of intravenous gamma globulin and nine days post transplantation the patient receives one dose of anti-CD20 such as rituximab. The patient is then followed for six months.

Interview with Dr Stanley Jordan

Director, Nephrology & Transplant Immunology, Medical Director, Kidney Transplant Program at Comprehensive Transplant Center, Cedars-Sinai Medical Center, Los Angeles and Professor of Pediatrics & Medicine, David Geffen School of Medicine at UCLA

In the US, how many patients on dialysis are on the waiting list for a kidney transplant?
There are just over 114,000 patients on the transplant waiting-list right now. Of these, some 95,000 to 98,000 are waiting for a kidney.

In what way could fast depletion of IgG-antibodies improve the situation for patients waiting for a new kidney?
It would mean a breakthrough in transplantation of highly sensitized patients. These patients often have to wait a long period of time – about one third of the patients on the waitlist are moderately or highly sensitized. Many of them never get transplanted and these patients die while waiting for an organ.

How has the new Kidney Allocation System (KAS) implemented in 2014 improved the possibilities for transplantation for the highly sensitized patients?
It has definitely helped, we use the allocation system and it is a valuable complement. However, the allocation system is great, but it does not solve the problem with matching for the highly sensitized patients. For those patients, desensitization still is the needed therapy.

Why is desensitization so important for kidney transplantation?
It is in fact a growing problem. Back when I started, and for many years – it was the general belief that the problem of sensitization would diminish over time.

It has not. For women, pregnancies are the major reason why they become sensitized. Another general reason is actually previous kidney transplantation. We lose about 5,000 kidneys a year – usually due to antibody-mediated rejection. Some 70% of these patients will be highly sensitized when they return to the waiting list. Patients also become highly sensitized due to other reasons such as following blood transfusions.

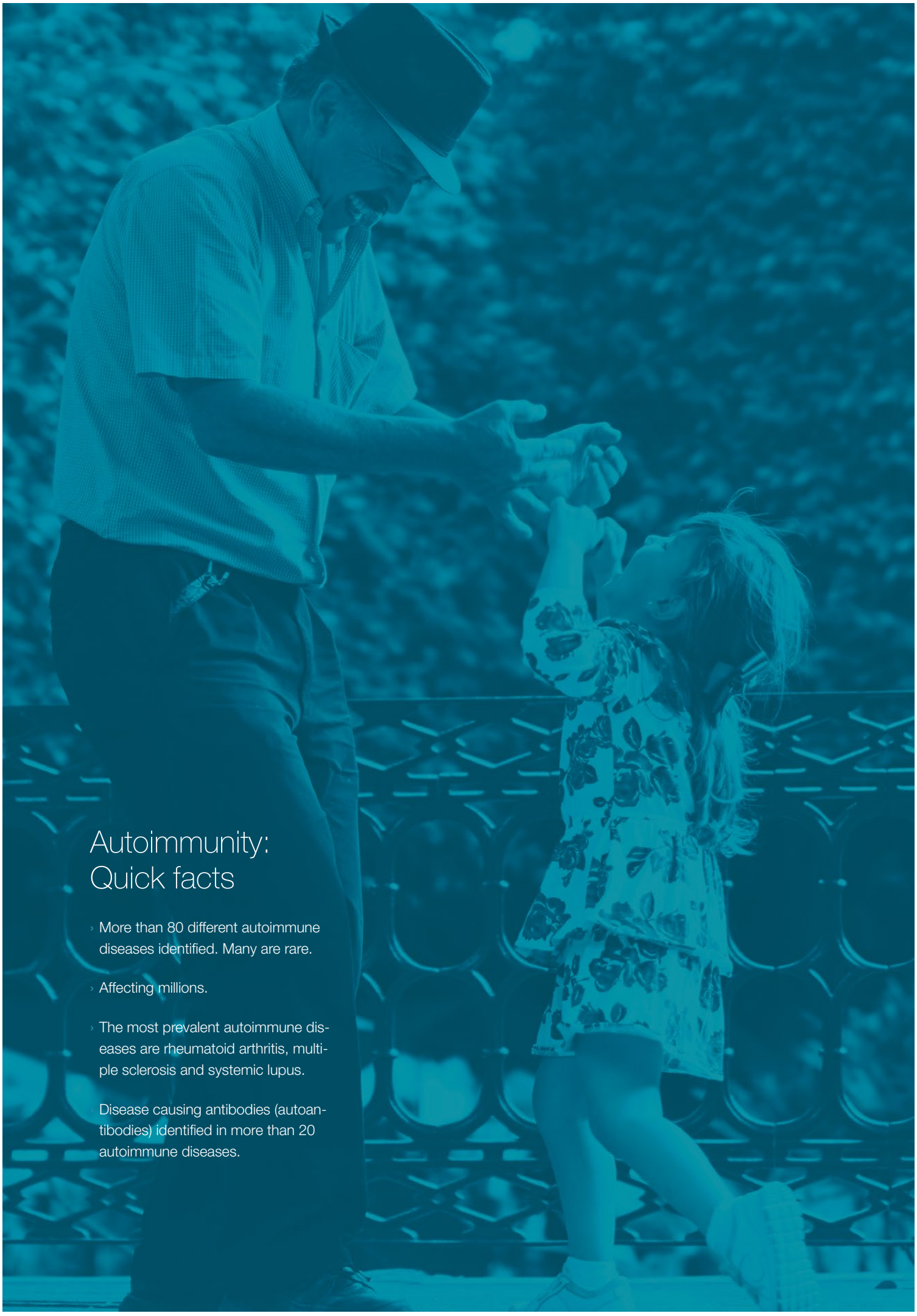
For me and my colleagues, antibodies are the problem “de jour”. The attention has definitely moved from the T-cells back to the antibodies. Fast IgG removal has the potential to enable more transplantations.

You have extensive experience from working with desensitization for many years. Which methods do you use and what can you accomplish with these methods?
At our center, we transplant about 220 kidney patients a year – 40-45% of which are highly sensitized patients. We use intravenous immunoglobulin, plasmapheresis and rituximab. These methods combined have given good results, but it is still very difficult to address the patients with the highest levels of antibodies. It is also hard to directly affect the levels of circulating antibodies.

What are the most important findings from your clinical study with IdeS that was published in The New England Journal of Medcine in July?
That IdeS depleted donor specific antibodies in all of the 25 treated patients, which allowed for performance of incompatible transplants. Of the 25 treated and transplanted patients, 24 patients had good kidney function at study completion, six months following transplantation. One graft loss occurred due to non-HLA

IgM and IgA antibodies. Five biopsy confirmed episodes of acute antibody-mediated rejection (AMR) occurred in the 24 patients but all responded well to treatment. The most common adverse events were temporary infections that all resolved. IdeS has a unique mechanism of action. The fact the Journal *(The New England Journal of Medicine)* found the results interesting in a comparatively small number of patients speaks for itself.

The next step is to find out if it also can treat antibody-mediated rejection. We have put together a protocol with the team at Hansa Medical for treating AMR. It will be an exciting multi-center study with 15 to 25 patients.



Autoimmunity: Quick facts

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

Clinical studies with IdeS in acute autoimmune diseases and additional transplant indications

GOOD-IDES, the investigator-initiated Phase II in Anti-GBM antibody disease – Enrollment ongoing

Anti-GBM antibody disease, also known as Goodpasture disease, is a rare and acute autoimmune disease where autoantibodies directed against type IV collagen cause acute inflammation of the kidney and/or the lungs. In severe anti-GBM, the disease may progress to renal failure or death. Anti-GBM antibody disease is a rare disease affecting one in a million annually[8] and less than one third of the patients survive with a preserved kidney function after six months follow-up[9].

In June 2017, an open label investigator-initiated Phase II study in severe anti-GBM antibody disease was initiated with Hansa Medical lead candidate IdeS. The study (ClinicalTrials.gov identifier NCT03157037) is coordinated by Professor Mårten Segelmark at Linköping University Hospital, Sweden, who is also the principal investigator/sponsor. Approximately 15 patients will be recruited to the study at up to 15 clinics in Europe. The primary objective of the study is to evaluate the safety and tolerability of IdeS in patients with severe anti-GBM antibody disease in addition to standard-of-care. IdeS efficacy will be assessed by evaluating renal function at six months after IdeS treatment.

As of March 21, 2018 seven patients had been included in the investigator-initiated Phase II study in severe anti-GBM. Limited follow-up data is currently available from five of these seven patients who have all responded favorably. IdeS appears to be well tolerated. In addition, prior to site initiation of this ongoing study, three patients were treated on a named patient basis in Sweden. Hence, a total of ten patients with anti-GBM disease have been treated with IdeS as of March 21 2018.

Additional Phase II studies with IdeS under planning

AMR post kidney transplantation

There is no effective therapy for the treatment of antibody-mediated rejection (AMR). In heart, lung and kidney transplants, AMR occurs in up to 10–20 percent[10] of patients and remains a significant unmet medical need associated with loss of graft function. IdeS is highly effective in inactivating IgG and has the potential to halt progression of AMR and be an effective treatment in severe AMR.

In May 2017, IdeS was discussed in a two-day workshop titled Antibody Mediated Rejection in Kidney Transplantation, organized by the FDA. Transcripts from the workshop have been released and are available on the FDA website. The presenters and the audience at the well-attended workshop were generally very optimistic about the potential of IdeS in kidney transplantation.

Guillain-Barré syndrome

The acute immune-mediated polyneuropathies (damage affecting peripheral nerves) are classified under the eponym Guillain-Barré syndrome (GBS). Most often, GBS presents as an acute monophasic paralyzing illness provoked by a preceding infection and occurs worldwide with an overall incidence of one to two per 100,000 per year[11]. Patients are treated with either IVIG or plasmapheresis; however, there remains a significant unmet medical need.

Approximately 20–30 percent[12] experience respiratory failure and five to ten percent of patients with GBS have a prolonged course with several months of ventilator dependency and very delayed and incomplete recovery. Four to five percent of patients with GBS die despite intensive care. The proportion of patients with GBS who cannot walk unaided six months after onset is approximately 20 percent.

In February 2017, preclinical data demonstrating the treatment potential of IdeS in GBS were published[13]. In a model of GBS, inactivation of IgG by IdeS treatment significantly promoted the recovery and reduced the degeneration of peripheral nerves. The data show that treatment with IdeS could potentially become a novel therapeutic strategy for the treatment of GBS.

In February 2018, IdeS (INN: imlifidase) received orphan drug designation from the FDA for the treatment of GBS.

Finalized and ongoing clinical studies with IdeS

Type of study	Clinical trials.gov identifier	Subjects	Status	Results	Publication
Phase I in healthy subjects	NCT01802697	29	Completed	IdeS is efficacious and well tolerated with a favorable safety profile.	*PLOS ONE* (2015) [1]
Phase II in sensitized patients	NCT02224820	8	Completed	IdeS treatment resulted in HLA levels acceptable for transplantation in all patients.	*American Journal of Transplantation* (2018) [2]
Phase II in sensitized patients	NCT02475551	10	Completed	IdeS enabled kidney transplantation for all patients with a favourable safety profile.	*The New England Journal of Medicine* (2017) [3]
Phase II in highly sensitized patients	NCT02426684	17	Fully enrolled. Final results by Q3 2018	IdeS effectively reduced the level of DSAs in all patients and has enabled transplantation for all patients. All patients will be followed for six months.	*The New England Journal of Medicine* (2017) [3]
Multicenter Phase II in highly sensitized patients (Highdes)	NCT02790437	18	Fully enrolled. Final results by Q3 2018	The primary objective of the study – to turn a positive cross-match test into a negative and thereby enable kidney transplantation - accom- plished in all treated patients. All patients will be followed for six months.	
Phase II in Anti-GBM disease (GOOD-IDES)	NCT03157037	Approx. 15	Enrolling		

Strategy in regulatory, medical affairs and commercialization

Regulatory strategy for IdeS as pre-treatment in kidney transplantation
The Highdes study has enrolled patients with a positive crossmatch test against their available live or deceased donor. These patients have either failed on previous attempts of desensitization or are highly likely to fail desensitization with currently available methods due to their immunological state.

In May 2017, the EMA granted IdeS access to its Priority Medicines (PRIME) scheme for desensitization of highly sensitized kidney patients. Through PRIME, EMA offers early and proactive Scientific Advice meeting support. A product that benefits from PRIME can be expected to be eligible for accelerated assessment of the Marketing Authorization Application (MAA) once submitted. In US there are also expedited programs in place for products that address an unmet medical need in the treatment of a serious condition. Hansa Medical is planning to request a formal meeting with the FDA to discuss the potential for expedited development and review of the IdeS (INN: imlifidase) Biologics License Application (BLA). Hansa Medical is planning to meet with both the FDA and EMA as soon as six months follow up data from the ongoing Highdes study is available.

Orphan drug designation for IdeS
Orphan drug designation is granted to drugs intended for the treatment of life-threatening or chronically debilitating rare diseases where no therapeutic options are either authorized or where the drugs will be of significant benefit to those affected by the condition. Rare diseases are those defined as having a prevalence of no more than five in 10,000 persons in Europe or affecting less than 200,000 patients in the US.

The designation provides development and commercial incentives, including up to ten years of market exclusivity in the EU and up to seven years in the US, protocol assistance on the development of the drug, including clinical studies and certain exemptions from or reductions in regulatory fees.

In January 2017, EMA approved Hansa Medical's application for orphan drug designation of IdeS for the prevention of graft rejection following solid organ transplantation. In September 2015, IdeS was granted orphan drug designation for the prevention of antibody-mediated organ rejection in solid organ transplant patients by the FDA.

In February 2018, the FDA granted orphan drug designation to IdeS (INN: imlifidase) for the treatment of GBS.

Medical affairs
Hansa Medical has started to build a medical affairs department. In the US, we have engaged senior medical science liaisons (MSLs) that are part of the medical community. These MSLs are able to help provide insight into currently published data from clinical studies with IdeS. As we gain more and more clarity on the regulatory path and timelines, we will further shape our US presence and underlying organization.

Commercialization strategy
Hansa Medical aims at attaining market approval for lead candidate IdeS as pre-treatment of sensitized patients prior to kidney transplantation as soon as possible in the US and in EU. In preparation, the first layers of a commercial infrastructure have been laid out by our commercial operations department. In Europe we are building a similar organization, and we will continue with the recruitment of senior expertise in market access and patient advocacy.

Manufacturing of IdeS

During 2017, Hansa Medical has made significant investments in process development. The IdeS manufacturing process has been transferred to two manufacturers suitable for commercialization. The manufacturing processes have been optimized and the product for commercialization is a lyophilized product. A lyophilized version of IdeS brings the advantages of easy off-the-shelf use and is convenient and effective for world-wide distribution.

The first GMP batch for further clinical studies was produced in late 2017. Full process characterization and validation for commercial supply will be completed during 2018.

Addressable patient population and currently available treatments

Addressable patient population in prioritized indications

The potential indication universe for IdeS as an effective and safe IgG-eliminating treatment is comprehensive and our long-term goal is to establish Hansa Medical as the world leading IgG-modulating company. We estimate the number of addressable patients within the seven major markets (US, EU5 and Japan) in the currently prioritized indications, organ and tissue transplantation, anti-GBM and GBS, to be between 30,000 to 40,000 [4,7,9,10] [14–22] patients annually.

Our ambition is to seek regulatory approval for IdeS as pre-treatment of sensitized patients, initially in the US and in EU. In parallel, we conduct and plan Phase II studies in closely related transplant indications and in a few selected acute autoimmune diseases.

Additional treatment potential for IdeS

Incompatible blood type (ABOi) kidney transplant

Many potential transplant recipients with otherwise suitably matched donors with respect to HLA are relegated to the ever-expanding waiting list due to ABO blood group incompatibility (ABOi) [14]. The presence of anti-blood group antigen antibodies can prevent transplantation if the donor and recipient have different blood groups. If not adequately removed, the presence of such antibodies is likely to result in severe antibody-mediated rejection (AMR) and early graft loss.

Based upon the distribution of blood groups in the US, approximately one-third of potential living donors are eliminated from consideration based on ABOi. The two methods currently used to reduce circulating ABO antibody titers are plasmapheresis and immuno-absorption. Splenectomy and anti-CD20 are often used as adjunctive therapies.

The current methods require careful planning and are not feasible for deceased donor transplants. Approximately 70 percent [4] of all kidney transplantations in the US and Europe are from deceased donors.

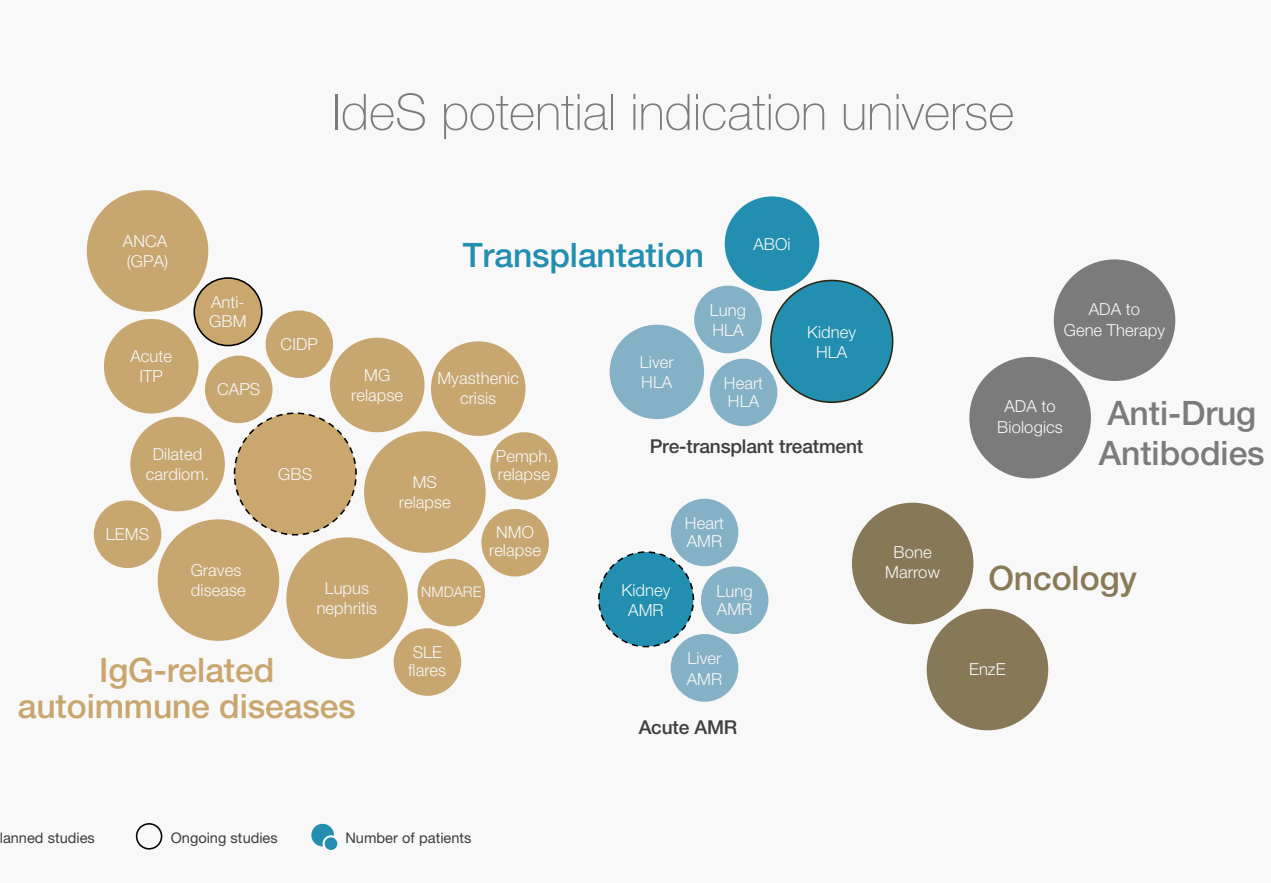


Figure I. IdeS and other IgG-eliminating enzymes (Project NiceR) from Hansa Medical have the potential to treat several acute IgG-mediated diseases and medical conditions.

Heart and lung transplantation (Desensitization and AMR)
According to *The International Society for Heart and Lung Transplantation* [15], about 4,300 heart and 3,600 lung transplants, respectively are performed annually. About 15 percent [16, 17] of patients are HLA-sensitized, i.e. have antibodies against Human Leukocyte Antigen, making it more difficult or impossible to find suitable donors. The number of sensitized patients awaiting heart transplantation is increasing due to increasing use of mechanical pumps that support heart function. Antibody-mediated rejection (AMR) post transplantation occurs in 10–20 percent [15] of heart transplant patients.

Hematopoietic stem cell transplantation (Desensitization)
Hematopoietic stem cell transplantation (HSCT) is a potentially curative treatment for a wide range of blood cancers as well as non-cancerous blood disorders. Also, HSCT is a possible treatment for patients with bone marrow failure caused by chemotherapy in the treatment of other forms of cancer. The stem cells necessary for this method are usually obtained from the peripheral blood or bone marrow of a related or unrelated donor.

Transplantation from an unrelated, or related, donor is referred to as allogeneic whereas transplantation with stem cells derived from the patient is referred to as autologous transplantation. Relatives can usually be asked to donate stem cells much more quickly than unrelated volunteer donors. The closer the HLA match between a donor and recipient, the greater the chance a transplant will be successful.

However, as is the situation in solid organ transplantation, patients may become sensitized to HLA by prior blood transfusions, transplantation or pregnancy. With patients referred for allogeneic HCT, approximately 20 to 23 percent will have measurable HLA antibodies and 15 percent will have donor specific antibodies (DSA) [18, 22]. Desensitization regimens with IdeS can potentially inactivate DSA facilitating engraftment and thereby increase the number of eligible donors.

Other IgG-mediated autoimmune diseases and acute immunogenicity
IdeS can potentially be used in many different acute autoimmune conditions in which IgG antibodies are proven or suspected to play a significant role for disease progression. Hansa Medical's 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 suboptimal which further strengthens the rational for considering further clinical development with IdeS in these indications. IdeS could potentially make a significant therapeutic difference in several of these acute indications. In addition, IdeS may have the potential to inactivate anti-drug antibodies developed against biological drugs and gene therapies.

Current treatment possibilities in acute IgG-mediated disease
There are currently no approved interventions for desensitization prior to organ transplantation or stem cell transplantation. At some clinics in the US and Europe, experimental protocols based on pre-treatment with plasmapheresis, intravenous gamma globulin (e.g. Gamunex®) or rituximab (e.g. Rituxan®), or combinations thereof, are used for desensitization. Usually, these protocols require pre-treatment for days or weeks prior to transplantation and are therefore primarily applicable to living donor transplantation. Additional experimental desensitization protocols have been tested or are occasionally applied involving proteasome inhibitors (e.g. Velcade®) or complement inhibitors (e.g Soliris® and Cinryze®).

There are currently no approved interventions for treatment of antibody-mediated rejection (AMR) of a transplanted organ. The acute treatment of AMR is today based on the use of plasmapheresis and steroids. Some clinics also use drugs such as Soliris® and Rituxan®. A clinical Phase III study is currently ongoing with Cinryze® in AMR. There are currently no approved drugs for interventions of anti-GBM antibody disease (Goodpasture syndrome). The acute treatment of anti-GBM primarily involves plasmapheresis, steroids and cyclophosphamide.

Desensitization to enable blood-group incompatible (ABOi) transplantation is today performed with plasmapheresis if the transplant recipient has a living donor candidate identified. For transplant patients awaiting a transplant from a deceased donor, plasmapheresis is usually not possible. 70 percent of all kidney transplantations in the US and Europe are from deceased donors. All lung and heart transplantations are from deceased donors.

Preclinical development projects

NiceR – Novel immunoglobulin cleaving enzymes for Repeat dosing

Hansa Medical is developing completely new IgG-degrading enzymes based on experience from IdeS and similar molecules. The aim of the development is to create novel IgG-inactivating drugs that can be used for repeated dosing in autoimmune conditions, oncology and transplantation where patients could benefit from more than one dose of an IgG-modulating enzyme.

Several novel immunoglobulin cysteine endopeptidases have been developed and patented. The development program is currently in lead optimization phase with the ambition to select a lead candidate suitable for clinical development.

EnzE – Enzyme-based antibody Enhancement

Many antibody-based cancer therapies rely on activation of the immune system via so called Antibody-Dependent Cell-mediated Cytotoxicity (ADCC). The antibodies bind to antigens on cancer cells and once attached, the antibody attracts immune cells to destroy the cancer cells. For instance, the anti-CD20 antibody, which is used for treatment of lymphoma and leukemia, binds to surface molecules on cancer cells and activates cytotoxic immune cells to kill the cancer cells. The immune cells are activated through binding of the Fc-part of the antibody to so called Fc-gamma receptors on the cell surface of the immune cells.

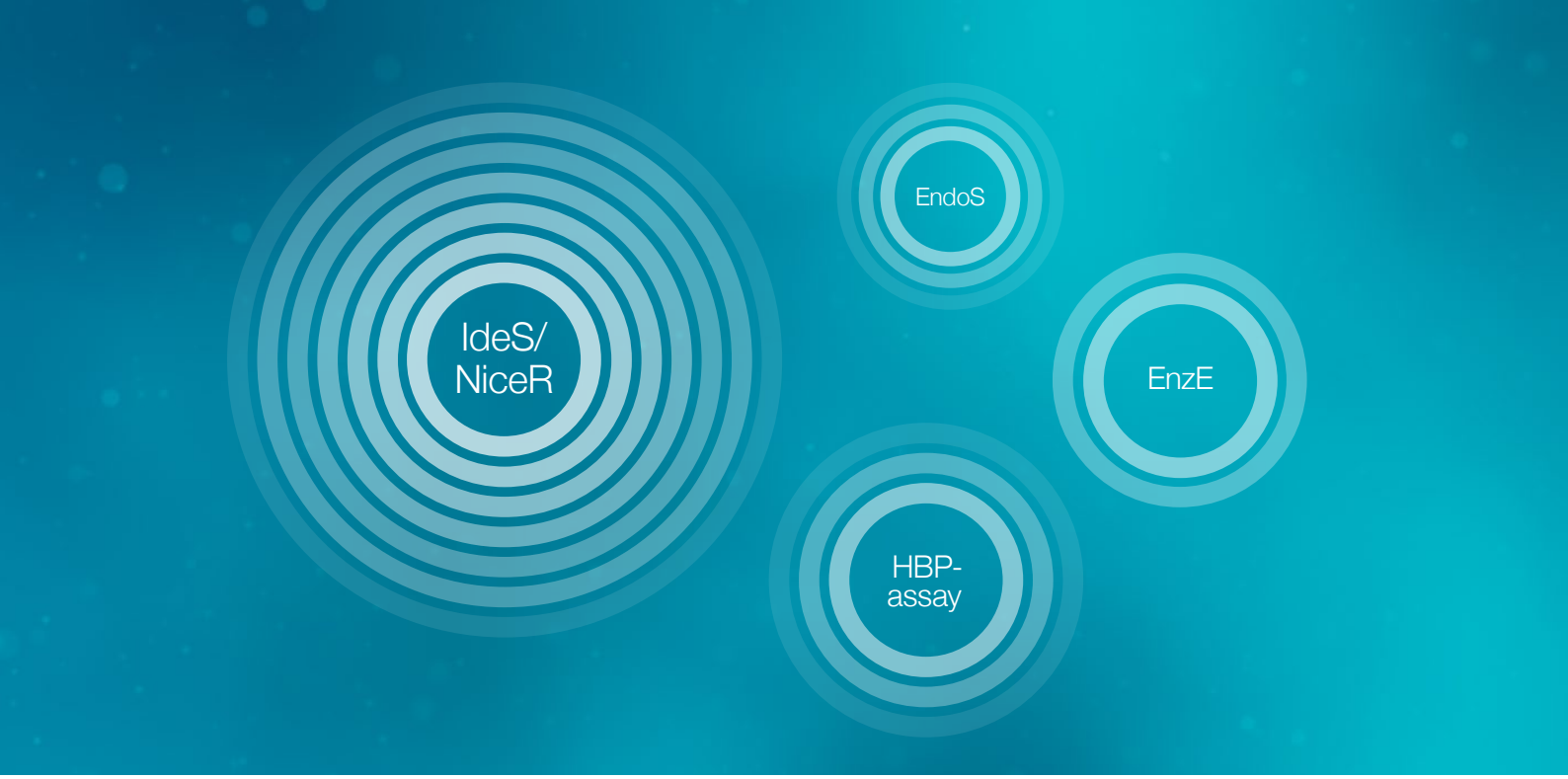
The Fc-gamma receptors are involved in the therapeutic effector functions of many different antibodies and often needed to acquire sufficient effect. However, due to the abundance of normal IgG in blood, the Fc-gamma receptors are occupied by IgG and the therapeutic antibodies have to compete for binding to the Fc-gamma receptors. Hence pre-treatment with IdeS has the potential to potentiate presently available antibody-based cancer therapies. Results from *in vitro* and *in vivo* testing of the concept have been published [23, 24].

Out-licensed royalty-generating programs

HBP – A biomarker for prediction of severe sepsis
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[25] 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
IMPRESSED, IMproved PREdiction of Severe Sepsis in the Emergency Department, is a completed[26] 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 percent) developed severe sepsis within 72 hours. Seventy eight percent 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), C-reactive protein (CRP) and 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 percent and the specificity was 95 percent 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 and China. In addition, Axis-Shield has launched 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.



Intellectual property and exclusivity

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 seven 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 and oncology 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 patent families protecting IdeS and similar molecules expire between 2021 and 2035, with the possibility of 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 five years of supplemental protection.

Various applications covering the IgG-modulating enzyme EndoS are protected by three different patent families that include both granted patents and pending patent applications.

Orphan drug designation and data exclusivity

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

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

In January 2017, the EMA approved Hansa Medical's application for orphan drug designation of IdeS for the prevention of graft rejection following solid organ transplantation. In September 2015, IdeS was granted orphan drug designation for the prevention of antibody-mediated organ rejection in solid organ transplant patients by the FDA. In February 2018, the FDA granted orphan drug designation to IdeS (INN: imlifidase) for the treatment of Guillain-Barré syndrome.

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

US and European Medical Advisory Boards

Professor Stanley Jordan

Chairman US Medical Advisory Board

Stanley Jordan, MD, PhD, is a 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. Dr. Jordan's focus is on immunology and transplantation. He has performed extensive research funded by dozens of research grants and awards, including National Institutes of Health controlled clinical trials in kidney transplantation. Dr. Jordan has written hundreds of articles in scientific journals and authored about two dozen book chapters. He was appointed by the National Institutes of Health's National Institute of Allergy and Infectious Diseases to advise Congress on the safety and efficacy of intravenous gamma globulin products. Dr. Jordan has been principal investigator on 3 NIH Controlled Clinical Trials in Kidney Transplantation. Dr. Jordan has received the Medical Sciences Award from the UCLA Alumni Association, Gift of Life Award from the National Kidney Foundation, Established Investigator Award from the American Society of Transplantation and Distinguished Alumni Award from the University of North Carolina-Chapel Hill School of Medicine. Dr. Jordan is a member of national and international professional societies and has served on the editorial boards of numerous professional journals.

Professor Robert Montgomery

US Medical Advisory Board

Robert A. Montgomery, MD, DPhil, FACS is Director at NYU Langone Transplant Institute, New York, NY. Dr. Montgomery is the inaugural recipient of the Margery K. and Thomas Pozefsky Endowed Professorship in Kidney Transplantation. He was part of the team that developed the laparoscopic procedure for live kidney donation, a procedure that has become the standard throughout the world. Dr. Montgomery is considered a world expert on kidney transplantation for highly sensitized and ABO incompatible patients. He has received important awards and distinctions including a Fulbright Scholarship, a Thomas J. Watson Fellowship and memberships in the Phi Beta Kappa and Alpha Omega Alpha academic honor societies. He has been awarded multiple scholarships from The American College of Surgeons and The American Society of Transplant Surgeons. The National Kidney Foundation of Maryland has recognized his contributions to the field of transplantation with the Champion of Hope Award and the National Kidney Registry recognized him with the Terasaki Medical Innovation Award.

Professor Kathryn Wood

US and European Medical Advisory Board

Kathryn Wood, PhD, is Professor of Immunology in the Nuffield Department of Surgical Sciences, University of Oxford where she runs the Transplantation Research Immunology Group. Professor Wood is an internationally renowned medical researcher in transplant tolerance induction, immune regulation and interaction between the immune system and stem cell derived tissues. She is a Fellow of The Academy of Medical Sciences and has received several international awards for her distinguished research, including the Royal Society Wolfson Merit Award for research excellence. Professor Wood has served as President of the Transplantation Society and currently leads the Women in Transplantation Initiative and functions as editor of the journal Transplantation.

Professor Christophe Legendre

European Medical Advisory Board

Christophe Legendre, MD, PhD is Professor of Nephrology at the Paris Descartes University and Head of the Adult Nephrology and Transplantation unit at Necker Hospital in Paris. Professor Legendre's main research interests include clinical evaluation of new immunosuppressants, viral infection after transplantation, transplantation in high risk recipients, screening kidney biopsies and recurrence of disease post transplantation. He has published around 340 papers in English peer reviewed journals. Professor Legendre is member of several professional societies including the American Society of Transplantation, the European Society for Organ Transplantation and the Transplantation Society as well as associate editor of the American Journal of Transplantation and Europe Regional Associate Editor of the journal Transplantation.

Professor Gunnar Tufveson

Chairman of European Medical Advisory Board

Gunnar Tufveson, MD, PhD, former Professor of Transplant Surgery at Uppsala University at Uppsala University Hospital. Professor Tufveson has more that 30 years of experience in all aspects of kidney and pancreas transplantation. His research has focused on immunological and pathophysiological mechanisms in transplantation, resulting in more than 300 articles and book chapters. Professor Tufveson has served as Primary Investigator in several clinical trials sponsored by the pharmaceutical industry as well as the US National Institutes of Health.

In Memoriam – Göran Arvidson

It was with sadness that on November 8, 2017, Hansa Medical announced the passing of Göran Arvidson at the age of 57. His death was both deeply tragic and completely unexpected.

Göran was recruited to Hansa Medical as CFO in January 2015. He became acting CEO shortly afterwards and was appointed permanent CEO on April 30 the same year. Before joining Hansa Medical, he had a long and successful career in the pharmaceutical industry, including senior positions at Pharmacia and later Biovitrum (Sobi), where he was one of the founders.

With his solid experience from the pharmaceutical industry and through his deep and genuine commitment, Göran was an appreciated and accomplished leader for Hansa Medical, which, under his leadership, developed into a promising pharmaceutical company with its lead project IdeS currently in late-stage clinical development for kidney transplant patients. Göran was also a caring and thoughtful friend, and a devoted husband and father. He will be sadly missed by all of us.

Shareholder information

The Hansa Medical share is listed on Nasdaq OMX Stockholm, under the ticker HMED and in the following indexes:
- OMX Nordic Mid Cap
- OMX Nordic Health Care index
- OMX Stockholm Benchmark Index
- OMX Stockholm Health Care
- OMX Stockholm Pharmaceuticals & Biotechnology
- MSCI Global Small Cap
- NASDAQ Biotechnology Index

Brief facts, the HMED share

Listing	Nasdaq OMX Stockholm
Number of shares	38,208,386 (37,807,386 A-shares and 401,000 C-shares)
Market capitalization (Dec. 31, 2017)	SEK 9,433m
Ticker	HMED
ISIN	SE0002148817

Closing price for the HMED share in 2016 and 2017

	2016		2017	
SEK	High	Low	High	Low
1st quarter	34.9	18.8	141.3	96.8
2nd quarter	66.5	34.0	271.5	127.0
3rd quarter	83.0	56.5	222.0	158.0
4th quarter	152.0	70.0	260.0	184.5

Shareholder categories, December 31, 2017

Owner	Shares	Capital (%)
Nexttobe AB	9,443,761	24.7
Swedish private individuals	10,160,256	26.6
Swedish institutions	7,638,299	20.0
Other owners	4,531,760	11.9
Foreign institutions	3,580,805	9.4
Other foreign	2,452,505	6.4
Treasury shares	401,000	1.0
Total	**38,208,386**	**100.0**

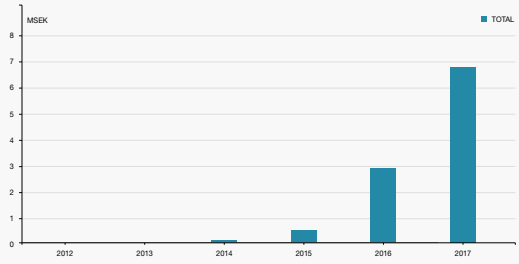
Share capital

Total shares outstanding as of 31 December 2017 amounted to 38,208,386 (37,807,386 A-shares and 401,000 C-shares). At year end the share capital amounted to SEK 38,208,386. 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.

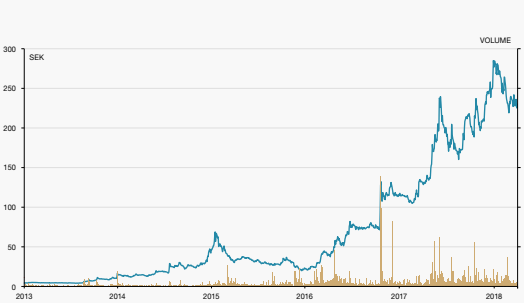
Shareholders by country

Country	Number of shares	Share (%)
Sweden	31,186,039	81.6
USA	1,775,063	4.7
Great Britain	864,958	2.2
Denmark	677,211	1.8
Luxembourg	620,279	1.6
France	255,427	0.7
Norway	192,232	0.5
United Arab Emirates	58,469	0.1
Finland	58,380	0.1
Germany	53,045	0.1
Others	147,810	0.4
Anonymous foreign ownership	2,319,473	6.2
Total	**38,208,386**	**100.0**

Turnover of the HMED share at Nasdaq Stockholm 2012 to 2017



HMED share price and trading volume January 1, 2013 to March 15, 2018



15 largest shareholders, December 31, 2017

	Number of shares		
Owners	HMED	HMED C	Capital (%)
Nexttobe AB	9,443,761	0	24.7
AFA Försäkring	1,825,959	0	4.8
Thomas Olausson (private and via company)	1,548,569	0	4.1
Avanza Pension	1,346,278	0	3.5
Handelsbanken Fonder	1,305,157	0	3.4
Gladiator	1,168,530	0	3.1
Oppenheimer	1,103,232	0	2.9
Polar Capital	609,589	0	1.6
BWG Invest Sàrl	600,370	0	1.6
Tredje AP-fonden	572,594	0	1.5
Sven Sandberg	539,700	0	1.4
Catella Fonder	488,280	0	1.3
C WorldWide Asset Management	440,541	0	1.2
Invesco	412,085	0	1.1
Hansa Medical AB	0	401,000	1.0
Others	16,402,741	0	42.8
Total	**37,807,386**	**401,000**	**100.0**

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

Dividend

The Board proposes no dividend for the financial year of 2017. For more information about Hansa Medical's dividend policy, please refer to the Hansa Medical Corporate Governance Report available at the company website at http://hansamedical.com/en/investors-media/corporate-governance/corporate-governance-report/

Long-term incentive programs

Hansa Medical has two ongoing incentive programs for the company's employees as of April 2018, of which a share warrant program adopted by the Annual General Meeting on June 2, 2015 and a performance based share program (LTIP 2016) adopted by the Extraordinary General Meeting on November 21, 2016. Descriptions of the various programs can be found in the section of the Directors' Report.

Subscription for shares in the share warrant program may take place during the period June 15, 2018 and June 15, 2019. Increase of the company's share capital upon full exercise of the warrants will amount to SEK 355,000, which corresponds to a dilution of 1.1 percent of the total number of ordinary shares and of the total number of votes in the company.

The share rights granted in LTIP 2016 are divided into two vesting periods, the first one ending November 28, 2019 and the second May 18, 2020. At maximum of 305,000 ordinary shares may be allotted to the participants and 96,000 ordinary shares can be used to cover social security contributions due to the program, which means a dilution effect of 1.2 percent of the total number of ordinary shares and of the total number of votes.

Analysts following Hansa Medical

SEB	Richard Koch
Rx Securities	Samir Devani
RBC Capital Markets	Nick Keher
Redeye	Mathias Spinnars
Chardan Capital Markets	Gbola Amusa
ABG Sundal Collier	Andrew Carlsen
B. Riley FBR	Madhu Kumar
Evercore ISI	Josh Schimmer

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Glossary

AMR
Antibody mediated transplant rejection.

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

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

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

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

Biopharmaceutical
A pharmaceutical drug that is manufactured using biotechnology.

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

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

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

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

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

Clinical Phase 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.

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

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

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.

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

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

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

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

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

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

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

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

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

IVD
IVD, In vitro diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

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

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

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

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

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

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

Streptococcus pyogenes
A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

Five-year summary

KSEK, unless other stated	2013	2014	2015	2016	2017
Profit number					
Net revenue	1,705	1,677	6,675	2,579	3,442
Operating profit/loss	-17,629	-24,709	-66,201	-111,135	-176,083
Net profit/loss	-17,562	-29,042	-66,266	-111,129	-176,660
Capital					
Total assets	50,614	54,311	224,088	310,672	680,415
Capital employed	46,036	49,934	211,617	284,289	631,262
Equity	45,349	49,804	211,526	283,693	630,661
Investments (intangible and tangible fixed assets)	64	1,204	1,317	984	2,409
Cash and cash equivalents including short term investments	90	10,152	175,683	253,578	616,061
Cash flow					
Cash flow from operations before change in working capital	-17,520	-23,522	-65,078	-106,944	-162,894
Cash flow from operating activities	-14,830	-23,623	-57,799	-94,563	-150,105
Cash flow from investing activities	-4,529	-1,319	-2,796	-45,414	2,693
Cash flow from financing activities	483	-35,004	226,126	177,882	514,902
Net change in cash	-18,876	10,062	165,531	37,905	367,490
Key ratios					
Return on capital employed (%)	-38	-49	-31	-39	-28
Return on equity (%)	-33	-61	-51	-45	-39
Equity ratio (%)	90	92	94	91	93
Debt/Equity ratio (%)	12	9	6	10	8
Share overview					
Earnings/loss per share (SEK)	-0.75	-1.09	-2.12	-3.37	-4.97
Shareholders' equity per share (SEK)	2.04	1.92	6.53	8.09	16.68
Dividend (SEK)	–	–	–	–	–

Directors' report

Operations

Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for transplantation and acute autoimmune diseases. The lead project IdeS is a proprietary antibody-degrading enzyme currently in late-stage clinical development for kidney transplant patients, with significant potential for further development in other solid organ transplants and a wide range of acute autoimmune indications. The company also has a strong pipeline of preclinical assets that may provide a second wave of potential drugs. Under the project name NiceR, novel immunoglobulin cleaving enzymes are developed for repeat dosing translating the Hansa Medical technology into relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden, its shares (ticker: HMED) are listed on Nasdaq Stockholm.

Business review January–December 2017

The New England Journal of Medicine publishes results from Phase II studies of Hansa Medical's lead candidate IdeS in highly sensitized patients

Combined data from three independent clinical Phase II studies with Hansa Medical's lead candidate IdeS was published in *The New England Journal of Medicine* 2017;377:442-53, August 3, 2017 issue. The published results demonstrate that treatment with IdeS is effective in reducing donor-specific antibodies (DSAs) to levels allowing lifesaving kidney transplantation of highly sensitized patients.

IdeS selected for EMA Priority Medicines (PRIME) scheme

The European Medicines Agency (EMA) granted Hansa Medical access to its Priority Medicines (PRIME) scheme for IdeS in enabling kidney transplantation for highly sensitized patients. PRIME is a scheme launched by the EMA to enhance support for the development of medicines that target an unmet medical need.

Directed share issue of SEK 545 million to selected international and Swedish investors completed

Hansa Medical successfully raised SEK 545 million (USD 65 million), gross, through a directed share issue to a number of US, UK and Swedish specialist healthcare investors. The proceeds will enable the timely completion of ongoing clinical studies with IdeS evaluating the efficacy of this drug candidate to enable kidney transplantation in highly sensitized patients. The proceeds are also being used to expand the company's commercial and medical affairs' capabilities. Hansa Medical will also carry out several clinical studies in related transplant indications and in selected acute autoimmune diseases.

Update on number of patients included in the anti-GBM study

Continued patient enrollment in the investigator-initiated Phase II study with IdeS in anti-GBM. The study began in June 2017, and as of December 31, seven patients have been recruited and treated with IdeS. Limited follow-up data is currently available, but all patients have responded favorably and IdeS appears to be well tolerated. Patients enrolled in the study will be monitored for six months.

Hansa Medical announces sudden death of CEO Göran Arvidson

Ulf Wiinberg, the company's Non-Executive chairman, was appointed Acting CEO, following the tragic and unexpected death of the company's CEO, Göran Arvidson. Board member Birgit Stattin Norinder was appointed chairman.

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 a need to carry out further clinical studies, the recall of products, stopped import, denial of registration, the withdrawal of previously approved applications, or criminal charges. Even if a pharmaceutical manufactured by Hansa 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 trials 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.

Dependence on key product

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

Market and competition

The products Hansa Medical has under development risk being exposed to competition from new pharmaceuticals and diagnostic methods. Developing a new pharmaceutical from invention to finished product requires a long time. Not the least for this reason, when development is underway it is uncertain whether there will be any market for the product when it is finally developed and, in such case, how large this market will be, as well as which competing products the company's products will encounter when they reach the market. To the extent competition consists of existing preparations or methods, Hansa 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.

Manufacturing
The manufacturing process for IdeS is made in collaboration with contract manufacturers in Europe. Hansa Medical is dependent on the quality of the manufacturing processes as well as the availability and maintenance of the production facilities. Regulatory authorities require that all manufacturing processes and methods, as well as all equipment comply with current requirements of Good Manufacturing Practice, GMP Requirements and consequences for the Company in the event of deficiencies in GMP requirements may lead to delays in clinical trials or to market products.

Purchasing and pricing
On many markets, purchases of pharmaceuticals of the type being developed by the company are financed, in whole or in part, by a party other than the patient, for example caregivers, insurance companies or governmental authorities subsidizing pharmaceuticals. If the company does not achieve acceptance for its products and the pricing of the products by such financiers, this may make it more difficult for the products to reach the market and may prejudice their commercial potential, which may negatively affect the Group's earnings and financial position.

Dependence on key persons
Hansa 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 25.

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 microorganisms (GMM) in its research and development work (research activities). The company's operations are subject to a notification obligation under the Swedish Environmental Code with a reporting obligation to the municipality of Lund.

Financial review

Financial result
Net revenue for the 2017 financial year amounted to SEK 3.4 m (2.6) and comprised of royalty income from Axis-Shield Diagnostics and re-invoiced expenses.

Other operating income and expenses amounted to SEK 1.5 m (-0.9) for the full year 2017 and is comprised mainly of grant from Vinnova.

Operating result for the 2017 financial year amounted to SEK -176.1 m (-111.1). Research and development expenses increased during the year with intensified CMC-development, continued build-up of the clinical and medical affairs organization, commercial build-up and regulatory work. In the operating result for 2017, recorded non-cash costs for the company's long term incentive programs (LTIP 2016) amounting to SEK 9.9 m is included.

Net profit/loss for 2017 amounted to SEK -176.7 m (-111.1).

Cash flow and financial position
Cash flow from operating activities amounted to SEK -150.1 m (-94.6) for the 2017 financial year. The cash flow after financing was positively impacted by the share issue in December. Cash and cash equivalents including short term investments amounted to SEK 616.1 m at the end of the 2017 financial year, as compared with SEK 253.6 m at the year end 2016.

Investments
Investments during the 2017 financial year amounted to SEK 243.3 m (200.4) Investments during 2017 related primarily to:

- Laboratory equipment in the amount of SEK 1.4 m
- Production equipment in the amount of SEK 0.6 m
- Capitalized patent costs of SEK 0.2 m
- Computer equipment in the amount of SEK 0.2 m
- Short term investments of commercial papers of SEK 240.9 m

Shareholders' equity
On December 31, 2017 equity amounted to SEK 630.7 m compared with SEK 283.7 m at the end of the financial year 2016.

Share issue 2017
In the fourth quarter, Hansa Medical finalized a directed share issue, which brought the company SEK 545 m before deduction of costs. The directed issue was comprised of 2,752,526 shares at SEK 198 per share. The number of outstanding shares amounts to 37,087,386 shares after the share issue. The rights issue has enabled the company to broaden the ownership structure with strategic and institutional investors as well as to secure the capital needed for completion of the ongoing clinical studies with IdeS evaluating the efficacy of this drug candidate to enable kidney transplantation in highly sensitized patients, preparations for market approvals in the EU and the US and allow for continued Investments in the next generation of IgG-cleaving enzymes for repeated dosage.

Parent company
The Parent company's net revenue for the 2017 financial year amounted to SEK 3.7 m (2.6). The result after net financial items for the Parent company amounted to SEK -176.4 m (-108.4) for the 2017 financial year. On December 31, 2017, cash and cash equivalents including short-term investments amounted to SEK 613.8 m compared with SEK 128.6 m at the end of 2016.

The Parent company's equity amounted to SEK 625.5 m as per December 31, 2017, as compared with SEK 281.8 m at the end of 2016.

The Group consists of the Parent company Hansa Medical AB and the subsidiaries Cartela R&D AB and Immago Biosystems Ltd. Immago Biosystems Ltd is owner of patent rights to the Enze concept.

Group – Key ratios and other information

	1 January – 31 December	
KSEK, unless other stated	2017	2016
Profit numbers		
Net revenue	3,442	2,579
Operating profit/loss	-176,083	-111,135
Net profit/loss	-176,660	-111,129
Per share data		
Earnings/loss per share before and after dilution (SEK)	-4.97	-3.37
Shareholders' equity per share (SEK)	16.68	8.09
Other information		
Shareholders' equity	630,661	283,693
Equity ratio (%)	93	91
Cash flow from operating activities	-150,105	-94,563
Cash and cash equivalents including short term investments	616,061	253,578
Number of employees end of the year	33	27

Organization and employees

At the close of 2017, the Board of Directors consisted of the chairman Birgit Stattin Norinder and directors Ulf Wiinberg, Stina Gestrelius, Per Olof Wallström, Hans Schikan and Angelica Loskog. The board's audit committee consisted of Per-Olof Wallström (chairman), Birgit Stattin Norinder and Hans Schikan. The remuneration committee consisted of Birgit Stattin Norinder (chairman) and Hans Schikan and the scientific committee consisted of Birgit Stattin Norinder (chairman), Stina Gestrelius, Hans Schikan and Angelica Loskog.

Corporate management consisted of the acting president and the CEO Ulf Wiinberg; the Senior vice president, Research and Development Christian Kjellman; the Vice president, Chief Financial Officer Eva-Maria Joed; the Vice president, Project Management Lena Winstedt; the Vice president, Business Development and Investor Relations Emanuel Björne; the Vice president, Chief Medical Officer Sam Agus; the Vice president, Corporate Strategy Max Sakajja; the Vice president, Commercial Operations Henk Doude van Troostwijk and the Vice president, Regulatory Affairs Karin Aschan. There were 33 employees at the end of 2017 as compared with 27 employees at the end of 2016.

Share capital and ownership

Total shares outstanding as of December 31 2017 comprised of 37,807,386 ordinary shares and 401,000 C-shares. At year end the share capital amounted to SEK 38,208,386. At the general meeting, each ordinary share entitles the holder to one vote and C-shares to one tenth of a vote each and do not entitle to dividends. Each shareholder may vote the full number of shares held by him or her. The company's share capital is denominated in Swedish kronor (SEK) and divided amongst the company's outstanding shares with a quotient value of SEK 1 per share. As per December 31, 2017, the single largest shareholder in Hansa Medical was Nexttobe AB, with a total of 9,443,761 shares, representing 24.7 per cent of the voting rights and the capital.

Share warrant program

Hansa Medical's Annual General Meeting adopted on June 2, 2015 a share warrant program for the company's employees. 355,000 warrants were acquired by the company's employees during 2015 and 2016. Each warrant entitles the holder to subscribe for one new share in Hansa Medical. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 15, 2018 to June 15, 2019. The warrants were sold to the company's employees on market terms at a price established on the basis of an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute.

The increase in the company's share capital upon full exercise of the share warrants will amount to SEK 355,000, and corresponds to a dilution of 1.1 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 former CEO, have been given a one-time bonus as part of the stock option purchase. The options are linked to continued employment with the company only in the sense that, if the employment would be terminated, the stock option owner shall offer the warrants to the company and repay the resulting subsidy. The subsidy will affect the company's results proportionately during the option period in accordance with the same principles as in IFRS 2.

Long-term incentive program (LTIP 2016)

The Hansa Medical's Extraordinary General Meeting November 21, 2016 resolved to adopt a long-term incentive program (LTIP 2016) in the form of a performance based share program for all employees of the Hansa Medical Group, meaning that not more than 30 individuals within the group may participate. The rationale for LTIP 2016 is to create conditions for motivating and retaining competent employees of the Hansa Medical group and for the alignment of the targets of the employees with those of the shareholders and the company, as well as to increase the motivation of meeting and exceeding the company's financial targets. A maximum of 305,000 rights may be allotted to participants under LTIP 2016 and 289,750 rights have been totally allocated at December 31, 2017. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. The rights allocated on December 31, 2017, are divided into two vesting periods, the first of which ends November 28, 2019 and the second May 18, 2020.

The general meeting further resolved, in order to implement LTIP 2016 cost effectively, to authorize the Board to decide on a directed share issue of a maximum of 401,000 Class C shares to participating bank, of which a maximum of 96,000 Class C shares to be issued to cover any social costs arising from the program and to authorize the Board to resolve to repurchase all issued C-shares. The directed share issue of the 401,000 Class C-shares and the repurchase were executed in May 2017. After the conversion of C shares to ordinary shares, these shall partly be transferred to participants in LTIP 2016 and partly divested in the market for cash flow purposes to secure certain payments related to LTIP 2016, mainly social security costs. Not more than 305,000 ordinary shares can be transferred to participants under LTIP 2016 and 96,000 common shares can be used to cover any social security contributions due to the LTIP 2016, which means a dilution of 1.2 per cent of the ordinary shares and votes in the company.

LTIP 2016 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost of LTIP 2016, calculated in accordance IFRS 2, including social security contributions is expected to amount to approximately SEK 31.5 m, of which SEK 9.9 m is included in the results for the parent company and the group for 2017. The program is not expected to have any net effect on cash flow provided it is secured fully in the manner described above.

Other information

For additional information, please see the Corporate governance report.

Annual general meeting 2018

The annual general meeting of Hansa Medical AB (publ) will take place on May 29, 2018 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

Søren Tulstrup appointed new President and CEO of Hansa Medical

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

Completed enrollment in Hansa Medical's international multi-center Phase II study Highdes in January, 2018

The primary objective of the study – to turn a positive crossmatch test into a negative and thereby enable kidney transplantation - has been accomplished in all 18 treated patients at five clinics in the US and Europe. All patients will be monitored for six months.

Finalized enrollment in US Phase II study with IdeS in highly sensitized patients in January, 2018

IdeS effectively reduced the level of DSAs in all 17 treated patients and turned the crossmatch tests from positive to negative, thereby enabling transplantation for all patients. All patients will be followed for six months to monitor safety, kidney function and DSA levels.

FDA Orphan Drug Designation for IdeS and the treatment of Guillain-Barré syndrome in February, 2018

In February 2018, the FDA granted orphan drug designation to IdeS for the treatment of GBS. Orphan drug designation qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits, protocol assistance and potentially seven years of orphan drug exclusivity.

Financial calendar

Interim report for January–March 2018	25 April 2018
Annual General Meeting	29 May 2018
Interim report for January–June 2018	19 July 2018
Interim report for January–September 2018	1 November 2018

Proposal for dividend

Unrestricted shareholders' equity in the parent company

SEK	
Share premium reserve	946,569,767
Own shares	-401,000
Profit carried forward	-182,475,952
Result for the year	-176,372,699
Total	**587,320,116**

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

SEK	
Share premium reserve	946,569,767
Own shares	-401,000
Profit carried forward	-358 848 651
Total	**587,320,116**

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	2017	2016
Net revenue	2, 3	3,442	2,579
Direct cost of net revenue		-221	-217
Gross profit		**3,221**	**2,362**
Other operating income	4	1,479	–
Sales, general and administration expenses		-43,723	-29,703
Research and development expenses		-137,060	-82,850
Other operating expenses	4		-944
Operating profit/loss	5, 6, 7, 25	**-176,083**	**-111,135**
Financial income			
Financial expenses		-616	-17
Net financial income/expenses	8	**-616**	**-17**
Result before tax		**-176,699**	**-111,152**
Tax	9	39	23
Result for the year		**-176,660**	**-111,129**
Attributable to			
Parent company shareholders		-176,660	-111,129
		-176,660	**-111,129**
Earnings per share	10		
before dilution (SEK)		-4.97	-3.37
after dilution (SEK)		-4.97	-3.37

Statement of comprehensive income

		1 January – 31 December	
KSEK	Note	2017	2016
Result for the year		-176,660	-111,129
Other comprehensive income			
Items that have been, or may be reclassified to profit or loss for the year			
Translation differences for the year		-22	-26
Changes in fair value for the year on available-for-sale financial assets		3,535	4,690
Other comprehensive income for the year		**3,513**	**4,664**
Comprehensive income for the year		**-173,147**	**-106,465**
Total net comprehensive income attributable to			
The parent company's owner		-173,147	-106,465
		-173,147	**-106,465**

Balance sheet

KSEK	Note	As of 31 December 2017	2016
ASSETS			
Fixed assets			
Intangible fixed assets	11	33,749	36,554
Tangible fixed assets	12	3,976	2,570
Financial fixed assets	14	18,508	14,566
Total fixed assets		**56,233**	**53,690**
Current assets			
Tax receivable		–	–
Accounts receivable	17	508	74
Prepaid expenses and accrued income	18	320	656
Other receivables	16	7,293	2,674
Short term investments		34,983	39,990
Cash and cash equivalents	19	581,078	213,588
Total currents assets		**624,182**	**256,982**
TOTAL ASSETS		**680,415**	**310,672**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	20		
Share capital		38,208	35,055
Other paid in capital		946,570	429,207
Own shares		-401	–
Reserves		9,801	6,288
Retained earnings including result for the year		-363,517	-186,857
Shareholders' equity attributable to parent company shareholders		**630,661**	**283,693**
Total shareholders' equity		**630,661**	**283,693**
Long term liabilities			
Deferred tax liabilities	9	538	581
Other provisions	21	5,017	114
Long term liabilities, interest bearing	22	601	552
Total long-term liabilities		**6,156**	**1,247**
Current liabilities			
Current interest-bearing liabilities	22	–	44
Accounts payable		3,771	6,482
Tax liabilities		–	84
Other liabilities	23	7,285	1,824
Accrued expenses and deferred income	24	32,542	17,298
Total current liabilities		**43,598**	**25,732**
Total liabilities		**49,754**	**26,979**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**680,415**	**310,672**

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

Changes in equity

		Equity attributable to the parent company's shareholders							
KSEK	Note	Share capital	Additional contributed capital	Own shares	Translation reserve	Fair value reserve	Retained earnings including profit or loss for the year	Total	Total shareholders' equity
Opening shareholders' equity, 1 Jan 2016	20	32,412	253,218	–	–	1,624	-75,728	211,526	211,526
Net comprehensive income									
Result for the year		–	–	–	–	–	-111,129	-111,129	-111,129
Other comprehensive income for the year		–	–	–	-26	4,690	–	4,664	4,664
Net comprehensive income		**–**	**–**	**–**	**-26**	**4,690**	**-111 129**	**-106,465**	**-106,465**
Transactions with the group's owner									
New share issue		2,643	182,357	–	–	–	–	185,000	185,000
Expenses attributable to new share issue		–	-7,504	–	–	–	–	-7,504	-7 504
Issued warrants		–	772	–	–	–	–	772	772
Long term incentive program		–	364	–	–	–	–	364	364
Total transactions with the group's owner		**2,643**	**175,989**	**–**	**–**	**–**	**–**	**178,632**	**178,632**
Closing shareholders' equity, 31 Dec 2016		**35,055**	**429,207**	**–**	**-26**	**6,314**	**-186,857**	**283,693**	**283,693**

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

Cash flow statement

		1 January – 31 December	
KSEK	Note	2017	2016
Operating activities			
Operating income		-176,083	-111,135
Adjustment for items not included in cash flow [1]	30	13,827	4,269
Interest received		–	5
Interest paid		-638	-83
Cash flow from operating activities before changes in working capital		**-162,894**	**-106,944**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) of account receivable		-434	551
Increase (-)/Decrease (+) of other operating receivables		-3,835	-1,450
Increase (+)/Decrease (-) of accounts payable		-2,711	5,482
Increase (+)/Decrease (-) of other operating liabilities		19,769	7,798
Cash flow from operating activities		**-150,105**	**-94,563**
Investing activities			
Acquisition of business, net cash effect	31	–	-1,924
Acquisition of intangible fixed assets		-214	-57
Acquisition of tangible fixed assets		-2,195	-927
Acquisition of financial assets		–	-2,588
Short term investments		-240,898	-194,918
Divestment short term investments		246,000	155,000
Cash flow from investing activities		**2,693**	**-45,414**
Financing activities			
New share issue [2]		545,401	185,000
Issue expenses		-30,050	-7,504
Repurchase of own shares [2]		-401	–
Issued warrants		–	429
Repayment of leasing liabilities		-48	-43
Cash flow from financing activities		**514,902**	**177,882**
Net change in cash		367,490	37,905
Cash and cash equivalents, beginning of year		213,588	175,683
Cash and cash equivalents, year-end		**581,078**	**213,588**

[1] Values for 2017 pertain mainly to costs of share based incentive program (LTIP 2016) including social contributions.

[2] Values for 2017 refer to directed share issue and repurchase of 401,000 class C shares for financing of the company's long term incentive program (LTIP 2016) and directed share issue in Q4 2017 of 2,752,526 ordinary shares.

Parent company

Income statement

		1 January – 31 December	
KSEK	Note	2017	2016
Net revenue	2, 3	3 739	2,579
Direct cost of net revenue		-221	-217
Gross profit		**3 518**	**2,362**
Other operating income	4	1,479	–
Sales, general and administration expenses		-43,740	-29,690
Research and development expenses		-137,015	-82,735
Other operating expenses	4	–	-944
Operating profit/loss	5, 6, 25	**-175,758**	**-111,007**
Result from financial items:			
Result from other securities and receivables which are fixed assets		–	2,628
Other interest income and similar profit/loss items		97	86
Interest expenses and similar profit/loss items		-712	-100
Result after financial items	8	**-176,373**	**-108,393**
Result before taxes		**-176,373**	**-108,393**
Tax	9	–	–
Net result		**-176,373**	**-108,393**

Statement of comprehensive income

		1 January – 31 December	
KSEK	Note	2017	2016
Net result		-176,373	-108,393
Other comprehensive income		–	–
Other net comprehensive income		**–**	**–**
Net comprehensive income		**-176,373**	**-108,393**

Balance sheet

KSEK	Note	As of 31 December 2017	2016
ASSETS			
Fixed assets			
Intangible fixed assets	11	30,709	33,513
Tangible fixed assets	12	3,976	2,554
Financial fixed assets			
Interests in group companies	29	4,818	4,818
Other long term holdings of securities	15	12,499	12,499
Total financial fixed assets		17,317	17,317
Total fixed assets		**52,002**	**53,384**
Current assets			
Current receivables			
Accounts receivable	17	508	74
Receivables in group companies	13	469	101
Other receivables	16	7,291	2,673
Prepaid expenses and accrued income	18	320	656
Total currents receivables		8,588	3,504
Current liabilities		34,992	39,995
Cash and cash equivalents		578,795	211,329
Total currents assets		**622,375**	**254,828**
TOTAL ASSETS		**674,377**	**308,212**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	20		
Restricted equity			
Share capital		38,208	35,055
Unrestricted shareholders' equity			
Share premium reserve		946,570	429,207
Own shares		-401	–
Retained earnings		-182,476	-74,083
Net result		-176,373	-108,393
Total shareholders' equity		**625,528**	**281,786**
Long-term liabilities			
Other provisions	21	5,017	114
Liabilities to group companies		98	98
Long-term liabilities, non interest bearing	22	601	548
Total long-term liabilities		**5,716**	**760**
Current liabilities			
Accounts payable		3,724	6,460
Tax liabilities		–	84
Other liabilities	23	6,882	1,824
Accrued expenses and deferred income	24	32,527	17,298
Total current liabilities		**43,133**	**25,666**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**674,377**	**308,212**

Changes in equity

	Restricted equity	Unrestricted equity				
KSEK	Share capital	Share premium reserve	Own shares	Retained earnings	Result for the year	Total shareholders' equity
Opening shareholders' equity, 1 Jan 2016	32,412	253,218	–	-9,460	-64,623	211,547
Net comprehensive income						
Result for the year	–	–	–	–	-108,393	-108,393
Other comprehensive income for the year	–	–	–	–	–	–
Net comprehensive income	**–**	**–**	**–**	**–**	**-108,393**	**-108,393**
Appropriation of profits	–	–	–	-64,623	64,623	–
New share issue	2,643	182,357	–	–	–	185,000
Costs attributable to new share issue	–	-7,504	–	–	–	-7,504
Issued warrants	–	772	–	–	–	772
Long term incentive program	–	364	–	–	–	364
Closing shareholders' equity, 31 Dec 2016	**35,055**	**429,207**	**–**	**-74,083**	**-108,393**	**281,786**

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

Cash flow statement

		1 January – 31 December	
KSEK	Note	2017	2016
Operating activities			
Operating income		-175,758	-111,007
Adjustment for items not included in cash flow [1]	30	13,621	4,118
Interest received		–	5
Interest paid		-637	-79
Cash flow from operating activities before changes in working capital		**-162,774**	**-106,393**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) of account receivable		-434	551
Increase (-)/Decrease (+) of other operating receivables		-4,201	-1,551
Increase (+)/Decrease (-) of accounts payable		-2,736	5,460
Increase (+)/Decrease (-) of other operating liabilities		19,754	7,843
Cash flow from operating activities		**-150,391**	**-94,660**
Investing activities			
Acquisition of business, net cash effect	31	–	-1,924
Acquisition of tangible fixed assets		-2,195	-927
Acquisition of financial assets		–	-2,588
Short term investments		-240,898	-194,918
Divestment short term investments		246,000	155,000
Cash flow from investing activities		**2,907**	**-45,357**
Financing activities			
New share issue [2]		545,401	185,000
Issue expenses		-30,050	-7,504
Repurchase of own shares [2]		-401	–
Cash flow from financing activities		**514,950**	**177,496**
Net change in cash		367,466	37,479
Cash and cash equivalents, beginning of year		211,329	173,850
Cash and cash equivalents, year-end		**578,795**	**211,329**

[1] Values for 2017 pertain mainly to costs of share based incentive program (LTIP 2016) including social contributions.

[2] Values for 2017 refer to directed share issue and repurchase of 401,000 class C shares for financing of the company's long term incentive program (LTIP 2016) and directed share issue in Q4 2017 of 2,752,526 ordinary shares.

Notes

Note 1 Material accounting principles

(a) Compliance with norms and legislation
The consolidated accounts have been prepared in accordance with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) as adopted by the EU. In addition, recommendation RFR 1 issued by the Swedish Financial Reporting Board (Supplemental Accounting Rules for Corporate Groups) has been applied

The parent company applies the same accounting principles as the group with the exception of those cases set forth below under the section entitled "The parent company's accounting principles".

(b) Valuation grounds applied in the preparation of the financial reports
Assets and liabilities are reported at historic acquisition value, with the exception of certain financial assets and liabilities which are valued at net realizble value. Financial assets and liabilities valued at net realizable value consist of shares listed on an exchange, investments in interest-bearing commercial papers and contingent purchase price, not yet paid.

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

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

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

(e) Changes in accounting principles
(i) Changes in accounting principles due to new or amended IFRS
The following describes the changed accounting principles applied by the Group as of 1 January 2017. Other amendments to IFRS with effect from January 1, 2017 have not had any significant effect on the Group's accounts.

(ii) Voluntary change of accounting principle
As of December 31, 2017, the Group has changed to settlement date accounting for the purchase and sale of financial assets. Previously, business day accounting was applied. The Group acquired as of December 28, 2017, interest funds of SEK 430m. As a result of the change, the acquired interest funds are reported in the balance sheet only on the day of settlement on January 2, 2018, except for the change in fair value between the business day and the balance sheet date of SEK -403k, which has been reported as one current liability against other comprehensive income. The change of accounting principle has not had any effect on comparison periods. The Group's accounting principles are otherwise unchanged compared to Annual Report for 2016.

(iii) 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.

IFRS 16 Lease replaces from 2019 existing IFRS releated to recognition of lease, such as IAS 17 Lease and IFRIC 4 Determining whether and agreement contains a lease. Hansa Medical does not plan to apply IFRS 16 earlier.

IFRS 16 mainly affects the lessee and the main effect is that all leases currently accounted for as operating leases should be accounted for in a manner similar to the current accounting for financial leases. This means that even under operating leases have assets and liabilities reported, with associated reporting of costs for depreciation and interest - in contrast to today where no accounting is made of the leased asset and related liability, and where the lease payments are amortized linearly as the lease cost.

Hansa Medical will as operating lessee be affected by the introduction of IFRS 16. Amounts calculations of the impact of IFRS 16 and choice regarding the transition methods have not yet been implemented. The information provided in Note 26 on operating leases gives an indication of the type and scope of the agreements that currently exist.

Estimated effect of the transition to IFRS 9 and IFRS 15
Effects of IFRS 15: Revenue from contracts with customers
IFRS 15 comes into force as of January 1, 2018. The Group's revenue from contracts with customers consists above all of royalty income from the contract with Axis-Shield Diagnostics (ASD).The introduction of IFRS 15 will not affect how Hansa Medical reports revenue from the contract with ASD.

Effects of IFRS: 9 Financial Instruments
IFRS 9 comes into force as of January 1, 2018 and replaces IAS 39 Financial Instruments: Accounting and valuation as a standard for reporting of financial instruments in IFRS.Compared with IAS 39, IFRS 9 applies changes in particular regarding the classification

and valuation of financial assets and financial liabilities, impairment of financial assets and hedge accounting. IFRS 9 will affect how the Group reports holdings in interest funds. Under IAS 39, these have been reported at fair value via other comprehensive income. Interest funds however, does not meet the criteria in IFRS 9 for reporting of changes in value through other comprehensive income. The changes in value of the interest funds will be reported in IFRS 9 in the income statement instead. This entails that accumulated changes in value of the interest funds of SEK -403k will be transferred from "Real value reserve "to" Retained earnings "in the consolidated opening balance sheet as at 1 January 2018.

The Group also has holdings of commercial papers which, under IAS 39, have been valued at fair value through other comprehensive income. Holdings of commercial papers are included in IFRS 9 instead of being reported at accrued acquisition value The accumulated change in value of the certificates with SEK 9k will be removed from "Real value reserve" against the value of the papers in the balance sheet so that these are reported at an accrued acquisition value of SEK 34,992k in the consolidated opening balance sheet as at January 1, 2018.

The introduction of IFRS 9 does not have any other significant effects on the Group.

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

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

(h) Consolidation principles
(i) Subsidiary
Subsidiaries are companies under the controlling influence of Hansa Medical AB.

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

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

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

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

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

(j) Net sales
(i) Revenues
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.

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

(k) Leasing
(i) Operational leasing agreements
Costs regarding operational leasing agreements are reported in the earnings for the year using a straight line method over the leasing term. Benefits obtained in conjunction with the execution of an agreement are reported in the earnings for the year as a reduction

in the leasing fees using a straight line method over the term of the leasing agreement. Variable fees are booked as expenses in the periods in which they arise.

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

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

(i) Reporting in, and removal from, the statement of financial position
A financial asset or financial liability is reported in the balance sheet 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 statement of financial position 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 statement of financial position 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 and investments in interest-bearing commercial papers, are reported in this category. Assets in this category are measured at fair value with the

period changes in value recognized in other comprehensive income and the accumulated changes in value in a separate component of shareholders' equity, excluding such changes in value due to impairment losses (see accounting principle (q)), nor interest on debt instruments or dividend income which are recognized in net income. At the disposal of the asset, accumulated gains/losses previously recognized in other comprehensive income are recognized in net income.

Financial liabilities valued at fair value through results
In this category, contingent purchase price, changes in fair value are recognized in net income.

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	3–10 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 and there is no capatilized development expense.

(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.

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

In 2016 a long-term incentive program (LTIP 2016) was initiated. The participants in the program will be given the oppurtunity to receive ordinary shares if certain performance conditions are met. The fair value of options granted is recognized as a personnel cost with a corresponding increase in equity. The fair value is measured at grant date and spread over the vesting period. Social costs relating to share-based payments to employees as compensation for services rendered are expensed in the periods in which the services are performed. The charge is based on the fair value at the time of the report.

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

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

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

Voluntary change of accounting principle
At December 31, 2017, the parent company has changed to settlement date reporting for acquisition of financial assets. See above for the Group.

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 Net revenue

Income per significant category of income

	1 January – 31 December	
KSEK	2017	2016
Group		
Net revenue		
Royalty and licensing revenue	2,140	2,169
Re-invoiced expenses	1,302	410
	3,442	**2,579**
Parent company		
Net revenue		
Royalty and licensing revenue	2,140	2,169
Re-invoiced expenses	1,302	410
	3,442	**2,579**

Note 3 Operating segment

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 mainly allocated to Sweden.

Note 4 Other operating income and expenses

	1 januari – 31 december	
KSEK	2017	2016
Group		
Government grant	1,439	–
Profit on sale of fixed assets	37	–
Profit/loss on receivables/liabilities from operating activities	3	-944
	1,479	**-944**
Parent company		
Government grant	1,439	–
Profit on sale of fixed assets	37	–
Profit/loss on receivables/liabilities from operating activities	3	**-944**
	1,479	**-944**

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

Note 5 Employees and personnel costs

Costs for remuneration to employees

	1 January – 31 December	
KSEK	2017	2016
Group		
Salaries and remuneration, etc.	32,905	21,315
Pension costs, contribution plan	4,682	3,125
Social charges	13,444	5,441
	51,031	**29,881**

Average number of employees

	2017		2016	
	Number	of which men	Number	of which men
Parent company				
Sweden	32	35%	22	33%
Total parent company	**32**	**–**	**22**	**–**
Total group	**32**	**33%**	**22**	**33%**

Breakdown of corporate management according to gender

	Share of women	
	2017-12-31	2016-12-31
Parent company		
Board of Directors	50%	50%
Other senior management	38%	38%
Total group		
Board of Directors	50%	50%
Other senior management	38%	38%

Salaries, other remuneration and employer payroll taxes

KSEK	2017	2016
Parent company		
Salaries and remuneration	32,905	21,315
Social charges	18,126	8,566
(of which, pension costs)	[1] (4,682)	[1] (3,125)

[1] Of the parent company's pension costs, SEK 859k (760) relates to the Board of Directors and CEO.

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

	2017		2016	
KSEK	Senior management	Other employees	Senior management	Other employees
Parent company				
Sweden	16,321	16,584	8,739	12,576
(of which commissions and similar remunerations)	(0)	(0)	(0)	(0)
Parent company total	16,321	16,584	8,739	12,576
(of which commissions and similar remunerations)	(0)	(0)	(0)	(0)
Group total	16,321		8,739	
(of which commissions and similar remunerations)	(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 2017 annual general meeting resolved that fees paid to directors for work during 2017 will be SEK 600,000 to the chairman of the Board of Directors and SEK 150,000 to each of the other directors, SEK 40,000 to the chairman and SEK 30,000 each to the other directors who are members of the Audit Committee, SEK 40,000 to the chairman and SEK 25,000 each to other directors who are members of the Remuneration Committee and SEK 25,000 each to directors who are members of the Scientific Committe, however no fee is payable to Angelica Loskog. There are no contracts regarding severance compensation or other benefits for the chairman of the Board of Directors or other directors.

Remuneration to CEO
Remuneration
To the former CEO, remuneration has been paid in the form of a fixed salary and pension and to the acting CEO, a fixed consultancy fee, but no pension. During 2017, the basic salary per month was SEK 240,000 for the former CEO and to the acting CEO a monthly consultancy fee corresponding to a basic salary of SEK 510,000. In addition to this, remuneration to the former CEO could be paid in the form of variable salary, severance compensation and non-monetary benefits. The variable salary has been based on the achievement of quanitative and qualitative goals. In 2017 the remuneration paid to the former CEO was SEK 2,760 k and corresponding to the acting CEO SEK 883 k.

Notice of termination periods and severance compensation
Upon termination by the Company or the CEO, a one month notice of termination period has been applied for the acting CEO. Upon termination by the company the acting CEO has not had any right to severance compensation at the end of his employment. The above-stated also applies upon termination by the CEO where the grounds for termination are gross breach of contract by the company.

Pension remuneration
The company has set aside 30% of the CEO's monthly salary on a monthly basis for the occupational pension insurance indicated by the CEO. No pension provision has been done for the acting CEO. In 2017, the cost premium for the CEO was SEK 859 k.

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 2017 for members of group management other than CEO amounted to SEK 12 802 k.

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

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

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

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

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

Salary and other remuneration and other benefits paid to senior management, parent company 2016

KSEK	Base salary Directors' fees	Variable compensation	Share-based payments	Pension cost	Other benefits	Total
Chairman of the Board of Directors Ulf Wiinberg	372	–	–	–	–	372
Director Birgit Stattin-Norinder	292	–	–	–	–	292
Director Stina Gestrelius	150	–	–	–	–	150
Director Per-Olof Wallström	162	–	–	–	–	162
Director Hans Schikan*	363	–	–	–	–	363
Director Angelica Loskog	–	–	–	–	–	–
Director Cindy Wong	52	–	–	–	–	52
Director Anders Blom	–	–	–	–	–	–
CEO	2,400	–	112	760	–	3,272
Other senior management (5 persons)	4,847	218	410	817	90	6,382
Total	**8,638**	**218**	**522**	**1,577**	**90**	**11,045**

*For Hans Schikan paid consulting fees of SEK 207 k is included.

Share-based payments

Share warrant program

In 2015 a share warrant program was adopted which gives the company's employees the right to acquire shares in Hansa Medical. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 15, 2018 to June 15, 2019. The warrants were sold to the company's employees on market terms at a price established on the basis of an estimated market value of the warrants using the Black & Scholes model. In connection with the stock option program participants received a subsidy to acquire options. The value of the subsidy will affect the group's results proportionately during the vesting period of the warrants.

Changes in number of share warrants

KSEK, unless other stated	2017	2016
Opening balance 1 Jan	355,000	296,000
Assigned	–	59,000
Closing balance 31 Dec	**355,000**	**355,000**
Input for valuation of share warrants according to Black & Scholes		
Calculated price (SEK)	8.40	–
Volume-weighted share price (SEK)	36.04	–
Risk-free interest rate (%)	-0.043	–
Expected volatility (%)*	41	–
Reported personnel costs during 2016	190	–
Annual cost for the program	190	–
Total cost for the program allocated to the 3 years vesting period	**791**	**–**

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

Long-term incentive program (LTIP 2016)
The Hansa Medical's Extraordinary General Meeting November 21, 2016 resolved to adopt a long-term incentive program (LTIP 2016) in the form of a performance based share program for all employees of the Hansa Medical group, meaning that not more than 30 individuals within the group may participate. Participants will, provided continued employment throughout the vesting period, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting periods ending November 28, 2019 and May 18, 2020.

Changes in number of rights

KSEK, unless other stated	2017	2016
Opening balance 1 January	234,750	–
Assigned	55,000	234,750
Closing balance 31 December	**289,750**	**234,750**
Calculated fair value per performance share (SEK) *	89.30	62.01
Risk-free interest rate (%)	-0.51	-0.52
Expected volatility (%) **	55	55
Reported personnel costs during 2016	9,877	478
Annual cost for the program	9,877	5,739
Total cost for the program allocated to the 3 years vesting period	**31,534**	**17,218**

* Calculated by Monte Carlo-simulation
** Based partly on historical volatility of the share price for the Hansa Medical share and partly on historical volatility for listed companies with similar business.

Note 6 Fees and competition for costs, auditors

KSEK	2017	2016
Group		
KPMG		
Auditing services	607	441
Other services	38	63
Parent company		
KPMG		
Auditing services	592	441
Other services	38	63

"Auditing services" means statutory audit of the annual report and group accounts and the management by the Board of Directors and CEO, as well as the audit and other reviews carried out as agreed.

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 7 Operating costs by type of cost

	Group	
KSEK	2017	2016
Other operating income	1,479	–
Personnel costs	-56,853	-30,913
Other external costs	-120,151	-78,412
Depreciation	-3,779	-3,445
Other costs	–	-944
	-179,304	**-113,714**

Note 8 Net financial items

Group

KSEK	2017	2016
Other interest income	97	23
Net profit transferred from equity on disposal of available-for sale financial assets	-1	56
Net currency differences	–	7
Financial income	**96**	**86**
Interest expenses, other	-695	-103
	-17	
Financial expenses	**-712**	**-103**
Net financial items	**-616**	**-17**

Parent company

KSEK	2017	2016
Results from other securities and claims which are fixed assets		
Impairment recovered of shares in Genovis AB	–	2,628
	–	**2,628**
Interest income and similar income statement items		
Interest income, other	97	23
Net profit transferred from equity on disposal of available-for sale financial assets	-1	56
Net currency differences	–	7
	96	**86**
Interest expenses and similar income statement items		
Interest expenses, other	-711	-100
	-711	**-100**

Note 9 Taxes

Deferred tax claims

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

KSEK	2017	2016
Opening balance beginning of the year	581	–
Deferred tax liability due to acqusition during the year	–	612
Tax income in the income statement	-39	-23
Currency differences for the year	-4	-8
Closing balance end of the year	**538**	**581**

Unreported deferred tax claims

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

The group's losses carried forward in 2016 amounted to SEK 480,390k (314,051).

Note 10 Earnings per share

Earnings per share

SEK	2017	2016
Earnings per share prior to and after dilution	-4.97	-3.37

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	2017	2016
Profit/loss for the year related to the parent company's shareholders	-176,660	-111,129
Earnings attributable to the parent company's shareholders prior to and after dilution	**-176,660**	**-111,129**

Weighted average number of outstanding shares prior to and after dilution

Number of shares	2017	2016
Total number of shares 1 January	35,054,860	32,412,003
Effect of new share issue in November 2016	–	361,301
Effect of new share issue in December 2017	464,169	235,389
Weighted average number of shares during the year prior to and after dilution	**35,519,029**	**33,008,693**

The weighted average number of shares is affected by new share issues carried out in 2016 and 2017. The weighted number of shares for 2016 has been recalculated taking into consideration the new share issue carried out in 2017.

Note 11 Intangible fixed assets

Group

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2016	4,485	125	33,515	38,125
Acquisition of business	–	3,113	–	3,113
Other acquisitions	–	58	–	58
Currency differences for the year	–	-41	–	-41
Closing balance 31 Dec 2016	4,485	3,255	33,515	41,255
Accumulated write-offs and impairment				
Opening balance 1 Jan 2016	–	-121	-1,677	-1,798
Depreciaton for the year	-2,243	-96	-567	-2,906
Currency differences for the year	–	3	–	3
Closing balance 31 Dec 2016	-2 243	-214	-2,244	-4,701
Reported values				
As of 1 Jan 2016	4,485	4	31,838	36,327
As of 31 Dec 2016	2,242	3,041	31,271	36,554

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

Parent company

	Developed in-house	Acquired intangible assets		
KSEK	Development fees	Patents	Development fees	Total
Accumulated acquisition value				
Opening balance 1 Jan 2016	4,485	125	33,515	38,125
Closing balance 31 Dec 2016	4,485	125	33,515	38,125
Accumulated write-offs and impairment				
Opening balance 1 Jan 2016	–	-121	-1,677	-1,798
Depreciaton for the year	-2,243	-4	-567	-2,814
Closing balance 31 Dec 2016	-2,243	-125	-2,244	-4,612
Reported values				
As of 1 Jan 2016	4,485	4	31,838	36,327
As of 31 Dec 2016	2,242	0	31,271	33,513

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

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, of which product development costs for IdeS where fully depreciated for the year.

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 designation by FDA during 2015 and in January 2017 by European Commission. Promising initial data from investigator sponsored Phase II study with highly sensitized patients in the US was presented at the 2016 American Transplant Congress. A second Phase II study conducted at Uppsala University Hospital and Karolinska University Hospital, where 10 sensitized patients were given IdeS prior to transplantation, was successfully completed in 2016. Patient recruitment for Phase II multicenter study Highdes with 18 highly sensitized kidney transplant patients in the US and Europe was completed in January 2018. Patients will be followed for six months for safety and renal function and final results are expected in the third quarter of 2018.
HPB-assay	HBP-assay is a method of analysis used to predict severe sepsis in emergency clinics. A first version has been launched, primarily intended for research purposes and interested specialists.	The product has been licensed to a cooperating partner, Axis-Shield Diagnostics, which is currently developing a fully commercial product. Hansa Medical receives milestone compensation and additional royalty revenues upon the sale of the sublicensed technology.

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

The Value-In-Use for 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 margin 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 assessment on December 31, 2017 and 2016 demonstrated that there was no need for impairment. The discount rates of interest before tax was 15.0 percent per year.

Capitalized development expenses regarding HBP are written off over the term of the underlying patent in the amount of SEK 562 k 2017 and SEK 567 k 2016.

Note 12 Tangible fixed assets

Group

	Equipment, tools and facilities	
KSEK	2017-12-31	2016-12-31
Accumulated acquisition values		
Opening balance on 1 January	4,621	3,694
Investments during the year	2,195	927
Closing balance on 31 December	6,816	4,621
Accumulated depreciation and write-offs		
Opening balance on 1 January	-2,051	-1,512
Depreciaton during the year	-789	-539
Closing balance on 31 December	-2,840	-2,051
Reported values		
As of 1 January	2,570	2,182
As of 31 December	3,976	2,570

Financial leasing

KSEK	2017-12-31	2016-12-31
Group		
Reported value for assets under financial leasing agreements	–	16

The group used to lease automobiles under financial leasing agreements, but the ageement was terminated in 2017.
The leased asset constituted security for the leasing obligations. See also note 22 and note 27.

Parent company

	Equipment, tools and facilities	
KSEK	2017-12-31	2016-12-31
Accumulated acquisition values		
Opening balance on 1 January	4,317	3,390
Investments during the year	2,195	927
Closing balance on 31 December	6,512	4,317
Accumulated depreciation and write-offs		
Opening balance on 1 January	-1,763	-1,280
Depreciaton during the year	-773	-483
Closing balance on 31 December	-2,536	-1,763
Reported values		
As of 1 January	2,554	2,110
As of 31 December	3,976	2,554

Note 13 Receivables from group companies

Parent company

KSEK	2017-12-31	2016-12-31
Accumulated acquisition values		
1 January	101	–
Additional receivables	367	101
Currency differences for the year	1	–
Reported value on 31 December	**469**	**101**

Note 14 Financial fixed assets

Group

KSEK	2017-12-31	2016-12-31
Financial investments which are fixed assets		
Realizable financial assets		
Shares and participating interests	18,508	14,566
	18,508	**14,566**

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

Note 15 Other long-term securities holdings

Parent company

KSEK	2017-12-31	2016-12-31
Accumulated acquisition values		
1 January	12,499	9,911
Purchases	–	2,588
Closing balance on 31 December	12,499	12,499
Accumulated impairment		
1 January	–	-2,628
Impairment recovered during the year	–	2,628
Closing balance on 31 December	–	–
Reported value on 31 December	12 499	12,499

Note 16 Other receivables

Group

KSEK	2017-12-31	2016-12-31
Other receivables which are current assets		
VAT receivables	1,388	1,147
Other receivables	5,905	1,527
	7,293	**2,674**

Parent company

KSEK	2017-12-31	2016-12-31
Other receivables (current)		
VAT receivables	1,388	1,147
Other receivables	5,903	1,526
	7,291	**2,673**

Note 17 Accounts receivable

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

Note 18 Prepaid expenses and deferred income

Group

KSEK	2017-12-31	2016-12-31
Prepaid insurance	92	343
Prepaid marketing	128	222
Other	100	91
	320	**656**

Parent company

KSEK	2017-12-31	2016-12-31
Prepaid insurance	92	343
Prepaid marketing	128	222
Other	100	91
	320	**656**

Note 19 Cash and cash equivalents

Group

KSEK	2017-12-31	2016-12-31
The following subcomponents are included in cash and cash equivalents:		
Cash and bank deposits	581,078	213,588
The total according to balance sheet	581,078	213,588
Total according to cash flow analysis	**581,078**	**213,588**

Note 20 Shareholders' equity

Group

Share capital and number of shares

Number of shares	2017	2016
Issued as of 1 January	35,054,860	32,412,003
New share issue November 2016	–	2,642,857
New share issue December 2017	2,752,526	–
Issued as of 31 December – paid up	**37,807,386**	**35,054,860**

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.

Repurchased own shares included in equity capital retained earnings, including profit for the year.

	Number of shares		Reported value	
	2017	2016	2017	2016
Opening balance repurchased own shares	–	–	–	–
Purchases during the year	401	–	401	–
Closing balance repurchased own shares	**401**	**–**	**401**	**–**

Other contributed capital

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

Reserves

Translation reserve

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

Fair value of reserves

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 29, 2018.

No dividend was paid for 2016.

Parent company

Unrestricted shareholders' equity

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

Retained earnings

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

Management of capital

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

Note 21 Provisions

Provisions consist of social contributions for a long-term incentive program in 2016.

Note 22 Long term interest-bearing liabilities

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

Group

KSEK	2017	2016
Long-term liabilities		
Contingent purchase price, not yet paid	601	548
Financial leasing liabilities	–	4
	601	**552**
Current liabilities		
Current portion of financial leasing liabilities	–	44
	–	**44**

Parent company

KSEK	2017	2016
Long-term liabilities		
Contingent purchase price, not yet paid	601	548
	601	**548**

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

Financial leasing liabilities
On December 31, 2017, there where no financial leasing liabilities. On December 31, 2016, financial leasing liabilities where due and payable as follows:

Group	2016		
KSEK	Minimun leasing fees	Interest	Principal amount
Within one year	45	1	44
Between one and five years	4	–	4
	49	**1**	**48**

Note 23 Other liabilities

Group

KSEK	2017-12-31	2016-12-31
Other current liabilities		
Personnel-related liabilities	5,424	1,824
Fair value interest rate derivatives	403	–
Accumulated development costs government grant	1,458	–
	7,285	**1,824**

Parent company

KSEK	2017-12-31	2016-12-31
Personnel-related liabilities	5,424	1,824
Accumulated development costs government grant	1,458	–
	6,882	**1,824**

Note 24 Accrued costs and deferred income

Group

KSEK	2017-12-31	2016-12-31
Holiday pay	3,538	2,326
Social charges	1,152	755
Incentive accrual	1,749	2,239
Directors' fee	1,111	368
Project cost	8,998	9,602
Royalties to researchers	214	217
Consulting fees	1,522	1,049
Costs attributable to new share issue	10,624	–
Other	3,634	742
	32,542	**17,298**

Parent company

KSEK	2017-12-31	2016-12-31
Holiday pay	3,538	2,326
Social charges	1,152	755
Incentive accrual	1,749	2,239
Directors' fee	1,111	368
Project cost IdeS	8,998	9,602
Royalties to researchers	214	217
Consulting fees	1,522	1,049
Costs attributable to new share issue	10,624	–
Other	3,619	742
	32,527	**17,298**

Note 25 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 2017 amounted to SEK 581,078 k (213,588).

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. Cash and cash equivalents consisted on the balance sheet date of bank deposits. Short term investments in interest-bearing commercial papers amounted to SEK 34,983 k (39,990).

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

2017

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

2016

KSEK	Nominal amount	0–3 months	3–12 months	1–5 years
Long-term interest-bearing liabilities	552	–	–	552
Current interest-bearing liabilities	44	11	33	–
Accounts payable	6,482	6,482	–	–
Total	**7,078**	**6,493**	**33**	**552**

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

A strengthening of SEK in relation to EUR by an average of 10% would affect the group's earnings before tax by approximately SEK +5,953 k (+2,678). Correspondingly, a strengthening of SEK in relation to GBP by an average of 10% would affect the group's earnings before tax by approximately SEK +679 k (+235), a strengthening of SEK in relation to DKK by an average of 10% would affect the group's earnings before tax by approximately SEK +94 k (+216), while a 10% strengthening of SEK in relation to USD would affect earnings before tax by approximately SEK +1,061 k (+766).

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

Interest rate risk
The interest rate risk consists of the risk that a change in market interest rates will have a negative effect on earnings. The group's exposure to interest rate risks is considered to be small since the group only has very limited interest-bearing liabilities. There is certain exposure to interest rate risks in cash and cash equivalents in the form of bank deposits and holdings of short term interest-bearing papers. At the end of December 2017, the Group acquired shares in an interest fund. Changes in market interest rates will influence the fund's market value.

Interest rate risk shows how the value of an interest fund changes when interest rates change. Interest rate risk for the shares in the interest fund is 0.7.

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.

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 fair value of the short term investments is calculated on the basis of the closing price at the balance sheet date. The valuation of the holdings is, thereby, in accordance with Level 1 in the valuation hierarchy.

The fair value of contingent purchase price is calculated at the discounted value of expected future cash flows. A purchase price of GBP 70k enters if a clinical trial is registrated linked to the acquired patent rights. The valuation of the contingent purchase price is in accordance with Level 3 in the valuation hierarchy.

The reported value of financial assets and financial liabilities per valuation category
The table below shows the reported value of financial assets and financial liabilities broken down by valuation category in IAS 39.

Group

	Loan claims and accounts receivable		Realizable financial assets	
KSEK	2017	2016	2017	2016
Financial assets valued at net realizable value				
Financial fixed assets				
Listed shares	–	–	18,508	14,566
Short term investments	–	–	34,983	39,990
Financial assets not valued at net realizable value				
Accounts receivable	508	74	–	–
Other receivables	5,093	1,527	–	–
Cash and cash equivalents	581,078	213,588	–	–
Total financial assets	**586,679**	**215,189**	**53,491**	**54,556**

	Financial liabilities valued at accrued acquisition value		Financial liabilities valued at fair value by the income statement	
KSEK	2017	2016	2017	2016
Long-term interest bearing liabilities	–	–	–	–
Contingent purchase price	–	–	601	548
Other	–	4	–	–
Current interest-bearing liabilities	–	44	–	–
Accounts payable	3,771	6,482	–	–
Total financial assets	**3,771**	**6,530**	**601**	548

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

	Contingent purchase price	
KSEK	2017	2016
Opening balance	**548**	**–**
Acquisition during the year	–	532
Reported in net result for the year		
Currency differences	-3	-7
Interest expense	56	23
Closing balance	**601**	**548**

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

Note 26 Operational leasing

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

Group

KSEK	2017-12-31	2016-12-31
Within one year	1,769	2,540
Between one and five years	1,670	–
	3,439	**2,540**

Parent company

KSEK	2017-12-31	2016-12-31
Within one year	1,769	2,540
Between one and five years	1,670	–
	3,439	**2,540**

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	2017	2016
Total leasing costs	**3,324**	**2,582**

Parent company

KSEK	2017	2016
Total leasing costs	**3,359**	**2,746**

Note 27 Collateral provided, contingent liabilities and contingent assets

Group

KSEK	2017-12-31	2016-12-31
Collateral provided		
In the form of collateral for own liabilities and provisions		
Assets subject to retention of title	–	16
Total collateral provided	**–**	**16**

Note 28 Closely-associated persons

Relationships with closely-associated persons
The group has a closely-associated relationship with Nexttobe AB and key persons in management positions. Nexttobe AB is the company's largest shareholder with holdings of 24.7%.

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

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

Note 29 Group companies

Holdings in subsidiaries

		Share ownership percentage (%)	
Subsidiaries	Registered office / Country	2017	2016
Cartela R & D AB	Lund / Sweden	100	100
Immago Biosystems Ltd	Cheltenham / United Kingdom	100	100

Parent company

KSEK	2017-12-31	2016-12-31
Accumulated acquisition values		
On 1 January	4,818	1,933
Shareholder contribution Cartela R&D	–	429
Acquisition Immago Biosystems Ltd	–	2,456
Reported value on 31 December	**4,818**	**4,818**

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

			Reported value	
Subsidiaries / Company reg. no. / Registered office	Number of shares	Share (%)	2017-12-31	2016-12-31
Cartela R & D AB / 556746-0083 / Lund	1,000	100	2,362	2,362
Immago Biosystems Ltd / 08361712 / Cheltemham, United Kingdom	100,000	100	2,456	2,456
			4,818	**4,818**

Note 30 Cash flow analysis

Adjustment for items not included in cash flow
Group

KSEK	2017	2016
Depreciation/writedown	3,779	3,445
Unrealised currency differences	-19	3
Costs related to incentive program	9,877	478
Share warrants	190	343
	13,827	**4,269**

Parent company

KSEK	2017	2016
Depreciation/writedown	3,576	3,297
Unrealised currency differences	-22	–
Costs related to incentive program	9,877	478
Share warrants	190	343
	13,621	**4,118**

Reconciliation of liabilities arising from the financing activities
Group

KSEK	UB 2016	Cash flow	New leasing agreeements*	UB 2017
Leasing payables	48	-48	–	–
Total liabilities arising from financing activities	**48**	**-48**	**–**	**–**

* Non cash flow changes of debt

Note 31 Acquisition of business

Acquisitions 2017
No aquisitions in 2017.

Acquisitions 2016
19th of July, 2016, Immago Biosystems Ltd was acquired. Through the acquisition of the company, Hansa Medical acquired patent rights to the EnZe-concept.

The acquisition has only affected the net profit/loss for the Group by amortizations on patents. The acquisition has the following effects on the Group's assets and liabilities. The acquired company's net assets at the acquisition date:

KSEK	Book value before the acquisition	Real value, adjustment	Real value booked in the consolidated accounts
Intangible fixed assets	45	3,068	3,113
Current liabilities	-45	–	-45
Deferred tax liability	–	-612	-612
Net identifiable, assets and liabilities	**–**	**2,456**	**2,456**

Goodwill	–
Total purchase price	2,456
Contingent purchase price, not yet paid	-532
Paid purchase price, in cash	**1,924**
Cash (acquired)	–
Net cash outflow	**1,924**

Note 32 Events after the balance sheet dates

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

Completed enrollment in Hansa Medical's international multi-center Phase II study Highdes in January 2018
The primary objective of the study – to turn a positive crossmatch test into a negative and thereby enable kidney transplantation - has been accomplished in all 18 treated patients. All patients will be monitored for six months.

Finalized enrollment in US Phase II study with IdeS in highly sensitized patients in January 2018
IdeS effectively reduced the level of DSAs in all 17 treated patients and turned the crossmatch tests from positive to negative, thereby enabling transplantation for all patients. All patients will be followed for six months to monitor safety, kidney function and DSA levels.

FDA granted Orphan Drug Designation for IdeS and the treatment of Guillain-Barré syndrome in February 2018
In February 2018, U.S. Food and Drug Administration (FDA), granted Hansa Medical Orphan Drug Designation (ODD) to IdeS for the treatment of Guillain-Barré syndrome (GBS). Orphan drug designation qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits, protocol assistance and potentially seven years of orphan drug exclusivity

Note 33 Important estimates and opinions

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

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 34 Information regarding the parent company

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

The parent company's shares are registered on Nasdaq OMX, Stockholm. The address of the headquarters is Scheelevägen 22, 223 63 Lund. The consolidated accounts for 2016 cover the parent company and its subsidiaries, jointly referred to as the group.

Note 35 Proposal for dividend

Unrestricted shareholders' equity in the parent company

KSEK	
Share premium reserve	946,569,767
Own shares	-401,000
Profit carried forward	-182,475,952
Result for the year	-176,372,699
Total	**587,320,116**

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

KSEK	
Share premium reserve	946,569,767
Own shares	-401,000
Profit carried forward	-358,848,651
Total	**587,320,116**

Definitions

Earnings per share prior to dilution
Profit/loss for the period divided by the weighted average numberof 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 the end of the period.

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

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

Signatures

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

Lund April 10 2018

Ulf Wiinberg
Chairman of the Board

Birgit Stattin Norinder
Director

Stina Gestrelius
Director

Per-Olof Wallström
Director

Angelica Loskog
Director

Hans Schikan
Director

Søren Tulstrup
CEO and Executive President

The Board of Directors and CEO approved the annual report for publication on April 11 2018. The consolidated income statement, report on comprehensive income and balance sheet as well as the parent company's income statement, report on comprehensive income and balance sheet will be subject to adoption at the annual general meeting to be held on May 29 2018.

Our auditors' report was submitted on April 10 2018.
KPMG AB

Dan Kjellqvist
Authorized Public Accountant
Lead Auditor

Jonas Nihlberg
Authorized Public Accountant

Translation from the Swedish original

Auditor's Report

To the general meeting of the shareholders of Hansa Medical AB (publ), corp. id 556734-5359

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of Hansa Medical AB (publ) for the year 2017. The annual accounts and the consolidated accounts are included in this document on pages 40-84.

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 2017 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2017 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

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

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

Basis for Opinions

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

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

Key Audit Matters

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

Going concern

See disclosure 43 and accounting principles on pages 56-60 in the annual account and consolidated accounts for detailed information and description of the matter.

Description of key audit matter

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

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

In the fourth quarter, it was decided at an extraordinary general meeting to conduct a private placement of a maximum of 2,752,526 new shares, the subscription price was set at SEK 198 per share. This issue was then carried out during the financial year and brought the company SEK 545 million.

Cash and cash equivalents amounts to SEK 581 million at December 31, 2017. In addition, the group has short-term investments of SEK 35 million.

Response in the audit

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

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

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

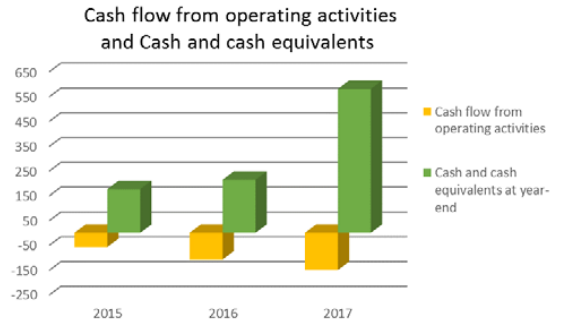
- Payments based on the agreement with Axis-Shield;
- Expected payouts based on budgeted project costs;
- The availability of future financing such as new share issues.

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

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

We have followed the decision of the Extraordinary General Meeting to perform a private placement and verified that payment has been made equivalent to SEK 545 million.

Translation from the Swedish original



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

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

Other Information than the annual accounts and consolidated accounts

This document also includes other information than the annual accounts and consolidated accounts and may be found on page 3-39 The Board of Directors and the Managing Director are responsible for this other information.

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

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

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

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.

Translation from the Swedish original

- Conclude on the appropriateness of the Board of Directors' and the Managing Director's, use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Directors of Hansa Medical AB (publ) for the year 2017 and the proposed appropriations of the company's profit or loss.

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

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner.
The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

Translation from the Swedish original

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

KPMG AB, Box 227, 201 22 , Malmö, was appointed auditor of Hansa Medical AB (publ) by the general meeting of the shareholders on the 23rd May 2017. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2014.

Malmö 2018-04-10

KPMG AB

Dan Kjellqvist
Authorized Public Accountant
Auditor in-charge

KPMG AB

Jonas Nihlberg
Authorized Public Accountant

Corporate governance report

Introduction

The Board of Directors of Hansa Medical AB (publ), company reg. no. 556734-5359 (the "company") hereby submits the 2017 corporate governance report in accordance with the requirements of the Swedish Annual Accounts Act (1995:1554) (Sw. årsredovisningslagen) and the Swedish Code of Corporate Governance (the "Code"; see the Swedish Corporate Governance Board website at www.bolagsstyrning.se). The company's shares were admitted for trading on Nasdaq Stockholm in November 2015. The company's shares were previously, since 2007, listed on Nasdaq First North. The company's corporate governance is mainly regulated by the provisions of the company's articles of association, the Swedish Companies Act (2005:551) (Sw. aktiebolagslagen) and other Swedish legislation, the Nasdaq Stockholm Rulebook for issuers and the Code.

There are no deviations from the Code to report from the financial year of 2017.

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 subsidiaries Cartela R & D AB and Immago Biosystems Ltd. Immago Biosystems Ltd is owner of patent rights to the Enze concept.

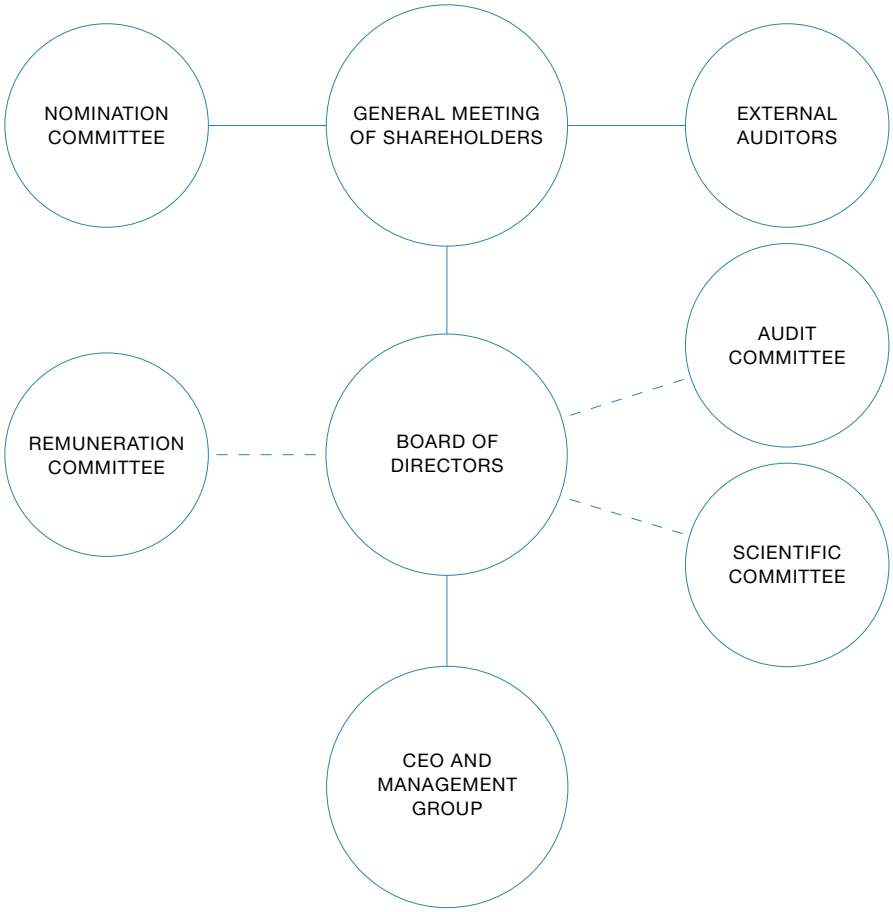
Shareholders

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 24.7 percent.

There was no infringement of Nasdaq Stockholm's 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 2017.



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

Significant internal regulations and policies:

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

Significant external regulations:

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

Information regarding Hansa Medical's shares

The shares in the Company are divided into ordinary shares and C-shares. On 31 December 2017, the total number of shares was 38,208,386, with 37,807,386 ordinary shares and 401,000 C-shares, with a quotient value of SEK 1. Each ordinary share carries one vote and each C-share carries one tenth. Each person entitled to vote may vote for his or her full number of shares. Each share confers the right to an equally large percentage of the Company's distributable profits.

General meeting

The Company's highest decision-making body is the general meeting, where the shareholders' influence over the Company is exercised. Shareholders who wish to participate at a general meeting, personally or through a proxy, must be entered in the share register maintained by Euroclear Sweden AB five business days prior to the general meeting and must give the Company notice of intention to attend as described in the notice to attend the general meeting. Notices to attend general meetings are given through advertisement as well as on the Company's website (www.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.

2017 Annual General Meeting

At the annual general meeting, which was held on May 23 2017, 25 shareholders representing 43.7 percent of the total number of votes in the Company were represented. The annual general meeting adopted the 2016 annual accounts, adopted a resolution regarding treatment of the Company's loss, and granted the directors and CEO a discharge from liability. The general meeting resolved that no dividend would be paid. In accordance with the proposals of the nomination committee, the general meeting resolved to re-elect Stina Gestrelius, Hans Schikan, Birgit Stattin Norinder, Per Olof Wallström, Angelica Loskog and Ulf Wiinberg as members of the board. Ulf Wiinberg was elected as chairman of the board. The general meeting adopted resolutions regarding election of an auditor and remuneration to the board and auditors in accordance with the nomination committee's proposal. The general meeting also resolved on guidelines for remuneration to senior management in accordance with the board of directors' proposal.

Minutes from the annual general meeting are available at Hansa Medical's web site (www.hansamedical.com). The annual general meeting 2018 will take place on 29 May 2018.

2015/2019 incentive programme

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

The employees were offered the opportunity to acquire warrants entitling them to exercise the warrants for subscription of shares in the Company at a price equal to the market value of the share at the time of the issuance of the warrants (SEK 36.04) adjusted upwards annually in the amount of seven per cent. 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 per cent of the current market value of the share and after four years will amount to approximately 131.1 per cent.

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 Pricewaterhouse-Coopers, 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 per cent 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. 355,000 warrants were subsequently transferred to the employees of the Company, corresponding to a dilution effect of 1.1 per cent of the number of shares and votes if all of the warrants are exercised. For all employees, with the exception of the former CEO, up to 60 per cent 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 SEK 1,500 k. The subsidy in the amount of approximately SEK 800k is booked as a current expense during the term of the warrants. In the event a warrant holder's employment with the Company terminates before the warrants are exercised and the Company elects to buy back the warrants according to the repurchase condition, the buyback must take place at market value less any subsidy received.

Long-term incentive programme 2016

An extraordinary general meeting in Hansa Medical was held on 21 November 2016, regarding resolutions to carry out a directed issue of ordinary shares and a proposal to adopt a long-term incentive programme for employees within Hansa Medical.

At the extraordinary general meeting, it was resolved to adopt a long-term incentive programme in the form of a performance based share programme for employees of the group ("LTIP 2016"). LTIP 2016 has been implemented to motivate and retain competent employees as well as for the alignment of the targets of the employees with those of the shareholders and the Company, as well as to increase the motivation of meeting and exceeding the Company's financial targets.

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

As of December 31 2017, 26 employees had chosen to participate in LTIP 2016, meaning that the total number of shares which may be allotted under LTIP 2016 will not exceed 289,750 ordinary shares. Together with a maximum of 96,000 ordinary shares which may be used to secure social charges arising as a result of LTIP 2016, this corresponds to in total 1.1 percent of the existing number of ordinary shares in Hansa Medical. The costs for LTIP 2016 are reported in accordance with IFRS 2.

Nomination committee

Prior to the 2018 annual general meeting, Hansa Medical's nomination committee comprises Erika Kjellberg Eriksson (representing Nexttobe AB), Max Mitteregger (representing Gladiator) and Sven Sandberg (representing Thomas Olausson). It also includes the chairman of the board Ulf Wiinberg. Erika Kjellberg Eriksson has been elected as 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 prior to the annual general meeting 2019. The proposals will be published in connection with the notice to the annual general meeting 2018.

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. The annual general meeting 2017 resolved to re-elect KPMG AB as auditor with Dan Kjellqvist as auditor in charge. Dan Kjellqvist is a member of the Swedish Institute of Authorized Public Accountants. Dan Kjellqvist was personally 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. For information regarding fees paid to the auditors, please refer to note 6 in the 2017 annual report.

Board of Directors

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

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

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

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

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

Directors' fees were set at the Company's 2017 annual general meeting for a period up to and including the next annual general meeting. The fees for the board of directors' work in 2017 were set as follows. The chairman is paid SEK 600,000, and each other director besides Angelica Loskog is paid SEK 150,000, 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. No remuneration other than the above mentioned fees have been paid to the board of directors except for a consulting fee for Hans Schikan of SEK 90,000. No pension premiums or similar benefits were paid to directors. None of the directors are entitled to benefits after completion of their duties. Please see the management report and note 5 in the 2017 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 March 21 2018. Holdings in the Company includes one's own holdings as well as those of closely-related persons.

Ulf Wiinberg

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

Ulf Wiinberg is an experienced healthcare industry professional who has served on the boards of several healthcare industry associations. At Wyeth, he has been both President of the global consumer health care business and President for the European pharma business and he has also held the position as CEO of H Lundbeck A/S, a pharmaceutical company specialized in psychiatric and neurological disorders, for several years. Ulf is a non-executive member of the board of Alfa Laval AB, Agenus Inc and at the Belgian pharmaceutical company UCB. He is also chairman of the board of Sigrid Therapeutics AB as well as CEO and chairman of the board of Ulf Wiinberg consulting&invest AB. Born 1958.

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

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

Holdings: 75,000 shares

Birgit Stattin Norinder

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

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

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

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

Holdings: 39,205 shares

Dr. Stina Gestrelius

Member of the board since 2007

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

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

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

Holdings: 5,833 shares

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 Bistrol-Meyers Scquibb. In addition, he has served as CEO of Q-Med AB, Melacure Therapeutics AB and Karo Bio AB. Per-Olof is also member of the boards of Camurus AB (chairman), Arosia Communication AB (founder) and NeoDynamics AB (member). Per-Olof holds a M.Sc. in Pharmacy from Uppsala University. Born 1949.

Per-Olof is chairman of Hansa Medical's audit committee.

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

Holdings: 23,000 shares

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 Asceneuron (Switzerland), Complix (Belgium) and InteRNA Technologies (The Netherlands) and member of the board of Sobi and Wilson Therapeutics (Sweden) as well as Therachon (Switzerland). He is also member of the Core Team of the Dutch Top Sector Life Sciences & Health and adviser to several life sciences 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 Hansa Medical's remuneration committee and scientific committee.

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

Holdings: 10,000 shares

Dr. Angelica Loskog

Member of the board since 2016

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

Angelica is member of Hansa Medical's scientific committee.

Independent of Hansa Medical and its senior management.

Holdings: –

The Board of Directors' work in 2017

During 2017, the board has held fifteen meetings, of which nine were held per telephone and one was the inauguration meeting. The board has also made resolutions per capsulam at four occasions during 2017. In 2017, the board primarily worked with the following issues: a resolution to carry out a new share issue, evaluation of appropriate new clinical studies with IdeS and organizational issues.

At the board meetings held during the 2017 financial year, the directors were present as set forth below. The number of meetings and the maximum number of directors who could have been present are stated in parentheses during the financial year.

The reporting period is 1 January – 31 December 2017

Director	Elected	Present at meetings of the board	Present at meetings of the remuneration committee	Present at meetings of the audit committee	Independent in relation to the company and corporate management	Independent in relation to the company's largest shareholders
Ulf Wiinberg	2016	15 (15)	2 (2)	4 (5)	No	Yes
Birgit Stattin Norinder	2012	14 (15)	2 (2)	5 (5)	Yes	Yes
Stina Gestrelius	2007	15 (15)	–	–	Yes	Yes
Per-Olof Wallström	2011	15 (15)	–	5 (5)	Yes	Yes
Hans Schikan	2015	15 (15)	2 (2)	–	Yes	Yes
Angelica Loskog	2016	15 (15)	–	–	Yes	No

Evaluation of the Board of Directors' work

Pursuant to the Code, the board of directors is to evaluate its work annually, using a systematic and structured process, with the aim of developing the board's working methods and efficiency. The evaluation has been carried out by the chairman of the board by, in the end of 2017, interviewing the directors with questions about the work of the board of directors. The result of the responses has been compiled in a report which has been declared to the directors and the members of the nomination committee.

Board committees

Remuneration committee
The remuneration committee consists of Ulf Wiinberg, chairman, Birgit Stattin Norinder and Hans Schikan. 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. During the period between November 9 2017 to March 20, 2018 Birgit Stattin Norinder was chairman of the remuneration committee and Ulf Wiinberg excluded as a member.

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 consists of Per-Olof Wallström, chairman, Birgit Stattin Norinder and Ulf Wiinberg. 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. Hans Schikan was a member of the committee instead of Ulf Wiinberg between November 9, 2017 and March 20, 2018.

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 consists of Birgit Stattin Norinder, chairman, Hans Schikan, Angelica Loskog and Stina Gestrelius. The committee is obligated to keep minutes of its meetings and make the minutes available the Board of Directors.

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

The scientific committee has not had any separate meetings during 2017, but the duties above were handled at board meetings in February, September and December 2017.

Company management

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

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

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

The CEO's responsibility

The CEO is responsible for managing the Company's day-to-day operations pursuant to the board's guidelines and instructions. The CEO is also responsible, in accordance with the board's written instructions, for preparing and presenting to the board issues which fall beyond the scope of day-to-day management and he must act in accordance with the instructions to the CEO adopted by the board, the decisions of the board and the general meeting, and in the best interests of all shareholders. He must also respect the fiduciary duty and duty of confidentiality which apply to affairs and circumstances which might cause damage to the Company if disclosed, as well as the duty to report matters and circumstances which are material to the Company.

The CEO must take any and all measures which are necessary to ensure that the Company's bookkeeping is legally compliant and to ensure that funds are managed in a satisfactory manner. Accordingly, it is the CEO's responsibility to ensure that the Company has good internal management and routines to ensure application of the adopted principles for financial reporting and internal control. The CEO shall each month (with the exception of January and July) compile a report regarding the Company's financial situation. He is responsible for ensuring that the Company complies with applicable laws and guidelines, including Swedish law, the Nasdaq Stockholm Rulebook for issuers and the Code. The CEO must ensure, at a minimum, that the six-month report or the nine-month report is examined by an auditor. The CEO also has specific responsibility to ensure the competitive supply of all purchases of goods or services exceeding SEK 1 million. The CEO must provide the board with all necessary background information and documentation, both before and between board meetings. The CEO must attend board meetings unless the chairman informs him that he need not 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 eight individuals: the President and the CEO Søren Tulstrup; the Senior Vice President, Research and Development Christian Kjellman; the Vice President, Chief Financial Officer Eva-Maria Joed; the Vice President, Project Management Lena Winstedt; the Vice President, Business Development and Investor Relations Emanuel Björne; the Vice President, Commercial Operations Henk Doude van Troostwijk; the Vice President, Regulatory Affairs Karin Aschan and the Vice President, Corporate Strategy Max Sakajja.

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 March 21 2018 are listed below. Holdings in the Company includes both one's own holdings and/or those of closely-related persons.

Søren Tulstrup

CEO

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

Shareholding: –
Share warrants: –

Christian Kjellman

Senior Vice President, Research and Development

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. Born 1967.

Shareholding: –
Share warrants: 40,000

Eva-Maria Joed

Vice President, 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 M.Sc. in Business and Economics from Lund University. Born 1969.

Shareholding: 1,000
Share warrants: 25,000

Emanuel Björne

Vice President, Business 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. Born 1973.

Shareholding: 21,300
Share warrants: 15,000

Max Sakajja

Vice President, Corporate Strategy

Max joined Hansa Medical in 2017. He has broad corporate development background and had previously worked with corporate finance at Biovitrum/SOBI in the position of Director Mergers & Acquisitions. Before joining Hansa Medical, Max worked with strategy and business development at Envirotainer as the Global Product and Service Development Manager. Max holds a M.Sc. in Biotechnology from the Royal Institute of Technology. Born 1981.

Shareholding: 3,100
Share warrants: 25,000

Karin Aschan

Vice President, Regulatory Affairs

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

Shareholding: –
Share warrants: –

Henk Doude van Troostwijk

Vice President, Commercial Operations

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

Shareholding: –
Share warrants: –

Lena Winstedt

Vice President, Project Management

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. Born 1969.

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

he 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 manual and automated control activities on both the overall and more detailed levels. Access to IT systems is limited in accordance with powers and authorization. The CFO must compile monthly financial reports which, among other things, are to report earnings and cash flow for the preceding period and state budget deviations. These reports, and above all the budget deviations, must be analysed and commented upon by company management. Follow-up takes place through regular meetings for review of these reports and analyses with the various managers and project managers. In this way, significant fluctuations and deviations are followed-up, minimizing the risk of errors in the financial reporting. The work involved with annual accounts and annual reports are processes which pose additional risks for errors in the financial reports. This work is of a less repetitive nature and contains more evaluative elements. Important control activities include, among other things, ensuring that there is a properly functioning reporting structure in which the various managers and project managers report pursuant to standardized reporting templates, and that important income statement and balance sheet items are specified and commented upon.

Information and communication

The informational activities are governed by an information policy. There are guidelines for external communications which ensure that the Company meets high standards for providing correct information to the shareholders and the financial market. Hansa 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 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 releases 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 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.

Auditor statement on the corporate governance report

To the Annual General Meeting of Hansa Medical AB, company reg. no. 556734-5359.

The Board of Directors is responsible for the corporate governance report for 2017 set forth on pages 89–101 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, April 10 2018
KPMG AB

Dan Kjellqvist
Authorized public accountant
Lead auditor

Jonas Nihlberg
Authorized public accountant

www.hansamedical.com