Hansa Medical

Interim report April – June 2018

Positive long-term data further demonstrate the significant potential of imlifidase (IdeS) in kidney transplantation

April–June 2018 in brief

- Long-term follow-up data from the 17 patients treated with imlifidase in the investigator-initiated Phase II study in highly sensitized patients was presented at the 2018 American Transplant Congress in early June by Professor Stanley C. Jordan, M.D., Director of Nephrology, Cedars-Sinai Medical Center.
  - Patients show good renal function and minimal evidence of antibody-mediated rejection (AMR) at a mean 19 months post kidney transplantation, with graft and patient survival at 94%.
  - Two-year follow-up data demonstrate good patient and graft survival without increased infection risk and that no serious adverse events related to imlifidase have been reported in the study.
- The board of directors strengthened its expertise in biopharma commercialization and R&D through the appointments of Anders Gersel Pedersen and Andreas Eggert.
  - Anders Gersel Pedersen, MD, Ph.D, currently serves as Executive Vice President, Research & Development at H. Lundbeck A/S and is a member of the boards of Genmab A/S and Bavarian Nordic A/S.
  - Andreas Eggert, MBA has more than 20 years of cross-functional leadership experience in biopharma commercialization, including Senior Group Vice President, Global Product Strategy & Portfolio Development at H. Lundbeck A/S and Vice President & Global Business Manager at Wyeth/Pfizer in the US.
- Hansa Medical formed the US subsidiary Hansa Medical Inc. for the continued build-up of US organization and presence.

Significant events after the end of the reporting period

- The U.S. Food and Drug Administration (FDA) granted orphan drug designation to imlifidase for the treatment of the rare and acute kidney disease anti-GBM antibody disease, also known as Goodpastures disease.
  - Orphan drug designation qualifies the sponsor of the drug for various development incentives, including tax credits, protocol assistance and up to seven years of US marketing exclusivity from time of approval of Biologics License Application (BLA).
  - The approval confirms the high unmet medical need and further encourages continued clinical investigations with imlifidase in this devastating disease in which less than one third [5] of the patients survive with a preserved kidney function after six months follow-up.

Financial summary for the Group

	Q2		H1		Year
KSEK, unless otherwise stated	2018	2017	2018	2017	2017
Net revenue	900	693	1,488	1,751	3,442
Operating profit/loss	-58,768	-44,901	-105,390	-89,728	-176,083
Net profit/loss	-58,796	-45,151	-105,294	-90,145	-176,660
Earnings per share before and after dilution (SEK)	-1.55	-1.28	-2.78	-2.55	-4.97
Shareholders' equity	542,966	198,600	542,966	198,600	630,661
Cash flow from operating activities	-48,989	-38,797	-93,083	-82,536	-150,105
Cash and cash equivalents including short term investments	534,178	169,953	534,178	169,953	616,061

CEO statement

It has been a pleasure to join Hansa Medical. I am impressed by what has been accomplished to date, and the more I learn, the more I see how strongly positioned we are to bring a unique treatment to market and build a global biopharma enterprise. This impression has not only been gained through interactions with our teams in Sweden and the US, but also through my meetings with key opinion leaders and with healthcare specialist investors across the US and Europe.

Step by step we have continued to progress our strategy and I feel confident that we will be able to launch a lifesaving product. Since I joined Hansa Medical in March, we have continued to expand the organization in order to develop our capabilities to launch imlifidase (formerly called IdeS) on our own. We have also continued to grow the R&D team in order to initiate and complete additional clinical studies in antibody-mediated kidney transplant rejection (kidney AMR) and the devastating acute neurological disease Guillain-Barré syndrome.

The development of imlifidase continues to progress according to plan. To date, we have successfully designed and managed a series of clinical studies, demonstrating its ability to enable lifesaving kidney transplantation in highly sensitized patients, an indication where there is significant unmet medical need.

Earlier this year, we completed patient enrollment in the two ongoing Phase II studies with imlifidase in highly sensitized kidney transplant patients. A total of 18 patients were enrolled in the international multicenter study Highdes, and 17 patients were enrolled in the US investigator-initiated study at Cedars-Sinai Medical Center, led by principal investigator Professor Stanley Jordan.

The objective, to enable kidney transplantation for highly sensitized patients with donor-specific antibodies, was achieved in all 35 patients in the two studies. The patients' cross-match tests for donor specific antibodies have all been shifted from positive to negative following the treatment with imlifidase. At the *2018 American Transplant Congress* in early June, Professor Jordan presented follow-up data from the 17 patients treated in the Cedars-Sinai study. The results from the study demonstrate that patients show good renal function and minimal evidence of antibody-mediated rejection (AMR) at a mean 19 months post kidney transplantation, with graft and patient survival at 94 percent. In addition, Professor Jordan highlighted that the two-year follow-up data demonstrate good patient and graft survival, with no evidence of increased infection risk. Additionally, no serious adverse events related to imlifidase were reported in his study.

These results are very encouraging. The patients treated in the Cedars-Sinai study exhibited extensive sensitization with a median calculated Panel Reactive Antibody (cPRA- a measure of sensitization for transplant candidates) score of 95 percent and we have managed to enable transplantation for patients who have been on dialysis for more than 20 years.

We continue to follow the 18 patients who have been treated with imlifidase and subsequently transplanted in the Highdes study. All treated patients are to be monitored for six months to collect follow-up data with respect to safety, kidney function and management of rejection episodes. We expect to have access to six-month follow up data from the 18 patients in the Highdes study and the 17 patients in the Cedars Sinai study, by the end of the third quarter this year. This is going to be a very important milestone for us and the continued development program with imlifidase.

Ahead of this, we are preparing meetings with both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to discuss a potential route towards filing of a Biologics License Application (BLA) in the US and the filing of an Market Authorization Application (MAA) in Europe at the end of 2018 or early 2019. In addition to the six-month follow-up data, important items for these discussions will be the positive data demonstrating the efficacy and safety of imlifidase to enable kidney transplantations, the validation of the manufacturing process for imlifidase, and most importantly, the significant medical need for these highly sensitized patients who today have very limited chances, if any, to be transplanted.

We are determined to bring imlifidase to market in kidney transplantation as soon as possible. Our long-term vision is to bring imlifidase to a wide range of patients suffering from acute IgG-mediated diseases. To us and many key opinion leaders, it is quite apparent that imlifidase has the potential to significantly contribute to the critical care in acute autoimmune diseases and several additional transplant-related indications. Today, many of these conditions are acutely treated with plasma exchange or immunoglobulin therapy in order to remove or modulate pathogenic IgG, which can be lengthy and inefficient processes. We believe imlifidase can potentially eliminate pathogenic IgG significantly faster and more effectively in these acute diseases.

Consequently, we continue to increase our engagement in the evaluation of imlifidase in these conditions. Currently, a Phase II study is ongoing in the acute kidney disease severe anti-GBM, a disease in which two-thirds [5] of the patients lose their kidneys, requiring chronic dialysis and the need for kidney transplantation. This study is ongoing in Denmark, Sweden and Austria and soon clinics in France, UK and the Czech Republic will join the study. Around 15 patients are to be enrolled and to date seven patients have been treated and responded favorably with a good safety profile. In early July, the FDA approved our application for orphan drug designation for imlifidase and the treatment of anti-GBM (Goodpastures disease). The approval confirms the high unmet medical need and further encourages us to continue clinical investigations with imlifidase in this devastating disease.

In addition, we are preparing the initiation of two more Phase II studies in the fall. The first study to be initiated is likely to be treatment of antibody-mediated kidney transplant rejection. We are aiming at enrolling 15-25 patients to this study in the US and in Europe. The second study will be a Phase II study in the acute neurological disease Guillain-Barré syndrome (GBS), to which we aim to enroll around 30 patients, primarily in Europe.

With a growing body of clinical evidence, different opportunities to broaden the use of imlifidase to a multitude of indications, and a number of next-generation drug candidates in development, I believe we are well-positioned to become a global biopharmaceutical company providing unique, proprietary and life-saving IgG-eliminating drugs to patients across a range of conditions where IgG plays a key role in disease progression or forms a barrier for patients to receive appropriate treatment. I look forward to updating you on our continued progress.

Søren Tulstrup
President and CEO of Hansa Medical
Lund, Sweden, July 19, 2018

Hansa Medical in brief

Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for transplantation and acute autoimmune diseases. The company's lead product, imlifidase (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 in acute autoimmune indications. The company also has a strong pipeline of preclinical projects that may provide a second wave of next generation potential drugs. Under the project name NiceR, novel immunoglobulin cleaving enzymes are developed for repeat dosing with the objective of treating relapsing autoimmune diseases and potentially cancer. Hansa Medical is based in Lund, Sweden, and its shares are listed on Nasdaq Stockholm (ticker: HMED). www.hansamedical.com

Business overview

Imlifidase (IdeS) is an enzyme, currently in late stage clinical development, that specifically cleaves immunoglobulin G (IgG). Our strategy takes advantage of the ability of imlifidase to specifically and efficiently inactivate IgG to prevent and treat patients who have developed pathogenic IgG. Imlifidase-mediated IgG elimination constitutes a novel therapeutic principle for the treatment of IgG-mediated acute human diseases.

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

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

HBP-assay is a novel diagnostic method to help predict severe sepsis in patients with symptoms of infectious disease. The method has been evaluated in two clinical studies and is available on the market. HBP-assay has been out-licensed to UK-based Axis-Shield Diagnostics and the agreement is associated with royalties to Hansa Medical.

Pipeline

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

In planning Ongoing Completed

[1] 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).

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

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

Lead candidate imlifidase

Imlifidase – A novel therapeutic principle

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

Overview of Hansa Medical's clinical program with imlifidase

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

Imlifidase 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 imlifidase is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation and is well tolerated.

Currently, the efficacy and safety of imlifidase are being investigated in two Phase II studies in highly sensitized kidney transplantation patients: The Hansa Medical sponsored multicenter Phase II study Highdes in the US, Sweden and France and an investigator initiated Phase II study at Cedars-Sinai Medical Center in Los Angeles, USA. The objective, to enable kidney transplantation for highly sensitized patients with donor specific antibodies, has been achieved in all 35 patients in the two studies. All treated patients are to be monitored for six months to collect follow-up data with respect to safety, kidney function and management of rejection episodes. Results from these two studies are expected by end of the third quarter of 2018.

An investigator-initiated Phase II study with imlifidase 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 imlifidase are being planned within acute AMR and treatment of the acute autoimmune neurological disease Guillain-Barré syndrome (GBS).

Ongoing clinical studies with imlifidase

Imlifidase – Pre-treatment of patients with donor-specific antibodies (DSA)

Latest developments

In January 2018, patient enrollment was closed in two ongoing open label single arm Phase II clinical studies with imlifidase in highly sensitized patients; the Hansa Medical-sponsored multicenter study named Highdes and an investigator-initiated study at Cedars-Sinai Medical Center in Los Angeles, led by Professor Stanley Jordan.

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 imlifidase 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 efficacy and safety of imlifidase in removing DSAs and thereby converting a positive crossmatch test to negative. All treated and transplanted patients will be followed for six months to collect follow-up data with respect to safety, kidney function and management of rejection. The primary objective of the study – to turn a positive cross match test into a negative and thereby enable kidney transplantation – has been accomplished in all 18 treated patients.

Intermediate clinical results from seven of the 18 patients in the Highdes-study were presented at the *138th Annual Meeting of the American Surgical Association (ASA)* in Phoenix, Arizona, in late April 2018. An abstract from the presentation summarizes that all seven patients were highly sensitized, with PRA levels 99-100 percent, (PRA=Panel Reactive Antibody) and positive crossmatches prior to imlifidase treatment and thus prohibited for transplantation. Imlifidase treatment resulted in negative crossmatch tests for all patients, who thereafter could be successfully transplanted. Three of the seven patients experienced episodes of antibody-mediated rejection (AMR) which responded to standard of care. Three of the seven patients had delayed graft function which ultimately resolved. No serious adverse events were associated with imlifidase, and all seven patients had functioning kidneys at a median follow up of 171 days (5.5 months). All seven patients were enrolled at NYU Langone Medical Center in New York and the abstract summarizing the presentation is available at the ASA website through the following link:
http://www.americansurgical.org/meeting/abstracts/2018/10.cgi

The ongoing US investigator-initiated Phase II study has enrolled and transplanted a total of 17 patients at Cedars-Sinai Medical Center with Professor Stanley Jordan as principal investigator. (ClinicalTrials.gov Identifier: NCT02426684). The included patients had DSAs and a positive cross-match test prior to imlifidase treatment. Attempts to desensitize these patients using currently available methods had been made prior to inclusion in the imlifidase-study. The enrolled patients all exhibited extensive sensitization with a median cPRA of 95 percent upon enrollment prior to treatment with imlifidase. The treatment with imlifidase effectively reduced the level of DSAs in all patients and turned the cross-match tests from positive to negative, thereby enabling transplantation for all 17 patients. As previously reported one of the 17 grafts was lost due to rejection caused by non-HLA IgM and IgA antibodies.

At the *2018 American Transplant Congress* in early June, Professor Jordan presented follow-up data from the 17 patients treated in the Cedars-Sinai study. The results from the study demonstrate that patients show good renal function and minimal evidence of antibody-mediated rejection (AMR) at a mean 19 months post kidney transplantation, with graft and patient survival at 94%. In addition, Professor Jordan highlighted that the two-year follow-up data demonstrate good patient and graft survival without increased infection risk and that no serious adverse events related to imlifidase have been reported in his study. An abstract with a summary of the presentation of the long-term data and conclusions is available through the ATC website, http://atcmeetingabstracts.com

Imlifidase – Treatment of anti-GBM antibody disease
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[4] and less than one third of the patients survive with a preserved kidney function after six months follow-up [5].

In June 2017, an open label investigator-initiated Phase II study in severe anti-GBM antibody disease was initiated with Hansa Medical lead candidate imlifidase. The study (ClinicalTrials.gov Identifier NCT03157037) is coordinated by Professor Mårten Segelmark at Linköping University Hospital, Linköping, 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 imlifidase in patients with severe anti-GBM antibody disease in addition to standard-of-care. The efficacy of imlifidase will be assessed by evaluating renal function at six months after imlifidase treatment.

Latest developments
To date, seven patients have been included in the study. Limited follow-up data is currently available from five of these seven patients who have all responded favorably and imlifidase 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 imlifidase as of the end of June 2018.

In early July, FDA approved Hansa Medical's application for Orphan Drug Designation for imlifidase and treatment of anti-GBM. Orphan Drug Designation means access to development incentives such as tax credits, support for the design of protocols for clinical studies and up to seven years of market exclusivity from the date of market approval.

Finalized and ongoing clinical studies with imlifidase

Type of study	Clinical trials.gov identifier	Subjects	Status	Results	Publication
Phase I in healthy subjects	NCT01802697	29	Completed	Imlifidase is efficacious and well tolerated with a favorable safety profile.	*PLOS ONE* (2015) [1]
Phase II in sensitized patients	NCT02224820	8	Completed	Imlifidase treatment resulted in HLA levels acceptable for transplantation in all patients.	*American Journal of Transplantation* (2018) [3]
Phase II in sensitized patients	NCT02475551	10	Completed	Imlifidase enabled kidney transplantation for all patients with a favourable safety profile.	*The New England Journal of Medicine* (2017) [2]
Phase II in highly sensitized patients	NCT02426684	17	Fully enrolled. Final results by the end of Q3 2018	Imlifidase enabled transplantation for all patients. Top line results demonstrate good renal function at a mean 18.76 months post kidney transplantation, with graft and patient survival at 94%.	*The New England Journal of Medicine* (2017) [2]
Multicenter Phase II in highly sensitized patients (Highdes)	NCT02790437	18	Fully enrolled. Final results by the end of Q3 2018	The primary objective of the study – to turn a positive crossmatch test into a negative and thereby enable kidney transplantation – accomplished in all treated patients. All patients will be followed for six months.	
Phase II in Anti-GBM disease (GOOD-IDES)	NCT03157037	Approx. 15	Enrolling		

Manufacturing of imlifidase

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

Regulatory strategy for imlifidase in desensitization

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, EMA granted imlifidase 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 the 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 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.

Planned clinical studies with imlifidase in additional indications

Treatment of kidney transplant antibody-mediated rejection (AMR)

There is no effective therapy for the treatment of AMR. In heart, lung and kidney transplants, AMR occurs in 10–20 percent [6] of patients and remains a significant unmet medical need associated with loss of graft function. Imlifidase is highly effective in inactivating IgG and has the potential to halt progression of AMR and be an effective treatment in severe AMR. It is anticipated that imlifidase with its ability to instantly remove DSAs damaging the kidney, can make a significant difference in the treatment of these patients.

Treatment of Guillain-Barré syndrome (GBS)

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

Preclinical development projects

NiceR – Novel Immunoglobulin Cleaving Enzymes for Repeat dosing

Hansa Medical is developing completely new IgG-degrading enzymes based on experience from imlifidase 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 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.

EnzE – Enzyme-based antibody Enhancement

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

Out-licensed royalty generating programs

HBP – Prediction of severe sepsis

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

Financial review January–June 2018

Net revenue

Net revenue for the second quarter 2018 amounted to SEK 0.9m (0.7) and to SEK 1.5m (1.8) for the year to date 2018 and is comprised of royalty income from Axis-Shield Diagnostics and re-invoiced expenses.

Other operating income and expenses

Other operating income amounted to SEK 0.1m for the second quarter 2018 and to SEK 0.3m for the year to date 2018 and is comprised of a grant from Vinnova. Other operating expense, comprised of net currency differences, amounted to SEK 0.9m (1.0) for the second quarter 2018 and to SEK 1.3m (0.8) for the year to date 2018.

Sales, general and administration expenses

Sales, general and administration expenses for the second quarter 2018 amounted to SEK 14.8m (10.7) and to SEK 30.3m (20.5) for the year to date 2018. The expenses reflect the continued build-up of the organization to prepare for commercial launch and include recorded non-cash costs for the company's employee long term incentive programs (LTIP 2016 and LTIP 2018) amounting to SEK 5.5m.

Research and development expenses

Research and developments expenses amounted to SEK 44.0m (33.8) for the second quarter 2018 and to SEK 75.5m (70.1) for the year to date 2018. Compared with the previous year, the higher expenses are due to intensified activities to prepare for filing together with an expansion of the organization.

Financial result

Operating result for the second quarter 2018 amounted to SEK -58.8m (-44.9) and SEK -105.4m (-89.7) for the year to date 2018.

Profit/loss for the second quarter 2018 amounted to SEK-58.8m (-45.2) and to SEK -105.3m (-90.1) for the year to date 2018.

Cash flow and investments

Cash flow from operating activities amounted to SEK-49.0m (-38.8) for the second quarter 2018 and to SEK -93.1m (-82.5) for the year to date 2018. Cash and cash equivalents including short term investments amounted to SEK 534.2m on June 30, 2018, as compared with SEK 575.0m at the end of first quarter 2018.

Investments for the second quarter 2018 amounted to SEK 1.3m (0.5) and to SEK 1.6m (1.0) for the year to date 2018.

Shareholders' equity

On June 30, 2018 equity amounted to SEK 543.0m compared with SEK 198.6m at the end of the corresponding period 2017.

Parent company

The parent company's net revenue for the second quarter 2018 amounted to SEK 1.0m (0.7) and to SEK 1.6m (1.8) for the year to date 2018. Profit/loss for the parent company amounted to SEK-58.7m (-45.1) for the second quarter and to SEK -105.5m (-90.0) for the year to date 2018. On June 30, 2018, cash and cash equivalents including short term investments amounted to SEK 531.4m compared with SEK 572.8m at the end of first quarter 2018.

The parent company's equity amounted to SEK 534.3m as per June 30, 2018, as compared with SEK 194.0m at the end of the corresponding period 2017.

The Group consists of the parent company Hansa Medical AB and the subsidiaries Cartela R&D AB, Immago Biosystems Ltd and Hansa Medical Inc was registered in May, 2018, but had no business at the end of the second quarter, 2018. Immago Biosystems Ltd is owner of patent rights to the Enze concept.

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Cash and cash equivalents including short term investments	534,178	169,953	534,178	169,953	616,061

Shareholder information

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

According to the shareholder register maintained by Euroclear Sweden AB, as of June 30, 2018, Hansa Medical had 12,628 shareholders. On June 30, 2017, Hansa Medical had 9,873 shareholders. Information regarding shareholders and shareholdings is updated each quarter on the company's website, www.hansamedical.com.

Brief facts, the HMED share

Listing	Nasdaq OMX Stockholm
Number of shares	38,413,386
	(38,083,125 A-shares and 330,261 C-shares)
Market capitalization June 30, 2018	SEK 7,700 m
Ticker	HMED
ISIN	SE0002148817

15 largest shareholders, June 30, 2018

Name	Number of shares	Share (%)
Nexttobe AB	6,643,761	17.4
Handelsbanken Funds	1,578,566	4.1
Thomas Olausson (private and via company)	1,548,569	4.1
Oppenheimer	1,416,700	3.7
Avanza Pension	1,274,812	3.3
Gladiator	1,025,000	2.7
Norron Funds	1,010,743	2.7
Polar Capital Funds PLC	826,135	2.2
Fourth Swedish National Pension Fund	770,000	2.0
Third Swedish National Pension Fund	765,073	2.0
BWG Invest Sàrl	600,370	1.6
Catella Funds	590,526	1.6
AFA Insurance	546,404	1.4
Sven Sandberg	507,000	1.3
C WorldWide Asset Management	482,291	1.3
Other	18,497,175	48.6
In total	**38,083,125**	**100.0**

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

Other information

Employees and organization

The number of employees at the end of the second quarter 2018 was 40, compared to 34 at the end of corresponding period 2017.

Share warrant program

On September 2, 2015, Hansa Medical's Annual General Meeting adopted a share warrant program for the company's employees. 355,000 warrants have been acquired by the company's employees during 2015 and 2016. Each warrant entitles the holder to subscribe for one new share in Hansa 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 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

At June 30, 2018, 205,000 out of 355,000 warrants have been exercised for subscription of shares at the subscription price SEK 44.15 per share and consequently 205,000 shares have been issued during June.

The increase in the company's share capital upon full exercise of the warrants will amount to SEK 355,000 and corresponds to a dilution of 1.1 percent of the total number of shares and the total number of votes in the company.

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. At June 30, 2018, 289,750 rights have been allocated in total, of which 75,000 rights previously allocated have been excluded due to accelerated vesting or termination so remaining allocated rights at June 30, 2018 are 214,750. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. The rights allocated are divided into two vesting periods, the first of which ends November 28, 2019 and the second May 18, 2020.

The general meeting further resolved, to implement LTIP 2016 cost effectively, to authorize the Board to decide on a directed share issue of a maximum of 401,000 Class C shares to a participating bank, of which a maximum of 96,000 Class C shares to be issued to cover any social costs arising from the program and to authorize the Board to resolve to repurchase all issued C-shares. The directed share issue of the 401,000 Class C-shares and the repurchase were executed in May 2018. After the conversion of C shares to ordinary shares, these shall partly be transferred to participants in LTIP 2016 and partly divested in the market for cash flow purposes to secure certain payments related to LTIP 2016, mainly social security costs. Not more than 305,000 ordinary shares can be transferred to participants under LTIP 2016 and 96,000 ordinary shares can be used to cover any social security contributions due to the LTIP 2016, which means a dilution of 1.2 percent of the ordinary shares and votes in the company.

LTIP 2016 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost of LTIP 2016, calculated in accordance with IFRS 2, including social security contributions is expected to amount to approximately SEK 22.4m, of which SEK 5.5m is included in the results for the parent company and the group for the year to date 2018. The program is not expected to have any net effect on cash flow provided it is secured fully in the manner described above.

Long-term incentive program (LTIP 2018)

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

6,701 warrants have been acquired by the participants in LTIP 2018 at June 30, 2018. Each warrant entitles the holder to subscribe for one new share in Hansa Medical. The warrants were sold to the company's employees on market terms at a price established based on an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute. For participants who have not yet joined the Hansa Medical-group, acquisitions must be made at the current market value on the day of allocation. Subscription for shares in accordance with the terms of the warrants may take place during the period from

June 12, 2021 through June 12, 2022. The subscription price will be the market value of the share at the offer for subscription of the warrants with an annual enumeration of 7 percent. This means that the subscription price after three years will amount to approximately 122.5 percent of the current market value of one ordinary share, and after four years amount to approximately 131.1 percent. Except for the CEO, all participants will be offered a subsidy to partially finance the acquisition of warrants. The subsidy will be equal to 25 percent of the warrant investment (after tax). The options are linked to continued employment with the company only in the sense that, if the employment would be terminated, the stock option owner shall offer the warrants to the company and repay the resulting subsidy. The subsidy will affect the company's results proportionately during the option period in accordance with the same principles as in IFRS 2. At a maximum allocation of warrants, 491,419 warrants will be acquired by the participants, which means a dilution effect of approximately 1.3 percent of the number of shares and votes in the company.

105,460 share rights have been totally allocated at June 30, 2018. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. A share right may be exercised provided that the participant, with certain exceptions, from the date of the start of LTIP 2018 for each participant, up until and including the date three years thereafter (the "Vesting Period"), maintains his or her employment within the Hansa Medical-group. The latest start date to receive Share Awards shall be the day prior to Hansa Medical's Annual General Meeting 2019. The vesting period for the rights allocated until June 30, 2018, ends June 15, 2021.

The general meeting further resolved, to implement LTIP 2018 cost effectively, to authorize the Board to decide on a directed share issue of a maximum of 391,503 Class C shares to a participating bank, of which a maximum of 93,601 Class C shares to be issued to cover any social costs arising from the program and to authorize the Board to resolve to repurchase all issued C-shares. After the conversion of C shares to ordinary shares, these shall partly be transferred to participants in LTIP 2018 and partly divested in the market for cash flow purposes to secure certain payments related to LTIP 2018, mainly social security costs. Not more than 297,902 ordinary shares can be transferred to participants under LTIP 2018 and 93,601 ordinary shares can be used to cover any social security contributions due to the LTIP 2018, which means a dilution of 1.0 percent of the ordinary shares and votes in the company. The cost for the share rights in LTIP 2018 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost calculated in accordance with IFRS 2 including social security contributions (based on social security tax of 31.42 percent), for the share rights allocated until June 30, 2018, is expected to amount to approximately SEK 12.4m, of which SEK 1.4m is included in the results for the parent company and the group for the year to date 2018.

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

Financial calendar

Interim report for January-September 2018	November 1, 2018

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.

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Condensed financial statements

Consolidated statement of comprehensive income

	Q2		H1		Year
KSEK	2018	2017	2018	2017	2017
Net revenue	900	693	1,488	1,751	3,442
Direct cost of net revenue	-51	-53	-101	-114	-221
Gross profit	**849**	**640**	**1,387**	**1,637**	**3,221**
Other operating income	87	–	301	–	1,479
Sales, general and administration expense	-14,835	-10,675	-30,305	-20,486	-43,723
Research and development expenses	-43,962	-33,847	-75,499	-70,073	-137,060
Other operating expenses	-907	-1,019	-1,274	-806	–
Operating profit/loss	**-58,768**	**-44,901**	**-105,390**	**-89,728**	**-176,083**
Financial income/expenses	-38	-259	76	-436	-616
Profit/loss for the period before tax	**-58,806**	**-45,160**	**-105,314**	**-90,164**	**-176,699**
Tax	10	9	20	19	39
Net profit/loss for the period	**-58,796**	**-45,151**	**-105,294**	**-90,145**	**-176,660**
Attributable to					
Parent company shareholders	-58,796	-45,151	-105,294	-90,145	-176,660
Earnings per share					
Before dilution (SEK)	-1.55	-1.28	-2.78	-2.55	-4.97
After dilution (SEK)	-1.55	-1.28	-2.78	-2.55	-4.97
Other comprehensive income					
Items that have been, or may be reclassified to profit or loss for the year					
Translation differences	-8	-25	115	-35	-22
Changes in fair value on available-for-sale financial assets	-341	2,552	3,208	2,850	3,535
Other comprehensive income for the year	**-349**	**2,527**	**3,323**	**2,815**	**3,513**
Total net comprehensive income	**-59,145**	**-42,624**	**-101,971**	**-87,330**	**-173,147**

Consolidated balance sheet

	June 30		December 31
KSEK	2018	2017	2017
ASSETS			
Non-current assets			
Intangible fixed assets	33,571	35,006	33,749
Tangible fixed assets	5,123	3,208	3,976
Financial fixed assets	21,705	17,442	18,508
Total non-current assets	**60,399**	**55,636**	**56,233**
Current assets			
Current receivables, non-interest bearing	9,315	3,232	8,121
Short-term investments	474,073	104,932	34,983
Cash and cash equivalents	60,105	65,021	581,078
Total current assets	**543,493**	**173,185**	**624,182**
TOTAL ASSETS	**603,892**	**228,821**	**680,415**
EQUITY AND LIABILITIES			
Shareholders' equity	**542,966**	**198,600**	**630,661**
Long term liabilities			
Deferred tax liabilities	549	554	538
Other provisions	4,538	2,026	5,017
Long term liabilities, interest bearing	668	567	601
Total long term liabilities	**5,755**	**3,147**	**6,156**
Current liabilities			
Current liabilities, interest bearing	–	27	–
Current liabilities, non-interest bearing	10,455	6,678	11,056
Accrued expenses and deferred income	44,716	20,369	32,542
Total current liabilities	**55,171**	**27,074**	**43,598**
TOTAL EQUITY AND LIABILITIES	**603,892**	**228,821**	**680,415**

Consolidated changes in equity

	Jan-Jun		Year
KSEK	2018	2017	2017
Opening shareholders' equity	**630,661**	**283,693**	**283,693**
Result for the period	-105,294	-90,145	-176,660
Other comprehensive income for the period	3,323	2,815	3,513
Net comprehensive income	**-101,971**	**-87,330**	**-173,147**
Transactions with the group's owner			
New share issue [1]	–	401	545,401
Expenses attributable to new share issue	-1,070	-110	-30,049
Repurchase own shares [1]	4,473	-401	-401
Issued warrants	327	131	190
Long term incentive program	1,495	2,216	4,974
By employees redeemed stock options	9,051	–	–
Total transactions with the group's owner	**14,276**	**2,237**	**520,115**
Closing shareholders' equity	**542,966**	**198,600**	**630,661**

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

Consolidated cash flow statement

	Q2		H1		Year
KSEK	2018	2017	2018	2017	2017
Operating activities					
Operating profit/loss	-58,768	-44,901	-105,390	-89,728	-176,083
Adjustment for items not included in cash flow [1]	570	3,797	2,283	6,103	13,827
Interest received and paid, net	-150	-264	-357	-442	-638
Cash flow from operations before change in working capital	**-58,348**	**-41,368**	**-103,464**	**-84,067**	**-162,894**
Change in working capital	9,359	2,571	10,381	1,531	12,789
Cash flow from operating activities	**-48,989**	**-38,797**	**-93,083**	**-82,536**	**-150,105**
Investing activities					
Investments in intangible fixed assets	1	–	-24	–	-214
Investments in tangible fixed assets	-1,329	-467	-1,604	-979	-2,195
Short term investments	-43,989	-89,939	-493,984	-170,920	-240,898
Divestment short term investments	45,000	76,000	55,000	106,000	246,000
Cash flow from investing activities	**-317**	**-14,406**	**-440,612**	**-65,899**	**2,693**
Financing activities					
New share issue [2]	–	401	–	401	545,401
Issue expenses	–	-110	-1,070	-110	-30,050
Repurchase own shares [2]	–	-401	4,473	-401	-401
By employees redeemed stock options	9,051	–	9,051	–	–
Issued warrants	268	–	268	–	–
Repayment of leasing liabilities	–	-22	–	-22	-48
Cash flow from financing activities	**9,319**	**-132**	**12,722**	**-132**	**514,902**
Net change in cash	**-39,987**	**-53,335**	**-520,973**	**-148,567**	**367,490**
Cash and cash equivalents, beginning of year	100,092	118,356	581,078	213,588	213,588
Cash and cash equivalents, end of period	**60,105**	**65,021**	**60,105**	**65,021**	**581,078**

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

Consolidated key ratios and other information

	Q2		H1		Year
KSEK, unless otherwise stated	2018	2017	2018	2017	2017
Profit numbers					
Net revenue	900	693	1,488	1,751	3,442
Operating profit/loss	-58,768	-44,901	-105,390	-89,728	-176,083
Net profit/loss	-58,796	-45,151	-105,294	-90,145	-176,660
Per share data					
Earnings/loss per share before and after dilution (SEK)	-1.55	-1.28	-2.78	-2.55	-4.97
Shareholders' equity per share (SEK)	14,26	5,67	14,26	5,67	16,68
Other information					
Equity ratio (%)	90	87	90	87	93
Cash and cash equivalents including short term investments	534,178	169,953	534,178	169,953	616,061
Number of outstanding shares at the end of the period	38,083,125	35,054,860	38,083,125	35,054,860	37,807,386
Weighted average number of shares before and after dilution	37,882,630	35,306,636	37,868,665	35,306,636	35,519,029

Parent company – Statement of comprehensive income

	Q2		H1		Year
KSEK	2018	2017	2018	2017	2017
Net revenue	953	693	1,638	1,751	3,739
Direct cost of net revenue	-51	-53	-101	-114	-221
Gross profit	**902**	**640**	**1,537**	**1,637**	**3,518**
Other operating income	87	–	301	–	1,479
Sales, general and administration expenses	-14,746	-10,716	-30,209	-20,490	-43,740
Research and development expenses	-43,919	-33,770	-75,494	-69,951	-137,015
Other operating expenses	-906	-1,019	-1,273	-806	–
Operating profit/loss	**-58,582**	**-44,865**	**-105,138**	**-89,610**	**-175,758**
Result from short term financial receivables	16	27	19	27	97
Other financial expenses	-173	-286	-425	-462	-712
Profit/loss for the period (before and after taxes)	**-58,739**	**-45,124**	**-105,544**	**-90,045**	**-176,373**
Other comprehensive income for the period	**–**	**–**	**–**	**–**	**–**
Total net comprehensive income	**-58,739**	**-45,124**	**-105,544**	**-90,045**	**-176,373**

Parent company – Balance sheet

	June 30		December 31
KSEK	2018	2017	2017
ASSETS			
Non-current assets			
Intangible fixed assets	30,430	32,110	30,709
Tangible fixed assets	5,123	3,208	3,976
Financial fixed assets	17,594	17,317	17,317
Total non-current assets	**53,147**	**52,635**	**52,002**
Current assets			
Current receivables, non-interest bearing	10,058	3,364	8,588
Short-term investments	473,994	104,943	34,992
Cash and cash equivalents	57,421	62,764	578,795
Total current assets	**541,473**	**171,071**	**622,375**
TOTAL ASSETS	**594,620**	**223,706**	**674,377**
EQUITY AND LIABILITIES			
Shareholders' equity	**534,260**	**193,978**	**625,528**
Long term liabilities			
Other provisions	4,538	2,026	5,017
Long term liabilities, non-interest bearing	668	567	601
Total long term liabilities	**5,206**	**2,593**	**5,618**
Current liabilities			
Liabilities to group companies	1	98	98
Current liabilities, non-interest bearing	10,456	6,668	10,606
Accrued expenses and deferred income	44,697	20,369	32,527
Total current liabilities	**55,154**	**27,135**	**43,231**
TOTAL EQUITY AND LIABILITIES	**594,620**	**223,706**	**674,377**

Parent company – Changes in equity

	Jan-Jun		Year
KSEK	2018	2017	2017
Opening shareholders' equity	**281,786**	**211,547**	**211,547**
Result for the period	-105,544	-90,045	-176,373
New share issue [1]	–	401	545,401
Expenses attributable to new share issue	-1,070	-110	-30,049
Repurchase own shares [1]	4,473	-401	-401
Issued warrants	327	131	190
Long term incentive program	1,495	2,216	4,974
By employees redeemed stock options	9,051	–	–
Total transactions with the group's owner	**14,276**	**2,237**	**520,115**
Closing shareholders' equity	**534,260**	**193,978**	**625,528**

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

Financial notes

Note 1 Basis of Preparation and Accounting policies

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

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

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

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

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

Note 2 Fair value of financial instruments

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

The fair value of the interest funds as per the balance sheet date June 30, 2018 was SEK 430,079k and SEK 429,597k as per December 31, 2017. The fair value of the shares as per the balance sheet date June 30, 2018 was SEK 21,706k, SEK 18,507k as per December 31, 2017 and SEK 17,422k as per June 30, 2017. The fair value of the financial instruments is calculated based on the closing price. The valuation of the holdings is, thereby, in accordance with Level 1 in the valuation hierarchy.

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9. Linder et al., “Heparin-binding protein improves prediction of severe sepsis in the emergency”,Crit Care. 2013; 17(Suppl 4): P3

10. Mayr et al., “Epidemiology of severe sepsis”, Virulence 5:1, 4-11, January 1, 2014

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.

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