Hansa Medical

Interim report July – September 2018

Strong clinical data generated through four successfully completed Phase 2 studies in HLA-sensitized patients opens a possible path towards regulatory approval for Hansa's lead candidate imlifidase

July–September 2018 in brief

- Hansa successfully completed two Phase 2 clinical studies evaluating imlifidase for kidney transplantation in highly sensitized patients, with imlifidase enabling transplantation in all 35 patients.
  - Imlifidase met all primary and secondary endpoints in each study.
  - Treatment with imlifidase enabled highly sensitized patients to receive life-saving transplants.
  - Hansa plans to submit Biologics License Application (BLA) and Marketing Authorization Application (MAA) filings by Q1 2019, with their potential acceptance of submission within 60 days.
- Hansa initiated a long-term observational prospective follow-up study. The primary objective of the study is evaluation of graft survival in patients who have undergone kidney transplantation after treatment with imlifidase. The study aims to encompass all patients from the four completed Phase 2 studies evaluating imlifidase in sensitized kidney transplantation patients. The study will provide regular follow-up data on graft survival for up to five years and interim results will be available on an ongoing basis.
- The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to imlifidase for the treatment of the rare and acute kidney disease anti-GBM antibody disease, also known as Goodpasture's disease. 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 the BLA.
- Vincenza Nigro was appointed as Vice President, Global Medical Affairs. Ms. Nigro brings more than two decades of international life sciences industry experience in medical affairs, clinical development and commercial leadership roles, including significant expertise in transplantation and orphan diseases.

Significant events after the end of the reporting period

- The U.S. Food and Drug Administration (FDA) granted imlifidase Fast Track Designation for the investigation of imlifidase for transplantation. The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs to treat serious or life-threatening conditions that demonstrate the potential to address an unmet medical need.
- The Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) has issued a positive opinion on Orphan Drug Designation for imlifidase in the treatment of anti-GBM antibody disease. A positive opinion by the COMP precedes official designation by the European Commission.

Financial summary for the Group

	July–September		January–September		Year
KSEK, unless otherwise stated	2018	2017	2018	2017	2017
Net revenue	484	678	1,972	2,429	3,442
Operating profit/loss	-60,503	-37,434	-165,893	-127,162	-176,083
Net profit/loss	-61,451	-37,527	-166,745	-127,672	-176,660
Earnings per share before and after dilution (SEK)	-1.61	-1.06	-4.39	-3.62	-4.97
Shareholders' equity	506,302	167,890	506,302	167,890	630,661
Cash flow from operating activities	-54,011	-38,427	-147,094	-120,963	-150,105
Cash and cash equivalents including short term investments	483,403	130,871	483,403	130,871	616,061

CEO statement

Since I joined Hansa a little over six months ago, I have been continuously impressed by what has been accomplished by our skilled team and distinguished collaborators. 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 around our proprietary program of immunomodulatory enzymes for organ transplantation and acute autoimmune conditions.

The development of our lead candidate imlifidase, formerly known as IdeS, continues to progress according to plan. To date, we have successfully designed and managed a series of clinical studies, demonstrating its ability to enable life-saving kidney transplantation in highly sensitized patients, an indication where there is significant unmet medical need. At the end of the quarter, we announced the successful completion of two Phase 2 clinical studies of imlifidase for kidney transplantation in highly sensitized patients, in which imlifidase enabled transplantation in all 35 evaluated patients.

The outcome of these studies, which are described in greater detail on page 7 in this report, demonstrates that imlifidase is capable of enabling organ transplantation for highly sensitized patients who would otherwise remain on dialysis, associated with high cost, a poor quality of life and an increased mortality rate. In October the U.S. Food and Drug Administration (FDA) granted imlifidase Fast Track Designation for the investigation of imlifidase for transplantation. This designation is further validation of imlifidase's potential to address the significant unmet medical need for these highly sensitized patients. We continue to actively engage with the regulatory agencies and anticipate submitting a Biologic License Application (BLA), as well as a Marketing Authorisation Application (MAA) by the first quarter of 2019, with their potential acceptance of submission with 60 days.

Beyond the six-month follow-up data, the filings will include positive data collected across four Phase 2 clinical studies demonstrating the efficacy and safety of imlifidase to enable kidney transplantations, the validation of the manufacturing process for imlifidase and evidence of the significant medical need for these highly sensitized patients who today have a limited opportunity for transplantation.

We are determined to bring imlifidase to market in kidney transplantation as soon as possible. In parallel, our long-term vision is to offer imlifidase to a wide range of patients suffering from acute, IgG-mediated diseases. We believe imlifidase can eliminate IgG in these acute diseases which may potentially translate into significant clinical benefit for these patients.

In early July, the FDA granted Orphan Drug Designation to imlifidase for the treatment of anti-GBM antibody disease (anti-GBM) and in October the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) issued a positive opinion on Orphan Drug Designation for imlifidase in the treatment of anti-GBM antibody disease. We believe imlifidase, with the ability to rapidly, effectively and tolerably eliminate IgG, has the potential to help preserve kidney function and prevent progression to dialysis for individuals with anti-GBM. We believe the receipt of Orphan Drug Designation confirms this high unmet medical need, and we remain committed to the clinical advancement of imlifidase for the treatment of this devastating disease.

In June 2017, an open-label, investigator-initiated Phase 2 study in severe anti-GBM was initiated with Professor Mårten Segelmark at Linköping University Hospital as coordinating principal investigator and sponsor. The aim is to enroll approximately 15 patients in Sweden, Denmark, Austria, Czech Republic, France and the UK.

We continue to increase our engagement in the evaluation of imlifidase in other acute autoimmune conditions. We are preparing the initiation of enrollment for two more Phase 2 studies during the fourth quarter of 2018. The first study will be a Phase 2 study to evaluate the treatment of antibody-mediated kidney transplant rejection, with a target enrollment of approximately 30 patients across the U.S. and Europe. The second study will be a Phase 2 study in the acute neurological disease Guillain-Barré syndrome (GBS), which is designed to enroll approximately 30 patients, primarily in Europe. To support imlifidase's clinical development across these indications, we have continued to grow the R&D team.

We have also continued to expand our commercial organization in advance of the potential commercial launch of imlifidase. In September, we were very fortunate to appoint Vincenza Nigro as Vice President, Global Medical Affairs. Vincenza brings more than two decades of international life sciences industry expertise in medical affairs, clinical development and commercial leadership roles, including deep experience in transplantation and orphan diseases.

With her extensive experience building and leading high-performance medical affairs teams and of life cycle management of innovative transplant-related and immunology products, she will be a strong and valuable addition to our team as we transform Hansa into a full-fledged, global, commercial-stage biotech company.

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 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, November 1, 2018

Hansa Medical in brief

Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for organ transplantation and acute autoimmune diseases. The Company's lead product, imlifidase, is a proprietary, antibody-degrading enzyme in late-stage clinical development for kidney transplant patients, with the potential for further development in other solid organ transplantation and acute autoimmune indications. Hansa also has a strong pipeline of preclinical projects, including NiceR, through which the Company is developing novel immunoglobulin-cleaving enzymes for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden, and its shares are listed on NASDAQ Stockholm (HMED). www.hansamedical.com

Business overview

Imlifidase is an enzyme, currently in late-stage clinical development, that cleaves immunoglobulin G (IgG) with a high degree of specificity. Our clinical development strategy leverages imlifidase's ability 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 enable broader usage in relapsing autoimmune diseases and oncology.

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

HBP-assay is a novel diagnostic method to help predict severe sepsis in patients with infectious disease symptoms. 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.

Pipeline

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

In planning Ongoing Completed

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

Imlifidase

Imlifidase – A novel therapeutic principle

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

Overview of imlifidase clinical program

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

Imlifidase has been evaluated in a Phase 1 study[1] in healthy subjects and in four Phase 2 studies in sensitized patients awaiting kidney transplantation[2, 3]. The results from these studies demonstrate that imlifidase is highly effective in reducing anti-human leukocyte antigen (HLA) antibodies to levels acceptable for transplantation, and that imlifidase is well-tolerated. Based on the successful outcome from these five clinical studies, Hansa is seeking a path towards regulatory approval from the FDA and the EMA, and Hansa anticipates filing for marketing authorization by Q1 2019 with potential acceptance of file within 60 days from filing.

An investigator-initiated Phase 2 study evaluating imlifidase in the rare and acute autoimmune kidney disease anti-GBM antibody disease is ongoing in collaboration with several European nephrology clinics. Furthermore, two additional Phase 2 studies in acute antibody mediated rejection (AMR) and treatment of the acute autoimmune neurological disease Guillain-Barré syndrome (GBS) are being planned with expected filing of clinical trial applications by the FDA and EMA during fourth quarter 2018 and initiation of patient enrollment during the first quarter of 2019.

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

Latest developments

In September, Hansa announced the successful completion of the third and fourth Phase 2 studies evaluating imlifidase in highly sensitized patients. Across both studies, treatment with imlifidase successfully enabled life-saving transplants in all 35 patients. The Hansa Medical-sponsored, multi-center Highdes study (ClinicalTrials.gov identifier NCT02790437) enrolled 18 patients at five sites in the U.S., France and Sweden; the U.S. investigator-initiated study (ClinicalTrials.gov identifier NCT02426684) enrolled 17 patients at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center, Los Angeles.

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

Summary of Results

- Imlifidase enabled kidney transplantation for all 35 highly sensitized patients. At study completion, six months post-transplantation, graft survival was 91%. 32 patients were off dialysis with good kidney function with estimated glomerular filtration rates (eGFR) within the expected range. Three patients experienced graft loss unrelated to the treatment with imlifidase.
- Following imlifidase treatment, patients had a rapid cross-match conversion and a clinically significant reduction in DSAs, enabling transplantation.
- Preliminary data demonstrate that <25% of patients experienced clinical or subclinical episodes of acute antibody mediated rejection (AMR), which is lower than expected for a highly sensitized patient population after desensitization. All AMR episodes were effectively treated. Approximately 20–60% of sensitized patients desensitized with experimental protocols such as plasma exchange, experience AMRs[4, 5].
- Results demonstrate favorable safety profile after six-month follow-up.

Concurrently, Hansa has initiated a long-term observational prospective follow up study. The primary objective of the study is evaluation of graft survival across a five-year time frame in patients who have undergone kidney transplantation after treatment with imlifidase, aiming to encompass all patients from the Phase 2 studies with imlifidase in sensitized kidney transplantation patients. Interim results will be available on an ongoing basis.The objective of the study is to collect long-term outcome data in patients that have received a kidney transplant following imlifidase dosing to provide further support to future prescribers, payers and patients on the long-term outcomes of imlifidase-mediated transplantation.

Imlifidase – Treatment of anti-GBM antibody disease

Anti-GBM antibody disease, also known as Goodpasture's disease, is a rare, acute autoimmune disease where autoantibodies directed against type IV collagen cause acute inflammation of the kidney and/or the lungs. In severe anti-GBM, the disease may progress to renal failure or death. Anti-GBM antibody disease affects one in a million patients annually[6], and less than one third of the patients survive with preserved kidney function after six-months follow-up[7].

An open-label, investigator-initiated Phase 2 study in severe anti-GBM antibody disease with imlifidase is ongoing. Approximately 15 patients will be recruited to the study at up to 15 clinics in Europe. The primary objective of the study is to evaluate the safety and tolerability of imlifidase in patients with severe anti-GBM 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 enrolled 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 September 2018.

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

In October, the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) issued a positive opinion on Orphan Drug Designation for imlifidase in the treatment of anti-GBM antibody disease. A positive opinion by the COMP precedes official designation by the European Commission. A designation provides development and commercial incentives, including 10 years of market exclusivity, protocol assistance on the development of the drug, including clinical studies, and certain exemptions from or reductions in regulatory fees

Finalized and ongoing clinical studies with imlifidase

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

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

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

Regulatory strategy for imlifidase in desensitization
The recently completed Phase 2 studies have enrolled highly sensitized patients who had either failed previous attempts of desensitization or were highly unlikely to receive a compatible kidney transplant. Based on the results from these successfully completed Phase 2 studies, Hansa will seek a path towards regulatory approval from the FDA and the EMA with the ambition to file for marketing authorization by Q1 2019, their potential acceptance of submission within 60 days.

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 MAA once submitted.

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

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[8] 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's ability to rapidly remove DSAs damaging the kidney has the potential to make a significant difference in the treatment of these patients.

A Phase 2 study evaluating imlifidase for the treatment of AMR is being planned with expected filing of clinical trial applications by the FDA and EMA during fourth quarter 2018 and initiation of patient enrollment during the first quarter of 2019. Approximately 30 patients will be enrolled in the study.

Treatment of Guillain-Barré syndrome (GBS)

GBS is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG-antibodies. It affects one in 100,000 people annually[9]. While patients are typically treated with either IVIG or plasmapheresis, there remains a significant unmet medical need. In February 2018, imlifidase received Orphan Drug Designation from the FDA for the treatment of GBS.

A Phase 2 study evaluating imlifidase for the treatment of GBS is being planned with expected filing of clinical trial application by the EMA during fourth quarter 2018 and initiation of patient enrollment during the first quarter of 2019. Approximately 30 patients will be enrolled in the study.

Preclinical development projects

NiceR – Novel Immunoglobulin Cleaving Enzymes for Repeat dosing

Hansa is developing novel IgG-degrading enzymes with the objective of enabling repeat dosing in autoimmune conditions, oncology and transplantation where patients benefit from more than one dose of an IgG-modulating enzyme. Several novel immunoglobulin cysteine endopeptidases have been developed and patented. The development program is being prepared for pre-clinical development, including CMC development and toxicology studies.

EnzE – Enzyme-based antibody Enhancement

Recently published findings[10] demonstrate how pre-treatment with imlifidase in tumor animal models can increase the efficacy of currently available antibody-based cancer therapies. This treatment concept is currently being investigated under the project name EnzE, Enzyme-based antibody Enhancement. Published data demonstrate the potential of an IgG-clearing agent as a pre-treatment for cancer patients. High levels of plasma IgG have been shown to limit the efficacy of therapeutic antibodies, as plasma IgG can saturate the receptors of the patient's immune cells, preventing them from efficiently killing the tumor cells. Removing inhibiting IgG antibodies with imlifidase or novel IgG-clearing enzymes prior to dosing the patient with a therapeutic antibody can potentially increase the efficacy of the given cancer therapy. The EnzE-program is in the pre-clinical research phase.

Out-licensed royalty generating programs

HBP – Prediction of severe sepsis

The HBP-assay for measurement of heparin-binding protein (HBP) in plasma is a novel diagnostic method originally developed and patented by Hansa to assist in predicting severe sepsis in patients with infectious disease symptoms at emergency departments[11]. Hundreds of thousands of patients die every year due to severe sepsis as a complication of infections, e.g. urinary tract infection and pneumonia. Many of these infections can be effectively treated with antibiotics in order to prevent progression to severe sepsis, although early prediction of risk patients is crucial for successful treatment. Severe sepsis affects 300 of 100,000 people annually[12]. The HBP-assay has been out-licensed by Hansa to UK-based Axis-Shield Diagnostics, a subsidiary to Abbott, and Hansa holds the right to royalty payments from Axis-Shield. Axis-Shield is engaged in further product development and clinical development with the HBP-assay.

Financial review January – September 2018

Net revenue

Net revenue for the third quarter 2018 amounted to SEK 0.5 m (0.7) and to SEK 2.0 m (2.4) for the year to date 2018 and is comprised of royalty income from Axis-Shield Diagnostics.

Other operating income and expenses

Other operating income amounted to SEK 0.4 m (2.8) for the third quarter 2018 and to SEK 0.7 m (2.0) for the year to date 2018 and is comprised of a grant from Vinnova. For the previous year, net currency differences is also included. Other operating expense, comprised of net currency differences, amounted to SEK 1.1 m for the third quarter 2018 and to SEK 2.4 m (0.1) for the year to date 2018.

Sales, general and administration expenses

Sales, general and administration expenses for the third quarter 2018 amounted to SEK 23.8 m (9.6) and to SEK 54.1 m (30.1) for the year to date 2018. The expenses reflect the continued activities and build-up of the organization to prepare for commercial launch and include recorded non-cash costs for the company's employee long-term incentive programs (LTIP 2016 and LTIP 2018) amounting to SEK 10.3 m (2.9).

Research and development expenses

Research and developments expenses amounted to SEK 36.4 m (31.2) for the third quarter 2018 and to SEK 111.9 m (101.3) for the year to date 2018 and include non-cash costs for the company's long-term incentive programs amounting to SEK 4.4 m (3.6). 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 third quarter 2018 amounted to SEK -60.5 m (-37.4) and SEK -165.9 m (-127.2) for the year to date 2018.

Profit/loss for the third quarter 2018 amounted to SEK -61.5 m (-37.5) and to SEK -166.7 m (-127.7) for the year to date 2018.

Cash flow and investments

Cash flow from operating activities amounted to SEK -54.0 m (-38.4) for the third quarter 2018 and to SEK -147.1 m (-121.0) for the year to date 2018. Cash and cash equivalents including short term investments amounted to SEK 483.4 m on September 30, 2018, as compared with SEK 534.2 m at the end of second quarter 2018.

Investments for the third quarter 2018 amounted to SEK 0.1 m (0.7) and to SEK 1.8 m (1.7) for the year to date 2018.

Shareholders' equity

On September 30, 2018 equity amounted to SEK 506.3 m compared with SEK 167.9 m at the end of the corresponding period 2017.

Parent company

The parent company's net revenue for the third quarter 2018 amounted to SEK 0.5 m (0.7) and to SEK 2.2 m (2.4) for the year to date 2018. Profit/loss for the parent company amounted to SEK -61.5m (-37.5) for the third quarter and to SEK -167.0 m (-127.5) for the year to date 2018. On September 30, 2018, cash and cash equivalents including short term investments amounted to SEK 477.7 m compared with SEK 531.4 m at the end of second quarter 2018.

The parent company's equity amounted to SEK 479.0 m as per September 30, 2018, as compared with SEK 157.9 m 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. Hansa Medical Inc was registered in May, 2018, and includes medical affairs and market access operations. Immago Biosystems Ltd is owner of patent rights to the EnzE concept.

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Operating profit/loss	-60,503	-37,434	-165,893	-127,162	-176,083
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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 September 30, 2018, Hansa Medical had 12,953 shareholders. On September 30, 2017, Hansa Medical had 11,469 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	38,463,386 (38,133,125 A-shares and 330,261 C-shares)
Market capitalization September 30, 2018	SEK 12 836 m
Ticker	HMED
ISIN	SE0002148817

15 largest shareholders, September 30, 2018

Name	Number of shares	Share (%)
Nexttobe AB	6,643,761	17.4
Oppenheimer	1,865,379	4.9
Handelsbanken funds	1,708,566	4.5
Thomas Olausson (private and via company)	1,548,569	4.1
Avanza Pension	1,276,397	3.3
Gladiator	1,200,000	3.1
Norron Funds	932,344	2.4
AFA Insurance	920,534	2.4
Polar Capital Funds PLC	888,057	2.3
Fourth Swedish National Pension Fund	814,058	2.1
Third Swedish National Pension Fund	762,505	2.0
BWG Invest Sarl.	600,370	1.6
Invesco	504,374	1.3
Sven Sandberg	501,000	1.3
C WorldWide Asset management	482,291	1.3
Other	17,484,920	45.9
In total	**38,133,125**	**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 third quarter 2018 was 49, 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.

Until September 30, 2018, 255,000 out of 355,000 warrants have been exercised for subscription of shares at the subscription price SEK 44.15-44.85 per share and consequently 255,000 shares have been issued until September.

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. 289,750 rights have been allocated in total, of which 78,250 rights previously allocated have been excluded due to accelerated vesting or terminated, so remaining allocated rights at September 30, 2018 are 211,500. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. The rights allocated are divided into two vesting periods, the first of which ends November 28, 2019 and the third 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 32.6 m, of which SEK 13.2 m 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 the participants in LTIP 2018 during the year. 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 approx-

imately 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 during the year, of which 580 have been excluded due to termination, so remaining allocated rights at September 30, 2018 are 104,880. 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 15.9 m, of which SEK 1.5 m 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.

Committee for the 2019 Annual General Meeting

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

Financial calendar

Interim report January–December 2018	February 8, 2019
Annual report 2018	April 15, 2019
Interim report January–March 2019	April 29, 2019
Annual General Meeting	May 22, 2019
Interim report January–June 2019	July 18, 2019
Interim report January–September 2019	October, 31, 2019

Legal disclaimer

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

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556734-5359

Condensed financial statements

Consolidated statement of comprehensive income

	July–September		January–September		Year
KSEK	2018	2017	2018	2017	2017
Net revenue	484	678	1,972	2,429	3,442
Direct cost of net revenue	-50	-54	-151	-168	-221
Gross profit	**434**	**624**	**1,821**	**2,261**	**3,221**
Other operating income	370	2,778	671	2,047	1,479
Sales, general and administration expense	-23,797	-9,617	-54,102	-30,103	-43,723
Research and development expenses	-36,424	-31,219	-111,923	-101,292	-137,060
Other operating expenses	-1,086	–	-2,360	-75	–
Operating profit/loss	**-60,503**	**-37,434**	**-165,893**	**-127,162**	**-176,083**
Financial income/expenses	-958	-103	-882	-539	-616
Profit/loss for the period before tax	**-61,461**	**-37,537**	**-166,775**	**-127,701**	**-176,699**
Tax	10	10	30	29	39
Net profit/loss for the period	**-61,451**	**-37,527**	**-166,745**	**-127,672**	**-176,660**
Attributable to					
Parent company shareholders	-61,451	-37,527	-166,745	-127,672	-176,660
Earnings per share					
Before dilution (SEK)	-1.61	-1.06	-4.39	-3.62	-4.97
After dilution (SEK)	-1.61	-1.06	-4.39	-3.62	-4.97
Other comprehensive income					
Items that have been, or may be reclassified to profit or loss for the year					
Translation differences	-23	-31	92	-66	-22
Changes in fair value on available-for-sale financial assets	–	5,439	–	8,289	3,535
Shares valued at fair value through other comprehensive income	18,621	–	21,828	–	–
Other comprehensive income for the year	**18,598**	**5,408**	**21,920**	**8,223**	**3,513**
Total net comprehensive income	**-42,853**	**-32,119**	**-144,825**	**-119,449**	**-173,147**

Consolidated balance sheet

	September 30		December 31
KSEK	2018	2017	2017
ASSETS			
Non-current assets			
Intangible fixed assets	33,395	34,221	33,749
Tangible fixed assets	5,605	3,701	3,976
Financial fixed assets	40,328	22,849	18,508
Total non-current assets	**79,328**	**60,771**	**56,233**
Current assets			
Current receivables, non-interest bearing	7,257	3,275	8,121
Short-term investments	429,343	104,975	34,983
Cash and cash equivalents	54,060	25,896	581,078
Total current assets	**490,660**	**134,146**	**624,182**
TOTAL ASSETS	**569,988**	**194,917**	**680,415**
EQUITY AND LIABILITIES			
Shareholders' equity	**506,302**	**167,890**	**630,661**
Long term liabilities			
Deferred tax liabilities	531	537	538
Other provisions	11,969	3,030	5,017
Long term liabilities, interest bearing	1,177	574	601
Total long term liabilities	**13,677**	**4,141**	**6,156**
Current liabilities			
Current liabilities, interest bearing	–	18	–
Current liabilities, non-interest bearing	15,453	4,379	11,056
Accrued expenses and deferred income	34,556	18,489	32,542
Total current liabilities	**50,009**	**22,886**	**43,598**
TOTAL EQUITY AND LIABILITIES	**569,988**	**194,917**	**680,415**

Consolidated changes in equity

	January–September		Year
KSEK	2018	2017	2017
Opening shareholders' equity	**630,661**	**283,693**	**283,693**
Result for the period	-166,745	-127,672	-176,660
Other comprehensive income for the period	21,920	8,223	3,513
Net comprehensive income	**-144,825**	**-119,449**	**-173,147**
Transactions with the group's owner			
New share issue [1]	–	401	545,401
Expenses attributable to new share issue	-1,150	-110	-30,049
Repurchase own shares [1]	4 473	-401	-401
Issued warrants	340	161	190
Long term incentive program	3,288	3,595	4,974
By employees redeemed stock options	11,271	–	–
New share issue during registration	2,243	–	–
Total transactions with the group's owner	**20,466**	**3,646**	**520,115**
Closing shareholders' equity	**506,302**	**167,890**	**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

	July–September		January–September		Year
KSEK	2018	2017	2018	2017	2017
Operating activities					
Operating profit/loss	-60,503	-37,434	-165,893	-127,162	-176,083
Adjustment for items not included in cash flow [1]	9,922	3,364	12,205	9,467	13,827
Interest received and paid, net	-225	-139	-582	-581	-638
Cash flow from operations before change in working capital	**-50,806**	**-34,209**	**-154,270**	**-118,276**	**-162,894**
Change in working capital	-3,205	-4,218	7,176	-2,687	12,789
Cash flow from operating activities	**-54,011**	**-38,427**	**-147,094**	**-120,963**	**-150,105**
Investing activities					
Investments in intangible fixed assets	–	–	-24	–	-214
Investments in tangible fixed assets	-149	-698	-1,753	-1,677	-2,195
Short term investments	–	-34,989	-493,984	-205,909	-240,898
Divestment short term investments	44,000	35,000	99,000	141,000	246,000
Cash flow from investing activities	**43,851**	**-687**	**-396,761**	**-66,586**	**2,693**
Financing activities					
New share issue [2]	–	–	–	291	545,401
Issue expenses	-80	–	-1,150	–	-30,050
Repurchase own shares [2]	–	–	4,473	-401	-401
By employees redeemed stock options	4,195	–	13,246	–	–
Issued warrants	–	–	268	–	–
Repayment of leasing liabilities	–	-11	–	-33	-48
Cash flow from financing activities	**4,115**	**-11**	**16,837**	**-143**	**514,902**
Net change in cash	**-6,045**	**-39,125**	**-527,018**	**-187,692**	**367,490**
Cash and cash equivalents, beginning of year	60,105	65,021	581,078	213,588	213,588
Cash and cash equivalents, end of period	**54,060**	**25,896**	**54,060**	**25,896**	**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

	July–September		January–September		Year
KSEK, unless otherwise stated	2018	2017	2018	2017	2017
Profit numbers					
Net revenue	484	678	1,972	2,429	3,442
Operating profit/loss	-60,503	-37,434	-165,893	-127,162	-176,083
Net profit/loss	-61,451	-37,527	-166,745	-127,672	-176,660
Per share data					
Earnings/loss per share before and after dilution (SEK)	-1.61	-1.06	-4.39	-3.62	-4.97
Shareholders' equity per share (SEK)	13.28	4.79	13.28	4.79	16.68
Other information					
Equity ratio (%) [1]	89	86	89	86	93
Cash and cash equivalents including short term investments	483,403	130,871	483,403	130,871	616,061
Number of outstanding shares at the end of the period	38,133,125	35,054,860	38,133,125	35,054,860	37,807,386
Weighted average number of shares before and after dilution	38,120,082	35,306,636	37,953,392	35,306,636	35,519,029

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

Parent company – Statement of comprehensive income

	July–September		January–September		Year
KSEK	2018	2017	2018	2017	2017
Net revenue	541	678	2,179	2,429	3,739
Direct cost of net revenue	-50	-54	-151	-168	-221
Gross profit	**491**	**624**	**2,028**	**2,261**	**3,518**
Other operating income	370	2 778	671	2,047	1,479
Sales, general and administration expenses	-22,370	-9,629	-52,579	-30,119	-43,740
Research and development expenses	-38,015	-31,154	-113,509	-101,105	-137,015
Other operating expenses	-1,087	–	-2,360	-75	–
Operating profit/loss	**-60,611**	**-37,381**	**-165,749**	**-126,991**	**-175,758**
Result from other securities and receivables which are fixed assets	–	–	–	–	97
Result from short term financial receivables	5	42	24	69	–
Other financial expenses	-887	-145	-1,312	-607	-712
Profit/loss for the period (before and after taxes)	**-61,493**	**-37,484**	**-167,037**	**-127,529**	**-176,373**
Other comprehensive income for the period	**–**	**–**	**–**	**–**	**–**
Total net comprehensive income	**-61,493**	**-37 484**	**-167,037**	**-127 529**	**-176,373**

Parent company – Balance sheet

	September 30		December 31
KSEK	2018	2017	2017
ASSETS			
Non-current assets			
Intangible fixed assets	30,291	31,410	30,709
Tangible fixed assets	4,992	3,701	3,976
Financial fixed assets	17,594	17,317	17,317
Total non-current assets	**52,877**	**52,428**	**52,002**
Current assets			
Receivables group-companies	3,486	–	–
Current receivables, non-interest bearing	7,254	3,433	8,588
Short-term investments	429,343	104,974	34,992
Cash and cash equivalents	48,320	23,623	578,795
Total current assets	**488,403**	**132,030**	**622,375**
TOTAL ASSETS	**543,998**	**184,458**	**674,377**
EQUITY AND LIABILITIES			
Shareholders' equity	**478,957**	**157,903**	**625,528**
Long term liabilities			
Other provisions	11,969	3, 030	5,017
Liabilities to group companies	–	98	98
Long term liabilities, non-interest bearing	675	574	601
Total long term liabilities	**12,644**	**3,702**	**5,716**
Current liabilities			
Current liabilities, non-interest bearing	15,148	4,364	10,606
Accrued expenses and deferred income	34,531	18,489	32,527
Total current liabilities	**49,679**	**22,853**	**43,133**
TOTAL EQUITY AND LIABILITIES	**541,280**	**184,458**	**674,377**

Parent company – Changes in equity

	January–September		Year
KSEK	2018	2017	2017
Opening shareholders' equity	**625,528**	**281,786**	**211,547**
Result for the period	-167,037	-127, 529	-176,373
New share issue [1]	–	401	545,401
Expenses attributable to new share issue	-1,150	-110	-30,049
Repurchase own shares [1]	4,473	-401	-401
Issued warrants	340	161	190
Long term incentive program	3,288	3,595	4,974
By employees redeemed stock options	11,271	–	–
New share issue under registration	2,243	–	–
Total transactions with the group's owner	**20,466**	**3,646**	**520,115**
Closing shareholders' equity	**481,674**	**157,903**	**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 recognized in other comprehensive income. Instead, under IFRS 9 the changes in the fair values of the funds has been reported in profit or loss. Therefore, accumulated changes in fair values of the funds of SEK -403 k has been transferred from the "Fair value reserve" to "Retained earnings" in the opening balance as per January 1, 2018.

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

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

New IFRS which have not yet begun to be applied

IFRS 16 Lease Agreement replaces, as of January 1, 2019, existing IFRS related to the recognition of leasing agreements, such as IAS 17 Leasing and IFRIC 4 Determining whether an agreement contains a lease. Hansa Medical does not plan to apply IFRS 16 earlier. IFRS 16 primarily affects leasers and the central effect is that all leases that are currently reported as operating leases are to be accounted for in a manner similar to the current accounting of financial leases. This means that even for operational leases, assets and liabilities need to be 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.

Note 2 Fair value of financial instruments

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

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

Financial instrument	Valuation hierarchy	Sep 30, 2018	Dec 31, 2017	Sep 30, 2017
Interest funds	Level 2	429,343	429,597	–
Shares	Level 1	40,328	18,507	22,849

Reference list

1. Winstedt el al., ”Complete Removal of Extracellular IgG Antibodies in a Randomized Dose Escalation Phase I Study with the Bacterial Enzyme IdeS – A Novel Therapeutic Opportunity”, PLOS ONE 2015, 10(7)

2. Jordan et al., ”IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation”, N Engl J Med 2017;377:442-53.

3. Lorant et al., ”Safety, immunogenicity, pharmacokinetics and efficacy of degradation of anti-HLA antibodies by IdeS (imlifidase) in chronic kidney disease patients” American Journal of Transplantation, publicerad online 21 mars 2018, http://asts.org/news-and-pub- lications/american-journal-of-transplantation

4. Abu Jawdeh et al., “Desensitization in kidney transplantation: review and future perspectives”, Clin Transplant. 2014 Apr;28(4):494-507

5. Riella et al., ”Long-term outcomes of kidney transplantation across a positive complement-dependent cytotoxicity crossmatch”, Transplantation. 2014 Jun 27;97(12):1247-52

6. Kluth et al., ”Anti-Glomerular Basement Membrane Disease”, J Am Soc Nephrol. 1999 Nov;10(11):2446-53

7. Hellmark et al., Journal of Autoimmunity 48-49 (2014) 108e112. ”Diagnosis and classification of Goodpasture’s disease (anti-GBM)”

8. Puttarajappa et al., ”Antibody-Mediated Rejection in Kidney Transplantation: A Review”, J. Transplant.Volume 2012 (2012), Article ID 193724

9. McGrogan et al., ”The Epidemiology of Guillain-Barré Syndrome Worldwide“, Neuroepidemiology;2009, 32(2):150-63

10. Järnum et al., ”Enzymatic inactivation of endogenous IgG by IdeS enhances therapeutic antibody efficacy”, Molecular Cancer Therapeutics, 2017, May 22

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

12. 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.

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

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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