Hansa Medical

Interim report April – June 2017

Continued enrolment in three Phase II studies with lead candidate IdeS and strengthened regulatory support from EMA through PRIME

April–June 2017 in brief

- Continued patient enrolment in two ongoing Phase II studies with lead candidate IdeS in highly sensitized patients in the US and Europe. The objective is to have all 40 patients recruited and treated in the two separate studies by the end of 2017. All treated patients will be monitored for six months post treatment.
- First patient treated in Phase II study with IdeS for acute renal failure in anti-GBM antibody disease. Approximately 15 patients will be recruited in this investigator initiated study at up to 15 clinics in Europe. The primary objective of this study is to evaluate the safety and tolerability of IdeS, as well as efficacy assessed by evaluating renal function at six months after IdeS treatment.
- Published preclinical results confirm IdeS' potential in cancer immunotherapy. The published findings demonstrate how pre-treatment with IdeS in tumour animal models can increase the efficacy of currently available antibody based cancer therapies.
- The European Medicines Agency (EMA) grants access to its Priority Medicines (PRIME) scheme for IdeS in enabling kidney transplantation for highly sensitized patients. Access to PRIME allows for accelerated development of IdeS, a potentially transformative treatment option for patients in need of lifesaving kidney transplantations.
- Lead candidate IdeS discussed in a two-day workshop titled *Antibody Mediated Rejection in Kidney Transplantation*, organized by the U.S. Food and Drug Administration (FDA). Transcripts from the workshop have been released and are available on the FDA website. Presenters and audience engaged in extensive discussions around the potential of IdeS in kidney transplantation.

"Encouraged both by the positive development of IdeS and the reception we have so far received from the medical community, I feel that Hansa Medical is in a strong position to continue the journey to become a biopharmaceutical company with important lifesaving products."

Göran Arvidson
President and CEO of Hansa Medical

Financial summary for the Group (KSEK)

	Q2		H1		Year
KSEK, unless otherwise stated	2017	2016	2017	2016	2016
Net revenue	693	542	1,751	1,129	2,579
Operating profit/loss	-44,901	-30,674	-89,728	-50,619	-111,135
Net profit/loss	-45,151	-30,672	-90,145	-50,647	-111,129
Earnings per share before and after dilution (SEK)	-1.29	-0.94	-2.57	-1.56	-3.39
Shareholders' equity	198,600	160,201	198,600	160,201	283,693
Cash flow from operating activities	-38,797	-22,043	-82,536	-39,603	-94,563
Cash and cash equivalents including short term investments	169,953	133,686	169,953	133,686	253,578

CEO statement

The first six months of 2017 were characterized by the continued development of our program around novel and innovative immunomodulatory enzymes. As we reached several important milestones during this period, we remained focused on our strategy around our lead candidate IdeS and continue to advance our clinical development.

As our program continued to develop according to plan, we noticed an increasing interest by the medical and scientific communities. As a result, principal investigators have been able to present data from our recent studies with IdeS at several renowned scientific and medical meetings.

On April 30, top-line clinical results from the ongoing investigator initiated US study with IdeS were presented at the American Transplant Congress (ATC) in Chicago. These encouraging results demonstrate that treatment with IdeS eliminates donor specific antibodies (DSAs) and enables transplantation of HLA incompatible patients. They also support our belief that IdeS has the potential to become the first approved therapy to enable highly sensitized kidney disease patients to be transplanted.

IdeS was also in focus at a two-day workshop titled *Antibody Mediated Rejection in Kidney Transplantation* arranged by the US Food and Drug Administration (FDA). In the workshop, novel opportunities for the treatment and prevention of Antibody Mediated Rejection (ABMR) were discussed.

The discussions covered the potential risk-benefit profile of IdeS as a desensitization treatment and the treatment of severe ABMR in kidney transplantation. Presenters and audience engaged in extensive discussions around the potential of IdeS in kidney transplantation.

This adds to our firm belief that IdeS has a significant potential to become a novel treatment option to enable patients to receive the lifesaving transplantation they desperately need. We continue to make progress and are committed to spread more knowledge about the profile of IdeS.

In May, the European Medicines Agency (EMA) granted access to its Priority Medicines (PRIME) scheme for IdeS. PRIME is intended to enhance support for the development of medicines that target an unmet medical need.

The designation was based on data from four independent Phase II studies in the US and Europe, including data from 30 HLA sensitized patients who received IdeS immediately before transplantation. The access to PRIME allows us to continue to accelerate the development of IdeS.

In parallel with our pioneering work in organ transplantation, we are also pursuing the therapeutic potential of IdeS in several other indications. We believe that the fast onset and efficacy of IdeS has the potential to bring significant contribution to the critical care in several transplant-related indications and acute autoimmune diseases, including Anti-GBM antibody disease, also known as Goodpasture disease.

In June, we announced that the first patient had been treated with IdeS in an investigator-initiated Phase II study in severe anti-GBM antibody disease. In total, approximately 15 patients will be recruited to the study at up to 15 clinics across Europe.

We also see opportunities with IdeS as a potential treatment in cancer immunotherapy. Pre-clinical data, published in the peer-reviewed journal *Molecular Cancer Therapeutics (Järnum et al., Mol Cancer Ther May 22 2017 DOI: 10.1158/1535-7163.MCT-17-0108)*, confirm this potential of IdeS and demonstrate how pre-treatment with IdeS in tumor animal models can increase the efficacy of currently available antibody-based cancer therapies.

In preparation of the next phase of the company's growth, we are continuously building a strong, committed team. We are further establishing our footprint in the US via recruitment of two senior medical affairs professionals.

In short, encouraged both by the positive development of IdeS and the reception we have so far received from the medical community, I feel that Hansa Medical is in a strong position to continue the journey to become a biopharmaceutical company with important lifesaving products. I look forward to providing further updates about our exciting development.

Göran Arvidson
President and CEO of Hansa Medical

Hansa Medical in brief

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

Business overview

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

NiceR: In parallel with the development of IdeS, Hansa Medical is also developing novel IgG inactivating drug candidates for repeat dosing under the project name NiceR, which may translate to wider usage in relapsing autoimmune diseases and oncology.

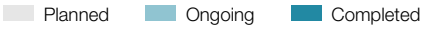
EndoS is an IgG-modulating enzyme that has proven efficacious in a range of autoimmune models. Preclinical research and development aiming at enabling clinical trials with EndoS in autoimmune diseases is ongoing.

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 Medical.

Pipeline

Candidate/ Method/Project	Indication	Research/ Preclinical	Phase I[1]	Phase I/II	Phase II	Pivotal	Registration
THERAPEUTICS							
IdeS	Kidney transplantation in sensitized patients[2]						
	Other kidney transplant indications (ABMR, ABOi)[3]						
	Anti-GBM antibody disease						
	Other acute autoimmune diseases[4]						
NiceR	Recurring treatment in autoimmune disease						
EndoS	Autoimmune disease						
EnzE	Cancer immunotherapy						
DIAGNOSTICS							
HBP-assay (IVD)	Prediction of severe sepsis[5]						



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 sensitized patients are currently ongoing.
3) Phase II studies in antibody mediated rejection (ABMR) post kidney transplantation and blood-group incompatible (ABOi) kidney transplantation are being planned.
4) Phase II studies in rare autoimmune conditions like GBS are being planned.
5) Out-licensed to Axis-Shield Diagnostics Ltd.

Lead candidate IdeS

IdeS – A novel therapeutic principle

Our lead candidate drug, IdeS, represents a unique and novel approach to rapidly and effectively eliminate pathogenic IgG-antibodies. IdeS, Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, 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 IdeS 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 IdeS

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

IdeS has been evaluated in a Phase I study [1] in healthy subjects and in two completed Phase II studies in sensitized patients awaiting kidney transplantation. The results from these studies demonstrate that IdeS is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation with a favorable safety profile.

The efficacy and safety of IdeS is currently being investigated in two ongoing Phase II studies in sensitized kidney transplantation patients. Additional Phase II studies within kidney transplantation are being planned in Acute Antibody Mediated Rejection (ABMR) post-kidney transplantation and desensitization prior to blood group incompatible (ABOi) kidney transplantation.

An investigator initiated Phase II study with IdeS in the rare and acute autoimmune kidney disease anti-GBM antibody disease has been initiated in collaboration with several European nephrology clinics. In addition, a Phase II study with IdeS in the rare and acute autoimmune disease Guillain-Barré syndrome (GBS) is being planned.

Ongoing clinical studies with IdeS

IdeS – Desensitization prior to kidney transplantation

Latest developments

In December 2016, a Swedish Phase II study evaluating the safety, tolerability, efficacy and pharmacokinetics of intravenous ascending doses of IdeS in kidney transplantation was successfully completed, and the primary and secondary objectives were met. In the study, ten sensitized kidney patients were given IdeS, which enabled all of them to subsequently have a kidney transplantation.

In March 2017, top-line results based on 15 patients in an ongoing US clinical study with IdeS were reported demonstrating that treatment with IdeS completely eliminates donor-specific IgG antibodies (DSAs) and enabled transplantation for all the treated patients. The clinical results were subsequently presented at the American Transplant Congress in Chicago, Illinois, on April 30, 2017. Principal investigator Professor Stanley Jordan is aiming at recruiting 20 patients in total to this ongoing study. All patients are then followed for six months post IdeS treatment.

The ongoing Hansa Medical-sponsored multicenter study named Highdes, initiated in October 2016, is enrolling patients according to plan. The primary objective of the study is to assess the efficacy of IdeS in creating a negative crossmatch test in highly sensitized patients with antibodies to the donor. Removing donor-specific antibodies will enable transplantation in patients who would otherwise not qualify for transplantation. The study will also evaluate safety, kidney function and immunogenicity during the six-month follow-up period. The aim is to complete enrolment of approximately 20 patients during 2017.

In May, the European Medicines Agency (EMA) granted Hansa Medical access to its Priority Medicines (PRIME) scheme for IdeS in enabling kidney transplantation for highly sensitized patients. The scheme enables early proactive, continuous and strengthened regulatory dialogue between the applicant and the EU regulatory network, ensuring generation of a data package designed to address MAA requirements. Access to the PRIME scheme for IdeS was granted on the basis of data from four independent Phase II studies in the U.S. and Sweden (ClinicalTrials.gov Identifiers NCT02224820, NCT02426684, NCT02475551 and NCT02790437), the request included data from 30 HLA sensitized patients.

IdeS in transplantation was discussed in a recent two-day workshop titled "*Antibody Mediated Rejection in Kidney Transplantation*", arranged by the U.S. Food and Drug Administration (FDA). In the workshop, novel opportunities for the treatment and prevention of Antibody Mediated Rejection (ABMR or AMR) were discussed. Initial data from studies using IdeS were presented by Professor Robert Montgomery, MD, Director of NYU Transplant Institute in New York, and Professor Steve Woodle, MD, Director of the Division of Transplantation at the University of Cincinnati, Ohio. The discussions covered the potential risk-benefit profile of IdeS as a desensitization treatment and the treatment of severe AMR in kidney transplantation.

The presentations by Professor Montgomery and Professor Woodle, as well as the transcripts from the workshop are available on the FDA website:
https://www.fda.gov/Drugs/NewsEvents/ucm532070.htm
In the transcripts, IdeS is discussed on pages 285-289, 300-306 and 311 from Day one of the workshop and on pages 66-68 and 98-100 from Day two of the workshop.

IdeS – 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-GMB antibody disease is a rare disease affecting one in a million annually [2].

Latest developments
The first patient has been treated with IdeS in an investigator initiated Phase II study in severe anti-GBM antibody disease. The study (ClinicalTrials.gov identifier NCT03157037) is an open label investigator initiated Phase II study in severe anti-GBM disease with Professor Mårten Segelmark at Linköping University Hospital, Sweden, as Sponsor/Coordinating principal investigator. Approximately 15 patients will be recruited to the study at up to 15 clinics in Europe. The primary objective of this study is to evaluate the safety and tolerability of IdeS in patients with severe anti-GBM disease in addition to standard care consisting of pulse-methylprednisolone, oral prednisolone and intravenous cyclophosphamide (CYC) combined with plasma exchange (PLEX). IdeS efficacy will be assessed by evaluating renal function at 6 months after IdeS treatment.

Overview of completed and ongoing clinical trials with lead candidate IdeS

Study	Study site	Subjects	Status
Phase I	Lund University Hospital, Sweden	29 healthy subjects, randomized placebo controlled dose-escalation study.	● Completed 2014. Conclusion: IdeS is efficacious and well tolerated with a favorable safety profile.
Phase II in kidney transplantation	Uppsala University Hospital, Sweden	8 sensitized patients, dose finding study.	● Completed 2015. Conclusion: All IdeS treated patients possible to transplant. Manageable safety profile with favorable risk benefit profile.
Phase II in kidney transplantation	Uppsala University Hospital, Sweden Karolinska University Hospital, Sweden	10 sensitized patients, with transplantation.	● Completed 2016. Conclusion: Primary and secondary objectives achieved.
Phase II in kidney transplantation (Investigator initiated)	Cedars Sinai Medical Center, Los Angeles, USA	20 sensitized patients, with transplantation.	● Ongoing. Top line results demonstrate that IdeS completely eliminates donor specific IgG antibodies (DSAs) and enabled transplantation for all the treated patients.
Highdes – Phase II in kidney transplantation	Cedars Sinai Medical Center, Los Angeles, USA NYU Langone Medical Center, New York, USA Johns Hopkins Medicine, Baltimore, USA Uppsala University Hospital, Sweden Necker Hospital, Paris, France	20 refractory HLA sensitized patients, with transplantation.	● Ongoing. Aim to complete recruitment 2017.
Phase II in anti-GBM (Investigator initiated)	Europe. Several sites.	15 patients with anti-GBM antibody disease.	● First patient treated in June 2017.

Table A. IdeS has been evaluated in a Phase I study in healthy subjects and in two Phase II studies in sensitized patients awaiting kidney transplantation. The results in these studies indicate that IdeS is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation with a favorable safety profile. Currently, two additional Phase II studies are ongoing with IdeS in sensitized patients prior to kidney transplantation – an investigator-initiated US Phase II study at Cedars-Sinai Medical Center in Los Angeles, and a Hansa Medical-sponsored multi-center study in the US, Sweden and France.

Regulatory strategy for IdeS in desensitization
The Highdes study will recruit patients who have either failed on previous attempts of desensitization or are likely to fail desensitization with currently available methods. Hansa Medical aims to obtain market authorization in the US and Europe for IdeS for this category of patients as soon as possible. The company anticipates that the Highdes study, together with the completed and ongoing studies, will provide compelling data to support a Biologics License Application (BLA) in the US and a Marketing Authorization Application (MAA) in the EU.

Planned clinical studies with IdeS in additional indications

Treatment of kidney transplant antibody-mediated rejection (ABMR)
Approximately 10 percent [3] of all transplant patients experience ABMR post-transplant. Although different experimental protocols are used in the treatment of ABMR, there is currently no approved treatment. In the more severe cases of ABMR, these experimental protocols are generally not sufficient to rescue the kidney since the magnitude of the antibody response exceeds the capacity of the treatment, e.g. plasmapheresis, to clear the antibodies.

Blood-group incompatible (ABOi) kidney transplantation
ABOi transplantations have increased worldwide in order to shorten the long waiting times for transplantation [4]. If not adequately removed, the presence of preformed antibodies to donor blood group antigens is likely to result in severe ABMR and early graft loss.

Acute 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 annually [5]. In February 2017, preclinical data demonstrating the treatment potential of IdeS in GBS were published [6]. In a model of GBS, inactivation of IgG by IdeS treatment significantly promoted the recovery and reduced the degeneration of peripheral nerves. The data shows that treatment with IdeS could be a novel therapeutic strategy for the treatment of GBS.

Preclinical development projects

NiceR – Novel immunoglobulin cleaving enzymes for repeat dosing
Hansa Medical develops completely novel IgG-degrading enzymes. The aim of project NiceR is to create novel IgG-inactivating biopharmaceuticals which can be used for repeated dosing in acute autoimmune conditions where patients would benefit from more than one dose of an IgG-modulating enzyme. Several novel IgG-eliminating enzymes have been designed and the development program is currently in preclinical optimization phase with the ambition to select a lead candidate for clinical development.

EndoS – Treatment of autoimmune diseases
EndoS, Endoglycosidase of *Streptococcus pyogenes*, is an enzyme that specifically hydrolyzes the functionally important glycan in IgG. EndoS has proven to be active in a range of preclinical autoimmune models, including rheumatoid arthritis (RA), immune thrombocytopenic purpura (ITP), autoimmune hemolysis, multiple sclerosis (MS) and autoimmune blistering skin disorder. Given the importance, we believe that EndoS may have the potential to become a novel therapy for autoimmune diseases.

EnzE – Enzyme-based antibody Enhancement
Recently published findings [7] demonstrate how pre-treatment with IdeS in tumour 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 IdeS 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 tumour cells. Removing inhibiting IgG antibodies with IdeS prior to dosing the patient with a therapeutic antibody could potentially increase the efficacy of the given cancer therapy.

IdeS is an enzyme that depletes IgG antibodies fast and effectively. The article entitled "*Enzymatic inactivation of endogenous IgG by IdeS enhances therapeutic antibody efficacy*" show that IdeS is a potent tool to reboot the human antibody repertoire and to generate a window to preferentially load therapeutic antibodies onto effector cells. Pre-treatment with IdeS could be a potential new treatment to unblock the receptors of immune cells thereby enabling the full potential of the therapeutic antibodies.

Hansa Medical is currently evaluating strategic options for EnzE.

Out-licensed royalty generating programs

HBP – Prediction of severe sepsis
HBP-assay (measurement of Heparin Binding Protein) is a novel diagnostic method originally developed and patented by Hansa Medical to help predict severe sepsis in patients with infectious disease symptoms at emergency departments [8]. 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 [9].

HBP-assay has been fully out-licensed by Hansa Medical to UK-based Axis-Shield Diagnostics, a subsidiary to Alere Inc. (NYSE:ALR) and Hansa Medical holds the right to royalty payments from Axis-Shield. Axis-Shield is engaged in further product development and clinical development with HBP-assay. For more information, please visit: www.heparinbindingprotein.com

Financial review January–June 2017

Net revenue

Net revenue for the second quarter 2017 amounted to SEK 0.7m (0.5) and to SEK 1.8m (1.1) year to date 2017 and is comprised of royalty income from Axis-Shield Diagnostics and re-invoiced expenses.

Sales, general and administration expenses

Sales, general and administration expenses for the second quarter 2017 amounted to SEK 10.7m (8.3) and to SEK 20.5m (13.3) year to date 2017. The increase year to date is explained by commercial build-up and recorded non-cash costs for the company's employee long term incentive program (LTIP 2016) amounting to SEK 1.8m.

Research and development expenses

Research and developments expenses amounted to SEK 33.8m (23.0) for the second quarter 2017 and to SEK 70.1m (38.4) year to date 2017 and include recorded non-cash costs for the company's long term incentive programs (LTIP 2016) amounting to SEK 2.3m. The increase year to date was mainly due to intensified CMC development and continued build-up of the clinical and regulatory organization.

Financial result

Operating result for the second quarter 2017 amounted to SEK -44.9m (-30.7) and SEK -89.7m (-50.6) year to date 2017.

Profit/loss for the second quarter 2017 amounted to SEK-45.2m (-30.7) and to SEK -90.1m (-50.6) year to date 2017.

Cash flow and investments

Cash flow from operating activities amounted to SEK-38.8m (-22.0) for the second quarter 2017 and to SEK -82.5m (-39.6) year to date 2017. Cash and cash equivalents including short term investments amounted to SEK 170.0m on June 30 2017, as compared with SEK 209.4m at the end of first quarter 2017.

Investments for the second quarter 2017 amounted to SEK 0.5m (2.8) and to SEK 1.0m (2.8) year to date 2017.

Shareholders' equity

On June 30, 2017 equity amounted to SEK 198.6m compared with SEK 160.2m at the end of the corresponding period 2016.

Parent company

The parent company's net revenue for the second quarter 2017 amounted to SEK 0.7m (0.5) and to SEK 1.8m (1.1) year to date 2017. Profit/loss for the parent company amounted to SEK -45.1m (-31.3) for the second quarter and to SEK -90.0m (-52.0) year to date 2017. On June 30, 2017, cash and cash equivalents including short term investments amounted to SEK 167.7m compared with SEK 207.1m at the end of first quarter 2017.

The parent company's equity amounted to SEK 194.0m as per June 30, 2017, as compared with SEK 160.2m at the end of the corresponding period 2016.

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

Financial summary for the Group (KSEK)

	Q2		H1		Year
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Net profit/loss	-45,151	-30,672	-90,145	-50,647	-111,129
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Shareholders' equity	198,600	160,201	198,600	160,201	283,693
Cash flow from operating activities	-38,797	-22,043	-82,536	-39,603	-94,563
Cash and cash equivalents including short term investments	169,953	133,686	169,953	133,686	253,578

Other information

Employees and organization

The number of employees at the end of the second quarter 2017 was 34, compared to 21 at the end of corresponding period 2016.

Share warrant program

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

Long-term incentive program (LTIP 2016)

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

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

LTIP 2016 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost of LTIP 2016, calculated in accordance with IFRS 2, including social security contributions is expected to amount to approximately SEK 28.6m, of which SEK 4.1m is included in the results for the parent company and the group for the first half year 2017. The program is not expected to have any net effect on cash flow provided it is secured fully in the manner described above.

Financial calendar

Interim report for January-September 2017	November 14, 2017

Shareholder information

The Hansa Medical share is listed on Nasdaq OMX Stockholm, under the ticker HMED and included in the following indexes:

- OMX Nordic Mid Cap
- OMX Nordic Health Care index
- OMX Stockholm Benchmark Index
- OMX Stockholm Health Care
- OMX Stockholm Pharmaceuticals & Biotechnology
- MSCI Global Small Cap
- NASDAQ Biotechnology Index

Brief facts, the HMED share

Listing	Nasdaq OMX Stockholm
Number of shares	35,455,860
	(35 054 860 A-shares and 401 000 C-shares)
Market capitalization June 30, 2017	SEK 7,554 m
Ticker	HMED
ISIN	SE0002148817

10 largest shareholders, June 30, 2017

Name	Number of shares	Share (%)
Nexttobe AB	9,443,761	26.9
Gladiator	1,800,200	5.1
Afa Försäkring	1,520,700	4.3
Försäkringsaktiebolaget, Avanza Pension	1,257,519	3.6
Olausson, Thomas	1,000,412	2.9
Handelsbanken Fonder	901,835	2.6
Farstorps Gård AB	826,223	2.4
Tredje AP-Fonden	708,488	2.0
BWG Invest	600,370	1.7
Catella Fondförvaltning	552,351	1.6
Other	16,443,001	46.9
In total	**35,054,860**	**100.0**

According to the shareholder register maintained by Euroclear Sweden AB, as of June 30, 2017, Hansa Medical had 9,873 shareholders. On June 30, 2016, Hansa Medical had 2,699 shareholders. Information regarding shareholders and shareholdings is updated each quarter on the company's website, www.hansamedical.com.

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	2017	2016	2017	2016	2016
Net revenue	693	542	1,751	1,129	2,579
Direct cost of net revenue	-53	-54	-114	-108	-217
Gross profit	**640**	**468**	**1,637**	**1,021**	**2,362**
Other operating income	–	139	–	37	–
Sales, general and administration expense	-10,675	-8,327	-20,486	-13,300	-29,703
Research and development expenses	-33,847	-22,974	-70,073	-38,377	-82,850
Other operating expenses	-1,019	–	-806	–	-944
Operating profit/loss	**-44,901**	**-30,674**	**-89,728**	**-50,619**	**-111,135**
Financial income/expenses	-259	2	-436	-28	-17
Profit/loss for the period before tax	**-45,160**	**-30,672**	**-90,164**	**-50,647**	**-111,152**
Tax	9	–	19	–	23
Net profit/loss for the period	**-45,151**	**-30,672**	**-90,145**	**-50,647**	**-111,129**
Attributable to					
Parent company shareholders	-45,151	-30,672	-90,145	-50,647	-111,129
Earnings per share					
Before dilution (SEK)	-1.29	-0,94	-2,57	-1,56	-3,39
After dilution (SEK)	-1.29	-0,94	-2,57	-1,56	-3,39
Other comprehensive income					
Items that have been, or may be reclassified to profit or loss for the year					
Translation differences	-25	–	-35	–	-26
Changes in fair value on available-for-sale financial assets	2,552	-587	2,850	-1,315	4,690
Other comprehensive income for the year	**2,527**	**-587**	**2,815**	**-1,315**	**4,664**
Total net comprehensive income	**-42,624**	**-31,259**	**-87,330**	**-51,962**	**-106,465**

Consolidated balance sheet

	June 30		December 31
KSEK	2017	2016	2016
ASSETS			
Non-current assets			
Intangible fixed assets	35,006	34,919	36,554
Tangible fixed assets	3,208	2,151	2,570
Financial fixed assets	17,442	8,556	14,566
Total non-current assets	**55,636**	**45,626**	**53,690**
Current assets			
Current receivables, non-interest bearing	3,232	1,908	3,404
Short-term investments	104,932	99,955	39,990
Cash and cash equivalents	65,021	33,731	213,588
Total current assets	**173,185**	**135,594**	**256,982**
TOTAL ASSETS	**228,821**	**181,220**	**310,672**
EQUITY AND LIABILITIES			
Shareholders' equity	**198,600**	**160,201**	**283,693**
Long term liabilities			
Deferred tax liabilities	554	–	581
Other provisions	2,026	–	114
Long term liabilities, interest bearing	567	27	552
Total long term liabilities	**3,147**	**27**	**1,247**
Current liabilities			
Current liabilities, interest bearing	27	43	44
Current liabilities, non-interest bearing	6,678	3,175	8,390
Accrued expenses and deferred income	20,369	17,774	17,298
Total current liabilities	**27,074**	**20,992**	**25,732**
TOTAL EQUITY AND LIABILITIES	**228,821**	**181,220**	**310,672**

Consolidated changes in equity

	Jan-Jun		Year
KSEK	2017	2016	2016
Opening shareholders' equity	**283,693**	**211,526**	**211,526**
Result for the period	-90,145	-50,647	-111,129
Other comprehensive income for the period	2,815	-1,315	4,664
Net comprehensive income	**-87,330**	**-51,962**	**-106,465**
Transactions with the group's owner			
New share issue [1]	401	–	185,000
Expenses attributable to new share issue	-110	–	-7,504
Repurchase own shares [1]	-401	–	–
Issued warrants	131	637	772
Long term incentive program	2,216	–	364
Total transactions with the group's owner	**2,237**	**637**	**178,632**
Closing shareholders' equity	**198,600**	**160,201**	**283,693**

1) Values for 2017 refer to directed share issue and repurchase of 401,000 class C shares for financing of the company's long term incentive program (LTIP 2016).

Consolidated cash flow statement

	Q2		H1		Year
KSEK	2017	2016	2017	2016	2016
Operating activities					
Operating profit/loss	-44,901	-30,674	-89,728	-50,619	-111,135
Adjustment for items not included in cash flow [1]	3,797	921	6,103	1,862	4,269
Interest received and paid, net	-264	2	-442	-28	-78
Income taxes received and paid, net	51	-489	-69	-409	–
Cash flow from operations before change in working capital	**-41,317**	**-30,240**	**-84,136**	**-49,194**	**-106,944**
Change in working capital	2,520	8,197	1,600	9,591	12,381
Cash flow from operating activities	**-38,797**	**-22,043**	**-82,536**	**-39,603**	**-94,563**
Investing activities					
Acquisition of business, net cash effect	–	–	–	–	-1,924
Investments in intangible fixed assets	–	–	–	–	-57
Investments in tangible fixed assets	-467	-198	-979	-216	-927
Investment of financial assets	-89,939	-2,588	–	-2,588	-2,588
Short term investments	–	–	-170,920	-99,949	-194,918
Divestment short term investments	76,000	–	106,000	–	155,000
Cash flow from investing activities	**-14,406**	**-2,786**	**-65,899**	**-102,753**	**-45,414**
Financing activities					
New share issue [2]	401	–	401	–	185,000
Issue expenses	-110	–	-110	–	-7,504
Repurchase own shares [2]	-401	–	-401	–	–
Issued warrants	–	426	–	426	429
Repayment of leasing liabilities	-22	-11	-22	-22	-43
Cash flow from financing activities	**-132**	**415**	**-132**	**404**	**177,882**
Net change in cash	**-53,335**	**-24,414**	**-148,567**	**-141,952**	**37,905**
Cash and cash equivalents, beginning of year	118,356	58,145	213,588	175,683	175,683
Cash and cash equivalents, end of period	**65,021**	**33,731**	**65,021**	**33,731**	**213,588**

1) Values for 2017 pertain mainly to costs of share based incentiveprograms including social contributions

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

Consolidated key ratios and other information

	Q2		H1		Year
KSEK, unless otherwise stated	2017	2016	2017	2016	2016
Profit numbers					
Net revenue	693	542	1,751	1,129	2,579
Operating profit/loss	-44,901	-30,674	-89,728	-50,619	-111,135
Net profit/loss	-45,151	-30,672	-90,145	-50,647	-111,129
Per share data					
Earnings/loss per share before and after dilution (SEK)	-1.29	-0.94	-2.57	-1.56	-3.39
Shareholders' equity per share (SEK)	5,67	4,93	5,67	4,93	8,09
Other information					
Equity ratio (%)	87	88	87	88	91
Cash and cash equivalents including short term investments	169,953	133,686	169,953	133,686	253,578
Number of outstanding shares at the end of the period	35,054,860	32,485,477	35,054,860	32,485,477	35,054,860
Weighted average number of shares before and after dilution	35,054,860	32,485,477	35,054,860	32,485,477	32,773,304

Parent company – Statement of comprehensive income

	Q2		H1		Year
KSEK	2017	2016	2017	2016	2016
Net revenue	693	542	1,751	1,129	2,579
Direct cost of net revenue	-53	-54	-114	-108	-217
Gross profit	**640**	**488**	**1,637**	**1,021**	**2,362**
Other operating income	–	139	–	37	–
Sales, general and administration expenses	-10,716	-8,322	-20,490	-13,292	-29,690
Research and development expenses	-33,770	-22,974	-69,951	-38,377	-82,735
Other operating expenses	-1,019	–	-806	–	-944
Operating profit/loss	**-44,865**	**-30,669**	**-89,610**	**-50,611**	**-111,007**
Result from other securities and receivables which are fixed assets	–	-587	–	-1,315	2,628
Result from short term financial receivables	27	35	27	21	–
Other financial expenses	-286	-31	-462	-46	-14
Profit/loss for the period (before and after taxes)	**-45,124**	**-31,252**	**-90,045**	**-51,951**	**-108,393**
Other comprehensive income for the period	**–**	**–**	**–**	**–**	**–**
Total net comprehensive income	**-45,124**	**-31,252**	**-90,045**	**-51,951**	**-108,393**

Parent company – Balance sheet

	June 30		December 31
KSEK	2017	2016	2016
ASSETS			
Non-current assets			
Intangible fixed assets	32,110	34,919	33,513
Tangible fixed assets	3,208	2,107	2,554
Financial fixed assets	17,317	10,917	17,317
Total non-current assets	**52,635**	**47,943**	**53,384**
Current assets			
Current receivables, non-interest bearing	3,364	1,908	3,504
Short-term investments	104,943	99,955	39,995
Cash and cash equivalents	62,764	31,472	211,329
Total current assets	**171,071**	**133,335**	**254,828**
TOTAL ASSETS	**223,706**	**181,278**	**308,212**
EQUITY AND LIABILITIES			
Shareholders' equity	**193,978**	**160,232**	**281,786**
Long term liabilities			
Other provisions	2,026	–	114
Long term liabilities, non-interest bearing	567	–	548
Total long term liabilities	**2,593**	–	**662**
Current liabilities			
Liabilities to group companies	98	98	98
Current liabilities, non-interest bearing	6,668	3,174	8,368
Accrued expenses and deferred income	20,369	17,774	17,298
Total current liabilities	**27,135**	**21,046**	**25,764**
TOTAL EQUITY AND LIABILITIES	**223,706**	**181,278**	**308,212**

Parent company – Changes in equity

	Jan-Jun		Year
KSEK	2017	2016	2016
Opening shareholders' equity	**281,786**	**211,547**	**211,547**
Result for the period	-90,045	-51,951	-108,393
New share issue [1]	401	–	185,000
Expenses attributable to new share issue	-110	–	-7,504
Repurchase own shares [1]	-401	–	–
Issued warrants	131	636	772
Long term incentive program	2,216	–	364
Total transactions with the group's owner	**2,237**	**636**	**178,632**
Closing shareholders' equity	**193,978**	**160,232**	**281,786**

1) Values for 2017 refer to directed share issue and repurchase of 401,000 class C shares for financing of the company's long term incentive program (LTIP 2016).

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 2016. The Annual report 2016 was published on April 26, 2017 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.

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. The financial instruments reported at fair value in the balance sheet are comprised partly of the Group's holding of shares in Genovis, which are listed on Nasdaq First North and partly of holdings of short-term commercial papers. The fair value of the shares as per the balance sheet date June 30, 2017 was SEK 17,422k, SEK 8,556k on June 30, 2016 and SEK 14,566k on December 31, 2016. The fair value of the commercial papers as per the balance sheet date June 30, 2017 was SEK 104,932k, SEK 99,955k on June 30, 2016 and SEK 39.990k on December 31, 2016. The fair value of the financial instruments are calculated on the basis of the closing price. The valuation of the holdings is, thereby, in accordance with Level 1 in the valuation hierarchy.

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

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

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

Glossary

ABMR
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.

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.

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.

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

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

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

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

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.

Guillain–Barré syndrome
GBS, Guillain–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.

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

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

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 percent and 99 percent. 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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