Hansa Medical

Interim report January–June 2015

Excellent development in clinical program

January – June 2015 in summary

Operations Summary

Q1

- Phase II clinical study of IdeS in highly sensitized patients awaiting kidney transplantation successfully completed
- Cooperation initiated with leading US transplantation expert Dr Stanley Jordan at Cedars-Sinai Medical Center, Los Angeles
- Development of a new generation of IdeS molecules for repeat dosing initiated
- Preliminary application for listing on Nasdaq Stockholm submitted

Q2

- IdeS Phase II study initiated at Uppsala University Hospital and Karolinska University Hospital. The first patient treated with IdeS was subsequently transplanted from a deceased donor
- Investigator sponsored Phase II study with IdeS initiated at Cedars-Sinai Medical Center, US
- Hansa Medical established a US medical advisory board
- Göran Arvidson new President and CEO of Hansa Medical
- Hansa Medical secured MSEK 246 in funding through a fully subscribed rights issue

Financial Summary Q2 and Year to Date

- Net sales for the group in Q2 amounted to MSEK 0.5 (0.3). YTD: MSEK 4.4 (1.5)
- Operating result in Q2 was MSEK -22.5 (-4.8). YTD: MSEK -33.2 (-10.7)
- Consolidated net result in Q2 was MSEK -22.5 (-4.8). YTD: MSEK -33.2 (-10.8)
- Earnings per share before and after dilution in Q2 was SEK -0.70 (-0.18). YTD: SEK -1.11 (-0.42)
- Cash position on June 30, 2015, of MSEK 209.1

Significant events after the reporting period

- IdeS Phase I data published in the scientific journal PLOS ONE
- First patient treated with IdeS and subsequently transplanted in an investigator sponsored US Phase II study at Cedars-Sinai Medical Center, Los Angeles

"The development of Hansa Medical in the first half of this year shows that we are in an excellent position to build a biopharmaceutical company of lasting value with important, life-saving products"

Göran Arvidson, President and CEO of Hansa Medical

Financial summary for the Group (KSEK)

	Q2		H1		Year
KSEK, unless otherwise stated	2015	2014	2015	2014	2014
Net sales	529	349	4,376	1,461	1,618
Operating profit/loss	-22,496	-4,834	-33,185	-10,730	-24,709
Net profit/loss	-22,505	-4,848	-33,230	-10,846	-29,042
Earnings per share before and after dilution (SEK)	-0.70	-0.18	-1.11	-0.42	-1.10
Shareholders' equity	244,072	68,612	244,072	68,612	49,804
Cash flow from operating activities	-17,523	-7,167	-25,385	-9,946	-23,623
Liquidity	209,110	25,216	209,110	25,216	10,152

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CEO Statement

In the second quarter of 2015, we continued to build on the good start of the year, when we took some important steps – both financially and in clinical development – to shape Hansa Medical's future. Ultimately, we want to create a strong biopharmaceutical company with life-saving pharmaceuticals on the market. I feel certain that we are on the right track.

Our lead project IdeS has attracted a lot of attention in the international scientific community. The results from the earlier clinical Phase I trial of IdeS were published in the scientific journal PLOS ONE in July. Among other things, the study results showed that a single dose of IdeS rapidly and efficiently inactivates IgG in humans, which could make it a very attractive therapeutic approach for acute IgG driven conditions.

In June, we announced that the first patient after treatment with IdeS in a clinical Phase II study was successfully transplanted from a deceased donor. The study will evaluate the safety, tolerability and efficacy of IdeS in kidney transplantation of sensitized patients. It is also aimed at identifying the appropriate dose that in the majority of patients will result in anti-HLA antibody levels acceptable for transplantation within 24 hours from dosing.

In parallel with the ongoing Phase II study in Sweden, other studies are being initiated, one of which is run by Professor Stanley Jordan, a leading expert in transplant immunology, at Cedars-Sinai Medical Center in Los Angeles. It is an open-label study to assess the safety and efficacy of IdeS in eliminating donor specific antibodies and thus prevent antibody-mediated rejection in sensitized patients.

This important collaboration with Dr Jordan is a further acknowledgement that IdeS is an exciting project, quoting Dr Jordan: "IdeS has the potential to revolutionize the whole area of transplantation, especially in sensitized patients." We are also planning for further studies in transplantation and other IgG mediated indications where there is a significant unmet medical need.

As you will see in this report, we have summarized and in more detail explained our projects and the various studies we have conducted and are conducting at the moment. We will continuously update this information on the website.

During the period, we also strengthened our scientific network. In May, we announced the formation of a US medical advisory board for IdeS in kidney transplantation. This board is connected with the previously initiated advisory board of leading transplantation experts in Europe. These advisory boards are valuable components in establishing IdeS as a potential pharmaceutical product of great importance.

Early in April, we announced that the MSEK 246 rights issue was fully subscribed, which means that we now have the means to finance the next exciting phase, the clinical development of IdeS and our other research projects. We believe that IdeS has other potential medical indications, including relatively rare and serious – even life-threatening – acute immune diseases.

We have also continued to strengthen the organisation in and around the company, in time for the planned change of market place to Nasdaq Stockholm's main market. At the annual general meeting on 2 June, Hans Schikan was elected new board member, adding more first-class biotech experience to the board. The management was also strengthened with Steven Glazer as CMO and Eva-Maria Joed as CFO.

On November 13, 2015, we will have the honor to summon interested shareholders and research partners to a combined investor and research day in Stockholm. During this event some of the prominent US and European clinical experts we collaborate with will give us a review from their daily practice and present their view on the potential of IdeS. We will get back shortly with more details about this event and how to attend.

The development of Hansa Medical in the first half of this year shows that we are in an excellent position to build a biopharmaceutical company of lasting value with important, life-saving products.

Göran Arvidson
President and CEO

Business Review Q2 2015

IdeS Phase II study initiated at Uppsala University Hospital and Karolinska University Hospital
A Phase II study with IdeS was initiated at Uppsala University Hospital and Karolinska University Hospital in Huddinge. The study will evaluate the safety, tolerability and efficacy of IdeS in kidney transplantation of sensitized patients. Up to 10 patients will be included in the study and the first patient in the study was transplanted from a deceased donor at Uppsala University Hospital. The study also aim at identifying the appropriate dose that in the majority of patients will result in anti-HLA antibody levels acceptable for transplantation within 24 hours from dosing. All patients will undergo kidney transplantation and it is expected that top-line results will be available around half-year 2016.

Hansa Medical initiated clinical collaboration with Cedars-Sinai Medical Center and Professor Stanley Jordan
Hansa Medical AB initiated a clinical collaboration with Professor Stanley Jordan at Cedars-Sinai Medical Center in Los Angeles, California in order to perform a Phase II study in kidney transplantation. The study is an open label study to assess the safety and efficacy of IdeS in eliminating donor specific antibodies and thus prevent antibody-mediated rejection in highly sensitized patients. Dr. Jordan, the principal investigator, has submitted an IND for IdeS in collaboration with Hansa Medical, and a Letter to Proceed has been received from the US Food and Drug Administration (FDA). Also, the institutional review board of Cedars-Sinai Medical Center has approved the study. The first patient in the study has been treated with IdeS and subsequently transplanted.

Hansa Medical established a US medical advisory board
Hansa Medical AB established a US medical advisory board for IdeS in kidney transplantation with world leading experts in desensitization and transplantation. The board will assist the company in developing IdeS within transplantation in sensitized patients. Hansa Medical AB has previously initiated a similar European advisory board with leading transplantation experts in Europe. The US medical advisory board consist of Dr Stanley Jordan (chairman), Dr Robert Montgomery and Professor Kathryn Wood.

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

Hansa Medical secured MSEK 246 in funding through a fully subscribed rights issue
Hansa Medical raised MSEK 246 before emission costs, through a fully subscribed rights issue with preferential rights. 53 percent of the shares were subscribed through preferential rights and 13 percent of the shares were subscribed for without preferential rights. Underwriters subscribed for the remaining part of the rights issue. The rights issue comprised of 6,482,400 shares at SEK 38 per share. The subscription period for the offer was between March 19 and April 2, 2015. The proceeds will enable Hansa Medical to bring the candidate drug IdeS into several clinical Phase II trials as well as preparing the IdeS production process for clinical pivotal studies and product launch.

Significant events after the reporting period

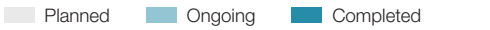
IdeS Phase I data published in the scientific journal PLOS ONE
The results from the Phase I trial with IdeS in healthy subjects were published in PLOS ONE (http://dx.plos.org/10.1371/journal.pone.0132011). The Phase I trial was a first-in-man, double blind, randomized study with single-ascending doses of IdeS in 29 healthy male subjects who were given intravenous doses of placebo or IdeS. IdeS was considered safe with no serious adverse events. Full or close to full effect on IgG was seen in all subjects in the two highest dose groups. Data demonstrated that the entire extracellular IgG pool and not only the plasma pool, is cleaved by IdeS. This remarkable efficacy of IdeS outcompetes the effect of plasma exchange, which typically leaves approximately 35 percent remaining IgG. The complete, rapid, but temporary removal of IgG provides a new potent therapeutic opportunity in IgG-mediated pathogenic conditions.

First patient treated and transplanted with IdeS in US Phase II study at Cedars-Sinai Medical Center, Los Angeles
The first patient in an investigator sponsored Phase II clinical study at Cedars-Sinai Medical Center in Los Angeles, California, was treated with IdeS and subsequently transplanted. The study is an open-label study to assess the safety and efficacy of IdeS in eliminating donor specific antibodies and thus prevent antibody-mediated rejection in highly sensitized patients. The study will include up to 20 highly sensitized patients on the UNOS (United Network for Organ Sharing) waiting list.

Project Overview [1]

Pipeline

Candidate/Method	Indication	Preclinical	Phase I	Phase II	Pivotal
IdeS	Sensitized kidney transplantation patients (EU) [2] / (US) [3]				
	Highly sensitized kidney transplantation patients (US)				
	Acute Antibody Medicated Kidney Transplant Rejection				
IdeS 2nd gen.	Recurring treatment in autoimmune disease				
EndoS	Acute Autoimmune Disease				
HBP-assay (IVD)	Prediction of severe sepsis [4]				



Hansa Medical is a biopharmaceutical company focused on novel immunomodulatory enzymes. The lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Other projects include EndoS, an antibody-modulating bacterial enzyme in pre-clinical development, and HBP, a market introduced diagnostic marker for severe sepsis.

IdeS

Background and pre-clinical development

Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes* (IdeS) is an enzyme that specifically cleaves immunoglobulin G (IgG). Our strategy takes advantage of the ability of IdeS to specifically and efficiently inactivate IgG, to prevent and treat patients that have developed pathogenic IgG. IdeS-mediated IgG degradation constitutes a novel therapeutic principle for the treatment of IgG-driven human diseases.

IdeS has been pre-clinically tested regarding efficacy and safety. The therapeutic effect of IdeS has been studied in various animal disease models; e.g. collagen antibody induced arthritis (CAIA), idiopathic thrombocytopenic purpura (ITP) and Goodpasture's disease (GP). IdeS was found to efficiently neutralize IgG in all three models. Experiments on serum collected from highly sensitized kidney patients clearly demonstrated that IdeS rapidly reduced the level of anti-HLA antibodies and that IdeS could turn a positive cross-match into a negative.

This was a strong support for us to further investigate IdeS for desensitization of patients before transplantation.

Our initial clinical studies are focused on desensitization of HLA-immunized patients before kidney transplantation and treatment of antibody mediated graft rejection. Beyond transplantation, we have identified therapeutic options for IdeS treatment within the areas of neurology, nephrology and hematology.

IdeS 2nd generation

Hansa Medical is also developing a new generation of molecules based on IdeS with the ambition to create versions of IdeS that can be used for repeated dosing. Repeated dosing is relevant in several IgG mediated autoimmune conditions. Hansa Medical has filed patent applications covering improved versions of IdeS.

Clinical Phase I study

During 2013 and 2014, Hansa Medical conducted a clinical first-in-human Phase I study. The study was a randomized placebo controlled dose-escalation study with 29 (20 active plus 9 placebo) healthy subjects. The primary objective was to assess the safety and tolerability of IdeS following intravenous administration. Secondary objectives were efficacy in IgG cleavage, the pharmacokinetics and the immunogenicity of IdeS. The starting dose was 0.01 mg/kg BW and the highest dose group received 0.24 mg/kg BW. IdeS was considered safe; no adverse events were reported as serious.

[1] We will continuously update the information around our projects, study programs and therapeutic areas on our corporate website (www.hansamedical.com).

[2] Phase II in Uppsala and Stockholm.

[3] Phase II in Los Angeles (Investigator sponsored).

[4] A CE-marked for research use only version of HBP-assay has been launched. Several clinical trials are ongoing and planned for the amendment of medical claims and for FDA approval.

In July 2015, the results from the Phase I study was published in PLOS ONE. http://dx.plos.org/10.1371/journal.pone.0132011.

Based on the data from this study, it was decided to move from healthy subjects into patients where it is possible to measure not only IdeS effect on plasma IgG but also the effect on specific pathogenic IgG. The Phase I data suggested that IdeS could prove to be a therapeutic option in several clinical conditions.

IdeS IN TRANSPLANTATION

Transplantation of sensitized patients

Approximately one third of kidney patients requiring dialysis are sensitized to human leukocyte antigens (HLA). The presence of antibodies that react with a potential organ donor, donor specific HLA antibodies (DSA), has, until recently, been an absolute barrier to transplantation due to antibody mediated rejection (AMR) and hyperacute graft failure. Sensitized patients have an increased waiting time for transplantation and despite highest priority and various strategies to increase the donor pool only a fraction of highly sensitized patients are transplanted each year. Patients who are not possible to transplant are maintained on dialysis at a high cost, with a poor quality of life and an increased mortality risk.

The long-term survival rate in patients transplanted following desensitization is significantly better compared to patients remaining on dialysis despite their increased risk of AMR. However, these desensitization protocols are not always effective, is time consuming and expensive, can be associated with serious side effects and have a significant impact on patient well-being. We hypothesized that IdeS treatment would rapidly and substantially reduce the level of anti-HLA IgG in sensitized patients thereby making them eligible for transplantation.

Antibody mediated graft rejection

Kidney transplantation improves the survival and quality of life and lowers costs compared to dialysis and is therefore the preferred treatment for kidney patients in dialysis. The immune response against the transplanted organ has always been the major obstacle to success. Antibody-mediated mechanisms have lately been recognized to lead to high rates of graft loss in HLA-incompatible kidney transplants and more than 60 percent of the late kidney failures have been attributed to AMR.

There are no approved drugs for treatment of AMR and no strong evidence to support treatment guidelines. Transplantation after desensitization of patients that are DSA positive has created a new population of patients at higher risk of developing AMR.

If AMR cannot be treated adequately, severe AMR results in graft loss. Based on the superior effect and efficacy of IdeS to inactivate IgG we belive that IdeS holds potential to prevent progression of AMR and be an effective treatment also in severe AMR.

Clinical development program in transplantation

IdeS is a candidate drug that effectively degrades IgG within minutes after intravenous injection. Since it is an injectable drug and not an advanced technological method, it will be undemanding to handle and easy to access. Within transplantation we have identified two main situations where IgG removal is crucial: desensitization before transplantation and treatment of AMR.

First clinical Phase II in transplantation

During 2014 and 2015, the first clinical Phase II study with IdeS treatment in sensitized patients was conducted and completed.

The study was a dose-finding study, and the intention was not to transplant patients by means of IdeS treatment. There were eight dialysis patients, ranging from very highly and broadly immunized to more moderately immunized, included in the study. One group of patients was given 0.12 mg/kg BW and one group received 0.25 mg/kg BW IdeS, and the patients were followed for two months after treatment.

The effect was measured as level of HLA antibodies, cytotoxic cross-match reactivity against hypothetical donors and level of IgG in serum/blood at different time-points after IdeS treatment. Taken into account the efficacy of the drug and the medical need for a treatment of sensitized patients, we conclude that the risk-benefit favors IdeS for desensitization prior to transplantation.

The patients participating in this trial were not intended for transplantation under the study protocol. However, the patients were not removed from the waiting list, and the second patient in the study was transplanted with an incompatible kidney just after completing IdeS treatment. Before IdeS treatment the cross match between donor and recipient was positive, but after treatment it was turned negative and the patient was eligible for transplantation. Stable graft function has been maintained for more than one year with normal creatinine and no rejection episodes.

Data strongly support further development in three possible directions: (i) as a replacement for plasmapheresis/immunoadsorption in moderately sensitized patients today considered suitable for desensitization and transplantation, (ii) for desensitization of very highly/broadly sensitized patients that today cannot be desensitized and transplanted using current protocols and (iii) for treatment of severe AMR.

(i) Desensitization in moderately sensitized patients
IdeS is currently investigated in two separate Phase II studies, in order to explore the possibility to replace plasmapheresis in the current desensitization protocols. The first study is run at two transplantation centers in Sweden: Uppsala University Hospital in Uppsala and Karolinska University Hospital in Stockholm. The second study is an investigator sponsored study run by Professor Stanley Jordan at Cedars-Sinai in Los Angeles.

Phase II in Uppsala and Stockholm
The first patient in this study was dosed with 0.25 mg/kg BW IdeS in the first half year of 2015. The study will include up to ten sensitized patients on the waiting list for transplantation and the study allows dose escalation. The selected group is patients that are moderately sensitized to HLA and hence could be considered for desensitization using e.g. plasmapheresis. The objectives are to investigate both effect on HLA antibodies and the safety of IdeS in the transplantation setting. The patients will receive a single dose of IdeS and if the patients are cross-match negative, they will be transplanted with a kidney from either a living or diseased donor. Each patient will be followed for six months and results are expected mid 2016.

Investigator sponsored Phase I/II in Los Angeles
This study is an investigator sponsored study run by Professor Stanley Jordan at Cedars-Sinai and the first patient was treated in mid 2015. Dr. Jordan has developed a desensitization protocol that allows transplantation of highly sensitized patients using kidneys from diseased donors something that is very difficult using other protocols based on plasmapheresis.

Several hundred sensitized patients have been transplanted at Cedars-Sinai using this protocol, and Dr. Jordan has a large database of historical controls. The protocol is based on alternating high dose IVIg and anti-CD20 treatments in order to lower the levels of anti-HLA antibodies and to prevent rebound of antibodies after incompatible transplantation. The patients are kept in the program for many months waiting for an organ offer from a diseased donor.

Dr. Jordan has demonstrated that the combination of high dose IVIg and anti-CD20 can increase the likelihood of finding an acceptable donor. In cases where the treatment is considered not sufficient, plasmapheresis is added before transplantation. IdeS is investigated in combination with the high dose IVIg and anti-CD20 procedure. The study will include up to 20 patients and the patients will be followed for six months.

The objectives are to investigate both efficacy (i.e. decrease in PRA, reduction in HLA antibody levels and reduction in AMR frequency) and safety of IdeS. IdeS is expected to effectively and efficiently remove the HLA antibodies creating a window for transplantation and the combination of IdeS with treatments such as IVIg and anti-CD20 aimed at preventing the rebound of antibodies is very attractive.

(ii) Desensitization in very highly/broadly sensitized patients
The first Phase II study completed in Uppsala and Stockholm clearly demonstrated that IdeS effectively removes antibodies also in the very highly/broadly sensitized patients. There is a defined group of patients that have very high levels of broad HLA antibodies, have been on dialysis for very long and is in urgent need of a transplant. These patients have highest priority and are referred to specialized clinics in the US but still have a negligible chance of being transplanted using the current protocols.

Considering the strong effect and speed of IdeS, we believe that IdeS can be a life-saving treatment to allow transplantation of these patients from both living and diseased donors. We are currently investigating the possibility to conduct a clinical trial in this category of patients.

(iii) Treatment of severe AMR
The primary aim of current AMR treatment is to remove the existing donor specific antibodies. In severe AMR plasmapheresis is not sufficient to rescue the kidney since the magnitude of the antibody response exceeds the capacity of plasmapheresis to clear antibodies. The completed Phase I and II studies demonstrated that IdeS cleaves and inactivates IgG very rapidly and effectively with no reflux of IgG from the tissues. This makes IdeS very interesting to investigate as a treatment for AMR and particularly severe AMR. The high-risk patients for severe AMR are those that have been desensitized and transplanted with an incompatible kidney. We are currently investigating the possibility to conduct a clinical trial in severe AMR.

Pivotal studies in transplantation
The experiences from these distinct but closely related clinical studies will be highly valuable for designing a pivotal study in one or several transplantation indications.

IdeS BEYOND TRANSPLANTATION

IdeS has other potential medical applications. These include relatively rare and serious, or even life-threatening, acute autoimmune diseases within neurology, nephrology and hematology. In addition, IdeS may also be used to degrade IgG in order to enable other forms of treatment that have lost their effect due to anti-drug antibody formation. Hansa Medical is currently investigating the possibility to conduct Phase II studies in these indication areas.

EndoS

EndoS is a secreted enzyme from *Streptococcus pyogenes* that specifically hydrolyzes the functionally important glycan in IgG. EndoS has proven effective in a range of autoimmune animal models including rheumatoid arthritis (RA), immune thrombocytopenic purpura (ITP), autoimmune hemolysis, Multiple sclerosis (MS) and autoimmune blistering skin disorder.

Given the importance of the IgG glycans in orchestrating the IgG's effector functions and the unique specificity of EndoS for these glycans, we believe that EndoS has great potential as a novel therapy for antibody-mediated autoimmune diseases.

HBP-assay

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

HBP has been evaluated as a biomarker for prediction of severe sepsis in two clinical studies in Sweden and the US. The studies demonstrate that serum HBP is elevated in more than 80 percent of the patients who develop severe sepsis within 72 hours. HBP, Heparin Binding Protein, also known as Azurocidin, resides in certain immune cells called neutrophils. HBP is a multifunctional inflammatory mediator and can be released from neutrophils in the presence of bacteria.

Commercial development of HBP-assay
Hansa Medical and Axis-Shield Diagnostics Limited signed a collaborative agreement in 2009 for the commercialization of the HBP-assay. Axis-Shield is responsible for all clinical trials and further developments of the assay and Hansa Medical carries certain rights to royalties from Axis-Shield derived from sales of the HBP-assay as well as milestones payments and minimum royalties.

Axis-Shield is developing the HBP testing market globally and is working to attract major global IVD players as potential sublicensees. In order to further strengthen the clinical validity of HBP-assay, Axis-Shield is currently coordinating additional clinical trials with HBP-assay in the US, Europe, China, South Korea and India. In addition, Axis-Shield is also developing alternative versions of the HBP-assay for improved routine clinical applicability.

Financial Review January – June 2015

Net sales

Net sales for the second quarter 2015 amounted to MSEK 0.5 (0.3) and to MSEK 4.4 (1.5) for the first half of 2015. The increase is attributable to increased revenues from the partnership with Axis-Shield Diagnostics and comprised of licensing and royalty income.

Operating result for the second quarter 2015 amounted to MSEK -22.5 (-4.8) and to MSEK -33.2 (-10.7) for the first half of 2015. Operating result was negatively impacted by increased activity level together with the continued expansion of the organization, but also cost for the planned listing on Nasdaq OMX, bonus to the former CEO and a one-time cash bonus when warrants were acquired by the company's employees. The non-recurring costs amounted to approx. MSEK 8.0 in the first half of 2015, the majority classified as administrative expenses.

Net profit/loss for the second quarter 2015 amounted to MSEK -22.5 (-4.8) and to MSEK -33.2 (-10.8) for the first half of 2015.

Cash flow and investments

Cash flow from operating activities for the second quarter 2015 amounted to MSEK -17.5 (-7.2) and to MSEK -25.4 (-9.9) for the first half of 2015. The cash flow was positively impacted by the proceeds from the sale of warrants to employees. On June 30, 2015, cash and cash equivalents amounted to MSEK 209.1 compared with MSEK 7.1 at the end of the first quarter of 2015. Investments for the second quarter 2015 amounted to MSEK 1.6 (0.2) and to MSEK 1.8 (0.3) for the first half of 2015.

Equity

On June 30, 2015, equity amounted to MSEK 244.1 compared with MSEK 39.5 at the end of the first quarter of 2015.

Rights issue 2015

In the second quarter, Hansa Medical finalized a fully subscribed rights issue with preferential rights for existing shareholders. The rights issue raised MSEK 246 before deduction of costs. The rights issue comprised of 6,482,400 at SEK 38 per share. The number of outstanding shares amounts to 32,412,003 shares after the rights issue. The proceeds will enable Hansa Medical to bring the candidate drug IdeS into several clinical Phase II trials as well as to prepare the IdeS production process for clinical pivotal studies.

Parent Company

The Parent Company's net sales for the second quarter 2015 were MSEK 0.5 (0.3) and to MSEK 4.4 (1.5) for the first half of 2015. Result after net financial items for the Parent Company for the second quarter 2015 amounted to MSEK -21.6 (-4.8) and to MSEK -31.9 (-10.8) for the first half of 2015. On June 30, 2015, liquidity amounted to MSEK 207.3 compared with MSEK 7.1 at the end of the first quarter 2015.

The Parent Company's equity amounted to MSEK 244.1 as per June 30, 2015, compared with MSEK 70.8 the end of the corresponding period 2014.

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

Financial summary for the Group (KSEK)

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Cash flow from operating activities	-17,523	-7,167	-25,385	-9,946	-23,623
Liquidity	209,110	25,216	209,110	25,216	10,152

Other information

Employees and organisation

The number of employees at the end of the second quarter 2015 was 16, compared to 10 at the end of the same period 2014.

Share warrant program

A total of 296,000 warrants were acquired by the company's employees under the warrant program that Hansa Medical's Annual General Meeting adopted on June 2, 2015. Each warrant entitles the holder to subscribe for one new share in Hansa Medical. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 15, 2018, and June 15, 2019.

The warrants were sold to the company's employees on market terms at a price established on the basis of an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute. The value has been set at SEK 8.40 per option based on a share price of SEK 36.04 with a future annual increase of 7 percent. The increase in the company's share capital upon full exercise of the share warrants will amount to SEK 296,000, and corresponds to a dilution of approximately 0.9 percent of the total number of shares and the total number of votes in the company.

The option program is subsidized by the company and the employees 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 IFRS 2.

Shareholders, June 30, 2015

Name	Number of shares	Percentage (%)
Nexttobe AB	9,443,761	29.1
Farstorps Gård AB	7,122,952	22.0
Försäkringsbolaget, Avanza Pension	2,411,944	7.4
Handelsbanken Fonder AB RE JP MEL	1,228,871	3.8
JP Morgan Clearing Corp, W9	906,901	2.8
SEB London – Luxemburg, (Sicav Fond)	822,367	2.5
Merrill Lynch International	637,906	2.0
JP Morgan Bank Luxembourg	530,631	1.6
Sven Sandberg	481,403	1.5
Banque Carnegie Luxembourg SA	380,000	1.2
Other	8,445,267	26.1
In total	**32,412,003**	**100.00**

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.

Auditors' Review

To the Board of Directors of Hansa Medical AB (publ), corp. id 556734-5359

Introduction

We have reviewed the summary interim financial information (interim report) of Hansa Medical AB (publ) as of 30 June 2015 and the six-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Malmö 25 August 2015
KPMG AB

Dan Kjellqvist
Authorized Public Accountant

Financial calendar

Interim Report for January – September 2015	October 28, 2015
Year-end Report 2015	February 2016
Annual report 2015	April 2016

Address

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P.O. Box 785, SE-220 07 Lund, Sweden

Certified Adviser

Hansa Medical's Certified Adviser is Remium Nordic AB.

Registration number

556734-5359

Affirmation

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

Lund, 24 August 2015

Birgit Stattin Norinder
Chairman of the Board

Anders Blom
Board member

Stina Gestrelius
Board member

Per-Olof Wallström
Board member

Hans Schikan
Board member

Cindy Wong
Board member

Göran Arvidson
President and CEO

Financial Statements

Financial Statements

Group – Statement of comprehensive income

	Q2		H1		Year
KSEK	2015	2014	2015	2014	2014
Net sales	529	349	4,376	1,461	1,618
Other operating income	36	1,037	694	1,537	3,157
Total operating income	**565**	**1,386**	**5,070**	**2,998**	**4,775**
Sales and administration expenses	-11,544	-1,765	-17,892	-3,249	-7,609
Research and development expenses	-11,513	-4,455	-20,316	-10,479	-21,742
Other operating expenses	-4		-47		-133
Operating profit/loss	**-22,496**	**-4,834**	**-33,185**	**-10,730**	**-24,709**
Financial income/expenses	-9	-14	-45	-116	-4,333
Profit/loss for the period	**-22,505**	**-4,848**	**-33,230**	**-10,846**	**-29,042**
Attributable to					
Parent company shareholders	-22,505	-4,848	-33,230	-10,846	-29,042
Earnings per share					
Before dilution (SEK)	-0.70	-0.18	-1.11	-0.42	-1.10
After dilution (SEK)	-0.70	-0.18	-1.11	-0.42	-1.10
Other comprehensive income					
Items that have been, or may be reclassified to profit or loss for the year					
Fair value changes for the year on financial assets which can be sold	898	-21	1,333	-1,810	-2,064
Other comprehensive income for the year	**898**	**-21**	**1,333**	**-1,810**	**-2,064**
Total net comprehensive income	**-21,607**	**-4,869**	**-31,897**	**-12,656**	**-31,106**

Group – Balance sheet

KSEK	30 June 2015	30 June 2014	31 Dec 2014
ASSETS			
Non-current assets			
Intangible fixed assets	36,612	38,022	36,898
Tangible fixed assets	1,407	413	1,283
Financial fixed assets	6,992	8,687	4,180
Total non-current assets	**45,011**	**47,122**	**42,361**
Current assets			
Current receivables, non-interest bearing	2,555	1,288	1,798
Cash and cash equivalents	209,110	25,216	10,152
Total current assets	**211,665**	**26,504**	**11,950**
TOTAL ASSETS	**256,676**	**73,626**	**54,311**
EQUITY AND LIABILITIES			
Shareholders' equity	**244,072**	**68,612**	**49,804**
Long term liabilities	**69**	**111**	**91**
Current liabilities			
Current liabilities, interest bearing	41	39	39
Current liabilities, non-interest bearing	5,306	754	2,834
Accrued expenses and deferred income	7,188	4,110	1,543
Total current liabilities	**12,535**	**4,903**	**4,416**
TOTAL EQUITY AND LIABILITIES	**256,676**	**73,626**	**54,311**
Pledged assets	100	156	128
Contingent liabilities	None	None	None

Group – Changes in equity

	January–June		Year
KSEK	2015	2014	2014
Opening shareholders' equity	49,804	45,349	45,349
Result for the year	-33,230	-10,846	-29,042
Other comprehensive income for the year	1,333	-1,810	-2,064
Net comprehensive income	**-31,897**	**-12,656**	**-31,106**
Transactions with the group's owner			
New share issue	246,331	37,042	37,042
Expenses attributable to new share issue	-21,999	-1,123	-1,481
Issued warrants	1,833		
Total transactions with the group's owner	**226,165**	**35,919**	**35,561**
Closing shareholders' equity	**244,072**	**68,612**	**49,804**

Group – Cash flow statement

	Q2		H1		Year
KSEK	2015	2014	2015	2014	2014
Operating activities					
Operating profit/loss	-22,496	-4,834	-33,185	-10,730	-24,709
Adjustment for items not included in cash flow	256	47	485	85	1,349
Interest received and paid, net	-38	-36	-45	-116	-81
Income taxes paid	-51	-50	10	18	-81
Cash flow from operations before change in working capital	**-22,329**	**-4,873**	**-32,735**	**-10,743**	**-23,522**
Change in working capital	4,806	-2,294	7,350	797	-101
Cash flow from operations	**-17,523**	**-7,167**	**-25,385**	**-9,946**	**-23,623**
Investing activities					
Investments in tangible fixed assets	-124	-134	-323	-194	-1,204
Investment/Divestment of financial assets	-1,479	-115	-1,479	-115	-115
Cash flow from investing activities	**-1,603**	**-249**	**-1,802**	**-309**	**-1,319**
Financing activities					
New share issue	246,331	37,042	246,331	37,042	37,042
Issue expenses	-21,999	-1,123	-21,999	-1,123	-1,481
Issued warrants	1,833		1,833		
Repayment of loans	-5,000	-3,277		-519	-519
Repayment of leasing liabilities	-11	-10	-20	-19	-38
Cash flow from financing activities	**221,154**	**32,632**	**226,145**	**35,381**	**35,004**
Net change in cash	**202,028**	**25,216**	**198,958**	**25,126**	**10,062**
Cash and cash equivalents, beginning of period	7,082		10,152	90	90
Cash and cash equivalents, year-end	**209,110**	**25,216**	**209,110**	**25,216**	**10,152**

Group – Key ratios and other information

	Q2		H1		Year
KSEK, unless otherwise stated	2015	2014	2015	2014	2014
Profit numbers					
Total operating income	565	1,386	5,070	2,998	4,775
Operating profit/loss	-22,496	-4,834	-33,185	-10,730	-24,709
Net profit/loss	-22,505	-4,848	-33,230	-10,846	-29,042
Per share data					
Earnings/loss per share before and after dilution (SEK)	-0.70	-0.18	-1.11	-0.42	-1.10
Shareholders' equity per share (SEK)	7.53	2.65	7.53	2.65	1.92
Other information					
Equity ratio (%)	95	93	95	93	92
Number of outstanding shares at the end of the period	32,412,003	25,929,603	32,412,003	25,929,603	25,929,603
Weighted average number of shares, before and after dilution	32,355,842	26,997,738	29,842,582	25,774,713	26,471,803

Parent Company – Statement of comprehensive income

	Q2		H1		Year
KSEK	2015	2014	2015	2014	2014
Net sales	529	349	4,376	1,461	1,618
Other operating income	36	1,037	694	1,537	3,157
Total operating income	**565**	**1,386**	**5,070**	**2,998**	**4,775**
Sales and administration expenses	-11,541	-1,768	-17,885	-3,254	-7,615
Research and development expenses	-11,513	-4,455	-20,316	-10,479	-21,742
Other operating expenses	-5		-47		-133
Operating profit/loss	**-22,494**	**-4,837**	**-33,178**	**-10,735**	**-24,715**
Result from participating interests in group companies					-2,398
Result from other securities and receivables which are fixed assets	898		1,333		-4,252
Other financial income					42
Other financial expenses	-8	-11	-42	-111	-115
Profit/loss for the period	**-21,604**	**-4,848**	**-31,887**	**-10,846**	**-31,438**

Parent Company – Balance sheet

	30 June		31 Dec
KSEK	2015	2014	2014
ASSETS			
Non-current assets			
Intangible fixed assets	36,612	38,022	36,898
Tangible fixed assets	1,307	257	1,155
Financial fixed assets	8,925	10,831	4,280
Total non-current assets	**46,844**	**49,110**	**42,333**
Current assets			
Current receivables non-interest bearing	2,554	1,294	1,798
Cash and cash equivalents	207,277	25,216	10,152
Total current assets	**209,831**	**26,510**	**11,950**
TOTAL ASSETS	**256,675**	**75,620**	**54,283**
EQUITY AND LIABILITIES			
Shareholders' equity	**244,084**	**70,756**	**49,806**
Current liabilities			
Liabilities to group companies	99		100
Current liabilities, non-interest bearing	5,304	754	2,834
Accrued expenses and deferred income	7,188	4,110	1,543
Total current liabilities	**12,591**	**4,864**	**4,477**
Total equity and liabilities	**256,675**	**75,620**	**54,283**
Pledged assets	None	None	None
Contingent liabilities	None	None	None

Parent Company – Changes in equity

	January–June		Year
KSEK	2015	2014	2014
Opening shareholders' equity	**49,806**	**45,683**	**45,683**
Result for the year	-31,887	-10,846	-31,438
New share issue	246,331	37,042	37,042
Expenses attributable to new share issue	-21,999	-1,123	-1,481
Issued warrants	1,833		
Closing shareholders' equity	**244,084**	**70,756**	**49,806**

Financial Notes

Note 1 Basis of Preparation and Accounting policies

This 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. For the Group and the Parent Company the same accounting policy and basis of calculation has been used as in the latest interim report (2015-03-31) except that the company has switched from a cost type-based Income statement to a function-based.

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 solely of the Group's holding of shares in Genovis, which is listed on Nasdaq First North. The fair value of the shares as per the balance sheet date 2015-06-30 was KSEK 6,992 and 8,687 per 2014-06-30 and 4,180 per 2014-12-31. The fair value of the shares are calculated on the basis of the closing price. The valuation of the holding is, thereby, in accordance with Level 1 in the valuation hierarchy.

Glossary

Anti-GBM
Anti-GBM – or Goodpasture syndrome – is an autoimmune disease, which primarily affects kidneys and lungs.

Antibody
One type of proteins produced by the body's immune system with the ability to recognise foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins.

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

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

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

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

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

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

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

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

FDA
US Food and Drug Administration.

Guillain-Barré syndrome
A rare and acute autoimmune disease of the nerves where antibodies are formed mainly directed towards the insulating myelin sheath of nerves and nerve roots.

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

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

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

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

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

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

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

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

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

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

Sepsis
Diagnosed or suspected infection in combination with the patient is 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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