# Hansa Medical

Interim report January – March 2016

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# Significant and steady progress in clinical program

## Hansa Medical highlights

**January – March 2016**

- Article in the New England Journal of Medicine supporting the need for and benefit of desensitization
- Strengthened shareholder base with several longterm institutional investors

**After the period**

- FDA clears Hansa Medical's IND application for IdeS in kidney transplantation
- Ulf Wiinberg proposed as new chairman and Angelica Loskog as new board member
- Patient recruitment completed in Swedish Phase II clinical study with IdeS in kidney transplantation

**Financial summary first quarter 2016**

- Net revenue for the group in Q1 amounted to MSEK 0.5 (3.8)
- Operating result in Q1 was MSEK -19.9 (-10.7)
- Consolidated net result in Q1 was MSEK -20.0 (-10.7)
- Earnings per share before and after dilution in Q1 were SEK -0.62 (-0.39)
- Cash position including short term investments on March 31, 2016, of MSEK 158.1 (7.1)

"We currently have two Phase II studies ongoing in Sweden and the US, as well as additional studies planned for initiation later this year. Recruitment in the Swedish study has been completed and the 10 included patients have all been treated with IdeS and subsequently transplanted. The ongoing US study also progresses as planned. To date, 9 patients have been included in the US study, thus bringing the total to 20 patients that have been treated and transplanted. This, together with the attention we have gained from the scientific community, gives me reason to feel very optimistic about the future of IdeS"

Göran Arvidson, President and CEO of Hansa Medical

## Hansa Medical in brief

Hansa Medical AB (publ) is a biopharmaceutical company focusing 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. Additional projects focus on development of new antibody modulating enzymes, as well as HBP, a diagnostic biomarker for prediction of severe sepsis at emergency departments that is already introduced on the market. The company is based in Lund, Sweden. Hansa Medical's share (ticker: HMED) is listed on Nasdaq OMX Stockholm.

# CEO statement

We have already reached several important milestones that I am pleased to share. We finalized the recruitment in the ongoing Phase II study in Sweden. We also gained FDA clearance to start our own clinical study in the US and we broadened our shareholder base with several long-term institutional investors.

We currently have two Phase II studies ongoing in Sweden and the US, as well as additional studies planned for initiation later this year. Recruitment in the Swedish study has been completed and the 10 included patients have all been treated with IdeS and subsequently transplanted. The ongoing US study also progresses as planned. To date, 9 patients have been included in the US study, thus bringing the total to 20 patients that have been treated and transplanted in the ongoing Phase II studies and the finalized Phase I/II study. This, together with the attention we have gained from the scientific community, gives me reason to feel very optimistic about the future of IdeS.

Additionally, The New England Journal of Medicine published an article on March 10 that further strengthens our belief in the potential of IdeS. The study demonstrated a significant survival benefit in 1,025 patients undergoing HLA-incompatible kidney transplantation following desensitization with currently available methods, when compared to non-transplanted patients on the transplant wait list. Although IdeS was not the subject of this study, it highlights the need for and benefit of desensitization in kidney transplantation, and further strengthens our belief that IdeS has the potential to play a very important role in kidney transplantation going forward. Our ultimate vision for IdeS is to make effective desensitization available to sensitized patients and for IdeS to be the preferred desensitization method for HLA-sensitized patients that rely on donation from either deceased or living donors.

Our current focus is on patients with very high levels of broad HLA antibodies and who have been on dialysis for a long time and are therefore in urgent need of transplantation. They have the highest priority for transplantation, however, also have a negligible chance of being transplanted using the current protocols.

In early April, the US Food and Drug Administration (FDA) notified us that they have completed the safety review of our Investigational New Drug application (IND). The FDA concluded that the proposed clinical investigation of IdeS can proceed, which enables us to start a clinical study to primarily evaluate the efficacy of IdeS in making highly sensitized kidney patients with positive crossmatches eligible for transplantation by removing donor specific antibodies.

The FDA clearance of the IND is a milestone for the company defining a potential path toward product approval.

This clinical trial, which will include up to 20 kidney transplantation patients that have either failed on previous attempts of desensitization or in whom effective desensitization using currently available methods is highly unlikely, is scheduled to begin as soon as possible at reputable medical institutions in the US, with the aim to complete recruitment during the first half of 2017.

We are hopeful that successful results from this planned study, in combination with the results from the finalized Phase I/II and the two ongoing Phase II trials will serve as a foundation for market approval for IdeS in this patient group.

The effective and fast IgG cleaving mode-of-action makes it highly relevant to also consider evaluating the efficacy and safety of IdeS in IgG-driven rare autoimmune indications. The three acute conditions TTP (Thrombotic Thromocytopenic Purpura), GBS (Guillain-Barré syndrome) and anti-GBM disease are among a number of diseases in which it is relevant to evaluate the treatment potential of IdeS. We are collaborating with world renowned clinical experts in these diseases with the ambition to run Phase II trials in the near future for proof-of-concept in these devastating acute conditions.

In early March, a group of long-term institutional investors acquired shares from Farstorps Gård AB, which after the divesture still holds shares equivalent to approximately 3 percent of the outstanding shares in Hansa Medical. In the last 12 months, we have gained a lot of investor interest both in Sweden and internationally and we will continue to work actively with both existing and potential investors to show how we can provide greater value to our shareholders and better health outcomes for patients.

**Göran Arvidson**
President and CEO

# Business overview

**Article in the New England Journal of Medicine supporting the need for and benefit of desensitization**
A study published on March 10, 2016 in the New England Journal of Medicine (Orandi et al. 2016;374:940-50) demonstrates a clear survival benefit in 1,025 patients who received kidney transplants from HLA-incompatible live donors, compared to patients who remained on the waiting list for kidneys from deceased donors, or no transplant at all. The study highlights the need for and benefit from desensitization in kidney transplantation. Although IdeS was not subject of this particular study, it strengthens Hansa Medical's belief that IdeS has the potential to play a very important role in kidney transplantation.

Hansa Medical's vision for IdeS is to make desensitization possible for highly and moderately HLA-sensitized patients relying on either deceased or living donor donation. Current protocols for desensitization, primarily involving plasmapheresis, immune globulins and rituximab, require meticulous planning and timing and these are not feasible in most cases for deceased donor kidney transplantation. IdeS with its rapid and powerful pharmacological effect is to be administered just prior to transplantation and has the potential to increase the number of sensitized patients receiving kidney transplants. In 2015, 70 percent of donated kidneys in the US were donated from deceased donors.

**FDA clears Hansa Medical's IND application for IdeS in kidney transplantation**
In April 2016, the US Food and Drug Administration (FDA) completed the safety review of Hansa Medical's Investigational New Drug application (IND) and has concluded that the proposed clinical investigation can proceed. This enables the company to start a Hansa Medical sponsored clinical study to primarily evaluate the efficacy of IdeS in making highly sensitized kidney patients with positive crossmatches eligible for transplantation by removing donor specific antibodies. This study is scheduled to begin within the next couple of months.

The single arm study will include up to 20 kidney transplantation patients that have either failed on previous attempts of desensitization or in whom effective desensitization using currently available methods is highly unlikely. The trial is scheduled to begin as soon as possible at reputable medical institutions in the US, with the aim to complete recruitment during the first half of 2017. FDA clearance of the IdeS IND is a milestone for the company defining a potential path toward product approval.

The first trial to be conducted under this IND is titled "A Phase II Study to Evaluate the Efficacy of IdeS (IgG endopeptidase) to Desensitize Transplant Patients with a Positive Crossmatch Test". The primary objective is to assess the efficacy of IdeS in creating a negative crossmatch test. The trial will also evaluate the safety, kidney function and immunogenicity during the 6-month follow-up period.

**Patient recruitment completed in Phase II clinical study with IdeS**
By mid-April, the last patient was recruited in the ongoing Phase II study with IdeS at Uppsala University Hospital and Karolinska University Hospital in Huddinge. The Phase II clinical trial is an open label, single arm study. Ten patients have been included. The study evaluates safety, tolerability, efficacy and pharmacokinetics of the candidate drug IdeS in sensitized kidney transplantation patients. The study is also aimed at confirming the appropriate dose that results in anti-HLA antibody levels acceptable for transplantation within 24 hours from dosing. All of the included patients have been transplanted following treatment with IdeS. The patients are followed for six months for safety and graft function. Results from the study are expected in Q4 2016.

**Phase II trials with IdeS to be initiated in rare autoimmune conditions**
IdeS has significant potential in several rare autoimmune diseases. The three acute conditions TTP (Thrombotic Thromocytopenic Purpura), GBS (Guillain-Barré syndrome) and anti-GBM disease are among a number of diseases relevant for treatment with IdeS and Hansa Medical has the ambition to engage in Phase II trials in order to establish proof-of-concept in these devastating conditions.

Currently, Hansa Medical is preparing the initiation of a Phase II trial in TTP. Site, study design and start of study will be communicated in the near future.

Hansa Medical collaborates with Professor Shahram Attarian at Hôpital de la Timone in Marseille, France. The ambition of the collaboration is to investigate the design of a possible Phase II trial with IdeS in GBS.

In anti-GBM disease Hansa Medical collaborates with Professor Mårten Segelmark at Linköping University Hospital. Planning for a Phase II trial is ongoing.

**Ulf Wiinberg proposed as new chairman and Angelica Loskog new board member**
In April 2016, the nomination committee of Hansa Medical AB (publ) proposed Angelica Loskog and Ulf Wiinberg as new board members of the Hansa Medical Board to be elected during the annual general meeting on May 11, 2016 in Lund. Ulf Wiinberg is proposed as new chairman.

Ulf Wiinberg, born in 1958 is an experienced healthcare industry professional. At Wyeth, he was President of the global consumer health care business, and later President for the European pharma business. Ulf was also CEO of H. Lundbeck A/S for several years, a pharmaceutical company specialized in psychiatric and neurological disorders. Ulf has served on the boards of several healthcare industry associations. He is today a non-executive Board member at Alfa Laval, a Swedish industrial company, and Nestle Health and Science; he is also chairman of Avillion LLP. Ulf is also nominated to

the Board of the Belgian pharmaceutical company UCB. Ulf Wiinberg purchased 75,000 shares in Hansa Medical during April 5-6, 2016. Ulf is independent of the company and its management as well as of major shareholders of Hansa Medical.

Angelica Loskog, born in 1973, is Doctor of Philosophy (Faculty of Medicine) and adjunct professor at the Department of Immunology, Genetics and Pathology at Uppsala University. Angelica is scientific advisor to Nexttobe AB, CEO of Lokon Pharma AB, as well as chairman of Vivolux AB and Repos Pharma AB. She is independent of the company and its management but not of major shareholders of Hansa Medical. She owns no shares in the company.

The nomination committee of Hansa Medical AB (publ) also proposes re-election of Birgit Stattin Norinder, Stina Gestrelius, Per Olof Wallström and Hans Schikan. Anders Blom and Cindy Wong have declined re-election.

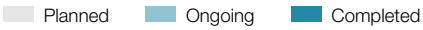
**Shareholder base strengthened**
During the first quarter of 2016, several long-term institutional investors have acquired shares from Farstorps Gård AB, the estate of Hansa Medical's founder Bo Håkansson. There were several additions to the list of the largest shareholders as of March 31, 2016, see *10 largest shareholders, March 31, 2016*.

Following the divestiture, Farstorps Gård AB holds approximately 1 million shares in Hansa Medical, equivalent to approximately 3 percent of the number of outstanding shares in Hansa Medical. The owners of Farstorps Gård AB have informed Hansa Medical that Farstorps Gård AB will remain a long-term shareholder in the company and they have committed not to divest any further shares within a 12-month lock-up period.

# Project overview

## Pipeline

| Candidate/Method | Indication | Research/ Preclinical | Phase I [1] | Phase I/II | Phase II | Phase II/III | Registration |
|---|---|---|---|---|---|---|---|
| **IdeS** | Kidney transplantation in sensitized patients [2] | | | | | | |
| | Acute autoimmune disease [3] | | | | | | |
| | 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] | | | | | | |




[1] Present and future IdeS Phase II and Phase II/III studies to be based on the same Phase I study.

[2] Two Phase II trials are currently ongoing in Sweden (Uppsala/Huddinge) and the US (Cedars-Sinai Medical Center, Los Angeles). An additional trial in highly sentisized patients is being planned.

[3] Phase II trials in rare autoimmune conditions like GBS, TTP and anti-GBM are being planned.

[4] Outlicensed to Axis-Shield Diagnostics Ltd.

## Lead Candidate IdeS

**IdeS – a novel therapeutic principle**

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, and treat patients who have developed pathogenic IgG. IdeS-mediated IgG degradation constitutes a novel therapeutic principle for the treatment of IgG-mediated human diseases. Our clinical studies are focused on desensitization of HLA-immunized patients before kidney transplantation, also referred to as sensitized patients. In addition, several additional indications are planned for clinical trials including antibody mediated graft rejection as well as several autoimmune indications within the areas of neurology, nephrology and hematology.

**Transplantation of sensitized patients**

Approximately one third of the kidney patients that require dialysis are sensitized to human leukocyte antigens (HLA)[1].The presence of antibodies that react with a potential donor organ – i.e. donor specific HLA antibodies (DSA) – is a significant barrier to transplantation due to the risk of acute antibody mediated rejection (AMR) and hyper acute graft failure. Sensitized patients in general have an increased waiting time for transplantation. Depending on the level of HLA-immunization, some sensitized patients can be transplanted with treatment procedures using plasmapheresis or intravenous gamma globulin at some specialized clinics. The most highly sensitized patients are today very difficult to desensitize and transplant despite highest priority and the engagement of various strategies to increase the donor pool. 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.

The long-term survival rate in patients that are transplanted following desensitization is significantly better compared to patients remaining on dialysis[2]. More than 32,000 patients awaiting kidney transplantation in the US are sensitized. The presence of anti-HLA antibodies makes it very difficult to find a match with a compatible donor. Sensitized patients can remain on the waiting list for a kidney transplant for years without a suitable donor ever being identified. Remaining on the wait list is associated with a high mortality rate.

A recently published[2] study concludes that sensitized patients receiving an incompatible kidney transplant have a higher survival rate than sensitized patients remaining on the transplant waitlist. The eight-year survival rate for transplanted sensitized patients is estimated to be 76.5 percent. The study compared this survival rate with two control groups: wait-list-or-transplant or wait-list only. The eight-year survival rate for the wait-list-or-transplant group was 62.9 percent while the eight-year survival rate for wait-list was only 43.9 percent. This study clearly demonstrates the benefit for sensitized patients to become transplanted as opposed to long-term dialysis treatment.

However, currently available desensitization protocols using plasmapheresis or intravenous gamma globulin are not always effective, and are time consuming, expensive, associated with serious side effects and have a significant impact on patient well being.

**Desensitization with IdeS**
Hansa Medical's primary development goal is to make transplantation possible for sensitized kidney transplantation patients through one 15-minute infusion dose of IdeS. IdeS inactivates both circulating and extravascular IgG very effectively and very fast. Within a couple of hours, basically all IgG antibodies are cleaved.

Current protocols for desensitization, primarily involving plasmapheresis, intravenous gammaglobulin and rituximab, require meticulous planning and timing and this is not feasible in most cases for deceased donor kidney transplantation. In many cases these currently available protocols are also not effective enough for living donor transplantation.

IdeS with its rapid and powerful pharmacological effect is currently in clinical development. It is administered just prior to transplantation and has the potential to significantly increase the number of sensitized patients receiving kidney transplants.

**Clinical Phase I study with IdeS**
During 2013 and 2014, Hansa Medical conducted a clinical first-in-human Phase I study with IdeS. The study was a randomized placebo controlled dose-escalation study with 29 healthy subjects. The primary objective was to assess the safety and tolerability of IdeS following intravenous administration. Secondary study objectives were the efficacy of IgG cleavage, the pharmacokinetics and the potential immunogenicity of IdeS. IdeS was considered safe; no adverse events were reported as serious. In July 2015, the results from the Phase I study were published in PLOS ONE [3].

**First clinical Phase I/II study in sensitized patients with IdeS**
During 2014 and 2015, the first clinical Phase I/II study with IdeS in sensitized patients was conducted and completed. The study was a dose-finding study in eight dialysis patients, ranging from very highly and broadly sensitized to more moderately sensitized patients.

The results from the study show that IdeS can effectively reduce anti-HLA antibodies to levels acceptable for transplantation. Both the primary and secondary objectives of the study were met and IdeS had an acceptable safety profile in the study. Even though it was not an objective of the study, one sensitized patient with donor specific antibodies who was on a waiting list for kidney transplant was subsequently successfully transplanted after having received two doses of IdeS. Stable graft function has been maintained to date (20 months) with normal creatinine and no rejection episodes.

**Ongoing Phase II trials in sensitized patients in Sweden and the US**
In July 2015, a Phase II study in sensitized patients was initiated in Sweden. The study includes ten sensitized patients on the waiting list for transplantation and the study allows dose escalation. The last patient in this study was recruited by mid-April 2016. The objectives are to investigate the effect on HLA-antibodies as well as the safety of IdeS in the transplantation setting.
The patients will receive a single dose of IdeS and if the patients become cross-match negative, they will be transplanted with a kidney from either a living or deceased donor. The patients are followed for six months after treatment and subsequent transplantation for safety, including graft function. Results from the study are expected in Q4 2016.

In August 2015, an investigator sponsored study using IdeS was initiated and run by Professor Stanley Jordan at Cedars-Sinai Medical Center in Los Angeles. Professor Jordan has developed a desensitization protocol that allows transplantation of highly sensitized patients using kidneys from deceased donors. The protocol is based on the use of alternating high dose intravenous gamma globulin 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 deceased donor.

IdeS is investigated concomitantly with the high dose intravenous gamma globulin and anti-CD20 procedure. The study will include 10–20 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.

**Planned clinical study in highly sensitized patients**
The first Phase I/II study completed with IdeS clearly demonstrated that IdeS effectively inactivates antibodies also in the highly/broadly sensitized patients. There is a defined group of patients with very high levels of broad HLA-antibodies and who have been on dialysis for a long period of time and are therefore in urgent need of transplantation. These patients have highest priority for transplantation and are referred to specialized clinics in the US. However, they have a negligible chance of being transplanted using the current protocols. Considering the effect and rapid onset of action of IdeS, we believe that IdeS can be a life-saving treatment to allow transplantation of these patients with kidneys from both living and deceased donors. In April 2016, the US Food and Drug Administration (FDA) completed the safety review of Hansa Medical's Investigational New Drug application (IND) and has concluded that this clinical trial can be initiated.

**IdeS in other indications**
IdeS can potentially be used in many different acute and rare autoimmune conditions in which IgG antibodies are proven or suspected to play a significant role for disease progression. Hansa Medicals long-term vision is to make IdeS available for several of these indications. In a number of these indications, IgG removal through plasmapheresis has proven to be somewhat effective which further strengthens the rational for considering further clinical development with IdeS in these IgG dependent autoimmune conditions. IdeS with its rapid and powerful pharmacological effect could potentially make a significant therapeutic difference in several of these acute indications.

A few indications have been identified as especially interesting to evaluate further in Phase II studies. These indications are antibody mediated graft rejection (AMR) and the acute autoimmune conditions Thrombotic Thrombocytopenic Purpura (TTP), anti-GBM disease and Guillain-Barré syndrome (GBS).

Approximately ten percent [4] of all transplanted patients experience antibody mediated rejection post transplant. 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 I/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.

TTP is a rare thrombotic disorder. In the majority of patients, TTP is a result of autoantibody-mediated inhibition of an enzyme (ADAMTS13) that is vital in controlling blood clotting.

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.

GBS is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies. Hansa Medical has initiated collaboration with Professor Shahram Attarian at Hôpital de la Timone in Marseille, France. The ambition of the collaboration is to investigate the design of a possible Phase II trial with IdeS in GBS.

**Next generation of IgG proteases**
Hansa Medical is also developing new drug candidates related to IdeS with the ambition to create an IgG inactivating drug that can be used for repeated dosing. Repeated dosing is relevant in several IgG mediated autoimmune conditions. Hansa Medical has filed patent applications covering these molecules.

## 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 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 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 patient with an infectious disease can within hours develop severe sepsis as manifested through clinical symptoms like organ failure and circulatory failure. Early prediction and treatment of risk patients is key to prevent death from severe sepsis.

**Results from the IMPRESSED study** [5]
IMPRESSED, *IMproved PREdiction of Severe Sepsis in the Emergency Department*, is a completed prospective clinical multicenter trial involving 759 patients admitted to emergency departments in Sweden and the US with infectious disease symptoms. In the study, 674 patients were diagnosed with an infection, of which 487 did not have organ dysfunction at enrollment. Of these 487 patients, 141 developed severe sepsis within 72 hours. 78 % of these patients had elevated levels plasma-HBP prior to developing severe sepsis.

HBP outperformed those biomarkers available today for predicting severe sepsis including Procalcitonin, White blood cell count (WBC), CRP, Lactate. Samples from a Canadian validation cohort of 104 patients confirmed the results of the combined Sweden/US study. The diagnostic accuracy for HBP in predicting severe sepsis in the Canadian cohort was even higher than in the Sweden/US cohort. The sensitivity was 78 % and the specificity was 95 % in predicting severe sepsis among infected patients in the Canadian cohort.

**Commercial development of HBP-assay**
Hansa Medical's development partner Axis-Shield Diagnostics is the global developer of the HBP testing market. In order to further strengthen the clinical validity of the 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 developing upgraded versions of the HBP-assay for improved routine clinical applicability. Hansa Medical carries rights to royalties from Axis-Shield derived from sales and sublicensing of the HBP-assay as well as milestones payments.

# Financial review January–March 2016

## Net revenue

Net revenue for the first quarter 2016 amounted to MSEK 0.5 (3.8) and comprised of royalty income from Axis-Shield Diagnostics. In net revenue for previous year is also a licensing income of MSEK 3.3 from Axis-Shield Diagnostics included.

Operating result for the first quarter 2016 amounted to MSEK -19.9 (-10.7). R&D expenses increased during the first quarter due to continued high project activity with focus on clinical studies and CMC development.

Net profit/loss for the first quarter amounted to MSEK -20.0 (-10.7).

## Cash flow

Cash flow from operating activities amounted to MSEK -17.6 (-7.9) for the first quarter 2016. Cash and cash equivalents including short term financial investments amounted to MSEK 158.1 at the end of the first quarter 2016, as compared with MSEK 7.1 at the corresponding time in 2015.

## Shareholders' equity

On March 31, 2016, equity amounted to MSEK 190.9 compared with MSEK 39.5 at the end of the corresponding period 2015.

## Parent company

The Parent company's net revenue for the first quarter 2016 amounted to MSEK 0.5 (3.8). Result after net financial items for the Parent company amounted to MSEK -20.7 (-10.3) for the first quarter. On March 31, 2016, cash and cash equivalents including short term financial investments amounted to MSEK 156.2 compared with MSEK 7.1 at the end of first quarter 2015.

The Parent company's equity amounted to MSEK 190.9 as per March 31, 2016, as compared with MSEK 39.5 at the end of the corresponding period 2015.

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

| | Q1 | | Year |
|---|---|---|---|
| KSEK, unless otherwise stated | 2016 | 2015 | 2015 |
| Net revenue | 542 | 3,847 | 5,434 |
| Operating profit/loss | -19,946 | -10,689 | -66,201 |
| Net profit/loss | -19,976 | -10,725 | -66,266 |
| Earnings per share before and after dilution (SEK) | -0.62 | -0.39 | -2.13 |
| Shareholders' equity | 190,922 | 39,514 | 211,526 |
| Cash flow from operating activities | -17,560 | -7,862 | -57,799 |
| Cash and cash equivalents including short term invesments | 158,080 | 7,082 | 175,683 |

# Other information

## Employees and organisation

Number of employees at the end of the first quarter 2016 was 20, compared to 14 at the end of same period 2015.

## Annual General Meeting 2016

The shareholders of Hansa Medical AB (publ) are hereby summoned to attend the Annual General Meeting ("AGM") on May 11th, 2016, at 17.00 CET at the auditorium next to the company's premises, Scheelevägen 22, Lund, Sweden. Registration starts at 16.30 CET and will be possible until the meeting starts. Refreshments will be served after the meeting. Those who have been recorded as shareholders in the share register kept by Euroclear Sweden AB as per May 4th, 2016, and who, no later than May 4th, 2016 at 12.00 CET, give notice to the company of their intent to participate at the AGM have a right to participate in the AGM. Notice to participate shall be given in writing to Hansa Medical AB, c/o Fredersen Advokatbyrå AB, Turning Torso, 211 15 Malmö, by e-mail to hansamedical@fredersen.se or by fax to +46-40-232003. The notice shall contain the shareholder's name, personal identity number or registration number and daytime telephone number and, where applicable, the number of advisors (maximum two). After giving notice of participation the shareholder will receive a confirmation. If no confirmation is received, notice has not been duly given.

## Financial calendar

| | |
|---|---|
| Annual General Meeting | May 11, 2016 |
| Interim report for January–June 2016 | July 21, 2016 |
| Interim report for January–September 2016 | November 10, 2016 |

## Shareholder information

The Hansa Medical share is listed on Nasdaq OMX Stockholm, under the ticker HMED and included in both the OMX Nordic Small Cap and Health Care sector index.

## Brief facts, the HMED share

| | |
|---|---|
| Listing | Nasdaq OMX Stockholm |
| Number of shares | 32,412,003 |
| Market capitalization (160426) | MSEK 1,245 |
| Ticker | HMED |
| ISIN | SE0002148817 |

## 10 largest shareholders, March 31, 2016

| Name | Number of Shares | Share (%) |
|---|---|---|
| Nexttobe AB | 9,443,761 | 29.1 |
| Gladiator | 2,550,000 | 7.9 |
| Tredje AP-fonden | 1,385,659 | 4.3 |
| Försäkringsaktiebolaget, Avanza Pension | 1,197,427 | 3.7 |
| Farstorps Gård AB | 1,084,070 | 3.3 |
| Catella Småbolagsfond | 1,000,000 | 3.1 |
| Handelsbanken Fonder AB | 962,316 | 3.0 |
| Rhenman Healthcare Equity L/S | 822,367 | 2.5 |
| Skandinaviska Enskilda Banken S.A. | 628,578 | 1.9 |
| JP Morgan Bank Luxembourg | 563,631 | 1.7 |
| Övriga | 12,774,194 | 39.4 |
| **Totalt** | **32,412,003** | **100.0** |

According to the shareholder register maintained by Euroclear Sweden AB, as of March 31, 2016, Hansa Medical had 3,517 shareholders. In March 31 2015, Hansa Medical had 1,917 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 companys intellectual property rights and preclusions of potential third party's intellectual property rights, technological development, exchange rate and interest rate fluctuations and political risks.

## Address

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Scheelevägen 22, SE-223 63 Lund, Sweden

## Postal address

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

# Condensed financial statements

## Consolidated statement of comprehensive income

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2016 | 2015 | 2015 |
| Net revenue | 542 | 3,847 | 5,434 |
| Other operating income | 108 | 658 | 1,721 |
| **Total operating income** | **650** | **4,505** | **7,155** |
| | | | |
| Direct cost of net revenue | -54 | – | -658 |
| **Gross profit** | **596** | **4,505** | **6,497** |
| | | | |
| Sales, general and administration expense | -4,974 | -6,348 | -28,241 |
| Research and development expenses | -15,403 | -8,803 | -44,262 |
| Other operating expenses | -165 | -43 | -195 |
| **Operating profit/loss** | **-19,946** | **-10,689** | **-66,201** |
| | | | |
| Financial income/expenses | -30 | -36 | -65 |
| **Profit/loss for the period (before and after taxes)** | **-19,976** | **-10,725** | **-66,266** |
| | | | |
| **Attributable to** | | | |
| Parent company shareholders | -19,976 | -10,725 | -66,266 |
| | | | |
| **Earnings per share** | | | |
| Before dilution (SEK) | -0.62 | -0.39 | -2.13 |
| After dilution (SEK) | -0.62 | -0.39 | -2.13 |
| | | | |
| **Other comprehensive income** | | | |
| Items that have been, or may be reclassified to profit or loss for the year | | | |
| Changes in fair value on available-for-sale financial assets | -728 | 435 | 1,624 |
| **Other comprehensive income for the year** | **-728** | **435** | **1,624** |
| | | | |
| **Total net comprehensive income** | **-20,704** | **-10,290** | **-64,642** |

# Consolidated balance sheet

| | March 31 | | December 31 |
|---|---|---|---|
| KSEK | 2016 | 2015 | 2015 |
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible fixed assets | 35,623 | 36,755 | 36,327 |
| Tangible fixed assets | 2,077 | 1,396 | 2,182 |
| Financial fixed assets | 6,555 | 4,615 | 7,283 |
| **Total non-current assets** | **44,255** | **42,766** | **45,792** |
| **Current assets** | | | |
| Current receivables, non-interest bearing | 1,670 | 4,707 | 2,613 |
| Short-term investments | 99,935 | – | – |
| Cash and cash equivalents | 58,145 | 7,082 | 175,683 |
| **Total current assets** | **159,750** | **11,789** | **178,296** |
| **TOTAL ASSETS** | **204,005** | **54,555** | **224,088** |
| **EQUITY AND LIABILITIES** | | | |
| **Shareholders' equity** | **190,922** | **39,514** | **211,526** |
| **Long term liabilities** | **38** | **81** | **49** |
| **Current liabilities** | | | |
| Current liabilities, interest bearing | 42 | 5,040 | 42 |
| Current liabilities, non-interest bearing | 2,312 | 5,106 | 2,294 |
| Accrued expenses and deferred income | 10,691 | 4,814 | 10,177 |
| **Total current liabilities** | **13,045** | **14,960** | **12,513** |
| **TOTAL EQUITY AND LIABILITIES** | **204,005** | **54,555** | **224,088** |
| Pledged assets | 58 | 114 | 72 |
| Contingent liabilities | None | None | None |

# Consolidated changes in equity

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2016 | 2015 | 2015 |
| **Opening shareholders' equity** | **211,526** | **49,804** | **49,804** |
| Result for the period | -19,976 | -10,725 | -66,266 |
| Other comprehensive income for the period | -728 | 435 | 1,624 |
| **Net comprehensive income** | **-20,704** | **-10,290** | **-64,642** |
| **Transactions with the group's owner** | | | |
| New share issue | – | – | 246,331 |
| Expenses attributable to new share issue | – | – | -21,999 |
| Issued warrants | 100 | – | 2,032 |
| **Total transactions with the group's owner** | **100** | **–** | **226,364** |
| **Closing shareholders' equity** | **190,922** | **39,514** | **211,526** |

# Consolidated cash flow statement

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2016 | 2015 | 2015 |
| **Operating activities** | | | |
| Operating profit/loss | -19,946 | -10,689 | -66,201 |
| Adjustment for items not included in cash flow | 941 | 229 | 1,188 |
| Interest received and paid, net | -30 | -7 | -65 |
| Income taxes paid | 80 | 61 | 184 |
| **Cash flow from operations before change in working capital** | **-18,955** | **-10,406** | **-64,894** |
| Change in working capital | 1,395 | 2,544 | 7,095 |
| **Cash flow from operating activities** | **-17,560** | **-7,862** | **-57,799** |
| **Investing activities** | | | |
| Investments in tangible fixed assets | -18 | -199 | -1,317 |
| Investment/Divestment of financial assets | – | – | -1,479 |
| Short term investments | -99,949 | – | – |
| **Cash flow from investing activities** | **-99,967** | **-199** | **-2,796** |
| **Financing activities** | | | |
| New share issue | – | – | 246,331 |
| Issue expenses | – | – | -21,999 |
| Loans raised | – | 5,000 | – |
| Issued warrants | – | – | 1,833 |
| Repayment of leasing liabilities | -11 | -9 | -39 |
| **Cash flow from financing activities** | **-11** | **4,991** | **226,126** |
| **Net change in cash** | **-117,538** | **-3,070** | **165,531** |
| Cash and cash equivalents, beginning of year | 175,683 | 10,152 | 10,152 |
| **Cash and cash equivalents, end of period** | **58,145** | **7,082** | **175,683** |

# Consolidated key ratios and other information

| | Q1 | | Year |
|---|---|---|---|
| KSEK, unless otherwise stated | 2016 | 2015 | 2015 |
| Total operating income | 650 | 4,505 | 7,155 |
| Operating profit/loss | -19,946 | -10,689 | -66,201 |
| Net profit/loss | -19,976 | -10,725 | -66,266 |
| Earnings/loss per share before and after dilution (SEK) | -0.62 | -0.39 | -2.13 |
| Cash and cash equivalents including short term invesments | 158,080 | 7,082 | 175,683 |
| | | | |
| Number of outstanding shares at the end of the period | 32,412,003 | 25,929,603 | 32,412,003 |
| Weighted average number of shares before and after dilution | 32,412,003 | 27,301,397 | 31,137,852 |

# Parent company – Statement of comprehensive income

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2016 | 2015 | 2015 |
| Net revenue | 542 | 3,847 | 5,434 |
| Other operating income | 108 | 658 | 1,721 |
| **Total operating income** | **650** | **4,505** | **7,155** |
| | | | |
| Direct cost of net revenue | -54 | – | -658 |
| **Gross profit** | **596** | **4,505** | **6,497** |
| | | | |
| Sales, general and administration expenses | -4,970 | -6,343 | -28,228 |
| Research and development expenses | -15,403 | -8,803 | -44,262 |
| Other operating expenses | -165 | -43 | -195 |
| **Operating profit/loss** | **-19,942** | **-10,684** | **-66,188** |
| | | | |
| Result from other securities and receivables which are fixed assets | -728 | 435 | 1,624 |
| Result from short term financial receivables | -14 | – | – |
| Other financial expenses | -15 | -34 | -59 |
| **Profit/loss for the period (before and after taxes)** | **-20,699** | **-10,283** | **-64,623** |
| | | | |
| **Other comprehensive income for the period** | **–** | **–** | **–** |
| | | | |
| **Total net comprehensive income** | **-20,699** | **-10,283** | **-64,623** |

# Parent company – Balance sheet

| | March 31 | | December 31 |
|---|---|---|---|
| KSEK | 2016 | 2015 | 2015 |
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible fixed assets | 35,623 | 36,755 | 36,327 |
| Tangible fixed assets | 2,019 | 1,282 | 2,110 |
| Financial fixed assets | 8,488 | 4,715 | 9,216 |
| **Total non-current assets** | **46,130** | **42,752** | **47,653** |
| | | | |
| **Current assets** | | | |
| Current receivables non-interest bearing | 1,669 | 4,707 | 2,612 |
| Short-term investments | 99,935 | – | – |
| Cash and cash equivalents | 56,314 | 7,082 | 173,850 |
| **Total current assets** | **157,918** | **11,789** | **176,462** |
| | | | |
| **TOTAL ASSETS** | **204,048** | **54,541** | **224,115** |
| | | | |
| **EQUITY AND LIABILITIES** | | | |
| **Shareholders' equity** | **190,948** | **39,523** | **211,547** |
| | | | |
| **Current liabilities** | | | |
| Liabilities to credit institutions | – | 5,000 | – |
| Liabilities to group companies | 98 | 98 | 98 |
| Current liabilities, non-interest bearing | 2,311 | 5,106 | 2,293 |
| Accrued expenses and deferred income | 10,691 | 4,814 | 10,177 |
| **Total current liabilities** | **13,100** | **15,018** | **12,568** |
| | | | |
| **TOTAL EQUITY AND LIABILITIES** | **204,048** | **54,541** | **224,115** |
| | | | |
| Pledged assets | None | None | None |
| Contingent liabilities | None | None | None |

# Parent company – Changes in equity

| | Q1 | | Year |
|---|---|---|---|
| KSEK | 2016 | 2015 | 2015 |
| **Opening shareholders' equity** | **211,547** | **49,806** | **49,806** |
| Result for the period | -20,699 | -10,283 | -64,623 |
| New share issue | – | – | 246,331 |
| Expenses attributable to new share issue | – | – | -21,999 |
| Issued warrants | 100 | – | 2,032 |
| **Total transactions with the group's owner** | **100** | **–** | **226,364** |
| **Closing shareholders' equity** | **190,948** | **39,523** | **211,547** |

# 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. A full description of the accounting principles applied in this interim report can be found in the Annual Report 2015. The Annual 2015 was published on March 31, 2016. It's available on www.hansamedical.com.

## 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 are listed on Nasdaq First North. The fair value of the shares as per the balance sheet date March 31, 2016 was KSEK 6,555, KSEK 4,615 on March 31, 2015 and 7,283 on December 31, 2015. 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.

This interim report has not been audited

# Reference list


1. Jordan et al., British Medical Bulletin, 2015, 114:113–125.
2. Orandi et al., New England Journal of Medicine (2016;374:940-50)
3. Winstedt el al., (2015) PLOS ONE 10(7).
4. Puttarajappa et al., J. Transplant.Volume 2012 (2012), Article ID 193724.
5. Linder et al., Critical Care Medicine. 43(11):2378-2386, Nov 2015

# Glossary

**AMR**
Antibody mediated transplant rejection

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

**Anti-GBM disease**
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.

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

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

**FDA**
US Food and Drug Administration.

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

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

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

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

**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.

**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.

**Thrombotic Thombocytopenic Purpura**
TTP, Thrombotic Thombocytopenic Purpura, is a rare thrombotic disorder. In the majority of patients, TTP is a result of autoantibody-mediated inhibition of an enzyme (ADAMTS13) that is vital in controlling clotting.

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