# Hansa Medical

Interim report January – September 2015

# Important Phase II trials ongoing and new trials planned

## January–September 2015 in summary

**Significant events during the third quarter**

- Hansa Medical received FDA Orphan Drug Designation for IdeS in solid organ transplant patients
- First patient treated and transplanted with IdeS in US Phase II study at Cedars-Sinai Medical Center, Los Angeles
- Positive IdeS Phase I data published in scientific journal PLOS ONE
- Data from Hansa Medical's first Phase II study of IdeS in Sensitized Kidney Transplantation Patients presented at an oral session at ESOT 2015
- Results from a clinical multicenter trial with HBP-assay published in Critical Care Medicine

**Financial Summary Third Quarter and Year to Date**

- Net sales for the group in Q3 amounted to MSEK 0.5 (0). YTD: MSEK 4.9 (1.5)
- Operating result in Q3 was MSEK -13.9 (-5.4). YTD: MSEK -47.1 (-16.2)
- Consolidated net result in Q3 was MSEK -13.9 (-5.4). YTD: MSEK -47.2 (-16.3)
- Earnings per share before and after dilution in Q3 was SEK -0,43 (-0,20). YTD: SEK -1,54 (-0,62)
- Cash position on September 30, 2015, of MSEK 192.6

"In the third quarter, we continued to make good progress with our prioritized projects, with the ultimate aim to build a sustainable biopharmaceutical company with pharmaceuticals that significantly improve health outcomes in patients."

Göran Arvidson, President and CEO of Hansa Medical

## Financial summary for the Group

| | Q3 | | January-September | | Year |
|---|---|---|---|---|---|
| KSEK, unless otherwise stated | 2015 | 2014 | 2015 | 2014 | 2014 |
| Net sales | 529 | 0 | 4,905 | 1,461 | 1,618 |
| Operating profit/loss | -13,927 | -5,421 | -47,112 | -16,151 | -24,709 |
| Net profit/loss | -13,932 | -5,425 | -47,162 | -16,271 | -29,042 |
| Earnings per share before and after dilution (SEK) | -0.43 | -0.20 | -1.54 | -0.62 | -1.10 |
| Shareholders' equity | 230,058 | 61,871 | 230,058 | 61,871 | 49,804 |
| Cash flow from operating activities | -16,466 | -5,879 | -41,851 | -15,825 | -23,623 |
| Liquidity | 192,628 | 18,405 | 192,628 | 18,405 | 10,152 |

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# CEO Statement

In the third quarter, we continued to make good progress with our prioritized projects, with the ultimate aim to build a sustainable biopharmaceutical company with pharmaceuticals that significantly improve health outcomes in patients.

A lot of our work is focused on our lead project IdeS, which continues to attract 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. The study results showed that a single dose of IdeS rapidly and efficiently inactivates IgG in humans, which makes it an attractive therapeutic approach for acute IgG-mediated conditions.

In September, data from the first Phase II study with IdeS in sensitized kidney transplantation patients were presented at the 17th Congress of the European Society for Organ Transplantation (ESOT) in Brussels. The data clearly support further development in transplantation, and we are pleased that the investigators were given the opportunity to present these interesting and encouraging data. IdeS' effect in reducing anti-HLA antibodies to levels acceptable for transplantation has gained a lot of attention in the scientific community, which strengthens our belief in this exciting project.

In parallel with the ongoing Phase II study in Sweden, further studies are ongoing or planned, 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 preventing antibody-mediated rejection in highly sensitized patients. In August, the first patient in this study was successfully treated and transplanted with IdeS.

We now plan to initiate further pilot studies within transplantation and life threatening autoimmune diseases, including Phase II studies addressing antibody mediated graft rejection and very highly/broadly sensitized patients. Furthermore, we will continue to further explore the potential disease indications that can be treated with IdeS, including rare and serious acute autoimmune diseases within neurology, nephrology and hematology.

During the period, we also received Orphan Drug Designation for IdeS for the prevention of antibody mediated organ rejection in patients undergoing all types of solid organ transplants. Approximately 30 percent of the patients on the waiting lists for kidney, heart, lung and pancreas transplantation, equivalent to approximately 35,000 patients in the US alone, are sensitized to Human Leukocyte Antigen (HLA). HLA sensitization constitutes a significant barrier for transplantation for thousands of patients annually.

Our partnership project HBP-assay in severe sepsis also continued to develop in a positive way. In August, results from a clinical multicenter study were published ahead of print in the scientific journal Critical Care Medicine. The study results show that the diagnostic method for assessing Heparin Binding Protein (HBP) predicts severe sepsis with significantly higher accuracy than other biomarkers available today. The study demonstrates that the HBP-assay has the potential to become a significant tool to help predict severe sepsis at emergency departments and infectious disease clinics.

We furthermore continued to strengthen the organization in the company as we advance our clinical programs, but also for the change to Nasdaq Stockholm's main list. The first day of trading is on November 2, 2015. This upgrade will hopefully make Hansa Medical even more attractive to existing and new potential investors.

On November 13, 2015, interested shareholders and research partners can join us at our Capital Markets Day in Stockholm where we plan to go into more detail to describe our portfolio and its possibilities. Also, some of the prominent US and European clinical experts with whom we collaborate will give us a review from their daily practice and present their view on the potential of IdeS. For more information about the event, visit our website www.hansamedical.com.

Looking back at the year so far, I believe we took a number of important steps – strategically, financially and scientifically. And what is most important: we continued to drive our clinical projects to get all the cornerstones in place for future growth. It is my firm belief that we have exciting times ahead of us.

**Göran Arvidson**
*President and CEO*

# Business Review Q3 2015

**Positive IdeS Phase I data published in scientific journal PLOS ONE**
The Phase I trial was a first-in-man, double blind, randomized study with single-ascending doses of IdeS in 29 healthy subjects who were given intravenous doses of placebo or IdeS. Treatment with 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 what has been observed using plasmapheresis which typically leaves approximately 35 percent of remaining IgG. The complete, rapid, but temporary removal of IgG provides a new potent therapeutic opportunity in IgG-mediated pathogenic conditions.

For access to the full article:
http://dx.plos.org/10.1371/journal.pone.0132011

**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.

**Results from a clinical multicenter trial with HBP-assay published in Critical Care Medicine**
Results from a clinical multicenter trial with samples from Emergency Departments in Sweden, the US and Canada collected during 2011-2014 was published online by the scientific journal Critical Care Medicine. The study results show that the diagnostic method for assessing Heparin Binding Protein (HBP) predicts severe sepsis with significantly higher accuracy than other biomarkers available today.

The study demonstrates that the HBP-assay has the potential to become a significant tool in helping predicting severe sepsis at emergency departments and infectious disease clinics. Hundreds of thousands of patients die every year due to severe sepsis as a complication to infections like urinary tract infection and pneumonia. Hansa Medical's development partner Axis-Shield Diagnostic is responsible for commercialization of the HBP-assay, and Hansa Medical has rights to royalties and milestone payments from the sale of HBP-assays.

For access to the full article: http://journals.lww.com/ccmjournal/Fulltext/2015/11000/Heparin_Binding_Protein_Measurement_Improves_the.14.aspx

**Hansa Medical receives FDA Orphan Drug Designation for IdeS**
The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to IdeS for the prevention of antibody mediated organ rejection in patients undergoing solid organ transplant patients. Approximately 30 percent of the patients on the waiting lists for kidney, heart, lung and pancreas, equivalent to approximately 35,000 patients in the US, are sensitized to Human Leukocyte Antigen (HLA).

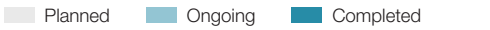
**Data from Hansa Medical's first Phase II study of IdeS in sensitized kidney transplantation patients were presented in oral session at ESOT 2015**
Principal investigator, Dr. Tomas Lorant from Uppsala University Hospital, presented data from the first completed Phase II study of IdeS in sensitized patients at the 17th Congress of the European Society for Organ Transplantation (ESOT) in Brussels. Data from the Hansa Medical sponsored 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 has an acceptable safety profile. Even though it was not an objective of the study, one 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.

An abstract titled "*Rapid removal of anti-HLA antibodies in immunized patients awaiting renal transplantation – A dose finding study of the IgG degrading enzyme IdeS*" from the presentation is available at the ESOT congress website under Abstract Program:
http://esot2015.esot.org/abstracts

# Project Overview

## Pipeline

| Candidate/Method | Indication | Preclinical | Phase I | Phase II | Pivotal |
|---|---|---|---|---|---|
| **IdeS** | Sensitized kidney transplantation patients (EU)[1,2]/(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 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. Other projects include EndoS, an antibody-modulating bacterial enzyme in pre-clinical development, and HBP, a market introduced diagnostic biomarker for severe sepsis.

## 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, to prevent 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 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 additional therapeutic indications for IdeS treatment within the areas of neurology, nephrology and hematology.

**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 objectives were efficacy in IgG cleavage, the pharmacokinetics and the 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. (http://dx.plos.org/10.1371/journal.pone.0132011).

**Transplantation of sensitized patients**

Approximately one third of the kidney patients that require 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 a significant barrier to transplantation due to acute antibody mediated rejection (AMR) and hyper acute 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, are time consuming and expensive, can be associated with serious side effects and have a significant impact on patient well-being.

[1] First Phase II in Uppsala completed in 2015

[2] Second Phase II in Uppsala and Stockholm initiated in June 2015

[3] Investigator sponsored Phase II at Cedars-Sinai Medical Center initiated in August 2015

[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.

**First clinical Phase II in sensitized patients with IdeS successfully completed**

During 2014 and 2015, the first clinical Phase 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 immunized to more moderately immunized. The two groups of patients were given 0.12 and 0.25 mg/kg BW IdeS respectively, and the patients were followed for two months after treatment.

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 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 for more than one year with normal creatinine and no rejection episodes.

**Ongoing Phase II trials in sensitized patients in Sweden and the US**

In mid 2015, a Phase II study in sensitized patients was initiated in Sweden. The study will include up to ten sensitized patients on the waiting list for transplantation and the study allows dose escalation. 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 become cross-match negative, they will be transplanted with a kidney from either a living or deceased donor. Each patient will be followed for six months and results are expected in 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. Dr. Jordan has developed a desensitization protocol that allows transplantation of highly sensitized patients using kidneys from deceased donors, a procedure that is very difficult using other protocols based on plasmapheresis. The protocol is based on the use of 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 deceased donor.

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. The first patient has been transplanted in this study.

**Planned Phase II with IdeS in antibody mediated graft rejection**

Antibody-mediated mechanisms have recently 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 antibody mediated rejection, AMR. There are no approved drugs for treatment of AMR and no strong evidence to support treatment guidelines. Based on the superior effect and efficacy of IdeS to inactivate IgG we believe that IdeS is a potential treatment for severe AMR and may potentially prevent progression of 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. We are currently investigating the possibility to conduct a clinical trial in patients with severe AMR.

**Planned Phase II in very highly/broadly sensitized patients**

The first Phase II study completed with IdeS clearly demonstrated that IdeS effectively removes antibodies also in the very 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 very long 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. We are currently planning a clinical trial in this category of patients.

**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. Hansa Medical is currently investigating the possibility to conduct Phase II studies in these indication areas.

**IdeS 2nd generation**

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**

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 whom 487 did not have organ dysfunction at enrollment. Of these 487 patients, 141 (29%) developed severe sepsis within 72 hours. 78% of these patients had elevated levels plasma-HBP prior to developing severe sepsis.

HBP clearly outperformed those biomarkers available today for diagnosing or 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 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 upgraded versions of the HBP-assay for improved routine clinical applicability. Hansa Medical carries certain rights to royalties from Axis-Shield derived from sales of the HBP-assay as well as milestones payments.

# Financial Review January – September 2015

## Net sales

Net sales for the third quarter 2015 amounted to MSEK 0.5 (0) and to MSEK 4.9 (1.5) year to date 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 third quarter 2015 amounted to MSEK -13.9 (-5.4) and to MSEK -47.1 (-16.2) year to date 2015. Operating result was negatively impacted by increased activity level with the start of clinical studies and CMC development costs 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 1.6 in the quarter and MSEK 9.6 year to date September 2015, the majority classified as administrative expenses.

Net profit/loss for the third quarter 2015 amounted to MSEK -13.9 (-5.4) and to MSEK -47.2 (-16.3) year to date September 2015.

## Cash flow and investments

Cash flow from operating activities for the third quarter 2015 amounted to MSEK -16.5 (-5.9) and to MSEK -41.9 (-15.8) year to date 2015. The cash flow after financing year to date were positively impacted by the rights issue in April and the proceeds from the sale of warrants to employees. On September 30, 2015, cash and cash equivalents amounted to MSEK 192.6 compared with MSEK 209.1 at the end of the second quarter of 2015. No investments for the third quarter (MSEK 0.6) and to MSEK 1.8 (0.9) year to date 2015.

## Equity

On September 30, 2015, equity amounted to MSEK 230.1 compared with MSEK 244.1 at the end of the second 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 third quarter 2015 were MSEK 0.5 (0) and to MSEK 4.9 (1.5) year to date September 2015. Result after net financial items for the Parent Company for the third quarter 2015 amounted to MSEK -14.1 (-5.4) and to MSEK -46.0 (-16.3) year to date 2015. On September 30, 2015, liquidity amounted to MSEK 190.8 compared with MSEK 207.3 at the end of the second quarter 2015.

The Parent Company's equity amounted to MSEK 230.1 as per September 30, 2015, compared with MSEK 65.0 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

| | Q3 | | January-September | | Year |
|---|---|---|---|---|---|
| KSEK, unless otherwise stated | 2015 | 2014 | 2015 | 2014 | 2014 |
| Net sales | 529 | 0 | 4,905 | 1,461 | 1,618 |
| Operating profit/loss | -13,927 | -5,421 | -47,112 | -16,151 | -24,709 |
| Net profit/loss | -13,932 | -5,425 | -47,162 | -16,271 | -29,042 |
| Earnings per share before and after dilution (SEK) | -0.43 | -0.20 | -1.54 | -0.62 | -1.10 |
| Shareholders' equity | 230,058 | 61,871 | 230,058 | 61,871 | 49,804 |
| Cash flow from operating activities | -16,466 | -5,879 | -41,851 | -15,825 | -23,623 |
| Liquidity | 192,628 | 18,405 | 192,628 | 18,405 | 10,152 |

# Other information

## Employees and organisation

Number of employees at the end of the third quarter 2015 was 18, compared to 11 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.

## Committee for the 2016 Annual General Meeting

Hansa Medical AB's Nomination Committee for the AGM 2016 will consist of Anders Blom representing Nexttobe AB, Fredrik Bogren representing Farstorps Gård AB and Astrid Samuelsson representing Handelsbanken Fonder. It also includes the chairman of the board Birgit Stattin Norinder as convener.

## Financial calendar

| | |
|---|---|
| Year-end report 2015 | 18 February 2016 |
| Annual report 2015 | 31 March 2016 |
| Interim report for January – March 2016 | 27 April 2016 |
| Annual General Meeting | 27 April 2016 |
| Interim report for January–June 2016 | 21 July 2016 |
| Interim report for January–September 2016 | 10 November 2016 |

## Shareholders, September 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 | 2,464,171 | 7.6 |
| Handelsbanken Fonder AB RE JPMEL | 1,013,157 | 3.1 |
| JP Morgan Clearing Corp, W9 | 906,901 | 2.8 |
| SEB London – Luxemburg, (Sicav Fond) | 822,367 | 2.5 |
| Goldman Sachs International Ltd, W8IMY | 696,298 | 2.2 |
| JP Morgan Bank Luxembourg | 530,631 | 1.6 |
| Sven Sandberg | 482,278 | 1.5 |
| Banque Carnegie Luxembourg SA | 480,000 | 1.5 |
| Other | 8,449,487 | 26.1 |
| **In total** | **32,412,003** | **100.0** |

According to the shareholder register maintained by Euroclear Sweden AB, as of September 30, 2015, Hansa Medical had 2,699 shareholders. Information regarding shareholders and shareholdings is updated each quarter on the company's website, www.hansamedical.com.

## Legal disclaimer

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

## Certified Adviser

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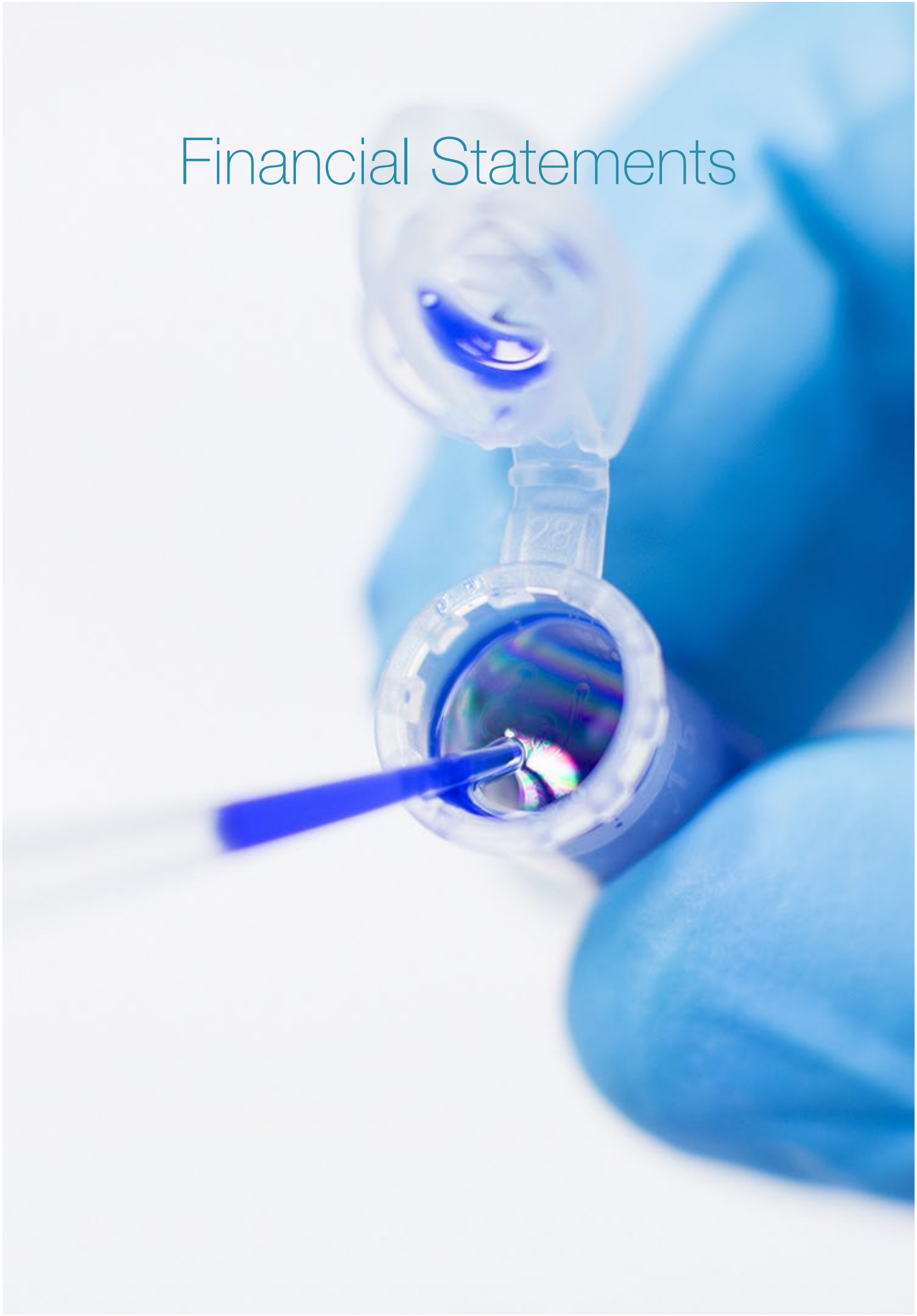
## Registration number

556734-5359

# Financial Statements



# Condensed Financial Statements

## Group – Statement of comprehensive income

| | Q3 | | January–September | | Year |
|---|---|---|---|---|---|
| KSEK | 2015 | 2014 | 2015 | 2014 | 2014 |
| Net sales | 529 | | 4,905 | 1,461 | 1,618 |
| Other operating income | 149 | 877 | 843 | 2,414 | 3,157 |
| **Total operating income** | **678** | **877** | **5,748** | **3,875** | **4,775** |
| | | | | | |
| Sales, general and administration expense | -6,010 | -2,354 | -23,902 | -5,603 | -7,609 |
| Research and development expenses | -8,592 | -3,944 | -28,908 | -14,423 | -21,742 |
| Other operating expenses | -3 | | -50 | | -133 |
| **Operating profit/loss** | **-13,927** | **-5,421** | **-47,112** | **-16,151** | **-24,709** |
| | | | | | |
| Financial income/expenses | -5 | -4 | -50 | -120 | -4,333 |
| **Profit/loss for the period (before and after tax)** | **-13,932** | **-5,425** | **-47,162** | **-16,271** | **-29,042** |
| | | | | | |
| **Attributable to** | | | | | |
| Parent company shareholders | -13,932 | -5,425 | -47,162 | -16,271 | -29,042 |
| | | | | | |
| **Earnings per share** | | | | | |
| Before dilution (SEK) | -0.43 | -0.20 | -1.54 | -0.62 | -1.10 |
| After dilution (SEK) | -0.43 | -0.20 | -1.54 | -0.62 | -1.10 |
| | | | | | |
| **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 | -182 | -958 | 1,151 | -2,768 | -2,064 |
| **Other comprehensive income for the year** | **-182** | **-958** | **1,151** | **-2,768** | **-2,064** |
| | | | | | |
| **Total net comprehensive income** | **-14,114** | **-6,383** | **-46,011** | **-19,039** | **-31,106** |

# Group – Balance sheet

| KSEK | 30 September 2015 | 30 September 2014 | 31 Dec 2014 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible fixed assets | 36,470 | 38,019 | 36,898 |
| Tangible fixed assets | 1,320 | 926 | 1,283 |
| Financial fixed assets | 6,809 | 7,729 | 4,180 |
| **Total non-current assets** | **44,599** | **46,674** | **42,361** |
| | | | |
| **Current assets** | | | |
| Current receivables, non-interest bearing | 2,693 | 1,633 | 1,798 |
| Cash and cash equivalents | 192,628 | 18,405 | 10,152 |
| **Total current assets** | **195,321** | **20,038** | **11,950** |
| | | | |
| **TOTAL ASSETS** | **239,920** | **66,712** | **54,311** |
| | | | |
| **EQUITY AND LIABILITIES** | | | |
| **Shareholders' equity** | **230,058** | **61,871** | **49,804** |
| | | | |
| **Long term liabilities** | **60** | **101** | **91** |
| | | | |
| **Current liabilities** | | | |
| Current liabilities, interest bearing | 41 | 39 | 39 |
| Current liabilities, non-interest bearing | 3,329 | 2,499 | 2,834 |
| Accrued expenses and deferred income | 6,432 | 2,202 | 1,543 |
| **Total current liabilities** | **9,802** | **4,740** | **4,416** |
| | | | |
| **TOTAL EQUITY AND LIABILITIES** | **239,920** | **66,712** | **54,311** |
| | | | |
| Pledged assets | 86 | 142 | 128 |
| Contingent liabilities | None | None | None |

# Group – Changes in equity

| | January–September | | Year |
|---|---|---|---|
| KSEK | 2015 | 2014 | 2014 |
| **Opening shareholders' equity** | 49,804 | 45,349 | 45,349 |
| Result for the year | -47,162 | -16,271 | -29,042 |
| Other comprehensive income for the year | 1,151 | -2,768 | -2,064 |
| **Net comprehensive income** | **-46,011** | **-19,039** | **-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 | -1,481 | -1,481 |
| Issued warrants | 1,933 | | |
| **Total transactions with the group's owner** | **226,265** | **35,561** | **35,561** |
| | | | |
| **Closing shareholders' equity** | **230,058** | **61,871** | **49,804** |

# Group – Cash flow statement

| | Q3 | | January–September | | Year |
|---|---|---|---|---|---|
| KSEK | 2015 | 2014 | 2015 | 2014 | 2014 |
| **Operating activities** | | | | | |
| Operating profit/loss | -13,927 | -5,421 | -47,112 | -16,151 | -24,709 |
| Adjustment for items not included in cash flow | 335 | 53 | 820 | 138 | 1,349 |
| Interest received and paid, net | -5 | -4 | -50 | -120 | -81 |
| Income taxes paid | -49 | -50 | -39 | -32 | -81 |
| **Cash flow from operations before change in working capital** | **-13,646** | **-5,422** | **-46,381** | **-16,165** | **-23,522** |
| | | | | | |
| Change in working capital | -2,820 | -457 | 4,530 | 340 | -101 |
| **Cash flow from operations** | **-16,466** | **-5,879** | **-41,851** | **-15,825** | **-23,623** |
| | | | | | |
| **Investing activities** | | | | | |
| Investments in tangible fixed assets | -6 | -564 | -329 | -758 | -1,204 |
| Investment/Divestment of financial assets | | | -1,479 | -115 | -115 |
| **Cash flow from investing activities** | **-6** | **-564** | **-1,808** | **-873** | **-1,319** |
| | | | | | |
| **Financing activities** | | | | | |
| New share issue | | | 246,331 | 37,042 | 37,042 |
| Issue expenses | | -358 | -21,999 | -1,481 | -1,481 |
| Issued warrants | | | 1,833 | | |
| Repayment of loans | | | | -519 | -519 |
| Repayment of leasing liabilities | -10 | -10 | -30 | -29 | -38 |
| **Cash flow from financing activities** | **-10** | **-368** | **226,135** | **35,013** | **35,004** |
| | | | | | |
| **Net change in cash** | **-16,482** | **-6,811** | **182,476** | **18,315** | **10,062** |
| Cash and cash equivalents, beginning of period | 209,110 | 25,216 | 10,152 | 90 | 90 |
| **Cash and cash equivalents, year-end** | **192,628** | **18,405** | **192,628** | **18,405** | **10,152** |

# Group – Key ratios and other information

| | Q3 | | January–September | | Year |
|---|---|---|---|---|---|
| KSEK, unless otherwise stated | 2015 | 2014 | 2015 | 2014 | 2014 |
| **Profit numbers** | | | | | |
| Total operating income | 678 | 877 | 5,748 | 3,875 | 4,775 |
| Operating profit/loss | -13,927 | -5,421 | -47,112 | -16,151 | -24,709 |
| Net profit/loss | -13,932 | -5,425 | -47,162 | -16,271 | -29,042 |
| | | | | | |
| **Per share data** | | | | | |
| Earnings/loss per share before and after dilution (SEK) | -0.43 | -0.20 | -1.54 | -0.62 | -1.10 |
| Shareholders' equity per share (SEK) | 7.10 | 2.39 | 7.10 | 2.39 | 1.92 |
| | | | | | |
| **Other information** | | | | | |
| Equity ratio (%) | 96 | 93 | 96 | 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 | 32,412,003 | 27,301,397 | 30,708,468 | 26,275,869 | 26,471,803 |

# Parent Company – Statement of comprehensive income

| | Q3 | | January–September | | Year |
|---|---|---|---|---|---|
| KSEK | 2015 | 2014 | 2015 | 2014 | 2014 |
| Net sales | 529 | | 4,905 | 1,461 | 1,618 |
| Other operating income | 149 | 877 | 843 | 2,414 | 3,157 |
| **Total operating income** | **678** | **877** | **5,748** | **3,875** | **4,775** |
| | | | | | |
| Sales, general and administration expense | -6,007 | -2,354 | -23,892 | -5,608 | -7,615 |
| Research and development expenses | -8,592 | -3,944 | -28,908 | -14,423 | -21,742 |
| Other operating expenses | -3 | | -50 | | -133 |
| **Operating profit/loss** | **-13,924** | **-5,421** | **-47,102** | **-16,156** | **-24,715** |
| | | | | | |
| Result from participating interests in group companies | | | | | -2,398 |
| Result from other securities and receivables which are fixed assets | -182 | | 1,151 | | -4,252 |
| Other financial income | | | | | 42 |
| Other financial expenses | -3 | -3 | -45 | -114 | -115 |
| **Profit/loss for the period (before and after taxes)** | **-14,109** | **-5,424** | **-45,996** | **-16,270** | **-31,438** |

# Parent Company – Balance sheet

| | 30 September | | 31 Dec |
|---|---|---|---|
| KSEK | 2015 | 2014 | 2014 |
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible fixed assets | 36,470 | 38,019 | 36,898 |
| Tangible fixed assets | 1,234 | 783 | 1,155 |
| Financial fixed assets | 8,742 | 10,831 | 4,280 |
| **Total non-current assets** | **46,446** | **49,633** | **42,333** |
| | | | |
| **Current assets** | | | |
| Current receivables non-interest bearing | 2,692 | 1,637 | 1,798 |
| Cash and cash equivalents | 190,795 | 18,405 | 10,152 |
| **Total current assets** | **193,487** | **20,042** | **11,950** |
| | | | |
| **TOTAL ASSETS** | **239,933** | **69,675** | **54,283** |
| | | | |
| **EQUITY AND LIABILITIES** | | | |
| **Shareholders' equity** | **230,075** | **64,974** | **49,806** |
| | | | |
| **Current liabilities** | | | |
| Liabilities to group companies | 98 | | 100 |
| Current liabilities, non-interest bearing | 3,328 | 2,499 | 2,834 |
| Accrued expenses and deferred income | 6,432 | 2,202 | 1,543 |
| **Total current liabilities** | **9,858** | **4,701** | **4,477** |
| | | | |
| **Total equity and liabilities** | **239,933** | **69,675** | **54,283** |
| | | | |
| Pledged assets | None | None | None |
| Contingent liabilities | None | None | None |

# Parent Company – Changes in equity

| | January–September | | Year |
|---|---|---|---|
| KSEK | 2015 | 2014 | 2014 |
| **Opening shareholders' equity** | **49,806** | **45,683** | **45,683** |
| Result for the year | -45,996 | -16,270 | -31,438 |
| New share issue | 246,331 | 37,042 | 37,042 |
| Expenses attributable to new share issue | -21,999 | -1,481 | -1,481 |
| Issued warrants | 1,933 | | |
| **Closing shareholders' equity** | **230,075** | **64,974** | **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. A full description of the accounting principles applied in this interim report can be found in the Year-End Report 2014 except that the company has switched from a cost type-based Income statement to a function-based. The Year-End Report 2014 was published on February 13, 2015. It is 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 2015-09-30 was KSEK 6,809 and 7,729 per 2014-09-30 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

**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.

**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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