Hansa Medical

Year-End Report 2015

Several significant milestones reached in 2015

January–December 2015 in summary – Highlights

October – December

- Hansa Medical's shares began trading on Nasdaq Stockholm on November 2, 2015
- Data from the first patient in the ongoing US study with IdeS in highly sensitized patients presented at Hansa Medical's Capital Markets Day on November 13, 2015, showed that one dose of IdeS effectively inactivates donor specific antibodies
- Data published in *Journal of Immunology* shows that IdeS temporarily can silence B-cells, preventing B-cells from developing into antibody producing cells

January – September

- Phase II clinical study of IdeS in highly sensitized patients awaiting kidney transplantation successfully completed
- Development of new generation of IdeS molecules for repeat dosing announced
- US medical advisory board established
- First patient in second IdeS Phase II study at Uppsala University Hospital transplanted
- Positive data on IdeS Phase I study published in scientific journal *PLOS ONE*
- First patient treated and transplanted with IdeS in investigator sponsored US Phase II study at Cedars-Sinai Medical Center, Los Angeles
- FDA Orphan Drug Designation for IdeS in solid organ transplant patients received
- First Phase II study of IdeS in sensitized kidney transplantation patients presented at *ESOT* 2015
- Hansa Medical secured MSEK 246 in funding through a fully subscribed rights issue
- Göran Arvidson appointed new President and CEO of Hansa Medical
- Results from a clinical multicenter trial with HBP-assay published in *Critical Care Medicine*

Financial summary Fourth quarter and Full Year

- Net revenue for the group in Q4 amounted to MSEK 0.5 (0.2). Full year: MSEK 5.4 (1.6)
- Operating result in Q4 was MSEK -19.1 (-8.6). Full year: MSEK -66.2 (-24.7)
- Consolidated net result in Q4 was MSEK -19.1 (-12.8). Full year: MSEK -66.3 (-29.0)
- Earnings per share before and after dilution in Q4 were SEK -0.59 (-0.47). Full year: SEK -2.13 (-1.09)
- Cash position on December 31, 2015, of MSEK 175.7 (10.2)

"We are very pleased with the progress and preliminary results of the two ongoing clinical studies and expect patient enrollment to be completed in Q1 and Q2 2016, respectively. To date, 11 sensitized patients have been treated with IdeS and then transplanted."

Göran Arvidson, President and CEO of Hansa Medical

Financial summary for the Group

	Q4		Year	
KSEK, unless otherwise stated	2015	2014	2015	2014
Net revenue	529	157	5,434	1,618
Operating profit/loss	-19,089	-8,558	-66,201	-24,709
Net profit/loss	-19,104	-12,771	-66,266	-29,042
Earnings per share before and after dilution (SEK)	-0.59	-0.47	-2.13	-1.09
Shareholders' equity	211,526	49,804	211,526	49,804
Cash flow from operating activities	-15,948	-7,798	-57,799	-23,623
Liquidity	175,683	10,152	175,683	10,152

CEO Statement

2015 was, in many ways, a truly remarkable year for Hansa Medical. We reached a number of important milestones and continued to pave the way to build a biopharmaceutical company with a product candidate that has the potential to significantly improve health outcomes in patients.

Much of our work centered on our lead project IdeS, which continues to attract attention in the international scientific community. In July, results from the clinical Phase I study were published in the scientific journal PLOS ONE. Later, in the autumn, data from the subsequent successful Phase II study in sensitized kidney transplantation patients were presented at the 17th Congress of the European Society for Organ Transplantation.

The study results showed that a single dose of IdeS rapidly and efficiently inactivates IgG in humans. This makes it an attractive therapeutic approach for acute IgG-mediated conditions. The data clearly supports further development in the area of transplantation and supports our decision to keep this as our main focus right now. IdeS ability to reduce anti-HLA antibodies to levels acceptable for transplantation strengthens our belief in and commitment to this exciting project.

Also during the year, we initiated two additional clinical Phase II studies; one at Uppsala University Hospital and one investigator-sponsored study at Cedars-Sinai Medical Center in Los Angeles, led by the renowned transplantation expert Professor Stanley Jordan. Professor Jordan also participated as one of several keynote speakers at our Capital Markets Day in Stockholm last November. All in all, we are very pleased with the progress and preliminary results of the two ongoing clinical studies and expect patient enrollment to be completed in Q1 and Q2 2016, respectively. To date, 11 sensitized patients have been treated with IdeS and then transplanted.

In May, we announced the inception of a US medical advisory board for IdeS in kidney transplantation. The board will assist the company in developing IdeS within transplantation in sensitized patients. Apart from Professor Jordan as chairman, the board consists of Professor Robert Montgomery from Johns Hopkins Medicine in Baltimore, and Professor Kathryn Wood from University of Oxford. Professor Wood is also on the previously initiated European advisory board with the European transplantation experts Professor Gunnar Tufveson, Uppsala University Hospital and Professor Christophe Legendre at Necker Hospital in Paris.

Together with these experts, and our highly motivated team of scientists in Lund, we intend to build upon current success and continue with the development of IdeS in the field of transplantation.

This strategy was further bolstered by being awarded Orphan Drug Designation for IdeS for the prevention of antibody-mediated organ rejection in patients undergoing all types of solid organ transplants. Human Leukocyte Antigen (HLA) sensitization constitutes a significant barrier for transplantation for thousands of patients annually.

Approximately 30 percent[1] 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 HLA. Gaining Orphan Drug Status is an important step closer to helping those with HLA sensitization.

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. However, they have a negligible chance of being transplanted using the current protocols. We believe that IdeS can be a life-saving treatment to allow transplantation of these patients. We are planning to initiate a clinical trial in this category of patients in the US shortly. 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 bring us closer to approval to market IdeS in this patient group.

In addition to transplantation, we plan to further broaden the potential disease indications that can be treated with IdeS, including rare and serious acute autoimmune diseases within neurology, nephrology and hematology. We aim to initiate company or investigator sponsored studies to be able to show Proof of Concept in these patient groups.

Besides the scientific milestones last year, we also secured the necessary capital to ensure that our operations and our R&D efforts are well funded. The rights issue last year gave us the financial strength and flexibility to continue this focused drive to achieve our objectives to take a product to market as soon as possible and to affect better health in patients quickly and efficiently. In 2016, we intend to build on the successes we had in 2015 and follow the path that we have carefully and strategically laid out in order to provide greater value to our shareholders and better health outcomes for all those who can benefit from our work.

Göran Arvidson
President and CEO

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[1] Jordan et al. British Medical Bulletin, 2015, 114:113–125

Hansa Medical in brief

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. 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 Stockholm.

Business Review January – December 2015

Hansa Medical received 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).

Positive IdeS Phase I data published in scientific journal PLOS ONE[1]
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 from Hansa Medical's first Phase II study of IdeS in sensitized kidney transplantation patients 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 showed 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. Stable graft function has been maintained to date (18 months) with normal creatinine and no rejection episodes.

Development of a new generation of IdeS molecules for repeat dosing announced
In 2015, Hansa Medical announced the ongoing development of a new generation of molecules based on IdeS that will have the potential of repeat dosing and thereby broadening the therapeutic opportunities into more chronic disease areas. The new generation IdeS molecules reduce anti-drug antibody binding and have reduced immunogenicity as well as increased specific activity.

IdeS Phase II study initiated at Uppsala University Hospital and Karolinska University Hospital
A second Phase II study with IdeS was initiated at Uppsala University Hospital and Karolinska University Hospital in Huddinge. The study will evaluate the safety, tolerability and efficacy of IdeS in kidney transplantation of sensitized patients. Up to 10 patients will be included in the study. All patients will undergo kidney transplantation and it is expected that top-line results will be available around half-year 2016.

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 in highly sensitized patients. The study will include 10-20 highly sensitized patients. At Hansa Medical's Capital Markets Day in Stockholm on November 13, 2015, principle investigator Professor Stanley Jordan, presented data regarding the first patient included in the study. The data showed that the patient had been successfully desensitized with IdeS and subsequently transplanted.

[1] Winstedt el al. (2015) PLOS ONE 10(7)

Data published in Journal of Immunology showed that IdeS can silence memory B-cells[1]

The scientific article entitled "The bacterial enzyme IdeS cleaves the IgG-type of B-cell receptor, abolishes BCR-mediated cell signaling and inhibits memory B-cell activation", by Järnum et al., shows that IdeS not only inactivates plasma IgG but also cleaves IgG present on B-cells. The IdeS-treated cells are temporarily silenced and prevented from developing into antibody producing cells. In transplantation, a delay in the activation of memory B-cells and production of IgG could help the organ to accommodate in its new host. Furthermore, the concept indicates therapeutic possibilities not only in transplantation but also in other situations where a memory B-cell response must be prevented or delayed.

Hansa Medical established a US medical advisory board

Hansa Medical AB established a US medical advisory board for IdeS in kidney transplantation with world leading experts in desensitization and transplantation. The board will assist the company in developing IdeS within transplantation in sensitized patients. The US medical advisory board consists of Professor Stanley Jordan (chairman) at Cedars-Sinai Medical Center, Los Angeles, Professor Robert Montgomery, Johns Hopkins Medicine, Baltimore and Professor Kathryn Wood, University of Oxford.

Göran Arvidson appointed new President and CEO of Hansa Medical

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

Hansa Medical secured MSEK 246 in funding through a fully subscribed rights issue

Hansa Medical raised MSEK 246 before emission costs, through a fully subscribed rights issue with preferential rights. The rights issue comprised of 6,482,400 shares at SEK 38 per share. The proceeds will enable Hansa Medical to bring the candidate drug IdeS into several clinical Phase II trials as well as preparing the IdeS production process for clinical pivotal studies and product launch.

Results from a clinical multicenter trial with HBP-assay published in Critical Care Medicine[2]

Results from a clinical multicenter trial with samples from Emergency Departments in Sweden, the US and Canada collected during 2011-2014 was published by the scientific journal Critical Care Medicine. The study results showed 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.

[1)] The Journal of Immunology, December 15, 2015, vol. 195 no. 12 5592-5601

[2)] Critical Care Medicine. 43(11):2378-2386, November 2015

Project Overview

Pipeline

Candidate/Method	Indication	Research/ Preclinical	Phase I [1]	Phase I/II	Phase II	Phase II/III	Registration
IdeS	Sensitized kidney transplantation 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 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] Pilot 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, 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 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) [5]. 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 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 [6]. 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.

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 [7].

[5] Jordan et al. British Medical Bulletin, 2015, 114:113–125

[6] Montgomery et al., N Engl J Med 2011;365:318-26

[7] Winstedt el al. (2015) PLOS ONE 10(7)

First clinical Phase I/II in sensitized patients with IdeS successfully completed

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 (18 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 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. Professor 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 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 in combination 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 pivotal studies in highly sensitized patients

The first Phase I/II study completed with IdeS clearly demonstrated that IdeS effectively inactivates 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 in other indications

Several additional indications are being planned for Phase II trials including antibody mediated graft rejection (AMR) and the rare and acute autoimmune conditions Thrombotic Thrombocytopenic Purpura (TPP) and anti-GBM disease. Hansa Medical has initiated a 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 pilot Phase II trial with IdeS in Guillian Barré syndrome (GBS) in collaboration with Professor Attarian and Hôpital de la Timone.

Approximately ten percent [1] 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 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 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.

IdeS, with its rapid and effective elimination of IgG, has the potential to be an excellent therapeutic option leading to a significant reduction in morbidity and mortality in these indications and Hansa Medical plans to initiate pilot Phase II trials in these indications during 2016.

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.

[1] Journal of Transplantation Volume 2012 (2012), Article ID 193724

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[1]

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 (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 rights to royalties from Axis-Shield derived from sales and sublicensing of the HBP-assay as well as milestones payments.

[1] Critical Care Medicine. 43(11):2378-2386, November 2015

Financial Review January – December 2015

Net revenue

Net revenue for the fourth quarter 2015 amounted to MSEK 0.5 (0.2) and to MSEK 5.4 (1.6) for the full year 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 fourth quarter 2015 amounted to MSEK -19.1 (-8.6) and to MSEK -66.2 (-24.7) for the full year 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 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 1.2 in the quarter and MSEK 10.8 for the full year 2015, the majority classified as administrative expenses.

Net profit/loss for the fourth quarter 2015 amounted to MSEK -19.1 (-12.8) and to MSEK -66.3 (-29.0) for the full year 2015.

Cash flow and investments

Cash flow from operating activities for the fourth quarter 2015 amounted to MSEK -15.9 (-7.8) and to MSEK -57.8 (-23.6) for the full year 2015. The cash flow after financing was positively impacted by the rights issue in April and the proceeds from the sale of warrants to employees. On December 31, 2015, cash and cash equivalents amounted to MSEK 175.7 compared with MSEK 192.6 at the end of the third quarter 2015. Investments for the fourth quarter amounted to MSEK 1.0 (0.5) and to MSEK 2.8 (1.3) for the full year 2015.

Equity

On December 31, 2015, equity amounted to MSEK 211.5 compared with MSEK 230.1 at the end of the third 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 246.3 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 revenue for the fourth quarter 2015 were MSEK 0.5 (0.2) and to MSEK 5.4 (1.6) for the full year 2015. Result after net financial items for the Parent Company for the fourth quarter 2015 amounted to MSEK -18.6 (-15.2) and to MSEK -64.6 (-31.4) for the full year 2015. On December 31, 2015, liquidity amounted to MSEK 173.8 compared with MSEK 190.8 at the end of the third quarter 2015.

The Parent Company's equity amounted to MSEK 211.5 as per December 31, 2015, compared with MSEK 49.8 the end of 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

	Q4		Year	
KSEK, unless otherwise stated	2015	2014	2015	2014
Net revenue	529	157	5,434	1,618
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Liquidity	175,683	10,152	175,683	10,152

Other information

Employees and organisation

Number of employees at the end of the fourth quarter 2015 was 19, compared to 14 at the end of 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, except the CEO, have been given a one-time bonus as part of the stock option purchase. The options are linked to continued employment with the company only in the sense that, if the employment would be terminated, the stock option owner shall offer the warrants to the company and repay the resulting subsidy. The subsidy will affect the company's results proportionately during the option period in accordance with 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.

Financial calendar

Annual report 2015	March 31, 2016
Interim report for January–March 2016	April 27, 2016
Annual General Meeting	April 27, 2016
Interim report for January–June 2016	July 21, 2016
Interim report for January–September 2016	November 10, 2016

Shareholders, December 31, 2015

Name	Number of Shares	Percentage (%)
Nexttobe AB	9,443,761	29.14
Fam Håkansson, incl. Farstorps Gård AB	5,350,182	16.51
Avanza Pension	2,271,847	7.01
Handelsbanken Fonder	1,114,913	3.44
Rhenman Healthcare Equity L/S	822,367	2.54
JP Morgan Bank Luxembourg	560,631	1.73
Shaps Capital AB	557,000	1.72
Banque Carnegie Luxembourg SA	505,000	1.56
SEB Enskilda	485,969	1.50
Sven Sandberg	476,278	1.47
Other	10,819,127	33.38
In total	**32,412,003**	**100.0**

According to the shareholder register maintained by Euroclear Sweden AB, as of December 31, 2015, Hansa Medical had 3,050 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.

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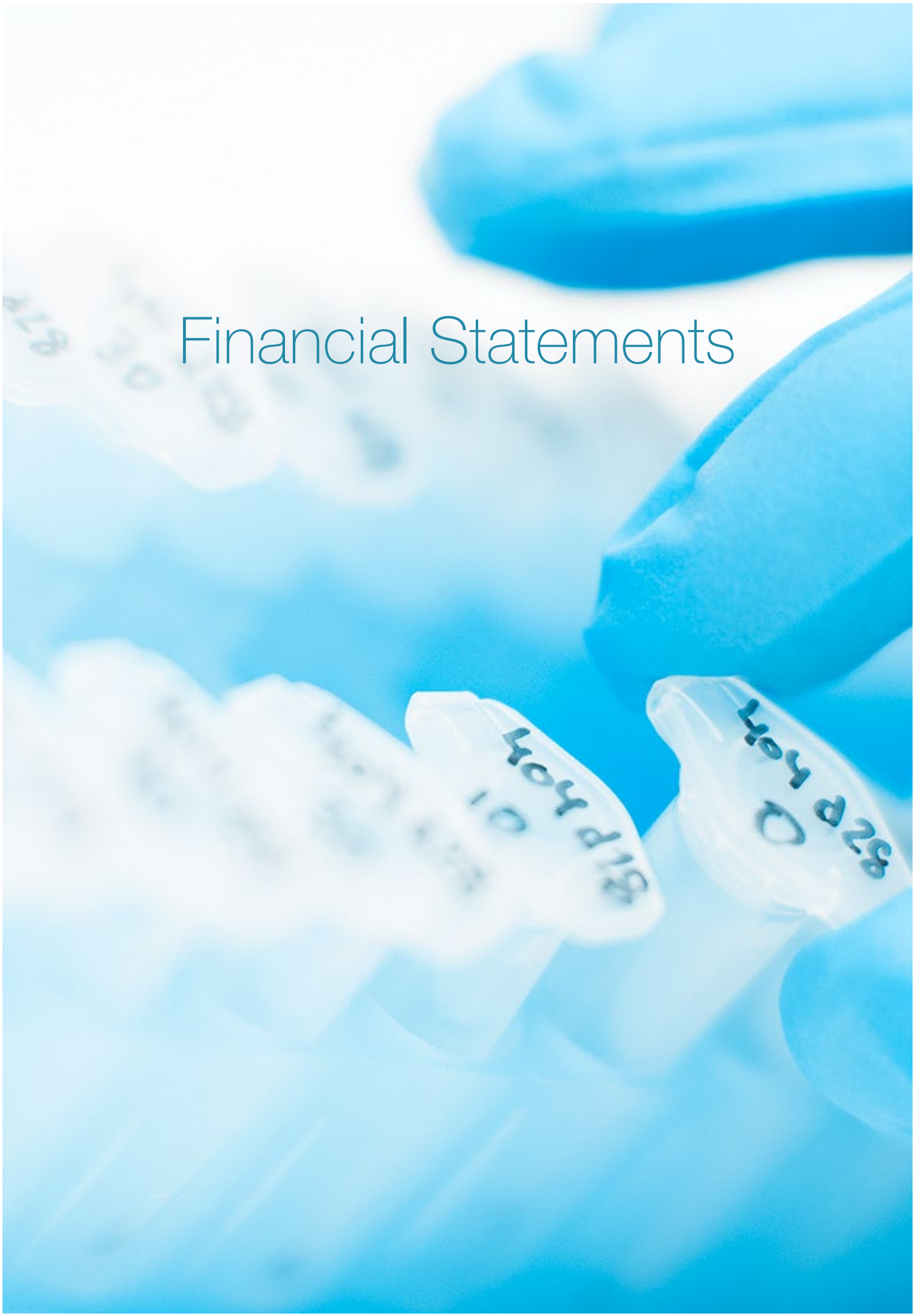
Financial Statements



Condensed Financial Statements

Group – Statement of comprehensive income

	Q4		Year	
KSEK	2015	2014	2015	2014
Net revenue	529	157	5,434	1,618
Other operating income	806	743	1,721	3,157
Total operating income	**1,335**	**900**	**7,155**	**4,775**
Direct cost of net revenue	-658		-658	
Gross profit	**677**	**900**	**6,497**	**4,775**
Sales, general and administration expense	-4,339	-2,006	-28,241	-7,609
Research and development expenses	-15,354	-7,319	-44,262	-21,742
Other operating expenses	-73	-133	-195	-133
Operating profit/loss	**-19,089**	**-8,558**	**-66,201**	**-24,709**
Financial income/expenses	-15	-4,213	-65	-4,333
Profit/loss for the period (before and after taxes)	**-19,104**	**-12,771**	**-66,266**	**-29,042**
Attributable to				
Parent company shareholders	-19,104	-12,771	-66,266	-29,042
Earnings per share				
Before dilution (SEK)	-0.59	-0.47	-2.13	-1.09
After dilution (SEK)	-0.59	-0.47	-2.13	-1.09
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	473	703	1,624	-2,064
Other comprehensive income for the year	**473**	**703**	**1,624**	**-2,064**
Total net comprehensive income	**-18,631**	**-12,068**	**-64,642**	**-31,106**

Group – Balance sheet

KSEK	December 31 2015	2014
ASSETS		
Non-current assets		
Intangible fixed assets	36,327	36,898
Tangible fixed assets	2,182	1,283
Financial fixed assets	7,283	4,180
Total non-current assets	**45,792**	**42,361**
Current assets		
Current receivables, non-interest bearing	2,613	1,798
Cash and cash equivalents	175,683	10,152
Total current assets	**178,296**	**11,950**
TOTAL ASSETS	**224,088**	**54,311**
EQUITY AND LIABILITIES		
Shareholders' equity	**211,526**	**49,804**
Long term liabilities	**49**	**91**
Current liabilities		
Current liabilities, interest bearing	42	39
Current liabilities, non-interest bearing	2,294	2,834
Accrued expenses and deferred income	10,177	1,543
Total current liabilities	**12,513**	**4,416**
TOTAL EQUITY AND LIABILITIES	**224,088**	**54,311**
Pledged assets	72	128
Contingent liabilities	None	None

Group – Changes in equity

	Year	
KSEK	2015	2014
Opening shareholders' equity	**49,804**	**45,349**
Result for the year	-66,266	-29,042
Other comprehensive income for the year	1,624	-2,064
Net comprehensive income	**-64,642**	**-31,106**
Transactions with the group's owner		
New share issue	246,331	37,042
Expenses attributable to new share issue	-21,999	-1,481
Issued warrants	2,032	
Total transactions with the group's owner	**226,364**	**35,561**
Closing shareholders' equity	**211,526**	**49,804**

Group – Cash flow statement

	Q4		Year	
KSEK	2015	2014	2015	2014
Operating activities				
Operating profit/loss	-19,089	-8,558	-66,201	-24,709
Adjustment for items not included in cash flow	368	1,211	1,188	1,349
Interest received and paid, net	-15	39	-65	-81
Income taxes paid	223	-49	184	-81
Cash flow from operations before change in working capital	**-18,513**	**-7,357**	**-64,894**	**-23,522**
Change in working capital	2,565	-441	7,095	-101
Cash flow from operating activities	**-15,948**	**-7,798**	**-57,799**	**-23,623**
Investing activities				
Investments in tangible fixed assets	-988	-446	-1,317	-1,204
Investment/Divestment of financial assets			-1,479	-115
Cash flow from investing activities	**-988**	**-446**	**-2,796**	**-1,319**
Financing activities				
New share issue			246,331	37,042
Issue expenses			-21,999	-1,481
Issued warrants			1,833	
Repayment of loans				-519
Repayment of leasing liabilities	-9	-9	-39	-38
Cash flow from financing activities	**-9**	**-9**	**226,126**	**35,004**
Net change in cash	**-16,945**	**-8,253**	**165,531**	**10,062**
Cash and cash equivalents, beginning of period	192,628	18,405	10,152	90
Cash and cash equivalents, year-end	**175,683**	**10,152**	**175,683**	**10,152**

Group – Key ratios and other information

	Q4		Year	
KSEK, unless otherwise stated	2015	2014	2015	2014
Profit numbers				
Total operating income	1,335	900	7,155	4,775
Operating profit/loss	-19,089	-8,558	-66,201	-24,709
Net profit/loss	-19,104	-12,771	-66,266	-29,042
Per share data				
Earnings/loss per share before and after dilution (SEK)	-0.59	-0.47	-2.13	-1.09
Shareholders' equity per share (SEK)	6.53	1.92	6.53	1.92
Other information				
Equity ratio (%)	94	92	94	92
Liquidity	175 683	10 152	175 683	10 152
Number of outstanding shares at the end of the period	32,412,003	25,929,603	32,412,003	25,929,603
Weighted average number of shares, before and after dilution	32,412,003	27,301,397	31,137,852	26,544,329

Parent Company – Statement of comprehensive income

	Q4		Year	
KSEK	2015	2014	2015	2014
Net revenue	529	157	5,434	1,618
Other operating income	806	743	1,721	3,157
Total operating income	**1,335**	**900**	**7,155**	**4,775**
Direct cost of net revenue	-658		-658	
Gross profit	**677**	**900**	**6,497**	**4,775**
Sales, general and administration expense	-4,336	-2,007	-28,228	-7,615
Research and development expenses	-15,354	-7,319	-44,262	-21,742
Other operating expenses	-73	-133	-195	-133
Operating profit/loss	**-19,086**	**-8,559**	**-66,188**	**-24,715**
Result from participating interests in group companies		-2,398		-2,398
Result from other securities and receivables which are fixed assets	473	-4,252	1,624	-4,252
Other financial income		42		42
Other financial expenses	-14	-1	-59	-115
Profit/loss for the period (before and after taxes)	**-18,627**	**-15,168**	**-64,623**	**-31,438**
Other comprehensive income for the year	**0**	**0**	**0**	**0**
Total net comprehensive income	**-18,627**	**-15,168**	**-64,623**	**-31,438**

Parent Company – Balance sheet

	December 31	
KSEK	2015	2014
ASSETS		
Non-current assets		
Intangible fixed assets	36,327	36,898
Tangible fixed assets	2,110	1,155
Financial fixed assets	9,216	4,280
Total non-current assets	**47,653**	**42,333**
Current assets		
Current receivables non-interest bearing	2,612	1,798
Cash and cash equivalents	173,850	10,152
Total current assets	**176,462**	**11,950**
TOTAL ASSETS	**224,115**	**54,283**
EQUITY AND LIABILITIES		
Shareholders' equity	**211,547**	**49,806**
Current liabilities		
Liabilities to group companies	98	100
Current liabilities, non-interest bearing	2,293	2,834
Accrued expenses and deferred income	10,177	1,543
Total current liabilities	**12,568**	**4,477**
Total equity and liabilities	**224,115**	**54,283**
Pledged assets	None	None
Contingent liabilities	None	None

Parent Company – Changes in equity

	Year	
KSEK	2015	2014
Opening shareholders' equity	**49,806**	**45,683**
Result for the year	-64,623	-31,438
New share issue	246,331	37,042
Expenses attributable to new share issue	-21,999	-1,481
Issued warrants	2,032	
Closing shareholders' equity	**211,547**	**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 is listed on Nasdaq First North. The fair value of the shares as per the balance sheet date 2015-12-31 was KSEK 7,283 and 4,180 per 2014-12-31. The fair value of the shares is 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.

Glossary

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.

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 immunoglobulins.

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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