Hansa Medical

Interim report April – June 2016

Continued positive development of IdeS in clinical studies

Second quarter in brief

Business highlights

- US Food and Drug Administration (FDA) cleared Hansa Medical's IND application for a study with IdeS in kidney transplantation
- All patients are recruited and successfully desensitized in Swedish Phase II study with IdeS in kidney transplantation
- Successful desensitization with IdeS in all recruited patients in ongoing US Phase II study with kidney transplantation
- Hansa Medical appointed Henk Doude van Troostwijk as Vice President, Commercial Operations
- Annual General Meeting elected Ulf Wiinberg as new chairman of the board and Angelica Loskog as new member of the board

Significant events after the period

- Hansa Medical initiated a pivotal multicenter U.S. study with IdeS for treatment of refractory highly sensitized kidney patients
- Hansa Medical acquired rights to cancer immunotherapy using antibody modulating enzymes

Financial summary

- Net revenue for the group in Q2 amounted to MSEK 0.5 (0.5). YTD: MSEK 1.1 (4.4).
- Operating result in Q2 was MSEK -30.7 (-22.5). YTD: MSEK -50.6 (-33.2).
- Consolidated net result in Q2 was MSEK -30.7 (-22.5). YTD: MSEK -50.6 (-33.2).
- Earnings per share before and after dilution in Q2 were SEK -0.95 (-0.70). YTD: SEK -1.56 (-1.11).
- Cash position including short-term investments on June 30, 2016, of MSEK 133.7.

"I am very pleased to report that all Phase II studies are progressing nicely as planned. The advancement includes the start of a Hansa sponsored multicenter study initiated at Cedars-Sinai Medical Center in Los Angeles. The IND clearance from the FDA sets the path towards product approval in the US. We are now about to start clinical studies with IdeS in other orphan indications and we will explore combination use in cancer immunotherapy."

Göran Arvidson, President and CEO of Hansa Medical

Hansa Medical in brief

Hansa Medical AB (publ) is a biopharmaceutical company focusing on novel immunomodulatory enzymes. The lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Additional projects focus on development of novel antibody modulating enzymes, as well as HBP, a diagnostic biomarker for prediction of severe sepsis at emergency departments that is already introduced on the market. The company is based in Lund, Sweden. Hansa Medical's share (ticker: HMED) is listed on Nasdaq OMX Stockholm. www.hansamedical.com

CEO statement

I am very pleased to report that all Phase II studies are progressing nicely as planned. The advancement includes the start of a Hansa sponsored multicenter study initiated at Cedars-Sinai Medical Center in Los Angeles. The IND clearance from the FDA sets the path towards product approval in the US. We are now about to start clinical studies with IdeS in other orphan indications and we will explore combination use in cancer immunotherapy.

As previously announced, the Swedish study is now fully recruited. This, together with the interim results that we have been able to present, as well as encouraging progress of the investigator initiated study in the US, gives me great reason to be very optimistic about the future of our lead candidate IdeS. And of Hansa Medical.

The FDA clearance of the IND and the start of a pivotal clinical study – HighdeS – in the US to evaluate the efficacy of IdeS in making highly sensitized kidney patients with positive crossmatches eligible for transplantation by removing donor specific antibodies are important milestones for Hansa Medical, which are two more benchmarks that are helping to define the path toward product approval.

In June, Professor Stanley Jordan, who heads the investigator-sponsored Phase II clinical study at Cedars-Sinai Medical Center, presented initial data from the trial at the 2016 American Transplant Congress in Boston. The data showed that IdeS completely eliminates donor specific antibodies and allows for kidney transplantation in all sensitized patients. All ten included patients have been successfully desensitized and subsequently transplanted.

We are of course very encouraged by these results. Equally uplifting are the interim results from our Swedish Phase II clinical study, conducted at Uppsala University Hospital and Karolinska University Hospital, Huddinge. The study, which was fully recruited in the second quarter of this year, primarily evaluates safety and tolerability of IdeS in sensitized kidney transplantation patients. Dr. Tomas Lorant, who is the principal investigator, will present the results at the 26th International Congress of the Transplantation Society in Hong Kong in August of this year. In the abstract published ahead of the presentation, Dr. Lorant and co-authors conclude that IdeS treatment significantly reduced the level of HLA antibodies and eliminated complement (C1q) binding antibodies.

Hansa Medical's clinical development program of IdeS is currently focused on treatment prior to kidney transplantation, but our vision is to establish IdeS as an IgG-eliminating therapy in several IgG-driven autoimmune diseases and in several sub-sets of transplant indications.

The effective and fast IgG-cleaving mode-of-action makes treatment with IdeS highly relevant to evaluating the efficacy and safety in many IgG-driven rare autoimmune indications. The three acute conditions TTP (Thrombotic Thrombocytopenic Purpura), GBS (Guillain-Barré syndrome) and anti-GBM disease are among a number of diseases in which it is relevant to evaluate the treatment potential of IdeS. We aim to initiate Phase II clinical studies for proof-of-concept in these devastating acute conditions, starting with TTP.

Our preclinical programs are progressing nicely as well. Under the project name NiceR (Novel immunoglobulin cleaving enzymes for Repeat dosing) we are developing completely new IgG-degrading enzymes aimed for repeat dosing in autoimmune diseases. Further on, EndoS is an enzyme that modulates IgG antibodies by cleaving the important Fc bound glycan in IgG. EndoS has proven effective in a range of autoimmune preclinical models and confirmatory mechanistic studies are ongoing as well as preparations for toxicology studies.

EnzE - Enzyme based antibody Enhancement – is a recently added development program. Preclinical research performed at the University of Oxford indicated that using IdeS or EndoS prior to an antibody based cancer immunotherapy, like anti-CD20 in the treatment of lymphoma and leukemia, has the potential to increase the efficacy and improve outcome for patients suffering from cancer diseases. Our researchers have independently verified and extended the research findings on the EnzE concept and in July 2016, we subsequently acquired all patent rights to these findings through the acquisition of UK-based Immago Biosystems.

Taken together, these research programs give me great hope for an exciting time ahead of us. We plan to share more details on all these programs when we host our annual Capital Markets Day later this year. More information regarding our annual Capital Markets Day will follow.

At the Annual General Meeting on May 11, Ulf Wiinberg and Angelica Loskog were elected new board members. Ulf, who was elected new chairman, and Angelica bring both strength and expertise to the company.

Over the last twelve months, we have continued to build a strong team at Hansa Medical. We are now 21 employees in all, and plan to add more competence to the organization, as we get closer to the commercialization phase. In the second quarter, we appointed Henk Doude van Troostwijk as Vice President of Commercial Operations. His focus includes creating market access, pricing and reimbursement strategies for the company. The appointment of Henk comes at a deciding time when we have passed several important scientific milestones on our road to take product to market. This will benefit all our stakeholders, not the least the patients.

Göran Arvidson
President and CEO of Hansa Medical

Business overview

Pipeline

Candidate/ Method/Project	Indication	Research/ Preclinical	Phase I [1]	Phase I/II	Phase II	Pivotal	Registration
THERAPEUTICS							
IdeS	Kidney transplantation in sensitized patients[2]						
	Antibody mediated kidney transplant rejection						
	Thrombotic Thrombocytopenic Purpura						
	Other acute autoimmune diseases[3]						
NiceR	Recurring treatment in autoimmune disease						
EndoS	Autoimmune disease						
EnzE	Cancer Immunotherapy						
DIAGNOSTICS							
HBP-assay (IVD)	Prediction of severe sepsis[4]						

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

[2] Three separate Phase II studies are currently ongoing. One study in Sweden (Uppsala/Huddinge) and two in the US (Cedars-Sinai Medical Center, Los Angeles).

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

[4] Outlicensed to Axis-Shield Diagnostics Ltd.

Lead Candidate IdeS

IdeS – A novel therapeutic principle

The candidate drug IdeS constitutes a unique and novel approach to rapidly and effectively eliminate pathogenic IgG antibodies. IdeS, Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, is an enzyme that specifically and rapidly cleaves immunoglobulin G (IgG). Several autoimmune diseases are characterized by pathogenic IgG antibodies. In organ and tissue transplantation, pathogenic IgG antibodies can both prevent patients from becoming transplanted or cause organ rejection after transplantation.

Hansa Medical develops IdeS as a single intravenous treatment for fast and effective elimination of pathogenic IgG antibodies in transplantation and autoimmune diseases. The clinical development program is currently focused on treatment prior to kidney transplantation but the vision for Hansa Medical is to establish IdeS as an IgG eliminating therapy in several autoimmune diseases and in several sub-sets of transplant indications.

In 2014, a Phase I clinical trial including 29 healthy subjects was finalized, demonstrating IdeS as efficacious and well tolerated with a favorable safety profile[1].

IdeS – Desensitization prior to kidney transplantation

Approximately one third of the kidney patients who require dialysis are sensitized to human leukocyte antigens (HLA). The presence of antibodies that react with a potential donor organ is a significant barrier to transplantation due to the risk of acute antibody mediated rejection. Sensitized patients in general have an increased waiting time for transplantation with poor long-term survival rate[2].

Current protocols for desensitization, primarily involving plasmapheresis, intravenous gamma globulin and rituximab, require meticulous planning and timing and this is not feasible in most cases for deceased donor kidney transplantation. Also, in many cases the available protocols are not effective enough for living donor transplantation. Desensitization with IdeS immediately prior to kidney transplantation constitutes a completely unique and novel approach with the potential to desensitize all sensitized patients.

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 a clinically manageable safety profile in the study.

Latest developments
Currently, three separate Phase II studies are ongoing with IdeS in sensitized patients prior to kidney transplantation; a Swedish Phase II study at Uppsala University Hospital and Karolinska University Hospital in Huddinge, an investigator initiated US Phase II study at Cedars Sinai Medical Center in Los Angeles and a pivotal multicenter study in the US fully sponsored by Hansa Medical.

The studies primarily evaluate safety and tolerability of the candidate drug IdeS in sensitized kidney transplantation patients, as well as identifying an IdeS dose that results in anti-HLA antibody levels acceptable for transplantation within 24 hours from dosing. All patients in the Swedish study have been treated with IdeS and subsequently transplanted. Positive crossmatches against the donors were converted to negative by IdeS treatment and the treatment allowed transplantation in all patients treated with IdeS. All ten included patients in the sponsor-initiated study in the US have been successfully desensitized and subsequently transplanted. The recruitment continues according to plan. The pivotal multicenter study in the US has opened for recruitment.

Hansa Medical has initiated a pivotal multicenter study with IdeS – HighdeS - for treatment of refractory highly sensitized kidney patients in the US. HighdeS is sponsored by Hansa Medical, and results from this study could potentially form the basis for filing a Biologics License Application, i.e. an application to FDA for authorization to commercialize IdeS in the U.S. The aim is to complete recruitment of approximately 20 patients over a 12-month period. FDA cleared this study in April 2016.

The efforts to prepare IdeS for commercialization have been intensified, and Hansa Medical has recently appointed Henk Doude van Troostwijk as Vice President, Commercial Operations. He has significant management experience in sales and marketing from the areas of transplantation and orphan drugs. Lately, Henk served as Business Unit Director Oncology and Transplantation at Genzyme and most recently as General Manager of European Commercial Operations and Emerging Markets at Raptor Pharmaceuticals, an orphan disease focused global biopharma company based in the US.

IdeS – Acute treatment of antibody mediated kidney transplant rejection
The clinical data generated to date, demonstrates 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. Approximately ten percent[3] 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.

Latest developments
An investigator sponsored Phase II study in antibody mediated kidney transplant rejection is being prepared.

IdeS – Acute treatment of rare autoimmune diseases
IdeS can potentially be used in many different acute and rare autoimmune conditions in which IgG antibodies are proven or suspected to play a significant role for disease progression. A select group of indications have been identified as especially interesting to evaluate further in Phase II studies. These are: Thrombotic Thrombocytopenic Purpura (TTP), anti-GBM disease and Guillain-Barré syndrome (GBS).

- TTP is a rare thrombotic disorder characterized by autoantibody-mediated inhibition and depletion of an enzyme (ADAMTS13) that is vital in controlling blood clotting.
- Anti-GBM antibody disease is a disorder in which antibodies directed against the basement membrane of the kidney and lung cause acute and rapidly progressive glomerulonephritis and lung hemorrhage.
- GBS is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies.

Latest developments
An open label, single arm Phase II study in TTP is being prepared in collaboration with the University College in London. The aim of the study is to investigate the effect of IdeS on ADAMTS13 antibodies as well as ADAMTS13 levels following IdeS dosing.

An investigator sponsored open label, single arm Phase II study in anti-GBM antibody disease with up to 10 patients is being prepared. The study is foreseen to include several European sites.

Hansa Medical has initiated collaboration with Hôpital de la Timone in Marseille, France. The ambition of the collaboration is to investigate the design of a possible Phase II study through retrospective analysis of GBS patients treated with plasmapheresis.

NiceR – Novel immunoglobulin cleaving enzymes for Repeat dosing
Hansa Medical is developing completely new IgG degrading enzymes based on experience from IdeS and similar molecules. The aim of the development is to create novel IgG inactivating drugs that can be used for repeated dosing in autoimmune conditions where patients benefit from more than one dose of an IgG-modulating enzyme. Hansa Medical has filed patent applications covering these molecules.

Latest developments
A broad repertoire of novel immunoglobulin cysteine endopeptidases has been developed and patented. The development program is currently in lead optimization phase with the ambition to select a lead candidate suitable for clinical development.

EndoS – Treatment of autoimmune diseases

EndoS - Endoglycosidase of *Streptococcus pyogenes* - is an enzyme that specifically hydrolyzes the functionally important glycan in IgG. EndoS has proven 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 may have a potential as a novel therapy for antibody-mediated autoimmune diseases.

Latest developments

EndoS is currently in lead optimization. Confirmatory mechanistic studies as well as preparation for toxicology studies are ongoing.

EnzE - Enzyme based antibody Enhancement

Recent preclinical research[4] performed at University of Oxford, indicated that using IdeS or EndoS treatment prior to an antibody based cancer immunotherapy like anti-CD20 in the treatment of lymphoma and leukemia, has the potential to increase the efficacy and improve outcome for patients suffering from various cancer diseases.

At physiological conditions, the majority of Fc-gamma receptors bind normal IgG from the plasma and tissues. The activation of immune cells by a therapeutic antibody is dependent on the displacement of these plasma antibodies from the Fc-gamma receptors and pre-clinical research has demonstrated that the bacterial enzymes IdeS and EndoS can accomplish this. IdeS treatment is highly efficient and has been shown to be well tolerated in clinical studies. Treatment with IdeS clears the Fc-gamma receptors from plasma IgG leaving room for therapeutic antibodies to be loaded onto effector cells generating dedicated tumor seeking immune cells.

Latest developments

Researchers at Hansa Medical have independently verified and extended the research findings on the EnzE concept discovered by Dr Max Crispin with colleagues at University of Oxford. In July 2016, Hansa Medical acquired all patent rights to the receptor refocusing findings (the EnzE concept), through the acquisition of Immago Biosystems Ltd.

HBP – Prediction of severe sepsis

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 at emergency departments. Hundreds of thousands of patients die every year due to severe sepsis as a complication to infections, e.g. 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.

The results from a completed prospective clinical multicenter trial involving 759 patients admitted to emergency departments in Sweden and the US with infectious disease symptoms were published and show that quantification of plasma-HBP is a superior method for the prediction of severe sepsis when compared with presently available biomarkers for systemic inflammation. The HBP program has been fully out-licensed to Axis-Shield Diagnostics, a subsidiary to Alere Inc. (NYSE:ALR). Hansa Medical carries rights to royalties from Axis-Shield derived from sales and sublicensing of the HBP-assay as well as milestones payments.

Latest developments

In order to further strengthen the clinical validity of the HBP-assay, Axis-Shield is coordinating clinical trials with the HBP-assay in the US, Europe, China, South Korea and India. In addition, Axis-Shield is developing upgraded versions of the HBP-assay for improved routine clinical applicability. It is anticipated that a fast version with medical claims, will be available on the market in 2016.

Financial review January– June 2016

Net revenue

Net revenue for the second quarter 2016 amounted to MSEK 0.5 (0.5) and to MSEK 1.1 (4.4) for the first half of 2016 and comprised of royalty income from Axis-Shield Diagnostics. In net revenue for the previous year is also a licensing income of MSEK 3.3 from Axis-Shield Diagnostics included. Operating result for the second quarter 2016 amounted to MSEK -30.7 (-22.5) and to MSEK -50.6 (-33.2) for the first half of 2016. In the second quarter, activities in clinical studies and CMC development have further intensified, which has led to higher R&D expenses. Net profit/loss for the second quarter amounted to MSEK -30.7 (-22.5) and to MSEK -50.6 (-33.2) for the first half of 2016.

Cash flow and investments

Cash flow from operating activities amounted to MSEK -22.0 (-17.5) for the second quarter 2016 and to MSEK -39.6 (-25.4) for the first half of 2016. Cash and cash equivalents including short-term financial investments amounted to MSEK 133.7 on June 30, 2016, as compared with MSEK 158.1 at the end of first quarter 2016. Investments for the second quarter 2016 amounted to MSEK 2.8 (1.6) and to MSEK 2.8 (1.8) for the first half of 2016.

Shareholders' equity

On June 30, 2016, equity amounted to MSEK 160.2 compared with MSEK 244.1 at the end of the corresponding period 2015.

Parent company

The Parent company's net revenue for the second quarter 2016 amounted to MSEK 0.5 (0.5) and to MSEK 1.1 (4.4) for the first half of 2016. Result after net financial items for the Parent company amounted to MSEK -31.3 (-21.6) for the second quarter and to MSEK -52.0 (-31.9) for the first half of 2016. On June 30, 2016, cash and cash equivalents including short-term financial investments amounted to MSEK 131.4 compared with MSEK 156.2 at the end of first quarter 2016.

The Parent company's equity amounted to MSEK 160.2 as per June 30, 2016, as compared with MSEK 244.1 at the end of the corresponding period 2015.

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

Financial summary for the Group (KSEK)

	Q2		H1		Year
KSEK, unless otherwise stated	2016	2015	2016	2015	2015
Net revenue	542	529	1,084	4,376	5,434
Operating profit/loss	-30,674	-22,496	-50,619	-33,185	-66,201
Net profit/loss	-30,672	-22,505	-50,647	-33,230	-66,266
Earnings per share before and after dilution (SEK)	-0.95	-0.70	-1.56	-1.11	-2.13
Shareholders' equity	160,201	244,072	160,201	244,072	211,526
Cash flow from operating activities	-22,043	-17,523	-39,603	-25,385	-57,799
Cash and cash equivalents including short term investments	133,686	209,110	133,686	209,110	175,683

Other information

Employees and organisation

The number of employees at the end of the second quarter 2016 was 21, compared to 16 at the end of same period 2015. The Annual General Meeting of 2016 elected Ulf Wiinberg as new chairman of the board and Angelica Loskog as new member of the board.

Share warrant program

Hansa Medical's Annual General Meeting adopted on June 2, 2015 a share warrant program for the company's employees. 296,000 warrants were acquired by the company's employees during 2015. In 2016, 59,000 warrants have been acquired by recently joined employees within the program. Each warrant entitles the holder to subscribe for one new share in Hansa Medical. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 15, 2018 to June 15, 2019. The warrants were sold to the company's employees on market terms at a price established on the basis of an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute.

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

Financial calendar

Interim report for January–September 2016	November 9, 2016

Shareholder information

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

Brief facts, the HMED share

Listing	Nasdaq OMX Stockholm
Number of shares	32,412,003
Market capitalization (160630))	MSEK 1,807
Ticker	HMED
ISIN	SE0002148817

10 largest shareholders, June 30, 2016

Name	Number of Shares	Share (%)
Nexttobe AB	9,443,761	29.1
Gladiator	2,640,483	8.2
Försäkringsaktiebolaget, Avanza Pension	1,180,147	3.6
Farstorps Gård AB	1,084,070	3.3
Catella Småbolagsfond	1,000,000	3.1
Handelsbanken Fonder AB RE JPMEL	844,223	2.6
Rhenman Healthcare Equity L/S FUND	737,367	2.3
Tredje AP-fonden	699,304	2.2
BWG Invest	600,000	1.9
SANDBERG, SVEN	546,373	1.7
Other	13,636,275	42.0
Total	**32,412,003**	**100.0**

According to the shareholder register maintained by Euroclear Sweden AB, as of June 30, 2016, Hansa Medical had 4,106 shareholders. In June 30 2015, Hansa Medical had 2,726 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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Condensed financial statements

Consolidated statement of comprehensive income

	Q2		H1		Year
KSEK	2016	2015	2016	2015	2015
Net revenue	542	529	1,084	4,376	5,434
Other operating income	253	36	361	694	1,721
Total operating income	**795**	**565**	**1,445**	**5,070**	**7,155**
Direct cost of net revenue	-54	–	-108	–	-658
Gross profit	**741**	**565**	**1,337**	**5,070**	**6,497**
Sales, general and administration expense	-8,327	-11,544	-13,300	-17,892	-28,241
Research and development expenses	-22,974	-11,513	-38,377	-20,316	-44,262
Other operating expenses	-114	-4	-279	-47	-195
Operating profit/loss	**-30,674**	**-22,496**	**-50,619**	**-33,185**	**-66,201**
Financial income/expenses	2	-9	-28	-45	-65
Profit/loss for the period (before and after taxes)	**-30,672**	**-22,505**	**-50,647**	**-33,230**	**-66,266**
Attributable to					
Parent company shareholders	-30,672	-22,505	-50,647	-33,230	-66,266
Earnings per share					
Before dilution (SEK)	-0.95	-0.70	-1.56	-1.11	-2.13
After dilution (SEK)	-0.95	-0.70	-1.56	-1.11	-2.13
Other comprehensive income					
Items that have been, or may be reclassified to profit or loss for the year					
Changes in fair value on available-for-sale financial assets	-587	898	-1,315	1,333	1,624
Other comprehensive income for the year	**-587**	**898**	**-1,315**	**1,333**	**1,624**
Total net comprehensive income	**-31,259**	**-21,607**	**-51,962**	**-31,897**	**-64,642**

Consolidated balance sheet

	June 30		December 31
KSEK	2016	2015	2015
ASSETS			
Non-current assets			
Intangible fixed assets	34,919	36,612	36,327
Tangible fixed assets	2,151	1,407	2,182
Financial fixed assets	8,556	6,992	7,283
Total non-current assets	**45,626**	**45,011**	**45,792**
Current assets			
Current receivables, non-interest bearing	1,908	2,555	2,613
Short-term investments	99,955	–	–
Cash and cash equivalents	33,731	209,110	175,683
Total current assets	**135,594**	**211,665**	**178,296**
TOTAL ASSETS	**181,220**	**256,676**	**224,088**
EQUITY AND LIABILITIES			
Shareholders' equity	**160,201**	**244,072**	**211,526**
Long term liabilities	**27**	**69**	**49**
Current liabilities			
Current liabilities, interest bearing	43	41	42
Current liabilities, non-interest bearing	3,175	5,306	2,294
Accrued expenses and deferred income	17,774	7,188	10,177
Total current liabilities	**20,992**	**12,535**	**12,513**
TOTAL EQUITY AND LIABILITIES	**181,220**	**256,676**	**224,088**
Pledged assets	44	100	72
Contingent liabilities	None	None	None

Consolidated changes in equity

	Jan-Jun		Year
KSEK	2016	2015	2015
Opening shareholders' equity	**211,526**	**49,804**	**49,804**
Result for the period	-50,647	-33,230	-66,266
Other comprehensive income for the period	-1,315	1,333	1,624
Net comprehensive income	**-51,962**	**-31,897**	**-64,642**
Transactions with the group's owner			
New share issue	–	246,331	246,331
Expenses attributable to new share issue	–	-21,999	-21,999
Issued warrants	637	1,833	2,032
Total transactions with the group's owner	**637**	**226,165**	**226,364**
Closing shareholders' equity	**160,201**	**244,072**	**211,526**

Consolidated cash flow statement

	Q2		H1		Year
KSEK	2016	2015	2016	2015	2015
Operating activities					
Operating profit/loss	-30,674	-22,496	-50,619	-33,185	-66,201
Adjustment for items not included in cash flow	921	256	1,862	485	1,188
Interest received and paid, net	2	-38	-28	-45	-65
Income taxes paid	-489	-51	-409	10	184
Cash flow from operations before change in working capital	**-30,240**	**-22,329**	**-49,194**	**-32,735**	**-64,894**
Change in working capital	8,197	4,806	9,591	7,350	7,095
Cash flow from operating activities	**-22,043**	**-17,523**	**-39,603**	**-25,385**	**-57,799**
Investing activities					
Investments in tangible fixed assets	-198	-124	-216	-323	-1,317
Investment/Divestment of financial assets	-2,588	-1,479	-2,588	-1,479	-1,479
Short term investments	–	–	-99,949	–	–
Cash flow from investing activities	**-2,786**	**-1,603**	**-102,753**	**-1,802**	**-2,796**
Financing activities					
New share issue	–	246,331	–	246,331	246,331
Issue expenses	–	-21,999	–	-21,999	-21,999
Issued warrants	426	1,833	426	1,833	1,833
Repayment of loans	–	-5,000	–	–	–
Repayment of leasing liabilities	-11	-11	-22	-20	-39
Cash flow from financing activities	**415**	**221,154**	**404**	**226,145**	**226,126**
Net change in cash	**-24,414**	**202,028**	**-141,952**	**198,958**	**165,531**
Cash and cash equivalents, beginning of year	58,145	7,082	175,683	10,152	10,152
Cash and cash equivalents, end of period	**33,731**	**209,110**	**33,731**	**209,110**	**175,683**

Consolidated key ratios and other information

	Q2		H1		Year
KSEK, unless otherwise stated	2016	2015	2016	2015	2015
Total operating income	795	565	1,445	5,070	7,155
Operating profit/loss	-30,674	-22,496	-50,619	-33,185	-66,201
Net profit/loss	-30,672	-22,505	-50,647	-33,230	-66,266
Earnings/loss per share before and after dilution (SEK)	-0.95	-0.70	-1.56	-1.11	-2.13
Cash and cash equivalents including short term investments	133,686	209,110	133,686	209,110	175,683
Number of outstanding shares at the end of the period	32,412,003	32,412,003	32,412,003	32,412,003	32,412,003
Weighted average number of shares before and after dilution	32,412,003	32,355,842	32,412,003	29,842,582	31,137,852

Parent company – Statement of comprehensive income

	Q2		H1		Year
KSEK	2016	2015	2016	2015	2015
Net revenue	542	529	1,084	4,376	5,434
Other operating income	253	36	361	694	1,721
Total operating income	**795**	**565**	**1,445**	**5,070**	**7,155**
Direct cost of net revenue	-54	–	-108	–	-658
Gross profit	**741**	**565**	**1,337**	**5,070**	**6,497**
Sales, general and administration expenses	-8,322	-11,542	-13,292	-17,885	-28,228
Research and development expenses	-22,974	-11,513	-38,377	-20,316	-44,262
Other operating expenses	-114	-4	-279	-47	-195
Operating profit/loss	**-30,669**	**-22,494**	**-50,611**	**-33,178**	**-66,188**
Result from other securities and receivables which are fixed assets	-587	898	-1,315	1,333	1,624
Result from short term financial receivables	35	–	21	–	–
Other financial expenses	-31	-8	-46	-42	-59
Profit/loss for the period (before and after taxes)	**-31,252**	**-21,604**	**-51,951**	**-31,887**	**-64,623**
Other comprehensive income for the period	**–**	**–**	**–**	**–**	**–**
Total net comprehensive income	**-31,252**	**-21,604**	**-51,951**	**-31,877**	**-64,623**

Parent company – Balance sheet

KSEK	June 30 2016	June 30 2015	December 31 2015
ASSETS			
Non-current assets			
Intangible fixed assets	34,919	36,612	36,327
Tangible fixed assets	2,107	1,307	2,110
Financial fixed assets	10,917	8,925	9,216
Total non-current assets	**47,943**	**46,844**	**47,653**
Current assets			
Current receivables, non-interest bearing	1,908	2,554	2,612
Short-term investments	99,955	–	–
Cash and cash equivalents	31,472	207,277	173,850
Total current assets	**133,335**	**209,831**	**176,462**
TOTAL ASSETS	**181,278**	**256,675**	**224,115**
EQUITY AND LIABILITIES			
Shareholders' equity	**160,232**	**244,084**	**211,547**
Current liabilities			
Liabilities to credit institutions	–	–	–
Liabilities to group companies	98	99	98
Current liabilities, non-interest bearing	3,174	5,304	2,293
Accrued expenses and deferred income	17,774	7,188	10,177
Total current liabilities	**21,046**	**12,591**	**12,568**
TOTAL EQUITY AND LIABILITIES	**181,278**	**256,675**	**224,115**
Pledged assets	None	None	None
Contingent liabilities	None	None	None

Parent company – Changes in equity

	Jan-Jun		Year
KSEK	2016	2015	2015
Opening shareholders' equity	**211,547**	**49,806**	**49,806**
Result for the period	-51,951	-31,887	-64,623
New share issue	–	246,331	246,331
Expenses attributable to new share issue	–	-21,999	-21,999
Issued warrants	636	1,833	2,032
Total transactions with the group's owner	**636**	**226,165**	**226,364**
Closing shareholders' equity	**160,232**	**244,084**	**211,547**

Financial notes

Note 1 Basis of Preparation and Accounting policies

This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act. The interim report for the Parent Company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting. A full description of the accounting principles applied in this interim report can be found in the Annual Report 2015. The Annual report 2015 was published on March 31, 2016. It is available on www.hansamedical.com. Disclosures in accordance with IAS 32.16A are as applicable in the notes or on the pages before the consolidated income statement.

Note 2 Fair value of financial instruments

The reported value is assessed as being a fair approximation of the fair value for all of the Group's financial instruments. The financial instruments reported at fair value in the balance sheet are comprised partly of the Group's holding of shares in Genovis, which are listed on Nasdaq First North and partly of holdings of short-term commercial papers. The fair value of the shares as per the balance sheet date June 30, 2016 was KSEK 8,556, KSEK 6,992 on June 30, 2015 and KSEK 7,283 on December 31, 2015. The fair value of the commercial papers as per the balance sheet date June 30, 2016 was KSEK 99,955. The fair value of the financial instruments are calculated on the basis of the closing price. The valuation of the holdings is, thereby, in accordance with Level 1 in the valuation hierarchy.

This interim report has not been audited

Reference list

1. Winstedt et al. (2015) “Complete Removal of Extracellular IgG Antibodies in a Randomized Dose-Escalation Phase I Study with the Bacterial Enzyme IdeS – A Novel Therapeutic Opportunity.” PLoS ONE 10(7)Orandi et al., New England Journal of Medicine (2016;374:940-50)

2. Orandi et al. (2016) “Survival Benefit with Kidney Transplants from HLA-Incompatible Live Donors” N Engl J Med 2016; 374:940-950 March 10, 2016

3. Puttarajappa et al. (2012), “Antibody-Mediated Rejection in Kidney Transplantation: A Review”, J. Transplant.Volume 2012 (2012), Article ID 193724

4. Baruah et al. (2012), Journal of Molecular Biology, ”Selective deactivation of serum IgG: a general strategy for the enhancement of monoclonal antibody receptor interactions.”, 2012 Jun 29;420(1-2):1-7

Glossary

AMR
Antibody mediated transplant rejection

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

Anti-GBM disease
Anti-GBM antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

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

Biopharmaceutical
A pharmaceutical drug that is manufactured using biotechnology.

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

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

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

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

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

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

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

FDA
US Food and Drug Administration.

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

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

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

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

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

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

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

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

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

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

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

Sepsis
Diagnosed or suspected infection in combination with the patient being in a systemic inflammatory state (SIRS). Clinical symptoms of systemic inflammation may be a combination of fever, increased heart rate and increased respiratory rate.

Severe sepsis
Sepsis is progressing into severe sepsis when the patient may suffer circulatory effects and reduced functions of vital organs such as the brain, heart, lungs, kidneys or liver.

Streptococcus pyogenes
A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

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

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