

Hansa Medical

Interim report July–September 2016

IdeS 7 ml Concentrate
Concentrate for solution
Batch No: BX100268

Sponsor: Hansa Medical
Hansa Medical
Hansa Medical

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Multicenter study initiated with IdeS in transplantation and expansion of clinical program into autoimmunity

Third quarter in brief

Business highlights

- › Preliminary results presented from the Swedish ongoing Phase II study with IdeS in sensitized patients
- › Hansa Medical initiated Highdes, a multicenter study in the US with IdeS for treatment of highly sensitized kidney transplantation patients
- › Hansa Medical investigates cancer immunotherapy applications with IdeS and EndoS through the acquisition of UK based biotech company Immago Biosystems Ltd

Significant events after end of period

- › First patient treated with IdeS in Phase II study in acquired Thrombotic Thrombocytopenic Purpura (TTP)
- › Subject to approval by the Extraordinary General Meeting, the Board of Directors of Hansa Medical decided on a directed share issue of approximately MSEK 185 to selected international and Swedish investors, and a long-term incentive programme (performance share programme) for employees of Hansa Medical

Financial summary

- › Net revenue for the group in Q3 amounted to MSEK 0.5 (0.5). YTD: MSEK 1.6 (4.9).
- › Operating result in Q3 was MSEK -27.0 (-13.9). YTD: MSEK -77.6 (-47.1).
- › Consolidated net result in Q3 was MSEK -26.9 (-13.9). YTD: MSEK -77.6 (-47.2).
- › Earnings per share before and after dilution in Q3 were SEK -0.83 (-0.43). YTD: SEK -2.39 (-1.54).
- › Cash position including short-term investments on September 30, 2016, of MSEK 103.9.



“To date, we have demonstrated in more than 30 patients that our lead candidate IdeS effectively and swiftly removes pathogenic IgG-antibodies and thereby enables kidney transplantation in sensitized patients.”

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.

CEO statement

We are convinced that our novel and innovative immunomodulatory enzymes hold significant therapeutic potential for patients either in need of a lifesaving transplantation or with acute and severe auto-immune diseases.

To date, we have demonstrated in more than 30 patients that our lead candidate IdeS effectively and swiftly removes pathogenic IgG-antibodies and thereby enables kidney transplantation in sensitized patients.

In the two ongoing Phase II studies with IdeS in Sweden and the US, treatment with IdeS has enabled kidney transplantation in all patients. So far we can conclude that IdeS, by cleaving IgG-antibodies into two fragments, effectively eliminates the antibody barrier in sensitized patients, which makes it possible to transplant these patients in a similar way as with non-sensitized patients.

We now intend to demonstrate that this mode of action is sufficient also for the most severe cases of HLA-sensitization, in order to enable transplantation for patients that have been too long on the transplant waitlist. In October 2016, we treated the first patient in a clinical study – titled Highdes – that is exclusively aimed at the highly sensitized patients.

The Highdes study will recruit approximately 20 highly sensitized patients in the US and Europe. We anticipate that the Highdes study together with the completed and ongoing studies will provide data to support a Biologics License Application (BLA) in the US and a Marketing Authorization Application (MAA) in the European Union.

We are equally determined to pursue the therapeutic potential of IdeS in a number of other indications.

We believe that the fast onset and efficacy of IdeS has the potential to revolutionize the critical care in many acute autoimmune diseases and transplant related indications. Initially, we have narrowed in on a number of carefully selected indications, including Thrombotic Thrombocytopenic Purpura (TTP) and Guillain-Barré syndrome (GBS), in which we believe that IdeS may make a difference. In October 2016, the first patient was treated in a Phase II study in TTP at University College London Hospitals.

In order to fully execute this value creation strategy, we decided to raise SEK 185 million in a directed share issue to selected international specialist investors, as well as from Swedish institutional and strategic investors. The share issue, which will broaden our shareholder base towards institutional and specialist investors, is to be resolved on an extraordinary general meeting on November 21, 2016. We have already received full subscription of the shares in accordance with separate agreements from the investors.

It has certainly been an exciting 2016 to date. The success of our clinical trials, the hope this is bringing to patients, and the steadily increasing interest from investors and other stakeholders acknowledging our long term value creation strategy, give strength and inspiration to all of us here at Hansa Medical.

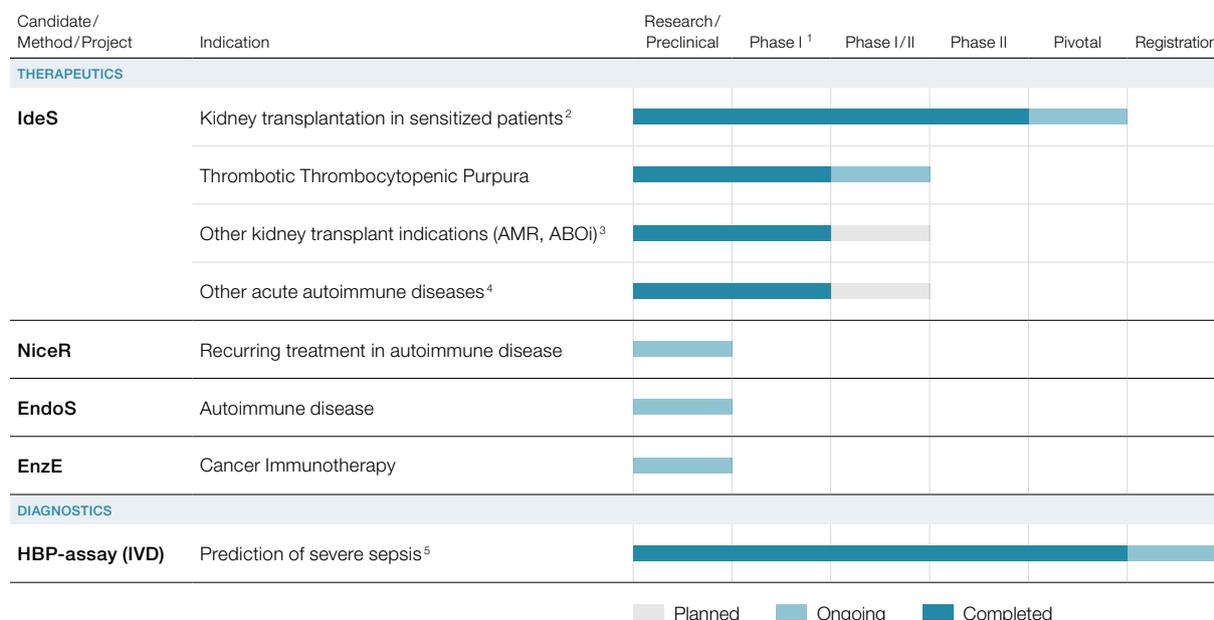
We have an exciting time ahead of us.

Göran Arvidson

President and CEO of Hansa Medical

Business overview

Pipeline



¹ Present and future IdeS Phase II studies to be based on the same Phase I study. Results from the Phase I study have been published, Winstedt et al. (2015) PLOS ONE 10(7).

² Three separate Phase II studies are currently ongoing in sensitized patients. One study in Sweden and two in the US. All patients have been recruited to the ongoing Swedish study.

³ Phase II studies in antibody mediated rejection (AMR) post kidney transplantation and blood-group incompatible (ABOi) kidney transplantation are being planned.

⁴ Phase II studies in rare autoimmune conditions like GBS and anti-GBM are being planned.

⁵ Out-licensed 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* – specifically cleaves immunoglobulin G (IgG). Several autoimmune diseases are characterized by pathogenic IgG-antibodies and in organ and tissue transplantation, pathogenic IgG-antibodies can prohibit patients from being 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.

Overview of Hansa Medical's clinical program with IdeS

The clinical development program is currently focused on treatment prior to kidney transplantation. The long term vision for Hansa Medical is to establish IdeS as a therapy for fast and efficient elimination of pathogenic IgG in several autoimmune diseases and in several transplant related indications.

IdeS has been evaluated in a Phase I study in healthy subjects and in a Phase II study in sensitized patients awaiting kidney transplantation. The results^[1] show that IdeS is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation with a favorable safety profile.

The efficacy and safety of IdeS is currently investigated in four ongoing Phase II studies, three Phase II studies in sensitized kidney transplantation patients and one Phase II study in the rare autoimmune disease acquired Thrombotic Thrombocytopenic Purpura (TTP). Additional Phase II studies are being planned in the rare autoimmune diseases anti-Glomerular Basement Membrane disease (anti-GBM disease) and Guillain-Barré syndrome (GBS), as well as in Acute Antibody Mediated Rejection (AMR) post kidney transplantation and desensitization prior to blood group incompatible (ABOi) kidney transplantation.

Ongoing clinical studies with IdeS

IdeS – Desensitization prior to kidney transplantation

Desensitization with IdeS immediately prior to kidney transplantation constitutes a completely unique and novel approach with the potential to desensitize all sensitized patients.

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 Hansa Medical-sponsored multicenter study in the US and Europe. These studies primarily evaluate safety and tolerability of IdeS in sensitized kidney transplantation patients, as well as identifying a dose that results in anti-HLA antibody levels acceptable for transplantation. The ongoing Swedish study is fully recruited, and top line results from the study are expected during Q4 2016.

Data from the ongoing Swedish Phase II study and the ongoing investigator-initiated US Phase II study demonstrate that IdeS has enabled kidney transplantation in all patients. IdeS effectively eliminated anti-HLA antibodies in all treated patients.

In the multicenter study, titled *A Phase II Study to Evaluate the Efficacy of IdeS to Desensitize Transplant Patients with a Positive Crossmatch Test* (short name: Highdes), the first patient was treated with IdeS and subsequently transplanted in early October 2016. The recruitment continues according to plan. The primary objective of the study is to assess the efficacy of IdeS in creating a negative crossmatch test in highly sensitized patients with a positive crossmatch test to their available donor.

Removing donor-specific antibodies, thus converting the crossmatch test, will enable transplantation in patients who would otherwise not qualify for transplantation. The study will also evaluate safety, kidney function and immunogenicity during the 6-month follow-up period. The aim is to complete recruitment of approximately 20 patients over a 12-month period.

Regulatory strategy for IdeS in desensitization

The Highdes study will recruit patients that have either failed on previous attempts of desensitization or are likely to fail desensitization with presently available methods. Hansa Medical aims to reach market authorization in the US and Europe for IdeS for this category of patients as soon as possible. It is anticipated that the Highdes study, together with the completed and ongoing studies, will provide data to support a Biologics License Application (BLA) in the US and a Marketing Authorization Application (MAA) in the European Union.

IdeS – Treatment of Thrombotic Thrombocytopenic Purpura (TTP)

Acquired TTP is a rare, acute, autoimmune blood clotting disorder, affecting 1/100,000/year^[2]. It has a sudden onset caused by impaired activity of the ADAMTS13 enzyme (typically <10% of that in plasma of healthy individuals), leaving ultra-large multimers of von Willebrand Factor (vWF) molecules uncleaved.

Latest developments

An open-label, single-arm Phase II study in patients with acquired TTP has been initiated in collaboration with Dr. Marie Scully, consultant hematologist at University College London Hospitals. Dr. Scully is a leading expert in patient care and clinical research in TTP. The Hansa Medical-sponsored study will evaluate the safety, tolerability, efficacy, pharmacodynamics and pharmacokinetics of IdeS in asymptomatic patients with acquired TTP. The study will include up to six patients with acquired TTP and low ADAMTS13 activity who are asymptomatic at the time of enrolment into this study. The first patient is recruited to the study, which is planned to be completed during 2017.

Planned clinical studies with IdeS in additional indications

Acute treatment of Guillain-Barré syndrome (GBS)

GBS is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG-antibodies. It affects 1/100,000/year^[3].

Acute treatment of anti-GBM disease

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. It affects 1/1,000,000/year^[4].

Treatment of kidney transplant antibody-mediated rejection (AMR)

Approximately 10%^[5] of all transplanted patients experience AMR post-transplant. Currently, there are no approved treatments for AMR, although different experimental protocols are used in the treatment. However, in the more severe cases of AMR, these protocols are generally not sufficient to rescue the kidney since the magnitude of the antibody response exceeds the capacity of e.g. plasmapheresis to clear the antibodies.

Blood-group incompatible (ABOi) kidney transplantation

ABOi transplantations have increased worldwide in order to shorten the long waiting times for transplantation. If not adequately removed, the presence of preformed antibodies to donor blood group antigens is likely to result in severe AMR and early graft loss.

Preclinical development projects

NiceR – Novel immunoglobulin cleaving enzymes for Repeat dosing

Hansa Medical develops completely novel IgG-degrading enzymes based on experience from IdeS and similar molecules. The aim of the development is to create novel IgG-inactivating biopharmaceuticals that can be used for repeated dosing in autoimmune conditions where patients benefit from more than one dose of an IgG-modulating enzyme.

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 preclinical 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 autoimmune diseases.

EnzE – Enzyme based antibody Enhancement

Recent preclinical research^[6] performed at University of Oxford indicates that 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 preclinical 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.

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

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 incidence of severe sepsis is 300/100,000/year^[7]. HBP-assay has been fully out-licensed by Hansa Medical to UK-based Axis-Shield Diagnostics, a subsidiary to Alere Inc. (NYSE:ALR) and Hansa Medical hold the right to royalty payments from Axis-Shield. Axis-Shield is engaged in further product development and clinical development with HBP-assay. For more information, please visit: www.heparinbindingprotein.com

Financial review January – September 2016

Net revenue

Net revenue for the third quarter 2016 amounted to MSEK 0.5 (0.5) and to MSEK 1.6 (4.9) year to date 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 third quarter 2016 amounted to MSEK -27.0 (-13.9) and MSEK -77.6 (-47.1) year to date 2016. R&D expenses are derived from several ongoing clinical studies and CMC development.

Consolidated net result for the third quarter amounted to MSEK -26.9 (-13.9) and to MSEK -77.6 (-47.2) year to date 2016.

Cash flow and investments

Cash flow from operating activities amounted to MSEK -27.8 (-16.5) for the third quarter 2016 and to MSEK -67.4 (-41.9) year to date 2016. Cash and cash equivalents including short term investments amounted to MSEK 103.9 on September 30 2016, as compared with MSEK 133.7 at the end of second quarter 2016.

Investments for the third quarter 2016 amounted to MSEK 2.0 (0) and to MSEK 4.8 (1.8) year to date 2016.

Shareholders' equity

On September 30, 2016 equity amounted to MSEK 138.8 compared with MSEK 230.1 at the end of the corresponding period 2015.

Parent company

The Parent company's net revenue for the third quarter 2016 amounted to MSEK 0.5 (0.5) and to MSEK 1.6 (4.9) year to date 2016. Net result for the Parent company amounted to MSEK -23.0 (-14.1) for the third quarter and to MSEK -74.9 (-46.0) year to date 2016. On September 30, 2016, cash and cash equivalents including short term investments amounted to MSEK 101.7 compared with MSEK 131.4 at the end of second quarter 2016.

The Parent company's equity amounted to MSEK 137.3 as per September 30, 2016, as compared with MSEK 230.1 at the end of the corresponding period 2015.

The Group consists of the Parent company Hansa Medical AB and the subsidiaries Cartela R&D AB and Immago Biosystems Ltd, in which no business is currently conducted. Immago Biosystems Ltd was acquired in July 2016.

Financial summary for the Group

KSEK, unless otherwise stated	Q3		January – September		Year
	2016	2015	2016	2015	2015
Net revenue	543	529	1,627	4,905	5,434
Operating profit/loss	-26,954	-13,927	-77,573	-47,112	-66,201
Net profit/loss	-26,926	-13,932	-77,573	-47,162	-66,266
Earnings per share before and after dilution (SEK)	-0.83	-0.43	-2.39	-1.54	-2.13
Shareholders' equity	138,806	230,058	138,806	230,058	211,526
Cash flow from operating activities	-27,775	-16,466	-67,378	-41,851	-57,799
Cash and cash equivalents including short term investments	103,948	192,628	103,948	192,628	175,683

Other information

Employees and organisation

The number of employees at the end of the third quarter 2016 was 23, compared to 18 at the end of same period 2015.

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.

Hansa Medical Extraordinary General Meeting (EGM) 2016

An extraordinary general meeting will be held for Hansa Medical AB November 21, 2016. The notice can be found at [Hansa Medical's webpage](#). At the meeting the board of directors' proposals for a directed issue, and a long-term incentive plan for the employees of Hansa Medical will be presented.

The board of directors has resolved on a directed issue of approximately MSEK 185 including not more than 2,642,857 new ordinary shares at a subscription price of SEK 70 to selected Swedish and international investors, which is subject to the approval by the EGM.

The board of directors proposes that the general meeting resolves to adopt a long-term incentive program (LTIP 2016). LTIP 2016 is proposed to include all employees of the group, whereby not more than 30 individuals within the Hansa Medical group may participate. The program is proposed to further motivate the company's employees and to attract as well as retain key personnel in an increasingly competitive environment. The participants will be granted the opportunity to receive ordinary shares, free of charge, in accordance with LTIP 2016, so called "Performance Shares" in accordance with certain terms and conditions. The company will under LTIP 2016 grant participants the right to Performance

Shares, meaning the right to obtain one Performance Share free of charge, provided that certain conditions are fulfilled. The program will not affect the company's cash flow.

Committee for the 2017 Annual General Meeting

Hansa Medical AB's Nomination Committee for the AGM 2017 will consist of Erika Kjellberg Eriksson representing Nexttobe AB, Fredrik Bogren representing Farstorps Gård AB and Max Mitteregger representing Gladiator AB. It also includes the chairman of the board Ulf Wiinberg as convener.

Financial calendar

Extraordinary General Meeting	21 November 2016
Year-end report 2016	15 February 2017
Annual report 2016	26 April 2017
Annual General Meeting	23 May 2017

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 Sep. 30, 2016	MSEK 2,520
Ticker	HMED
ISIN	SE0002148817

10 largest shareholders, September 30, 2016

Name	Number of Shares	Share (%)
Nexttobe AB	9,443,761	29.1
Gladiator	2,530,000	7.8
Försäkringsaktiebolaget, Avanza Pension	1,202,030	3.7
Farstorps Gård AB	1,084,070	3.3
Catella Fondförvaltning	1,006,200	3.1
Handelsbanken Fonder	829,149	2.6
AFA Försäkring	733,000	2.3
SEB London – Luxemburg, (SICAV FOND)	702,367	2.2
BWG Invest	600,370	1.9
Tredje AP-fonden	553,715	1.7
Other	13,727,341	42.3
Total	32,412,003	100.0

According to the shareholder register maintained by Euroclear Sweden AB, as of September 30, 2016, Hansa Medical had 4,923

shareholders. In 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.

Capital Markets Day

Hansa Medical has the ambition to arrange annual capital market days, welcoming all of our present and future investors. The timing of the forthcoming capital markets days will depend on the plans for new clinical studies, as well as taking data from finalized clinical studies into account. In early November 2016, two significant clinical Phase II studies with Hansa Medical's lead candidate IdeS were ongoing with anticipated time for result reporting in Q4 2016 and H1 2017 respectively. The timing of the next capital markets day will be announced as soon as top-line data are available from one or both of these studies.

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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Registration number

556734-5359

Condensed financial statements

Consolidated statement of comprehensive income

KSEK	Q3		January – September		Year
	2016	2015	2016	2015	2015
Net revenue	543	529	1,627	4,905	5,434
Other operating income	479	149	840	843	1,721
Total operating income	1,022	678	2,467	5,748	7,155
Direct cost of net revenue	-55	-	-163	-	-658
Gross profit	967	678	2,304	5,748	6,497
Sales, general and administration expenses	-7,972	-6,010	-21,272	-23,902	-28,241
Research and development expenses	-19,460	-8,592	-57,837	-28,908	-44,262
Other operating expenses	-489	-3	-768	-50	-195
Operating profit/loss	-26,954	-13,927	-77,573	-47,112	-66,201
Financial income/expenses	28	-5	-	-50	-65
Profit/loss for the period (before and after taxes)	-26,926	-13,932	-77,573	-47,162	-66,266
Attributable to					
Parent company shareholders	-26,926	-13,932	-77,573	-47,162	-66,266
Earnings per share					
Before dilution (SEK)	-0.83	-0.43	-2.39	-1.54	-2.13
After dilution (SEK)	-0.83	-0.43	-2.39	-1.54	-2.13
Other comprehensive income					
Items that have been, or may be reclassified to profit or loss for the period					
Translation differences	-32	-	-32	-	-
Changes in fair value on available-for-sale financial assets	5 496	-182	4,181	1,151	1,624
Other comprehensive income for the period	5,464	-182	4,149	1,151	1,624
Total net comprehensive income	-21,462	-14,114	-73,424	-46,011	-64,642

Consolidated balance sheet

KSEK	September 30		December 31
	2016	2015	2015
ASSETS			
Non-current assets			
Intangible fixed assets	37,287	36,470	36,327
Tangible fixed assets	2,097	1,320	2,182
Financial fixed assets	14,052	6,809	7,283
Total non-current assets	53,436	44,599	45,792
Current assets			
Current receivables, non-interest bearing	1,390	2,693	2,613
Short-term investments	49,983	-	-
Cash and cash equivalents	53,965	192,628	175,683
Total current assets	105,338	195,321	178,296
TOTAL ASSETS	158,774	239,920	224,088
EQUITY AND LIABILITIES			
Shareholders' equity	138,806	230,058	211,526
Long term liabilities			
Deferred tax liabilities	603	-	-
Long term liabilities, interest bearing	547	60	49
Total long term liabilities	1,150	60	49
Current liabilities			
Current liabilities, interest bearing	44	41	42
Current liabilities, non-interest bearing	1,852	3,329	2,294
Accrued expenses and deferred income	16,922	6,432	10,177
Total current liabilities	18,818	9,802	12,513
TOTAL EQUITY AND LIABILITIES	158,774	239,920	224,088
Pledged assets	30	86	72
Contingent liabilities	None	None	None

Consolidated changes in equity

KSEK	January – September		Year
	2016	2015	2015
Opening shareholders' equity	211,526	49,804	49,804
Result for the period	-77,573	-47,162	-66,266
Other comprehensive income for the period	4,149	1,151	1,624
Net comprehensive income	-73,424	-46,011	-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	704	1,933	2,032
Total transactions with the group's owner	704	226,265	226,364
Closing shareholders' equity	138,806	230,058	211,526

Consolidated cash flow statement

KSEK	Note	Q3		January – September		Year
		2016	2015	2016	2015	2015
Operating activities						
Operating profit/loss		-26,954	-13,927	-77,573	-47,112	-66,201
Adjustment for items not included in cash flow		907	335	2,769	820	1,188
Interest received and paid, net		-27	-5	-55	-50	-65
Income taxes paid		553	-49	144	-39	184
Cash flow from operations before change in working capital		-25,521	-13,646	-74,715	-46,381	-64,894
Change in working capital		-2,254	-2,820	7,337	4,530	7,095
Cash flow from operating activities		-27,775	-16,466	-67,378	-41,851	-57,799
Investing activities						
Acquisition of business, net cash effect	3	-1,924	–	-1,924	–	–
Acquisition of tangible fixed assets		-82	-6	-298	-329	-1,317
Acquisition of financial assets		–	–	-2,588	-1,479	-1,479
Short term investments		-44,978	–	-164,927	–	–
Divestment short term investments		95,000	–	115,000	–	–
Cash flow from investing activities		48,016	-6	-54,737	-1,808	-2,796
Financing activities						
New share issue		–	–	–	246,331	246,331
Issue expenses		–	–	–	-21,999	-21,999
Issued warrants	3	–	–	429	1,833	1,833
Repayment of leasing liabilities		-10	-10	-32	-30	-39
Cash flow from financing activities		-7	-10	397	226,135	226,126
Net change in cash		20,234	-16,482	-121,718	182,476	165,531
Cash and cash equivalents, beginning of year		33,731	209,110	175,683	10,152	10,152
Cash and cash equivalents, end of period		53,965	192,628	53,965	192,628	175,683

Consolidated key ratios and other information

KSEK, unless otherwise stated	Q3		January – September		Year	
	2016	2015	2016	2015	2016	2015
Total operating income	1,022	678	2,467	5,748	7,155	
Operating profit/loss	-26,954	-13,927	-77,573	-47,112	-66,201	
Net profit/loss	-26,926	-13,932	-77,573	-47,162	-66,266	
Earnings/loss per share before and after dilution (SEK)	-0.83	-0.43	-2.39	-1.54	-2.13	
Cash and cash equivalents including short term investments	103,948	192,628	103,948	192,628	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	32,412,003	32,412,003	30,708,468	31,137,852	

Parent company – Statement of comprehensive income

KSEK	Q3		January – September		Year	
	2016	2015	2016	2015	2016	2015
Net revenue	543	529	1,627	4,905	5,434	
Other operating income	479	149	840	843	1,721	
Total operating income	1,022	678	2,467	5,748	7,155	
Direct cost of net revenue	-55	-	-163	-	-658	
Gross profit	967	678	2,304	5,748	6,497	
Sales, general and administration expenses	-7,970	-6,007	-21,262	-23,892	-28,228	
Research and development expenses	-19,460	-8,592	-57,837	-28,908	-44,262	
Other operating expenses	-489	-3	-768	-50	-195	
Operating profit/loss	-26,952	-13,924	-77,563	-47,102	-66,188	
Result from other securities and receivables which are fixed assets	3,943	-182	2,628	1,151	1,624	
Other financial expenses	28	-3	3	-45	-59	
Profit/loss for the period (before and after taxes)	-22,981	-14,109	-74,932	-45,996	-64,623	
Other comprehensive income for the period	-	-	-	-	-	
Total net comprehensive income	-22,981	-14,109	-74,932	-45,996	-64,623	

Parent company – Balance sheet

KSEK	September 30		December 31
	2016	2015	2015
ASSETS			
Non-current assets			
Intangible fixed assets	34,216	36,470	36,327
Tangible fixed assets	2,067	1,234	2,110
Financial fixed assets	17,317	8,742	9,216
Total non-current assets	53,600	46,446	47,653
Current assets			
Current receivables non-interest bearing	1,389	2,692	2,612
Short-term investments	49,983	-	-
Cash and cash equivalents	51,706	190,795	173,850
Total current assets	103,078	193,487	176,462
TOTAL ASSETS	156,678	239,933	224,115
EQUITY AND LIABILITIES			
Shareholders' equity	137,319	230,075	211,547
Long term liabilities	532	-	-
Current liabilities			
Liabilities to group companies	98	98	98
Current liabilities, non-interest bearing	1,807	3,328	2,293
Accrued expenses and deferred income	16,922	6,432	10,177
Total current liabilities	18,827	9,858	12,568
TOTAL EQUITY AND LIABILITIES	156,678	239,933	224,115
Pledged assets	None	None	None
Contingent liabilities	None	None	None

Parent company – Changes in equity

KSEK	January – September		Year
	2016	2015	2015
Opening shareholders' equity	211,547	49,806	49,806
Result for the period	-74,932	-45,996	-64,623
New share issue	–	246,331	246,331
Expenses attributable to new share issue	–	-21,999	-21,999
Issued warrants	704	1,933	2,032
Total transactions with the group's owner	704	226,265	226,364
Closing shareholders' equity	137,319	230,075	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 September 30, 2016 was KSEK 14,052, KSEK 6,809 on September 30, 2015 and KSEK 7,283 on December 31, 2015. The fair value of the commercial papers as per the balance sheet date September 30, 2016 was KSEK 49,983. The fair value of the financial instruments is calculated on the basis of the closing price. The valuation of the holdings is, thereby, in accordance with Level 1 in the valuation hierarchy.

Note 3 Acquisition 2016

On July 19, 2016, Immago Biosystems Ltd was acquired. Through the acquisition of the company, Hansa Medical acquired all patent rights to the EnzE concept.

The net profit/loss for the Group has not been affected by the acquisition. The acquisition has the following effects on the Group's assets and liabilities. The acquired company's net assets at the acquisition date:

KSEK	Book value before the acquisition	Real value, adjustment	Real value booked in the consolidated accounts
Intangible fixed assets	45	3,068	3,113
Current liabilities	-45	–	-45
Deferred tax liability	–	-612	-612
Net identifiable, assets and liabilities	–	2,456	2,456
Goodwill			–
Total purchase price			2,456
Contingent purchase price, not yet paid			-532
Paid purchase price, in cash			1,924
Cash (acquired)			–
Net cash outflow			1,924

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4. Kluth et al. J Am Soc Nephrol. 1999 Nov;10(11):2446-53
5. Puttarajappa et al. (2012), "Antibody-Mediated Rejection in Kidney Transplantation: A Review", J. Transplant. Volume 2012 (2012), Article ID 193724
6. 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
7. Mayr et al. Virulence 5:1, 4-11, January 1, 2014

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.

