Hansa Medical

Year-End Report 2016

IdeS clinical proof of concept further strengthened. Multicenter study initiated in the US and EU.

Year-End Report 2016 – Business highlights

October-December in brief

- Swedish Phase II study successfully completed with lead candidate IdeS in sensitized kidney transplantation patients
- Application for EU Orphan Drug Designation for IdeS received positive opinion from EMA and the designation was formally granted by the European Commission in January 2017
- First patient treated with IdeS in US and EU multicenter Highdes study in highly sensitized kidney transplantation patients
- Phase II study in asymptomatic patients with Thrombotic Thrombocytopenic Purpura (TTP) was discontinued as initial results demonstrated a non-favorable risk benefit profile
- Completed a directed share issue of approximately SEK 185 m to selected international and Swedish investors
- Nasdaq Stockholm announced Hansa Medical to be traded in the Mid Cap segment as of January 2, 2017

January-September in brief

- Hansa Medical acquired UK-based biotech company Immago Biosystems Ltd to investigate cancer immunotherapy applications with IdeS and EndoS
- Promising initial results from investigator-initiated US Phase II study with IdeS in highly sensitized kidney transplantation patients were presented at the American Transplant Congress
- Henk Doude van Troostwijk appointed Vice President of Commercial Operations and Karin Aschan appointed Vice President of Regulatory Affairs
- Ulf Wiinberg elected new chairman and Angelica Loskog elected new board member

"We achieved several important scientific and regulatory milestones in 2016 with our lead candidate, IdeS. This drug candidate has shown significant potential to become an important new treatment option to enable patients to receive the lifesaving transplantation they desperately need."

Göran Arvidson
President and CEO of Hansa Medical

Financial summary – Fourth quarter and full year

	Q4		Year	
KSEK, unless otherwise stated	2016	2015	2016	2015
Net revenue	543	1,226	2,579	6,675
Operating profit/loss	-33,562	-19,089	-111,135	-66,201
Net profit/loss	-33,556	-19,104	-111,129	-66,266
Earnings per share before and after dilution (SEK)	-1.00	-0.59	-3.39	-2.12
Shareholders' equity	283,693	211,526	283,693	211,526
Cash flow from operating activities	-27,185	-15,948	-94,563	-57,799
Cash and cash equivalents including short term investments	253,578	175,683	253,578	175,683

CEO statement

2016 was in many ways a defining year for Hansa Medical. We successfully continued the development of our novel and innovative immunomodulatory enzymes, in particular our lead candidate, IdeS, enabling transplantation in sensitized patients.

Our unique business opportunity and value-creating strategy has been recognized by a number of investors with substantial investment experience in the life science industry. Furthermore, we have met a lot of interest for our research in the scientific and medical community, which has resulted in the presentation of the results from our clinical trials at several scientific and medical congresses. This was an exciting year – we continued to move our pipeline programs forward and delivered on our milestones. I am convinced we are well-positioned for the future.

In December, we announced the completion of the second Swedish open-label Phase II study with IdeS, conducted at Uppsala University Hospital and Karolinska University Hospital, Huddinge. In the study, 10 sensitized kidney patients were given IdeS prior to transplantation. The study met its primary and secondary objectives, and further supports our belief that IdeS holds significant therapeutic value for sensitized patients in need of a lifesaving transplantation.

In the completed and ongoing Phase II studies with IdeS in Sweden and the US, treatment with IdeS has effectively eliminated the antibody barrier in all sensitized patients. Fast and effective elimination of anti-HLA IgG antibodies enables kidney transplantation for sensitized patients, who otherwise would not be considered for kidney transplantation due to the apparent risk of hyperacute rejection.

Results from the recent studies with IdeS were presented by the principal investigators at a number of renowned scientific and medical meetings.

In June, Professor Stanley Jordan presented initial data from one of the US studies at the *2016 American Transplant Congress* in Boston, and in August, Professor Gunnar Tufveson presented equally encouraging results from one of the Swedish studies at the *26th International Congress of the Transplantation Society* in Hong Kong.

Our objective is now to demonstrate that the mode of action of IdeS is equally relevant for the more severe cases of HLA-sensitization, in order to enable transplantation for patients that have been on the waitlist far too long. In October, the first patient in our multicenter clinical study, Highdes, was treated with IdeS and subsequently transplanted. The Highdes study is exclusively aimed at highly sensitized patients and approximately 20 patients will be recruited in the US and Europe.

We believe that the Highdes study, together with the already 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 EU.

We have also obtained Orphan Drug Designation (ODD) for IdeS from the European Commission for the prevention of graft rejection following solid organ transplantation. IdeS was previously granted ODD by the US Food and Drug Administration. These are important regulatory milestones that will provide us with development and commercial incentives, including 10 years of market exclusivity in the EU, protocol assistance on the development of the drug, including clinical studies, and certain exemptions from or reductions in regulatory fees.

In parallel with our groundbreaking work in organ transplantation, 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 several transplant-related indications and acute autoimmune diseases, including Anti-GBM antibody disease and Guillain-Barré syndrome (GBS).

A clinical study in asymptomatic Thrombotic Thrombocytopenic Purpura (TTP) was discontinued in December after review of initial data from treatment of two patients since we were not able to demonstrate a convincing risk-benefit profile in these patients. We are optimistic about the clinical development of IdeS in our lead programs and the decision to end the study has no impact on Hansa Medical's ongoing studies with IdeS in kidney transplant or planned studies in other autoimmune indications.

In October, we decided to raise SEK 185 million in a directed share issue to selected international specialist investors, as well as Swedish institutional and strategic investors, in order to fully execute our strategy and continue developing our programs. The share issue was well-received and has broadened our shareholder base.

Over the last twelve months, we have also continued to build a strong, committed team at Hansa Medical. We are now more than 30 co-workers and plan to further strengthen 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 developing and executing our strategies for market access, pricing and reimbursement. In the third quarter we appointed Karin Aschan as Vice President of Regulatory Affairs. Karin brings many years of experience from regulatory strategy development.

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

Looking back at 2016, I feel that we have accomplished many important things, both scientifically and operationally.

Outlook

We achieved several important scientific and regulatory milestones in 2016 with our lead candidate, IdeS. This drug has shown significant potential to become an important new treatment option to enable patients to receive the lifesaving transplant they desperately need.

We have a solid and exciting value-creation strategy in place, and our novel immunomodulatory enzymes have the potential to deliver significant value. Furthermore, we have strengthened the company and have the right team in place to continue progressing our programs, benefiting all our stakeholders and, most importantly, the patients. With data expected from a number of clinical studies this year, we look forward to 2017 with continued optimism.

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 candidate, IdeS, is an antibody-degrading enzyme in clinical development, with potential benefit in transplantation and rare autoimmune diseases. Additional projects are focused on the development of novel antibody modulating enzymes, as well as HBP, a commercially available diagnostic biomarker for severe sepsis. The company is based in Lund, Sweden. Hansa Medical's share (ticker: HMED) is listed on Nasdaq OMX Stockholm.

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]						
	Other kidney transplant indications (AMR, ABOi) [3]						
	Anti-GBM antibody disease						
	Other acute autoimmune diseases [4]						
NiceR	Recurring treatment in autoimmune disease						
EndoS	Autoimmune disease						
EnzE	Cancer immunotherapy						
DIAGNOSTICS							
HBP-assay (IVD)	Prediction of severe sepsis [5]						

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

[2] Two separate Phase II studies with IdeS in sensitized patients are currently ongoing.

[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 are being planned.

[5] Out-licensed to Axis-Shield Diagnostics Ltd.

Lead candidate IdeS

IdeS – A novel therapeutic principle
Our lead candidate drug, IdeS, represents 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 transplant-related indications and autoimmune diseases.

IdeS has been evaluated in a Phase I study[1] in healthy subjects and in two Phase II studies in sensitized patients awaiting kidney transplantation. The results in these studies indicate 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 being investigated in two ongoing Phase II studies in sensitized kidney transplantation patients. Additional Phase II studies within kidney transplantation are being planned in Acute Antibody Mediated Rejection (AMR) post-kidney transplantation and desensitization prior to blood group incompatible (ABOi) kidney transplantation. Also, Phase II studies with IdeS are being planned in the rare autoimmune diseases anti-Glomerular Basement Membrane disease (anti-GBM disease) and Guillain-Barré syndrome (GBS).

Ongoing clinical studies with IdeS

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

Latest developments
In December 2016, the Phase II study to evaluate the safety, tolerability, efficacy and pharmacokinetics of intravenous ascending doses of IdeS in kidney transplantation was successfully completed, and the primary and secondary objectives were met. In the study, 10 sensitized kidney patients were given IdeS, which enabled all of them to have a kidney transplantation thereafter. Data generated from this study have been submitted for peer review in a scientific journal.

Two additional Phase II studies are ongoing with IdeS in sensitized patients prior to kidney transplantation – 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 are evaluating safety and tolerability, as well as efficacy of IdeS.

In early October 2016, the first patient was treated and subsequently transplanted in the Phase II multicenter study named Highdes, evaluating the efficacy of IdeS in desensitizing highly sensitized transplantation patients with a positive crossmatch test. The enrolment of this study 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 antibodies to the donor.

Removing donor-specific antibodies 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 enrolment 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 currently available methods. Hansa Medical aims to obtain 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.

Planned clinical studies with IdeS in additional indications

Treatment of kidney transplant antibody-mediated rejection (AMR)
Approximately 10%[2] of all transplant patients experience AMR post-transplant. Although different experimental protocols are used in the treatment of AMR, there is currently no approved treatment. In the more severe cases of AMR, these experimental protocols are generally not sufficient to rescue the kidney since the magnitude of the antibody response exceeds the capacity of the treatment, 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 compared to donor blood group antigens is likely to result in severe AMR and early graft loss.

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 one in a million annually[3].

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 one in 100,000 annually[4].

Discontinued clinical study with IdeS

IdeS – Treatment of Thrombotic Thrombocytopenic Purpura (TTP)
Acquired TTP is a severe and acute autoimmune blood disorder in which the presence of autoantibodies can result in systemic life threatening micro-clotting in vital organs.

Latest developments
In October 2016, Hansa Medical initiated an open-label study to evaluate the safety, tolerability, efficacy, pharmacodynamics and pharmacokinetics of IdeS in asymptomatic patients with acquired TTP. Hansa Medical later decided to stop enrolment to the study following a review of the initial results from the study demonstrating a non-favorable risk benefit profile. This decision has no impact on Hansa Medical's ongoing studies with IdeS in renal transplantation or planned studies in other autoimmune indications. The possibility to investigate the safety and efficacy of IdeS in symptomatic acute patients with TTP in a separate Phase II study is being evaluated.

Preclinical development projects

NiceR – Novel immunoglobulin cleaving enzymes for repeat dosing
Hansa Medical develops completely novel IgG-degrading enzymes. The aim of NiceR is to create novel IgG-inactivating biopharmaceuticals that can be used for repeated dosing in autoimmune conditions where patients would 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 to be 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, we believe that EndoS may have the potential to be a novel therapy for autoimmune diseases.

EnzE – Enzyme based antibody Enhancement
Many antibody-based cancer therapies rely on activation of the immune system via antibody dependent cell-mediated cytotoxicity (ADCC). The antibodies bind to antigens on cancer cells and once attached, the antibodies attract immune cells to destroy the cancer cells. For instance, the anti-CD20 antibody, which is used for treatment of lymphoma and leukemia, binds to CD20 on cancer cells and activates cytotoxic immune cells to kill the cancer cells. The immune cells are activated through binding of the Fc-part of the antibody to Fc-gamma receptors on the cell surface of the immune cells. The Fc-gamma receptors are involved in the therapeutic effector functions of many different antibodies and often needed to have sufficient effect. However, due to the abundancy of normal IgG in blood, the Fc-gamma receptors are occupied by IgG and the therapeutic antibodies have to compete for binding to the Fc-gamma receptors. Hence pre-treatment with IdeS or EndoS has the potential to potentiate presently available antibody-based cancer therapies. Results from *in vitro* testing of the concept have been published by Baruah et al [5].

Out-licensed royalty generating programs

HBP – Prediction of severe sepsis
HBP-assay (measurement of Heparin Binding Protein) 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. Many of 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. Severe sepsis affects 300 of 100,000 people annually [6].

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 holds 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 – December 2016

Financial result

Net revenue for the fourth quarter 2016 amounted to SEK 0.5 m (1.2) and to SEK 2.6 m (6.7) for the full year 2016 and is comprised of royalty income from Axis-Shield Diagnostics and re-invoiced expenses. In net revenue for the previous year is also a licensing income of SEK 3.3 m from Axis-Shield Diagnostics included.

Operating result for the fourth quarter 2016 amounted to SEK -33.6 m (-19.1) and SEK -111.1 m (-66.2) for the full year 2016. Research and development expenses increased continuously during the year in line with intensified CMC development, high activity in clinical studies and regulatory work for the market applications.

Profit/loss for the fourth quarter amounted to SEK -33.6 m (-19.1) and to SEK -111.1 m (-66.3) for the full year 2016.

Cash flow and investments

Cash flow from operating activities amounted to SEK -27.2 m (-15.9) for the fourth quarter 2016 and to SEK -94.6 m (-57.8) for the full year 2016. The cash flow after financing was positively impacted by the share issue in November. Cash and cash equivalents including short-term investments amounted to SEK 253.6 m on December 31 2016, as compared with SEK 103.9 m at the end of third quarter 2016. Investing activities during the fourth quarter 2016 resulted in a positive cash flow derived from divestment and ended with a net of SEK 9.3 m (-1.0) and to SEK -45.4 m (-2.8) for the full year 2016.

Shareholders' equity

On December 31, 2016 equity amounted to SEK 283.7 m compared with SEK 211.5 m at the end of the corresponding period 2015.

Share issue 2016

In the fourth quarter, Hansa Medical finalized a directed share issue, which brought the company SEK 185 m before deduction of costs. The directed issue was comprised of 2,642,857 shares at SEK 70 per share. The number of outstanding shares amounts to 35,054,860 shares after the share issue. The rights issue has enabled the company to secure the capital needed to continue clinical studies and the CMC development for IdeS as well as to broaden the ownership structure of the company with strategic and institutional investors.

Parent company

The Parent company's net revenue for the fourth quarter 2016 amounted to SEK 0.5 m (1.2) and to SEK 2.6 m (6.7) for the full year 2016. Profit/loss for the Parent company amounted to SEK -33.5 m (-18.6) for the fourth quarter and to SEK -108.4 m (-64.6) for the full year 2016. On December 31, 2016, cash and cash equivalents including short-term investments amounted to SEK 251.3 m compared with SEK 101.7 m at the end of third quarter 2016.

The Parent company's equity amounted to SEK 281.8 m as per December 31, 2016, as compared with SEK 211.5 m 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

	Q4		Year	
KSEK, unless otherwise stated	2016	2015	2016	2015
Net revenue	543	1,226	2,579	6,675
Operating profit/loss	-33,562	-19,089	-111,135	-66,201
Net profit/loss	-33,556	-19,104	-111,129	-66,266
Earnings per share before and after dilution (SEK)	-1.00	-0.59	-3.39	-2.12
Shareholders' equity	283,693	211,526	283,693	211,526
Cash flow from operating activities	-27,185	-15,948	-94,563	-57,799
Cash and cash equivalents including short term investments	253,578	175,683	253,578	175,683

Other information

Employees and organization

The number of employees at the end of the fourth quarter 2016 was 27, compared to 19 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 within the program have been acquired by recently joined employees. 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.

Long-term incentive program (LTIP 2016)

The Hansa Medical's Extraordinary General Meeting November 21, 2016 resolved to adopt a long-term incentive program (LTIP 2016) in the form of a performance based share program for all employees of the Hansa Medical Group, meaning that not more than 30 individuals within the group may participate. The rationale for LTIP 2016 is to create conditions for motivating and retaining competent employees of the Hansa Medical group and for the alignment of the targets of the employees with those of the shareholders and the company, as well as to increase the motivation of meeting and exceeding the company's financial targets. A maximum of 305,000 rights may be allotted to participants under LTIP 2016 and 234,750 rights have been totally allocated at December 31, 2016. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period November 28, 2019.

The general meeting further resolved, in order to implement LTIP 2016 cost effectively, to authorize the Board to decide on a directed share issue of a maximum of 401,000 Class C shares to participating bank, of which a maximum of 96,000 Class C shares to be issued to cover any social costs arising from the program and to authorize the Board to resolve to repurchase all issued C-shares. After the conversion of C shares to ordinary shares, these shall partly be transferred to participants in LTIP 2016 and partly divested in the market for cash flow purposes to secure certain payments related to LTIP 2016, mainly social security costs. Not more than 305,000 ordinary shares can be transferred to participants under LTIP 2016 and 96,000 common shares can be used to cover any social security contributions due to the LTIP 2016, which means a dilution of approximately 1.21 per cent of the ordinary shares and votes in the company.

LTIP 2016 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost of LTIP 2016, calculated in accordance IFRS 2, including social security contributions is expected to amount to approximately SEK 17.2 m, of which SEK 0.5 m is included in the results for the parent company and the group for 2016. The program is not expected to have any net effect on cash flow provided it is secured fully in the manner described above.

Committee for the 2017 Annual General Meeting

Hansa Medical AB's Nomination Committee for the AGM 2017 will consist of the three members Erika Kjellberg Eriksson representing Nexttobe AB, Sven Sandberg representing Thomas Olausson, Max Mitteregger representing Gladiator AB and the chairman of the board Ulf Wiinberg is adjunct.

Financial calendar

Annual report 2016	26 April 2017
Interim report for January-March 2017	26 April 2017
Annual General Meeting	23 May 2017
Interim report for January-June 2017	20 July 2017
Interim report for January-September 2017	14 November 2017

Shareholder information

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

Brief facts, the HMED share

Listing	Nasdaq OMX Stockholm
Number of shares	35,054,860
Market capitalization Dec. 31, 2016	SEK 4,084
Ticker	HMED
ISIN	SE0002148817

10 largest shareholders, December 31, 2016

Name	Number of shares	Share (%)
Nexttobe AB	9,443,761	26.9
Gladiator	2,230,500	6.4
AFA Försäkring AB	1,333,000	3.8
Försäkringsaktiebolaget, Avanza Pension	1,187,861	3.4
Olausson, Thomas	1,106,584	3.2
Farstorps Gård AB	1,084,070	3.1
Catella Fondförvaltning	700,055	2.0
Tredje AP-Fonden	686,152	2.0
Handelsbanken Fonder AB	649,085	1.9
BWG Invest	600,370	1.7
Other	16,033,422	45.6
In total	**35,054,860**	**100.0**

According to the shareholder register maintained by Euroclear Sweden AB, as of December 31, 2016, Hansa Medical had 7,470 shareholders. In 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.

Address

Hansa Medical AB (publ)
Scheelevägen 22, SE-223 63 Lund, Sweden

Postal address

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

Registration number

556734-5359

Condensed financial statements

Consolidated statement of comprehensive income

	Q4		Year	
KSEK	2016	2015	2016	2015
Net revenue	543	1,226	2,579	6,675
Direct cost of net revenue	-54	-658	-217	-658
Gross profit	**-489**	**568**	**2,362**	**6,017**
Other operating income	–	36	–	300
Sales, general and administration expenses	-8,431	-4,339	-29,703	-28,241
Research and development expenses	-25,013	-15,354	-82,850	-44,262
Other operating expenses	-607	–	-944	-15
Operating profit/loss	**-33,562**	**-19,089**	**-111,135**	**-66,201**
Financial income/expenses	-17	-15	-17	-65
Profit/loss before tax	**-33,579**	**-19,104**	**-111,152**	**-66,266**
Tax	23	–	23	–
Net profit/loss for the period	**-33,556**	**-19,104**	**-111,129**	**-66,266**
Attributable to				
Parent company shareholders	-33,556	-19,104	-111,129	-66,266
Earnings per share				
Before dilution (SEK)	-1.00	-0.59	-3.39	-2.12
After dilution (SEK)	-1.00	-0.59	-3.39	-2.12
Other comprehensive income				
Items that have been, or may be reclassified to profit or loss for the period				
Translation differences	6	–	-26	–
Changes in fair value on available-for-sale financial assets	509	473	4,690	1,624
Other comprehensive income for the period	**515**	**473**	**4,664**	**1,624**
Total net comprehensive income	**-33,041**	**-18,631**	**-106,465**	**-64,642**

Consolidated balance sheet

KSEK	December 31 2016	2015
ASSETS		
Non-current assets		
Intangible fixed assets	36,554	36,327
Tangible fixed assets	2,570	2,182
Financial fixed assets	14,566	7,283
Total non-current assets	**53,690**	**45,792**
Current assets		
Current receivables, non-interest bearing	3,404	2,613
Short-term investments	39,990	–
Cash and cash equivalents	213,588	175,683
Total current assets	**256,982**	**178,296**
TOTAL ASSETS	**310,672**	**224,088**
EQUITY AND LIABILITIES		
Shareholders' equity	**283,693**	**211,526**
Long term liabilities		
Deferred tax liabilities	581	–
Other provisions	114	–
Long term liabilities, interest bearing	552	49
Total long term liabilities	**1,247**	**49**
Current liabilities		
Current liabilities, interest bearing	44	42
Current liabilities, non-interest bearing	8,390	2,294
Accrued expenses and deferred income	17,298	10,177
Total current liabilities	**25,732**	**12,513**
TOTAL EQUITY AND LIABILITIES	**310,672**	**224,088**

Consolidated changes in equity

	Year	
KSEK	2016	2015
Opening shareholders' equity	**211,526**	**49,804**
Result for the period	-111,129	-66,266
Other comprehensive income for the period	4,664	1,624
Net comprehensive income	**-106,465**	**-64,642**
Transactions with the group's owner		
New share issue	185,000	246,331
Expenses attributable to new share issue	-7,504	-21,999
Issued warrants	772	2,032
Long term incentive program	364	–
Total transactions with the group's owner	**178,632**	**226,364**
Closing shareholders' equity	**283,693**	**211,526**

Consolidated cash flow statement

		Q4		Year	
KSEK	Note	2016	2015	2016	2015
Operating activities					
Operating profit/loss		-33,562	-19,089	-111,135	-66,201
Adjustment for items not included in cash flow		1,500	368	4,269	1,188
Interest received and paid, net		-23	-15	-78	-65
Income taxes paid		48	223	192	184
Cash flow from operations before change in working capital		**-32,037**	**-18,513**	**-106,752**	**-64,894**
Change in working capital		4,852	2,565	12,189	7,095
Cash flow from operating activities		**-27,185**	**-15,948**	**-94,563**	**-57,799**
Investing activities					
Acquisition of business, net cash effect	3	–	–	-1,924	–
Acquisition of intangible fixed assets		-57	–	-57	–
Acquisition of tangible fixed assets		-629	-988	-927	-1,317
Acquisition of financial assets		–	–	-2,588	-1,479
Short term investments		-29,991	–	-194,918	–
Divestment short term investments		40,000	–	155,000	–
Cash flow from investing activities		**9,323**	**-988**	**-45,414**	**-2,796**
Financing activities					
New share issue		185,000	–	185,000	246,331
Issue expenses		-7,504	–	-7,504	-21,999
Issued warrants		–	–	429	1,833
Repayment of leasing liabilities		-11	-9	-43	-39
Cash flow from financing activities		**177,485**	**-9**	**177,882**	**226,126**
Net change in cash		**159,623**	**-16,945**	**37,905**	**165,531**
Cash and cash equivalents, beginning of period		53,965	192,628	175,683	10,152
Cash and cash equivalents, end of period		**213,588**	**175,683**	**213,588**	**175,683**

Consolidated key ratios and other information

	Q4		Year	
KSEK, unless otherwise stated	2016	2015	2016	2015
Profit numbers				
Net revenue	543	1,226	2,579	6,675
Operating profit/loss	-33,562	-19,089	-111,135	-66,201
Net profit/loss	-33,556	-19,104	-111,129	-66,266
Per share data				
Earnings/loss per share before and after dilution (SEK)	-1.00	-0.59	-3.39	-2.12
Shareholders' equity per share (SEK)	8.09	6.53	8.09	6.53
Other information				
Equity ratio (%)	91	94	91	94
Cash and cash equivalents including short term investments	253,578	175,683	253,578	175,683
Number of outstanding shares at the end of the period	35,054,860	32,412,003	35,054,860	32,412,003
Weighted average number of shares before and after dilution	33,630,528	32,485,477	32,773,304	31,208,438

Parent company – Statement of comprehensive income

	Q4		Year	
KSEK	2016	2015	2016	2015
Net revenue	543	1,226	2,579	6,675
Direct cost of net revenue	-54	-658	-217	-658
Gross profit	**489**	**568**	**2,362**	**6,017**
Other operating income	–	36	–	300
Sales, general and administration expenses	-8,428	-4,336	-29,690	-28,228
Research and development expenses	-24,898	-15,354	-82,735	-44,262
Other operating expenses	-607	–	-944	-15
Operating profit/loss	**-33,444**	**-19,086**	**-111,007**	**-66,188**
Result from other securities and receivables which are fixed assets	–	473	2,628	1,624
Other financial expenses	-17	-14	-14	-59
Profit/loss for the period (before and after taxes)	**-33,461**	**-18,627**	**-108,393**	**-64,623**
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total net comprehensive income	**-33,461**	**-18,627**	**-108,393**	**-64,623**

Parent company – Balance sheet

KSEK	December 31 2016	2015
ASSETS		
Non-current assets		
Intangible fixed assets	33,513	36,327
Tangible fixed assets	2,554	2,110
Financial fixed assets	17,317	9,216
Total non-current assets	**53,384**	**47,653**
Current assets		
Current receivables non-interest bearing	3,504	2,612
Short-term investments	39,995	–
Cash and cash equivalents	211,329	173,850
Total current assets	**254,828**	**176,462**
TOTAL ASSETS	**308,212**	**224,115**
EQUITY AND LIABILITIES		
Shareholders' equity	**281,786**	**211,547**
Long-term liabilities		
Other provisions	114	–
Long term liabilities, non-interest bearing	548	–
Total long-term liabilities	**662**	**–**
Current liabilities		
Liabilities to group companies	98	98
Current liabilities, non-interest bearing	8,368	2,293
Accrued expenses and deferred income	17,298	10,177
Total current liabilities	**25,764**	**12,568**
TOTAL EQUITY AND LIABILITIES	**308,212**	**224,115**

Parent company – Changes in equity

KSEK	Year 2016	2015
Opening shareholders' equity	**211,547**	**49,806**
Result for the period	-108,393	-64,623
New share issue	185,000	246,331
Expenses attributable to new share issue	-7,504	-21,999
Issued warrants	772	2,032
Long term incentive program	364	–
Total transactions with the group's owner	**178,632**	**226,364**
Closing shareholders' equity	**281,786**	**211,547**

Financial notes

Note 1 Basis of Preparation and Accounting policies

This consolidated 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 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 December 31, 2016 was SEK 14,566 k and SEK 7,283 k on December 31, 2015. The fair value of the commercial papers as per the balance sheet date December 31, 2016 was SEK 39,990 k. 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

19th of July, 2016, Immago Biosystems Ltd was acquired. Through the acquisition of the company, Hansa Medical acquired 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**

Reference list

1. Winstedt el al., “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 2015, 10(7)

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

3. Kluth et al., “Anti-Glomerular Basement Membrane Disease” J Am Soc Nephrol. 1999 Nov;10(11):2446-53

4. McGrogan et al., “The Epidemiology of Guillain-Barré Syndrome Worldwide“ Neuroepidemiology;2009, 32(2):150-63

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

6. Mayr et al. “Epidemiology of severe sepsis” 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.

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