



YEAR-END REPORT

1 January – 31 December 2011

Hansa Medical is a biopharmaceutical development company focused on inflammatory diseases. The company develops innovative biopharmaceuticals and diagnostics in partnership with major companies with market presence as well as under full Hansa Medical management. At present, three primary product candidates are in development; IdeS, EndoS and HMD-301. Novel research projects and product candidates are generated through academic collaborations and in-house development. Hansa Medical is publicly traded at NASDAQ OMX First North under ticker symbol HMED. Remium Nordic AB is Certified Adviser to Hansa Medical.

FINANCIAL INFORMATION

- Net sales for the Group amounted to SEK 1.3 (4.4) M
- The Group reported a loss of SEK -24.6 (-18.8) M
- The Group's operating loss amounted to SEK -24.5 (-20.0) M
- The loss per share was SEK 2.26 (loss 2.44)

THE YEAR IN BRIEF

- Hansa Medical and Axis-Shield accomplish a clinical multi-center study in Sweden and the USA with HMD-301 (HBP assay) for the diagnosis of severe sepsis.
- Published clinical research results indicate that HBP has potential as biomarker for the diagnosis of bacterial meningitis
- A preferential rights issue of SEK 29 M was oversubscribed
- Hansa Medical and its collaboration partner, Alere Inc., terminated the development project, anti-alpha-11 for the treatment of rheumatoid arthritis
- Development resources focused on the clinical development of enzyme-based treatment of unusual diseases
- The development of the GMP process for the production of IdeS for clinical studies was finalized
- Toxicity and safety studies were executed with IdeS

SIGNIFICANT EVENTS AT THE END OF THE YEAR

- Hansa Medical executed in January 2012 a directed new share issue to Bengt Ågerup's investment company, NXT2B, for SEK 27.5 M. Also, a subsequent preferential new share issue of SEK 18.5 M is to be accomplished in march 2012. In total, Hansa Medical raises SEK 46 M.



CEO'S COMMENTS

We have now reached a position where we are able to commence clinical studies with our drug candidate IdeS in the middle of 2012. The groundwork for making this possible was laid during 2011, including the establishment of a quality-assured production process under GMP, as well as the implementation of toxicity and safety studies. The toxicity study has been completed in its entirety, although the final reports are not yet finalized, due to a large number of ongoing laboratory analyses. The preliminary results looks promising and it is our aim to announce the final results in conjunction with the submission of our application for clinical studies to the Swedish Medical Products Agency. We have also prepared the forthcoming Phase 1 study in mid 2012, by further strengthening the pre-clinical documentation and substantiating the experimental support, for safe administration of IdeS.

Together with our collaboration partner Alere Inc., we chose to close our engagement in the early drug development program anti-alpha-11 during the latter part of 2011. We acquired the anti-alpha-11 project in 2008 for two reasons: 1) Promising research data which identified anti-alpha-11 as an innovative drug target for the treatment of rheumatoid arthritis, and 2) the large pharmaceutical companies' sustained interest for new drug candidates for rheumatoid arthritis. At the end of 2011, it was clear to us that we had not succeeded, in a timely manner, in unambiguously reproducing the previous research results. We will not invest resources in this project from now on. We will, however, maintain basic patent rights for alpha-11, and cooperate with university researchers conducting research on alpha-11 as a drug target for diseases other than rheumatoid arthritis. This is an interesting research area definitely worthwhile monitoring. The release of internal resources from the anti-alpha-11 project was also a necessity in order to be able to focus on the preparations for the Phase 1 studies with IdeS during 2012.

During 2011, we have, together with the British-Norwegian company, Axis-Shield, implemented a comprehensive clinical study with approximately 700 patients in Sweden and the United States with the diagnostic method HMD-301. HMD-301 is an assay for the diagnosis of severe sepsis at emergency clinics. Evaluation of the comprehensive patient material is still ongoing and we look forward to announcing the outcome as soon as analyses, evaluation and reporting are completed. If the result from the study confirms the potential of HBP as a biomarker for severe sepsis, then Axis-Shield intends to launch a commercial assay based on these data. Hans Medical has the opportunity to receive milestone payments and royalty compensation from the product candidate and Axis-Shield. Axis-Shield bears the costs for the project.

When Phase 1 studies with IdeS commence, which we assume will take place in mid 2012, it will be possible for internal resources to be invested in the new pre-clinical project EndoS. The enzyme EndoS modifies the so called glycosylation of antibodies and a series of early preclinical research results indicates the potential of EndoS for the treatment of rare autoimmune diseases. EndoS and IdeS are both immunomodulating enzymes of bacterial origin. The promising research results with EndoS combined with significant know-how from the IdeS project forms the basis for our decision to dedicate development resources to the EndoS project as well.

Emanuel Björne, CEO Hansa Medical AB (publ)



SIGNIFICANT EVENTS DURING THE YEAR

Clinical multi-center registration study with HMD-301 (HBP-assay) for the diagnosis of severe sepsis completed

During 2011, Hansa Medical has, together with Axis-Shield, executed an extensive clinical study involving approximately 700 patients in Sweden and the US studying the diagnostic method HMD-301. HMD-301 is an assay for the diagnosis of severe sepsis in emergency clinics. The analysis and evaluation of the extensive patient material is underway. If the result from the study confirms the potential of HBP as a biomarker for severe sepsis, then Axis-Shield intends to launch a commercial assay based on these data. Hansa Medical has the opportunity to receive milestone payments and royalty compensation from the product candidate and Axis-Shield. Axis-Shield bears the costs for the project.

Published clinical research results indicates that HBP has the potential to be a good biomarker for the diagnosis of bacterial meningitis

In 2011, Hansa Medical's clinical collaboration partners published the results from a clinical study indicating that the diagnostic method, HMD-301, can diagnose bacterial meningitis with a very high degree of precision. The results from the study were published in the April issue of the scientific journal Critical Care Medicine, Vol. 39, 4: 812-817. The clinical study was executed at the Infection Clinic at the University Hospital in Lund and involved 174 patients with suspected infection of the central nerve system. Of these 174 patients, a total of 41 developed bacterial meningitis. By quantifying the level of HBP in the cerebrospinal fluid, these patients could be discerned with a sensitivity of 100% and with a specificity of 99.2%. Bacterial meningitis often results from infection of pneumococcus or meningococcus. This is a serious medical condition requiring immediate diagnosis and treatment. Bacterial meningitis affects 1-2 individuals per 100,000 inhabitants in the West per year and the death rate is estimated at approximately 34%, in spite of treatment with antibiotics. Hansa Medical estimates the need for diagnosis of bacterial meningitis to be 500,000 cases per year.

Preferential rights issue of SEK 29 M oversubscribed

During June 2011, a guaranteed preferential rights issue was executed providing 5.8 million shares to Hansa Medical's shareholders at a subscription rate of SEK 5. This new share issue was subscribed to at 116% and provided a total of SEK 29 M before share issue costs. The funds from the new share issue was dedicated to the development of the GMP process for IdeS, to execute toxicity and safety studies with IdeS and to strengthen the pre-clinical documentation for IdeS prior to the forthcoming Phase I study. Furthermore, the funds were also used for development activities within the now closed anti-alpha-11 project.

P.O. Wallström elected new Board member

At Hansa Medical's annual general meeting of shareholders held on 12 May 2011, Bo Håkansson was re-elected as Chairman of the Board and Per Belfrage, Stina Gestrelus and Paula Zeilon were re-elected as Board members. Per Olof Wallström was elected as a new member of the Board. Per Olof Wallström has extensive experience in the international pharmaceuticals industry and biotechnology. Wallström has held leading positions within Merck, Astra, Pharmacia and Bristol-Myers Squibb and has been CEO of Q-Med AB, Melacure Therapeutics AB and Karo Bio AB. Today, Wallström is Chairman of the Board of Aggal Invest AB and Arosgruppen Holding AB and Arosgruppen Fastigheter Fjärdingen AB, and is a Board member in Camurus AB, Arosia Communication AB and MediPlast AB. Wallström is a qualified pharmacist.



Hansa medical and its collaboration partner, Alere Inc., closes the rheumatoid arthritis development project anti-alpha-11

Together with its collaboration partner, Alere Inc., Hansa Medical decided, in December 2011, to terminate the project anti-alpha-11 for the treatment of rheumatoid arthritis. The project was in an early preclinical development phase and Hansa Medical has, together with its collaboration partner, Alere, worked to identify antibody-based product candidates for the drug target alpha-11. The starting point for the development work has been the early and very promising research results indicating the significance of the surface protein alpha-11 in the development of rheumatoid arthritis. This, in combination with the probable restrictive expression of alpha-11 in healthy tissue has implied that alpha-11, since the investment in the project in 2008, has been considered to be a very promising and innovative drug target. However, Hansa Medical has not succeeded in confirming, within a reasonable time the early research results in this project. Hansa Medical will not continue to invest resources in alpha-11. However, Hansa Medical will retain its basic patent rights associated with alpha-11 and will co-operate with the university researchers undertaking research regarding alpha-11 as a drug target for diseases other than rheumatoid arthritis

Focus on clinical development of the enzyme-based treatment of rare autoimmune diseases and significant progress within project IdeS

Hansa Medical determined, in December 2011, to focus its operations on the development of the enzymes IdeS and EndoS. Project IdeS has now progressed to the an intensive preparatory stage prior to the forthcoming Phase I study in mid 2012. During 2011, a qualified production process for IdeS under GMP has been developed and validated. Furthermore, toxicity and safety studies have been initiated and executed. In addition, significant resources has been dedicated to further strengthen the pre-clinical documentation and further develop the experimental support so that IdeS can be administered in a safe manner in the Phase I study.

The enzyme EndoS modifies the so-called glycosylation of antibodies. A series of early preclinical research studies highlights the therapeutic potential of EndoS in the treatment of rare autoimmune diseases. EndoS and IdeS are both immunomodulating enzymes of bacterial origin. The promising research results with EndoS combined with significant know-how from the IdeS project forms the basis for the decision to dedicate development resources to the EndoS project as well.

DEVELOPMENT PROJECTS IN BRIEF

Project IdeS

IdeS, Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, is a biopharmaceutical drug candidate which is being developed to make kidney transplantation for a certain group of patients that today are especially difficult to transplant due to so-called anti-donor antibodies. The patients have developed anti-donor antibodies directed towards most of the potential donors and are referred to as sensitized patients. A transplantation of sensitized patients is associated with a higher level of risk of graft rejection. IdeS has the potential to desensitize these patients through inactivation of the anti-donor antibodies immediately prior to transplantation. During 2011, a GMP process for the production of IdeS has been developed and toxicity and safety studies have been executed. The start of the clinical Phase I study is planned for the middle of 2012.

Project EndoS

The enzyme EndoS modifies the so-called glycosylation of antibodies. A series of published preclinical research studies highlights the therapeutic potential of EndoS in the treatment of rare autoimmune diseases. EndoS and IdeS are both immunomodulating enzymes of bacterial origin. The promising research results with EndoS

combined with significant know-how from the IdeS project forms the basis for the decision to dedicate development resources to the EndoS project as well. Hansa Medical intends to further strengthen the pre-clinical documentation supporting EndoS as a potential drug candidate with the goal to make clinical studies with EndoS in the near future. In addition, Hansa Medical collaborates with academic research groups around the concept of developing EndoS-modified antibodies as drug candidates.

Project HMD-301 (HBP)

HMD-301 is a diagnostic method intended for emergency departments for the prediction, diagnosis and prognosis of severe sepsis. The method is based on the quantification of the protein, HBP, in the blood. Together with the British-Norwegian company, Axis Shield Diagnostics Ltd., Hansa Medical is developing this product towards market introduction in 2012 and towards further licensing agreements with international diagnostics companies. In 2011, an extensive clinical study involving approximately 700 patients in Sweden and the US with HMD-301 was accomplished. The analysis and evaluation of the extensive patient material is ongoing. If the result from the study confirms the potential of HBP as a biomarker for severe sepsis, then Axis-Shield intends to launch a commercial assay based on the data from the clinical trial. Hans Medical has the opportunity to receive milestone payments and royalty compensation from the product candidate. Axis-Shield bears the costs for the project. The joint development goal is to reach further licensing agreements with international diagnostics companies with market presence for the optimum dissemination of the diagnostic method.

FINANCIAL INFORMATION

Sales and earnings

The Group's net sales during the period amounted to SEK 1.3 (4.4) M. The operating loss was SEK 24.5 (loss: 20.0) M, while the loss after financial items was SEK 24.6 (loss: 20.1) M. The loss for the period amounted to SEK 24.6 (loss: 18.8) M. Earnings per share amounted to a loss of SEK 2.26 (loss: 2.44).

The Group's operating expenses consisted primarily of personnel costs of SEK 5.9 (4.7) M, patent costs of SEK 1.5 (1.5) M, research agreements, SEK 2.6 (2.3) M, material costs of SEK 12.1 (6.9) M, premises costs of SEK 1.1 (0.8) M and depreciation/amortization of SEK 0.1 (0.4) M.

Financial position, cash flow and assets

On 31 December 2011, cash and cash equivalents for the Group amounted to SEK 1.2 (0.2) M and equity to SEK 34.7 (32.2) M. Cash flow for the period from operating activities was negative in an amount of SEK 27.1 (negative: 18.0) M. Cash flow from financing activities amounted to SEK 29.8 M and comprised of SEK 27.1 M from the new share issue and SEK 2.7 M from new raised loans.

The expenses for the implementation of the new share issue for 2011 amounted to SEK 1.9 M. During the period, the company has raised and repaid a bridge loan totaling SEK 10.4 M.

Investments

Investments in tangible assets totaled SEK 24,286 for the period. Investments in intangible assets have been made in an amount of SEK 1,714,655, which is entirely comprised of capitalized development costs for the establishment of a GMP process for the drug candidate IdeS.

Group structure

The Hansa Medical Group consists of the Parent Company Hansa Medical AB (publ) and the wholly-owned subsidiary Cartela R&D AB.

Employees

At the end of the year, the number of employees was 8 (6).

Number of shares

The number of shares at the start of the period on 1 January 2011 was 7,726,368 and the number of shares at the end of the period on 31 December 2011 was 13,521,144.

Ownership structure (30 Dec 2011)

Name	Number of shares	Proportion (%)
Håkansson, Bo (via company)	7,416,906	54.9
Försäkringsaktiebolaget, Avanza Pension	2,268,797	16.8
Nordnet Pensionsförsäkring AB	235,064	1.7
Sandberg, Sven	202,736	1.5
Aktiebolaget Protiga	140,000	1.0
Strategic Wisdom Nordic AB	130,626	1.0
Biolin Scientific AB	100,000	0.7
Elleson Ljunggren, Anja	84,546	0.6
Ostrander, Ingemar	81,859	0.6
Svenro Aktiebolag	70,000	0.5
Others	2,790,610	20.6
Total	13,521,144	100

BUSINESS RELATED RISKS AND UNCERTAINTIES

Hansa Medical's business is affected by a number of risks, the consequences of which could have a negative impact on the Company's future. These risks include intellectual property rights, secrecy, regulatory approval, clinical trials, dependence on financing for development, use of cash and cash equivalents, sensitivity in conjunction with valuations, dependence on partnerships and key individuals, product liability, dependence on sub-suppliers, competition and share-related risks.

ACCOUNTING PRINCIPLES

The accounts are prepared in accordance with the Annual Accounts Act and the general recommendations of the Swedish Accounting Standards Board.



REVIEW REPORT

Introduction

I have conducted a review of the year-end report for Hansa Medical AB (publ), Corporate Identity Number 556734-5359, for the period 1 January- 31 December 2011. The Board of Directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with the Swedish Annual Accounts Act. My responsibility is to express a conclusion on this interim report based on my review.

Focus and scope of the review

I have conducted my review in accordance with the Swedish Standard on Review Engagements SÖG 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*, issued by FAR. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review has a different focus and is substantially smaller in scope than an audit conducted in accordance with ISA and other generally accepted auditing standards. The procedures performed in a review do not enable me to obtain assurance that I would become aware of all significant matters that might be identified in an audit. Accordingly, I do not express an audit opinion.

Opinion

Based on my review, nothing has come to my attention that gives me reason to believe that the year-end report has not been prepared, in all material aspects, in accordance with the Swedish Annual Accounts Act

Malmö, 9 February 2012

Ann Theander

Authorized Public Accountant FAR

Grant Thornton Sweden AB

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FUTURE REPORTING DATES

Annual Report 2011	April 2012
Annual General Meeting	10 May 2012
Interim Report 1 January – 30 June 2012	26 July 2012
Year-End Report 2012	7 February 2013

The Board of Directors and the Chief Executive Officer certifies that this interim report provides a true and fair view of the Company's operations, financial position and results and that it describes the significant risk factors faced by the Company.

Lund, 9 February 2012

The Chief Executive Officer and Board of Directors of Hansa Medical AB (publ)

FOR FURTHER INFORMATION

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INCOME STATEMENT – Group (SEK)

	Jul – Dec 2011	Jul – Dec 2010	Full year 2011	Full year 2010
Net sales	882,433	4,157,241	1,282,219	4,448,186
Work capitalized on own account	1,714,655	0	1,714,655	
Operating expenses	-16,672,423	-16,653,240	-27,461,198	-24,441,041
Operating profit/loss	-14,075,335	-12,495,999	-24,464,324	-19,992,855
Profit /loss from financial items	45,166	776	-107,632	-150,481
Profit/loss after financial items	-14,030,169	-12,495,223	-24,571,956	-20,143,336
Tax on profit for the year	-65	1,300,097	-65	1,300,097
Profit/loss for the period	-14,030,234	-11,195,126	-24,572,021	-18,843,239
Average number of shares	13,521,144	7,726,368	10,865,205	7,726,368
Earnings per share	-1.04	-1.45	-2.26	-2.44

BALANCE SHEET – Group (SEK)

	31 Dec 2011	31 Dec 2010
<i>Fixed assets</i>		
Intangible fixed assets	37,675,187	35,973,032
Tangible fixed assets	313,028	406,141
Total fixed assets	37,988,215	36,379,173
<i>Current assets</i>		
Current receivables	1,751,099	1,200,648
Cash and bank balances	1,156,621	221,669
Total current assets	2,907,720	1,422,317
Total assets	40,895,935	37,801,490
Equity	34,707,106	32,166,121
Long-term liabilities	0	0
Current liabilities	6,188,829	5,635,369
Total equity and liabilities	40,895,935	37,801,490

CASH FLOW STATEMENT – Group (SEK)

	1 Jan – 31 Dec 2011	1 Jan – 31 Dec 2010
Cash flow from operations before changes in working capital	-24,442,057	-19,791,224
Cash flow from changes in working capital	-2,697,054	-1,697,267
Cash flow from operating activities	-27,139,111	-18,093,957
Cash flow from investing activities	-1,738,941	-383,800
Cash flow from financing activities	29,813,004	18,087,869
Cash and cash equivalents on the opening date	221,669	611,557
Cash and cash equivalents on the closing date	1,156,621	221,669

CHANGES IN EQUITY – Group (SEK)

	Share capital	Non-restricted reserves	Profit/loss for the period	Total
Amount 1 Jan 2010	19,315,920	21,417,721	-15,812,150,	24,921,491
Profit/loss brought forward		-15,812,150	15,812,150,	0
New share issue	19,315,920	6,771,949		26,087,869
Profit/loss for the period			-18,843,239	-18,843,239
Amount 1 Jan 2011	38,631,840	12,377,520	-18,843,239	32,166,121
Profit/loss brought forward		-18,843,239	18,843,239	0
New share issue	28,973,880	-1,860,875		27,113,005
Profit/loss for the period			-24,572,021	-24,572,021
Amount 31 Dec 2011	67,605,720	-8,326,594	-24,572,021	34,707,105

INCOME STATEMENT – Parent Company Hansa Medical AB (publ) (SEK)

	1 Jan – 31 Dec 2011	1 Jan – 31 Dec 2010
Net sales	1,282,219	4,448,186
Work capitalized on own account	1,714,655	0
Operating expenses	-27,461,204	-24,441,043
Operating profit/loss	-24,464,330	-19,992,857
Profit/loss from financial items	-107,626	-150,478
Profit/loss after financial items	-24,571,956	-20,143,335
Tax on loss for the period	0	1,301,455
Profit/loss for the period	-24,571,956	-18,841,880

BALANCE SHEET – Parent Company Hansa Medical AB (publ) (SEK)

	31 Dec 2011	31 Dec 2010
<i>Fixed assets</i>		
Intangible fixed assets	35,282,681	33,580,526
Tangible fixed assets	313,028	406,141
Financial non-current assets	2,385,906	2,297,462
Total fixed assets	37,981,615	36,284,129
<i>Current assets</i>		
Current receivables	1,750,584	1,200,435
Cash and bank balances	1,155,655	220,108
Total current assets	2,906,239	1,420,543
Total assets	40,887,854	37,704,672
Equity	34,708,529	32,167,479
Long-term liabilities	0	0
Current liabilities	6,179,325	5,537,193
Total equity and liabilities	40,887,854	37,704,672