



**Hansa Medical is a biotech development company focused on inflammatory diseases. The company develops innovative biological pharmaceuticals and diagnostic methods both independently and in partnership with large, market-established companies. Currently, three development projects are primarily being conducted: IdeS, anti-alpha-11 and HMD-301. New research projects and product candidates generated through collaboration with medicinal university researchers are continuously evaluated. Hansa Medical is publicly traded on First North, which is a part of NASDAQ OMX, and Remium AB is the company's financial adviser.**

## FINANCIAL INFORMATION

- Net sales for the Group amounted to SEK 4.4 M (3.0)
- The Group reported a loss of SEK 18.8 M (loss: 15.8)
- The Group's operating loss amounted to SEK 20.0 M (loss: 15.7)
- The loss per share was SEK 2.44 (loss: 4.1)

## THE YEAR IN BRIEF

- Rights issue totalling SEK 27 M oversubscribed
- Full-scale production process for IdeS developed
- Toxicology and safety studies initiated with IdeS
- Patent granted for IdeS in the USA
- Research studies with IdeS and EndoS published in scientific journals
- License agreement entered with Human Genome Sciences Inc., regarding anti-alpha-11 patents
- Milestone payment of USD 500,000 received from collaboration partner Alere Inc.
- Anti-alpha-11 antibodies generated through collaboration with Alere Inc.
- Optimised version of HBP assay developed in collaboration with Axis-Shield plc for pivotal clinical study

## SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

- Hansa Medical's collaboration partner Axis-Shield plc entered into an option agreement with Bio-Rad Laboratories for the commercialization of HBP

## CEO'S COMMENTS

An oversubscribed rights issue has enabled an offensive investment in project IdeS and has allowed us to retain the pace of development in project anti-alpha-11 and HMD-301. In cooperation with a contract manufacturing organization, we have brought our internally-developed production process to full scale for the fermentation, purification and quality control of the drug candidate, IdeS. The upscaling work has developed positively and we have now produced a first batch of IdeS with high yield and high purity. This batch will be primarily be used for pre-clinical toxicity and safety studies. These studies have been initiated and we plan to have them completed during the spring of 2011. If the outcome of these studies is positive, we will initiate Phase I at the end of 2011 or at the beginning of 2012.

Within project anti-alpha-11, a number of promising antibodies have been identified and the patent portfolio has been consolidated. We have entered a license agreement with Human Genome Sciences Inc. regarding anti-alpha-11 antibodies, and a strong patent position for the anti-alpha-11 program and upcoming pharmaceutical products, has been established.

Our collaboration with Axis-Shield plc has developed successfully. Using Hansa Medical's prototype assay (HMD-301) for quantifying HBP in plasma, Axis-Shield has developed an optimized version. The registration based trials with this optimized assay will commence at the beginning of 2011. In January 2011, Axis-Shield entered an option agreement with Bio-Rad Laboratories regarding HBP as bio-marker for severe sepsis. This option agreement confirms the potential of this exciting product candidate, as well as strengthening the possibilities of reaching the global market.

These are exciting times for Hansa Medical. During the next 12 months, our plan is to initiate introductory clinical studies with IdeS, to achieve the registration of HMD-301 and to identify an anti-alpha-11 drug candidate suitable for clinical development. *Emanuel Björne, CEO of Hansa Medical (publ).*

## SIGNIFICANT EVENTS DURING THE YEAR

### **Rights issue totalling SEK 27 M oversubscribed**

During the spring of 2010, Hansa Medical issued 3,863,184 new shares at a share price of SEK 7. The rights issue was targeted to existing shareholders, with one existing share entitling the holder to subscription to one new share. A total of 93.8% of the shares with preferential rights was subscribed and applications for subscription without preferential rights were received corresponding to 28.6% of the issue. A total of 240,437 shares, or 6.2% of the rights issue, were issued to individuals subscribing for shares without the support of preferential rights. The issue provided Hansa Medical with approximately SEK 27 M before issue costs. The rights issue increased the number of shares by 3,863,184 and, after the issue, share capital amounted to SEK 38,631,840 distributed among 7,726,368 shares.

### **Completed development of the production process for IdeS and production of a first batch**

Hansa Medical has independently developed methods for the production, purification and quality analysis of IdeS. This process has been transferred to a contract manufacturing organization for expansion on a larger scale and production in accordance with GMP (Good Manufacturing Practice). The transfer and increase in scale has worked out very well, and a first, full-scale batch has been produced with high yields and a high level of purity. This first batch will primarily be used for pre-clinical toxicity and safety studies. These studies have commenced and will conclude during spring 2011. If the outcome of the pre-clinical toxicity and safety studies is positive, Hansa Medical will initiate Phase 1 studies at the end of 2011 or at the beginning of 2012.

### **Patent granted for IdeS in the USA**

During the spring of 2010, Hansa Medical was granted a method patent in the USA. This patent protects the concept of cleaving IgG molecules with the help of IdeS. In addition to the approved patent, Hansa Medical has patent applications pending in a number of different countries, including the USA, Japan, China and countries in Europe, that apply to both substances and methods based on IdeS.

### **Research studies with IdeS and EndoS published in scientific journals**

During 2010, Hansa Medical partner researchers have published scientific studies showing that the enzymes, IdeS and EndoS, could probably be used to treat the autoimmune diseases Goodpasture's syndrome and hemolytic anemia.

In the study "Successful treatment of experimental glomerulonephritis with IdeS and EndoS, IgG-degrading streptococcal enzymes" published on 10 March 2010 in the scientific journal *Nephrology Dialysis Transplantation*, experimental results are presented supporting the suggestion that the enzymes IdeS and EndoS could probably be used to treat the kidney disease Goodpasture's syndrome.

In the study "The IgG-specific endoglycosidase EndoS inhibits both cellular and complement-mediated autoimmune hemolysis," published on 31 March 2010 in the scientific journal *Blood*, experimental results are presented supporting the idea that EndoS could possibly also be used for treatment of the blood disease autoimmune hemolytic anemia.

### **License agreement entered with Human Genome Sciences Inc., regarding anti-alpha-11 patents**

During autumn 2010, Hansa Medical entered into a license agreement with U.S. biotech company Human Genome Sciences Inc. (NASDAQ:HGSI) regarding patents and patent applications referring to the pharmaceutical target alpha-11. This license agreement grants Hansa Medical worldwide exclusive rights to all HGSI's patents and patent applications for inventions based on the integrin alpha-11, such as therapeutic anti-alpha-11 antibodies. By combining Hansa Medical's patent applications concerning alpha-11 with the patents surrounding alpha-11 which were developed by Human Genome Sciences, a strong patent portfolio is created for future anti-alpha-11 drug candidates, which now also includes the important U.S. market.

### **Milestone payment of USD 500,000 received from collaboration partner Alere Inc.**

During the second half of 2010, Hansa Medical received a milestone payment of USD 500,000 from Alere Inc. (NYSE: ALR) within the context of the cooperation established by the two companies in June 2009. The achieved milestone implies a beneficial in-licensing of significant patents and patent applications regarding the drug target alpha-11, and also implies that the patent portfolio concerning the integrin alpha-11 has been consolidated. The unification of all alpha-11 patents in a single patent portfolio has been highly prioritized in order to strengthen the commercial potential of the project anti-alpha-11.

### **Anti-alpha-11 drug candidates generated through collaboration with Alere Inc.**

In June 2009, Hansa Medical and Inverness Medical Innovations (NYSE:IMA) entered into a partnership and license agreement to develop and commercialize anti-alpha-11 antibodies for treatment of rheumatoid arthritis. Inverness Medical Innovations has changed its name to Alere Inc., effective 14 July 2010 (NYSE:ALR). In the partnership, Alere's antibody technology, Omniclonal®, is being used via its subsidiary, Biosite. The companies are working together toward the goal of identifying a drug candidate that can be brought into clinical development. Since the start of the partnership, Alere has generated a large number of anti-alpha-11 antibodies based on Hansa Medical's material. The generated antibodies are being characterized, evaluated and patented by Hansa Medical. The goal is to select a small number of antibodies for pre-clinical development. The common strategy is to seek a third-party alliance within the pharmaceutical industry in preclinical phase or early clinical stage.

### **Optimized version of the HBP-assay developed by Axis-Shield for the pivotal clinical study**

In June 2009, Hansa Medical entered a license agreement with diagnostics company Axis-Shield (LON:ASD) regarding HMD-301, Hansa Medical's patented analysis method for *in vitro* diagnostics (IVD) of severe sepsis, based on plasma quantification of the protein HBP. Since the agreement began, Axis-Shield and Hansa Medical successfully developed and optimized the analytical method. This optimized HBP-assay will now be used in a pivotal clinical trial in Sweden and the United States.

## SIGNIFICANT EVENTS AFTER YEAR END

### **Hansa Medical's partner, Axis-Shield enters an option agreement with Bio-Rad Laboratories for the commercialization of HBP.**

Axis-Shield plc (LSE: ASD) has entered into an option agreement with Bio-Rad Laboratories (NYSE: BIO) for the commercialization of Heparin-Binding Protein (HBP) as a biomarker for severe sepsis. Bio-Rad is a multinational producer and distributor of research tools in life science and clinical diagnostics. The option agreement provides a worldwide right for Bio-Rad to develop HBP as a biomarker for analysis with Bio-Rad laboratory instruments. The financial terms of the agreement were not disclosed. The option agreement between Axis-Shield and Bio-Rad confirms the potential of HBP as a biomarker for severe sepsis, and strengthens the chances of reaching the global market. The Cooperation Agreement between Hansa Medical and Axis-Shield provides Hansa Medical entitlement to milestone payments and royalties from Axis-Shield from license payments and sales of HBP-assays.

## PRIMARY DEVELOPMENT PROJECTS IN BRIEF

### **IdeS project**

IdeS, Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, is a protein-based drug candidate primarily developed to allow kidney transplantation for patients with renal disorders who cannot currently receive transplants. In collaboration with Henrik Ekberg, Professor of Transplantation Surgery at Skåne University Hospital in Malmö, and Professor Gunnar Tufvesson at Uppsala University Hospital, Hansa Medical has designed a development plan to enable a small-scale clinical trial for sensitized kidney transplantation patients. This development plan is based on four main stages: development of the production process, GMP production, toxicity and safety studies and a clinical phase I/II study.

Initially, Hansa Medical is developing IdeS for treatment in connection with organ transplantation, but in time, IdeS may also be developed for the treatment of certain acute autoimmune diseases, such as Goodpastures syndrome, Neuromyelitis optica and Guillian Barré syndrome. The global market for acute treatment of IgG-mediated diseases and conditions with transplantation and autoimmune diseases, is estimated to be over one billion SEK.

### **Anti-alpha-11 project**

Anti-alpha-11 is a novel antibody based treatment of Rheumatoid Arthritis (RA). RA is an autoimmune chronic inflammatory disease of the joints that affects approximately 1 percent of the world's adult population. The market for biological drugs for RA is dominated by the successful TNF blockers (Tumor necrosis factor blockers). Despite the great therapeutic and commercial success of TNF blockers, there is a substantial need for new RA drugs. TNF blockers are associated with side effects, and for an inordinately large proportion of RA patients, only limited treatment effects are achieved. In pre-clinical studies, anti-alpha-11 treatment has been shown to have better and more specific effects than the TNF blockers.

Alpha-11, with the complete designation alpha-11/beta-1, is a surface protein from certain cells that are primarily found in inflammatory joint membranes. Treatment targeting alpha-11 has been shown in pre-clinical studies to have a local anti-inflammatory effect in joints, as well as providing superior protection against the devastating degradation of the joints.

### **HMD-301 (HBP) project**

Severe sepsis is a life-threatening complication to infection requiring immediate attention and adequate treatment. In severe sepsis, bacteria from a local infection, often pneumonia or urinary tract infection, enter the bloodstream, where they cause a strong fall in blood pressure and coagulation disturbances that can lead to organ failure. Severe sepsis is a serious condition with high mortality. A variety of clinical studies shows that the incidence of severe sepsis is 50-300 per 100,000 in Europe and the United States per year, of which 20% of the patients does not survive the disease. In order to increase the patient's chance of survival and prevent comprehensive costs for care, the acute condition must be identified at an early stage and correct treatment initiated. HBP, Heparin Binding Protein, is a serum protein and biomarker for diagnosis and prognosis of severe sepsis, validated and patented by Hansa Medical in collaboration with clinical researchers. The method of analysis, with the project name HMD-301, has been tested on more than 300 patients and the method has shown that it can, with high precision, identify the patients who will develop severe sepsis. The project is licensed from Hansa Medical to Axis-Shield and is driven towards registration in late 2011.

## **FINANCIAL INFORMATION**

### **Sales and earnings**

The Group's net sales during the period amounted to SEK 4.4 M (3.0). The operating loss was SEK 20.0 M (loss: 15.7), while the loss after financial items was SEK 20.1 M (loss: 15.8). The loss for the period amounted to SEK 18.8 M (loss: 15.8). Earnings per share amounted to a loss of SEK 2.44 (loss: 4.1).

The Group's operating expenses consisted primarily of personnel costs of SEK 4.7 M (5.0), patent costs of SEK 1.5 M (4.5), research agreements of SEK 2.3 M (2.8), material costs of SEK 6.9 M (2.3), premises costs of SEK 0.8 M (0.8), and depreciation/amortization of SEK 0.4 M (0.4).

### **Financial position, cash flow and assets**

On 31 December 2010, cash and cash equivalents for the Group amounted to SEK 0.2 M (0.6) and shareholders' equity to SEK 32.2 M (25.0). Cash flow from operating activities was negative in an amount of SEK 18.0 M (neg. 13.8) for the year. Cash flow from financing activities amounted to SEK 19.0 M and consisted of income of SEK 27.0 M from the new share issue and an expense of SEK 8.0 M for repayment of bridge loans. Since the end of the period, the company has received bridge loans at SEK 4.0 M in total

Costs for implementation of the new share issue in 2010 amounted to SEK 1.0 M. During the period, the company repaid a bridge loan of SEK 9.8 M.

### **Investments**

Investments in tangible assets totalled SEK 383,800 for the period.

### Group structure

The Hansa Medical Group consists of the Parent Company Hansa Medical AB (publ) and the wholly-owned subsidiary Cartela R&D AB. Cartela R&D AB administers patents and patent applications for the anti-alpha-11 project.

### Employees

The number of employees at year-end was 6 (7).

### Number of shares

The number of shares at the beginning of the year, 1 January 2010, was 3,863,184, and the number of shares at year-end, 31 December 2010, was 7,726,368.

### Ownership structure (31 December 2010)

Name	Number of shares	Proportion (%)
Håkansson, Bo (via company)	3,278,115	42.3
Lönn, Mikael	1,420,000	18.4
JP Morgan Bank	425,009	5.5
Försäkringsaktiebolaget, Avanza Pension	214,195	2.8
Nordnet Pensionsförsäkring AB	128,717	1.7
Biolin Scientific AB	100,000	1.3
Aktiebolaget Protiga	80,000	1.0
Banque Carnegie Luxembourg SA	77,000	1.0
Strategic Wisdom Nordic AB	63,126	0.8
LPOS Förvaltning AB	60,000	0.8
Others	1 880,206	24.3
<b>Total</b>	<b>7,726,368</b>	<b>100</b>

### 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, confidentiality, 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 annual report has been prepared in accordance with the Swedish Annual Accounts Act and the general advice and guidelines of the Swedish Accounting Standards Board.

## REVIEW REPORT

### **Introduction**

I have conducted a comprehensive review of the interim report of Hansa Medical AB (publ), Corporate Identity Number 556734-5359, for the year 1 January- 31 December 2010. The Board of Directors and the CEO are responsible for the preparation and presentation of this financial information in accordance with the Swedish Annual Accounts Act. My responsibility is to express an opinion on this financial information based on my review.

### **The focus and scope of the comprehensive 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, published by FAR. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other comprehensive review procedures. A review has a different focus and is substantially more limited in scope than an audit conducted in accordance with Standards on Auditing in Sweden, RS, and other generally accepted auditing standards in Sweden. 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, a conclusion based on a review does not provide the same level of assurance as a statement based on an audit.

### **Conclusion**

Based on my review, nothing has come to my attention that causes me to believe that the accompanying interim report, in all material aspects, has not been prepared in accordance with the Annual Accounts Act.

Malmö, 10 February 2011

Ann Theander

Authorised Public Accountant FAR

Grant Thornton Sweden AB

## FUTURE REPORTING DATES

Annual Report 2010	April 2011
Annual General Meeting	5 May 2011
Interim report 1 January – 30 June 2011	28 July 2011
Year-end report 2011	9 February 2012

The Board of Directors and the Chief Executive Officer assure that this interim report provides a true overview of the company's operations, financial position and results and that it describes the significant risk factors that the company faces.

Lund, 10 February 2011

The Board of Directors and CEO of Hansa Medical AB (publ)

## FOR FURTHER INFORMATION

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## INCOME STATEMENT – Group (SEK)

	Jul – Dec 2010	Jul – Dec 2009	Full year 2010	Full year 2009
Net sales	4,157,241	153,780	4 448,186	2,983,759
Operating expenses	-16,653,240	-9,650,688	-24,441,041	-18,724,310
<b>Operating loss</b>	<b>- 12,495,999</b>	<b>-9,496,908</b>	<b>-19 992,855</b>	<b>-15,740,551</b>
Profit/loss from financial items	776	-78,774	-150,481	-71,599
<b>Loss after financial items</b>	<b>-12,495,223</b>	<b>-9,575,682</b>	<b>-20,143,336</b>	<b>-15,812,150</b>
Tax on profit for the year	1,300,097	0	1,300,097	0
Loss for the period	-11,195,126	-9,575,682	-18 843,239	-15,812,150
Average number of shares	7,726,368	3,863,184	7,726,368	3,863,184
<b>Earnings per share</b>	<b>-1.45</b>	<b>-2.48</b>	<b>-2,44</b>	<b>-4,09</b>

## BALANCE SHEET – Group (SEK)

	31 Dec 2010	31 Dec 2009
<i>Fixed assets</i>		
Intangible fixed assets	35,973,032	36,233,030
Tangible fixed assets	406,141	114,455
<b>Total fixed assets</b>	<b>36 379,173</b>	<b>36,347,485</b>
<i>Current assets</i>		
Current receivables	1,200,648	1,188,248
Cash and bank balances	221,669	611,557
<b>Total current assets</b>	<b>1,422,317</b>	<b>1 799 805</b>
<b>Total assets</b>	<b>37,801,490</b>	<b>38,147,290</b>
Shareholders' equity	32 166 121	24,921,491
Long-term liabilities	0	8,000,000
Current liabilities	5,635,369	5,225,799
<b>Total shareholders' equity and liabilities</b>	<b>37,801,490</b>	<b>38,147,290</b>

## CASH FLOW STATEMENT – Group (SEK)

	1 Jan – 31 Dec 2010	1 Jan – 31 Dec 2009
Cash flow from operations before changes in working capital	-17,895,845	-15,480,379
Cash flows from changes in working capital	-198,113	1,688,080
<b>Cash flows from operating activities</b>	<b>-18,093,957</b>	<b>-13,792,299</b>
Cash flows from investing activities	-383,800	487,350
Cash flows from financing activities	18,087,869	8,000,000
Cash and cash equivalents on the opening date	611,557	5,916,506
<b>Cash and cash equivalents on the closing date</b>	<b>221,669</b>	<b>611,557</b>

## CHANGE IN SHAREHOLDERS' EQUITY – Group (SEK)

	Share capital	Unrestricted reserves	Profit/loss for the period	Total
<b>Amount 1 Jan 2009</b>	<b>19,315,920</b>	<b>23,975,907</b>	<b>-2,558,185</b>	<b>40,733,642</b>
Profit/loss brought forward		-2,558,185	2,558,185	0
Loss for the period			-15,812,150	-15,812,150
<b>Amount 1 Jan 2010</b>	<b>19,315,920</b>	<b>21,417,721</b>	<b>-15,812,150</b>	<b>24,921,491</b>
Profit/loss brought forward		-15,812,150	15,812,150	0
New share issue	19,315,920	6,771,949		26,087,869
Loss for the period			-18,843,239	-18,843,239
<b>Amount 31 Dec 2010</b>	<b>38,631,840</b>	<b>12,377,520</b>	<b>-18,843,239</b>	<b>32,166,121</b>

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

	1 Jan – 31 Dec 2010	1 Jan– 31 Dec 2009
Net sales	4,448,186	2,933,759
Operating expenses	-24,441,043	-18,674,731
<b>Operating loss</b>	<b>-19,992,857</b>	<b>-15,740,972</b>
Profit/loss from financial items	-150,478	-71,178
<b>Loss after financial items</b>	<b>-20,143,335</b>	<b>-15,812,150</b>
Tax on loss for the period	1,301,455	0
<b>Loss for the period</b>	<b>-18,841,880</b>	<b>-15,812,150</b>

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

	31 Dec 2010	31 Dec 2009
<i>Fixed assets</i>		
Intangible fixed assets	33,580,526	33,593,024
Tangible fixed assets	406,141	114,455
Financial non-current assets	2,297,462	2,089,642
<b>Total fixed assets</b>	<b>36 284,129</b>	<b>35,797,121</b>
<i>Current assets</i>		
Current receivables	1,200,435	1,188,035
Cash and bank balances	220,108	610,293
<b>Total current assets</b>	<b>1,420,543</b>	<b>1,798,328</b>
<b>Total assets</b>	<b>37,704,672</b>	<b>37,595,449</b>
Shareholders' equity	32 167,479	24,921,490
Long-term liabilities		8,000,000
Current liabilities	5,537,193	4,673,959
<b>Total shareholders' equity and liabilities</b>	<b>37,704,672</b>	<b>37,595,449</b>