

# INTERIM REPORT

January 1 – June 30, 2010

**Hansa Medical is a biotech development company focused on inflammation. The company primarily conducts three development projects in pre-clinical and early clinical phases: IdeS, anti-alpha-11 and HMD-301, of which two are partnerships. IdeS is a drug candidate for treatment in conjunction with organ transplantation and autoimmune disease. Anti-alpha-11 is a novel treatment method under development for rheumatoid arthritis. HMD-301 is a method for diagnosis of severe sepsis. Hansa Medical is publicly traded on First North, which is part of NASDAQ OMX. Remium AB is the company's financial adviser.**

## FINANCIAL INFORMATION

- Net sales for the Group amounted to SEK 0.3 M (2.8)
- The Group reported a loss of SEK 8.6 M (loss: 6.2)
- The Group's operating loss amounted to SEK 7.5 M (loss: 6.2)
- The loss per share was SEK 1.11 (loss: 1.61)

## THE PERIOD IN BRIEF

- Rights issue totaling SEK 27 M oversubscribed by 22.4 percent
- Partnership with Axis-Shield proceeded according to plan, and clinical registration study is planned to start during autumn 2010
- Large number of drug candidates generated through the partnership with Alere Inc. (formerly Inverness Medical Innovations Inc.)
- Paula Zeilon new Board member of Hansa Medical
- Changed Articles of Association and authorization by the Annual General Meeting entitling the Board of Directors the right to decide on new share issues
- Internally developed production process for IdeS transferred to Contract Manufacturing Organization
- Patent granted for IdeS in the US
- Registration of the IDESENS® brand approved in the US, Europe and Australia
- Research studies with IdeS and EndoS published in scientific journals

## CEO'S COMMENTS

“Through an oversubscribed right issue, our shareholders have showed great confidence in our business and we now have the strength to continue developing our three projects – anti-alpha-11, IdeS and HMD-301 towards the next value-generating goals. We have taken a major step in our IdeS project and completed the transfer of our internally developed production process to a contract manufacturing organization. The next step in this work is to produce a full-scale batch for our planned pre-clinical toxicity and safety studies. The goal for project IdeS is to submit an application to conduct a clinical phase I study to the Medical Products Agency during the first half of 2011.

“Our partnership agreements with Alere (formerly Inverness Medical Innovations) and Axis-Shield are both proceeding according to plan with respect to both time and development activities. Alere has generated a large number of anti-alpha-11 antibodies that Hansa Medical is now characterizing, evaluating and gaining patent protection on. This evaluation work is extensive, and we will devote much of the autumn to carefully selecting a small number of antibodies for further development. In recent months, the Axis-Shield collaboration has focused on further development of Hansa Medical’s analysis prototype, HMD-301, for diagnosis and prognosis of severe sepsis. In addition, extensive planning work was conducted to have all logistical pieces in place prior to the clinical registration trial of HMD-301. The study will be conducted at emergency clinics in Sweden and the US. The clinical study is planned to start during autumn 2010, and the goal of achieving market launch of an initial version of the analysis method by the end of 2011 remains.” *Emanuel Björne, CEO of Hansa Medical (publ).*

## SIGNIFICANT EVENTS DURING THE PERIOD

### **Rights issue totaling SEK 27 M oversubscribed by 22.4 percent**

On March 4, the Board of Directors of Hansa Medical decided to issue at the most 3,863,184 new shares at a share price of SEK 7, which on full subscription provided Hansa Medical with about SEK 27 M before issue costs. The rights issue was targeted to existing shareholders, with one existing share entitling the holder to subscription for one new share. The subscription period extended from March 24 through April 14, 2010. A total of 3,622,747 shares were subscribed with preferential rights, corresponding to 93.8 percent of the number of shares in the share issue. Applications for subscription without preferential rights were received corresponding to 28.6 percent of the issue or 1,105,327 shares. Of these, 240,437 shares or 6.2 percent of the rights issue were issued to persons subscribing for shares without the support of preferential rights. The rights issue increased the number of shares by 3,863,184, and after the rights issue, the share capital amounted to SEK 38,631,840 distributed among 7,726,368 shares.

### **Partnership with Axis-Shield proceeded according to plan, and the clinical registration study is planned to start during autumn 2010**

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 diagnosis and prognosis for severe sepsis. The partnership is intended to optimize the analysis method prior to starting a clinical multi-center registration study during 2010 and to introduce the product on the market in late 2011. Through the agreement, Hansa Medical is entitled to milestone payments and royalty payments from Axis-Shield from sales of analysis reagents. Development work during the most recent six months was focused on refining Hansa Medical’s HMD-301 prototype into a product suitable for rapid routine analysis in hospital laboratories around the world. In addition, considerable work was devoted to putting all the logistical pieces into place prior to the forthcoming clinical trial with HMD-301. This relatively extensive study will involve emergency clinics in Sweden and the US. The clinical study is planned to start during autumn 2010.

### **Large number of drug candidates generated by Alere Inc. (formerly Inverness Medical Innovations 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 July 14, 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 patent-protected by Hansa Medical. The goal is to select a small number of antibodies for pre-clinical development. The common strategy of seeking a third-party alliance within the pharmaceuticals industry in the pre-clinical or early clinical phase remains.

### **Paula Zeilon new Board member of Hansa Medical**

At Hansa Medical's Annual General Meeting on April 29, Bo Håkansson (Board Chairman), Per Belfrage and Stina Gestrelus were re-elected and Paula Zeilon was newly elected as members of the Board of Directors. Paula Zeilon has more than 20 years of management experience from the life science industry, from a broad range of functions; international sales & marketing, business development, general management and product development. She is partner of Conlega Biobusiness Development and Management since 2000. Paula Zeilon is a member of the board of BioGaia AB (publ). Paula Zeilon holds a master of science degree in Chemical Engineering from Lund University.

### **Changed Articles of Association and authorization by the Annual General Meeting entitling the Board of Directors to decide on new share issues**

The Annual General Meeting approved a change in the Articles of Association as follows: The limit for the share capital was changed from not less than SEK 19,000,000 and not more than SEK 76,000,000 to not less than SEK 35,000,000 and not more than SEK 140,000,000. Limits for the number of shares were changed from not less than 3,800,000 and not more than 15,200,000 to not less than 7,000,000 and not more than 28,000,000. Furthermore, the Annual General Meeting granted authorization for the Board of Directors on one or more occasions prior to the next Annual General Meeting and with or without preferential shareholders' rights to take decisions on new share issues or issues of warrants or subscription warrants. The reasons for allowing deviation from shareholders' preferential rights is to enable the company to broaden its ownership structure, to raise or enable the raising of working capital, to increase liquidity in the share, to implement company acquisitions or to raise or enable the raising of capital for company acquisitions.

### **Internally developed production process for IdeS transferred to Contract Manufacturing Organization**

Hansa Medical has developed methods for production, purification and quality analysis of IdeS. This process has been transferred to a contract manufacturing organization and the initial test runs show that Hansa Medical's process is also suitable for production of IdeS on a larger scale. The next step is to produce a full-scale batch for use in pre-clinical toxicity and safety studies. These studies are planned to commence at the end of 2010. After completion of the pre-clinical toxicity and safety studies, an application for a clinical phase I study will be submitted to the Medical Products Agency during the first half of 2011.

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

Hansa Medical has been granted a method patent in the US. This patent protects the concept of cleaving IgG antibodies using IdeS. In addition to the approved patent, Hansa Medical has patent applications pending in a number of different countries, including the US, Europe, Japan and China, that apply to both substances and methods based on IdeS.

### **Registration of the IDESENS® brand approved in the US, Europe and Australia**

IdeS, Immunoglobulin G degrading enzyme of *Streptococcus Pyogenes*, is the name of the active substance in a future pharmaceutical. Hansa Medical has applied for and obtained approval for the IDESENS® brand in the US, Europe and Australia. IDESENS® is the proposed name of the pharmaceutical product based on IdeS.

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

Hansa Medical's partner researchers have published scientific studies showing that the enzymes IdeS and EndoS could probably treat the autoimmune diseases glomerulonephritis and hemolytic anemia.

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

In the study "The IgG-specific endoglycosidase EndoS inhibits both cellular and complement-mediated autoimmune hemolysis," published on March 31, 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 hypolytic anemia.

## **DEVELOPMENT PROJECTS IN BRIEF**

### **IdeS project**

IdeS, Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, is a protein-based drug candidate that is primarily developed to allow kidney transplantation for patients with renal disorders who cannot currently receive transplants. Together 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. The 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 application within organ transplantation, but in time, IdeS may also be developed for treatment of certain autoimmune diseases, such as ITP (Idiopathic Thrombocytopenic Purpura), SLE (Systemic Lupus Erythematosus), Glomerulonephritis, Autoimmune Hemolytic Anemia, Neuromyelitis Optica and Guillian Barré's syndrome.

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

Alpha-11 is a new and specific pharmaceutical for treatment of Rheumatoid Arthritis (RA). RA is an autoimmune chronic inflammatory disease of the joints that affects 1 to 2 percent of the world's adult population. The market for biological drugs for RA is dominated by the successful TNF (Tumor necrosis factor) blockers. Despite the great 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 or alpha-11/beta-1, which is the complete designation, 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 an inflammatory-inhibiting effect locally in joints, as well as providing protection against the devastating degradation of the joints.

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

Severe sepsis is a life-threatening complication to infection that requires immediate attention and adequate treatment. In severe sepsis, bacteria from a local infection, often pneumonia or urinary tract infection, enter the blood stream, resulting in a sharp drop in blood pressure and coagulation disturbances that can result in organ failure. Sepsis is a serious condition with a high mortality rate. In the US alone, some 210,000 persons die each year. To increase the patient's chance of survival, the acute condition must be identified at an early stage and correct treatment initiated. HBP, Heparin Binding Protein, is a serum protein and a biomarker for diagnosis and prognosis in severe sepsis that has been validated and patented by Hansa Medical in collaboration with clinical researchers. The analysis method, with the project name HMD-301, has been tested on more than 300 patients and shown to be able to identify with high precision which patients will develop severe sepsis. The project is licensed by Hansa Medical to Axis-Shield and is being developed towards market introduction in late 2011.

### **EndoS/TAME project**

EndoS, Endoglycosidase of *Streptococcus pyogenes*, is one of Hansa Medical's patented enzymes that is evaluated as a drug candidate and as a tool for creating antibody-based drug candidates. EndoS inactivates pathogenic IgG antibodies by modifying the glycosylation of the antibodies. The enzyme can also be used to give antibody-based drug candidates new and interesting therapeutic properties. This application of EndoS is in its early research phase and the project is called TAME (Therapeutic Antibodies Modified by EndoS).

## **FINANCIAL INFORMATION**

### **Sales and earnings**

The Group's net sales during the period amounted to SEK 0.3 M (2.8). The operating loss was SEK 7.5 M (loss: 6.2), while the loss after financial items was SEK 8.6 M (loss: 6.2). The loss for the period amounted to SEK 8.6 M (loss: 6.2). Earnings per share amounted to a loss of SEK 1.11 (loss: 1.61).

The Group's operating expenses consisted primarily of personnel costs of SEK 2.6 M (2.6), patent costs of SEK 0.8 M (1.9), research agreements of SEK 1.1 M (1.3), material costs of SEK 0.1 M (0.04), premises costs of SEK 0.4 M (0.4) and depreciation of SEK 0.2 M (0.2).

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

On June 30, 2010, cash and cash equivalents for the Group amounted to SEK 9.4 M (0.09) and shareholders' equity to SEK 43.4 M (34.5). Cash flow from operations was negative in an amount of SEK 9.8 M (neg. 6.3) for the period. 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 loans.

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

### **Investments**

Investment in tangible assets totaled SEK 383,000 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 on June 30, 2010 was six (7).

### Number of shares

The number of shares on January 1, 2010 was 3,863,184, and the number of shares on June 30, 2010 was 7,726,368.

### Ownership structure (June 30, 2010)

Name	No. of shares	Proportion (%)
Farstorp Invest AB	3,086,115	39.9
Lönn, Mikael	1,420,000	18.4
JP Morgan Bank	419,400	5.4
Försäkringsaktiebolaget, Avanza Pension	195,135	2.6
Håkansson, Oscar	182,000	2.4
Nordnet Pensionsförsäkring AB	161,241	2.1
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
Others	1,942,351	25.1
<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, 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 Swedish Accounting Standards Board.

## Review report

### **Introduction**

I have conducted a review of the interim report for Hansa Medical (publ), corporate registration number 556734-5359, for the period from January 1 to June 30, 2010. The Board of Directors and the CEO are responsible for correctly preparing and presenting the financial information in accordance with the Annual Accounts Act. My responsibility is to express an opinion on this financial information based on my review.

### **Scope and focus of the review**

I have conducted my review in accordance with the Standard on Review Engagements (SÖG) 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity, issued by the Swedish Institute of Authorized Public Accountants (FAR). A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially more limited in scope than an audit conducted in accordance with the Standards on Auditing in Sweden (RS) and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not provide the same level of assurance as a conclusion expressed 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 respects, was not prepared in accordance with the Annual Accounts Act.

Malmö, July 29, 2010

Ann Theander

Authorized Public Accountant

Grant Thornton Sweden AB

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## Future reporting dates

Year-end report 2010                      February 10, 2011  
Annual Report 2010                         April 2011

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, July 29, 2010

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

## For further information

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Corporate registration number: 556734-5359

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## INCOME STATEMENT – Group (SEK)

	Jan. 1 – June 30, 2010	Jan. 1 – June 30, 2009	Jan. 1 – Dec. 31, 2009
Net sales	290,945	2,779,979	2,983,759
Operating expenses	-7,787,801	-9,023,622	-18,724,310
<b>Operating loss</b>	<b>-7,496,856</b>	<b>-6,243,643</b>	<b>-15,740,551</b>
Profit/loss from financial items	-1,107,034	7,175	-71,598
<b>Loss after financial items</b>	<b>-8,603,890</b>	<b>-6,236,468</b>	<b>-15,812,150</b>
Tax on loss for the year	0	0	0
Loss for the period	-8,603,890	-6,236,468	-15,812,150
Average no. of shares	7,726,368	3,863,184	3,863,184
<b>Loss per share</b>	<b>-1.11</b>	<b>-1.61</b>	<b>-4.1</b>

## BALANCE SHEET – Group (SEK)

	June 30, 2010	June 30, 2009	Dec. 31, 2009
<i>Fixed assets</i>			
Intangible fixed assets	36,061,783	36,354,281	36,233,030
Tangible fixed assets	464,501	121,749	114,455
<b>Total fixed assets</b>	<b>36,526,284</b>	<b>36,476,030</b>	<b>36,347,485</b>
<i>Current assets</i>			
Current receivables	750,108	2,640,874	1,188,248
Cash and bank	9,459,277	94,702	611,557
<b>Total current assets</b>	<b>10,209,385</b>	<b>2,735,576</b>	<b>1,799,804</b>
<b>Total assets</b>	<b>46,735,669</b>	<b>39,211,606</b>	<b>38,147,290</b>
Shareholders' equity	43,359,888	34,497,173	24,921,491
Long-term liabilities	0	0	8,000,000
Current liabilities	3,375,781	4,714,432	5,225,799
<b>Total shareholders' equity and liabilities</b>	<b>46,735,669</b>	<b>39,211,606</b>	<b>38,147,290</b>

## CASH-FLOW STATEMENT – Group (SEK)

	Jan. 1 – June 30, 2010	Jan. 1 – June 30, 2009	Jan. 1 – Dec. 31, 2009
Cash flow from operations before changes in working capital	-8,398,890	-6,045,892	-15,480,379
Cash flow from changes in working capital	-1,411,878	-275,910	1,688,080
<b>Cash flow from operations</b>	<b>-9,810,768</b>	<b>-6,321,802</b>	<b>-13,792,299</b>
Cash flow from investing activities	-383,800	500,000	487,350
Cash flow from financing activities	19,042,288,	0	8,000,000
Cash and cash equivalents on the opening date	611,557	5,916,504	5,916,504
<b>Cash and cash equivalents on the closing date</b>	<b>9,459,277</b>	<b>94,703</b>	<b>611,557</b>

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

	Share capital	Unrestricted reserves	Profit/loss for the period	Total
<b>Amount on Jan. 1, 2009</b>	<b>19,315,920</b>	<b>23,975,907</b>	<b>-2,468,167</b>	<b>43,183,827</b>
Profit/loss brought forward		-2,558,185	2,558,185	0
Loss for the period			-6,236,468	-6,236,468,
<b>Amount on June 30, 2009</b>	<b>19,315,920</b>	<b>21,417,722,</b>	<b>-6,236,468</b>	<b>34,497,174</b>
<b>Amount on Jan. 1, 2010</b>	<b>19,315,920</b>	<b>21,417,721</b>	<b>-15,812,150</b>	<b>24,921,490</b>
Profit/loss brought forward		-15,812,150	15,812,150	0
New issue	19,315,920	7,726,368		27,042,288
Loss for the period			-8,603,890	-8,603,890
<b>Amount on June 30, 2009</b>	<b>38,631,840</b>	<b>13,331,939</b>	<b>-8,603,890</b>	<b>43,359,888</b>

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

	Jan. 1 – June 30, 2010	Jan. 1 – June 30, 2009	Jan. 1 – Dec. 31, 2009
Net sales	290,945	2,779,980	2,933,759
Operating expenses	-7,514,202	-7,652,946	-18,674,730
<b>Operating loss</b>	<b>-7,223,257</b>	<b>-4,872,966</b>	<b>-15,740,972</b>
Profit/loss from financial items	-1,105,673	219	-71,178
<b>Loss after financial items</b>	<b>-8,328,930</b>	<b>-4,872,747</b>	<b>-15,812,150</b>
Tax on loss for the period	0	0	0
<b>Loss for the period</b>	<b>-8,328,930</b>	<b>-4,872,747</b>	<b>-15,812,150</b>

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

	June 30, 2010	June 30, 2009	Dec. 31, 2009
<i>Fixed assets</i>			
Intangible fixed assets	33,586,777		33,593,024
Tangible fixed assets	464,501	10,148	114,455
Financial fixed assets	2,745,642	41,764,572	2,089,642
<b>Total fixed assets</b>	<b>36,796,920</b>	<b>41,774,720</b>	<b>35,797,121</b>
<i>Current assets</i>			
Current receivables	746,416	2,402,707	1,188,035
Cash and bank	9,444,532	75,664	610,293
<b>Total current assets</b>	<b>10,190,948</b>	<b>2,478,371</b>	<b>1,798,328</b>
<b>Total assets</b>	<b>46,987,868</b>	<b>44,253,091</b>	<b>37,595,449</b>
Shareholders' equity	43,634,848	32,644,918	24,921,490
Long-term liabilities	0	0	8,000,000
Current liabilities	3,353,020	11,608,173	4,673,959
<b>Total shareholders' equity and liabilities</b>	<b>46,987,868</b>	<b>44,253,091</b>	<b>37,595,449</b>