

## **Interim report**

## January 1 – June 30, 2008

Hansa Medical refines biomedical discoveries into candidate drugs and diagnostic analytical methods. The company is pursuing four development projects: IdeS/EndoS, sepsis diagnostics, alpha-11 and a sepsis therapy project. The company's goal is to enter into one or more collaboration agreements with pharmaceutical and diagnostics companies to develop and ultimately launch Hansa Medical's products in the market. Hansa Medical has about 600 shareholders and has been listed on First North, part of the OMX Nordic Exchange Stockholm, since October 2007. Kaupthing Bank is the certified adviser.

This document is a summary of the full Swedish report. For a full account of the company's operations, refer to the Swedish report.

#### Financial information

- o Net sales for the Group amounted to SEK 0.0 M
- o The operating loss for the Group was SEK 7.6 M
- Redemption of convertible loan positive impact on consolidated earnings of SEK 15.1
  M
- o Profit before tax for the Group totaled SEK 8.7 M
- Earnings per share amounted to SEK 0.85

## The period in brief

- Acquisition of all assets in Cartela AB
- o Pivotal research results published for IdeS and EndoS
- Lead project IdeS for the kidney transplantation indication proceeding as planned
- Strengthened research organization
- Collaboration discussions in progress



## CEO's comments – Strengthened research organization

"The acquisition of Cartela has strengthened Hansa Medical as a biopharmaceutical development company. In addition to working on the interesting alpha-11 project for the treatment of rheumatoid arthritis, we also recruited a number of highly skilled employees. These individuals possess the experience and motivation required by Hansa Medical to efficiently develop projects.

"In May, we moved from Malmö to the Ideon science park in Lund, and we are now carrying out extensive in-house laboratory activities, which have enhanced the cost-effectiveness of our research operations while also strengthening Hansa Medical's capacity and competence. This was particularly evident in our IdeS project – an area in which we have made major progress in process development. All of this was carried out in accordance with the company's plans but on a proprietary basis.

"However, the acquisition of Cartela and the recruitment of new employees have resulted in increased costs. The objective is to broaden our development portfolio and to more rapidly advance and create value in our projects." *Emanuel Björne, CEO Hansa Medical AB (publ)* 

## Significant events during the period

#### Acquisition of all assets in Cartela AB

On January 14, 2008, Hansa Medical acquired all assets in Cartela AB. The acquisition covered all patents and patent applications, equipment, laboratory equipment and all biological material that formed the basis of Cartela's alpha-11 and alpha-10 development projects. Alpha-11 is a potential drug target for treatment of rheumatoid arthritis and alpha-10 is a potential drug target for treatment of arthrosis. The acquisition entails a strengthening of Hansa Medical's patent portfolio and the company's expertise in the area of inflammatory diseases. The purchase consideration amounted to SEK 3.9 M.

#### Pivotal research results published for IdeS and EndoS

During the period, Hansa Medical's researchers published preclinical proof-of-concept for the IgG-inactivating enzymes IdeS and EndoS. The IdeS results were published in *PLOS One* on February 27 and the EndoS results were published in *PNAS* on March 18. Both articles describe the potential of IdeS and EndoS as an effective and safe protein drug for treatment of the autoimmune disease Idiopathic Thrombocytopenic Purpura, ITP.

### IdeS project proceeding as planned

All efforts are being directed toward the IdeS development plan for the treatment of transplantation patients and the focus during the period was on the development of fermentation and purification of the IdeS protein drug. Extensive in-house process development took place as a result of the acquisition of laboratory equipment in January and the relocation to laboratory facilities in the Ideon science park in Lund. This generated considerable savings for Hansa Medical, while also strengthening the company's development operation in terms of expertise and capacity. Toxicology and safety studies will be conducted in cooperation with a



well-established contract research organization (CRO), and procurement of this service in under way. The goal to launch clinical studies in 2009 stands firm.

#### Strengthened research organization

During the period, Hansa Medical employed three new key staff members from the former Cartela including a research engineer, a project manager and a development manager. The recruitments enhance Hansa Medical's ability to advance existing projects and capitalize on the new, attractive product opportunities generated by Hansa Medical's research collaborations.

#### Redemption of convertible loan

In connection with the spinoff of Hansa Medical from Biolin AB (publ) in July 2007, Hansa Medical (publ) acquired all shares in Hansa Medical Utvecklings AB from Biolin. Hansa Medical paid for the transfer of shares by way of an agreement regulating a convertible loan from Biolin amounting to SEK 33.6 M, corresponding to a discounted present value of SEK 22.1 M in the consolidated balance sheet. In May, Hansa Medical entered into an agreement with Biolin covering the repayment of the convertible loan. The convertible loan was redeemed through a cash payment totaling SEK 7.0 M. The transaction entailed a positive effect on earnings before tax of SEK 15.1 M in the Hansa Medical Group. The convertible loan corresponded to a dilution effect of about 26 percent for Hansa Medical. The transaction relating to the redemption of the loan was deemed highly favorable for the company and its shareholders.

#### **Collaboration discussions in progress**

Hansa Medical's goal is to enter into one or several collaboration agreements with pharmaceutical and diagnostics companies to develop and ultimately launch Hansa Medical's products in the market. In its efforts to identify and negotiate partnerships, Hansa Medical utilizes direct marketing activities, a cultivated network of contacts and various partnering events, such as BIO2008 in San Diego. There is marked interest in the IdeS project, the sepsis diagnostics project and the alpha-11 project, and Hansa Medical is conducting discussions with a number of potential partners for these projects.

## **Development projects**

#### **IdeS/EndoS projects**

IdeS is a protein drug that is primarily intended to facilitate an increase in the number of kidney transplantations. Hansa Medical is conducting a clinical development plan in collaboration with transplantation surgeon Professor Henrik Ekberg at Malmö University Hospital. The development plan consists of four primary phases; process development, production, toxicity and safety studies and a small-scale Phase I/II study. Hansa Medical is initially developing IdeS for application within transplantation, but looking ahead, IdeS can also be developed as a treatment to prevent flare-ups in the autoimmune diseases ITP (Idiopathic Thrombocytopenic Purpura), SLE (Systemic Lupus Erythematosus) and RA (Rheumatoid Arthritis).

#### Sepsis diagnostic project



HMD-301 is a serum protein and a biomarker for diagnosis and prognosis of severe sepsis, which has been validated and patented by Hansa Medical in cooperation with clinical researchers. The analytical method has been tested on more than 200 patients and it has demonstrated that it can which identify patients will develop severe sepsis with unparalleled sensitivity and specificity. In collaboration with a diagnostics company established in the market, Hansa Medical is pursuing the HMD-301 project toward the goal of establishing an analytical method as the standard method primarily at clinics for infectious diseases and emergency clinics.

#### alpha-11 project

alpha-11 is a novel and specific drug target for treatment of rheumatoid arthritis. Rheumatoid arthritis in an autoimmune chronic inflammatory disease of the joints that affects 1–2 percent of the adult population worldwide. The requirement for new drugs for the treatment of rheumatoid arthritis is considerable, since existing drugs are not sufficiently effective or are associated with side effects that are far too serious. Alpha-11, or alpha-11/beta-1, which is the full designation, is a surface protein on certain types of cells that can be found in synovial membranes, among other areas. In preclinical studies, treatments targeted to alpha-11 have demonstrated a local anti-inflammatory effect in the joints and have also provided protection against the devastating degradation of the joint. Interest in the alpha-11 project is considerable and Hansa Medical aims to enter into a partnership relating to the alpha-11 project in 2008.

#### Sepsis treatment project

The HMD-301 biomarker has also been identified as a promising drug target for the treatment of sepsis and Hansa Medical has now identified a total of three promising candidate drugs for the treatment of sepsis: the peptide HM-401 and two antibody-based candidates for inactivating HMD-301. Hansa Medical is pursuing these candidate drugs toward preclinical proof-of-concept.

#### **Financial information**

#### Sales and earnings

The Group's net sales for the period amounted to SEK 0.0 M and the operating loss was SEK 7.6 M. Profit after financial items was SEK 8.7 M and profit for the period amounted to SEK 3.3 M. Earnings per share were SEK 0.85 M. Operating expenses are distributed as follows: External costs SEK 5.2 M, personnel costs SEK 1.7 M, material costs SEK 0.5 M and depreciation/amortization SEK 0.2 M. External costs relate primarily to expenses for research agreements, contract research, premises and improvements to patents and patent applications.

#### Financial position and cash flow

On June 30, 2008, cash and cash equivalents for the Group amounted to SEK 13.5 M and shareholders' equity was SEK 46.6 M. Cash flow from operating activities was negative SEK 7.0 M for the period.



#### Earnings effect of redemption of convertible loan

The redemption of the convertible loan to Biolin for SEK 7.0 M entailed a positive earnings effect of SEK 26.6 M for the Parent Company and a positive earnings effect of SEK 15.1 M for the Group.

#### **Investments**

During the period, investments totaling SEK 3.8 M were made in intangible assets. Investments in intangible assets relating primarily to laboratory equipment amounted to SEK 0.1 M.

#### **Group structure**

The Hansa Medical Group comprises the Parent Company Hansa Medical AB (publ) and the subsidiaries Hansa Medical Utvecklings AB, Cartela i Malmö AB and Cartela R&D AB. Development operations are principally conducted in Hansa Medical Utvecklings AB and Cartela i Malmö AB.

#### **Employees**

During the period, the number of staff rose by two full-time employees. Furthermore, a Development Manager was employed by Hansa Medical. Hansa Medical's Chairman of the Board was employed as Executive Chairman of the Board. At the end of the period, Hansa Medical had five employees excluding the Development Manager and the Executive Chairman of the Board.

#### **Share warrants**

On May 7, 2008, Hansa Medical's Annual General Meeting resolved to issue a total of 90,000 share warrants to the company's employees. The warrants can be used to subscribe for shares during the period February 28, 2012 – May 31, 2012. On full exercise of all warrants, the share capital will increase SEK 450,000 through the issue of 90,000 shares, each with a par value of SEK 5.00. If all warrants are exercised, the new shares will give rise to dilution of 2.3% of the capital and votes.

#### **Number of shares**

At the beginning of the period (January 1, 2008), the number of shares totaled 3,863,184 and the number of shares at the close of the period (June 30, 2008) was 3,863,184.

#### **Business-related risks**

Hansa Medical's operation 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 and distributers, competition and share-related risks.



# For further information, please contact:

Emanuel Björne, CEO

Mobile: +46 (0)707-17 54 77

E-mail: emanuel.bjorne@hansamedical.com

Bo Håkansson, Chairman of the Board

Mobile: +46 (0)705-98 57 22 E-mail: boh@farstorp.com