

hansa medical

Interim report

January 1 – June 30, 2009

Hansa Medical is a preclinical and early clinical biopharmaceutical development company focused on inflammatory diseases. The company mainly pursues three lead projects: IdeS, alpha-11 and HMD-301, two of which are managed together with partners. IdeS is a protein drug for treatment in conjunction with organ transplantation and autoimmune disease. Alpha-11 is an entirely novel drug target for treatment of rheumatoid arthritis (RA). HMD-301 is an analytical method for the diagnosis of patients with severe sepsis. Hansa Medical is listed on NASDAQ OMX First North and Remium AB is the company's certified advisor.

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

- Net sales for the Group amounted to SEK 2.8 M
- The loss for the Group was SEK 6.2 M
- The operating loss for the Group totaled SEK 6.2 M
- The loss per share was SEK 1.61

The period in brief

- Hansa Medical and UK-based Axis-Shield plc signed an agreement covering HMD-301 (HBP), the company's analytical method for diagnosis of severe sepsis
- Hansa Medical and US company Inverness Medical Innovations entered into a partnership relating to Hansa Medical's alpha-11 drug target for the development of novel antibody drugs against rheumatoid arthritis
- Financing received from VINNOVA totaling SEK 0.5 M for the TAME research project, which aims to evaluate new therapy methods in the area of autoimmune diseases
- Collaboration discussions relating to the IdeS project initiated and in progress
- alpha-10 research project divested to Xintela AB
- Board of Directors re-elected and Articles of Association amended at the 2009 Annual General Meeting

CEO's comments – six highly successful months

“The most recent six-month period was a highly successful time for us. We entered into strategic partnerships with Axis-Shield and Inverness Medical Innovations for our HMD-301 diagnosis method and our promising alpha-11 drug target, respectively. Under these agreements, we receive an injection of resources and reduce the financial and technological risks for these two projects, which will accelerate the pace of development and market launch. Collaborations with Axis-Shield and Inverness Medical Innovations are well advanced and we are working jointly to achieve the preclinical and clinical development targets that can dramatically influence the values of our projects.” *Emanuel Björne, CEO Hansa Medical AB (publ)*

Significant events during the period

Hansa Medical and UK-based Axis-Shield plc enter into license and development agreement

In June, Hansa Medical and UK-based Axis-Shield plc (LON: ASD) entered into an exclusive, global collaboration agreement for the development and commercialization of Hansa Medical's patented sepsis marker HBP, Heparin Binding Protein. Axis-Shield will further develop Hansa Medical's HBP assay for diagnostics and monitoring of patients at risk of being affected by severe sepsis. Following further development, the analysis method will be validated in a clinical multi-center study to obtain regulatory approval primarily in the US and Europe. Hansa Medical will play an active role in the technological development and clinical validation of the product.

Axis-Shield will bear all development costs and the collaboration agreement also includes an up-front payment to Hansa Medical in addition to milestone payments that will total several million SEK. Hansa Medical is also entitled to sizable royalty payments from Axis-Shield for the sale of HBP assays on validation and launch of the analysis method. Market introduction is scheduled for late 2011.

Axis-Shield is an international in vitro diagnostics company, headquartered in Dundee, Scotland, with R&D and manufacturing bases in Dundee and Oslo, Norway. Axis-Shield specializes in the development and sale of instruments and analytical tests for the growing point-of-care market and the development, manufacture and marketing of innovative patented diagnostics kits in areas of considerable clinical need, including cardiovascular and neurological diseases, rheumatoid arthritis and diabetes.

Hansa Medical and Inverness Medical Innovations enter into a strategic partnership

In June, Hansa Medical and US company Inverness Medical Innovations Inc. (NYSE: IMA) launched an exclusive and global partnership and license agreement to develop and commercialize monoclonal antibodies for treatment of rheumatoid arthritis (RA). Through the collaboration agreement, Hansa Medical and Inverness Medical Innovations will jointly identify and develop monoclonal antibodies for Hansa Medical's patented drug target, the alpha-11 integrin. Novel candidate drugs will be generated at Inverness Medical Innovation's unit for

antibody development, Biosite Discovery. Biosite's well-established antibody technology, Omniclonal®, generates antibodies with high affinity and low cross-reactivity.

The primary endpoint of the collaboration is to identify a candidate drug that can be moved into clinical development. Inverness Medical Innovations will compensate Hansa Medical with significant milestone payments on achievement of development goals through the collaboration. The agreement entails that Hansa Medical will share the risk and cost for continued development of the alpha-11 project with a partner, meaning that Hansa Medical will be able to participate and invest in the project until a much later stage in the value-adding chain than if the company were to pursue development on a proprietary basis. Inverness Medical Innovations and Hansa Medical will equally share the development costs and future revenues from the time that preclinical proof-of-concept has been achieved.

In cooperation with Inverness Medical Innovations, Hansa Medical aims to establish a third-party alliance in the pharmaceutical industry during the late preclinical phase or early clinical phase. Examples of this type of agreement include the 2007 agreement between Roche and Toyama Chemical with respect to T-5224, or the 2008 agreement between Astellas and Maxygen covering MAXY- 4. Both of these licensing agreements relate to candidate drugs in late preclinical phase or early clinical phase valued at USD 170-370 M, plus double-digit royalty fees.

VINNOVA financing received for TAME research project

During the spring, Hansa Medical received a research grant totaling SEK 0.5 M from the VINNOVA program Forska&Väx (Research and Grow) to implement a preliminary study within the framework of Hansa Medical's TAME project. The aim of the project is to examine the therapeutic potential of antibodies modified using Hansa Medical's patented enzyme EndoS. TAME is an abbreviation for Therapeutic Antibodies Modified by EndoS.

The project's goal is to study whether EndoS-modified antibodies can be used to treat autoimmune diseases in a fundamentally new manner. Antibodies treated with EndoS are expected to impede inflammatory progression in connection with IgG-mediated autoimmune diseases. This technology should also make existing antibody-based drugs for the treatment of autoimmune diseases more effective. The grant from VINNOVA will enable Hansa Medical to invest in an early research project with interesting, but preliminary efficacy results. In the first round of Forska&Väx in 2009, 69 small companies received financing at a total value of SEK 80 M. Some 308 proposals were received at a combined value of more than SEK 420 M.

Collaboration discussions relating to IdeS in progress

The IdeS project is focused on transplantation and interest in this project is considerable among biotechnology and pharmaceutical companies currently specializing in new and innovative immunosuppressive protein drugs for treatment of, or administration in conjunction with, transplantation, and treatment of autoimmune diseases. Hansa Medical is conducting collaboration discussions aimed at a partnership for the IdeS project and, depending on the outcome of these, the company will make a decision on when and if a new share issue will be conducted in 2009.

alpha-10 research project divested to Xintela AB

In April, Hansa Medical entered into an agreement with Xintela AB covering the sale of the alpha-10 project. The divestment agreement included all patents and patent applications, as well as associated biological material that forms the basis for the development project. The purchase consideration was SEK 2.0 M, of which SEK 0.5 M was paid in conjunction with the signing of the agreement, with the remainder due for payment when Xintela AB receives revenues attributable to patents, patent applications or associated biological material.

Alpha-10/beta-1 is a surface protein that is only expressed by the cells that are directly responsible for the formation of cartilage tissue, chondrocytes. Hansa Medical's operations focus on projects in which the therapeutic effects have been proven in experimental studies and, in this regard, alpha-10 as a research project is at too early a stage. Xintela AB was founded by Professor Evy Lundgren-Åkerlund.

Board of Directors re-elected and Articled of Association amended at Annual General Meeting

At Hansa Medical's Annual General Meeting, Bo Håkansson, Per Belfrage and Stina Gestrelus were elected Board members. Bo Håkansson was re-elected Chairman of the Board.

The Annual General Meeting also approved amendments to the Articles of Association with regard to the relocation of the registered office from Malmö to Lund. Share capital restrictions were also changed from not less than SEK 10,000,000 kronor and not more than SEK 40,000,000 to not less than SEK 19,000,000 and not more than SEK 76,000,000 kronor and the limits for the number of shares were changed from not less than 2,000,000 and not more than 8,000,000 to not less than 3,800,000 and not more than 15,200,000.

The Annual General Meeting authorized the Board, for the period until the next Annual General Meeting, to decide on an increase of the company's share capital of not more than SEK 50,000,000 through a new share issue of not more than SEK 10,000,000 shares. The Board was authorized to make decisions concerning cash issues, non-cash issues or issues offsetting debt, with or without disapplying the shareholders' preferential rights. In the event that these rights are disappplied, the reason for so doing must be to broaden the company's ownership structure or to raise development capital.

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