Bavarian Nordic publishes its annual report 2009

Today Bavarian Nordic published the company’s Annual Report 2009. The report is available on the company’s website. Below is an extract of the most significant matters in the report as well as important events after the balance sheet date.

The financial result for the year 2009 was in line with the company’s expectations and latest guidance. Revenue was DKK 75 million and the company recorded a loss before tax of DKK 331 million. At year-end 2009, net free cash and cash equivalents stood at DKK 185 million.

The net proceeds of almost DKK 300 million from the successful completion of a rights issue in the beginning of 2010 enables Bavarian Nordic to maintain momentum in the production of IMVAMUNE® and continue preparations for Phase III for PROSTVAC™.

For 2010, Bavarian Nordic maintains its financial expectations with revenues in the level of DKK 475 million, a pre-tax loss in the level of DKK 250 million and net free cash and cash equivalents in the range of DKK 225 to DKK 275 million at year-end. Bavarian Nordic expects to deliver and invoice 4-5 million doses of IMVAMUNE® to the US authorities, which is the primary source of revenue, which furthermore derives from the ongoing RFP-2 contract and the RFP contract for freeze-dried IMVAMUNE®

2009 highlights

- PROSTVAC™ was presented at several international cancer conferences and gained scientific recognition due to the previously reported and promising Phase II results that demonstrated the potential to significantly extend the lives of patients with advanced prostate cancer.
  - A scientific paper on the mentioned Phase II study was submitted to the prestigious Journal of Clinical Oncology in 2009. The paper was published in the beginning of 2010.
  - A more detailed analysis of the data indicates a broader usage of the vaccine, including the potential for use of the vaccine in earlier disease settings, which was supported by a review, published by key investigators from the National Cancer Institute in the publication “Expert Opinion on Investigational Drugs”, Volume 18, Issue 7 2009.
- The delivery of IMVAMUNE® under the RFP-3 contract was delayed due to a GMP inspection of the production facilities, performed by the U.S. Food and Drug Administration (FDA). This led to a number of observations, requiring subsequent adjustments. By the end of 2009, Bavarian Nordic had submitted its responses to these observations as well as the required documentation of the changes to the FDA for review and acceptance. On this background the company expects delivery of IMVAMUNE® to the US authorities to be initiated before the end of first half of 2010.
- A new contract for the development and process validation of a freeze-dried version of IMVAMUNE® was awarded by the US authorities. The contract has a total prospective value of USD 40 million and will address potential procurement of IMVAMUNE® in excess of the RFP-3 contract.
- Bavarian Nordic continues to enter minor IMVAMUNE® contracts with countries outside the US. In 2009 the first contract with an EU country was entered. Furthermore the delivery of 20,000 doses to the Canadian authorities was completed under the contract, awarded in 2008. Subsequently, the Canadian health authorities recommended that Bavarian Nordic submit an NDS application for consideration to license IMVAMUNE®. The NDS is expected to be filed in 2010, possibly leading to the first license of IMVAMUNE® during 2011.

Important milestones in 2010

- In 2010, Bavarian Nordic expects to initiate the delivery of IMVAMUNE® to the US under the RFP-3 contract. Thus, the company will start invoicing the remainder of the contract, including payments of USD 375 million.
Based upon discussions with the European Medicines Agency and the U.S. Food and Drug Administration, Bavarian Nordic expects to clarify the regulatory strategy and outline the Phase III programme for PROSTVAC™ during first half of 2010. In the meantime, preparations are ongoing for the Phase III studies, expected to commence in late 2010.

Anders Hedegaard, President & CEO of Bavarian Nordic, said: “2009 was successful for our cancer business where our therapeutic prostate cancer vaccine, PROSTVAC™ attracted a lot of positive attention. Through our participation at several international cancer congresses we gained great recognition of the positive Phase II results that have been demonstrated, which have led to our decision to advance the programme into Phase III. Investors also saw great promise in the vaccine, which was the centre of attention during the many meetings we held throughout Europe and in the US, in connection with the rights issue in the beginning of this year. The net proceeds of almost DKK 300 million enables us to continue our Phase III preparations for PROSTVAC™ as well as maintain our focus on the first deliveries of IMVAMUNE® under the RFP-3 contract. Despite the delay that was caused by the FDA inspection, we have had a very constructive dialogue and collaboration with the FDA on the implementation of changes in our production, and we still believe that the first doses will be shipped during first half of 2010. Our good relations with the US were further strengthened with the award of a contract for the development of a freeze-dried version of IMVAMUNE® in the spring. Our contracts with the US combined with the proceeds from the rights issue makes up a solid base for the further development of Bavarian Nordic and are key to our success in 2010.”

Contact
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Webcast and conference call
A conference call will be held today at 9 a.m. (CET). President and CEO, Anders Hedegaard will present the annual results. The accompanying presentation is available on the company’s website: www.bavarian-nordic.com/ar2009. Additional participants from Bavarian Nordic are Reiner Laos, Executive Vice President og CEO of BN ImmunoTherapeutics, Ole Larsen, CFO and Rolf Sass Sørensen, Vice President Investor Relations.

Dial-in numbers for the conference call are: UK: +44 (0)20 7162 0077. USA: +1 334 323 6201
For additional countries and further details please visit www.bavarian-nordic.com/ar2009.

Financial Review 2009
A pre-tax loss of DKK 331 million (2008: loss of DKK 209 million) was recorded for the year, which was in line with our guidance in our announcement dated 18 December 2008.

Bavarian Nordic generated revenue of DKK 75 million in 2009 (DKK 209 million). The revenue was primarily composed of revenue from the ongoing contracts with the US health authorities (development contracts RFP-1 and RFP-2) and from delivery of IMVAMUNE® primarily to Canada.


Equity was DKK 704 million at 31 December 2009 (2008: DKK 1,015 million).

Outlook for 2010
For 2010, Bavarian Nordic expects revenue in the level of DKK 475 million and a pre-tax loss in the level of DKK 250 million.

Revenue will primarily be generated from the supply of IMVAMUNE® to the United States under the RFP-3 contract. Furthermore revenue derives from the ongoing RFP-2 contract and the RFP contract for freeze-dried IMVAMUNE®. Potential IMVAMUNE® contracts with other countries are not included in the forecast.

In 2010, Bavarian Nordic expects to deliver and invoice 4-5 million doses of IMVAMUNE® to the US authorities, including approximately 2 million doses which have already been produced and are awaiting delivery allowance from the US authorities. The remaining doses of the 20 million are expected to be evenly delivered in 2011 and 2012. It is assumed that already produced doses of IMVAMUNE® will be accepted for delivery.

Increased costs, including costs for the continued Phase III preparations for PROSTVAC™ and the continued increase in the production activities for IMVAMUNE®, will affect the 2010 result. Furthermore, a number of investments are required in 2010. These are primarily related to scale-up of the production of IMVAMUNE® at the Kvistgård facility, preparations for the production of PROSTVAC™ at the Berlin facility, continued
development of IMVAMUNE® and general maintenance. These investments are expected to amount to approximately DKK 90 million, of which one third relates to clinical development of IMVAMUNE®.

Based upon the assumptions for the expectations for 2010, including among others that the delivery allowance for IMVAMUNE® to US authorities is obtained no later than first half of 2010 and that a credit facility in the amount of DKK 150 to 200 million to finance working capital is obtained, the Company expects cash preparedness in the range of DKK 225 to 275 million by the end of 2010.

Provided that the RFP-3 contract and marketing of IMVAMUNE® will be fulfilled according to plan, Bavarian Nordic expects to have sufficient funds for its operations until the end of 2012, whereupon the Company expects its cash preparedness to cover the operational needs for an order-producing company.

Important events after the balance sheet date

Successful rights issue generates net proceeds of approximately DKK 300 million
In February 2010, Bavarian Nordic completed an offering in which 3,960,307 new shares with a nominal value of DKK 10 each were subscribed, corresponding to a subscription rate of 99.6%.

The new shares were subscribed at DKK 80 per share with a nominal value of DKK 10, resulting in gross proceeds to Bavarian Nordic of approximately DKK 317 million, equivalent to net proceeds of approximately DKK 298 million after deduction of expenses related to the offering.

Following registration of the 3,960,307 new shares with a nominal value of DKK 10 each, Bavarian Nordic’s nominal share capital will be DKK 119,120,520 corresponding to 11,912,052 shares with a nominal value of DKK 10 each.

PROSTVAC™ paper published by the peer-reviewed Journal of Clinical Oncology
In January 2010, a paper on the previously reported Phase II study with PROSTVAC™ was published in Journal of Clinical Oncology, the official journal of ASCO.

Bavarian Nordic and Oxford BioMedica settle all legal disputes on MVA-BN®
In January 2010 Bavarian Nordic and Oxford BioMedica reached a global settlement ending the legal disputes between the parties on matters relating to MVA-BN®.

Under the agreement, Bavarian Nordic granted a license to its MVA-BN® patents in return for Oxford BioMedica making milestone payments and royalties.

Under the settlement, the terms of which are confidential, all pending litigation will cease and all oppositions filed at the European Patent Office by Oxford BioMedica will be withdrawn. In addition both companies have agreed to initiate business discussions concerning a possible future collaboration based on each company’s expertise in poxvirus vaccines and Bavarian Nordic’s commercial manufacturing capability.
Income statements

Revenue 74.8 208.8 332.1 175.3 247.6
Production costs 140.1 196.7 64.5 136.3 132.2
Research and development costs 164.0 129.6 243.6 118.4 114.4
Distribution and Administrative costs 111.9 92.0 89.1 124.4 75.4
Other operating expenses - - - - 45.4
Income before interest and tax (EBIT) (341.2) (209.5) (65.0) (203.8) (119.8)
Financial items, net 10.1 26.2 14.5 (1.0) 3.4
Income before company tax (331.1) (183.3) (50.5) (204.8) (116.4)
Net profit for the year (266.3) (150.4) (63.5) (160.9) (94.7)

Balance sheet data

Total non-current assets 715.1 594.2 538.8 568.2 472.4
Total current assets 556.0 1,100.0 1,193.2 386.2 456.2
Total assets 1,271.1 1,694.3 1,732.1 954.4 928.6
Shareholders equity 704.2 1,015.1 1,127.7 691.4 630.1
Long-term current liabilities 113.0 52.7 134.7 150.6 212.2
Short-term current liabilities 453.9 626.5 379.7 112.4 86.3

Cash Flow Statements

Net cash including securities 185.0 795.9 913.6 332.7 269.0
Cash flow from operating activities (484.1) (22.4) 163.2 (194.5) (54.9)
Cash flow from investment activities 26.1 (81.5) (16.1) (192.2) (196.9)
Investment in tangible assets 50.6 12.0 5.8 73.9 151.2
Cash flow from financing activities (30.8) (15.1) 440.4 219.0 464.2

Financial Ratios (in DKK)

Earnings per share
- Basic earnings, per share of DKK 10 (34.0) (18.7) (8.0) (25.8) (17.6)
- Diluted earnings, per share of DKK 10 (34.0) (18.7) (8.0) (25.8) (17.6)
PE, price/earnings ratio 88.6 129.9 155.8 108.4 108.7
Share price at the year-end 144 132 293 582 476
Share price/Net assets value per share 1.6 1.0 1.9 5.4 4.4
Numbers of outstanding shares, year-end 7,952 7,816 7,816 6,376 5,797
Shareholders’ equity share 55% 60% 70% 72% 67%
Number of employees (full time), year-end 354 294 264 233 224

Earnings per share (EPS) is calculated in accordance with IAS 33 “Earning per share”. The financial ratios have been calculated in accordance with “Anbefalingen og Nøgletal 2005” (Recommendations and Financial ratios 2005).

Forward-looking statements

This announcement includes “forward-looking statements” that involve risks, uncertainties and other factors, many of which are outside of our control that could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

About Bavarian Nordic

Bavarian Nordic A/S is a leading industrial biotechnology company developing and producing novel vaccines for the treatment and prevention of life-threatening diseases with a large unmet medical need. The company’s pipeline is focused in the three areas: cancer, biodefence and infectious diseases, and includes seven development programmes. Two programmes are under preparation for Phase III: PROSTVAC®, a therapeutic vaccine for advanced prostate cancer is being developed under a collaboration agreement with the National Cancer Institute and IMVAMUNE®, a third-generation smallpox vaccine is being developed under a contract with the US government.

Bavarian Nordic is listed on NASDAQ OMX Copenhagen under the symbol BAVA.

For more information please visit www.bavarian-nordic.com

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