

Company Announcement no. 23 / 2015

# Bavarian Nordic Announces First Half 2015 Results

**COPENHAGEN, Denmark, August 25, 2015** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today publishes its interim financial results for the first half of 2015. Revenue for the period was DKK 624 million (2014: DKK 450 million), the income before interest and tax (EBIT) was a profit of DKK 85 million (2014: DKK 70 million loss) and the net profit was DKK 107 million (2014: DKK 54 million loss). Financial expectations for the full year are maintained.

### Significant events in the second quarter of 2015 and up to the reporting date

- In May, preliminary Phase 1 results were announced for the Ebola prime-boost vaccine regimen of MVA-BN<sup>®</sup> Filo and Janssen's AdVac<sup>®</sup> technology showing that the vaccine regimen was immunogenic, regardless of the order of vaccine administration. In July, a Phase 2 study of the vaccine regimen was initiated in Europe in more than 600 healthy adults.
- Furthermore in May, positive results from two pivotal clinical studies of IMVAMUNE smallpox vaccine were announced. Both studies, a pivotal Phase 2 study in 650 subjects comparing freeze-dried IMVAMUNE to liquid-frozen IMVAMUNE, and a Phase 3 study in 4,000 subjects demonstrating lot consistency with liquid-frozen IMVAMUNE, met their primary endpoints.
- In June, the U.S. Government exercised several contract options for the development of a multivalent MVA-BN-based filovirus vaccine, bringing the total value of the contract to approximately USD 33 million.
- In July, Bavarian Nordic received a new order from the U.S. Government (BARDA) for bulk supply of IMVAMUNE valued at USD 133 million. This bulk material could be converted into freeze-dried IMVAMUNE at a later date.
- In July, an NCI-sponsored Phase 2 study of PROSTVAC in up to 150 patients with localized prostate cancer was initiated.
- In August, a Phase 1 study investigating a new MVA-BN based vaccine against Respiratory Syncytial Virus (RSV) was initiated. The study will enroll 63 healthy adult subjects and assess safety, tolerability and immunogenicity of MVA-BN RSV.

Paul Chaplin, President & Chief Executive Officer of Bavarian Nordic said: "The second quarter has seen a number of successes. As we continue to work toward final data in the PROSPECT study, our partners at the NCI have continued to investigate PROSTVAC in the potential treatment landscape for men with prostate cancer, both with the initiation of a new, large phase 2 study for men with earlier stage disease, as well as the full recruitment of a study of PROSTVAC in combination with enzalutamide. We have secured U.S. government contracts of almost USD 150 million for IMVAMUNE and filovirus vaccine, with the IMVAMUNE order initiating the move towards a freeze dried formulation and the replacement of the 20 million dose stockpile. We have also seen the initiation of clinical trials with another commercial infectious disease candidate targeting RSV. This is a large, unmet illness with a massive cost to the healthcare system in both elderly and infant populations."

### Selected short-term objectives and opportunities

- Manufacture and deliver MVA-BN Filo vaccine to Janssen (targeting 2 million doses to contribute to the MVA-BN/AdVac Ebola prime-boost vaccine regimen) (2015)
- Initiation of Phase 3 clinical trials of the Ebola prime-boost vaccine regimen (2015)
- Complete transfer of validated freeze-dried manufacturing process for IMVAMUNE to a commercial scale facility (2015)

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- Complete enrollment and report Phase 1 data of MVA-BN RSV (H1, 2016)
- Manufacture IMVAMUNE bulk vaccine under USD 133 million contract with BARDA (2016)
- Finalize validation of the PROSTVAC commercial manufacturing process and prepare launch material (2016)
- Potential expanded collaboration with Janssen on additional infectious disease targets
- Secure IMVANEX/IMVAMUNE orders from rest of world
- Advance clinical studies exploring the therapeutic potential of PROSTVAC in combination with Yervoy<sup>®</sup> (ipilimumab) and potentially other checkpoint inhibitors as part of the clinical collaboration with Bristol-Myers Squibb
- Interim analyses of the PROSTVAC Phase 3 clinical trial

### The board of directors appoints Dr. Frank Verwiel

The board of directors has appointed Dr. Frank Verwiel as observer of the board with the intention to nominate him for election to the board at the ordinary general meeting in 2016. Dr. Verwiel previously served as President & CEO of Aptalis Pharma, Inc. and director of the board of Aptalis Holdings Inc. prior to its acquisition by Forest (now Allergan).

## Financials

Danish kroner (DKK) is the Company's functional currency. All USD figures provided below are based upon a USD/DKK exchange rate of 6.40.

	H1 2015	H1 2014	H1 2015	H1 2014
	DKK million	DKK million	USD million	USD million
Revenue	624	450	98	70
EBIT	85	(70)	13	(11)
Cash preparedness	1,669	423	261	66

Bavarian Nordic maintains its 2015 full-year financial expectations with revenue at the level of DKK 1,000 million and a break even result before interest and tax (EBIT). Revenue will primarily be generated from deliveries of bulk material totaling approximately 2 million doses of MVA-BN Filovirus vaccine under the Janssen license agreement and 0.3 million doses of IMVAMUNE to the U.S. Strategic National Stockpile, the Public Health Agency of Canada, Canadian Department of National Defence and an Asian country. Additional revenue is expected from ongoing research and development contracts. The upfront payment from the PROSTVAC option- and license agreement with Bristol-Myers Squibb will be revenue recognized when the option matures.

The cash preparedness at year end is expected to be in the level of DKK 1,450 million and includes the loan facility of EUR 50 million from the European Investment Bank.

As of the reporting date, all known external USD exposure is hedged.

Group key figures are found at the end of this announcement. The full financial statements for the period can be downloaded from the Company's website: <u>www.bavarian-nordic.com</u> along with a spreadsheet containing selected accounting figures.

### Conference call and webcast

The management of Bavarian Nordic will host a conference call today at 2 pm CET (8 am EST) to present the interim results followed by a Q&A session. Dial-in numbers for the conference call are: Denmark: +45 32 71 16 59, UK: +44 (0) 20 3427 1908, USA: +1 646 254 3360. A live and archived webcast of the call and relevant slides will be available at <a href="http://www.bavarian-nordic.com/investor/events.aspx?event=4209">http://www.bavarian-nordic.com/investor/events.aspx?event=4209</a>.

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#### About Bavarian Nordic

Bavarian Nordic is a biopharmaceutical company focused on the development and manufacturing of cancer immunotherapies and vaccines for infectious diseases. Through a long-standing collaboration with the U.S. Government, Bavarian Nordic has developed a portfolio of biological countermeasures, including the non-replicating smallpox vaccine, IMVAMUNE<sup>®</sup>, which is stockpiled for emergency use by the U.S. and other governments. The vaccine is approved in the EU (under the trade name IMVANEX<sup>®</sup>) and in Canada. Bavarian Nordic and its partner Janssen are pioneering the development of an Ebola vaccine, which has been fast-tracked by authorities in response to the current situation in West Africa. Additionally, in collaboration with the National Cancer Institute, Bavarian Nordic has developed a portfolio of active cancer immunotherapies based on its versatile pox-virus based technologies, including PROSTVAC<sup>®</sup>, which is currently in Phase 3 clinical development for the treatment of advanced prostate cancer. The company has partnered with Bristol-Myers Squibb for the potential commercialization of PROSTVAC. For more information visit <u>www.bavarian-nordic.com</u> or follow us on Twitter <u>@bavariannordic</u>.

#### 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.

# **Consolidated Key Figures**

DKK million	6m 2015	6m 2014	FY 2014
	un-audited	un-audited	audited
Income statements			
Revenue	623.9	450.4	1,216.8
Production costs	202.1	229.0	495.1
Research and development costs	219.2	191.6	478.9
Distribution costs	27.4	22.7	45.1
Administrative costs	90.4	76.8	181.0
Income before interest and taxes (EBIT)	84.8	(69.7)	16.7
Financial items, net	62.7	5.9	47.7
Income before company tax	147.5	(63.8)	64.4
Net profit for the period	106.7	(53.7)	25.9
Balance sheet			
Total non-current assets	518.0	582.1	568.1
Total current assets	1,702.6	673.1	1,319.2
Total assets	2,220.6	1,255.2	1,887.3
Equity	1,348.8	925.0	1,252.1
Non-current liabilities	50.9	82.7	51.9
Current liabilities	820.9	247.5	583.3
Cash flow statements			
Securities, cash and cash equivalents	1,285.0	302.5	979.7
Cash flow from operating activities	306.3	(169.5)	338.8
Cash flow from investment activities	(231.0)	(60.6)	(503.7)
- Investment in intangible assets	(14.2)	(31.0)	(53.6)
- Investment in property, plant and equipment	(6.7)	(27.8)	(52.4)
Cash flow from financing activities	15.1	(2.1)	216.3
Financial Ratios (DKK) <sup>1)</sup>			
Earnings (basic) per share of DKK 10	3.8	(2.1)	1.0
Net asset value per share $^{2)}$	48.5	33.3	45.0
Share price at period-end	312	124	198
Share price/Net asset value per share <sup>2)</sup>	6.4	3.7	4.4
Number of outstanding shares at period-end	27,812	26,113	27,671
Equity share Number of employees, converted to full-time, at	61%	74%	66%
period-end	419	421	422

1) Earnings per share (EPS) is calculated in accordance with IAS 33 "Earning per share". The financial ratios have been calculated in accordance with "Anbefalinger og Nøgletal 2015" (Recommendations and Financial ratios 2015).

2) Due to issue of new shares in 2015, net asset value per share for 2014 has been recalculated based on outstanding shares end Q2 2015.