



BAVARIAN NORDIC

# Interim Financial Report

## for the Period January 1 to September 30, 2015

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IMVAMUNE<sup>®</sup>, IMVANEX<sup>®</sup>, MVA-BN<sup>®</sup> and PROSTVAC<sup>®</sup> are  
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## Management's Review

### Financial Statement for the Period January 1 - September 30, 2015

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*Financial statements are un-audited. Comparison figures for the same period 2014 are stated in parentheses.*

Revenue generated for the nine months ending September 30, 2015 was DKK 703 million (DKK 676 million), which is in line with the Company's expectations. Revenue was generated from the sale of MVA-BN Filo bulk drug substance to Janssen, DKK 519 million (DKK 0 million), sale of IMVAMUNE to the U.S. Government and rest of world, DKK 78 million (DKK 576 million) and contract work, DKK 107 million (DKK 99 million). Revenue reported for the three months ended September 30, 2015 was DKK 79 million (DKK 225 million).

The production costs totaled DKK 246 million (DKK 328 million). Costs related directly to revenue amounted to DKK 199 million (DKK 322 million). Other production costs totaled DKK 47 million (DKK 6 million). The increase is primarily related to moving MVA-BN Filo production from clinical trial material production to commercial scale production in less than a year. In the third quarter of 2015, production costs were DKK 44 million (DKK 99 million).

Research and development costs totaled DKK 297 million (DKK 313 million).

Distribution costs totaled DKK 33 million (DKK 34 million) and administrative costs totaled DKK 125 million (DKK 121 million).

The income before interest and tax (EBIT) was DKK 2 million (2014: DKK 121 million loss).

Financial items totaled a net income of DKK 58 million (DKK 37 million net income), DKK 67 million is related to exchange rate adjustments (DKK 37 million).

Income before company tax was an income of DKK 60 million (loss of DKK 85 million).

Tax on income was an expense of DKK 3 million (income of DKK 13 million), corresponding to an effective tax rate of 5.6%. The low effective tax rate relates to an intercompany transaction that can be deducted in the taxable income for Bavarian Nordic A/S and is taxable in Bavarian Nordic, Inc. But since the income in Bavarian Nordic, Inc. can be offset in the non-recognized tax losses carry forward, the net impact at the group level in the third quarter is a tax income, leading to a low effective tax rate for the nine month period ended September 30, 2015.

For the first nine months of 2015, Bavarian Nordic reported a net income of DKK 57 million (net loss of DKK 72 million).

As a result of the agreement entered into with Bristol-Myers Squibb regarding PROSTVAC, Management reassessed the accounting treatment of acquired NCI licenses. Prior to March 2015, previously acquired licenses from the National Cancer Institute (NCI) have been recognized as an intangible asset because it has been undetermined whether the licenses would be recovered through use by the Company itself or through sale. The NCI licenses will effectively transfer to Bristol-Myers Squibb if the option related to the PROSTVAC agreement is exercised. In the first quarter of 2015, Management has therefore reclassified the acquired NCI licenses from intangible assets to development project for sale under current assets. Therefore, the carrying amount of the acquired licenses as of March 2015 (DKK 28 million) has been reclassified to development project for sale.

Accounts receivables have decreased by DKK 98 million compared to December 31, 2014 as the sales in the third quarter of 2015 have been low compared to the sale in the fourth quarter of 2014.

Prepayments from customers have increased by DKK 238 million compared to December 31, 2014. The second upfront payment from Janssen of DKK 222 million (USD 35.8 million) was received in January and the upfront option payment of DKK 399 million (USD 60 million) from Bristol-Myers Squibb was received in March. In the first nine months of 2015 DKK 379 million have been recognized as revenue along with the deliveries to Janssen.

As of September 30, 2015 the Group's cash preparedness was DKK 1,618 million (DKK 356 million), including unutilized credit lines of DKK 384 million (DKK 120 million). Cash flow contribution from operating activities was DKK 270 million (DKK -210 million). Cash flow spend on investment activities was DKK 238 million

(contribution DKK 13 million) primarily due to a net investment in securities of DKK 209 million. Cash flow from financing activities contributed with DKK 16 million (DKK -4 million) regarding proceeds from warrant exercise. The net change in cash and cash equivalents was DKK 48 million (DKK -201 million).

The Group's equity as of September 30, 2015 stood at DKK 1,303 million (DKK 881 million).

#### Financial Expectations

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

A significant part of the research and development costs in 2015 are expected to occur in the fourth quarter, and thus the overall R&D spend is maintained. Research and developments costs are expected to amount to approximately DKK 600 million, cf. table below.

<b>Research and development costs</b>	<b>DKK 600 million</b>
Of which:	
Contract costs recognized as production costs	DKK 100 million
<u>Capitalized development costs</u>	<u>DKK 25 million</u>
	<b>DKK 475 million</b>
Expensing (amortization) of prior-year costs attributable to <u>the IMVAMUNE development project</u>	<u>DKK 5 million</u>
<b>Research and development costs recognized in P&amp;L</b>	<b>DKK 480 million</b>

#### Significant Risks and Uncertainties

Bavarian Nordic faces a number of risks and uncertainties, common for the biotech industry. These relate to operations, research and development, manufacturing, commercial and financial activities. For further information about risks and uncertainties which Bavarian Nordic faces, refer to page 26 "Risk Management" in the 2014 annual report.

Since the publication of the 2014 annual report, the overall risk profile of the Company remains unchanged.

## Our Strategy

Bavarian Nordic's strategic ambition is focused on growth strategies that through private and public partnerships will develop and commercialize novel vaccines and immunotherapies against infectious diseases and cancer that address high unmet medical needs.

The strategy is currently underpinned by the Company's proven vaccine platform, a unique manufacturing infrastructure, expertise in viral-based vaccines and strong partnerships with governmental institutions and the pharmaceutical industry.

The main drivers to achieve the Company's strategy in the short term are:

<b>PROSTVAC</b>	Commercialize PROSTVAC globally through partnership with Bristol-Myers Squibb
<b>IMVAMUNE</b>	Maintain global leadership in smallpox preparedness and build a long-term revenue stream based on worldwide sales of IMVANEX/IMVAMUNE
<b>Janssen Collaboration</b>	Establish a global leadership in Ebola preparedness and treatment through collaboration with Janssen
<b>Commercial Vaccines</b>	Establish a global leadership position in the rapidly growing field of cancer immunotherapy by expanding our pipeline and introducing new combinations involving cancer immunotherapies  Utilize the proprietary vaccine platform to expand the infectious disease vaccine pipeline to meet high unmet medical needs such as RSV
<b>Additional Government Programs</b>	Continue expansion of platform opportunities through ongoing collaboration with NIAID <sup>1</sup> , BARDA <sup>2</sup> , DOD <sup>3</sup> , DHS <sup>4</sup> and NCI <sup>5</sup>

## Selected Short-term Objectives and Opportunities

Anticipated and potential events over the next 12-18 months.

### PROSTVAC

- Top-line data from the PROSTVAC Phase 3 clinical trial anticipated in 2017. Pre-specified, event-driven interim analyses will occur prior to that
- Initiate Phase 2 combination study of PROSTVAC and ipilimumab (Yervoy<sup>®</sup>) in collaboration with Bristol-Myers Squibb
- Initiate NCI-sponsored Phase 2 combination study of PROSTVAC, ipilimumab and nivolumab (Opdivo<sup>®</sup>)
- Report data from ongoing NCI-sponsored Phase 2 trials
- Initiation of new NCI-sponsored combination trials in various prostate cancer stages

### IMVAMUNE

- Finalize manufacturing activities to support a U.S. EUA for freeze-dried IMVAMUNE
- Initiate manufacturing and storage of IMVAMUNE bulk for the U.S. Government
- Respond to a request for proposal (RFP) from the U.S. Government for freeze-dried IMVAMUNE
- Additional orders from rest of world

### Ebola/Janssen collaboration

- Complete Phase 2 and Phase 3 studies of the Ebola prime-boost vaccine regimen
- Potential expanded collaboration with Janssen on additional infectious disease targets

### Other pipeline projects

- Report Phase 1 data of MVA-BN RSV
- Initiation of Phase 2 of MVA-BN RSV
- Initiation of Phase 2 of MVA-BN Brachyury

<sup>1</sup> National Institute of Allergy and Infectious Diseases, part of the U.S. National Institutes of Health (NIH).

<sup>2</sup> Biomedical Advanced Research and Development Authority, a division of the U.S. Department of Health and Human Services

<sup>3</sup> U.S. Department of Defense

<sup>4</sup> U.S. Department of Homeland Security

<sup>5</sup> National Cancer Institute, part of the U.S. National Institutes of Health (NIH).

- Initiation of Phase 2 of CV-301 + immune checkpoint inhibitor in lung cancer
- Initiation of Phase 2 studies of CV-301 + immune checkpoint inhibitor in additional indications
- Initiation of NCI-sponsored combination trials with CV-301
- Initiation of NIH-sponsored Phase 1 study of multivalent MVA-BN Filo prime-boost vaccine

## Product Pipeline

The clinical pipeline currently comprises seven active programs in infectious diseases and cancer, most of which are funded externally through either private or governmental partnerships.

In addition to the clinical pipeline, Bavarian Nordic has ongoing contracts with the U.S. Government for the preclinical evaluation of recombinant MVA-BN vaccine candidates for selected biological threats (e.g. filoviruses, foot-and-mouth disease virus and Burkholderia).

Product	Indication	Partner	Status
IMVANEX/IMVAMUNE <sup>1-4)</sup>	Smallpox	BARDA	Approved
IMVAMUNE <i>freeze-dried</i> <sup>1)</sup>	Smallpox	BARDA	Phase 2
PROSTVAC	Prostate Cancer	Bristol-Myers Squibb	Phase 3
PROSTVAC + enzalutamide	Prostate Cancer	NCI	Phase 2
PROSTVAC + ipilimumab	Prostate Cancer	NCI	Phase 1
MVA-BN Filo + AdVac <sup>®</sup> <sup>1)</sup>	Filoviruses (Ebola/Marburg)	Janssen, NIH	Phase 3
CV-301 Bladder combination <sup>1)</sup>	Bladder Cancer	NCI	Phase 2
MVA-BN Brachyury <sup>1)</sup>	Metastatic Tumors	NCI	Phase 1
MVA-BN RSV	Respiratory Syncytial Virus (RSV)		Phase 1

1) *Externally funded programs*

2) *Sold to government stockpiles*

3) *Approved in the European Union under the trade name IMVANEX<sup>®</sup> and in Canada under the trade name IMVAMUNE<sup>®</sup>*

4) *Phase 3 registration studies are ongoing in the United States*

## PROSTVAC Prostate Cancer Immunotherapy Candidate

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PROSTVAC is a prostate specific antigen (PSA)-targeted immunotherapy candidate, currently in Phase 3 development for the treatment of patients with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer (mCRPC). A robust data package has been established that includes 14 ongoing or completed clinical studies, comprising more than 1,800 patients of which more than 1,100 patients have been actively treated with PROSTVAC, which has been generally well-tolerated. The main findings from these studies include:

- An extension of the median overall survival in patients with advanced prostate cancer by 8-9 months compared to either their median predicted survival, or placebo-controlled patients<sup>6 7</sup>
- PROSTVAC results in the induction of a robust T cell response in the majority of the patients treated. This T cell response is induced to PSA (the prostate antigen encoded by the vaccine) and to other prostate associated antigens (not encoded by the vaccine); a process known as antigen cascade or spreading<sup>8</sup>
- Synergy in combining PROSTVAC at various stages of the cancer progression with:
  - Anti-androgen therapy (e.g. enzalutamide)<sup>9</sup>
  - Checkpoint inhibitors (e.g. ipilimumab) in patients with mCRPC<sup>10</sup>
  - Taxane-based chemotherapy (e.g. docetaxel) in androgen-independent prostate cancer<sup>11</sup>
  - Radiation therapy in patients with localized disease<sup>12</sup>

PROSTVAC has been designed to enhance or stimulate the body's immune response, specifically T cells that will home to and kill prostate cancer cells, altering the course of the disease and improving overall survival of patients with prostate cancer. In the most comprehensive analysis performed to date, the NCI analyzed the T cells responses induced in patients from 6 separate clinical studies evaluating PROSTVAC<sup>8</sup>. This analysis revealed that the majority of the men had a 5-fold increase in T cells recognizing PSA following PROSTVAC treatment. Moreover, the study revealed an antigen cascade had been induced in 67% of the men treated, demonstrating that PROSTVAC was able to mount a significant and strong T cell response against multiple proteins associated with prostate cancer.

PROSTVAC is being developed under a cooperative research and development agreement (CRADA) with the NCI. An agreement was entered with Bristol-Myers Squibb in March 2015, providing them an exclusive option to license and commercialize PROSTVAC.

### The PROSPECT Phase 3 Study

The PROSPECT study is a randomized, double-blind, placebo-controlled study in patients with asymptomatic or minimally symptomatic mCRPC. The trial is being conducted under a Special Protocol Assessment agreement with the FDA.

The primary objective of the study is to determine whether the overall survival of patients receiving PROSTVAC (with or without the addition of granulocyte macrophage colony-stimulating factor; GM-CSF), is superior to that of patients receiving placebo. The final analysis of the study will occur when 534 deaths have occurred in either one or both comparisons of the active treatment arms vs. placebo.

Although the study is powered to detect a difference in survival between active treatment and placebo at final analysis, three pre-specified, event-driven interim analyses of data have been integrated in the statistical plan to evaluate whether the trial should continue as planned or potentially be stopped early for efficacy. In such case, a Biologics License Application may be filed at an earlier stage, potentially shortening the overall development time. The trial was fully enrolled in January 2015, and top-line data is anticipated in 2017.

### *Additional enrollment details available after last treatment visit*

After completion of enrollment in early 2015, all patients have now completed their vaccination regimens and are in follow-up. The study enrolled 1,298 patients, of which 36% were enrolled in North America, 38% in

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<sup>6</sup> Gulley et al. Cancer Immunol Immunother. 2010;59:663.

<sup>7</sup> Kantoff et al. J Clin Oncol. 2010;28:1099.

<sup>8</sup> Gulley et al. Cancer Immunol Res. 2014;2:133.

<sup>9</sup> Madan et al. Clin Cancer Res. 2008;14:4526.

<sup>10</sup> Madan et al. Lancet Oncol. 2012;13:501.

<sup>11</sup> Arlen et al. Clin. Cancer Res. 2006;12:1260

<sup>12</sup> Gulley et al. Clin Cancer Res. 2005;11:3353

Western Europe and the remainder in rest of world countries, including Australia and Russia. Patients enrolled in North America were almost evenly split between oncology clinics and urology clinics with 239 and 229 patients respectively.

On average, patients received 6.1 injections (n=1,279), which is more than recorded in the randomized Phase 2 trial (n=122), where the average number of injections was 5.4. An increased number of injections is expected to improve the clinical outcome for patients receiving the active drug.

Since immunotherapy is characterized by a delayed onset of action, the trial was designed to enroll patients who were believed to have a sufficient life expectancy to benefit from PROSTVAC.

Using the previous randomized Phase 2 trial as a guide, certain entry criteria were amended to better identify patients who were hormone refractory, or showing increases in PSA with no evidence of disease progression, with metastatic disease, but with certain limitations with regard to markers known to identify rapid disease progression. Patients were monitored for markers such as PSA doubling time, alkaline phosphatase levels and minimum PSA values in an effort to select patients expected to progress less rapidly and therefore would have a better chance of benefiting from PROSTVAC.

#### **Other Ongoing PROSTVAC Clinical Studies**

PROSTVAC is currently the subject of five NCI-sponsored Phase 2 clinical studies.

- PROSTVAC in patients with localized prostate cancer undergoing active surveillance. The study is designed to enroll 90 patients with the potential to expand to 150 patients. The primary endpoint of the study is to determine how well PROSTVAC works in eliciting an immune response in patients with prostate cancer that is found only in the prostate and has not yet metastasized.
- PROSTVAC combined with enzalutamide (Xtandi®) to treat metastatic castration-resistant prostate cancer. Enzalutamide is a next-generation androgen deprivation therapy approved by the FDA. The study is expected to enroll 76 patients who will be randomized to receive enzalutamide with PROSTVAC treatment or enzalutamide alone. The primary endpoint is progression-free survival.
- PROSTVAC combined with enzalutamide to treat non-metastatic castration sensitive prostate cancer. The study has completed enrollment of 38 patients who were randomized to receive enzalutamide with PROSTVAC treatment or enzalutamide alone. The primary endpoint is based on PSA kinetics (tumor re-growth rate after enzalutamide is discontinued).
- PROSTVAC combined with flutamide (anti-androgen therapy) versus flutamide alone in 64 patients with non-metastatic prostate cancer. The study is fully enrolled and awaiting final data. Preliminary results from 41 patients indicate an improvement in time to progression (TTP) for those patients receiving PROSTVAC in combination with flutamide (median TTP = 192 days) compared to flutamide alone (median TTP = 108 days).
- PROSTVAC as neoadjuvant therapy in patients with prostate cancer undergoing treatment with radical prostatectomy. The study is expected to enroll 27 patients. The primary endpoint is the effect of PROSTVAC treatment on immune cells (measured by CD4 and CD8 cell infiltrate response) in the prostate.

#### **PROSTVAC Agreement with Bristol-Myers Squibb**

In March, Bavarian Nordic entered into an agreement with Bristol-Myers Squibb, potentially valued at up to nearly USD 1 billion. The agreement provides Bristol-Myers Squibb an exclusive option to license and commercialize PROSTVAC globally.

##### *Terms of the agreement*

Under the terms of the agreement, Bavarian Nordic received an upfront payment of USD 60 million and could be entitled to a payment of USD 80 million upon exercise of the option, which could occur after sufficient data for NDA filing is available from the ongoing Phase 3 trial.

In addition, Bavarian Nordic could be entitled to additional incremental payments starting at USD 50 million, but with a potential to exceed USD 230 million should the median overall survival benefit of PROSTVAC exceed the efficacy seen in Phase 2 results. Furthermore, Bavarian Nordic could receive regulatory milestone payments of USD 110 million, up to USD 495 million in sales milestones as well as tiered double-digit royalties on future sales of PROSTVAC.

The parties have also agreed to enter into a supply contract, under which Bavarian Nordic will undertake the future commercial manufacturing of PROSTVAC.

### **Exploring the full potential of PROSTVAC in combination trials**

In addition to the option and license agreement Bristol-Myers Squibb's also entered into a collaboration agreement to conduct one or more exploratory combination studies of PROSTVAC and agents from Bristol-Myers Squibb's immuno-oncology portfolio. The first Phase 2 trial will be a combination study of PROSTVAC and ipilimumab (Yervoy®) as neoadjuvant therapy that is planned for initiation around the turn of the year. This open label, randomized study, sponsored by the University of California, San Francisco, is planned to enroll 75 patients with localized prostate cancer. Patients will be randomized to PROSTVAC monotherapy, ipilimumab monotherapy, or combination therapy with both PROSTVAC and ipilimumab prior to radical prostatectomy.

Furthermore, a second Phase 2 study, sponsored by NCI, is designed to investigate PROSTVAC in combination with two Bristol-Myers Squibb's immune checkpoint inhibitors: ipilimumab (Yervoy) and nivolumab (Opdivo®) as neoadjuvant therapy. The study is expected to enroll 28 patients who will be randomized to receive combination therapy with PROSTVAC, ipilimumab and nivolumab, or combination therapy PROSTVAC and ipilimumab.

## **IMVAMUNE Smallpox Vaccine**

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*Approved in Canada and in the European Union (marketed under the trade name IMVANEX)*

IMVAMUNE is a non-replicating smallpox vaccine, suitable for use in people for whom replicating smallpox vaccines are contraindicated (e.g. people with HIV and atopic dermatitis). The vaccine is the only non-replicating smallpox vaccine approved for use in the general adult population. In the U.S., IMVAMUNE is stockpiled for emergency use in people for whom replicating smallpox vaccines are contraindicated. Registration studies are underway to support FDA approval for use of the vaccine in the entire population.

The development of IMVAMUNE is funded by the U.S. Government, through contracts with BARDA and NIH. Contracts awarded to date for the development and supply of the vaccine exceed USD 1.2 billion, including awards to advance MVA-BN as a broad platform for the development of medical countermeasures against other potential biological threats.

For a detailed overview of ongoing and completed contracts, see table 1 in the appendix (page 26).

### **Deliveries to the U.S. Strategic National Stockpile (SNS)**

Since 2010, Bavarian Nordic has delivered 28 million doses of IMVAMUNE to the SNS. The deliveries of the initial 20 million doses were completed in 2013, followed by replenishment orders for 8 million doses with final deliveries having occurred in early 2015.

By awarding a contract in 2009 to develop a freeze-dried formulation of IMVAMUNE, which is expected to reduce life cycle management costs based on a longer shelf life, the U.S. Government signaled its commitment to develop an improved formulation of IMVAMUNE to replace the liquid-frozen version of IMVAMUNE, currently stockpiled in the SNS. The freeze-dried version is well positioned to fulfil the U.S. Government's long-term requirements as previously stated for sufficient non-replicating smallpox vaccine to protect 66 million Americans, comprising those for whom a replicating smallpox vaccine is not recommended and their household contacts.

In July, Bavarian Nordic received a new order from BARDA for bulk supply of IMVAMUNE valued at USD 133 million. Under this new order, which is an extension of an existing contract, Bavarian Nordic will manufacture and store a bulk supply of IMVAMUNE. This bulk material could be converted into freeze-dried IMVAMUNE at a later date, once the freeze-drying manufacturing process is transferred to a commercial line, and is approved by the U.S. authorities. The bulk material will be produced and revenue recognized in 2016 and into 2017.

In May, the Company reported data from a pivotal Phase 2 study that enrolled 650 vaccinia-naïve healthy subjects to compare the safety and immunogenicity of a freeze-dried and a liquid-frozen formulation of IMVAMUNE. The freeze-dried vaccine induced an equivalent antibody response as the liquid-frozen version, meeting the primary endpoint of the study. Also both formulations recorded a similar safety profile, confirming that the clinical data generated cumulatively in more than 7,600 vaccinated subjects is relevant for both formulations of IMVAMUNE.

These results provided the final clinical data required to support emergency use (“EUA”) of this next-generation of the vaccine in the U.S., and the transfer of the manufacturing process remains the final step towards meeting the overall requirements for stockpiling of the freeze-dried vaccine. The transfer is currently ongoing, funded under another contract with BARDA.

### **Deliveries, Rest of World**

In October, the Public Health Agency of Canada (PHAC) ordered 143,000 doses of IMVAMUNE. This order, valued at USD 6.4 million, followed the delivery of an initial order for IMVAMUNE earlier this year to the national stockpile. This order, which is the result of an option exercise under an existing contract between Bavarian Nordic and PHAC, is the fourth order of IMVAMUNE by Canadian authorities over a seven-year period. After this exercise, an option for additional doses of IMVAMUNE remains under the contract with PHAC. Bavarian Nordic expects a continuation of the PHAC partnership and foresees additional contractual exercises in the future.

### **Phase 3 Registration Trials in the U.S.**

To support the registration of liquid-frozen IMVAMUNE in the U.S., two Phase 3 studies have been agreed upon with the FDA; a lot consistency study in 4,000 healthy individuals, which has successfully met its primary endpoint, and a second Phase 3 study comparing the safety and immunogenicity of IMVAMUNE to ACAM2000 was initiated at a U.S. military garrison in South Korea in the first quarter of 2015. Enrollment is expected to be completed in 2017.

## **Janssen Collaboration**

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For several years, Bavarian Nordic has been working with NIAID to develop a multivalent MVA-BN-based vaccine against filoviruses (Ebola, Sudan and Marburg), for which no approved treatment or vaccine exists. (See also section “[Additional Government Programs](#)”).

In a study conducted under NIAID’s preclinical services program, a monovalent prime-boost vaccine regimen, consisting of Janssen’s Ad26.ZEBOV vaccine and Bavarian Nordic’s MVA-BN Filo vaccine, was proven efficacious. When both vaccines were administered two months apart, complete protection from death due to Ebola was achieved. The findings from this and other preclinical studies indicate that a more robust and durable immune response is achieved with a prime-boost vaccine that includes MVA.

Upon these findings Bavarian Nordic and Janssen entered into a partnership in 2014 in order to accelerate the development and production of the prime-boost vaccine regimen. In addition to licensing MVA-BN Filo specifically for this prime-boost regimen, Janssen also ordered for bulk material equivalent to 2 million of doses of the vaccine (anticipated yield based on an agreed number of production batches). The 2 million doses have been produced and Bavarian Nordic remains on track to complete deliveries before year-end.

In September, BARDA supported the advanced development and manufacturing of the prime-boost vaccine regimen through a contract to Janssen, under which Bavarian Nordic was awarded a subcontract valued up to USD 33 million.

### **Clinical Development of the Prime-boost Ebola Vaccine Regimen**

Backed by worldwide health authorities, the clinical development of the prime-boost vaccine regimen is being fast-tracked by Janssen. First-in-human Phase 1 clinical studies began in the United Kingdom and United States in January 2015, followed by several sites in Africa. In May, Janssen presented positive preliminary data from the UK Phase 1 study to the U.S. Food and Drug Administration. A Phase 2 study, being carried out in the UK and France, started in July.

In October, the first Phase 3 study to evaluate the vaccine regimen in an Ebola outbreak country was initiated. The study called ‘EBOVAC-Salone’ is being conducted in Sierra Leone’s Kambia district, where some of the country’s most recent Ebola cases have been reported.

The study, coordinated by the London School of Hygiene & Tropical Medicine and sponsored by Janssen, is designed to evaluate the safety and immunogenicity of the combination regimen. Volunteers will first be given the Ad26.ZEBOV dose to prime their immune system, and then the MVA-BN Filo dose at a later date to boost their immune response, with the goal of creating stronger and longer-lasting immunity. The first stage of the study includes approximately 40 adults aged 18 years or older. In stage 2, approximately 400 individuals across different age groups will be vaccinated, including children and adolescents. Additional stages are being

finalized in consultation with the Sierra Leonean authorities and international health agencies. Further details of the study can be found at <http://clinicaltrials.gov/ct2/show/NCT02509494>.

A multi-site Phase 2 study in vulnerable populations is planned to commence in several West and East African countries. This study is planned to enroll approximately 1,200 individuals, including healthy adults, children, and HIV-infected subjects.

#### **Additional Infectious Diseases Targets under Janssen Collaboration**

Following the Ebola vaccine agreement, Bavarian Nordic and Janssen agreed to collaborate on the evaluation of MVA-BN for three additional infectious disease targets. Janssen is granted the exclusive option to collaborate on one or more of the targets following preclinical evaluation of MVA-BN-based vaccine candidates, which will be developed by Bavarian Nordic.

As with the Ebola vaccine regimen, using MVA-BN as a booster is expected to enhance and sustain the immune response after priming with an adenovirus-based vaccine, such as the Ad26 vaccine platform from Janssen, thus providing a strong rationale for this prime-boost approach in multiple infectious diseases.

## **Commercial Vaccines**

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Bavarian Nordic's pipeline contains a number of projects with a large commercial potential and the Company has prioritized two projects that are currently being accelerated into clinical trials; MVA-BN RSV against respiratory syncytial virus and CV-301 immunotherapy for multiple cancers.

#### **RSV (Respiratory Syncytial Virus)**

The development of an RSV vaccine using the MVA-BN vaccine platform is a key opportunity to further diversify the infectious disease pipeline and address a high unmet medical need, as currently there is no approved RSV vaccine.

RSV is the most common cause of lower respiratory tract infection in infants and children worldwide, resulting in a high number of hospitalizations. By 2 years of age virtually all infants have had an RSV infection. In addition, RSV causes serious disease in elderly and immune compromised individuals, and results in a comparable number of deaths in the elderly population as influenza. It is estimated that more than 64 million people are infected globally each year, thus representing a blockbuster market opportunity.

Bavarian Nordic's recombinant MVA-BN-based RSV vaccine candidate has been shown to induce a balanced humoral and cellular immune response against both RSV subtypes in preclinical models. Furthermore, the candidate has been shown to be highly efficacious in preclinical models, including in studies sponsored by the NIH.

In August, a Phase 1 clinical study of MVA-BN RSV was initiated in USA. The study will evaluate the safety, tolerability and immunogenicity of a recombinant MVA-BN-based RSV vaccine in 63 healthy adults, ages 18-65, enrolled into three groups to receive different doses of MVA-BN RSV. One group of subjects of 50-65 years of age will receive a higher dose of MVA-BN RSV in order to evaluate the immune responses in an elderly population, which is a key target for the vaccine.

This study has reached its target enrollment and top-line data is expected in the first half of 2016.

Upon the successful completion of the Phase 1 trial, the Company intends to rapidly progress the RSV vaccine candidate into multiple Phase 1 and Phase 2 trials in at-risk populations, as well as the pediatric population.

#### **CV-301 Cancer Immunotherapy Candidate for Multiple Cancers**

CV-301 is an active cancer immunotherapy candidate which targets two modified tumor-associated antigens (CEA and MUC-1) that are over-expressed in major cancer types, including breast, lung, ovarian, gastric, bladder, kidney, liver and colorectal cancer. CV-301 has been investigated in 7 ongoing or completed NCI-sponsored clinical studies in various cancers, and more than 300 patients have been treated with the product candidate. NCI continues to investigate CV-301 in various clinical settings as part of the CRADA signed in 2011.

Combination treatments continue to play an increasingly important role in the rapidly changing landscape of cancer treatment. The synergistic clinical benefit seen with PROSTVAC in combination settings is believed also to apply to CV-301. Specifically, recent preclinical data provide a clear rationale for combining CV-301 with immune checkpoint inhibitors.

Immune checkpoint inhibitors, which enhance the body's T cell response to kill cancer cells have shown promising efficacy as single agent treatments in clinical studies in various cancers. However, the majority of cancer patients are not responding to immune checkpoint inhibitors, which is believed to relate to the fact that most patients do not mount an immune response to their tumors and therefore there is nothing for this new class of drugs to enhance. The lack of a T cell response is associated with a low or negative expression of PD-L1 on the cancer cells, and low PD-L1 expression is associated with a reduced response rate to the anti-PD-1 immune checkpoint inhibitor treatment. CV-301 has been designed to stimulate the body's immune system in the majority of the patients treated and this response could be further enhanced by combining the treatment with immune checkpoint inhibitors.

With this strong rationale for combining active immunotherapy with immune checkpoint inhibitors, Bavarian Nordic is exploring three indications (non-small cell lung cancer, colorectal cancer and bladder cancer) for the development of a treatment that combines CV-301 with an immune checkpoint inhibitor such as an anti-PD-1 agent. The objective is to improve the progression-free survival, which offers relatively fast access to data.

The development program, sponsored by Bavarian Nordic, will initially focus on non-small cell lung cancer with anticipated initiation of a randomized, controlled clinical Phase 2 study in 2016 combining CV-301 and checkpoint inhibitors.

In keeping with the Company's stated goal of exploring the potential synergy of CV-301 in three separate cancer indications, additional investigations are ongoing in both bladder and colorectal cancer, leading to the possible initiation of additional Phase 2 studies in 2016 and 2017. Bavarian Nordic believes these indications, along with NSCLC, represent unique opportunities to show the potential synergy between CV-301 and checkpoint inhibitors. Bladder cancer is already known to be sensitive to older approved immunotherapies, such as BCG. Colorectal cancer is one of the highest expressing CEA and MUC-1 cancers, demonstrating expression levels of over 90% for each tumor-associated antigen, respectively. Previously, CV-301 has shown clinical activity, as a monotherapy, in a study of patients with colorectal cancer. These attributes, combined with the later stage clinical development of checkpoint inhibitors in these indications, help to provide a strong rationale for the clinical advancement of CV-301 in combination.

The future studies will employ a new generation of the CV-301 product candidate, which the Company has reengineered to include its MVA-BN vaccine as a primer, as opposed to the original construct which was vaccinia-based. Using MVA-BN furthermore entails an improved manufacturing yield. In addition, the tumor-associated antigens (CEA and MUC-1) included in the vaccine have been modified to make them more immunogenic.

## **Additional Government Programs**

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Additional growth opportunities could arise from ongoing collaborations with various U.S. government agencies, including NIH, DOD and DHS on the preclinical evaluation of recombinant MVA-BN vaccine candidates for selected biological threats (e.g. filoviruses, foot-and-mouth disease virus and Burkholderia), in addition to a collaboration with NCI on cancer immunotherapies.

### **MVA-BN Filo**

In June, NIAID exercised several contract options for the development of a vaccine that accelerates and enhances the immune response against Marburg virus, a member of the Filovirus family. The contract, originally awarded in 2012, will provide approximately USD 15 million in additional funds to bring the total value of the contract to approximately USD 33 million. The additional revenue will be recognized over the expanded contract period from 2015-2018.

The contract will support the development of a Filovirus vaccine using Bavarian Nordic's multivalent MVA-BN Filo vaccine in a heterologous prime-boost regimen with a multivalent fowlpox virus vaccine, developed by Bavarian Nordic. Both vaccines encode components from three different Filoviruses, and are thereby designed to protect not only against Marburg virus, but also against the Sudan and Zaire strains of Ebola virus as called for by various U.S. government agencies to ensure future preparedness.

Under the contract, immunogenicity and efficacy will be further evaluated in preclinical studies, clinical trial material will be manufactured and the safety and immunogenicity of the Filovirus vaccine will be investigated in a Phase 1 clinical trial, anticipated to start in 2016.

Most other Filovirus vaccine candidates currently in advanced development are monovalent, focusing solely on the Ebolavirus that is responsible for the current outbreak in West Africa. This includes Bavarian Nordic's MVA-BN Filo as part of a monovalent prime-boost vaccination regimen with Janssen's Ad26.ZEBOV, which is currently in clinical development. These monovalent development efforts are outside of the scope of the Company's contract with NIAID.

#### **MVA-BN Brachyury**

MVA-BN Brachyury is a novel, active immunotherapy developed using Bavarian Nordic's proprietary validated MVA-BN platform. It is designed to induce a robust T cell immune response against Brachyury, a tumor-associated antigen which is overexpressed in major solid tumor indications. Brachyury is reported to play a key role in the metastases and progression of tumors. Tumors which overexpress Brachyury are believed to be highly resistant to current therapies and are associated with decreased survival rates.

An NCI-sponsored, open label Phase 1 study of MVA-BN Brachyury in patients with advanced cancer or chordoma has completed enrollment of 38 patients that have received escalating doses of MVA-BN Brachyury in three cohorts. The objective of the study is to determine the safety and tolerability of MVA-BN Brachyury and to evaluate immunologic responses as measured by an increase in Brachyury-specific T cells.

Data from the study will be presented as a poster presentation at the SITC (Society for Immunotherapy of Cancer) 2015 Annual Meeting in National Harbor, Maryland on November 7, 2015. An abstract of the study results will be released on November 3, 2015 at 2 pm CET.

Additional studies of MVA-BN Brachyury used in combination with other treatments, including checkpoint inhibitors, are planned for initiation by the NCI in 2016 and beyond. These studies will investigate this novel approach across various cancer types.

#### **CV-301 in Bladder Cancer**

CV-301 is being investigated in an NCI-sponsored, randomized, prospective Phase 2 study in bladder cancer. The study investigates CV-301 alone or in combination with BCG (Bacillus Calmette-Guerin) treatment.

CV-301 is thought to activate a potent antitumor immune response against bladder cancer cells which express the CEA and MUC-1 antigens. Together with a BCG-induced immune response, the combination therapy has the potential to improve survival in patients whose disease has progressed following an induction course of BCG.

The study is expected to enroll 54 patients with high grade non-muscle invasive bladder cancer whose cancer has progressed after initial BCG treatment. The primary endpoint is to determine if there is an improvement in disease-free survival for patients receiving CV-301 immunotherapy in combination with BCG treatment compared to those receiving BCG treatment alone.

## **Other Developments**

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#### **Changes in Board and Management**

In August, the Company announced that James B. Breitmeyer, M.D. Ph.D., resigned his position as Executive Vice President and Chief Development Officer due to personal reasons, effective July 31, 2015.

In August, the board of directors 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). Dr. Verwiel holds a Medical Doctor degree from Erasmus University in Rotterdam, the Netherlands. He also attended INSEAD in Fontainebleau, France, where he earned his Masters of Business Administration. Dr. Verwiel is a Dutch national, born in 1962.

#### **Capital Increase as Result of Warrant Exercise**

In September, the Company's share capital was increased by nominally DKK 223,810 as a consequence of employees' exercise of warrants. The capital increase was effected without any pre-emption rights for the existing shareholders of the Company or others. The shares were subscribed for in cash at the following prices per share of nominally DKK 10: 3,881 shares at DKK 194.00 and 18,500 shares at DKK 54.00. The total proceeds to Bavarian Nordic A/S from the capital increase amounted to DKK 1.75 million. Subsequently, Bavarian Nordic A/S' share capital amounts to DKK 278,343,740.

## Statement from the Board of Directors and Corporate Management

The Board of Directors and Corporate Management have, today reviewed and approved the Bavarian Nordic A/S interim report for the period January 1 to September 30, 2015.

The interim report has been prepared in accordance with IAS 34 “Interim Financial Reporting” as adopted by the EU and additional Danish disclosure requirements for interim reports of listed companies, including those of Nasdaq Copenhagen. The interim report has not been audited or reviewed by the company’s auditors.

In our opinion, the interim report gives a true and fair view of the group’s assets and liabilities and financial position as of September 30, 2015 and the results of the group’s activities and cash flows for the period January 1 to September 30, 2015.

In our opinion, the management’s review provides a true and fair description of the development in the group’s activities and financial affairs, the results for the period and the group’s financial position as a whole as well as a description of the most important risks and uncertainty factors faced by the group.

Kvistgaard, November 3, 2015

### Corporate Management:

Paul Chaplin  
President and CEO

Ole Larsen  
CFO

### Board of Directors:

Gerard van Odijk  
Chairman of the Board

Anders Gersel Pedersen  
Deputy chairman

Claus Bræstrup

Erik G. Hansen

Peter Kürstein

# Financial Statements

## Consolidated Key Figures (unaudited)

DKK thousand	1/7 - 30/9 2015	1/7 - 30/9 2014	1/1 - 30/9 2015	1/1 - 30/9 2014	1/1-31/12 2014
<b>Income statements</b>					
Revenue	79,100	225,205	703,015	675,591	1,216,815
Production costs	43,542	99,135	245,678	328,116	495,081
Research and development costs	77,663	121,864	296,848	313,483	478,930
Distribution costs	5,573	11,666	32,998	34,365	45,107
Administrative costs	34,851	44,166	125,249	120,962	181,022
Income before interest and taxes (EBIT)	(82,529)	(51,626)	2,242	(121,335)	16,675
Financial items, net	(4,518)	30,883	58,225	36,788	47,685
Income before company tax	(87,047)	(20,743)	60,467	(84,547)	64,360
Net profit for the period	(49,625)	(18,403)	57,111	(72,040)	25,940
<b>Balance sheet</b>					
Total non-current assets			552,743	592,550	568,145
Total current assets			1,586,396	671,254	1,319,123
Total assets			2,139,139	1,263,804	1,887,268
Equity			1,302,663	881,442	1,252,094
Non-current liabilities			49,873	90,067	51,896
Current liabilities			786,603	292,295	583,278
<b>Cash flow statements</b>					
Securities, cash and cash equivalents			1,233,914	236,093	979,707
Cash flow from operating activities			269,969	(209,664)	338,749
Cash flow from investment activities			(238,467)	12,995	(503,665)
- Investment in intangible assets			(16,930)	(43,294)	(53,595)
- Investment in property, plant and equipment			(12,620)	(39,733)	(52,392)
Cash flow from financing activities			16,319	(4,259)	216,238
<b>Financial Ratios (DKK) <sup>1)</sup></b>					
Earnings (basic) per share of DKK 10			2.1	(2.8)	1.0
Net asset value per share <sup>2)</sup>			46.8	31.7	45.0
Share price at period-end			264	114	198
Share price/Net asset value per share <sup>2)</sup>			5.6	3.6	4.4
Number of outstanding shares at period-end			27,834	26,113	27,671
Equity share			61%	70%	66%
Number of employees, converted to full-time, at period-end			408	415	422

<sup>1)</sup> 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).

<sup>2)</sup> Due to issue of new shares in 2015, net asset value per share for 2014 has been recalculated based on outstanding shares end Q3 2015.

### Notes

(stated in the end of this document):

1. Accounting policies
2. Significant accounting estimates, assumptions and uncertainties
3. Revenue
4. Production costs
5. Research and development costs
6. Financial income
7. Financial expenses
8. Inventories
9. Other receivables
10. Prepayment from customer
11. Other liabilities
12. Financial instruments
13. Incentive plans
14. Loan facility agreement of EUR 50 million entered with the European Investment Bank
15. Significant changes in contingent liabilities and other contractual obligations
16. Significant events after the balance sheet date

## Unaudited Condensed Consolidated Income Statements for the Periods Ended September 30, 2015 and 2014

DKK thousand	Note	1/7 - 30/9 2015	1/7 - 30/9 2014	1/1 - 30/9 2015	1/1 - 30/9 2014	1/1-31/12 2014
Revenue	3	79,100	225,205	703,015	675,591	1,216,815
Production costs	4	43,542	99,135	245,678	328,116	495,081
<b>Gross profit</b>		<b>35,558</b>	<b>126,070</b>	<b>457,337</b>	<b>347,475</b>	<b>721,734</b>
Research and development costs	5	77,663	121,864	296,848	313,483	478,930
Distribution costs		5,573	11,666	32,998	34,365	45,107
Administrative costs		34,851	44,166	125,249	120,962	181,022
<b>Total operating costs</b>		<b>118,087</b>	<b>177,696</b>	<b>455,095</b>	<b>468,810</b>	<b>705,059</b>
<b>Income before interest and tax (EBIT)</b>		<b>(82,529)</b>	<b>(51,626)</b>	<b>2,242</b>	<b>(121,335)</b>	<b>16,675</b>
Financial income	6	2,941	31,998	78,853	40,037	57,385
Financial expenses	7	7,459	1,115	20,628	3,249	9,700
<b>Income before company tax</b>		<b>(87,047)</b>	<b>(20,743)</b>	<b>60,467</b>	<b>(84,547)</b>	<b>64,360</b>
Tax on income for the period		(37,422)	(2,340)	3,356	(12,507)	38,420
<b>Net profit for the period</b>		<b>(49,625)</b>	<b>(18,403)</b>	<b>57,111</b>	<b>(72,040)</b>	<b>25,940</b>
<b>Earnings per share (EPS) - DKK</b>						
Basic earnings per share of DKK 10		(1.8)	(0.7)	2.1	(2.8)	1.0
Diluted earnings per share of DKK 10		(1.8)	(0.7)	2.1	(2.8)	1.0

## Unaudited Condensed Consolidated Statements of Comprehensive Income for the Periods Ended September 30, 2015 and 2014

DKK thousand	1/7 - 30/9 2015	1/7 - 30/9 2014	1/1 - 30/9 2015	1/1 - 30/9 2014	1/1-31/12 2014
<b>Net profit for the period</b>	<b>(49,625)</b>	<b>(18,403)</b>	<b>57,111</b>	<b>(72,040)</b>	<b>25,940</b>
<b>Items that might be reclassified to the income statement:</b>					
Exchange rate adjustments on translating foreign operations	449	(26,934)	(32,152)	(29,498)	(41,552)
<b>Other comprehensive income after tax</b>	<b>449</b>	<b>(26,934)</b>	<b>(32,152)</b>	<b>(29,498)</b>	<b>(41,552)</b>
<b>Total comprehensive income</b>	<b>(49,176)</b>	<b>(45,337)</b>	<b>24,959</b>	<b>(101,538)</b>	<b>(15,612)</b>

**Unaudited Condensed Consolidated Statements of Financial Position - Assets as of September 30, 2015 and 2014 and December 31, 2014**

DKK thousand	Note	30/9 2015	30/9 2014	31/12 2014
<b>Assets</b>				
Acquired licenses		-	24,526	24,719
Software		3,740	3,473	4,835
IMVAMUNE development project		90,882	90,973	78,357
Intangible assets in progress		2,245	1,118	1,283
<b>Intangible assets</b>		<b>96,867</b>	<b>120,090</b>	<b>109,194</b>
Land and buildings		217,015	170,989	226,144
Leasehold improvements		678	962	892
Plant and machinery		58,214	68,408	64,606
Fixtures and fittings, other plant and equipment		17,878	21,244	20,900
Assets under construction		24,912	72,125	24,031
<b>Property, plant and equipment</b>		<b>318,697</b>	<b>333,728</b>	<b>336,573</b>
Other receivables		892	930	792
<b>Financial assets</b>		<b>892</b>	<b>930</b>	<b>792</b>
<b>Deferred tax assets</b>		<b>136,287</b>	<b>137,802</b>	<b>121,586</b>
<b>Total non-current assets</b>		<b>552,743</b>	<b>592,550</b>	<b>568,145</b>
<b>Development projects for sale</b>		<b>66,843</b>	-	-
<b>Inventories</b>	8	<b>154,113</b>	<b>232,752</b>	<b>121,847</b>
Trade receivables		88,900	184,442	186,783
Tax receivables		4,499	1,684	4,913
Other receivables	9	13,519	4,523	14,516
Prepayments		24,608	11,760	11,357
<b>Receivables</b>		<b>131,526</b>	<b>202,409</b>	<b>217,569</b>
Securities		771,569	90,056	581,350
Cash and cash equivalents		462,345	146,037	398,357
<b>Securities, cash and cash equivalents</b>		<b>1,233,914</b>	<b>236,093</b>	<b>979,707</b>
<b>Total current assets</b>		<b>1,586,396</b>	<b>671,254</b>	<b>1,319,123</b>
<b>Total assets</b>		<b>2,139,139</b>	<b>1,263,804</b>	<b>1,887,268</b>

**Unaudited Condensed Consolidated Statements of Financial Position - Equity and Liabilities as of September 30, 2015 and 2014 and December 31, 2014**

DKK thousand	Note	30/9 2015	30/9 2014	31/12 2014
<b>Equity and liabilities</b>				
Share capital		278,344	261,129	276,712
Retained earnings		1,052,132	601,799	972,321
Other reserves		(27,813)	18,514	3,061
<b>Equity</b>		<b>1,302,663</b>	<b>881,442</b>	<b>1,252,094</b>
Provisions		18,057	14,830	18,603
Debt to credit institutions		31,816	75,237	33,293
<b>Non-current liabilities</b>		<b>49,873</b>	<b>90,067</b>	<b>51,896</b>
Debt to credit institutions		1,956	2,283	1,885
Prepayment from customers	10	613,116	91,215	375,190
Trade payables		51,557	69,814	58,666
Company tax		43	38	40
Provisions		2,471	1,986	4,214
Other liabilities	11	117,460	126,959	143,283
<b>Current liabilities</b>		<b>786,603</b>	<b>292,295</b>	<b>583,278</b>
<b>Total liabilities</b>		<b>836,476</b>	<b>382,362</b>	<b>635,174</b>
<b>Total equity and liabilities</b>		<b>2,139,139</b>	<b>1,263,804</b>	<b>1,887,268</b>

**Unaudited Condensed Consolidated Statements of Cash Flow for the Periods Ended September 30, 2015 and 2014 and December 31, 2014**

DKK thousand	1/1 - 30/9 2015	1/1 - 30/9 2014	1/1-31/12 2014
<b>Net profit for the period</b>	<b>57,111</b>	<b>(72,040)</b>	<b>25,940</b>
Adjustment for non-cash items:			
Financial income	(78,853)	(40,037)	(57,385)
Financial expenses	20,628	3,249	9,700
Tax on income for the period	3,356	(12,507)	38,420
Depreciation, amortization and impairment losses	32,651	33,316	44,946
Expensing (amortization) of IMVAMUNE development project	2,692	25,400	45,535
Share-based payment	15,712	9,074	21,317
Adjustment for other non-cash items	-	(4)	-
Changes in development projects for sale	(39,918)	-	-
Changes in inventories	(32,266)	898	111,803
Changes in receivables	49,532	(57,716)	(78,322)
Changes in provisions	(2,140)	(287)	3,616
Changes in current liabilities	229,004	(97,872)	180,222
<b>Cash flow from operations (operating activities)</b>	<b>257,509</b>	<b>(208,526)</b>	<b>345,792</b>
Received financial income	32,255	5,896	19,412
Paid financial expenses	(2,181)	(3,249)	(4,177)
Paid company taxes	(17,614)	(3,785)	(22,278)
<b>Cash flow from operating activities</b>	<b>269,969</b>	<b>(209,664)</b>	<b>338,749</b>
Investments in and additions to intangible assets	(16,930)	(43,294)	(53,595)
Investments in property, plant and equipment	(12,620)	(39,733)	(52,392)
Disposal of property, plant and equipment	-	-	53
Investments in/disposal of financial assets	(100)	(99)	39
Investments in securities	(616,279)	(52,065)	(588,478)
Disposal of securities	407,462	148,186	190,708
<b>Cash flow from investment activities</b>	<b>(238,467)</b>	<b>12,995</b>	<b>(503,665)</b>
Payment on mortgage and construction loan	(1,406)	(6,368)	(49,019)
Proceeds from warrant programs exercised	17,821	-	14,357
Proceeds from direct placement	-	2,109	251,000
Cost related to issue of new shares	(96)	-	(100)
<b>Cash flow from financing activities</b>	<b>16,319</b>	<b>(4,259)</b>	<b>216,238</b>
<b>Cash flow of the period</b>	<b>47,821</b>	<b>(200,928)</b>	<b>51,322</b>
Cash as of 1 January	398,357	346,799	346,799
Currency adjustments 1 January	16,167	166	236
<b>Cash end of period</b>	<b>462,345</b>	<b>146,037</b>	<b>398,357</b>

**Unaudited Condensed Consolidated Statements of Changes in Equity for the Periods Ended September 30, 2015 and 2014**

DKK thousand	Share capital	Retained earnings	Reserves for currency adjustment	Share-based payment	Equity
<b>Equity as of January 1, 2015</b>	<b>276,713</b>	<b>972,320</b>	<b>(35,185)</b>	<b>38,246</b>	<b>1,252,094</b>
<b>Comprehensive income for the period</b>					
Net profit	-	57,111	-	-	57,111
<b>Other comprehensive income</b>					
Exchange rate adjustments on translating foreign operations	-	-	(32,152)	-	(32,152)
<b>Total comprehensive income for the period</b>	<b>-</b>	<b>57,111</b>	<b>(32,152)</b>	<b>-</b>	<b>24,959</b>
<b>Transactions with owners</b>					
Share-based payment	-	-	-	7,885	7,885
Warrant program exercised	1,631	22,661	-	(6,471)	17,821
Warrant program expired	-	136	-	(136)	-
Cost related to issue of new shares	-	(96)	-	-	(96)
<b>Total transactions with owners</b>	<b>1,631</b>	<b>22,701</b>	<b>-</b>	<b>1,278</b>	<b>25,610</b>
<b>Equity as of September 30, 2015</b>	<b>278,344</b>	<b>1,052,132</b>	<b>(67,337)</b>	<b>39,524</b>	<b>1,302,663</b>

DKK thousand	Share capital	Retained earnings	Reserves for currency adjustment	Share-based payment	Equity
<b>Equity as of January 1, 2014</b>	<b>260,944</b>	<b>652,021</b>	<b>6,368</b>	<b>56,958</b>	<b>976,291</b>
<b>Comprehensive income for the period</b>					
Net profit	-	(72,040)	-	-	(72,040)
<b>Other comprehensive income</b>					
Exchange rate adjustments on translating foreign operations	-	-	(29,498)	-	(29,498)
<b>Total comprehensive income for the period</b>	<b>-</b>	<b>(72,040)</b>	<b>(29,498)</b>	<b>-</b>	<b>(101,538)</b>
<b>Transactions with owners</b>					
Share-based payment	-	-	-	4,580	4,580
Warrant program exercised	185	2,923	-	(999)	2,109
Warrant program expired	-	18,895	-	(18,895)	-
<b>Total transactions with owners</b>	<b>185</b>	<b>21,818</b>	<b>-</b>	<b>(15,314)</b>	<b>6,689</b>
<b>Equity as of September 30, 2014</b>	<b>261,129</b>	<b>601,799</b>	<b>(23,130)</b>	<b>41,644</b>	<b>881,442</b>

## 1. Significant accounting policies

The interim financial statements are prepared in accordance with IAS 34, Interim Financial Reporting, as adopted by EU and the additional Danish requirements for submission of interim reports for companies listed on Nasdaq Copenhagen.

The interim financial statements are presented in Danish Kroner (DKK), which is considered the primary currency of the Group's activities and the functional currency of the parent company.

The accounting policies used in the interim financial statements are consistent with those used in the consolidated financial statements for 2014 and in accordance with the recognition and measurement policies in the International Financial Reporting Standards (IFRS) as adopted by EU. However, the Company entered into a new significant agreement with Bristol-Myers Squibb (BMS) and the following represents the accounting policies with regard to this agreement:

### Accounting for BMS PROSTVAC agreement

In March 2015, Bavarian Nordic entered into an Option and License Agreement with BMS under which the Company can receive up to USD 975 million in up-front and milestone payments. The agreement includes the following payments:

- up-front option grant payment of USD 60 million;
- option exercise and license payment of USD 80 million;
- Phase 3 completion milestone, including a variable milestone linked to the extended overall survival, or OS, in the Phase 3 trial. For example, should the Phase 3 OS data replicate the double blind placebo-controlled Phase 2 trial (8.5 months), the milestone will be USD 230 million;
- regulatory milestones of USD 110 million; and
- sales milestones of USD 495 million.

Bavarian Nordic received the up-front option grant payment of USD 60 million, which was recognized as a pre-payment from customers in the statement of financial position as of September 30, 2015 and will be recognized as revenue if and when BMS exercises the option (or if the option expires unexercised). Upon any such exercise of the option by BMS, the Company will recognize as revenue the option exercise and license payment. A portion of the payment may be allocated to the completion of the Phase 3 clinical trial of PROSTVAC if BMS exercises its option before Phase 3 is completed. Upon completion of the Phase 3 trial, the Company will recognize as revenue the Phase 3 completion milestone payments. Regulatory and sales milestone payments will be recognized as revenue when relevant milestones are achieved.

The National Cancer Institute (NCI) has rights to 10% of the up-front option payment of USD 60 million, which has been paid as of September 30, 2015, as well as 10% of the option exercise and license payment of USD 80 million, if and when BMS exercises the option.

### Acquired NCI licenses

As a result of the new agreement entered into with BMS regarding PROSTVAC, Management reassessed the accounting treatment of acquired NCI licenses. As part of the Company's business model and core operations, the Company acquires licenses for further development with subsequent disposal of the licenses either through a sale or by entering into a partnership agreement under which the licenses are assumed to be effectively transferred to the partner. Prior to March 2015, previously acquired licenses from the National Cancer Institute (NCI) have been recognized as an intangible asset because it has been undetermined whether the licenses would be recovered through use by the Company itself or through sale. The NCI licenses will effectively transfer to BMS if the option related to the PROSTVAC agreement is exercised. In the first quarter of 2015, Management has therefore reclassified the acquired NCI licenses from intangible assets to development project for sale under current assets. Therefore, the carrying amount of the acquired licenses as of March 2015 (DKK 28 million) has been reclassified. As the reclassification is a result of the change in the Company's expectations of how it will realize the asset as a consequence of the agreement with BMS and thus, the comparative figures for 2014 have not been restated.

Further, in accordance with the license agreement with NCI, Bavarian Nordic has an obligation to pay 10% of the received upfront option payment from BMS to NCI. This additional license payment of USD 6 million has been paid and is recognized as part of the development projects for sale (see below).

### Accounting policy for "Development projects for sale"

Development projects for sale consist of licenses that have been acquired with the intent to further develop the technology and subsequently disposal of the licenses either through a sale or by entering into a partnership agreement under which the licenses are assumed to be transferred to the partner.

Only the license payments to acquire the licenses are capitalized whereas all costs related to further development of the technology are expensed in the year they occur unless the criteria for recognition as an asset are met.

At initial recognition acquired licenses are measured at cost. Subsequently the acquired licenses are measured at the lower of cost and net realizable value.

The net realizable value is the estimated sales price in the ordinary course of business less relevant sales costs determined on the basis of marketability.

### Segment reporting

The Group is focused on growth strategies that through private and public partnerships will develop and commercialize novel vaccines and immunotherapies against infectious diseases and cancer.

The Group decided in March 2015 to abandon the divisional structure and merged the two divisions; "Cancer Immunotherapy" and "Infectious Diseases". Therefore, the Group does no longer prepare segment reporting internally, hence only has one operating segment to report externally.

The internal financial reporting no longer contains separate sections for the two divisions.

## 2. Significant accounting estimates, assumptions and uncertainties

In the preparation of the interim financial statements according to IAS 34, Interim Financial Reporting, as adopted by the EU, Management is required to make certain estimates as many financial statement items cannot be reliably measured, but must be estimated. Such estimates comprise judgments made on the basis of the most recent information available at the reporting date. It may be necessary to change previous estimates as a result of changes to the assumptions on which the estimates were based or due to supplementary information, additional experience or subsequent events.

Similarly, the value of assets and liabilities often depends on future events that are somewhat uncertain. In that connection, it is necessary to set out e.g. a course of events that reflects Management's assessment of the most probable course of events.

Further to the significant accounting estimates, assumptions and uncertainties, which are stated in the Annual Report 2014, the Management has not changed significant estimates and judgments regarding recognition and measurement.

In accordance with the Group's accounting policy, Management has assessed whether the upfront option payment of USD 60 million represents a transfer of goods or services that has value to Bristol-Myers Squibb on a stand-alone basis. As Management has concluded that no goods or services have been transferred yet, the upfront option payment of USD 60 million is recognized in the statement of financial position at September 30, 2015 as a prepayment from customers.

DKK thousand	1/7 - 30/9 2015	1/7 - 30/9 2014	1/1 - 30/9 2015	1/1 - 30/9 2014	1/1-31/12 2014
<b>3. Revenue</b>					
IMVAMUNE sale	170	190,237	77,592	576,256	1,024,236
Other product sale	17,608	-	518,908	-	-
Sale of goods	17,778	190,237	596,500	576,256	1,024,236
Contract work	61,322	34,968	106,515	99,335	192,579
Sale of services	61,322	34,968	106,515	99,335	192,579
<b>Revenue</b>	<b>79,100</b>	<b>225,205</b>	<b>703,015</b>	<b>675,591</b>	<b>1,216,815</b>
<b>4. Production costs</b>					
Cost of goods sold, IMVAMUNE sale	14	78,279	20,497	270,890	411,112
Cost of goods sold, other product sale	3,532	-	122,829	-	-
Contract costs	27,975	20,187	55,680	51,407	91,673
Other production costs	12,021	669	46,672	5,819	(7,704)
<b>Production costs</b>	<b>43,542</b>	<b>99,135</b>	<b>245,678</b>	<b>328,116</b>	<b>495,081</b>
<b>5. Research and development costs</b>					
Research and development costs occurred in the period	108,098	146,031	365,053	378,908	572,005
Of which:					
Contract costs recognized as production costs	(27,975)	(20,187)	(55,680)	(51,407)	(91,673)
Capitalized development costs	(2,640)	(11,795)	(15,217)	(39,418)	(46,937)
	77,483	114,049	294,156	288,083	433,395
Expensing (amortization) of prior-year costs attributable to the IMVAMUNE development project	180	7,815	2,692	25,400	45,535
<b>Research and development costs</b>	<b>77,663</b>	<b>121,864</b>	<b>296,848</b>	<b>313,483</b>	<b>478,930</b>
<b>6. Financial income</b>					
Financial income from bank and deposit contracts	-	-	-	-	12
Interest income from financial assets not measured at fair value in the income statement	-	-	-	-	12
Financial income from securities	4,172	906	11,423	2,177	-
Fair value adjustments on securities	-	44	-	895	4,028
Net gains on derivative financial instruments at fair value in the income statement	(757)	(1,772)	14,577	2,794	-
Net foreign exchange gains	(474)	32,820	52,853	34,171	53,345
<b>Financial income</b>	<b>2,941</b>	<b>31,998</b>	<b>78,853</b>	<b>40,037</b>	<b>57,385</b>
<b>7. Financial expenses</b>					
Interest expenses on debt	577	1,115	1,999	3,249	4,177
Interest expenses on financial liabilities not measured at fair value in the income statement	577	1,115	1,999	3,249	4,177
Fair value adjustments on securities	7,031	-	18,778	-	1,703
Adjustment of net present value of provisions	(149)	-	(149)	-	2,098
Net loss on derivative financial instruments at fair value in the income statement	-	-	-	-	1,722
<b>Financial expenses</b>	<b>7,459</b>	<b>1,115</b>	<b>20,628</b>	<b>3,249</b>	<b>9,700</b>

DKK thousand	30/9 2015	30/9 2014	31/12 2014
<b>8. Inventories</b>			
Raw materials and supply materials	29,122	20,568	21,676
Work in progress	168,648	173,194	115,313
Manufactured goods and commodities	14,011	102,872	30,749
Write-down on inventory	(57,668)	(63,882)	(45,891)
<b>Inventories</b>	<b>154,113</b>	<b>232,752</b>	<b>121,847</b>
Write-down on inventory 1 January	(45,891)	(68,530)	(68,530)
Write-down during the period	(11,777)	(7,442)	(490)
Use of write-down	-	-	11,039
Reversal of write-down	-	12,090	12,090
<b>Write-down end of period</b>	<b>(57,668)</b>	<b>(63,882)</b>	<b>(45,891)</b>
<b>9. Other receivables</b>			
Receivable VAT and duties	4,425	3,089	5,919
Accrued interest	8,975	1,434	8,448
Other receivables	119	-	149
<b>Other receivables</b>	<b>13,519</b>	<b>4,523</b>	<b>14,516</b>
<b>10. Prepayments from customers</b>			
Prepayments from customers as of January 1	375,190	150,425	150,425
Prepayments received during the period	631,158	104,274	458,857
Recognized as income during the period	(393,232)	(163,484)	(234,092)
<b>Prepayments from customers end of period</b>	<b>613,116</b>	<b>91,215</b>	<b>375,190</b>
<b>11. Other liabilities</b>			
Financial instruments at fair value	-	5,805	710
Liability relating to phantom shares	10,857	6,668	17,176
Payable salaries, holiday accrual etc.	57,513	55,115	61,934
Other accrued costs	49,090	59,371	63,463
<b>Other liabilities</b>	<b>117,460</b>	<b>126,959</b>	<b>143,283</b>

## 12. Financial instruments

### Method and assumption to determine fair value

The Group has financial instruments measured at fair value at level 1 and level 2.

#### Securities (level 1)

The portfolio of publicly traded government bonds and publicly traded mortgage bonds is valued at listed prices and price quotas.

#### Derivative financial instruments (level 2)

Currency forward contracts, currency option contracts and currency swap contracts are valued according to generally accepted valuation methods based on relevant observable swap curves and exchange rates.

### Fair value hierarchy for financial instruments measured at fair value

As of September 30, 2015

DKK thousand	Level 1	Level 2	Total
Securities	771,569	-	771,569
<b>Financial assets measured at fair value in the income statement</b>	<b>771,569</b>	<b>-</b>	<b>771,569</b>
Derivative financial instruments at fair value in the income statement (currency)	-	-	-
<b>Financial liabilities measured at fair value in the income statement</b>	<b>-</b>	<b>-</b>	<b>-</b>

As of December 31, 2014

DKK thousand	Level 1	Level 2	Total
Securities	581,350	-	581,350
<b>Financial assets measured at fair value in the income statement</b>	<b>581,350</b>	<b>-</b>	<b>581,350</b>
Derivative financial instruments at fair value in the income statement (currency)	-	(710)	(710)
<b>Financial liabilities measured at fair value in the income statement</b>	<b>-</b>	<b>(710)</b>	<b>(710)</b>

## 13. Incentive plans

Outstanding warrants as of September 30, 2015

	Outstanding as of January 1	Addition during the period	Options exercised	Annulled	Terminated	Trans- ferred	Outstanding as of Sep- tember 30
Board of Directors	65,000	-	(5,000)	-	-	-	60,000
CEO & President	130,000	-	(25,000)	-	-	-	105,000
Group Management	240,000	-	(25,000)	(60,000)	-	(60,000)	95,000
Other employees	1,028,550	-	(67,281)	(8,875)	-	(286,019)	666,375
Retired employees	255,171	-	(40,846)	-	(2,019)	346,019	558,325
<b>Total</b>	<b>1,718,721</b>	<b>-</b>	<b>(163,127)</b>	<b>(68,875)</b>	<b>(2,019)</b>	<b>-</b>	<b>1,484,700</b>
<b>Weighted average exercise price</b>	<b>90</b>	<b>-</b>	<b>109</b>	<b>104</b>	<b>194</b>	<b>-</b>	<b>87</b>
<b>Weighted average share price at exercise</b>	<b>-</b>	<b>-</b>	<b>334</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
Numbers of warrants which can be exercised as of September 30, 2015							80,500
at a weighted average exercise price of DKK							54

The total recognized cost of the warrant programs was DKK 7.9 million in the first nine months of 2015 (DKK 4.5 million).

#### Specification of parameters for Black-Scholes model

DKK	Aug 2011	May 2012	Aug 2012	Feb 2013	Aug 2013	Dec 2013	Aug 2014
Average share price	50.00	43.30	52.00	45.50	68.00	82.00	117.50
Average exercise price at grant	54.10	54.00	59.10	55.00	73.90	96.50	131.40
Average exercise price after rights issue <sup>1)</sup>	-	-	-	-	-	-	-
Expected volatility rate	73.4%	52.5%	50.0%	28.3%	36.4%	35.4%	39.7%
Expected life (years)	3.3	3.3	3.3	3.1	3.3	3.3	3.3
Expected dividend per share	-	-	-	-	-	-	-
Risk-free interest rate p.a.	1.08%	0.31%	-0.09%	0.22%	0.78%	0.74%	0.63%
Fair value at grant <sup>2)</sup>	24	13	16	6	16	17	29
Fair value after rights issue <sup>3)</sup>	-	-	-	-	-	-	-

The expected volatility is based on the historical volatility.

<sup>1)</sup> Determined at date of rights issue 27 May 2011

<sup>2)</sup> Fair value of each warrant at grant applying the Black-Scholes model

<sup>3)</sup> Fair value of each warrant at date of rights issue 27 May 2011 applying the Black-Scholes model

#### 14. Loan facility agreement of EUR 50 million entered with the European Investment Bank

In May 2015, Bavarian Nordic secured a loan facility of EUR 50 million from the European Investment Bank (EIB) in support of the Company's research and development of novel vaccines against Ebola and other infectious diseases as well as cancer immunotherapies. The loan facility, which is unsecured, is offered on favourable terms and may be utilized in one or more tranches.

Under the terms of the agreement, Bavarian Nordic will have up to 18 months to draw on these monies. The loan is a three to five year bullet loan and could potentially carry a fixed or variable interest payment. The margin associated with the loan facility is 3.26%.

#### 15. Significant changes in contingent liabilities and other contractual obligations

If and when Bristol-Myers Squibb exercises the option under the Option and License Agreement for PROSTVAC from March 2015, Bavarian Nordic will receive USD 80 million, and the National Cancer Institute (NCI) has a right to 10% of this payment, *i.e.* USD 8 million.

#### 16. Significant events after the balance sheet date

In October, Bavarian Nordic received an order valued at USD 6.4 million for 143,000 doses of IMVAMUNE from the Public Health Agency of Canada. See more on page 9.

## Appendix

Table 1

Overview of ongoing and completed contracts with the U.S. Government as of September 30, 2015.

USD million	P&L			Cash Flow	
	Contract value	Revenue recognized	To be recognized	Received	To be received
<b>IMVAMUNE RFP-3</b> Clinical development and registration of IMVAMUNE. Delivery of 28 million doses (2010-2015). Production of bulk vaccine (2016-2017)	911	763	148	763	148
<b>IMVAMUNE RFP-1 and RFP-2</b> Preclinical and early clinical development of IMVAMUNE	130	130	0	130	0
<b>IMVAMUNE Freeze-dried RFP</b> Development of freeze-dried IMVAMUNE	95	63	32	60	35
<b>MVA-BN Ebola/Marburg</b> Preclinical development	33	4	29	4	29
<b>MVA-BN Foot-and-mouth disease</b> Preclinical development	1	1	0	1	0
<b>MVA-BN Burkholderia</b> Preclinical development	1	1	0	1	0
<b>TOTAL</b>	<b>1,171</b>	<b>962</b>	<b>209</b>	<b>959</b>	<b>212</b>