# Interim Financial Report

for the Period January 1 to June 30, 2015

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# Management's Review

## Financial Statement for the Period January 1 – June 30, 2015

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

Revenue generated for the six months ending June 30, 2015 was DKK 624 million (DKK 450 million), which is in line with the Company's expectations. Revenue was primarily generated from the sale of MVA-BN Filo Bulk Drug Substance (BDS) to Janssen, DKK 501 million (DKK 0 million) and sale of the last 276 thousand doses of IMVAMUNE under the 8 million dose order from U.S. Government, DKK 49 million (DKK 382 million) and sale of IMVAMUNE to rest of world, DKK 28 million (DKK 4 million). Revenue reported for the three months ended June 30, 2015 was DKK 389 million (DKK 165 million).

The production costs totaled DKK 202 million (DKK 229 million). Costs related directly to revenue amounted to DKK 167 million (DKK 224 million). Other production costs totaled DKK 35 million (DKK 5 million). In the first six months of 2015 the scrap rates have been higher than the level realized in 2014, but still at a normal level for production of live vaccines. In the second quarter of 2015, production costs were DKK 110 million (DKK 85 million).

Research and development costs totaled DKK 219 million (DKK 192 million), see distribution in note 5. As part of the Company's growth strategy, research and development functions have been centralized and the divisional structure was merged earlier this year. As a result the organization headcount has been reduced by approx. 40 employees. The severance payments amount to DKK 12 million.

Distribution costs totaled DKK 27 million (DKK 23 million) and administrative costs totaled DKK 90 million (DKK 77 million). The increase in distribution costs is related to severance payments.

Financial items totaled a net income of DKK 63 million (DKK 6 million net income), DKK 69 million is related to exchange rate adjustments.

Income before tax was an income of DKK 148 million (loss of DKK 64 million).

Tax on income was an expense of DKK 41 million (income of DKK 10 million).

For the first six months of 2015, Bavarian Nordic reported a net income of DKK 107 million (net loss of DKK 54 million).

In the first quarter of 2015 management reassessed the accounting treatment of acquired licenses and it was decided to treat acquired licenses as a development project under current assets instead of an intangible asset. The carrying amount of acquired licenses as per December 31, 2014 (DKK 28 million) has been reclassified. For further description see note 1. In accordance with the license agreement with the National Cancer Institute (NCI) the Group has an obligation to pay 10% of the received upfront option payment from Bristol-Myers Squibb to NCI. This payment has been recognized as part of the development project.

Prepayments from customers have increased by DKK 253 million compared to December 31, 2014. The second upfront payment from Janssen of USD 35.8 million was received in January and the upfront option payment of USD 60 million from Bristol-Myers Squibb was received in March. In the first six months of 2015 DKK 365 million has been revenue recognized along with the deliveries to Janssen.

As of June 30, 2015 the Group's cash preparedness was DKK 1,669 million (DKK 423 million), including unutilized credit lines of DKK 384 million (DKK 120 million). Cash flow from operating activities was DKK 306 million (DKK -170 million). Cash flow from investment activities was DKK -231 million (DKK -61 million). Cash flow from financing activities was DKK 15 million (DKK -2 million) and relates to warrant exercise. The net change in cash and cash equivalents was DKK 90 million (DKK -232 million).

The Group's equity as of June 30, 2015 stood at DKK 1,349 million (DKK 925 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 (EIB).

Research and developments costs are expected to amount to approximately DKK 600 million, cf. table below.

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

**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 platforms, 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:

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

[1] National Institute of Allergy and Infectious Diseases, part of the U.S. National Institutes of Health (NIH).
[2] Biomedical Advanced Research and Development Authority, a division of the U.S. Department of Health and Human Services
[3] U.S. Department of Defense
[4] U.S. Department of Homeland Security
[5] National Cancer Institute, part of the U.S. National Institutes of Health (NIH).

## Our Short-term Objectives and Opportunities

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

- 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)
- 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® (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

## Product Pipeline

The clinical pipeline currently comprises nine 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 [1-4)] | Smallpox | BARDA | Approved |
| IMVAMUNE *freeze-dried* [1)] | 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 |
| CV-301 Bladder combination [1)] | Bladder Cancer | NCI | Phase 2 |
| MVA-BN Brachyury [1)] | Metastatic Tumors | NCI | Phase 1 |
| MVA-BN Filo + AdVac® [1)] | Filoviruses (Ebola/Marburg) | Janssen, NIH | Phase 2 |
| 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® and in Canada under the trade name IMVAMUNE®*
*4) Phase 3 registration studies are ongoing in the United States*

## PROSTVAC Prostate Cancer Immunotherapy Candidate

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[6] [7]
- 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[8]
- Synergy in combining PROSTVAC at various stages of the cancer progression with:
    - Radiation therapy in patients with localized disease[9]
    - Anti-androgen therapy (e.g. enzalutamide)[10]
    - Taxane-based chemotherapy (e.g. docetaxel) in androgen-independent prostate cancer[11]
    - Checkpoint inhibitors (e.g. ipilimumab) in patients with mCRPC[12]

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[8]. 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 global 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 study completed enrollment in December 2014. A total of 1,298 patients were enrolled at more than 200 investigative sites in 15 countries.

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.

[6] Gulley et al. Cancer Immunol Immunother. 2010;59:663.
[7] Kantoff et al. J Clin Oncol. 2010;28:1099.
[8] Gulley et al. Cancer Immunol Res. 2014;2:133.
[9] Gulley et al. Clin Cancer Res. 2005;11:3353
[10] Madan et al. Clin Cancer Res. 2008;14:4526.
[11] Arlen et al. Clin. Cancer Res. 2006;12:1260
[12] Madan et al. Lancet Oncol. 2012;13:501.

**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 up 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 Squib, potentially valued at up to nearly USD 1 billion. The agreement provides Bristol-Myers Squibb an exclusive option to license and commercialize PROSTVAC globally.

The agreement is a strong validation of Bavarian Nordic's cancer immunotherapy platform technology, which may benefit other current and future projects in the Company's pipeline.

*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*
As part of the agreement, the companies have also entered into an agreement by which they may conduct one or more exploratory combination studies of PROSTVAC and agents from Bristol-Myers Squibb's immuno-oncology portfolio. An investigator sponsored Phase 2 study is already in the planning stages to investigate the combination of PROSTVAC and a checkpoint inhibitor later this year.

**PROSTVAC and ipilimumab Combination Results Warrant Further Investigation**
In February, Bavarian Nordic announced updated overall survival data from an NCI sponsored Phase 1 combination study of PROSTVAC and ipilimumab.

30 patients with metastatic castration-resistant prostate cancer were enrolled in the study at a time where docetaxel was the only FDA-approved treatment that improved overall survival. The predicted median overall survival (OS) of the patients was 18.5 months. The range for median OS recorded in placebo arms from other Phase 2 and Phase 3 studies performed at the same time for men with mCRPC ranged from 12 to 22 months[13]. Patients were treated with PROSTVAC plus escalating doses of ipilimumab. The observed median OS was 31.3 months for all dose cohorts and 37.2 months for patients treated at 10 mg/kg based. Furthermore, approximately 20% of patients at 10 mg/kg were alive at 80 months.

These data provide a strong rationale to continue to evaluate the combination of PROSTVAC and checkpoint inhibitors in follow-on clinical studies.

**ASCO 2015 Annual Meeting**
Again this year, Bavarian Nordic participated in the American Society of Clinical Oncology's annual meeting in Chicago in May. Scientists from Bavarian Nordic held a poster presentation on preclinical studies conducted with the Company's cancer immunotherapies combined with PD-1 immune checkpoint inhibitors, demonstrating synergistic anti-tumor efficacy for this combination. Furthermore, collaborators from the National Cancer Institute held a trials-in-progress poster presentation on the ongoing Phase 3 study of PROSTVAC.

Abstracts of the presentations are available on ASCO's website:

- *Anti-tumor efficacy and PD-L1 expression in the tumor microenvironment after poxvirus-based active immunotherapy and PD-1 blockade*.
  http://abstracts.asco.org/156/AbstView_156_148122.html

- *Prospect: A randomized double-blind phase 3 efficacy study of PROSTVAC-VF immunotherapy in men with asymptomatic/minimally symptomatic metastatic castration-resistant prostate cancer*.
  http://abstracts.asco.org/156/AbstView_156_150300.html

Bavarian Nordic also held an event for investors and analysts, where the Company's management and collaborators from the National Cancer Institute gave an update on the clinical development of the Company's cancer immunotherapies and discussed the future treatment landscape. Presentations and a webcast from the event are available on the Company's website under "Investor & Media" -> "Events & Presentations".

## IMVAMUNE Smallpox Vaccine

*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 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 22).

[13] Higano et al., Genitourinary Cancers Symposium 2009.
Small et al., Genitourinary Cancers Symposium 2009.
Saad et al., J Natl Cancer Inst. 2002;94:1458.
Carducci et al., Cancer. 2007;110: 1959.
Sternberg et al., J. Clin Oncol. 2009;27:5431.
Petrylak et al., N Eng J Med. 2004;351:1513.
Tannock et al. N Engl J Med. 2004; 351:1502.
Higano CS et al., Cancer 2009;115: 3670.

**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 stockpiling of this next-generation of the vaccine in the SNS, and the transfer of the manufacturing process remains the final step towards meeting the overall requirements for stockpiling of the vaccine. The transfer is currently ongoing, funded under another contract with BARDA.

**Deliveries, Rest of World**
During the first quarter, Bavarian Nordic delivered 45,700 doses of IMVAMUNE to the Public Health Agency of Canada (PHAC), thus fulfilling the base contract awarded in 2014. PHAC has an option to acquire more than 300,000 doses. In addition, Bavarian Nordic has a contract with the Canadian Department of National Defence for 20,000 doses, which were delivered during second quarter.

A small recurrent order under a five-year contract with an Asian country was also delivered in second quarter.

**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, and a study in 440 military personnel which is designed to demonstrate non-inferiority between IMVAMUNE and ACAM2000®, the current U.S. licensed smallpox vaccine.

In May, the Company reported results from the first Phase 3 study, which was designed as a randomized, double-blind, placebo-controlled study in 4,000 vaccinia-naïve subjects. Three thousand (3,000) subjects were vaccinated with three different manufacturing lots of the liquid-frozen IMVAMUNE formulation (1,000 subjects per lot) and compared to 1,000 subjects that received placebo. The three lots of IMVAMUNE induced equivalent antibody responses, meeting the primary endpoint of the study, while the favorable safety profile of IMVAMUNE was confirmed in this largest clinical study performed to date. Despite close cardiac monitoring of all subjects, no serious adverse reactions were reported among the 3,000 subjects vaccinated with IMVAMUNE, confirming the results of a smaller Phase 2 placebo controlled study that was recently published and clearly differentiates the safety profile of IMVAMUNE when compared to traditional smallpox vaccines (e.g. ACAM2000) that have recorded high rates of cardiac complications in healthy vaccinees (5.73 events per thousand immunizations[14]).

[14] ACAM2000 Vaccines and Related Biological Products Advisory Committee (VRBPAC) Briefing Document, April 2007 http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4292B2-00-index.htm

The 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 2016.

## Janssen Collaboration

Bavarian Nordic and Janssen entered into a partnership in 2014 in order to accelerate the development and production of a new Ebola prime-boost vaccine regimen, consisting of Bavarian Nordic's MVA-BN Filo and Janssen's Ad26.ZEBOV vaccine.

This vaccine regimen was proven efficacious in a study conducted under NIAID's preclinical services program. 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.

Bavarian Nordic has been developing MVA-BN Filo since 2010, where a collaboration agreement was entered with NIAID. The aim was to advance Bavarian Nordic's MVA-BN technology to develop a multivalent vaccine against filoviruses (Ebola, Sudan and Marburg), for which no approved treatment or vaccine exists. For more information, see section "Additional Government Programs".

Janssen has licensed MVA-BN Filo for use in a prime-boost regimen, which targets the Ebola virus, responsible for the epidemic in Western Africa that has raged since late 2013. In addition, Janssen has ordered for 2 million of doses of the vaccine (anticipated yield based on an agreed number of production batches).

As of June 30, 2015, vaccine equivalent to approximately 1.3 million doses has been delivered to Janssen.

The overall value of the license and supply agreement with Janssen, including an equity investment of USD 43 million in Bavarian Nordic, was USD 187 million, excluding future potential royalties for commercial sales outside GAVI countries[15].

**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. A Phase 1 first in human trial of the vaccine regimen was initiated in the United Kingdom in January 2015 followed by additional Phase 1 trials in the USA and Africa.

Preliminary results from the first Phase 1 study were presented in May by Janssen at a meeting of the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee as part of discussions on the development and licensure of Ebola vaccines.

In the study, conducted by the Oxford Vaccines Group, 72 healthy volunteers were randomized into four groups receiving the vaccine regimen or placebo. A priming dose of either Ad26.ZEBOV or MVA-BN Filo was administered at day 1 and booster doses of the other vaccine were administered after 28 or 56 days. An open label arm with 15 healthy volunteers is also investigating a shorter prime-boost interval of 14 days for Ad26.ZEBOV prime and MVA-BN Filo boost.

Preliminary data from this ongoing study confirm the preclinical results previously reported, and show that the prime-boost vaccine regimen was immunogenic, regardless of the order of vaccine administration, and that both vaccines only provoked temporary reactions normally expected from vaccination. Immune responses post boost appeared to be well balanced with the induction of humoral and cellular immune response components, the latter being comprised of highly polyfunctional CD8+ and CD4+ T cell responses.

A multicenter Phase 2 clinical study was initiated in July. The study will evaluate the safety, tolerability and immunogenicity of the vaccine regimen. Also led by the Oxford Vaccines Group, the study will enroll 612 healthy adult volunteers in the United Kingdom and France, who will be randomized into three cohorts, all receiving the Ad26.ZEBOV prime or placebo on day 1 and then the MVA-BN Filo boost or placebo on days 29, 57 or 85.

[15] Countries with a Gross Net Income (GNI) per capita below or equal to USD 1,580 are eligible to receive support from GAVI – The Vaccine Alliance – a public/private organization providing access to vaccines to developing countries. Currently, 53 countries are eligible according to GAVI's website: http://www.gavi.org

A second Phase 2 study in 1,200 subjects is planned to be initiated in Africa during third quarter of 2015.

**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.

## Commercial Vaccines

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 and CV-301 in non-small cell lung cancer.

**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. The study, which is being conducted in USA, will evaluate the safety, tolerability and immunogenicity of a recombinant MVA-BN-based RSV vaccine in 63 healthy adults, ages 18-65. Subjects will be enrolled into three groups to receive different doses of MVA-BN RSV. One group will enroll subjects of 50-65 years of age who will receive the 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. Volunteers in each group will be randomized to receive two vaccinations of MVA-BN RSV vaccine or placebo.

Additional Phase 1 and Phase 2 studies are planned for initiation in 2016 to further advance the development of this vaccine candidate as well as to investigate the vaccine in risk groups, such as elderly and children.

**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 lung, bladder, head & neck and colorectal cancer. CV-301 and its precursors have been tested in 16 ongoing or completed NCI-sponsored clinical studies in various cancers, and more than 400 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 ever more important role in the rapidly changing cancer treatment paradigm. 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. In lung cancer 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 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 with an Immune checkpoint inhibitor.

In light of these developments, Bavarian Nordic's strategy for the development of CV-301 will focus on the combinatorial use of CV-301 with immune checkpoint inhibitors. While the Company has rights to multiple indications for CV-301, the initial target will be non-small cell lung cancer (NSCLC), which is often advanced and difficult to treat.

*CV-301 in non-small cell lung cancer*
Lung cancer is the second most common cancer and is by far the leading cause of cancer death. Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined. About 85% of lung cancers are non-small cell lung cancer (NSCLC) which has different subtypes (squamous cell carcinoma, adenocarcinoma, and large cell carcinoma). Analysts estimate that the global market for NSCLC treatments will increase from US$ 5 billion in 2013 to almost US$ 8 billion by 2020[16].

About 70% of NSCLC patients are reported to have low or negative PD-L1 expression, which is often correlated to a lesser response to checkpoint inhibition. This presents a significant opportunity to deploy optimized combination immunotherapy regimens for broader treatment efficacy.

With this strong rationale for combining active immunotherapy with immune checkpoint inhibitors, Bavarian Nordic has selected NSCLC as the primary indication 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. Regulatory discussions will take place in 2015, where also trial material will be manufactured to support a clinical Phase 1 study in 2016.

## Additional Government Programs

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.

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.

[16] GBI Research (www.gbiresearch.com)

An NCI-sponsored, open label Phase 1 study of MVA-BN Brachyury in patients with advanced cancer is ongoing. The study has reached its enrollment target of 38 patients receiving 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.

**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

**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). Prior to joining Aptalis, he held the position of Vice President, Hypertension, Worldwide Human Health Marketing, with Merck & Co., Inc., while concurrently serving as a member of Merck's worldwide hypertension business strategy team. He joined Merck in 1996 and was appointed managing director of MSD in the Netherlands in 1997. Prior to joining Merck, from 1988 to 1996, Dr. Verwiel held a number of executive positions with Laboratoires Servier in the EU. 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.

**Loan Facility Agreement of EUR 50 Million Entered with the European Investment Bank**
In May, 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 favorable 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%.

**Capital Increase as Result of Warrant Exercise**
In May, the Company's share capital was increased by nominally DKK 800,000 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 DKK 54.10 per share. The total proceeds to Bavarian Nordic A/S from the capital increase amounted to DKK 4.3 million. Subsequently, Bavarian Nordic A/S' share capital amounts to DKK 278,119,930.

**Changes in 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 in the Company due to personal reasons, effective July 31, 2015. Dr. Breitmeyer served as Executive Vice President of Bavarian Nordic A/S and as a member of its Executive Management since February 2013.

# 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 June 30, 2015.

The interim report has been prepared in accordance with IAS 34 "Presentation of interim reports" 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 June 30, 2015 and the results of the group's activities and cash flows for the period January 1 to June 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, August 25, 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

## Group Key Figures

| DKK million | 1/4 - 30/6 2015 | 1/4 - 30/6 2014 | 1/1 - 30/6 2015 | 1/1 - 30/6 2014 | 1/1-31/12 2014 |
|---|---|---|---|---|---|
| | *un-audited* | *un-audited* | *un-audited* | *un-audited* | *audited* |
| **Income statements** | | | | | |
| Revenue | 389.1 | 164.5 | 623.9 | 450.4 | 1,216.8 |
| Production costs | 110.0 | 84.6 | 202.1 | 229.0 | 495.1 |
| Research and development costs | 100.6 | 102.3 | 219.2 | 191.6 | 478.9 |
| Distribution costs | 10.0 | 11.9 | 27.4 | 22.7 | 45.1 |
| Administrative costs | 43.5 | 38.8 | 90.4 | 76.8 | 181.0 |
| Income before interest and taxes (EBIT) | 125.0 | (73.1) | 84.8 | (69.7) | 16.7 |
| Financial items, net | (40.5) | 5.2 | 62.7 | 5.9 | 47.7 |
| Income before company tax | 84.5 | (67.9) | 147.5 | (63.8) | 64.4 |
| Net profit for the period | 61.3 | (54.9) | 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)** [1)] | | | | | |
| 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 [2)] | | | 6.4 | 3.7 | 4.4 |
| Number of outstanding shares at period-end | | | 27,812 | 26,113 | 27,671 |
| Equity share | | | 61% | 74% | 66% |
| Number of employees, converted to full-time, at 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 have been recalculated based on outstanding shares end Q2 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. Inventories
7. Other receivables
8. Other liabilities
9. Financial instruments
10. Related party transactions
11. Incentive plans

## Income Statement

| DKK million | Note | 1/4 - 30/6 2015 | 1/4 - 30/6 2014 | 1/1 - 30/6 2015 | 1/1 - 30/6 2014 | 1/1-31/12 2014 |
|---|---|---|---|---|---|---|
| | | *un-audited* | *un-audited* | *un-audited* | *un-audited* | *audited* |
| Revenue | 3 | 389.1 | 164.5 | 623.9 | 450.4 | 1,216.8 |
| Production costs | 4 | 110.0 | 84.6 | 202.1 | 229.0 | 495.1 |
| **Gross profit** | | **279.1** | **79.9** | **421.8** | **221.4** | **721.7** |
| Research and development costs | 5 | 100.6 | 102.3 | 219.2 | 191.6 | 478.9 |
| Distribution costs | | 10.0 | 11.9 | 27.4 | 22.7 | 45.1 |
| Administrative costs | | 43.5 | 38.8 | 90.4 | 76.8 | 181.0 |
| **Total operating costs** | | **154.1** | **153.0** | **337.0** | **291.1** | **705.0** |
| **Income before interest and tax (EBIT)** | | **125.0** | **(73.1)** | **84.8** | **(69.7)** | **16.7** |
| Financial income | | (35.0) | 6.3 | 68.6 | 8.0 | 57.4 |
| Financial expenses | | 5.5 | 1.1 | 5.9 | 2.1 | 9.7 |
| **Income before company tax** | | **84.5** | **(67.9)** | **147.5** | **(63.8)** | **64.4** |
| Tax on income for the period | | 23.2 | (13.0) | 40.8 | (10.1) | 38.5 |
| **Net profit for the period** | | **61.3** | **(54.9)** | **106.7** | **(53.7)** | **25.9** |
| **Earnings per share (EPS) - DKK** | | | | | | |
| Basic earnings per share of DKK 10 | | 2.2 | (2.1) | 3.8 | (2.1) | 1.0 |
| Diluted earnings per share of DKK 10 | | 2.2 | (2.1) | 3.8 | (2.1) | 1.0 |

## Statement of comprehensive income

| DKK million | 1/4 - 30/6 2015 | 1/4 - 30/6 2014 | 1/1 - 30/6 2015 | 1/1 - 30/6 2014 | 1/1-31/12 2014 |
|---|---|---|---|---|---|
| | *un-audited* | *un-audited* | *un-audited* | *un-audited* | *audited* |
| **Net profit for the period** | **61.3** | **(54.9)** | **106.7** | **(53.7)** | **25.9** |
| **Items that might be reclassified to the income statement:** | | | | | |
| Exchange rate adjustments, investments in subsidiaries | 11.5 | (2.6) | (32.6) | (2.6) | (41.5) |
| **Other comprehensive income after tax** | **11.5** | **(2.6)** | **(32.6)** | **(2.6)** | **(41.5)** |
| **Total comprehensive income** | **72.8** | **(57.5)** | **74.1** | **(56.3)** | **(15.6)** |

## Statement of financial position

| DKK million | Note | 30/6 2015 | 30/6 2014 | 31/12 2014 |
|---|---|---|---|---|
| | | *un-audited* | *un-audited* | *audited* |
| **Assets** | | | | |
| Acquired patents and licenses | | - | 23.2 | 24.7 |
| Software | | 4.1 | 4.1 | 4.8 |
| IMVAMUNE development project | | 88.2 | 87.0 | 78.4 |
| Intangible assets in progress | | 2.4 | 1.0 | 1.3 |
| **Intangible assets** | | **94.7** | **115.3** | **109.2** |
| Land and buildings | | 220.6 | 174.2 | 226.2 |
| Leasehold improvements | | 0.8 | 1.0 | 0.9 |
| Plant and machinery | | 61.8 | 73.2 | 64.6 |
| Fixtures and fittings, other plant and equipment | | 18.6 | 22.6 | 20.9 |
| Assets under construction | | 21.3 | 60.2 | 24.0 |
| **Property, plant and equipment** | | **323.1** | **331.2** | **336.6** |
| Other receivables | | 0.8 | 0.8 | 0.8 |
| **Financial assets** | | **0.8** | **0.8** | **0.8** |
| **Deferred tax assets** | | **99.4** | **134.8** | **121.5** |
| **Total non-current assets** | | **518.0** | **582.1** | **568.1** |
| **Development projects** | | **66.9** | **-** | **-** |
| **Inventories** | 6 | **140.5** | **236.3** | **121.8** |
| Trade receivables | | 183.3 | 105.8 | 186.8 |
| Tax receivables | | 3.1 | 2.6 | 4.9 |
| Other receivables | 7 | 11.1 | 8.6 | 14.5 |
| Prepayments | | 12.7 | 17.3 | 11.5 |
| **Receivables** | | **210.2** | **134.3** | **217.7** |
| Securities | | 779.8 | 187.9 | 581.3 |
| Cash and cash equivalents | | 505.2 | 114.6 | 398.4 |
| **Securites, cash and cash equivalents** | | **1,285.0** | **302.5** | **979.7** |
| **Total current assets** | | **1,702.6** | **673.1** | **1,319.2** |
| **Total assets** | | **2,220.6** | **1,255.2** | **1,887.3** |

## Statement of financial position

| DKK million | Note | 30/6 2015 | 30/6 2014 | 31/12 2014 |
|---|---|---|---|---|
| | | *un-audited* | *un-audited* | *audited* |
| **Equity and liabilities** | | | | |
| Share capital | | 278.1 | 261.1 | 276.7 |
| Retained earnings | | 1,099.6 | 620.1 | 972.3 |
| Other reserves | | (28.9) | 43.8 | 3.1 |
| **Equity** | | **1,348.8** | **925.0** | **1,252.1** |
| Provisions | | 18.6 | 14.8 | 18.6 |
| Credit institutions | | 32.3 | 67.9 | 33.3 |
| **Non-current liabilities** | | **50.9** | **82.7** | **51.9** |
| Credit institutions | | 1.9 | 8.5 | 1.9 |
| Prepayment from customers | | 628.3 | 27.6 | 375.2 |
| Trade payables | | 47.2 | 87.4 | 58.7 |
| Provisions | | 4.2 | 2.3 | 4.2 |
| Other liabilities | 8 | 139.3 | 121.7 | 143.3 |
| **Current liabilities** | | **820.9** | **247.5** | **583.3** |
| **Total liabilities** | | **871.8** | **330.2** | **635.2** |
| **Total equity and liabilities** | | **2,220.6** | **1,255.2** | **1,887.3** |

## Statement of cash flow

| DKK million | 1/1 - 30/6 2015 | 1/1 - 30/6 2014 | 1/1-31/12 2014 |
|---|---|---|---|
| | *un-audited* | *un-audited* | *audited* |
| **Income before interest and tax (EBIT)** | **84.8** | **(69.7)** | **16.7** |
| Depreciation, amortization and impairment losses | 21.8 | 22.3 | 44.9 |
| Expensing (amortization) of IMVAMUNE development project | 2.7 | 17.6 | 45.5 |
| Share-based payment | 15.7 | 7.0 | 21.3 |
| Adjustment for other non-cash items | - | (0.1) | - |
| Changes in inventories | (18.7) | (2.7) | 111.8 |
| Changes in receivables | 229.4 | 0.7 | (78.3) |
| Changes in provisions | - | 0.1 | 3.6 |
| Changes in current liabilities | (37.7) | (144.1) | 180.4 |
| **Cash flow from operations (operating activities)** | **298.0** | **(168.9)** | **345.9** |
| Received financial income | 25.7 | 4.4 | 19.4 |
| Paid financial expenses | (1.5) | (2.1) | (4.2) |
| Paid corporation taxes | (15.9) | (2.9) | (22.3) |
| **Cash flow from operating activities** | **306.3** | **(169.5)** | **338.8** |
| Investments in and additions to intangible assets | (14.2) | (31.0) | (53.6) |
| Investments in property, plant and equipment | (6.7) | (27.8) | (52.4) |
| Disposal of property, plant and equipment | - | - | 0.1 |
| Investments in/disposal of securities | (210.1) | (1.8) | (397.8) |
| **Cash flow from investment activities** | **(231.0)** | **(60.6)** | **(503.7)** |
| Payment on mortgage and construction loan | (0.9) | (4.2) | (49.0) |
| Proceeds from warrant programs exercised | 16.0 | 2.1 | 14.4 |
| Proceeds from direct placement | - | - | 251.0 |
| Cost related to issue of new shares | - | - | (0.1) |
| **Cash flow from financing activities** | **15.1** | **(2.1)** | **216.3** |
| **Cash flow of the period** | **90.4** | **(232.2)** | **51.4** |
| Cash as of 1 January | 398.4 | 346.8 | 346.8 |
| Currency adjustments 1 January | 16.4 | - | 0.2 |
| **Cash end of period** | **505.2** | **114.6** | **398.4** |
| Securities - highly liquid bonds | 779.8 | 187.9 | 581.3 |
| Credit lines | 384.0 | 120.0 | 20.0 |
| **Cash preparedness** | **1,669.0** | **422.5** | **999.7** |

## Statement of changes in equity - Group

| DKK million | Share capital | Retained earnings | Reserves for currency adjustment | Share-based payment | Equity |
|---|---|---|---|---|---|
| **Equity as of January 1, 2015** | **276.7** | **972.3** | **(35.2)** | **38.3** | **1,252.1** |
| **Comprehensive income for the period** | | | | | |
| Net profit | - | 106.7 | - | - | 106.7 |
| **Other comprehensive income** | | | | | |
| Exchange rate adjustments, investments in subsidiaries | - | - | (32.6) | - | (32.6) |
| **Total comprehensive income for the period** | **-** | **106.7** | **(32.6)** | **-** | **74.1** |
| **Transactions with owners** | | | | | |
| Share-based payment | - | - | - | 6.6 | 6.6 |
| Warrant program exercised | 1.4 | 20.6 | - | (6.0) | 16.0 |
| **Total transactions with owners** | **1.4** | **20.6** | **-** | **0.6** | **22.6** |
| **Equity as of June 30, 2015** | **278.1** | **1,099.6** | **(67.8)** | **38.9** | **1,348.8** |

| DKK million | Share capital | Retained earnings | Reserves for currency adjustment | Share-based payment | Equity |
|---|---|---|---|---|---|
| **Equity as of January 1, 2014** | **260.9** | **652.0** | **6.4** | **57.0** | **976.3** |
| **Comprehensive income for the period** | | | | | |
| Net profit | - | (53.7) | - | - | (53.7) |
| **Other comprehensive income** | | | | | |
| Exchange rate adjustments, investments in subsidiaries | - | - | (2.6) | - | (2.6) |
| **Total comprehensive income for the period** | **-** | **(53.7)** | **(2.6)** | **-** | **(56.3)** |
| **Transactions with owners** | | | | | |
| Share-based payment | - | - | - | 2.9 | 2.9 |
| Warrant program exercised | 0.2 | 2.9 | - | (1.0) | 2.1 |
| Warrant program expired | - | 18.9 | - | (18.9) | - |
| **Total transactions with owners** | **0.2** | **21.8** | **-** | **(17.0)** | **5.0** |
| **Equity as of June 30, 2014** | **261.1** | **620.1** | **3.8** | **40.0** | **925.0** |

**1. Accounting policies**

The interim report is prepared in accordance with IAS 34, Presentation of interim reports, as adopted by EU and the additional Danish requirements for submission of interim reports for companies listed on Nasdaq Copenhagen.

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

**Segment reporting**
In March it was decided to merge the divisional structure hence the Group will no longer prepare segment reporting.

**Acquired licenses**
In the first quarter of 2015 management reassessed the accounting treatment of acquired licenses. As part of the Company's business model 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 transferred to the partner. Previously acquired licenses 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. Based on the latest development management has assessed that currently the correct accounting treatment is to recognize the acquired licenses as a development project under current assets. Therefore the carrying amount of the acquired licenses as per December 31, 2014 (DKK 28 million) has been reclassified. The comparative figures for 2014 have not been restated as the change relates to accounting estimates.

Except for the addition concerning development projects the accounting policies used in the interim report are consistent with those used in the Annual Report 2014 and in accordance with the recognition and measurement policies in the International Financial Reporting Standards (IFRS) as adopted by the EU and additional Danish disclosure requirements for the annual reports of listed companies. We refer to the Annual Report 2014 for further description of the accounting policies, including the definitions of financial ratios, calculated in accordance with "Anbefalinger og Nøgletal 2015" (Recommendations and Financial ratios 2015).

**Accounting policy for "Development projects"**
Development projects consist of licenses that have been acquired with the intent to further develop of 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 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.

**2. Significant accounting estimates, assumptions and uncertainties**

In the preparation of the interim report according to generally accepted accounting principles, 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 significant accounting estimates, assumptions and uncertainties which are stated in the Annual Report 2014, the Management has not performed significant estimates and judgments regarding recognition and measurement.

| DKK million | 1/4 - 30/6 2015 | 1/4 - 30/6 2014 | 1/1 - 30/6 2015 | 1/1 - 30/6 2014 | 1/1-31/12 2014 |
|---|---|---|---|---|---|
| | *un-audited* | *un-audited* | *un-audited* | *un-audited* | *audited* |
| **3. Revenue** | | | | | |
| IMVAMUNE sale | 12.5 | 131.9 | 77.4 | 386.0 | 1,024.2 |
| Other product sale | 357.0 | - | 501.3 | - | - |
| Sale of goods | 369.5 | 131.9 | 578.7 | 386.0 | 1,024.2 |
| Contract work | 19.6 | 32.6 | 45.2 | 64.4 | 192.6 |
| Sale of services | 19.6 | 32.6 | 45.2 | 64.4 | 192.6 |
| **Revenue** | **389.1** | **164.5** | **623.9** | **450.4** | **1,216.8** |
| **4. Production costs** | | | | | |
| Cost of goods sold, IMVAMUNE sale | 1.5 | 63.1 | 20.5 | 192.6 | 411.1 |
| Cost of goods sold, other product sale | 73.9 | - | 119.3 | - | - |
| Contract costs | 17.4 | 16.5 | 27.7 | 31.2 | 91.7 |
| Other production costs | 17.2 | 5.0 | 34.6 | 5.2 | (7.7) |
| **Production costs** | **110.0** | **84.6** | **202.1** | **229.0** | **495.1** |
| **5. Research and development costs** | | | | | |
| Research and development costs occured in the period | 123.2 | 122.4 | 256.8 | 232.8 | 572.0 |
| Of which: | | | | | |
| Contract costs recognized as production costs | (17.4) | (16.5) | (27.7) | (31.2) | (91.7) |
| Capitalized development costs | (5.4) | (9.5) | (12.6) | (27.6) | (46.9) |
| | 100.4 | 96.4 | 216.5 | 174.0 | 433.4 |
| Expensing (amortization) of prior-year costs attributable to the IMVAMUNE development project | 0.2 | 5.9 | 2.7 | 17.6 | 45.5 |
| **Research and development costs** | **100.6** | **102.3** | **219.2** | **191.6** | **478.9** |

| DKK million | 30/6 2015 | 30/6 2014 | 31/12 2014 |
|---|---|---|---|
| | *un-audited* | *un-audited* | *audited* |
| **6. Inventories** | | | |
| Raw materials and supply materials | 27.4 | 12.8 | 21.7 |
| Work in progress | 158.2 | 255.9 | 115.3 |
| Manufactured goods and commodities | 9.0 | 35.5 | 30.7 |
| Write-down on inventory | (54.1) | (67.9) | (45.9) |
| **Inventories** | **140.5** | **236.3** | **121.8** |
| Write-down on inventory 1 January | (45.9) | (68.5) | (68.5) |
| Write-down during the period | (8.2) | (11.5) | (0.5) |
| Use of write-down | - | - | 11.0 |
| Reversal of write-down | - | 12.1 | 12.1 |
| **Write-down end of period** | **(54.1)** | **(67.9)** | **(45.9)** |

| DKK million | 30/6 2015 | 30/6 2014 | 31/12 2014 |
|---|---|---|---|
| | *un-audited* | *un-audited* | *audited* |
| **7. Other receivables** | | | |
| Receivable VAT and duties | 3.6 | 4.2 | 5.9 |
| Financial instruments at fair value | 1.3 | 1.0 | - |
| Accrued interest | 6.2 | 2.3 | 8.4 |
| Other receivables | - | 1.1 | 0.2 |
| **Other receivables** | **11.1** | **8.6** | **14.5** |
| | | | |
| **8. Other liabilities** | | | |
| Financial instruments at fair value | - | - | 0.7 |
| Liability relating to phantom shares | 12.1 | 6.8 | 17.2 |
| Payable salaries, holiday accrual etc. | 61.5 | 53.2 | 61.9 |
| Other accrued costs | 65.7 | 61.7 | 63.5 |
| **Other liabilities** | **139.3** | **121.7** | **143.3** |

**9. 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 June 30, 2015 (un-audited)**

| DKK million | Level 1 | Level 2 | Total |
|---|---|---|---|
| Securities | 779.8 | - | 779.8 |
| **Financial assets measured at fair value in the income statement** | **779.8** | **-** | **779.8** |
| Derivative financial instruments at fair value in the income statement (currency) | - | 1.3 | 1.3 |
| **Financial liabilities measured at fair value in the income statement** | **-** | **1.3** | **1.3** |

**As of December 31, 2014 (audited)**

| DKK million | Level 1 | Level 2 | Total |
|---|---|---|---|
| Securities | 581.3 | - | 581.3 |
| **Financial assets measured at fair value in the income statement** | **581.3** | **-** | **581.3** |
| Derivative financial instruments at fair value in the income statement (currency) | - | (0.7) | (0.7) |
| **Financial liabilities measured at fair value in the income statement** | **-** | **(0.7)** | **(0.7)** |

**10. Related party transactions**

The nature and extent of transactions with related parties remain unchanged from last year. Reference is made to the description in the Annual Report 2014.

**11. Incentive plans**

**Outstanding warrants as of June 30, 2015**

| | Outstanding as of January 1 | Addition during the period | Options exercised | Annulled | Terminated | Trans-ferred | Outstanding as of June 30 |
|---|---|---|---|---|---|---|---|
| Board of Directors | 65.000 | - | (5.000) | - | - | - | 60.000 |
| CEO & President | 130.000 | - | (25.000) | - | - | - | 105.000 |
| Group Management | 240.000 | - | (25.000) | - | - | - | 215.000 |
| Other employees | 1.028.550 | - | (61.400) | (8.875) | - | (274.169) | 684.106 |
| Retired employees | 255.171 | - | (24.346) | - | - | 274.169 | 504.994 |
| **Total** | **1.718.721** | **-** | **(140.746)** | **(8.875)** | **-** | **-** | **1.569.100** |
| **Weighted average exercise price** | **90** | **-** | **114** | **-** | **-** | **-** | **115** |
| **Weighted average share price at exercise** | **-** | **-** | **340** | **-** | **-** | **-** | **-** |

| | |
|---|---|
| Numbers of warrants which can be exercised as of June 30, 2015 | 56.400 |
| at a weighted average exercise price of DKK | 69 |

The total recognized cost of the warrant programs was DKK 6.6 million in the first six months of 2015 (DKK 2.9 million).

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

| DKK | Dec 2010 | Aug 2011 | May 2012 | Aug 2012 | Feb 2013 | Aug 2013 | Dec 2013 | Aug 2014 |
|---|---|---|---|---|---|---|---|---|
| Average share price | 238.00 | 50.00 | 43.30 | 52.00 | 45.50 | 68.00 | 82.00 | 117.50 |
| Average exercise price at grant | 261.00 | 54.10 | 54.00 | 59.10 | 55.00 | 73.90 | 96.50 | 131.40 |
| Average exercise price after rights issue [1)] | 194.00 | - | - | - | - | - | - | - |
| Expected volatility rate | 49.5% | 73.4% | 52.5% | 50.0% | 28.3% | 36.4% | 35.4% | 39.7% |
| Expected life (years) | 3.0 | 3.3 | 3.3 | 3.3 | 3.1 | 3.3 | 3.3 | 3.3 |
| Expected dividend per share | - | - | - | - | - | - | - | - |
| Risk-free interest rate p.a. | 1.63% | 1.08% | 0.31% | -0.09% | 0.22% | 0.78% | 0.74% | 0.63% |
| Fair value at grant [2)] | 78 | 24 | 13 | 16 | 6 | 16 | 17 | 29 |
| Fair value after rights issue [3)] | 23 | - | - | - | - | - | - | - |

The expected volatility is based on the historical volatility (over 12 months).

[1)] Determined at date of rights issue 27 May 2011

[2)] Fair value of each warrant at grant applying the Black-Scholes model

[3)] Fair value of each warrant at date of rights issue 27 May 2011 applying the Black-Scholes model

# Appendix

*Table 1*
*Overview of ongoing and completed contracts with the U.S. Government as of June 30, 2015. The IMVAMUNE RFP-3 contract includes an expansion of USD 133 million awarded by BARDA in July 2015. Revenue from this contract will be recognized in 2016 and into 2017.*

| USD million | | P&L | | Cash Flow | |
|---|---|---|---|---|---|
| | Contract value | Revenue recognized | To be recognized | Received | To be received |
| **IMVAMUNE RFP-3**<br>Clinical development and registration of IMVAMUNE. Delivery of 28 million doses (2010-2015). Production of bulk vaccine (2016-2017) | **911** | 763 | 148 | 763 | 148 |
| **IMVAMUNE RFP-1 and RFP-2**<br>Preclinical and early clinical development of IMVAMUNE | **130** | 130 | 0 | 130 | 0 |
| **IMVAMUNE Freeze-dried RFP**<br>Development of freeze-dried IMVAMUNE | **95** | 56 | 39 | 55 | 40 |
| **MVA-BN Ebola/Marburg**<br>Preclinical development | **33** | 4 | 29 | 4 | 29 |
| **MVA-BN Foot-and-mouth disease**<br>Preclinical development | **1** | 1 | 0 | 1 | 0 |
| **MVA-BN Burkholderia**<br>Preclinical development | **1** | 1 | 0 | 1 | 0 |
| **TOTAL** | **1,171** | **955** | **216** | **954** | **217** |