# Interim Results as of 30 September 2009

11 November 2009

Anders Hedegaard

President and CEO



### **IMVAMUNE®**

- Responses to the FDA in progress and delivery allowance expected before end of Q2, 2010
- Ongoing RFP negotiations for freeze-dried IMVAMUNE®
- Contract with EU country
- Canada order delivered licensing being discussed

### **PROSTVAC™**

- Further validated throughout 2009 (ASCO, ECCO)
- Broader usage indicated
- Phase III preparations on track



## Acquisition of BNIT shares

- Bavarian Nordic acquires remaining shares and buys back stock options in BN ImmunoTherapeutics Inc.
  - Obtain full ownership of the subsidiary
  - Full control over cancer activities
- Strengthens negotiation position with regard to the out-licensing and continued development of PROSTVAC™



# Biodefence

• IMVAMUNE®



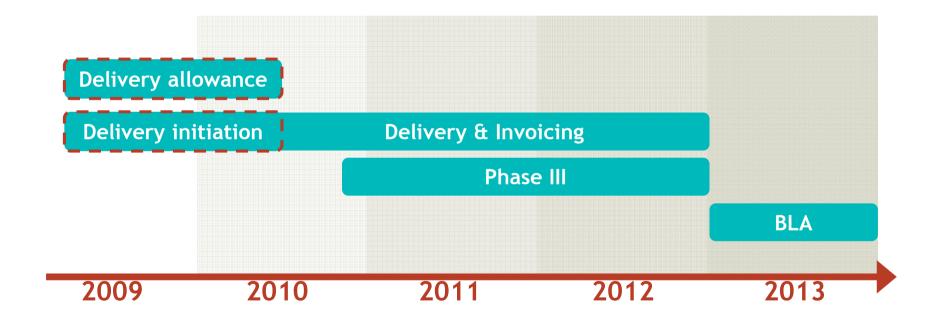
### IMVAMUNE® deliveries under RFP-3

- FDA performed a GMP inspection in Kvistgård and IDT in May 2009
- No concerns re. facilities or the validated manufacturing process
- Some observations were noted, requiring corrective actions
- Implementation of corrective actions ongoing
- Submission of responses nearly completed
- No further investments required
- Deliveries expected to be initiated before the end of Q2/10



## RFP-3 - Outlook

Delayed initiation of delivery, but overall schedule maintained





# IMVAMUNE® - advancing the product

- New BARDA RFP for freeze-dried IMVAMUNE®
- BN submitted its proposal in June
- Currently in late-stage negotiations
- Potential cost-plus contract includes:
  - Validation of production process
  - Preclinical and clinical development to support emergency use
- Freeze-dried IMVAMUNE® advantages:
  - Improved stability and shelf-life
  - Favourable logistics and storage
  - Applicable for other MVA-based vaccines



## IMVAMUNE® - non-US markets

### First contract with an EU country

• In September, Bavarian Nordic signed a contract with the military of an undisclosed EU country for the delivery of a small order for IMVAMUNE®. The vaccines have been delivered.

### Canada - delivery completed, license discussions initiated

- 20,000 doses of IMVAMUNE® delivered as planned
- Pre-New Drug Submission meeting with Health Canada was held in October 2009 to discuss the potential to file an NDS in 2010 for IMVAMUNE® as a safer smallpox vaccine under a Notice of Compliance with Conditions. Conclusions from the meeting have not yet been finalised.



## Cancer

### PROSTVAC™:

- extended median overall survival of 8.5 months
- reduced the risk of death by 44%
- is an off-the-shelf vial vaccine that does not require individualised therapy
- has a very favourable safety and tolerability profile
- also holds the promise of moving into earlier stages of the disease



# PROSTVAC™ - further data presented

### **GU-ASCO** (*Feb-2009*)

- Data from three different studies presented
- Indication that PROSTVAC™ can be used in earlier disease settings

### **ASCO Annual Meeting (May-2009)**

- Headline data confirmed (8.5 months improved survival)
- Improved statistical significance in the final data set (p=0.006)

### **ECCO** (Sep-2009)

Broader therapeutic use in metastatic prostate cancer indicated



# PROSTVAC™ - highlights

- End of phase II meeting with the FDA expected in January 2010
- SPA with FDA, Q1 2010
- Preparing the production for Phase III studies
- Phase III initiation expected in late 2010
- Five ongoing clinical Phase I and II studies (different populations)
- Scientific publication of data
- Ongoing discussions with prospective licensing partners



# Cancer strategy considerations

#### Prostate cancer market

- Great momentum in prostate cancer market
- Clinical evidence is building up
- Positive clinical results has lately led to attractive partnership deals:
  - Algeta, Medivation, Cougar etc.
- Worthwhile for companies to advance projects into Phase III, thus maximising their value before entering a licensing deal

### Bavarian Nordic to exploit market dynamics

- Maximise and retain the value of the cancer portfolio
- Investigate potential financing opportunities, allowing the company to:
  - Advance PROSTVAC™ into Phase III, while continue seeking partner for late-stage development and commercialisation



# Infectious Diseases

• MVA-BN® HIV multiantigen - Phase I/II completed



## MVA-BN® HIV multiantigen

Phase I/II study completed, safety and immunogenicity data reported 15 HIV infected individuals in three-vaccination course

- Well tolerated and no serious adverse events were recorded
- Induces a broad T cell response in HIV infected subjects
  - 87% of the HIV infected subjects generated a T cell response to HIV
  - 67% of the subjects had responses to at least two HIV antigens
  - ~50% had generated response to at least three HIV antigens
- The high number of responders to the vaccine is encouraging and warrant further studies
- Partner search for continued development of MVA-BN® HIV multiantigen in a full Phase II



# Financial Statements & Outlook



## **Financial Statements**

DKK million	9m 2009	9m 2008	FY 2008
Revenue	53	45	209
Production costs	126	101	197
Gross profit	(72)	(56)	12
Research and development costs	114	98	130
Sales and administrative costs	83	70	92
Total operating costs	197	168	222
Income before interest and taxes	(270)	(224)	(210)
Financial income/loss	8	29	26
Income before company tax	(261)	(195)	(183)
Tax	49	40	33
Net profit for the period	(212)	(155)	(150)
Net free liquidity (end of period)	304	782	796

# Financial guidance 2009

RevenueBetween DKK 100-300 millionResult before taxA loss between DKK 275-325 millionEstimated net free liquidity end of 2009Approx. DKK 175 million

A prerequisite for maintaining the high end of the guidance is that the company will receive delivery allowance from the US authorities no later than beginning of December, leading to the possible initiation of deliveries of IMVAMUNE® to the US Government before the end of 2009.

Potential delivery by late 2009 will not have a cash effect in 2009.

In order for Bavarian Nordic to gain the independence to execute its short and long term activities within biodefence and cancer, the company is exploring available options for securing an optimum financial position.



# Selected news flow and scientific triggers

#### **Biodefence**

#### IMVAMUNE® (Smallpox)

- Ongoing negotiations regarding non-US orders
- Completion of Phase II study in AD patients, 2010
- Completion of Phase II booster study, 2010
- Start up delivery of 20 million doses to the US, 2009/2010
- RFP contract for freeze-dried IMVAMUNE®
- Initiation of Phase III, 2010

#### **Anthrax**

Phase I start-up, 2010



# Selected news flow and scientific triggers

#### Cancer

#### **PROSTVAC™**

- Submit PROSTVAC™ papers to peer reviewed journals by Q4 2009
- EoP II meeting in Q1 2010
- Initiate Phase III in 2010
- Potential pharma partner
- Competitive news flow from Dendreon: FDA filing, approval, pharma partner and first sales figures

#### Cancer

#### **MVA-BN® HER-2**

New Phase I/II study 2009/2010

#### **MVA-BN® PRO**

Phase I/II, preliminary data Q4 2009

#### Infectious diseases

### HIV multiantigen

Partner search for full Phase II

#### Measles

 Phase I in children - complete recruitment Q4 2009



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

