# INTERIM RESULTS AS OF MARCH 31, 2015



CSE/OMX:BAVA, OTC:BVNRY

# FINANCIAL HIGHLIGHTS

- 0.3 million doses IMVAMUNE<sup>®</sup> delivered to the SNS during the first three months of 2015
- MVA-BN Filo deliveries to Janssen initiated
- Cash preparedness significantly improved recently as result of BMS deal
- FY revenue and results expectations maintained

	DKK million		USD million	
	3m 2015	3m 2014	3m 2015	3m 2014
Revenue	235	286	34	41
EBIT	(40)	3	(6)	0
Cash preparedness	1,619	535	231	76

USD/DKK = 7.00

# **RECENT HIGHLIGHTS**



# PROSTVAC

- Global commercialization agreement with Bristol-Myers Squibb
  \$60M upfront with potential of ~\$975M total in option and milestone payments
- Clinical collaboration also planned combining PROSTVAC and BMS immuno-oncology candidates
- Updated long-term survival data from combination study of PROSTVAC and ipilimumab warrants further studies

# IMVAMUNE

- Completed deliveries to the U.S. Strategic National Stockpile
- Manufacturing preparations for freeze-dried version on track
- Completed deliveries to the Public Health Agency of Canada

# Janssen/Ebola partnership

- Initiated deliveries of MVA-BN Filo to Janssen
- Phase 1 studies ongoing in US, UK and Africa.
- Phase 2 & 3 trials in the planning, subject to review of preliminary Phase 1 results

#### **BAVARIAN NORDIC**

Phase 1 Phase 2 Phase 3 Market Product Indication Partner IMVANEX/ IMVAMUNE 1-4) BARDA **Smallpox** IMVAMUNE freeze-dried 1) Smallpox BARDA PROSTVAC Prostate Cancer Bristol-Myers Squibb **PROSTVAC** + enzalutamide Prostate Cancer NCI PROSTVAC + ipilimumab Prostate Cancer NCI CV-301 Bladder Combo<sup>1)</sup> Bladder Cancer NCI MVA-BN Brachyury<sup>1)</sup> Metastatic Tumors NCI MVA-BN Filo + AdVac<sup>® 1)</sup> Ebola/Marburg Janssen, NIH **MVA-BN RSV** RSV In 2015

#### 1) Externally funded programs

2) Sold to government stockpiles

- 3) Approved in the European Union under the trade name IMVANEX  $\ensuremath{\mathbb{B}}$  and in Canada under the trade name IMVAMUNE  $\ensuremath{\mathbb{B}}$
- 4) Phase 3 registration studies are ongoing in the United States

# CLINICAL PIPELINE



# **5 KEY INDEPENDENT VALUE DRIVERS**



# MANUFACTURING CAPABILITIES



# Fully Approved Manufacturing Facility

- Over 28mm doses of IMVAMUNE delivered, to date
- Production of 2mm doses of MVA-BN Filo underway
  - 400,000 doses already produced and delivered to Janssen

# Expertise in poxvirus manufacturing

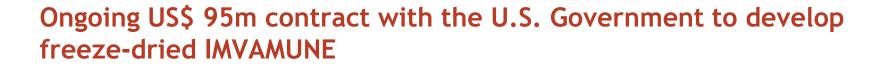
- Commercial partnerships in place with Janssen & BMS
  - All manufacturing retained by Bavarian Nordic.
- Modern vaccine facility meets or exceeds EU and US regulatory guidelines
- Company has developed IP and extensive know-how in the production of live poxvirus based vaccines.

# Multipurpose Facility:

- Highly scalable, fully integrated, reduces dependency on sub-contractors
- Fill/Finish established to support commercial launch of PROSTVAC
- Production of all clinical trial materials, IMVAMUNE, PROSTVAC, etc.



# **IMVAMUNE** GROWING THE BUSINESS WITH FREEZE-DRIED



#### **BENEFITS**

- Anticipated shelf life of greater than 10 years
- Easier logistics and storage

#### TIMELINES

- Ongoing transfer of FD process to commercial scale facility
- Phase 2 ongoing; anticipated EUA in 2016, which allows for federal stockpiling

#### POTENTIAL

- First wave of replenishment could replace 20M expiring doses in stockpile
- Long term stated goal of US Government calls for nonreplicating vaccine for 66M US citizens

Freeze Dried IMVAMUNE®	
MVAMUNE®	Vial No .: N/A to N/A
Content: 20 viale and	Lath to N/A
Reconstitute in WELL	LOI-NO.: COO010
Content: 20 vials, each containing 1 dose 0.5m Reconstitute in WFI before use. For s.c. or i.m. injection.	L of IMVAMUNE , freeze dried
Re-test Date: May 2014	
Storage: +2°C to and	K Marries
storage: +2°C to +8°C	
Caution: New Drug	
Manufacture - Limited by Federal La	
Caution: New Drug - Limited by Federal La Manufacturer: Bararian Nordic A/S, Hejreskovvej phone: +45-33-268383 US Patert Nos: 6.761.883, 6.913.752,7 140.454	v to investigational Lise
45-53-268383 Hejreskovvej	10A, DK-3490 K
US Patent Nos: 6.761.893 6.010 20	Kvistgård, Denmark
0.013.752, 7.189.536, 7.335.364 7	201.0
US Patent Nos: 6 761 693, 6 913 752, 7 169 536, 7 335 364, 7	044, 044, 7.459.270, 7.923.017 and 7 and
	Snee
	Spec.no.: L-POX-2012.010

# **PROSTVAC** PHASE 3 FULLY ENROLLED DECEMBER 2014

- Primary endpoint is overall survival
- Either one of the treatment arms must be superior to placebo
- Each comparison requires 534 deaths for the final analysis
- Interim analysis plan
  - Pre-specified interim data analyses will evaluate whether the trial should continue as planned or potentially be stopped early for efficacy or futility

#### PROSPECT

A Randomized, Double-blind, Global Phase 3 Efficacy Trial of PROSTVAC in Metastatic Castration-Resistant Prostate Cancer



1,298 patients

Enrolled at 214 sites in 15 countries Australia, Belgium, Canada, Denmark, Estonia, France, Germany, Iceland, Israel, Netherlands, Poland, Russia, Spain, UK & US

#### 3 study arms

#### PROSTVAC + GM-CSF

PROSTVAC

Placebo

Phase 2 results: Demonstrated hazard ratio 0.56 = 44% reduction in risk of death SPA terms for Phase 3: Required hazard ratio 0.82 or less = 18% reduction in risk of death



## License and option agreement

• Up to USD 975 million in upfront and milestone payments



## Supply contract

Bavarian Nordic to manufacture PROSTVAC

## **Clinical collaboration agreement**

- Explore combinations of PROSTVAC and BMS' oncology assets
- Represents a clear validation of our cancer immunotherapy platform
- One of the largest oncology deals in recent years

Supply of Ebola vaccine - potential expansion of agreement

## License agreement - USD 45m

- Janssen obtains full commercialization rights
- BN could receive royalties outside GAVI countries

## Supply agreement - USD 99m

• BN to manufacture and supply of >2 million vaccine doses

# Equity investment - USD 43m

JNJ now ~5% shareholder of BN

## Additional diseases targets being explored

• MVA-BN is being evaluated in three undisclosed infectious disease targets





# **COMMERCIAL VACCINES: CV-301**

# CV-301 development strategy

- Phase 2 study(s) starting 2016:
- Combination treatment with approved checkpoint inhibitor
- Short-term clinical outcomes possible (Overall Response Rate, Progression-Free Survival)
- Partnering opportunity based on proof-of-concept data

## Same base technology - different antigens



## **RSV: Respiratory Syncytial Virus**

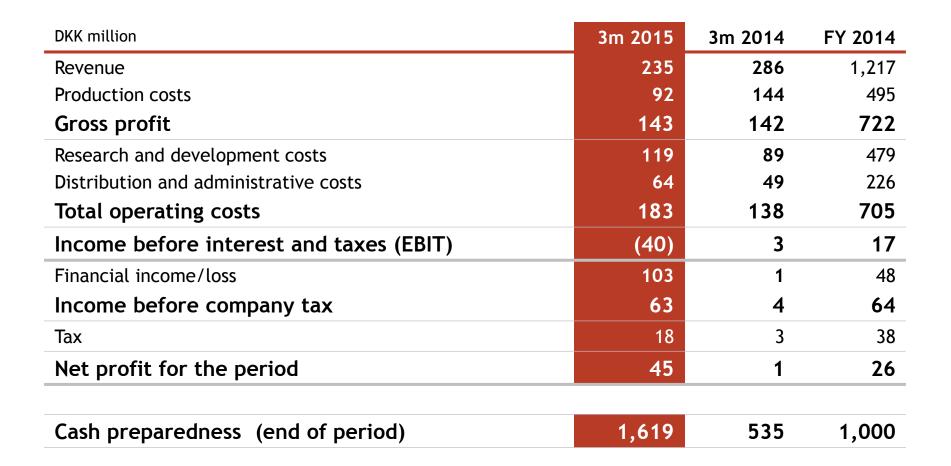
- Major cause of upper & lower respiratory tract infections in adults and children
- No approved vaccine; high unmet medical need
- Recurrent infections are common, particularly in individuals with respiratory & circulatory diseases

# **MVA-BN RSV vaccine candidate**

- Creates a strong immune response
- Protection against both RSV subtypes (A&B) in preclinical models
- Received NIH funding (preclinical efficacy)



# FINANCIAL STATEMENTS



# FINANCIAL OUTLOOK



#### **Assumptions:**

Deliver and revenue recognize bulk material totaling approximately 2 million doses of MVA-BN Filo to Janssen and 0.3 million doses of IMVAMUNE to the U.S. and Canada Total **R&D costs of DKK 600 million**, which include approximately DKK 100 million in contract expenses (stated under production costs in the P&L statement) as well as DKK 25 million capitalized in the balance sheet

All numbers are approximate

# ANTICIPATED SELECTED MILESTONES

- Manufacture and deliver MVA-BN Filo (Ebola/Marburg) vaccine; targeting 2 million doses (2015)
- Phase 2 and Phase 3 trials of MVA-BN Filo + AdVac<sup>®</sup> (Ebola)
- Potential expanded collaboration with Janssen on additional infectious disease targets
- Investigational New Drug submission for MVA-BN RSV followed by initiation of Phase 1 study (H1, 2015)
- Advance clinical studies exploring the therapeutic potential of **PROSTVAC** with checkpoint inhibitors in collaboration with BMS
- Complete Phase 2 study of freeze-dried IMVAMUNE to support a pre-EUA submission (requirement for stockpiling) (2015)
- Secure IMVANEX/IMVAMUNE orders from rest of world
- Interim analyses of **PROSTVAC**



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.