# INTERIM RESULTS AS OF JUNE 30, 2016



CSE/OMX:BAVA, OTC:BVNRY

# FORWARD-LOOKING STATEMENTS

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 regarding our short-term objectives and opportunities, financial expectations for the full year and financial preparedness as of year end, as well as statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. 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.

- US\$ 100 million order for bulk supply of IMVAMUNE awarded by the U.S. Government as part of transition to stockpiling of freeze-dried version
- US\$ 12.3 million milestone payment received from U.S. Government (holdback related to original RFP-3 contract)
- Canada has exercised option for additional 171,000 doses of IMVAMUNE valued at US\$ 7.7 million
- Phase 1 top-line results for MVA-BN RSV reported, Phase 2 planned for initiation in 2H 2016
- Phase 1 study of an MVA-BN-based vaccine against yellow fever initiated by the U.S. National Institute of Allergy and Infectious Diseases.
- Phase 2 study of PROSTVAC in 44 pts with locally recurrent prostate cancer initiated by Medical University of South Carolina
- Interim analysis #2 of PROSTVAC Phase 3 (at 60% or 321 events) confirmed that the study continues without modification
- Clinical agreement with BMS for nivolumab and CV301 combination study

# **FINANCIALS**



# Q2 revenues as expected

- More than 85% of revenues will be recognized in 2H 2016
- FY revenue and results expectations maintained
- Cash preparedness upgraded after successful capital increase in April
  - 2.77 million new shares sold, yielding DKK 665 (~\$100) million in gross proceeds

	DKK million			USD million			
	6m 2016	6m 2015	FY2016E	6m 2016	6m 2015	FY2016E	
Revenue	139	624	1,000	21	94	149	
EBIT	(207)	85	0	(31)	13	0	
Cash preparedness	1,894	1,669	1,900	283	249	284	

Main assumptions for FY2016E: Revenue of DKK 750 million from IMVAMUNE sales and DKK 250 million from R&D contracts. Total R&D costs of DKK 580 million, which include DKK 110 million in contract expenses (stated under production costs in the P&L statement) as well as DKK 25 million capitalized in the balance sheet. Cash preparedness includes cash, cash equivalents, investments in securities and the aggregate amount of undrawn credit lines.

USD/DKK = 6.70 (as of June 30, 2016)

All numbers are approximate.

# FINANCIAL STATEMENTS



# **IMVAMUNE PARTNERSHIP WITH THE U.S.**

Long-term stockpiling goal



# **IMVAMUNE SALES TO CANADA**

# Recurrent orders solidifies commitment to building and expand smallpox preparedness

• IMVAMUNE approved in Canada in 2013 for emergency use in individuals who are contraindicated to replicating smallpox vaccines

Year	DND	PHAC
2008	20,000	
2012	20,000	
2014	20,000	46,000
2015		143,000
2016		171,000
Total	60,000	360,000
Remaining options	140,000	-

### Doses ordered

**PHAC:** Public Health Agency of Canada **DND:** (Canadian) Department of National Defence





# **OUR COLLABORATION WITH JANSSEN**





# A sustained partnership

- Janssen took almost 5% equity stake in BN upon signing Ebola deal
- Validation of our MVA-BN technology & manufacturing
- Recent publication of Ebola Phase 1 data confirms durable immune responses when combining MVA-BN and AdVac.



# Large unmet medical need: children & elderly

- Global RSV disease burden is estimated at 64 million cases and 160,000 deaths every year
- The U.S. Centers for Disease Control and Prevention (CDC) reports that each year the disease causes 177,000 hospitalizations and 14,000 deaths among adults older than 65
- No approved prophylactic vaccine available



# **RSV PHASE 1 POSITIVE TOP LINE RESULTS**

# Safety

- No unexpected and/or serious adverse reactions
- Vast majority of events represent local and systemic reactions typical for vaccines - reported as mild to moderate and resolved rapidly without intervention (≤5 days)
- Low incidence of local and systemic reactions typical for vaccines and comparable between age groups

### Immunogenicity

- Dose response and differences between age groups was observed in the immune responses
- Antibodies against RSV significantly boosted in the majority of subjects
  - 2-fold increase in both IgG and IgA in elderly
  - Boosted neutralizing antibodies against both RSV subtypes (A&B)
- T cell responses were boosted in all elderly subjects
  - 3-5 fold increase in T cell responses (F, G, N proteins & whole RSV)
  - Robust T cell response (100% to 2 pools, 67% to 3 pools, 100% to RSV)

# NEXT STEPS: PHASE 2 DOSE RANGING IN ELDERLY (≥55 YEARS OLD)

### Randomized, blinded, placebo-controlled dose ranging study in 400 subjects

		Vaccina Daca	Schedu	Pouto	
Groups	IN		0	28	Koule
1	80	Low	MVA-BN RSV	Placebo	IM
2	80	Low	MVA-BN RSV	MVA-BN RSV	IM
3	80	High	MVA-BN RSV	Placebo	IM
4	80	High	MVA-BN RSV	MVA-BN RSV	IM
5	80	-	Placebo	Placebo	IM
Total	400				

Objectives     T	Timelines
<ul> <li>Identify optimal dose and schedule</li> </ul>	<ul><li>Initiate enrolment fall 2016</li><li>Topline data available mid-2017</li></ul>

# **PROSTVAC PHASE 3 STUDY**

### PROSPECT

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

# Randomization by region (N=1,297)



# 3 study arms

PROSTVAC + GM-CSF

PROSTVAC

Placebo

### Injections

- Average was 6.1 injections<sup>1</sup>
- Randomized Phase 2 trial (n=122) had average of 5.4 injections<sup>2</sup>
- An increased number of injections is expected to improve the clinical outcome for patients receiving the active drug.

1) Subjects who have completed study treatment phase or have completed  $7^{\text{th}}$  dosing visit. N=1,279

2) Kantoff et al., Journal of Clinical Oncology, January 2010

# PROSTVAC: INTERIM ANALYSES UNDERWAY

### Second interim analysis of the PROSPECT Phase 3 study has occurred

- A recent review by the Data Monitoring Committee informed BN to "Continue the trial without modification"
- Interim 2 was an analysis of each of the active PROSTVAC arms (with or without GM-CSF) versus placebo, thus requiring at least 321 events per comparison (equals 60% of the 534 events required for final overall survival analysis)
- 1 additional interim analysis remain
- Final overall survival data anticipated in 2017

Interim Analysis #1	$\checkmark$	214 events	40%
Interim Analysis #2	$\checkmark$	321 events	60%
Interim Analysis #3		427 events	80%
Final Overall Survival Analysis		534 events	100%



### Further investigation of PROSTVAC in collaboration with BMS

• Two new investigator-sponsored trials planned for initiation





### New and improved vaccine construct based on MVA-BN



### Leverage Existing Clinical Data

Preliminary evidence of efficacy generated in multiple clinical studies.

Safety data with over 300 subjects treated.

### CV301 in Combination with Immune Checkpoint Inhibitors



# NIVOLUMAB AGREEMENT WITH BMS

- On August 15<sup>th</sup> BN and BMS announced a joint collaboration for the supply of drug material (nivolumab)
- BMS will supply nivolumab at no cost to BN
- BN will sponsor a phase 1b/2 study in non-small cell lung cancer (NSCLC) of CV301

Bavarian Nordic maintains all commercial rights to CV301

# PHASE 2 CV301 & NIVOLUMAB COMBINATION IN NSCLC

Safety CV301 single agent (N=18) & Single dose combination with nivolumab (N=22)

![](_page_17_Picture_2.jpeg)

![](_page_17_Picture_3.jpeg)

Prime	Boost						
MVA-BN CV301	FPV 301						
2 vaccinations 4 wks apart	4 boosters9 boosters 4 weeks apart4 boosters 13 weeks apartapart9 boosters 4 weeks apart4 boosters 13 weeks apart						
Total 8 weeks	TotalTotalTotal8 weeks36 weeks52 weeks						
Total 2 years							

Endpoints:	Safety, tolerability Primary endpoint: OS Secondary endpoints: ORR, DOR, PFS, Immune effects
<u>Multi-center trial:</u>	Up to 20 sites in USA

# PIPELINE

![](_page_18_Picture_1.jpeg)

INFECTIOUS DISEASESIMVAMUNE liquid-frozen 1)Smallpox1Image: Colspan=10 and Colspan=	PRODUCT	INDICATION	ONGOING STUDIES	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	PARTNER
IMVAMUNE liquid-frozen ilSmallpox1Image: SmallpoxBARDAIMVAMUNE freeze-driedSmallpoxImage: SmallpoxBARDAMVA-BN FiloEbola/Marburg9Image: SmallpoxJanssenMVA-BN RSVRSV1Image: SmallpoxJanssenMVA-BN HPVChronic HPV InfectionImage: SmallpoxJanssenCANCER IMMUNOTHERAPYProstate Cancer9Image: SmallpoxSmallpoxPROSTVACBladder Cancer1Image: SmallpoxNCI	INFECTIOUS DISEASES								
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	CV301	Bladder Cancer	1						NCI
MVA-BN Brachyury Metastatic Tumors 1 NCI	MVA-BN Brachyury	Metastatic Tumors	1						NCI

1) Approved in the European Union under the trade name IMVANEX<sup>®</sup> and in Canada under the trade name IMVAMUNE<sup>®</sup>. Phase 3 registration studies are ongoing in the United States.

# ANTICIPATED SELECTED MILESTONES 2016/2017

![](_page_19_Picture_1.jpeg)

PROSTVAC	prostate cancer	IMVAMUNE	smallpox vaccine		
<ul> <li>Phase 3 top-line data including interim analyses</li> <li>Data from NCI-sponsored Phase 2 trials</li> <li>Initiate Phase 2 study in combination with ipilimumab in collaboration with BMS</li> <li>Initiate NCI-sponsored Phase 2 study in combination with ipilimumab and nivolumab</li> </ul>		<ul> <li>Finalize manufacturing activities to support a U.S. EUA for freeze-dried IMVAMUNE</li> <li>Additional Rest of World orders</li> <li>Complete enrolment of Phase 3 non-inferiority study</li> </ul>			
Janssen	partnership	Pipeline	projects		
<ul> <li>Complete Phase 2 and Phase 3 studies of the Ebola prime-boost vaccine regimen</li> <li>Initiate HPV Phase 1 study in cervical cancer</li> <li>Potential expanded collaboration with Janssen on two additional infectious disease targets</li> </ul>		<ul> <li>MVA-BN RSV Phase read out</li> <li>MVA-BN RSV Phase</li> <li>MVA-BN RSV Phase</li> <li>MVA-BN Brachyury</li> <li>CV301 + nivo Phase</li> <li>CV301 + checkpoir in two additional i</li> </ul>	2 dosing study initiation + 2 field efficacy initiation 1 pediatric study initiation Phase 2 initiation e 2 initiation in lung cancer at inhibitor Phase 2 initiation ndications		

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