# THE FUTURE OF VACCINES

### **2014 YEAR END RESULTS**



# A FOUNDATION OF VALUE CREATING ASSETS

1 approved product 7 active programs Validated Productive Platforms

2 Phase 3 products and near term value drivers

Broad Pipeline & Late-Stage Candidates

Trial supply to commercial product

Flexible GMP Manufacturing Facility

>\$1bn from US government in past 10 years; \$187m Janssen, Bristol Myers collaboration potential of ~\$975m

Track Record of Collaboration & Development Funding

### FINANCIAL HIGHLIGHTS



		2014 actual	2014 outlook
Revenue	1	DKK 1,217 m	DKK 1,200 m
Income before interest and tax	1	DKK 17 m	DKK 0 m
Cash preparedness at year-end	=	DKK 1,000	DKK 1000 m*

\* Adjusted from DKK 600 million on October 22, 2014 following Janssen Ebola agreement

### FINANCIAL STATEMENTS



DKK million	FY 2014	FY 2013
Revenue	1,217	1,213
Production costs	495	485
Gross profit	722	728
Research and development costs	479	497
Distribution and administrative costs	226	198
Total operating costs	705	694
Income before interest and taxes (EBIT)	17	33
Financial income/loss	48	(27)
Income before company tax	64	6
Tax	38	53
Net profit for the year	26	(47)
Cash preparedness (end of year)	1,000	652

### 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

R&D costs

\* DKK 600m

All numbers are approximate

\* R&D costs 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

### 2014 AND CURRENT 2015 HIGHLIGHTS



PROSTVAC	<b>Global agreement with Bristol-Myers Squibb</b> \$60M upfront with potential of ~\$975M total in option and milestone payments
	Clinical collaboration also planned combining PROSTVAC and BMS immuno-oncology candidates
	Phase 3 study has completed enrollment 1,298 patients enrolled at 200 sites in 15 countries
IMVAMUNE	\$118M option exercised by the USG for additional 4M doses
	\$22M option exercised for freeze-dried manufacturing
	Canada orders including options totaling 500,000+ doses
Ebola	License and supply agreement with Janssen BN to deliver bulk vaccine for 2 million doses of MVA-BN Filo for Ebola. Valued at up to \$187M including equity investment in BN

# PROSTVAC DEAL WITH BRISTOL-MYERS SQUIBB

### Global commercialization agreement on PROSTVAC

#### 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



# **DEAL STRUCTURE**

Elements	Value, mUSD
Upfront payment	60
License	80
Phase 3 data	50
Data-driven milestones	180*
Regulatory milestones	110
Sales milestones	495
Royalties on future sales	Double-digit

\* Based on Phase 2 data



### PROSTVAC PLUS IPILIMUMAB COMBINATION: IMPACT ON MEDIAN OVERALL SURVIVAL



Patients in 10mg/kg dose cohort (N=15) reported 37.2 months median overall survival

~20% of 10mg/kg patients remain alive at 80 months

Gulley J, NCI. Madan RA, et al. *Lancet Oncol*. 2012;3:501-508.

Kantoff PW, et al. J Clin Oncol. 2010;28:1099-1105.

# Looking to explore the full potential of PROSTVAC as stand-alone treatment and in combination with other treatment paradigms

- Scientific rationale exists to evaluate PROSTVAC in combination with Yervoy (ipilimumab), and other agents from Bristol-Myers Squibb's immuno-oncology portfolio.
- Based on existing preclinical and clinical data, an investigator sponsored Phase 2 study will investigate the combination of Yervoy and PROSTVAC.
- Under the agreement the companies may conduct one or more exploratory combination studies of PROSTVAC and agents from Bristol-Myers Squibb's immuno-oncology portfolio.



### **5 KEY INDEPENDENT VALUE DRIVERS**



### **RSV: RESPIRATORY SYNCYTIAL VIRUS** LARGE UNMET MEDICAL NEED: CHILDREN & ELDERLY

#### RSV

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



#### SERIOUS HEALTH RISK FOR ELDERLY

- 177,000 hospitalizations and 14,000 deaths annually among US adults older than 65 years
- Infection rate in adults ranges between 5-10% per year, 70-80% get respiratory symptoms, 10-20% are hospitalized, and 2-5% die
- High levels of transmission in nursing homes increase disease burden in these facilities
- Major risk factor for adults with chronic pulmonary conditions

#### LEADING CAUSE OF INFANT HOSPITALIZATION

- Up to 176,000 hospitalizations in the US annually in children under 5
- 1.5 million outpatient visits in the US annually in children under 5
- 90% of infants contract RSV infection by 2 years of age, infants < 6 months of age are most at risk for severe disease
- Children are major source of disease transmission

# **MVA-BN RSV VACCINE CANDIDATE**

#### **MVA-BN RSV**

- Highly immunogenic inducing strong mucosal and serological immunity (antibodies & T cells)
- No enhanced disease in animal models
- Protection against both RSV subtypes (A&B) in animal models
- Flexible administration options: intranasal or intramuscular
- Received NIH support (animal efficacy)
- Favorable pre-IND Phase 1 planned H1 2015

#### MVA-BN: IDEAL RSV VACCINE PLATFORM

- Licensed platform
- Extraordinary safety profile
- Vector tested safely in elderly and children

#### DEVELOPMENT STRATEGY



### CV-301 FOR MULTIPLE CANCERS CEA/MUC-1/TRICOM IMMUNOTHERAPY

- High level tumor antigen expression for many cancers
- CV-301 prime/boost regimen tested in 8 clinical trials and over 450 patients
- Promising preliminary evidence of efficacy in breast cancer, colorectal cancer
- Unmet medical need for patients with CEA+/MUC-1+ cancers but low immunogenicity and/or low/negative PD-L1 expression

Cancer Type	US Incidence	CEA +	MUC-1+	PD-L1 Low/Neg
Lung	~180,000	~70%	~80%	~70%

# CV-301 COMBINED WITH IMMUNE CHECKPOINT INHIBITOR: LUNG CANCER (NSCLC\*)

- Typically advanced, difficult to treat, short survival
- 25-50% response rates to anti-PD1 if tumor PD-L1pos
  - Pembrolizumab approved (Merck), Opdivo (BMS) others likely

# •9-15% response rates to anti-PD1 if tumor PD-L1<sup>low/neg</sup>

- ~70% of NSCLC are PD-L1<sup>low/neg</sup>
- CV-301 development strategy
  - Unmet medical need PD-L1<sup>low/neg</sup>
    - Expedited regulatory status to be evaluated
  - Phase 2 study(s) starting 2016:
    - Inoperable or advanced NSCLC
    - Low or negative PD-L1 expression
    - Treat with approved anti-PD1 ± CV-301
  - Short-term clinical outcomes possible (ORR, PFS)

\*NSCLC - Non-small cell lung cancer







	2015	2020
PROSTVAC	Target enrollment reached, data maturing, partnership in place, BLA/manufacturing prep begins	Approved & partnered Data on checkpoint inhibitors & anti-androgen combinations
IMVANEX/IMVAMUNE	IMVANEX approved EU/Canada IMVAMUNE/LF US Phase 3 program IMVAMUNE/FD in Phase 2	IMVAMUNE/IMVANEX Approved in US/EU/Canada FD acquisitions in US
Janssen Collaboration	Clinical trials initiating w/Janssen; deliver 2 million doses of Ebola vaccine in 2015	MVA-BN Filo approved Expansion of collaboration in 3 commercial targets
Commercial Vaccines	Preparing RSV Phase 1 initiation H1 2015	RSV in Phase III (Phase 2 POC data) CV-301 + PD1 combination Phase 2 POC data (lung, and 2 additional indications) 2 <sup>nd</sup> ID candidate in Phase II
Additional Government Programs	Ongoing funded collaboration with NIH, BARDA, DOD, DHS, NCI	Brachyury Phase 2 data Continued expansion of platform opportunities

# 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® (Ebola)
- Potential new orders for MVA-BN Filo
- 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.