

# ANNUAL GENERAL MEETING

APRIL 23, 2015



# AGENDA

1. The Board of Directors' report on the Company's activities in the past year.
2. Presentation of the Annual Report for adoption.
3. A proposal from the Board of Directors regarding the application of profit or covering of loss pursuant to the Annual Report as adopted.
4. A resolution to discharge the Board of Directors and the Board of Management from their obligations.
5. Election of Members to the Board of Directors.
6. Election of Auditors.
7. Any proposal from the Board of Directors or shareholders.



# GERARD VAN ODIJK

## CHAIRMAN OF THE BOARD

# A TREMENDOUSLY GOOD YEAR

WE MET AND EXCEEDED OUR FINANCIAL AND OPERATIONAL EXPECTATIONS

## Commercial validation through two significant agreements with industry leaders

- MVA-BN technology for Ebola vaccine
- VF-TRICOM prime-boost technology for cancer immunotherapies



## Industry validation of our manufacturing capabilities

- Multi-product manufacturing established



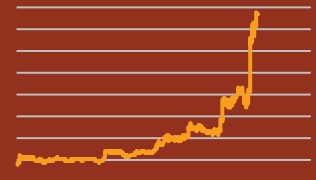
## Leadership

- New leadership in place
- Board structure improved through establishment of committees



## Strong strategic and financial foundation for further growth

- Strong cash position
- Balanced pipeline with commercial potential, partly supported by external funding



# A FOUNDATION OF VALUE CREATING ASSETS



1 approved product  
7 active programs



2 Phase 3 products and near  
term value drivers



Trial supply to  
commercial product



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

Validated  
Productive Platforms

Broad Pipeline  
& Late-Stage Candidates

Flexible GMP  
Manufacturing Facility

Track Record of Collaboration  
& Development Funding



**PAUL CHAPLIN**

**PRESIDENT & CHIEF EXECUTIVE OFFICER**

# 2014 AND CURRENT 2015 HIGHLIGHTS

Global agreement with Bristol-Myers Squibb on **PROSTVAC**

**PROSTVAC** Phase 3 study has completed enrollment

Combination treatments with **PROSTVAC** shows promise

License and supply agreement on **Ebola vaccine** with Janssen

Clinical studies of **Ebola vaccine** initiated

U.S. Government exercised \$118M option for additional 4 million doses **IMVAMUNE**

\$22M option also exercised for freeze-dried **IMVAMUNE** manufacturing

**IMVAMUNE** orders from Canada including options totaling 500,000+ doses

# 5 KEY INDEPENDENT VALUE DRIVERS



# SMALLPOX VACCINE STOCKPILES

## TRADITIONAL SMALLPOX VACCINES

**Traditional vaccines are based on a replicating vaccinia virus**

- Dryvax®, ACAM2000, LC16m8, Elstree-BN

**All have been shown to produce some/all of following serious side effects**

- Myocarditis, pericarditis, encephalitis, progressive or generalized vaccinia, eczema vaccinatum, inadvertent infection

**Significant population should not receive replicating vaccines**

- Congenital or acquired immunodeficiency, immunosuppressive medications, exfoliative skin disorders (e.g. eczema)



## IMVAMUNE®/IMVANEX®

**Based on a non-replicating virus**

**Approved in EU and Canada**

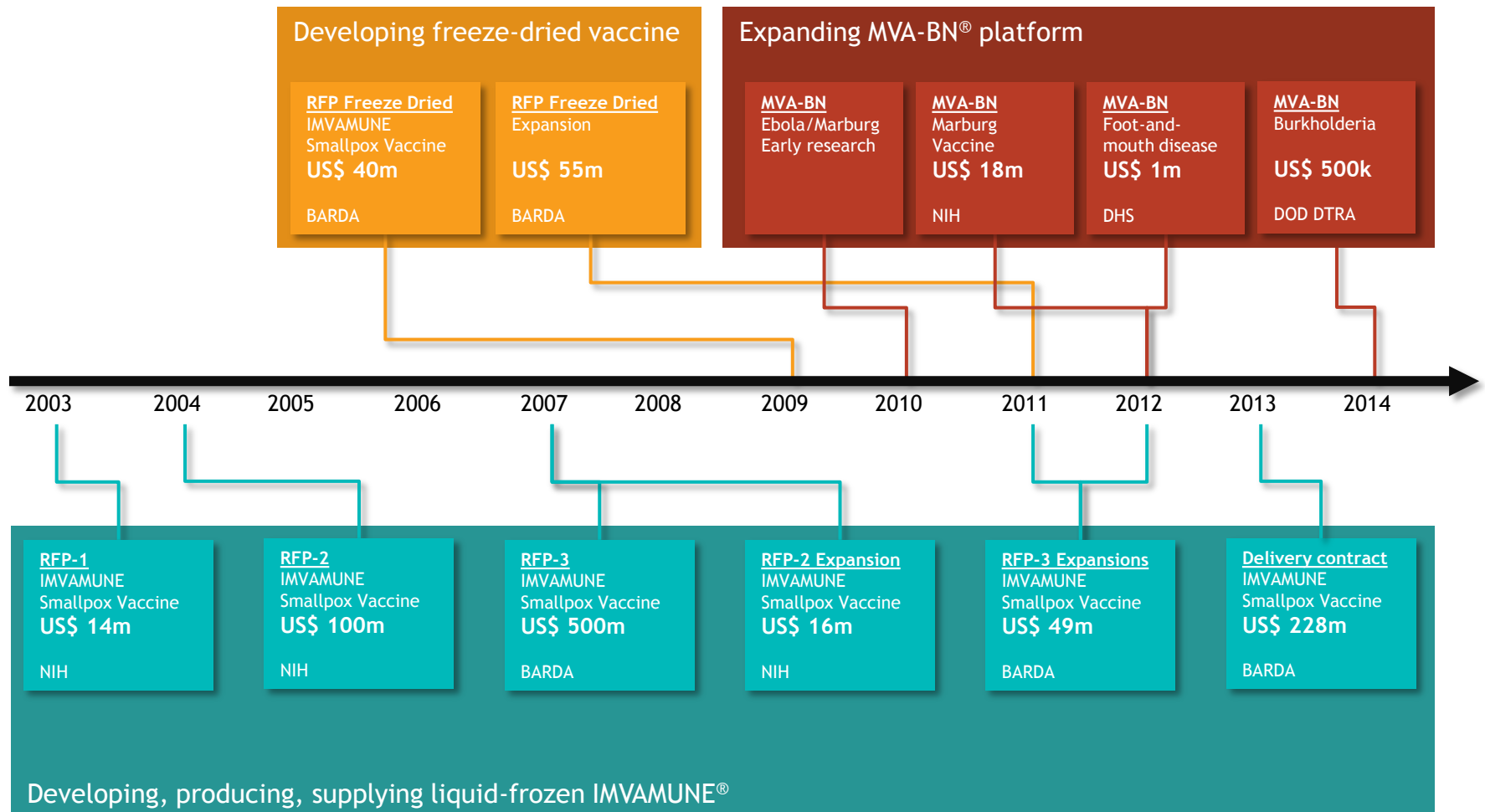
**More than 7,500 individuals have been vaccinated**

- Well tolerated - even in immune-compromised patients
- No reports of the serious adverse events reported with the use of replicating vaccinia vaccines in the smallpox eradication campaign



# SUCCESSFUL PARTNERSHIP WITH THE U.S. GOVERNMENT

## CONTRACTS AWARDED TO-DATE EXCEED US\$ 1BN



# 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

## 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

## 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

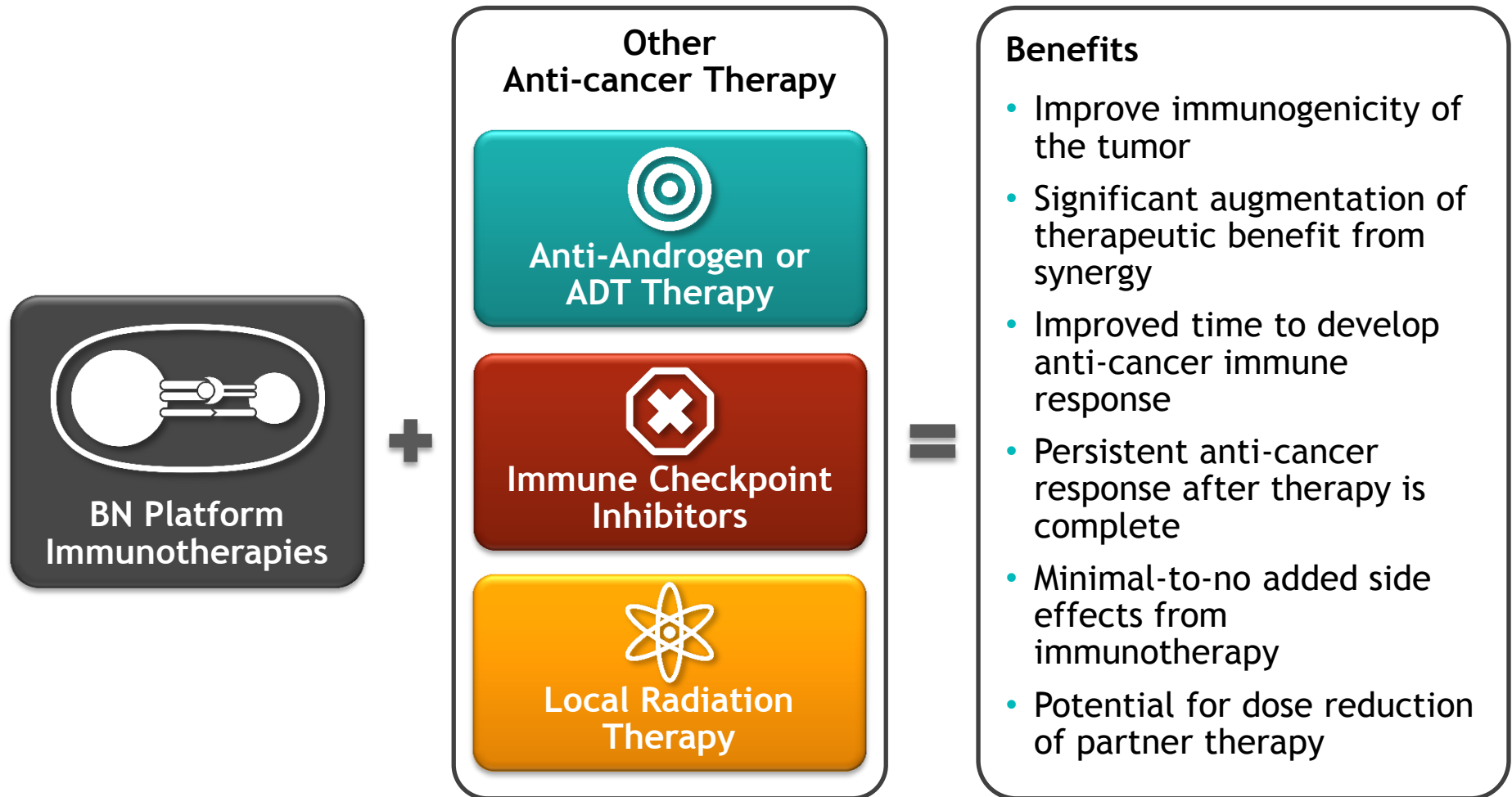
3 study arms

PROSTVAC + GM-CSF

PROSTVAC

Placebo

# COMBINATION RATIONALE: POXVIRUS IMMUNOTHERAPY



### Global commercialization agreement on PROSTVAC

#### License and option agreement

- Up to USD 975 million in upfront and milestone payments



Bristol-Myers Squibb

#### 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

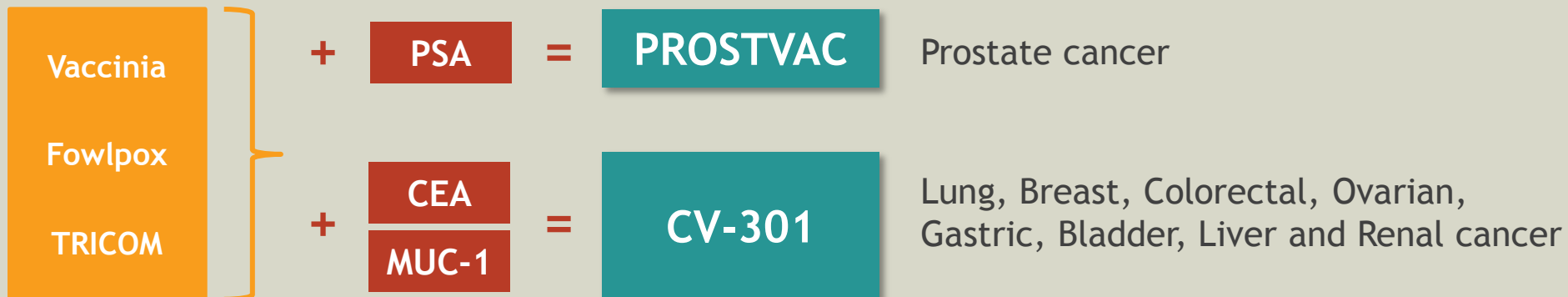
- MVA-BN is being evaluated in three undisclosed infectious disease targets

# 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



# COMMERCIAL VACCINES: RSV

LARGE UNMET MEDICAL NEED: CHILDREN & ELDERLY

## 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)

## Development strategy



# CLINICAL PIPELINE

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

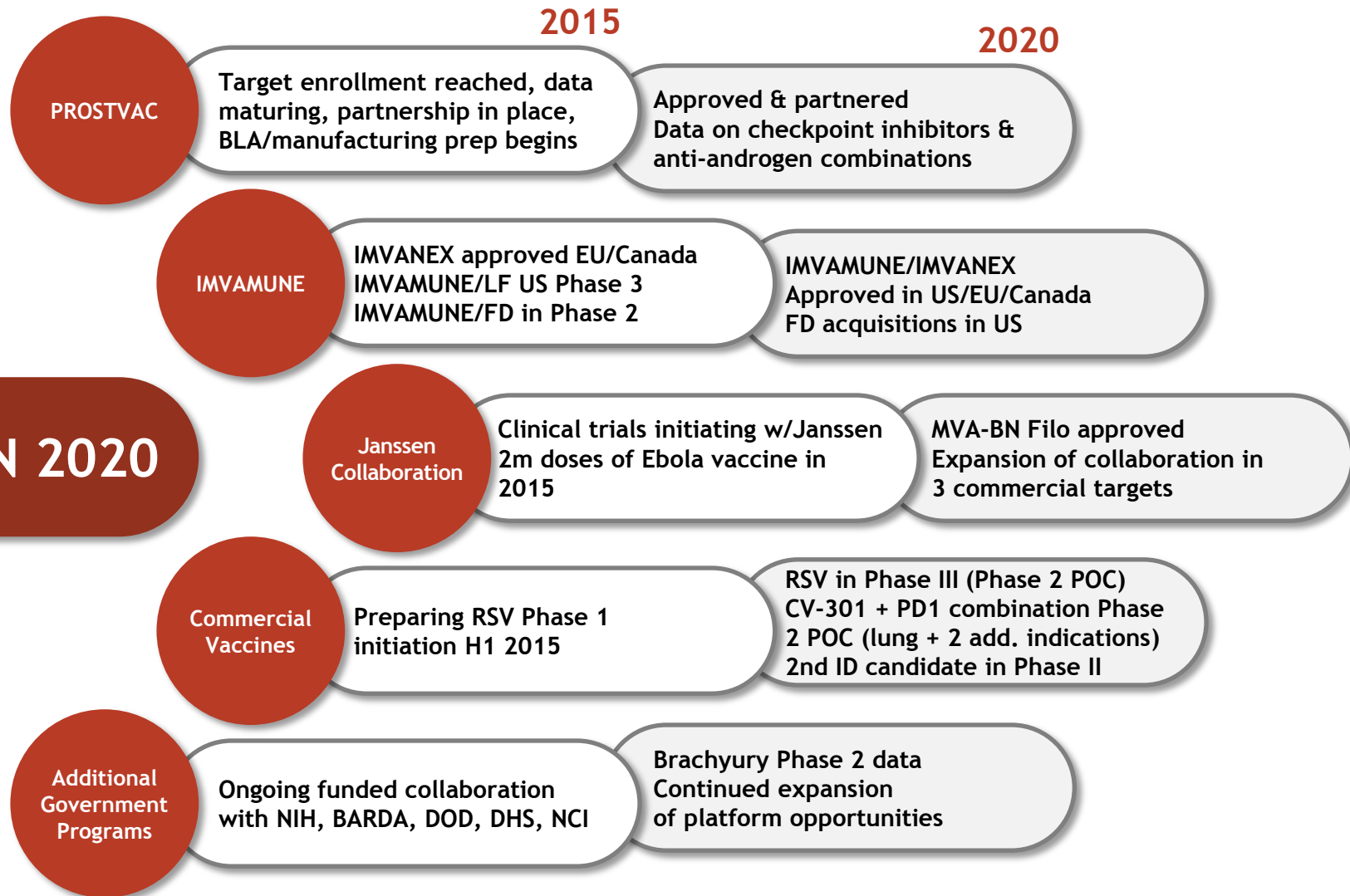
1) Externally funded programs

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

# WHERE ARE WE GOING?





**OLE LARSEN**

**EXECUTIVE VICE PRESIDENT & CHIEF FINANCIAL OFFICER**

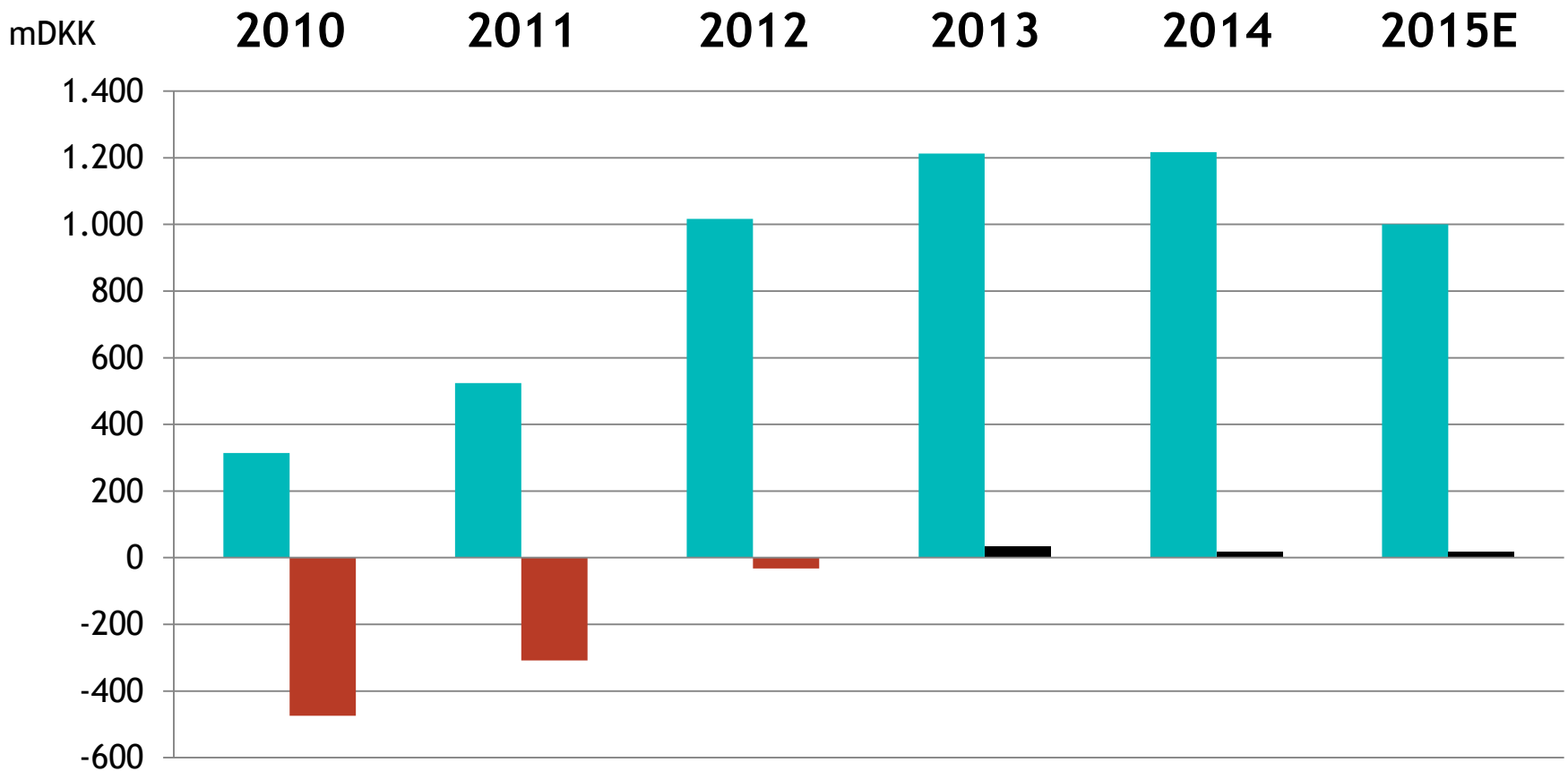
# FINANCIAL HIGHLIGHTS



	Realized	Expected
Revenue	DKK 1,217 m	DKK 1,200 m
Income before interest and tax	DKK 17 m	DKK 0 m
Cash preparedness at year-end	DKK 1,000 m	DKK 1,000 m*

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

# REVENUE AND RESULTS DEVELOPMENT



# FINANCIAL OUTLOOK 2015



Revenue	DKK 1,000 m
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EBIT	DKK 0 m
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Cash preparedness at year-end	DKK 1,100 m
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# RETURN ON INVESTMENT ON BN SHARES



# ANTICIPATED SELECTED MILESTONES

Manufacture and deliver 2 million doses of **MVA-BN Filo** (Ebola) vaccine (2015)

Phase 2 and Phase 3 trials of **MVA-BN Filo** + AdVac® (Ebola)

Potential expanded collaboration with **Janssen** on additional infectious diseases

**MVA-BN RSV** initiation of Phase 1 study (H1, 2015)

Advance clinical studies of **PROSTVAC** with checkpoint inhibitors from BMS

Complete Phase 2 study of freeze-dried **IMVAMUNE** to support a pre-EUA (2015)

Secure **IMVANEX/IMVAMUNE** orders from rest of world

Interim analyses of **PROSTVAC**

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## 5. ELECTION OF MEMBERS TO THE BOARD OF DIRECTORS



Gerard van Odiijk



Claus Bræstrup



Anders Gersel  
Pedersen



Erik G. Hansen



Peter Kürstein

## 6. ELECTION OF AUDITORS

The Board of Directors proposes that Deloitte is re-elected as the Company's auditor.

## 7. ANY PROPOSAL FROM THE BOARD OF DIRECTORS OR SHAREHOLDERS

### 7a. Issue of shares in the name of the holder

Proposal to amend Article 6 of the Articles of Association so that the Company's shares are changed from being issued to the bearer to being issued in the name of the holder

## 7. ANY PROPOSAL FROM THE BOARD OF DIRECTORS OR SHAREHOLDERS

### 7b. Remuneration policy

Proposal to adopt a remuneration policy including changing the general guidelines for incentive remuneration of the Board of Directors and the Executive Management

## 7. ANY PROPOSAL FROM THE BOARD OF DIRECTORS OR SHAREHOLDERS

### 7c. Authorisation to increase the share capital

The Board of Directors proposes to increase and extend the authorisations of the Board of Directors in Article 5a of the Articles of Association, so that the Board of Directors is authorised to increase the share capital of the Company in one or more issues by a total of nominally DKK 27,700,000 until 30 June 2016.

# 7. ANY PROPOSAL FROM THE BOARD OF DIRECTORS OR SHAREHOLDERS

## 7d. Warrants

Proposal to amend the authorisation of the Board of Directors in Article 5b of the Articles of Association, so that the Board of Directors is no longer authorised to issue warrants to members of the Board of Directors as a consequence of the proposed changes to the general guidelines for incentive remuneration of the Board of Directors and Board of Management (see item 7b of the agenda). Further, the Board of Directors proposes to increase and extend the authorisation of the Board of Directors, so that the Board of Directors is authorised to issue warrants, which entitle the holders to subscribe for shares in the Company at a nominal value of up to DKK 6,000,000 until 31 December 2016.

## 7. ANY PROPOSAL FROM THE BOARD OF DIRECTORS OR SHAREHOLDERS

### 7e. Remuneration of the Board

Proposal to approve remuneration of the Board of Directors and the Board Committees for the current financial year.

## 7. ANY PROPOSAL FROM THE BOARD OF DIRECTORS OR SHAREHOLDERS

### 7f. Authorisation to purchase own shares

Proposal to authorise the Board of Directors to purchase own shares



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.