

# **Q1 2017**

*INTERIM RESULTS AS OF MARCH 31, 2017*



BAVARIAN NORDIC

# 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.*

**SAVE THE DATE**  
**SEPTEMBER 21, 2017**



**BAVARIAN NORDIC CAPITAL MARKETS DAY**  
**LE PARKER MERIDIEN HOTEL**  
**NEW YORK CITY**

# HIGHLIGHTS

FOR THE FIRST QUARTER 2017 AND UP TO DATE



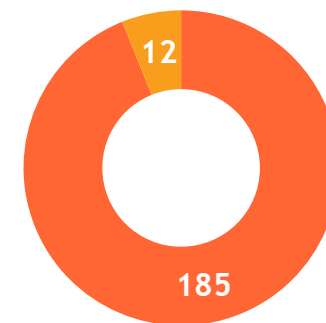
- Phase 2 combination study of PROSTVAC, ipilimumab and nivolumab initiated at the NCI.
- Drug supply agreement with Roche, providing Tecentriq® (atezolizumab) for a planned Phase 2 combination trial of CV301 in bladder cancer.
- Updated Phase 1 data for MVA-BN RSV
  - *Durable immune response lasting at least 6 months; a period spanning a normal RSV season.*
  - *Additional T cell responses show that MVA-BN RSV induced a strong (3-5 fold) booster response to all five RSV proteins included in the vaccine.*
- Henrik Birk appointed Chief Operating Officer

# FINANCIAL SUMMARY AND OUTLOOK

## Q1 financials as expected

- Revenues in Q1 2017 were largely derived from the sale of IMVAMUNE bulk drug substance to U.S. Government
- Remaining ~600mDKK related to IMVAMUNE expected over Q2 and Q3
- FY revenue and EBIT expectations maintained

## Revenue Q1 2017



■ IMVAMUNE US + RoW

■ R&D Contracts

	mDKK			mUSD		
	3m 2017	3m 2016	FY2017E	3m 2017	3m 2016	FY2017E
Revenue	198	23	1,300	28	3	187
EBIT	(3)	(153)	350	0	(22)	50
Cash preparedness at year-end	2,448	1,365	2,400	352	196	345

Cash preparedness includes cash, cash equivalents, investments in securities and the aggregate amount of undrawn credit lines.

USD/DKK = 6.96 (as of March 31, 2017)

All numbers are approximate.

# FINANCIAL STATEMENTS



mDKK	3m 2017	3m 2016	FY 2016
Revenue	198	23	1,007
Production costs	50	19	298
<b>Gross profit</b>	<b>148</b>	<b>4</b>	<b>709</b>
Research and development costs	100	104	463
Distribution and administrative costs	50	52	213
<b>Total operating costs</b>	<b>151</b>	<b>156</b>	<b>676</b>
<b>Income before interest and taxes (EBIT)</b>	<b>(3)</b>	<b>(153)</b>	<b>33</b>
Financial income/loss	(3)	(16)	7
<b>Income before company tax</b>	<b>(6)</b>	<b>(169)</b>	<b>40</b>
Tax	-	(40)	9
<b>Net profit for the period</b>	<b>(6)</b>	<b>(129)</b>	<b>31</b>
<b>Cash preparedness (end of period)</b>	<b>2,448</b>	<b>1,365</b>	<b>2,292</b>

USD/DKK = 6.96

# BAVARIAN NORDIC'S GOAL



To develop innovative and safe therapies against cancer and infectious diseases; to improve the health and quality of life for children and adults.

## CANCER

**PROSTVAC** *improving survival*

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**HPV** *preventing cancer before it starts*

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**CV301 &  
Brachyury  
in combination  
therapies** *potentially  
curing cancer*

## INFECTIOUS DISEASES










**RSV** *protecting the broader  
population against diseases  
with no approved therapies*

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**Smallpox /  
Ebola** *preparation and  
protection against  
global pandemic threats*

# PIPELINE



PRODUCT	INDICATION	ONGOING STUDIES	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	COMMERCIAL RIGHTS
INFECTIOUS DISEASES								
IMVAMUNE liquid-frozen <sup>1)</sup>	<i>Smallpox</i>	1						 BAVARIAN NORDIC
IMVAMUNE freeze-dried	<i>Smallpox</i>	-						 BAVARIAN NORDIC
MVA-BN Filo	<i>Ebola/Marburg</i>	10						 janssen <small>PHARMACEUTICAL COMPANY a Johnson &amp; Johnson company</small>
MVA-BN RSV	<i>RSV</i>	1						 BAVARIAN NORDIC
MVA-BN HPV	<i>Chronic HPV Infection</i>	-						 janssen <small>PHARMACEUTICAL COMPANY a Johnson &amp; Johnson company</small>
CANCER IMMUNOTHERAPY								
PROSTVAC mono	<i>Prostate Cancer</i>	1						 Bristol-Myers Squibb
PROSTVAC mono/combo	<i>Prostate Cancer</i>	10						 Bristol-Myers Squibb
CV301 + nivolumab	<i>Lung Cancer (NSCLC)</i>	1						 BAVARIAN NORDIC
MVA-BN Brachyury	<i>Metastatic Tumors</i>	-						 BAVARIAN NORDIC

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



# MOVING TOWARDS FINAL DATA FOR PROSTVAC

## ADDITIONAL COMBINATION STUDIES CONTINUES TO EXPAND POTENTIAL

- 4 new Phase 2 studies of PROSTVAC were initiated during 2016 and until today
- Now 11 ongoing trials and additional trials are in the planning
- Data from combination studies are expected from 2017 and onwards

### PROSPECT Phase 3 Trial

A Randomized, Double-blind,  
Global Phase 3 Efficacy Trial of  
PROSTVAC in Metastatic Castration-  
Resistant Prostate Cancer (N=1,297)

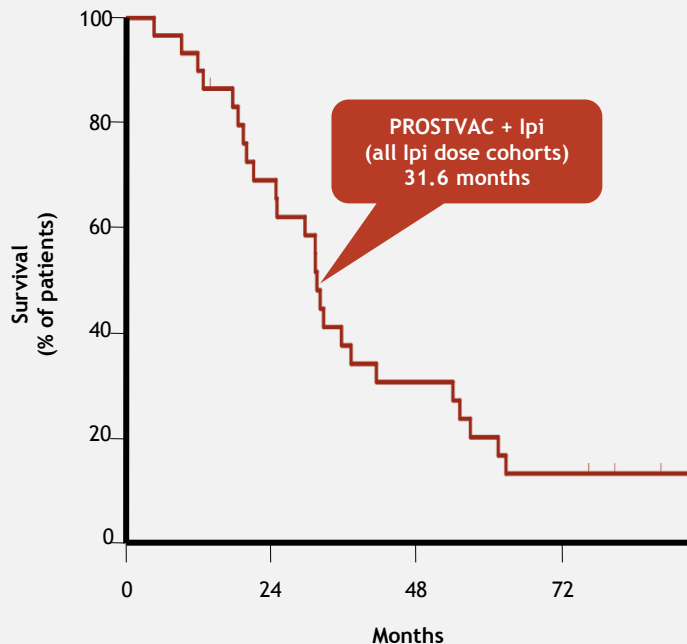
Primary endpoint: Overall survival

Interim Analysis #1	214 events	40%	✓
Interim Analysis #2	321 events	60%	✓
Interim Analysis #3	427 events	80%	Mid-2017
Final Analysis	534 events	100%	2H 2017

*Estimated timing of events*

# DEMONSTRATED POTENTIAL AS A COMBINATION THERAPY WITH BMS' IPILIMUMAB

## PROSTVAC + ipilimumab Phase 1 Trial



### 30 mCRPC Patients:

- Predicted survival average: 18.5 months
- 2 Phase 3 studies of Ipilimumab in prostate cancer **did not** show significant OS benefit

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

## Additional Phase 2 Combination Studies Neoadjuvant Prostate cancer

Phase 2  
(n=75)

PROSTVAC

ipilimumab

PROSTVAC + ipi

Ongoing  
Sponsor: UCSF  
NCT02506114

Phase 2  
(n=65)

PROSTVAC + ipi

PROSTVAC + nivo

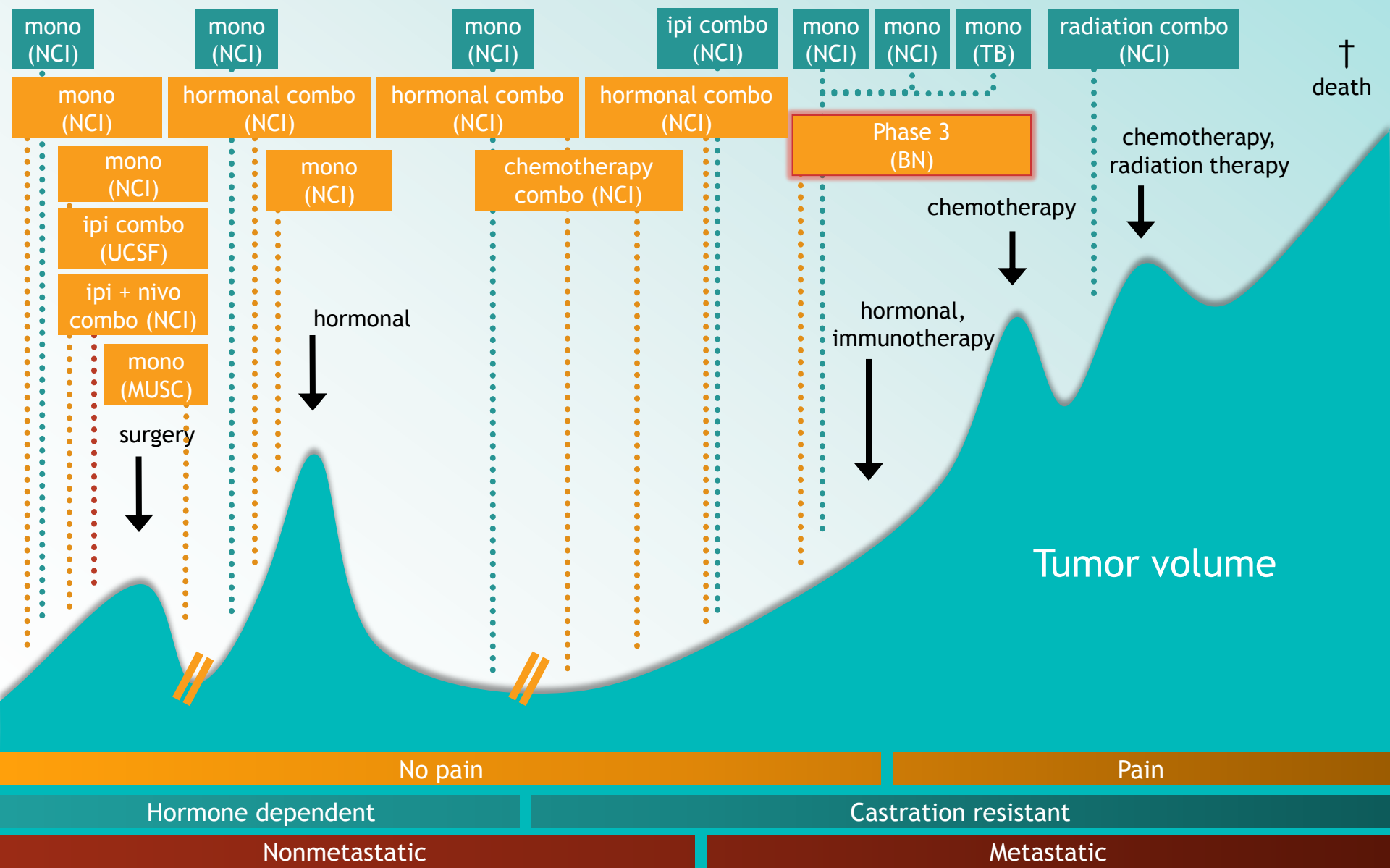
PROSTVAC + ipi + nivo

Ongoing  
Sponsor: NCI  
NCT02933255

# PROSTVAC STUDIES

## SPAN PROSTATE CANCER DISEASE LANDSCAPE

■ COMPLETED 
 ■ ONGOING 
 ■ PLANNED

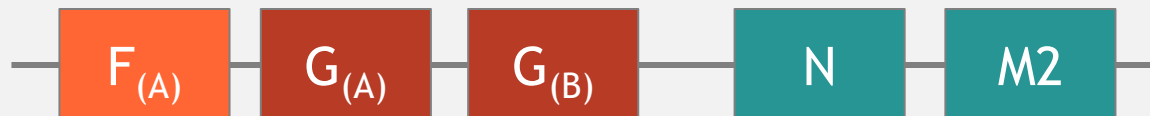


# RSV - WHY ARE WE DIFFERENT?

- RSV represents a high unmet medical need; similar disease burden and death rate in the elderly population as influenza
- Historical vaccine development provided incomplete protection
  - Possibly related to:
    - Lack of T cell production
    - Lack of mucosal protection
    - Poor duration of protection (i.e. not lasting a full season)
- Our platform allows for broad protection against multiple targets

## MVA-BN RSV - a highly differentiated approach

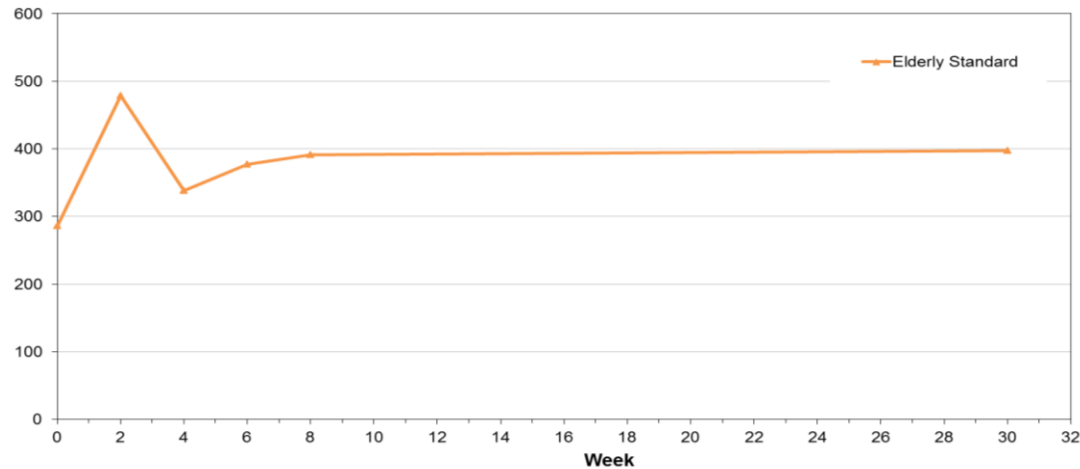
- Encodes two main surface proteins F & G
- Encodes the G surface protein from both RSV subtype A&B - poor cross reactivity between RSV subtypes
- Encodes two highly conserved internal RSV proteins (N & M2) - good inducers of T cell responses



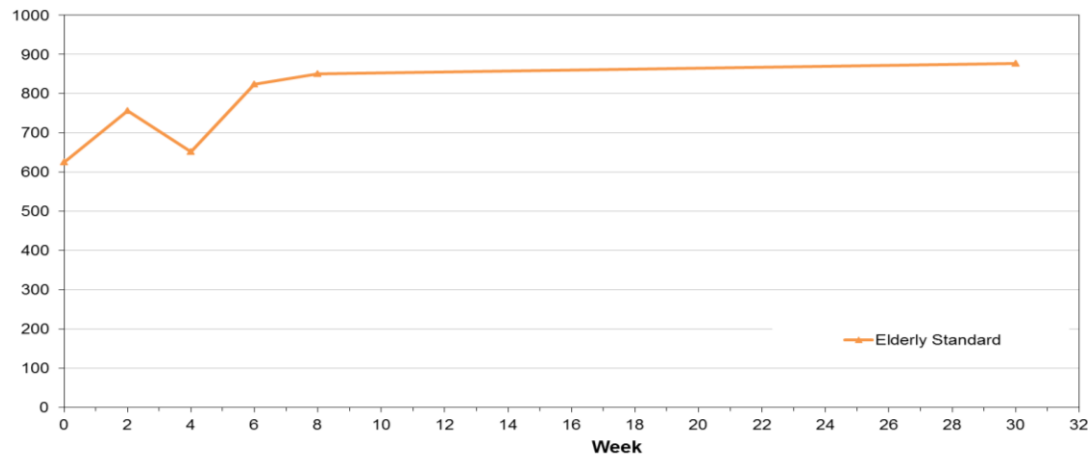
# MVA-BN RSV - PHASE 1 FOLLOW-UP DATA



## RSV antibody response by IgA ELISA (GMT)



## RSV antibody responses by PRNT (A strain)



vaccinations given at week 0 and week 4

# MVA-BN RSV PHASE 2 PROOF OF CONCEPT STUDY

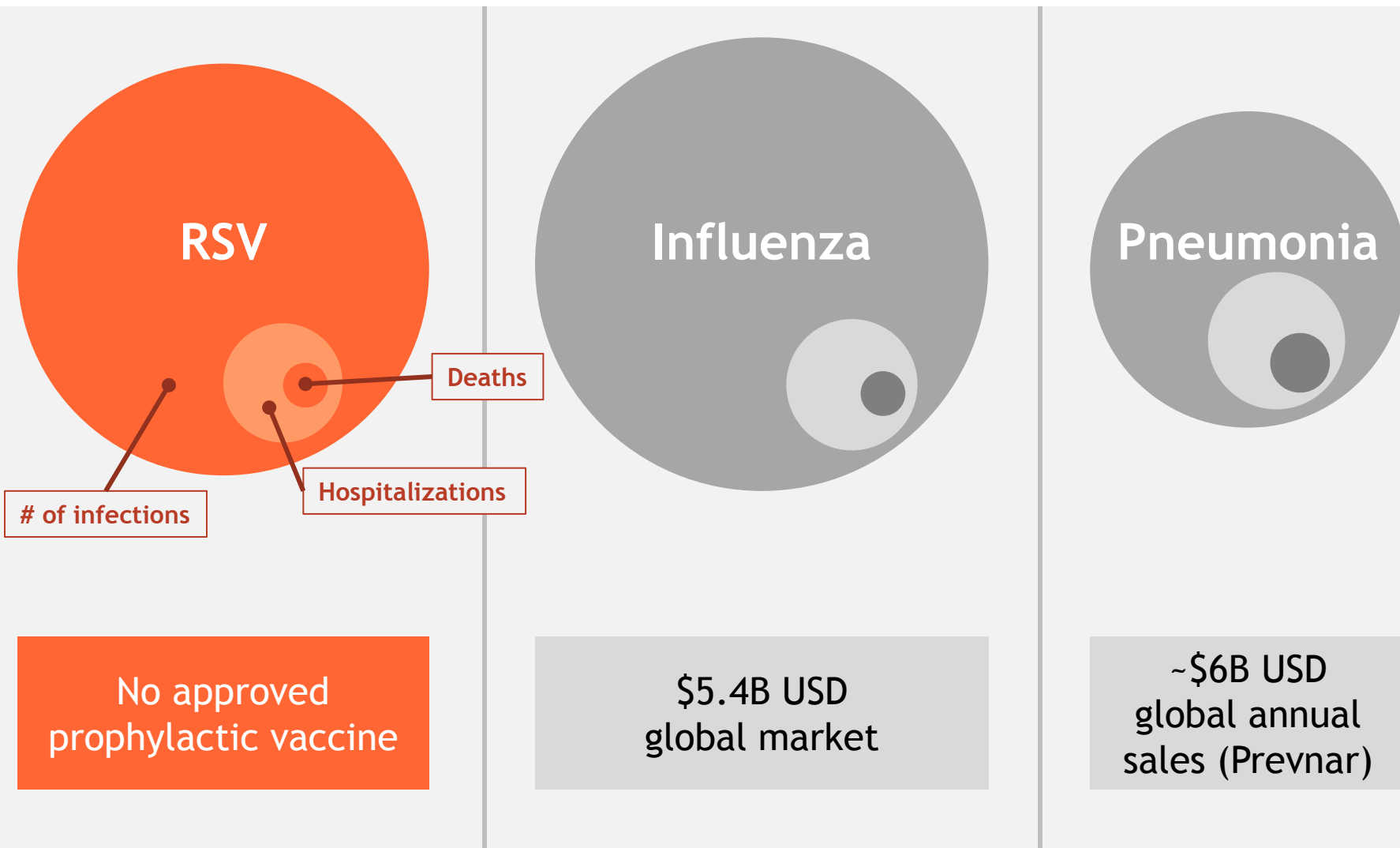
## Randomized, blinded, placebo-controlled study

- 400 healthy subjects ( $\geq 55$  years old)
- Study expected confirm results seen in phase 1 and help identify optimal dose and schedule
- Optimal group will be carried forward into 2017 RSV season with a booster dose

Groups	N	Vaccine Dose	Schedule (Day)		Route
			0	28	
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				

# RSV - A LARGE UNMET MEDICAL NEED

DEATH RATE OF RSV SIMILAR TO THAT OF INFLUENZA



# CV301

## IMMUNOTHERAPY FOR MULTIPLE CANCERS



### Exploring synergies in combination with checkpoint inhibitors

#### Non-small cell lung cancer

BN sponsored

- Ongoing proof-of-concept study of CV301 plus OPDIVO
- Collaboration with BMS to supply OPDIVO at no cost



Bristol-Myers Squibb

#### Bladder cancer

BN sponsored

- Collaboration with Roche to supply TECENTRIQ at no cost for planned Phase 2 study



#### Other indications

- Bavarian Nordic retains all commercial rights in lung, bladder, colorectal, breast, ovarian, gastric, liver and renal cancer

Exploring combinations in company collaborations or with NCI



*“Bioterrorism is a much larger risk than a pandemic”*

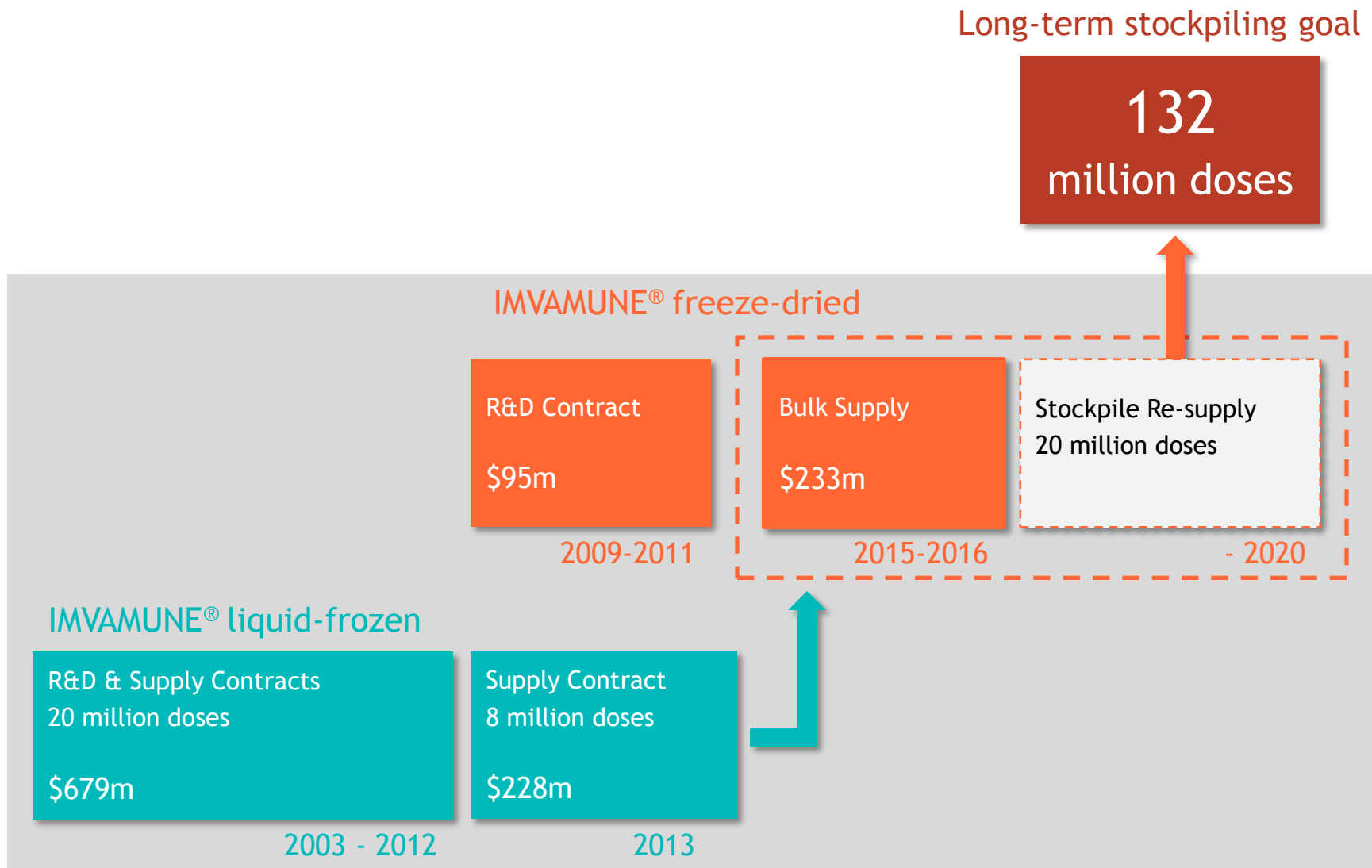


*“With nuclear weapons, you’d think you would probably stop after killing 100 million. Smallpox won’t stop. Because the population is naïve, and there are no real preparations. That, if it got out and spread, would be a larger number.”*

*“It doesn’t take much biology expertise nowadays to assemble a smallpox virus. Biology is making it way easier to create these things.”*

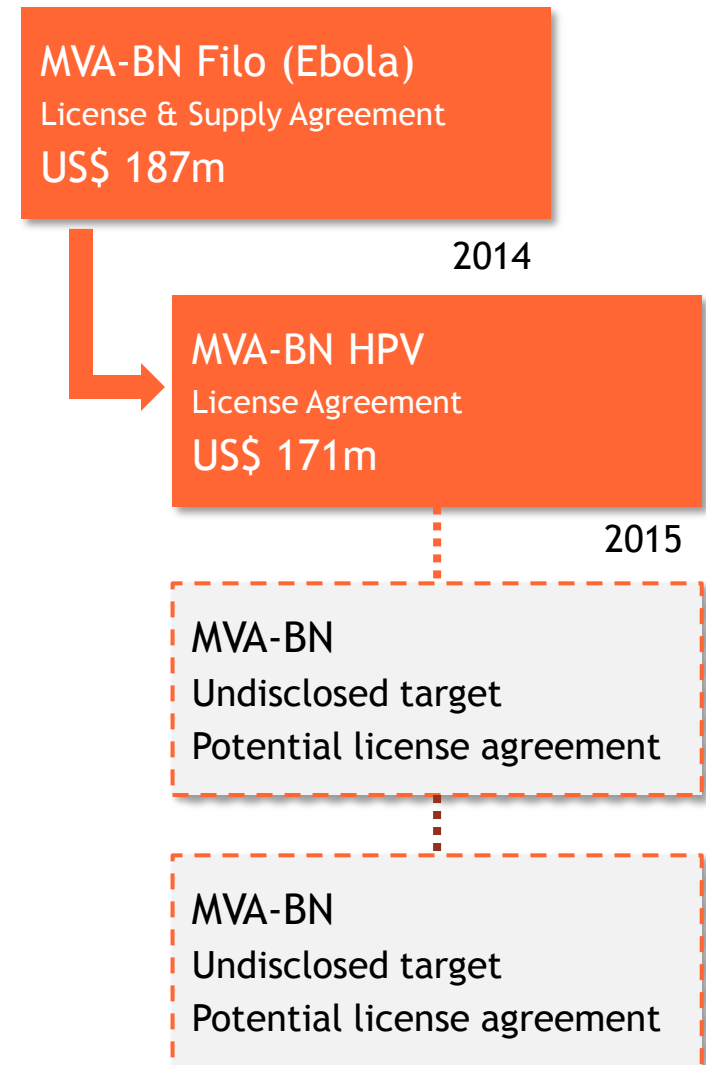
# SUCCESSFUL PARTNERSHIP WITH THE U.S. GOVERNMENT

MORE THAN \$1.2 BILLION IN R&D AND SUPPLY CONTRACTS TO-DATE



# OUR COLLABORATION WITH JANSSEN

- Janssen completed a submission for Emergency Use Assessment and Listing for the Ebola vaccine to the WHO
  - Phase 1, 2 and 3 studies ongoing
- HPV vaccine to start clinical trials in 2017
- Janssen retains option to license two additional disease targets



# ANTICIPATED SELECTED MILESTONES



## IMVAMUNE

- U.S. RFP for freeze-dried IMVAMUNE
- Top-line data for Phase 3 non-inferiority study
- Approval and Priority Review Voucher

## RSV

- MVA-BN RSV Phase 2 dosing study read out
- Select ideal dosing regimen and carry forward into second RSV season
- Establish meeting with FDA to determine appropriate registration pathway

## JANSSEN

- Initiate HPV Phase 1 study in cervical cancer
- Potential expanded collaboration on two additional infectious disease targets
- Data from Ebola prime-boost vaccine regimen
- Ebola vaccine pending approval for emergency use by WHO

## PROSTVAC

- Phase 3 top-line data including interim analyses
- Data from NCI-sponsored Phase 2 trials

## CV301

- Initiate Phase 2 study of CV301 + atezolizumab in bladder cancer
- CV301 + checkpoint inhibitor proof-of-concept studies in additional indications

## BRACHYURY

- MVA-BN Brachyury Phase 2 initiation

# Q&A



