THE FUTURE OF VACCINES

GOLDMAN SACHS
THIRD ANNUAL BIOTECH SYMPOSIUM, LONDON
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PAUL CHAPLIN, PRESIDENT & CEO
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.
**STRONG FOUNDATION FOR FURTHER DEVELOPMENT**

**PROSTVAC**

**prostate cancer**
- Partnered with Bristol-Myers Squibb
- Phase 3 fully enrolled
- Phase 3 top-line data expected in 2017
- Multiple clinical studies being advanced in earlier stages and in combination regimens

**IMVAMUNE**

**smallpox vaccine**
- Approved in EU & Canada
- 28 million doses delivered to US
- $233 million in bulk vaccine orders bridging to next-generation freeze-dried vaccine
- Recurrent orders from Canada

**Janssen**

**partnership**
- 2 license agreements in Ebola & HPV
- Moved Ebola vaccine from preclinical to Phase 3 in 9 months
- 2 million doses of Ebola vaccines produced

**Pipeline**

**projects**
- Advancing clinical development of RSV vaccine in elderly & children
- Advancing development of CV301 in combination treatment for multiple cancers
- Supporting NCI in clinical development of MVA-BN Brachyury
LIVE VIRUS VACCINE PLATFORM
VALIDATED AND MODULAR APPROACH EMPLOYING POXVIRUSES

Widely Applicable Technology for Infectious Disease and Cancer Immunotherapy
## PIPELINE

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>INDICATION</th>
<th>ONGOING STUDIES</th>
<th>PRECLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>MARKET</th>
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<td><strong>INFECTIOUS DISEASES</strong></td>
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<tr>
<td>IMVAMUNE liquid-frozen 1)</td>
<td>Smallpox</td>
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<td>BARDA</td>
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<td>IMVAMUNE freeze-dried</td>
<td>Smallpox</td>
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<td>MVA-BN Filo</td>
<td>Ebola/Marburg</td>
<td>9</td>
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<td>Janssen</td>
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<tr>
<td>MVA-BN HPV</td>
<td>Chronic HPV Infection</td>
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<td><strong>CANCER IMMUNOTHERAPY</strong></td>
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<td>PROSTVAC</td>
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<td>Bristol-Myers Squibb</td>
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<td>CV301</td>
<td>Bladder Cancer</td>
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<td>NCI</td>
<td></td>
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<td>MVA-BN Brachyury</td>
<td>Metastatic Tumors</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>NCI</td>
<td></td>
</tr>
</tbody>
</table>

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.
COMMERCIAL MANUFACTURING CAPABILITIES

Commercial Production Facility

- Inspected by the EMA and the FDA
- 28M doses of IMVAMUNE delivered to US national stockpile
- Over 2M doses of MVA-BN Filo (Ebola) delivered to Janssen

Poxvirus Manufacturing Expertise

- Commercial partnerships in place with Janssen & BMS
- All manufacturing performed by BN
- Company has developed IP and extensive know-how in the production of poxvirus based vaccines

Multi-Product Facility

- Highly scalable, fully integrated, reduces dependency on sub-contractors
- Fill/Finish established to support commercial launch of PROSTVAC
- Production of all clinical trial material
IMVAMUNE
SMALLPOX VACCINE
### Status

- Only non-replicating smallpox vaccine approved in the EU
- Commercialized in liquid frozen formulation
- Stockpiled by the US government (EUA)\(^{(a)}\)
- Phase 3 trial ongoing to support FDA approval
- 7,600 patients dosed

### Revenue Generation

- Awarded ~$1.2B in contracts from the US government, of which more than $950M has been received
- Recognized $126M and $154M in revenue in 2013 and 2014, respectively

### Freeze Dried

- Demonstrated bioequivalence
- Potential 10+ year shelf life
- Potentially no storage limitations
- Supports US government’s long-term stockpiling goals

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\(^{(a)}\) Emergency Use Authorization.
**IMVAMUNE PARTNERSHIP WITH THE U.S.**

**IMVAMUNE® liquid-frozen**
- R&D & Supply Contracts
  - 20 million doses
  - $679m
  - 2003 - 2012
- Supply Contract
  - 8 million doses
  - $228m
  - 2013

**IMVAMUNE® freeze-dried**
- R&D Contract
  - $95m
  - 2009-2011
- Bulk Supply
  - $233m
  - 2015-2016

**Long-term stockpiling goal**
- 132 million doses
- Stockpile Resupply
  - 20 million doses
  - 2013
- More than $1.2bn in R&D and supply contracts to-date

**BAVARIAN NORDIC**
JANSSEN COLLABORATION
OUR COLLABORATION WITH JANSSEN

MVA-BN Filo (Ebola)
License & Supply Agreement
US$ 187m

2014

MVA-BN HPV
License Agreement
US$ 171m

2015

MVA-BN
Undisclosed target
Potential license agreement

MVA-BN
Undisclosed target
Potential license agreement

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.
FIRST IN HUMAN DATA FOR THE BAVARIAN NORDIC/JANSSEN EBOLA PRIME-BOOST VACCINE

- 72 healthy volunteers randomized into four groups receiving prime-boost vaccine regimen or placebo at intervals of 28 or 56 days

- An open-label arm with 15 healthy volunteers is also investigating a shorter prime-boost interval of 14 days for Ad26.ZEBOV prime and MVA-BN Filo boost

AdVac + MVA-BN Provides Durable Response

Phase 2 & 3 Clinical Trials Ongoing in the US, EU and Africa
MVA-BN RSV
RESPIRATORY Syncytial Virus Vaccine Candidate
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

**Development strategy**

<table>
<thead>
<tr>
<th>2H2016</th>
<th>2017</th>
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</thead>
<tbody>
<tr>
<td>Elderly + Adults at risk</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Children &gt;5yrs</td>
<td>Phase 2 field efficacy</td>
</tr>
<tr>
<td></td>
<td>Phase 1/2</td>
</tr>
</tbody>
</table>
MVA-BN AN IDEAL RSV VACCINE PLATFORM

MVA-BN RSV

- Based upon the MVA-BN vaccine vector - favorable safety profile, approved in EU & Canada and commercial manufacturing in-place
- Designed to generate a balanced antibody and T cells responses to both RSV subtypes (A&B)
  - 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

Construct was designed for a balanced immune response to minimize the risk of enhanced disease & encourage cross strain reactivity (protection against both RSV subtypes)
MVA-BN-RSV INDUCES A BALANCED IMMUNE RESPONSE SIMILAR TO A NATURAL RSV INFECTION

**Total anti-RSV antibodies**

<table>
<thead>
<tr>
<th>Condition</th>
<th>RSV-IgG in serum (GMT +/− SEM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBS</td>
<td></td>
</tr>
<tr>
<td>RSV-A2</td>
<td></td>
</tr>
<tr>
<td>MVA-BN-RSV</td>
<td></td>
</tr>
<tr>
<td>FI-RSV</td>
<td></td>
</tr>
</tbody>
</table>

**RSV neutralizing antibodies**

<table>
<thead>
<tr>
<th>Condition</th>
<th>nAb in serum (GMT +/− SEM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBS</td>
<td></td>
</tr>
<tr>
<td>RSV-A2</td>
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<tr>
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<td></td>
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<tr>
<td>FI-RSV</td>
<td></td>
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</tbody>
</table>

**T cell responses**

<table>
<thead>
<tr>
<th>Condition</th>
<th>INFγ-secreting cells per million splenocytes</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBS</td>
<td></td>
</tr>
<tr>
<td>RSV-A2</td>
<td></td>
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<tr>
<td>MVA-BN-RSV</td>
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<tr>
<td>FI-RSV</td>
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</tbody>
</table>
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

Randomized, placebo controlled study, 63 healthy subjects
# NEXT STEPS: PHASE 2 DOSE RANGING IN ELDERLY (≥55 YEARS OLD)

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

<table>
<thead>
<tr>
<th>Groups</th>
<th>N</th>
<th>Vaccine Dose</th>
<th>Schedule (Day)</th>
<th>Route</th>
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<tbody>
<tr>
<td>1</td>
<td>80</td>
<td>Low</td>
<td>0: MVA-BN RSV</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>28: Placebo</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>80</td>
<td>Low</td>
<td>0: MVA-BN RSV</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>28: MVA-BN RSV</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>80</td>
<td>High</td>
<td>0: MVA-BN RSV</td>
<td>IM</td>
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<td></td>
<td></td>
<td></td>
<td>28: Placebo</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>80</td>
<td>High</td>
<td>0: MVA-BN RSV</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>28: MVA-BN RSV</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>80</td>
<td>-</td>
<td>0: Placebo</td>
<td>IM</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>28: Placebo</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>400</strong></td>
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</tbody>
</table>

**Objectives**
- Identify optimal dose and schedule

**Timelines**
- Initiate enrolment fall 2016
- Topline data available mid-2017
PROSTVAC
IMMUNOTHERAPY FOR PROSTATE CANCER
PROSTVAC
PRIME/BOOST PSA TARGETED “OFF THE SHELF” CANCER VACCINE

Heterologous prime/boost regimen

V

Vaccinia or MVA + Fowlpox

F

Subcutaneous administration

PSA
CEA, MUC-1
HER-2
Brachyury

Tumor antigens with epitopes enhanced for HLA binding

Prostate, lung, head & neck, bladder, colorectal, breast, ovarian and renal cancers

TRICOM (TRIad of COstimulatory Molecules)

Enhance T-Cell activation in synergistic manner

Strengthen the anticancer immune response

Safe and well tolerated (11 clinical trials)

Injection site reactions and flu-like symptoms
PROSTVAC INDUCES A STRONG T-CELL RESPONSE AND ANTIGEN CASCADE AGAINST PROSTATE CANCER CELLS

Summary of T-cell responses from six PROSTVAC clinical trials

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA-Specific Immune response</td>
<td>56.7% (59/104)</td>
<td>28 days after last vaccine</td>
</tr>
<tr>
<td>Median fold increase in PSA-specific immune response</td>
<td>5X</td>
<td>PSA response 30 / 10⁶ cells</td>
</tr>
<tr>
<td>PSA response 30 / 10⁶ cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flu response 33 / 10⁶ cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antigen Cascade</td>
<td>67.9% (19/28)</td>
<td></td>
</tr>
<tr>
<td>Anti-PSA Ab</td>
<td>0.57% (2/349)</td>
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</tbody>
</table>

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)

- **Rest of World** (n=333) - 25.7%
- **North America Oncology** (n=239) - 18.4%
- **North America Urology** (n=229) - 17.7%
- **Western Europe** (n=497) - 38.2%
- **Australia, Estonia, Israel, Poland, Russia**
- **USA, Canada**

3 study arms

- PROSTVAC + GM-CSF
- PROSTVAC
- Placebo

Injections

- Average was **6.1 injections**
- Randomized Phase 2 trial (n=122) had average of 5.4 injections
- 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 7th dosing visit. N=1,279
2) Kantoff et al., Journal of Clinical Oncology, January 2010
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

<table>
<thead>
<tr>
<th>Interim Analysis</th>
<th>✓</th>
<th>Events</th>
<th>Percentage</th>
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<tr>
<td>Interim Analysis #1</td>
<td>✓</td>
<td>214</td>
<td>40%</td>
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<tr>
<td>Interim Analysis #2</td>
<td>✓</td>
<td>321</td>
<td>60%</td>
</tr>
<tr>
<td>Interim Analysis #3</td>
<td></td>
<td>427</td>
<td>80%</td>
</tr>
<tr>
<td>Final Overall Survival</td>
<td></td>
<td>534</td>
<td>100%</td>
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## PROSTVAC COMMERCIAL LICENSE WITH BMS

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<th>Value</th>
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<tr>
<td>Upfront payment</td>
<td>$60M</td>
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<tr>
<td>License</td>
<td>$80M</td>
</tr>
<tr>
<td>Phase 3 data</td>
<td>$50M</td>
</tr>
<tr>
<td>Data-driven milestones</td>
<td>$180M*</td>
</tr>
<tr>
<td>Regulatory milestones</td>
<td>$110M</td>
</tr>
<tr>
<td>Sales milestones</td>
<td>$495M</td>
</tr>
<tr>
<td>Tiered royalties on future sales</td>
<td>High teens up to mid-twenties</td>
</tr>
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* Based on Phase 2 data
PROSTVAC PHASE 2 RESULTS

Significantly extended overall survival

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Deaths</th>
<th>Median OS</th>
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</thead>
<tbody>
<tr>
<td>Control</td>
<td>40</td>
<td>37</td>
<td>16.6</td>
</tr>
<tr>
<td>PROSTVAC</td>
<td>82</td>
<td>65</td>
<td>25.1</td>
</tr>
</tbody>
</table>

Δ 8.5 months improvement in OS

Hazard ratio
0.56 (95% CI 0.37–0.85)
p=0.0061

Pivotal data of approved agents:
Provenge®: ΔOS = 4.1 mo (AS/MS mCRPC)
Zytiga®: ΔOS = 5.2 mo (pre-chemo mCRPC)
Xtandi®: ΔOS = 2.2 mo (pre-chemo mCRPC)

Reference
Package insert Sipuleucel-T, enzalutamide and abiraterone

Overall Survival Analysis of a Phase II Randomized Controlled Trial of a Poxviral-Based PSA-Targeted Immunotherapy in Metastatic Castration-Resistant Prostate Cancer
Kantoff et al., Journal of Clinical Oncology, January 2010
PROSTVAC PHASE 2 RESULTS: ADDITIONAL ANALYSIS

Significantly extended overall survival

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Deaths</th>
<th>Median OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>41</td>
<td>33</td>
<td>16.3</td>
</tr>
<tr>
<td>PROSTVAC</td>
<td>84</td>
<td>57</td>
<td>26.2</td>
</tr>
</tbody>
</table>

Δ 9.9 months improvement in OS

Hazard ratio
0.50 (95% CI 0.32–0.78)
p=0.0019

Pivotal data of approved agents:
Provenge®: ΔOS = 4.1 mo (AS/MS mCRPC)
Zytiga®: ΔOS = 5.2 mo (pre-chemo mCRPC)
Xtandi®: ΔOS = 2.2 mo (pre-chemo mCRPC)

Reference
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Overall Survival Analysis of a Phase II Randomized Controlled Trial of a Poxviral-Based PSA-Targeted Immunotherapy in Metastatic Castration-Resistant Prostate Cancer
Kantoff et al., Journal of Clinical Oncology, January 2010

Revised in 2016
DEMONSTRATED POTENTIAL AS A COMBINATION THERAPY WITH BMS’ IPILIMUMAB

PROSTVAC + ipilimumab Phase 1 Trial

![Graph showing survival data for PROSTVAC + ipilimumab Phase 1 Trial]

- 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

Additional Phase 2 Combination Studies:

Neoadjuvant Prostate cancer

- **Phase 2 (n=75)**
  - PROSTVAC
  - ipilimumab
  - PROSTVAC + ipi
  - Sponsor: UCSF
  - Clinicaltrials.gov NCT02506114

- **Phase 2 (n=28)**
  - PROSTVAC + ipi + nivo
  - PROSTVAC + ipi
  - Sponsor: NCI

CV301
IMMUNOTHERAPY FOR MULTIPLE CANCERS
CV301 CANCER IMMUNOTHERAPY
DESIGNED FOR THE TREATMENT OF MULTIPLE CANCERS

New and improved vaccine construct based on MVA-BN

MVA-BN + CEA + MUC-1 = CV301

Lung, Breast, Colorectal, Ovarian, Gastric, Bladder, Liver and Renal cancer

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

NSCLC BN sponsored

Bladder Exploring combinations with PD-1/PD-L1 in company collaborations or with NCI

Colorectal
COMPLETE TUMOR REGRESSION FROM POXVIRUS-BASED IMMUNOTHERAPY COMBINED WITH PD-1 & LAG-3 BLOCKADE

CT26-HER2 solid tumor model:
MVA-BN-HER2 immunotherapy (s.c.) and/or anti-PD1 + anti-LAG3 antibody (i.p.)
Q2wks x2 (d1 and 15)

Durable Response After Mice Were Re-Challenged
PHASE 2 CV301 & NIVOLUMAB COMBINATION IN NSCLC

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

Randomization

CV301 + Nivolumab N=60
Nivolumab (Mono) N=60

Endpoints:
- Safety, tolerability
- Primary endpoint: OS
- Secondary endpoints: ORR, DOR, PFS, Immune effects

Multi-center trial: Up to 20 sites in USA

On August 15th BN and BMS announced a joint collaboration for the supply of drug material (nivolumab)
- BMS will supply nivolumab at no cost to BN
- Bavarian Nordic retains all commercial rights to CV301
MVA-BN BRACHYURY

NOVEL IMMUNOTHERAPY FOR CANCER METASTASIS
These findings show for the first time that advanced cancer patients can be safely immunized with an MVA-based vaccine targeting brachyury, and can develop brachyury-specific T-cell immune responses.¹

**Dose Level** | **Dose and Schedule**
---|---
1 (N=3) | 1 site of injection at 2 x 108 IU given every 28 days for 3 doses
2 (N=17) | 2 sites of injection at 2 x 108 IU given every 28 days for 3 doses
3 (N=18) | 4 sites of injection at 2 x 108 IU given every 28 days for 3 doses

¹Heery, Donahue, et al.
FINANCIALS & OUTLOOK
FINANCIAL PERFORMANCE

- Revenues of more than DKK 1bn for the fourth consecutive year
- Break-even result for third consecutive year
- Cash preparedness doubled since 2013
# ANTICIPATED SELECTED MILESTONES

## 2016/2017

### PROSTVAC

**prostate cancer**

- Phase 3 top-line data including interim analyses
- Data from NCI-sponsored Phase 2 trials
- Initiate Phase 2 study in combination with ipilimumab in collaboration with BMS
- Initiate NCI-sponsored Phase 2 study in combination with ipilimumab and nivolumab

### Janssen

**partnership**

- Complete Phase 2 and Phase 3 studies of the Ebola prime-boost vaccine regimen
- Initiate HPV Phase 1 study in cervical cancer
- Potential expanded collaboration with Janssen on two additional infectious disease targets

### IMVAMUNE

**smallpox vaccine**

- Finalize manufacturing activities to support a U.S. EUA for freeze-dried IMVAMUNE
- Additional Rest of World orders
- Complete enrolment of Phase 3 non-inferiority study

### Pipeline

**projects**

- MVA-BN RSV Phase 2 dosing study initiation + read out
- MVA-BN RSV Phase 2 field efficacy initiation
- MVA-BN RSV Phase 1 pediatric study initiation
- MVA-BN Brachyury Phase 2 initiation
- CV301 + nivo Phase 2 initiation in lung cancer
- CV301 + checkpoint inhibitor Phase 2 initiation in two additional indications