THE FUTURE OF VACCINES

JANUARY 2016
This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation constitute forward-looking statements, including statements regarding future results of operations, financial position, strategy and plans of Bavarian Nordic A/S (the “Company”), and the Company's expectations for future operations.

These forward-looking statements include, but are not limited to, statements about: the timing of data from our ongoing Phase 3 PROSPECT Trial of PROSTVAC and the ongoing Phase 3 trial of IMVAMUNE/IMVANEX; our receipt of future milestone payments from our collaboration partners, and the expected timing of such payments; our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use; our expectations regarding the potential advantages of our product candidates over existing vaccines or immunotherapies; our potential to enter into new collaborations; our expectations with regard to the ability to develop additional product candidates using our MVA-BN platform and file INDs for such product candidates; our expectations with regard to our current and future collaboration partners to pursue the development of our product candidates; our development plans with respect to our product candidates; our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials; the timing or likelihood of regulatory filings and approvals for our product candidates; the commercialization of our product candidates; our commercialization, marketing and manufacturing capabilities; the implementation of our business model and strategic plans for our business, product candidates and technology platform; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates; estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital; our financial performance; and developments and projections relating to our competitors and our industry. Moreover, the Company operates in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for the Company's management to predict all risks, nor can the Company assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied.

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MULTIPLE LAYERS OF VALUE

1 approved product
8 active programs

2 focus areas
Infectious Disease & Oncology

3 Phase 3 Products
Multiple near-term milestones

Validated Platform Technology
(NIH, BARDA, BMS, Janssen)

Expertise in T-Cell Stimulation & Antibody Response

$1.2B in US government contracts
$900M in revenues over past 10 years
$975M BMS deal - PROSTVAC
$358M Janssen deals - Ebola and HPV

Broad Pipeline & Late-Stage Candidates

Strong Revenue Base to Re-Invest in Clinical Pipeline
LIVE VIRUS VACCINE PLATFORM
VALIDATED AND MODULAR APPROACH EMPLOYING POXVIRUSES

Wide Variety of Target Diseases

Low

High

Vectors

Antigens

Promoters

Co-Stimulatory Molecules (TRICOM)

Antigenic Complexity

Wide Variety of Target Diseases

Recombinant Poxviruses

Customized Immunogenicity

Simple

Complex

Target Multiple Antigens for a Single Disease

Widely Applicable Technology for Infectious Disease and Cancer Immunotherapy
## MULTIPLE ASSETS DRIVING VALUE

<table>
<thead>
<tr>
<th>PRODUCT CANDIDATE</th>
<th>INDICATION</th>
<th>COMMERCIAL RIGHTS</th>
<th>PRIMER / BOOSTER</th>
<th>PRECLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>APPROVED</th>
<th>STATUS / EXPECTED MILESTONES</th>
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<td>janssen</td>
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<td></td>
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<td>• Phase 1 trial data in 1H16</td>
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</tr>
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</table>

(a) An adenovirus primer from Janssen.
(b) BMS would have complete commercial rights to PROSTVAC, regardless of treatment setting, should they exercise their licensing agreement.
(c) Anticipated transition to MVA primer.
(d) Anticipated transition to Fowlpox booster.
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
# Infectious Disease Pipeline

<table>
<thead>
<tr>
<th>Product Candidate</th>
<th>Indication</th>
<th>Commercial Rights</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
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<th>Approved</th>
<th>Status / Expected Milestones</th>
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Pipeline Driven by Live Virus Vaccine Platform
## IMVAMUNE / IMVANEX PRODUCT SUMMARY

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<tr>
<th>Status</th>
<th>Revenue Generation</th>
<th>Freeze Dried</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Only non-replicating smallpox vaccine approved in the EU</td>
<td>• Awarded ~$1.2B in contracts from the US government, of which more than $900M has been received</td>
<td>✓ Demonstrated bioequivalence</td>
</tr>
<tr>
<td>• Commercialized in liquid frozen formulation</td>
<td>• Recognized $126M and $154M in revenue in 2013 and 2014, respectively</td>
<td>✓ Potential 10+ year shelf life</td>
</tr>
<tr>
<td>• Stockpiled by the US government (EUA)(^{(a)})</td>
<td></td>
<td>✓ Potentially no storage limitations</td>
</tr>
<tr>
<td>• Phase 3 trial ongoing to support FDA approval</td>
<td></td>
<td>✓ Supports US government’s long-term stockpiling goals</td>
</tr>
<tr>
<td>• 7,600 patients dosed</td>
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</table>

\(^{(a)}\) Emergency Use Authorization.
SUCCESSFUL PARTNERSHIP WITH THE US GOVERNMENT
CONTRACTS AWARDED OF ~$1.2B TO DATE, OF WHICH MORE THAN $900M HAS BEEN RECEIVED
NEW CONTRACT SIGNALS THE BEGINNING OF FREEZE DRIED IMVAMUNE ORDERS

RECENT EVENTS CONTINUE TO DRIVE CONFIDENCE

• $22M expansion to higher capacity line for freeze dried (April 2014)
• 2016 presidential budget lists freeze dried IMVAMUNE (Feb 2015)
• Phase 2 freeze dried met primary endpoint of equivalence to liquid frozen (May 2015)
  • Meeting clinical criteria for EUA stockpiling
• $133M Bulk order of IMVAMUNE by BARDA (July 2015)
  • Allows for transition to freeze dried once RFP occurs and freeze dried pricing can be established
• Phase 3 lot-to-lot trial complete (May 2015)
• $6.4M order of IMVAMUNE by PHAC (October 2015)

FREEZE DRIED POTENTIAL

• 20M doses expired by mid-2017 (liquid frozen)
• Long-term stated goal of US government calls for non-replicating vaccine for 66M US citizens (132M doses)
  • Supplied liquid frozen doses at $29 per dose

(a) Public Health Agency of Canada
IMVAMUNE FREEZE DRIED & LIQUID FROZEN FORMULATIONS INDUCE EQUIVALENT IMMUNE RESPONSES

Pivotal Phase 2 randomized, double-blind in 650 healthy vaccinia-naïve volunteers

Antibody responses induced by freeze dried and liquid frozen formulations were equivalent

Similar data have also been generated in the various animal efficacy models
FIRST IMVAMUNE PHASE 3 DATA AVAILABLE

• First of two **Phase 3 trials** to support a BLA for **liquid frozen IMVAMUNE**

• Placebo-controlled lot consistency trial in 4,000 vaccinia-naïve subjects
  • 3,000 IMVAMUNE subjects (three arms) compared to 1,000 placebo subjects

• **Primary endpoint met:** The three lots induced equivalent antibody responses

• **No cardiac events** reported among IMVAMUNE vaccinated subjects
  • ACAM2000® (approved in the United States) has recorded high rates of cardiac complications in healthy vaccinees (5.73 events per 1000 immunizations\(^{(a)}\))

• **Second Phase 3 trial** ongoing in military personnel with enrollment completion expected in 2017

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### Janssen Deal
- $45M licensing agreement grants Janssen full commercialization rights
- BN eligible to receive royalties outside of Africa
- Additional supply agreement of $99M
- Equity investment of $43M (~5% of BN)

### Clinical Status
- Janssen presented preliminary Phase 1 data in May 2015
- Multicenter Phase 2 clinical trial initiated in July 2015 in the United Kingdom and France
- Phase 2 trial (n=1,200) and a Phase 3 trial have been initiated in Africa
  - Data expected in 2016

### Additional Commercial Targets
- Entered into subsequent $171M agreement with Janssen for a therapeutic HPV vaccine in December 2015
- Two additional undisclosed targets also being explored
- MVA-BN is a promising booster to existing Janssen technology (AdVac from Crucell)

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**Advanced from Phase 1 to Phase 3 in < 12 Months**
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
EXPANSION OF JANSSEN COLLABORATION: HPV VACCINE
$171M AGREEMENT SIGNED IN DECEMBER 2015

• Subsequent to the Ebola collaboration, BN and Janssen agreed to collaborate on three additional infectious disease targets

• The first indication now licensed with Janssen (December 2015)

• A therapeutic vaccine for individuals with an active human papillomavirus (HPV) infection
  • Represents a novel approach for early treatment and interception of HPV-induced cancers
  • High-risk HPV types cause approximately 5 percent of all cancers worldwide

### MVA-BN HPV DEAL STRUCTURE

• Total potential agreement value $171 million including $9 million upfront plus milestone payments and single-digit royalties on sales

• Janssen expected to initially focus on infected women at risk for cervical cancer, and then head and neck cancers

• Bavarian Nordic to retain manufacturing of MVA based component
RSV: Respiratory Syncytial Virus

- No approved vaccine; high unmet medical need
- Responsible for a similar number of deaths as the flu in children up to 14, as well as in the elderly population
- Results in a high number of hospitalizations

MVA-BN RSV vaccine candidate

- Demonstrated strong immune response
- Blood and mucosal protection (*key differentiator*)
- Protection against both RSV subtypes (A&B) in preclinical models
- Received NIH funding (*preclinical efficacy*)

DEVELOPMENT STRATEGY

2015

- **Elderly + Adults at risk**
  - Phase 1- Fully Enrolled

- **Children <5yrs**

2016

- **Phase 2 - Initiate 2H**
- **Phase 1/2**
MVA-BN RSV BOOSTS PRE-EXISTING MEMORY RESPONSES

MVA-BN Boosts Pre-Existing Responses

IgG in Serum

Mucosal IgA

Neutralizing Antibodies Boosted in Blood and Mucosa (Lung), As Well As T-Cells
MVA-BN RSV PHASE 1 INITIATED IN THE UNITED STATES

• Fully enrolled Phase 1, randomized, single-blind, monocenter, placebo controlled
• Healthy subjects, 18 - 65 years of age, N = 63
• **Primary objective:** Safety and reactogenicity of MVA-mBN294B (MVA-BN RSV vaccine)
• **Secondary objective:** RSV-specific (ELISA, PRNT, ELISPot/ICS) and vaccinia-specific immune response to MVA-BN-RSV vaccine

<table>
<thead>
<tr>
<th>Groups</th>
<th>N</th>
<th>Age (years)</th>
<th>Vaccine</th>
<th>Dose per 0.5 ml (nominal titers)</th>
<th>Schedule (Days)</th>
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<td>18+3</td>
<td>18-49</td>
<td>MVA-BN RSV /placebo</td>
<td>$1 \times 10^7 \text{ TCID}_{50}$</td>
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<td>2</td>
<td>18+3</td>
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<td>MVA-BN RSV /placebo</td>
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<td>3</td>
<td>18+3</td>
<td>50-65</td>
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<tr>
<td><strong>Total</strong></td>
<td>54+9 = 63</td>
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Data Expected 1H16
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<sup>(a)</sup> BMS would have complete commercial rights to PROSTVAC, regardless of treatment setting, should they exercise their licensing agreement.

<sup>(b)</sup> Treatment given to shrink the tumor before the main treatment.
## BMS Collaboration
- Up to $975M in upfront and milestone payments
  - $60M upfront payment
  - $420M in pre-commercial milestones
- Entitled to tiered double-digit royalties on future sales
- BN to retain all commercial production responsibilities

## Monotherapy
- Phase 3 PROSPECT trial fully enrolled (n=1,298)
- 3 interim analyses likely starting in 1Q16
- Top-line data expected in 2017

## Combination Potential With Checkpoint Inhibitor
- Induces antigen cascade, indicating promise with checkpoint inhibitors
- Demonstrated benefit with ipilimumab in NCI trial
- Five ongoing NCI trials
- BMS will initiate trial with a checkpoint inhibitor by early 2016

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**Phase 3 “Off-The-Shelf” Vaccine for Prostate Cancer**
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

V 
Heterologous prime/boost regimen

Vaccinia or MVA + Fowlpox

Subcutaneous administration

Safe and well tolerated (11 clinical trials)

Injection site reactions and flu-like symptoms
PROSTVAC INDUCES AN ANTIGEN CASCADE AGAINST PROSTATE CANCER CELLS

Summary of T-cell responses from six PROSTVAC clinical trials

<table>
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<th>Result</th>
<th>Comment</th>
</tr>
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<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 / $10^6$ cells flu response 33 / $10^6$ cells</td>
</tr>
<tr>
<td>Antigen Cascade</td>
<td>67.9% (19/28)</td>
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<tr>
<td>Anti-PSA Ab</td>
<td>0.57% (2/349)</td>
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PROSTVAC PHASE 2 DATA
MOST PRONOUNCED SURVIVAL TO DATE IN PROSTATE CANCER

Significantly extended overall survival

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<th>Group</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 2 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
32 mCRPC patients enrolled with median age 65.6

Improvement of 9.2 months compared to Halabi Score

# PREDICTED SURVIVAL (HALABI) VERSUS ACTUAL

<table>
<thead>
<tr>
<th></th>
<th>All patients</th>
<th>Patients with Halabi Predicted Survival &lt; 18 months</th>
<th>Patients with Halabi Predicted Survival ≥ 18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine PROSTVAC (n=32)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median survival predicted by Halabi score (months)</td>
<td>17.4</td>
<td>12.3</td>
<td>20.9</td>
</tr>
<tr>
<td>Actual median overall survival (months)</td>
<td>26.6</td>
<td>14.6</td>
<td>≥ 37.3 (not reached)</td>
</tr>
<tr>
<td>Patients surviving longer than predicted by Halabi nomogram</td>
<td>22 of 32 (69%)</td>
<td>10 of 17 (59%)</td>
<td>12 of 15 (80%)</td>
</tr>
<tr>
<td>Difference (months)</td>
<td>9.2</td>
<td>2.3</td>
<td>≥ 16.4</td>
</tr>
<tr>
<td>Median survival predicted by Halabi score (months)</td>
<td>16.5</td>
<td>13.0</td>
<td>21.0</td>
</tr>
<tr>
<td>Actual median overall survival (months)</td>
<td>15.5</td>
<td>15.4</td>
<td>16.9</td>
</tr>
<tr>
<td>Patients surviving longer than predicted by Halabi nomogram</td>
<td>11 of 22 (50%)</td>
<td>8 of 13 (62%)</td>
<td>3 of 9 (33%)</td>
</tr>
<tr>
<td>Difference (months)</td>
<td>(-1.0)</td>
<td>2.4</td>
<td>(-4.1)</td>
</tr>
</tbody>
</table>

## ENTRY CRITERIA

<table>
<thead>
<tr>
<th>Randomized Phase 2</th>
<th>PROSPECT Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ECOG &lt; 2</strong></td>
<td><strong>No visceral metastases</strong></td>
</tr>
<tr>
<td>No visceral metastases</td>
<td>Asymptomatic (no cancer-related pain requiring narcotics)</td>
</tr>
<tr>
<td>No prior chemotherapy</td>
<td>No prior chemotherapy</td>
</tr>
</tbody>
</table>
| - Gleason score ≤ 7 (from original biopsy) | - Removed Gleason score exclusion  
  - Gleason grade not associated with treatment effect in other phase 3 mCRPC trials (sip-T, ipilimumab) |
| - No alkaline phosphatase exclusion | - Changed to exclude patients with alk phos > 2 times ULN  
  - Excludes more advanced metastatic disease |
| - No LDH exclusion | - Changed to exclude patients with LDH > 2 times ULN  
  - Excludes more advanced metastatic disease |
| - No PSA doubling time (PSA-DT) exclusion | - Added exclusion for patients with PSA-DT < 1 month  
  - Excludes patients with fast growing tumors |
| - Minimum PSA value for determination of CRPC = 5 ng/mL (PCWG1) | - Minimum PSA value for determination of CRPC lowered to 2 ng/mL (PCWG2) |
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 between active and placebo 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
  • First interim analysis likely in 1Q16

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, United Kingdom & United States

3 trial arms
PROSTVAC + GM-CSF
PROSTVAC
Placebo
Randomization by region
N=1,298

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

Injections

- Average was 6.1 injections\(^1\)
- Randomized Phase 2 trial (n=122) had average of 5.4 injections\(^2\)
- 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\(^{th}\) dosing visit. N=1,279

2) Kantoff et al., Journal of Clinical Oncology, January 2010
DEMONSTRATED POTENTIAL AS A COMBINATION THERAPY WITH BMS’ IPILIMUMAB

PROSTVAC Phase 2 Trial

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

BMS to Initiate Combination Trial with a Checkpoint Inhibitor In Early 2016


Further investigation of PROSTVAC in collaboration with BMS

- Two new investigator-sponsored trials planned for initiation

**Phase 2**

- **(n=75)**
  - Open label combination trial in localized prostate cancer using PROSTVAC and ipilimumab as neoadjuvant therapy.
  - Randomization 1:1:1
  - PROSTVAC
  - ipilimumab
  - PROSTVAC + ipi
  - Sponsor: UCSF
  - Clinicaltrials.gov NCT02506114

- **(n=28)**
  - Open label combination trial in prostate cancer using PROSTVAC, ipilimumab and nivolumab as neoadjuvant therapy
  - PROSTVAC + ipi + nivo
  - PROSTVAC + ipi
  - Sponsor: NCI
## Ongoing NCI-Sponsored Prostvac Trials

<table>
<thead>
<tr>
<th>Stage</th>
<th>Indication</th>
<th>Trial Design</th>
<th>Key Endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 2 (n=38)</td>
<td>Non-metastatic castration sensitive prostate cancer</td>
<td>PROSTVAC + enzalutamide vs. enzalutamide alone</td>
<td>Decrease in tumor re-growth rate (PSA kinetics) after three months of enzalutamide</td>
</tr>
<tr>
<td>Phase 2 (n=76)</td>
<td>Metastatic castration sensitive prostate cancer</td>
<td>PROSTVAC + enzalutamide vs. enzalutamide alone</td>
<td>Time to progression</td>
</tr>
<tr>
<td>Phase 2 (n=27)</td>
<td>Patients undergoing treatment with radical prostatectomy</td>
<td>PROSTVAC as neoadjuvant therapy</td>
<td>Effect on immune cells (measured by CD4 and CD8 cell infiltrate response) in the prostate</td>
</tr>
<tr>
<td>Phase 2 (n=62)</td>
<td>Non-metastatic prostate cancer</td>
<td>PROSTVAC + flutamide vs. flutamide alone</td>
<td>Time to treatment failure</td>
</tr>
<tr>
<td>Phase 2 (n=90)</td>
<td>Localized prostate cancer, active surveillance</td>
<td>PROSTVAC</td>
<td>Immune response</td>
</tr>
</tbody>
</table>
TRIALS SPAN PROSTATE CANCER DISEASE LANDSCAPE

- **Active surveillance (NCI)**
- **enza combo (NCI)**
- **flutamide combo (NCI)**
- **enza combo (NCI)**
- **Phase 3 (BN)**

- **Neoadjuvant (NCI)**
- **Ipi combo (BN & BMS)**
- **Ipi + Nivo combo (NCI)**

- surgery

- **ADT**

- **Tumor volume**

- **No pain**

- **Pain**

- **Hormone dependent**

- **Castration resistant**

- **Nonmetastatic**

- **Metastatic**

- **Mechanism of action**
  - Immune infiltration to tumor, immune response, biomarkers, and PSA kinetics

- **Use in combination**
  - With currently approved therapies for mCRPC, and with checkpoint inhibitors

- **Use in earlier prostate cancer to support future label expansion**
  - More trials planned in early disease indications

Abbreviations:
- ADT
- docetaxel
- sip-T
- enza
- abi, enza, Ra-223, cabazitaxel
- Ipi
- Nivo
CV 301 IMMUNOTHERAPY VACCINE CANDIDATE

Heterologous prime/boost regimen

Vaccinia or MVA + Fowlpox

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 (six clinical trials)

Injection site reactions and flu-like symptoms

TRICOM

TAA
LFA-3
ICAM-1
B7.1
High unmet need remains for patients with PD-L1 low/negative tumors

- Scientific rationale for CV 301 combination:
  - Inducing antigen-specific tumor-infiltrating CD8 T-Cells provoke up-regulation of tumor PD-L1 expression in patients
  - Combination CV 301 + PD blockade therapy more likely to achieve efficacy in patients with PD-L1 low/negative tumors
  - CV 301 is believed to convert non-expressing PD-L1 tumors into immune-responsive tumors by inducing PD-L1 expression, potentially resulting in a higher overall therapeutic response
  - Poxvirus-based immunotherapy induces high IFNγ-producing CD8 TILs
  - PD-L1 tumor expression is up-regulated in response to CD8 TILs and IFNγ
UPREGULATION OF PD-L1 AFTER CV-301 TREATMENT
MC38-MUC1 MOUSE CRC MODEL

Control

Tissue harvest: day 25

CV-301 VFF

1E7 Inf. U CV-301-V on day 4
5E7 Inf. U CV-301-F on day 11 and
18
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
**OVEREXPRESSISON OF CEA AND MUC-1 IN CARCINOMAS**

<table>
<thead>
<tr>
<th>Carcinoma</th>
<th>CEA</th>
<th>MUC-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>&gt;90%</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>Pancreatic</td>
<td>&gt;95%</td>
<td>&gt;95%</td>
</tr>
<tr>
<td>Lung¹</td>
<td>70%</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>Bladder</td>
<td>70%</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>Breast</td>
<td>50%</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>Ovarian</td>
<td>15%</td>
<td>&gt;90%</td>
</tr>
</tbody>
</table>

¹ Expression higher in Adenocarcinoma than in Squamous

Expect to Initiate Phase 2 in 2016

Currently being evaluated
# MVA-BN BRACHYURY
**PHASE 1 NOVEL IMMUNOTHERAPY CANDIDATE WITH BROAD POTENTIAL**

<table>
<thead>
<tr>
<th>Indications</th>
<th>Development Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chordoma (ultra-orphan disease)</td>
<td>• NCI Phase 1 and Phase 2 trials</td>
</tr>
<tr>
<td>• Triple negative breast cancer</td>
<td>• NCI Phase 2 chemotherapy combination trial(s)</td>
</tr>
<tr>
<td>• NSCLC</td>
<td>• NCI erlotinib combination trial(s)</td>
</tr>
<tr>
<td>• Multiple solid tumors</td>
<td>• NCI and BN immune checkpoint inhibitor combinations</td>
</tr>
</tbody>
</table>

- Brachyury expression is highly correlated with metastatic disease, and multi-drug resistance
- Brachyury is not expressed in most normal tissue
- Brachyury is responsible for epithelial to mesenchymal transition (EMT), which is a major driver of metastasis
BRACHYURY IS ABERRANTLY OVEREXPRESSED IN LUNG TUMORS

Collaboration with Drs. Guadagni and Roselli, Rome, Italy

<table>
<thead>
<tr>
<th>Lung tumor</th>
<th>% Brachyury positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenocarcinoma</td>
<td>10/21 (48%)</td>
</tr>
<tr>
<td>Squamous carcinoma</td>
<td>3/12 (25%)</td>
</tr>
<tr>
<td>Other</td>
<td>3/6 (50%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>16/39 (41%)</strong></td>
</tr>
<tr>
<td>Normal Adjacent to Tumor</td>
<td>7/24 (29%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Normal Tissue</th>
<th>% Brachyury positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
<td>0/3 (0%)</td>
</tr>
<tr>
<td>Brain</td>
<td>0/3 (0%)</td>
</tr>
<tr>
<td>Liver</td>
<td>0/3 (0%)</td>
</tr>
<tr>
<td>Kidney</td>
<td>0/3 (0%)</td>
</tr>
<tr>
<td>Spleen</td>
<td>0/3 (0%)</td>
</tr>
<tr>
<td>Adrenal Gland</td>
<td>0/1 (0%)</td>
</tr>
<tr>
<td>Lung</td>
<td>0/3 (0%)</td>
</tr>
<tr>
<td>Skin</td>
<td>0/1 (0%)</td>
</tr>
<tr>
<td>Skeletal Muscle</td>
<td>0/3 (0%)</td>
</tr>
<tr>
<td>Testis</td>
<td>3/3 (100%)</td>
</tr>
<tr>
<td>Thyroid</td>
<td>4/6 (67%)</td>
</tr>
</tbody>
</table>

Brachyury Expression in Lung Cancer Correlates with Tumor Stage

- **Adenocarcinoma**: 10/21 (48%)
- **Squamous CA.**: 3/12 (25%)
- **Other**: 3/6 (50%)
- **Total**: 16/39 (41%)

- **Normal Adjacent to Tumor**: 7/24 (29%)

Roselli et al., Clin Can Res. 2012

Fernando et al., J Clin Invest. 2010
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

¹Heery, Donahue, et al.
## CANCER IMMUNOTHERAPY MILESTONES

<table>
<thead>
<tr>
<th>Product Candidate</th>
<th>Expected Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROSTVAC in mCRPC</td>
<td>Three interim analyses likely starting in 1Q16 with top-line data in 2017</td>
</tr>
<tr>
<td>PROSTVAC in Localized Prostate Cancer (neoadjuvant)</td>
<td>Phase 2 data in 2016</td>
</tr>
<tr>
<td>PROSTVAC in Non-Metastatic Prostate Cancer</td>
<td>Phase 2 data in 1H16</td>
</tr>
<tr>
<td>CV 301 in Lung Cancer</td>
<td>Initiate Phase 2 Trial in H216</td>
</tr>
</tbody>
</table>
## FINANCIAL OVERVIEW

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTM Revenue(^{(1)})</td>
<td>$187M(^*)</td>
</tr>
<tr>
<td>LTM EBIT(^{(1)})</td>
<td>$21M(^*)</td>
</tr>
<tr>
<td>Cash &amp; Equivalents(^{(2)})</td>
<td>$185M(^*)</td>
</tr>
</tbody>
</table>

### FACTS

- Founded 1994, IPO 1998
- Listed on Nasdaq Copenhagen: BAVA
- Level 1 ADR: BVNRY
- 28.0m shares outstanding/\~29.3m fully diluted
- Market cap DKK 10.0bn\(^{(3)}\) / $1.5B\(^*\)
- \~27,000 registered shareholders

\(^{(1)}\) For the twelve months ended September 30, 2015.
\(^{(2)}\) As of September 30, 2015.
\(^{(3)}\) As of December 31, 2015.
APPENDIX
PROSTVAC - PATIENT CASE HISTORY ("FRANK")
PUBLISHED 2013 CASE REPORT IN CLINICAL GENITOURINARY CANCER

Gleason grade: 4 + 3 = 7

- Trend before radical prostatectomy (■)
- Trend after radical prostatectomy. External beam radiation (■)
- Trend after first vaccine trial (■)
- Trend after second vaccine trial (■)

PSA

Trend before radical prostatectomy (■)
Trend after radical prostatectomy. External beam radiation (■)
Trend after first vaccine trial (■)
Trend after second vaccine trial (■)

Age

61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82

Radical Prostatectomy
External Beam Radiation
Vaccine Treatment
Second Vaccine Treatment

PSA

1,000,0
100,0
10,0
1,0
0,1

5.8 months DT (doubling time)
9.6 months DT
28.6 months DT
INCREASED LAG-3 STAINING AFTER COMBINATION TREATMENT

MVA-BN-HER2 immunotherapy (s.c.) and/or anti-PD1 mAb 10mg/kg (i.p.), Q2wks x 2 (d1 and d15)

Tissue harvest: day 16

MVA-BN-HER2 + anti-PD1
PSA Waterfall Plot: Ipi/Prostvac

Figure: Best PSA response after treatment
14 (58%) of 24 patients who were chemotherapy-naive had PSA declines; six (25%) had PSA declines greater than 50%. PSA = prostate specific antigen.
Patients with a strong PSA specific T-cell response responded better (p = 0.0055)

The median survival of placebo mCRPC patients from several Phase 3 trials reported in the same period ranged from 12.2 to 21.7.  

WHY DO SOME PATIENTS RESPOND BETTER TO PROSTVAC?

All patients could mount an immune response to the vaccine backbone.

Antibody titer to fowlpox

Less T regulatory cell activity in responders

% change in suppressive function

> predicted survival

< predicted survival

≥ 18 months

< 18 months

Predicted Survival by Halabi Nomogram

≥ 18 months

< 18 months
SYNERGY OF POXVIRUS-BASED IMMUNOTHERAPY COMBINED WITH PD-1 AXIS BLOCKADE

MVA-BN-HER2 immunotherapy (s.c.) and/or anti-PD1 mAb 10mg/kg (i.p.)

Q2wks x 2 (d1 and d15)

Very strong synergy
Chou-Talalay: CI < 0.031

** p < 0.01
**** p < 0.0001
TUMOR INFILTRATION BY HIGHLY ACTIVATED CYTOTOXIC T-CELLS

Lung/Tumors (day 25)

Antigen-specific CTL Activity

Day 1: CT26-HER2 i.v.
Day 4, 18: MVA-BN-HER2

Foy et al. (2014) ASCO poster; Manuscript submitted

Activated phenotype:
CD44⁺, ICOS⁺, PD-1<sup>mid</sup>
KLRG1⁺, CD127⁺/-
**BRACHYURY IS ABERRANTLY OVEREXPRESSED IN BREAST TUMORS**

<table>
<thead>
<tr>
<th>Breast tissue type</th>
<th>% Brachyury positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Invasive Ductal Ca.</td>
<td>27/30 (90%)</td>
</tr>
<tr>
<td>Benign Breast disease</td>
<td>2/16 (12.5%)*</td>
</tr>
<tr>
<td>Breast Ca. Metastases</td>
<td>6/6 (100%)</td>
</tr>
</tbody>
</table>

(*) focal staining

Brachyury expression correlates with high risk recurrence in breast cancer patients treated with Tamoxifen only

Data provided by Kim Lyerly, Duke Univ.
### COMMERCIAL LICENSE WITH BMS

<table>
<thead>
<tr>
<th>Elements</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upfront payment</td>
<td>$60M</td>
</tr>
<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>Double-digit</td>
</tr>
</tbody>
</table>

* Based on Phase 2 data