
# ANNUAL REPORT 2012

12 March 2013

BAVARIAN NORDIC

# Accomplishments 2012 & 2013

- Financial result and cash position strongly improved

## CANCER VACCINES

- PROSPECT study: 10 countries now active, remaining countries to open within the next 3 months
- Additional CRO resources engaged; intensified dialogue with sites
- Encouraging CV-301 data in breast cancer presented

## INFECTIOUS DISEASES

- 8.3m IMVAMUNE® doses delivered to the SNS in 2012 (1.3m above target)
- Productivity and profitability significantly improved; division now profitable
- Phase 3 trial for IMVAMUNE® initiated
- USG expanded the population eligible to receive IMVAMUNE®
- Additional USD 55 million in funding awarded by USG
- Marketing application submitted to the European Medicines Agency

# 2012 Financials Better Than Expected

| | | Realized | Outlook as of March 2012 |
|---|---|---|---|
| **Revenue** | ↑ | **DKK 1,017 m** | DKK 850 m |
| **Result (loss) before tax** | ↑ | **DKK -49 m** | DKK -200 m |
| **Cash preparedness at year-end** | ↑ | **DKK 670 m** | DKK 350 m |

# New Head of Cancer Vaccines Division

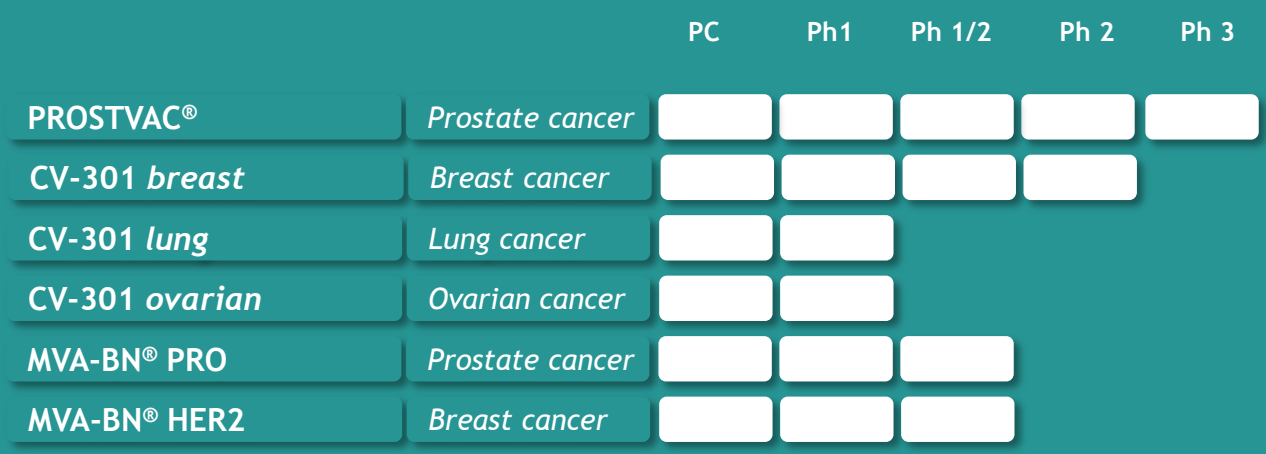
**James Breitmeyer, M.D., Ph.D.**
*EVP and Division President, Cancer Vaccines*

- More than 20 years of experience from the pharmaceutical industry, prior executive positions with Cadence Pharmaceuticals Inc, Applied Molecular Evolution Inc., (Eli Lilly), Harvard Clinical Research Institute and Serono
- Taught at Dana Farber Cancer Institute and Harvard Medical School
- 7 regulatory approvals
- Joined Bavarian Nordic in February 2013

# Cancer Vaccines

PROSTVAC

## Therapeutic vaccine platform for major cancers



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# PROSPECT study

- Global study in 1,200 mCRPC* patients
- Three study arms: PROSTVAC® + GM-CSF | PROSTVAC® | Placebo
- Primary endpoint is overall survival
- Enrolment rate increasing

**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**

- Trial execution improved at CRO and additional resources engaged
- 10 countries active, 80+ sites
  - US, Canada, Spain, UK, Iceland, Estonia, Belgium, Denmark, Israel & Russia
- Remaining countries to open within next 3 months



* mCRPC: Metastatic Castration-Resistant Prostate Cancer

# Ongoing PROSTVAC® Studies

| Study design | Target | Endpoint |
|---|---|---|
| Phase 3 randomized, double-blind, placebo-controlled efficacy trial of PROSTVAC® +/- GM-CSF (n=1,200) | Asymptomatic or minimally symptomatic mCRPC* | Overall survival |

**NCI funded studies:**

| | | |
|---|---|---|
| Phase 2 study comparing enzalutamide with/without PROSTVAC® (n=72) | mCRPC | Time to progression |
| Phase 2 study comparing flutamide (antihormone) with/without PROSTVAC® (n=65) | Non-metastatic prostate cancer | Time to progression |
| Phase 2 study of PROSTVAC® treatment followed by PROSTVAC® and hormonal therapy at disease progression. (n=50) | Patients with PSA progression after local therapy (surgery and/or radiation) | PSA progression at 6 months |

PROSTVAC® has more clinical data from combination trials and trials in earlier disease stages than other prostate cancer immunotherapies



* mCRPC: Metastatic Castration-Resistant Prostate Cancer

# CV-301 immunotherapy candidate

- CV-301 has been the subject of 16 ongoing or completed NCI-sponsored clinical trials in more than 500 patients with different cancers
- Most recently, encouraging data from a Phase 2 combination study of CV-301 and docetaxel in metastatic breast cancer indicated potential clinical benefit
- The preliminary analysis of the study showed PFS of 6.6 months in the CV-301 group versus 3.8 months among those receiving docetaxel alone (HR=0.67, p=0.12). The clear separation of the curves indicates potential clinical benefit
- Currently, the overall data generated for CV-301 are being assessed in order to determine the future development strategy
- Concurrently, the company is working to improve the CV-301 technology, through the design of new vaccine constructs based on the MVA-BN® technology

# Cancer Vaccines - Short Term Objectives

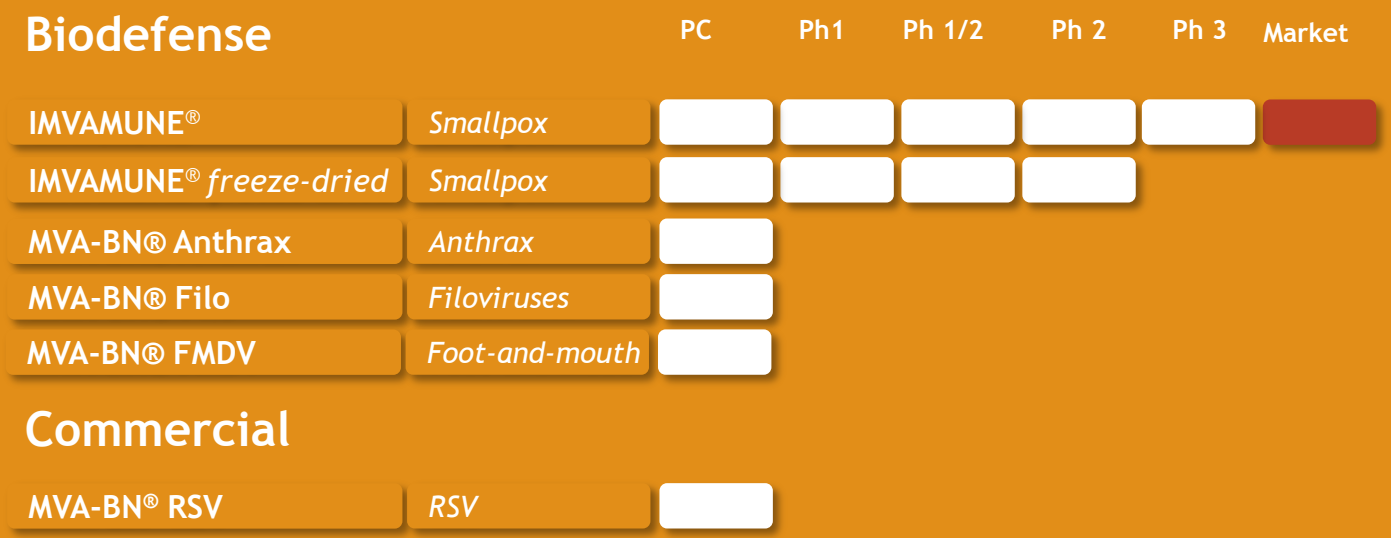
- Complete enrolment in the PROSTVAC® Phase 3 trial (PROSPECT)
- Report data from NCI-sponsored clinical trials of PROSTVAC®
- Report data from NCI-sponsored clinical trials of CV-301 and determine future development strategy
- Prepare the Kvistgaard facility for commercial manufacturing of PROSTVAC®

# Infectious Diseases

IMVAMUNE

## Leading supplier of vaccines for biodefense

### Biodefense




### Commercial



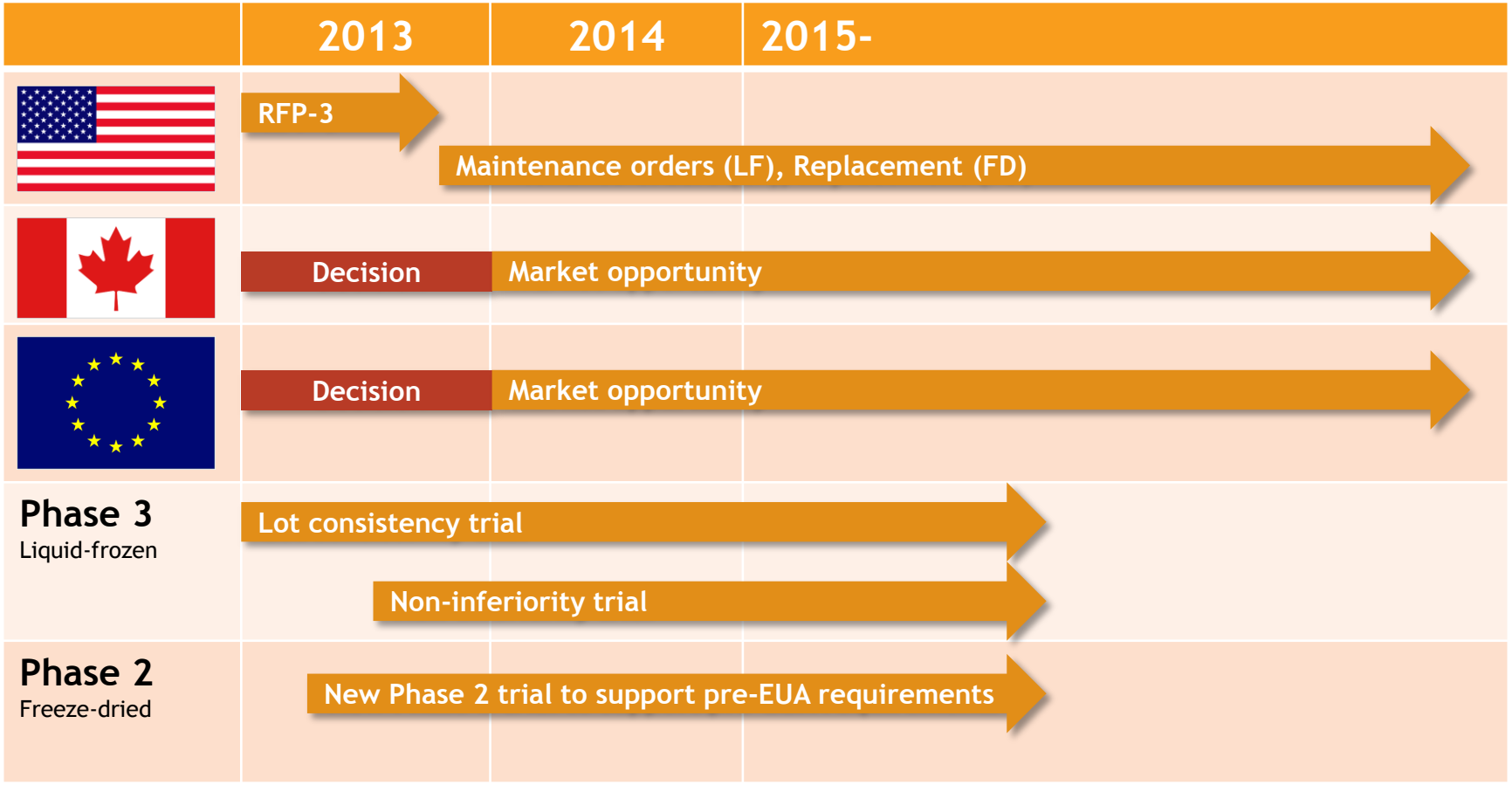

Sold to government stockpiles under national emergency rules

# IMVAMUNE® Delivery Status

| Deliveries to the U.S. Strategic National Stockpile | |
|---|---|
| Delivered in 2010 | 2m doses ✓ |
| Delivered in 2011 | 4m doses ✓ |
| Delivered in 2012 | 8.3m doses ✓ |
| *Planned deliveries in 2013* | *7m doses* |

1.3 million doses above target

# IMVAMUNE® - Anticipated Developments




**LF: Liquid-frozen**
**FD: freeze-dried**



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# Flexible Manufacturing

**Consolidation of manufacturing competences in Kvistgaard:**

- Benefit from the in-house expertise in poxvirus-based vaccines
- Optimize the use of the Kvistgaard facility
- BN obtains greater control and reduced dependence upon subcontractors
- Opportunity to further improve profitability

**Short, medium and long-term manufacturing requirements:**

- IMVAMUNE® for the U.S. and other government contracts
- Prepare for the future commercial production of PROSTVAC®
- Production of clinical trial material

# Infectious Diseases - Short Term Objectives

- Deliver 7 million doses of IMVAMUNE® to the U.S. Strategic National Stockpile in 2013
- Ensure sustainable and growing profitability in division
- Complete enrolment in the IMVAMUNE® Phase 3 lot consistency trial
- Initiate Phase 3 non-inferiority trial of IMVAMUNE®
- Obtain marketing authorization for IMVAMUNE® in Canada
- Obtain marketing authorization for IMVANEX® (IMVAMUNE®) in the EU
- Initiate Phase 2 study with the freeze-dried version of IMVAMUNE® to support emergency use

# 2012 Financial Expectations - Development

| *DKK million* | Mar-12 Annual Report | Aug-12 Q2 Report | Nov-12 Q3 Report | Nov-12 Canada order | Realized |
|---|---|---|---|---|---|
| **Revenue** | **850** | **900** | **975** | **1,000** | **1,017** |
| **Result (loss) before tax** | **-200** | **-150** | **-70** | **-50** | **-49** |
| **Cash preparedness at year-end** | **350** | **400** | **525** | **540** | **670** |
| ***Assumptions*** | | | | | |
| IMVAMUNE® - deliver and recognize | 7m doses | 7.5m doses | >8m doses | >8m doses | **8.3m doses** |
| R&D costs - GROUP | 400 | 400 | 370 | 370 | **357** |
| Infectious Disease Division, EBIT | 110 to 130 | 230 | 300 | 300 | **334** |
| Cancer Vaccines Division, EBIT | -250 to -270 | -280 | -250 | -250 | **-275** |

*All numbers are approximate.*
*Division's EBIT are before allocation of internal charges.*
*R&D costs include additional approx. DKK 100 million in contract costs (stated under production costs in the profit and loss statement) and capitalized R&D costs.*



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# Financial Outlook

| | 2013 |
|---|---|
| **Revenue** | **DKK 1,100m** |
| **Income before tax** | **DKK 0m** |
| **Cash preparedness at year-end** | **DKK 600m** |

**Assumptions:**

Figures are based upon the expected award of a new IMVAMUNE® delivery contract in H1 2013 and that up to 7 million doses will be delivered and revenue recognized

| | |
|---|---|
| R&D costs - GROUP | * DKK 460m |
| Infectious Disease Division, EBIT | DKK 360m |
| Cancer Vaccines Division, EBIT | DKK -325m |

*All numbers are approximate*
** R&D costs include additional approximately DKK 110 million in contract expenses (stated under production costs in the profit and loss statement).*

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.

# Financial Statements

| DKK million | FY 2012 | FY 2011 |
|---|---|---|
| Revenue | 1,017 | 524 |
| Production costs | 514 | 403 |
| **Gross profit** | **503** | **120** |
| Research and development costs | 357 | 262 |
| Distribution and administrative costs | 177 | 167 |
| **Total operating costs** | **535** | **428** |
| **Income before interest and taxes** | **(32)** | **(308)** |
| Financial income/loss | (17) | 12 |
| **Income before company tax** | **(49)** | **(296)** |
| Tax | 191 | 28 |
| **Net profit for the period** | **(240)** | **(268)** |
| | | |
| Cash preparedness **(end of period)** | **670** | **704** |

# RFP-3 Contract as of 31 December 2012

| USD million | | P&L | | Cash Flow | |
|---|---|---|---|---|---|
| | Contract value | Revenue recognised | To be recognised | Received | To be received |
| Upfront & Milestone | **183** | 152 | 31 | 182 | 1 |
| Deliveries 2010-2013 | **270** | 195 | 75 | 189 | 81 |
| Hold-back | **49** | - | 49 | - | 49 |
| Misc. Services | **47** | 20 | 27 | 20 | 27 |
| **TOTAL** | **549** | **367** | **182** | **391** | **158** |

*Based on 14.389 million doses delivered*



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# Overview of USG Contracts as of 31 December 2012

| USD million | | P&L | | Cash Flow | |
|---|---|---|---|---|---|
| | Contract value | Revenue recognised | To be recognised | Received | To be received |
| RFP-3 | **549** | 367 | 182 | 391 | 158 |
| RFP-2 | **116** | 115 | 1 | 115 | 1 |
| RFP-1 | **14** | 14 | 0 | 14 | 0 |
| RFP Freeze-dried | **95** | 24 | 71 | 22 | 73 |
| Marburg | **18** | 0 | 18 | 0 | 18 |
| Foot-and-mouth | **1** | 0 | 1 | 0 | 1 |
| **TOTAL** | **793** | **520** | **273** | **542** | **251** |



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