

# Interim Results as of 30 September 2013

# Q3

14 November 2013

# Financial Highlights

- Infectious Disease division remains profitable
- 5 million doses IMVAMUNE® delivered to the SNS during first nine months
- Full year financial expectations maintained

	9m 2013	9m 2012
Revenue	DKK 875m	DKK 750m
Income before tax	DKK -18m	DKK 17m
Cash preparedness	DKK 546m	DKK 666m

# Highlights from the third quarter

## Infectious Diseases

- IMVANEX® received marketing authorization in Europe - first product approval for the company
- Enrollment of all 4,000 subjects in the first of two U.S. Phase 3 studies of IMVAMUNE® was completed
- Deliveries of IMVAMUNE to the U.S. Strategic National Stockpile under 20m dose base contract nearly completed; now initiating deliveries under new contract

## Cancer Immunotherapy

- PROSPECT study: 160+ sites in 13 countries now active
- Two Phase 2 studies combining PROSTVAC® and enzalutamide initiated
- Pipeline assessment and prioritization performed; CV-301 in colorectal cancer will be the next target for further clinical development

# Short/Mid-Term Objectives

- Complete enrollment in the PROSTVAC Phase 3 trial (PROSPECT) (H1, 2014)
- Report data from NCI-sponsored clinical trials of PROSTVAC
- Prepare the Kvistgaard facility for commercial manufacturing of PROSTVAC
- Deliver 7 million doses of IMVAMUNE® to the U.S. Strategic National Stockpile in 2013
- Initiate final Phase 3 trial of IMVAMUNE®
- Decision on marketing application for IMVAMUNE® in Canada

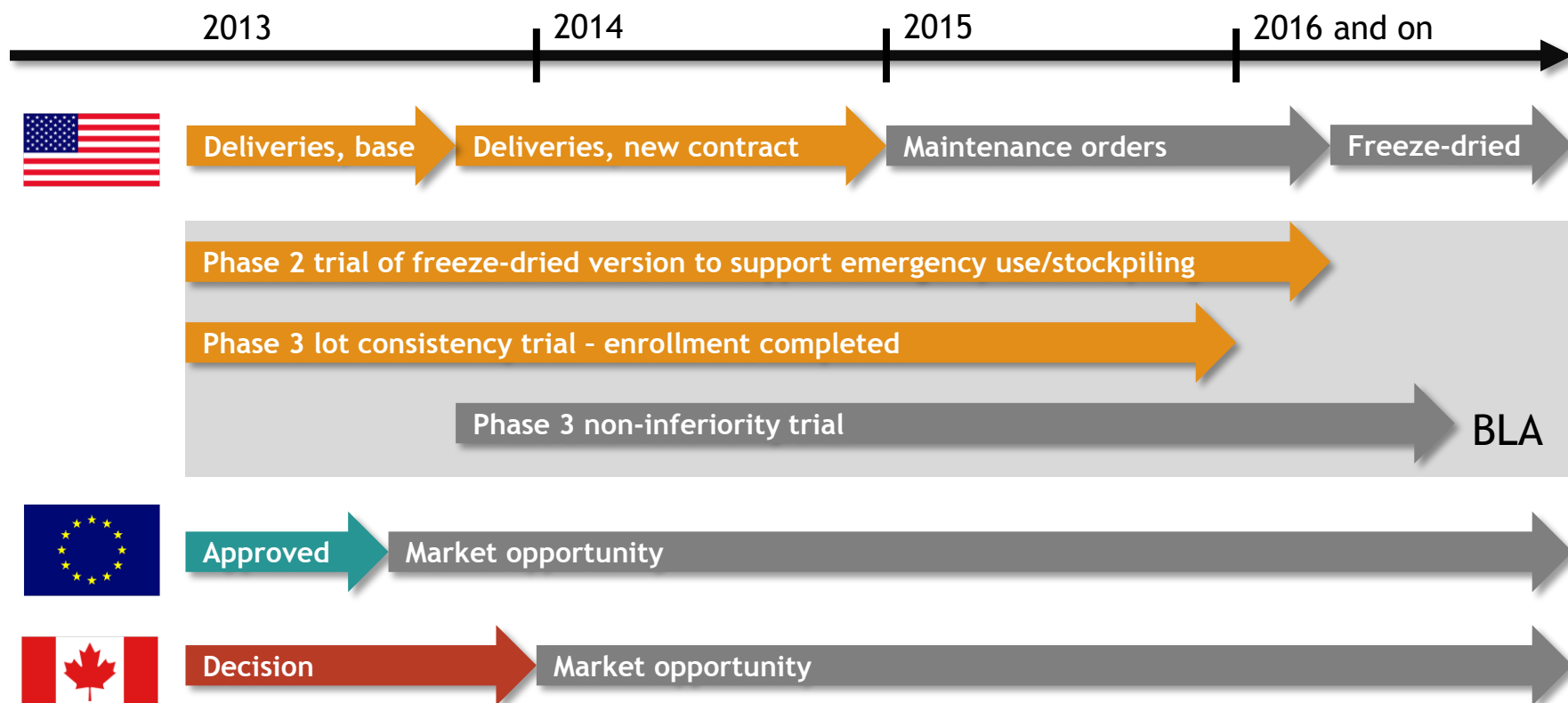
# Infectious Diseases

# IMVAMUNE

		Preclinical	Phase 1	Phase 1/2	Phase 2	Phase 3	Market
<b>BIODEFENSE</b>							
<i>Smallpox</i>	<b>IMVANEX®</b>						EU approved
<i>Smallpox</i>	<b>IMVAMUNE®</b>						Supplied*
<i>Smallpox</i>	<b>IMVAMUNE® freeze-dried</b>						
<i>Anthrax</i>	<b>MVA-BN® Anthrax</b>						
<i>Filoviruses</i>	<b>MVA-BN® Filo</b>						
<i>Foot-and-mouth disease</i>	<b>MVA-BN® FMDV</b>						
<b>COMMERCIAL</b>							
<i>RSV</i>	<b>MVA-BN® RSV</b>						

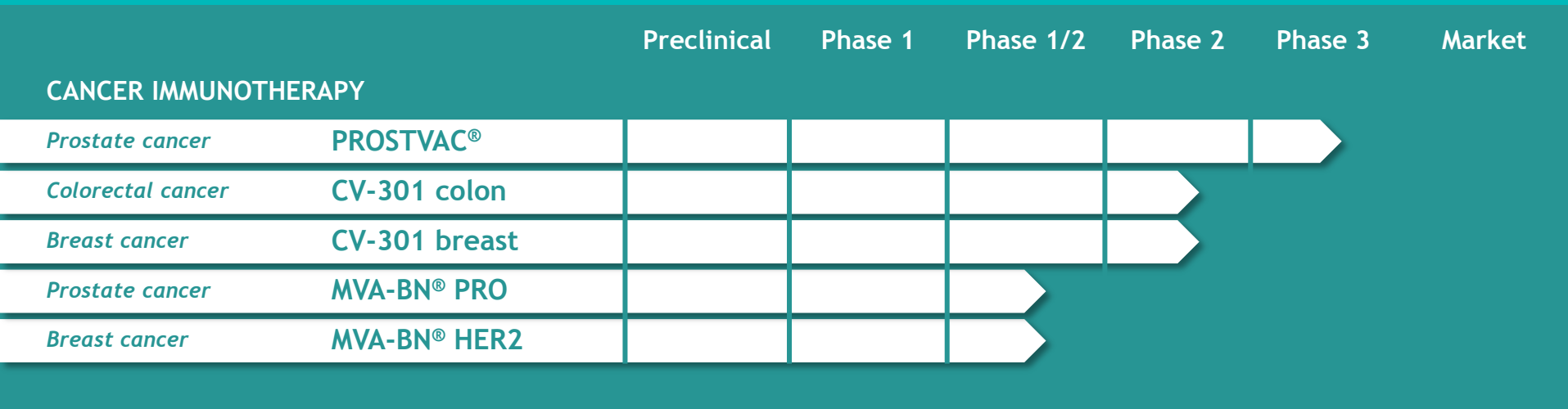
\* Sold to government stockpiles under national emergency rules.

# IMVAMUNE® - Anticipated Developments



# Cancer Immunotherapy

# PROSTVAC



# Pipeline Prioritization

A recent assessment of the cancer immunotherapy portfolio based on preclinical and clinical results to date has led to a prioritization of pipeline opportunities:

<b>PROSTVAC</b>	<ul style="list-style-type: none"><li>• Enrollment of the PROSPECT Phase 3 trial remains a top priority</li><li>• Combination therapy approaches in mCRPC are also being investigated</li></ul>
<b>CV-301</b>	<ul style="list-style-type: none"><li>• Priority indication will focus on colorectal cancer</li><li>• Discussions with regulatory authorities on a potential larger randomized, placebo controlled trial to further evaluate the potential in this setting</li></ul>
<b>MVA-BN PRO</b>	<ul style="list-style-type: none"><li>• Remains a strategically important element in the prostate cancer franchise, particularly as the company explores potential partnering opportunities</li></ul>
<b>MVA-BN HER2</b>	<ul style="list-style-type: none"><li>• Promising Phase 1 data in metastatic breast cancer and a new preclinical study demonstrating potential in combination with a checkpoint inhibitor make this candidate attractive for further clinical development by the Company or a partner.</li></ul>





# PROSPECT

## A Randomized, Double-blind, Global Phase 3 Efficacy Trial of PROSTVAC® in Metastatic Castration-Resistant Prostate Cancer

- 13 countries active, 160+ sites
  - US, Canada, Spain, UK, Iceland, Israel, Denmark, Estonia, Belgium, Russia, France, Poland, & Australia  
*as of November, 2013*
- Full enrollment anticipated in H1, 2014
- FDA - approved Interim Analysis
  - Pre-specified interim analyses of data that will be performed to evaluate whether the trial should continue as planned or potentially be stopped early for efficacy or futility
  - Only marginal impact on statistical power



1,200 patients

3 study arms

PROSTVAC + GM-CSF

PROSTVAC

Placebo

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

Phase 2 results:

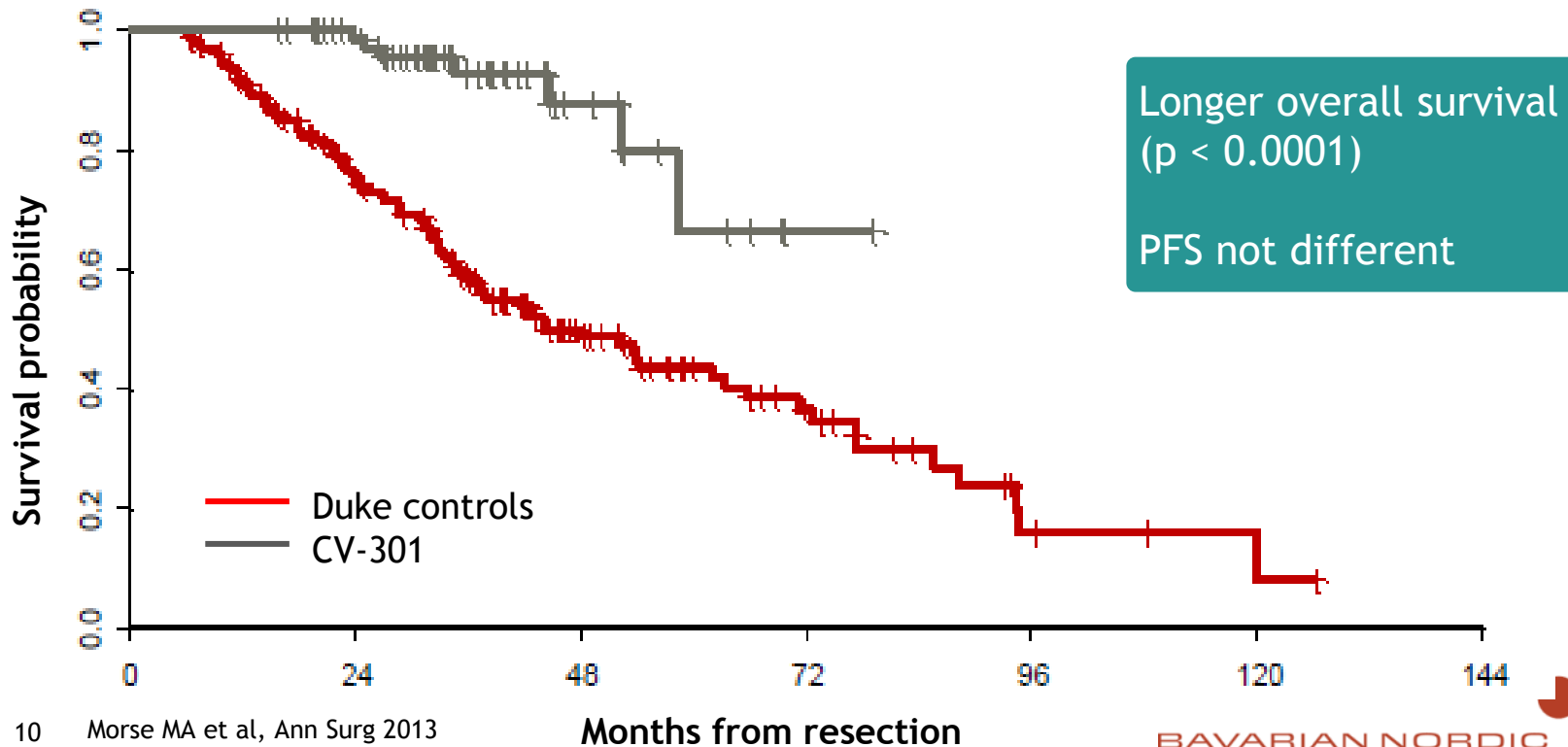
Demonstrated hazard ratio 0.56 = 44% reduction in risk of death

SPA terms for Phase 3:

Required hazard ratio 0.82 or less = 18% reduction in risk of death

# CV-301 colorectal cancer

- NCI-sponsored Phase 2 study at Duke University
- 74 patients with surgical resection and chemotherapy for metastatic colon cancer followed by CV-301 (with GM-CSF or dendritic cells)
- 161 concurrent, matched Duke control patients



# Financial Statements

DKK million	9m 2013	9m 2012	FY 2012
Revenue	875	750	1,017
Production costs	347	379	514
<b>Gross profit</b>	<b>528</b>	<b>371</b>	<b>503</b>
Research and development costs	397	225	357
Distribution and administrative costs	137	123	177
<b>Total operating costs</b>	<b>534</b>	<b>348</b>	<b>535</b>
<b>Income before interest and taxes (EBIT)</b>	<b>(6)</b>	<b>23</b>	<b>(32)</b>
Financial income/loss	(12)	(6)	(17)
<b>Income before company tax</b>	<b>(18)</b>	<b>17</b>	<b>(49)</b>
Tax	(2)	(195)*	191*
<b>Net profit for the period</b>	<b>(20)</b>	<b>(178)</b>	<b>(240)</b>
<b>Cash preparedness (end of period)</b>	<b>546</b>	<b>666</b>	<b>670</b>

\* Tax asset was written down as of 30 June 2012 by DKK 182m due to new legislation

# Financial Outlook

2013

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

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## Assumptions:

Deliver and revenue recognize 7 million doses of IMVAMUNE® to the U.S. Strategic National Stockpile

R&D costs - GROUP \* DKK 570m

Infectious Disease Division, EBIT DKK 360m

Cancer Immunotherapy Division, EBIT DKK -325m

*All numbers are approximate*

*\* R&D costs include approximately DKK 110 million in contract expenses (stated under production costs in the P&L statement) as well as DKK 100 million capitalized in the balance sheet*

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.