

APPROVED

Smallpox Vaccine

IMVANEX®

2013 ANNUAL RESULTS

MARCH 19, 2014

CSE/OMX:BAVA, OTC:BVNRY



BAVARIAN NORDIC

ACCOMPLISHMENTS IN 2013 AND 2014

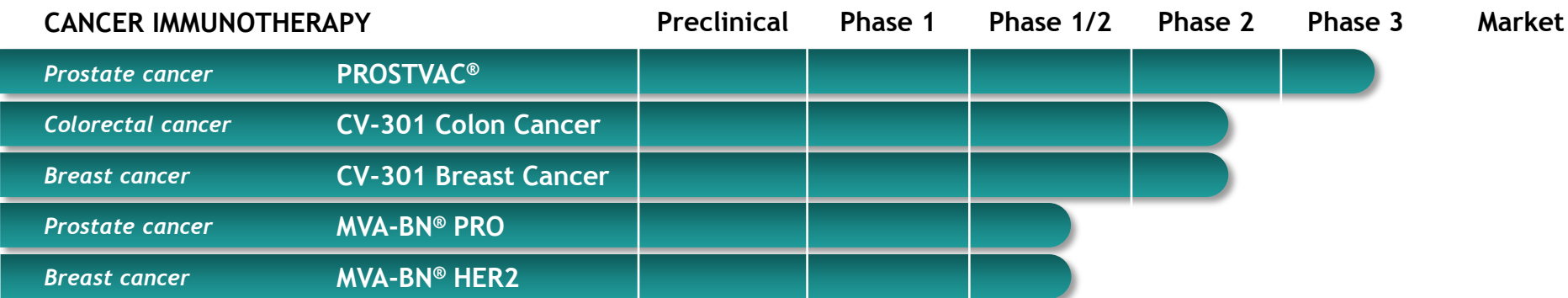
- ✓ IMVANEX® /IMVAMUNE® (smallpox vaccine) approved in Europe and Canada - first product approval for the company
- ✓ Awarded new contract valued up to USD 228 million by the U.S. Government for the continued production and deliveries of IMVAMUNE
- ✓ Continued improvement of efficiency in manufacturing of IMVANEX/IMVAMUNE
- ✓ Completed enrollment of 4,000 subjects in the first U.S. Phase 3 study of IMVAMUNE
- ✓ Completed enrollment in EUA enabling Phase 2 study of freeze-dried IMVAMUNE
- ✓ New biodefense vaccine contract (burkholderia) with DoD in February 2014
- ✓ PROSPECT Phase 3 study expanded to over 185 sites and 13 countries
- ✓ Interim analyses for the PROSPECT trial was agreed with the FDA
- ✓ Expansion of large scale manufacturing facility to include production of PROSTVAC® and clinical trial material
- ✓ CV-301 prioritized for clinical development in colorectal cancer based on very promising Phase 2 survival results

2013 FINANCIALS

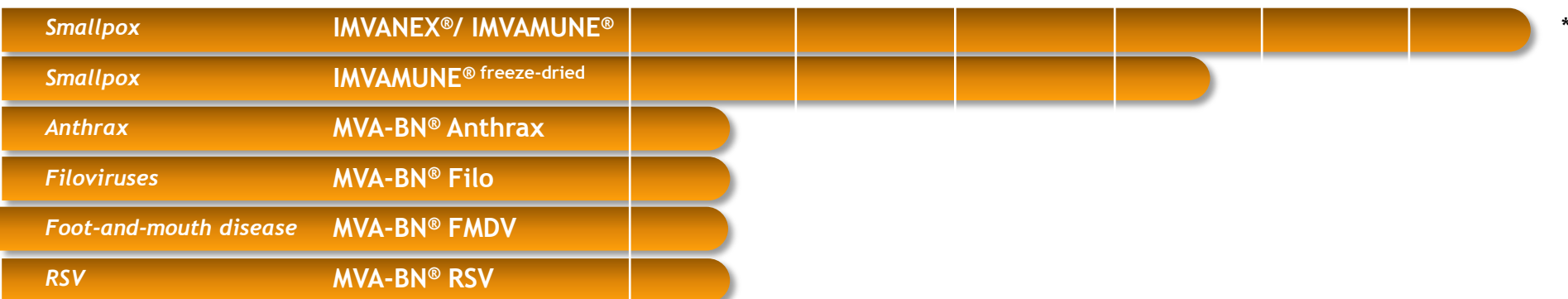
		2013 actual	2013 outlook
Revenue	↑	DKK 1,213 m	DKK 1,100 m
Income before tax	↑	DKK 6 m	DKK 0 m
Cash preparedness at year-end	↑	DKK 652 m	DKK 600 m

PIPELINE

CANCER IMMUNOTHERAPY



INFECTIOUS DISEASES



* Approved in the EU under the trade name IMVANEX® and in Canada under the trade name IMVAMUNE®. Sold to government stockpiles under national emergency rules. Phase 3 registration studies ongoing in the U.S.

PROSPECT

A RANDOMIZED, DOUBLE-BLIND, GLOBAL PHASE 3 EFFICACY TRIAL OF PROSTVAC IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

- More than 100 new sites during 2013 - increased rate of enrollment
- Regulatory delays in Europe continue to impact site initiation, particularly in Germany and the Netherlands. As a consequence, the study is now expected to be fully enrolled in H2 2014
- Investigators and patients are increasingly positive towards active immunotherapy
- Interim analyses of the PROSPECT study offer the opportunity to evaluate whether the trial should continue as planned or potentially be stopped early. The time to regulatory submission for PROSTVAC approval could be shortened if the trial surpasses the required efficacy threshold during one of these early assessments

PROSPECT

A RANDOMIZED, DOUBLE-BLIND, GLOBAL PHASE 3 EFFICACY TRIAL OF PROSTVAC IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

- 13 countries active, +185 sites
 - US, Canada, Spain, UK, Iceland, Israel, Denmark, Estonia, Belgium, Russia, France, Poland & Australia
as of March 2014
- Full enrollment anticipated in H2 2014
- 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
 - Potential for early data read-out



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:

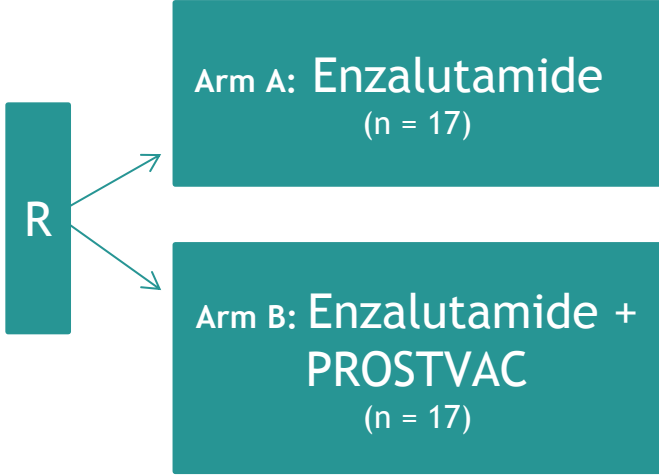
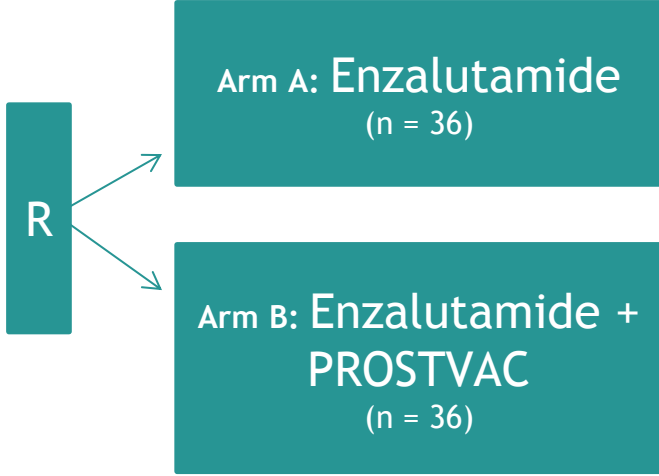
Demonstrated hazard ratio 0.56 = 44% reduction in risk of death

SPA terms for Phase 3:

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

OTHER ONGOING PROSTVAC STUDIES

CURRENTLY SUBJECT OF NCI-SPONSORED CLINICAL STUDIES IN COMBINATION WITH OTHER THERAPIES

Protocol	M0 hormone-naïve PC	mCRPC
Primary Endpoint	Decrease in tumor re-growth rate (PSA kinetics) after 3 months of enzalutamide	Time to progression
Study Design (open label)		

A Phase 2 clinical study comparing flutamide (anti-androgen therapy) with or without PROSTVAC has completed enrollment of 62 patients with non-metastatic prostate cancer

BN POXVIRUS-BASED IMMUNOTHERAPY: IN COMBINATION WITH CHECKPOINT INHIBITORS

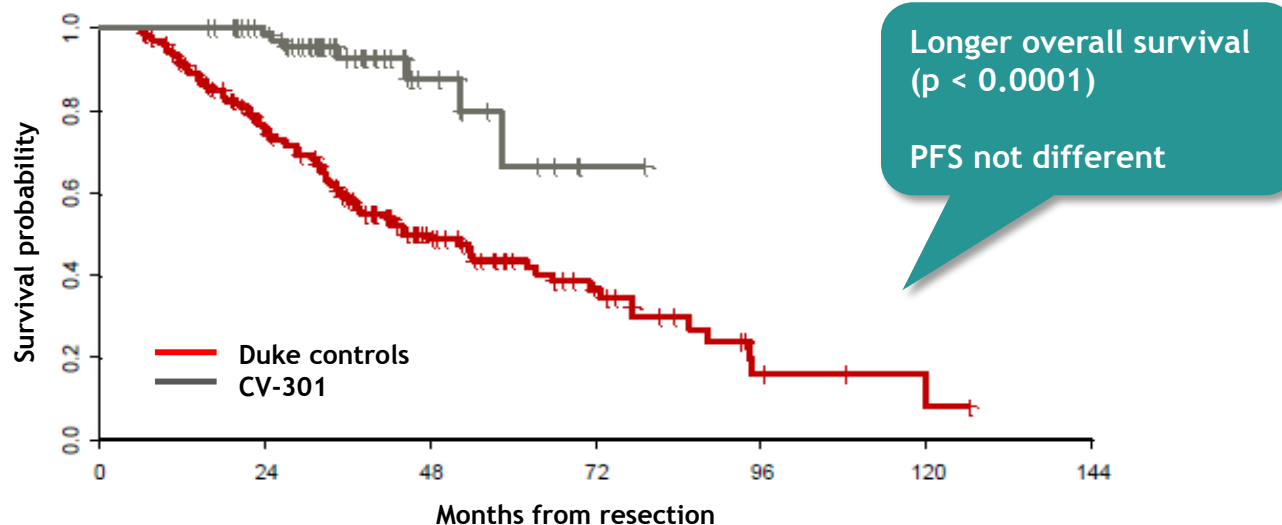
PROSTVAC/ipilimumab Combination Clinical Study Phase 1 dose escalation trial; 30 patients with mCRPC

		Median Halabi Predicted Survival (months)	Median Overall Survival (months)	Δ OS (months)	Alive at 24 months
Prior NCI Study	PROSTVAC alone ¹ (n=32)	17.2	26.3	+9.1	53%
ipilimumab combo study	PROSTVAC + ipilimumab ² (n=30)	18.5	34.4	+15.9	73%

¹ Gulley et al Immunol Immunother 2010; ² Madan et al Lancet Oncol 2012

CV-301 TARGETED FOR CLINICAL DEVELOPMENT IN COLORECTAL CANCER

- CRADA with NCI expanded in 2013 to include CV-301 in colorectal cancer
- Promising survival results from Phase 2 study (n=74) in patients with resected metastatic colorectal cancer published in May 2013¹
- Discussions with regulatory authorities on a potential larger randomized, placebo-controlled trial to further evaluate CV-301's potential in this setting are ongoing. Initiation of the trial will depend on availability of funds



1) Morse MA et al, Ann Surg 2013

COLLABORATION WITH NCI CONTINUES AND EXPANDS

MVA-BN Brachyury

- NCI plans to initiate a Phase 1 study in patients with advanced cancer (H1 2014)
- The brachyury protein is a novel tumor associated antigen that is overexpressed in a wide variety of cancers, including both adenocarcinomas (lung, breast, ovary, colorectal), as well as squamous carcinomas (lung, oral)
- Brachyury is believed to be involved in the process of tumor progression and development of metastases
- An MVA-BN based construct that also employs the TRICOM technology has been shown to be a good target for active T cell immunotherapy in preclinical models

CV-301 in bladder cancer

- NCI plans to initiate a Phase 2 study of CV-301 in patients with bladder cancer whose cancer has progressed after BCG treatment (H1 2014)
- This tumor is well known to respond to immunotherapy, and BCG (Bacillus Calmette-Guerin) for use in bladder cancer was the first modern immunotherapy to be approved in many countries to prevent the recurrence of superficial bladder tumors

IMVAMUNE®/IMVANEX® - FIRST PRODUCT APPROVAL

Indicated for:

- EU: Active immunization against smallpox for entire adult population
- CANADA: Active immunization against smallpox for adults with immune deficiencies or skin disorders

Procurement:

- Available for governments to purchase



Trade name:
IMVANEX®

*Approved
August 2013*

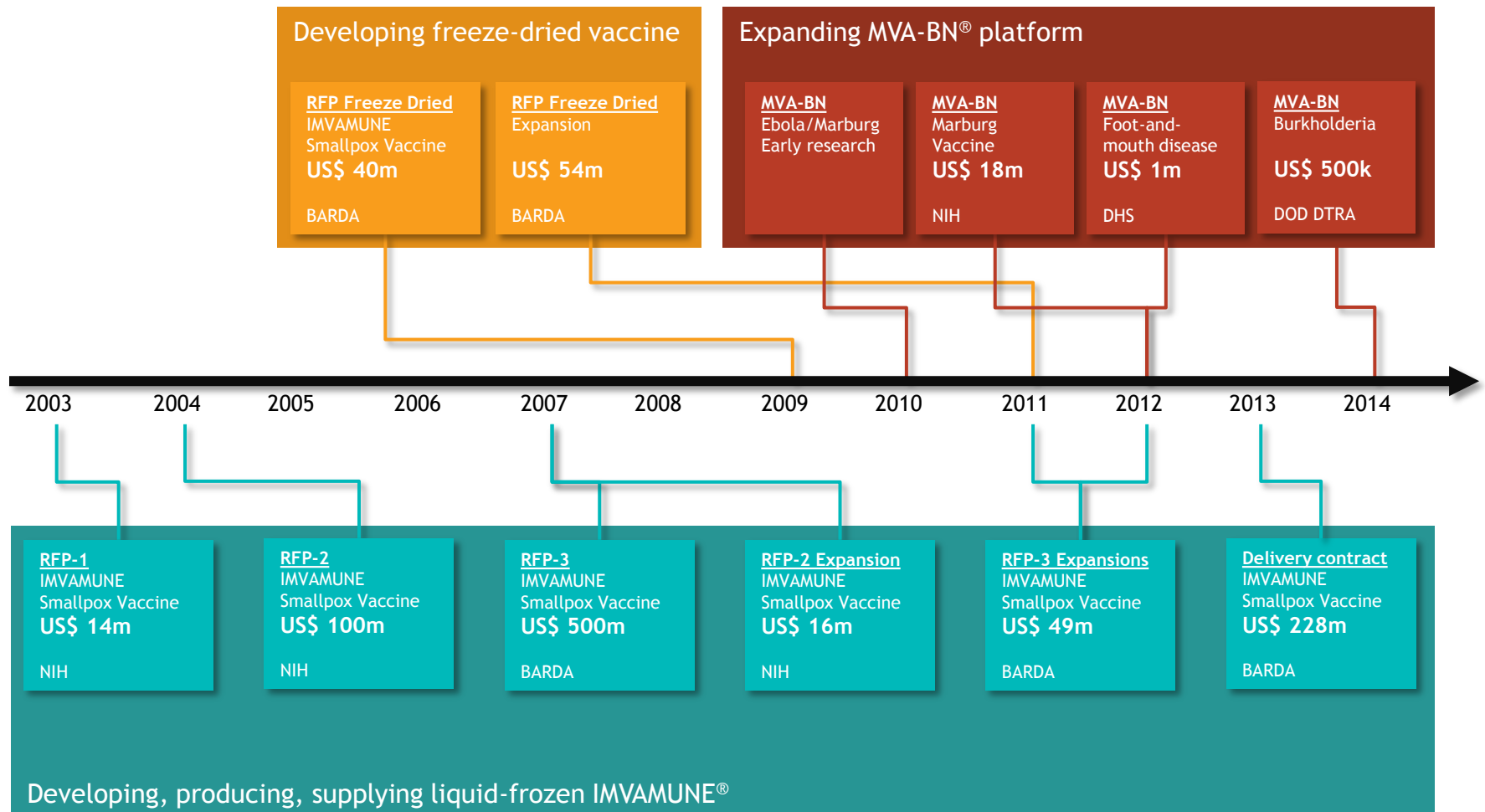


Trade name:
IMVAMUNE®

*Approved
November 2013*

SUCCESSFUL PARTNERSHIP WITH THE U.S. GOVERNMENT

CONTRACTS AWARDED TO-DATE EXCEED US\$ 1BN



U.S. GOVERNMENT CONTINUES ITS COMMITMENT

IMVAMUNE delivery contract

- New delivery contract for 8 million doses of IMVAMUNE valued up to USD 228 million awarded by the U.S. Government in April 2013
- The first portion of USD 110 million is secured. The second portion is expected in 2014. In January 2014, the U.S. Congress appropriated funds for the BioShield Special Reserve Fund, which supports procurement of biodefense medical countermeasures such as IMVAMUNE and Bavarian Nordic is now waiting for BARDA to finally execute the exercise of the option
- Deliveries under this contract began in November 2013, following completion of the delivery of 20 million doses under the initial contract awarded in 2007
- The contract stipulates that HHS intends to maintain the U.S. stockpile of IMVAMUNE and the necessary manufacturing capacity through future orders, pending of the availability of future funding beyond 2014

Expanded collaboration in biodefense

- New contract with DoD in February 2014 on burkholderia vaccine. DoD is the fourth USG agency to contract with Bavarian Nordic development of medical countermeasures

ANTICIPATED MILESTONES

- Complete enrollment in the PROSPECT trial (H2, 2014)
- Secure final portion of IMVAMUNE delivery contract with the U.S. government (USD 118 million)
- Complete Phase 2 study of freeze-dried IMVAMUNE to support a pre-EUA submission (requirement for stockpiling)
- Initiate final Phase 3 trial of IMVAMUNE (H1, 2014)
- Initiation of NCI-sponsored Phase 1 study of MVA-BN brachyury (H1, 2014)
- Initiation of NCI-sponsored Phase 2 study of CV-301 in bladder cancer (H1, 2014)
- Obtain regulatory feedback on the CV-301 development plan for colorectal cancer (H2, 2014), followed by initiation of a randomized, controlled trial depending on availability of funds
- Potential IMVANEX/IMVAMUNE orders from rest of world
- Investigational New Drug submission for MVA-BN RSV (2014) followed by initiation of Phase 1 study (2015)

FINANCIAL STATEMENTS

DKK million	FY 2013	FY 2012
Revenue	1,213	1,017
Production costs	485	514
Gross profit	728	503
Research and development costs	497	357
Distribution and administrative costs	198	177
Total operating costs	694	535
Income before interest and taxes (EBIT)	33	(32)
Financial income/loss	(27)	(17)
Income before company tax	6	(49)
Tax	53	191*
Net profit for the year	(47)	(240)
Cash preparedness (end of year)	652	670

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

FINANCIAL OUTLOOK

2014

Revenue	DKK 1,200m
EBIT	DKK 0m
Cash preparedness at year-end	DKK 600m

Assumptions:

Deliver and revenue recognize 6.5 million doses
of IMVAMUNE to the U.S. Strategic National Stockpile

R&D costs - GROUP	* DKK 600m
Infectious Disease Division, EBIT	DKK 400m
Cancer Immunotherapy Division, EBIT	DKK -400m

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 50 million capitalized in the balance sheet*

OVERVIEW OF USG CONTRACTS

AS OF 31 DECEMBER 2013

USD million		P&L		Cash Flow	
	Contract value	Revenue recognized	To be recognized	Received	To be received
IMVAMUNE: RFP-3	777	608	169	610	167
IMVAMUNE: RFP-2	116	115	1	115	1
IMVAMUNE: RFP-1	14	14	0	14	0
IMVAMUNE Freeze-dried	95	37	58	34	61
Marburg	18	2	16	1	17
Foot-and-mouth	1	0	1	0	1
TOTAL	1,021	776	245	774	247



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.