

OFF THE SHELF

DELIVERING THE VACCINE PROMISE

Anders Hedegaard, President & CEO

February 2010

Bavarian Nordic

Cancer Vaccines

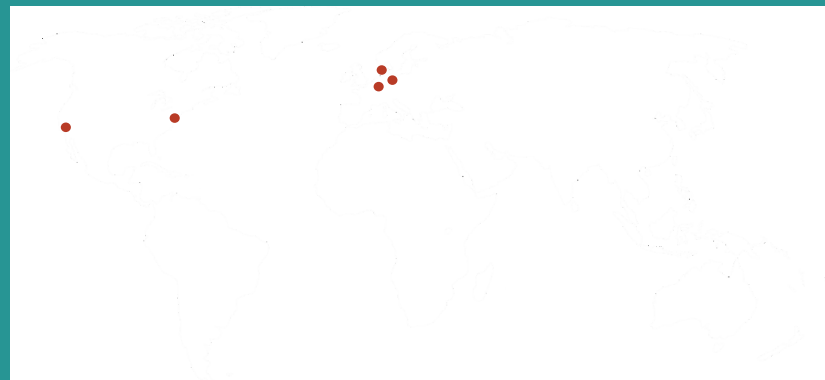
Therapeutics

- **PROSTVAC™** - Standard immunterapi til fremskreden prostatacancer
- Fase 3 påbegyndes i 2011
- Stærke data i et blockbuster marked: 8,5 mdr. forøget overlevelse
- CRADA med NCI

Infectious Diseases

Klassiske Vacciner

- **IMVAMUNE®** - Næste generation koppevaccine
- Fuldt finansieret biodefence program med den amerikanske regering
- Igangværende kontrakter med USA
 - 20 mio. doser ~ USD 505 mio. + option 60 mio. doser ~ USD 1,1 mia.



Industrial Scale Production (Denmark) R&D Infectious Diseases (Munich)
Pilot Manufacturing (Berlin) R&D Cancer (California) Governmental Affairs (Washington)

- International virksomhed
- Fuldt integreret virksomhed fra R&D til produktion og salg
- Stærk IP position på førende projekter og MVA-BN® teknologien
- Noteret på NASDAQ OMX: BAVA
- Market cap (Feb-2011): DKK 3.3 mia.
- 400+ medarbejdere

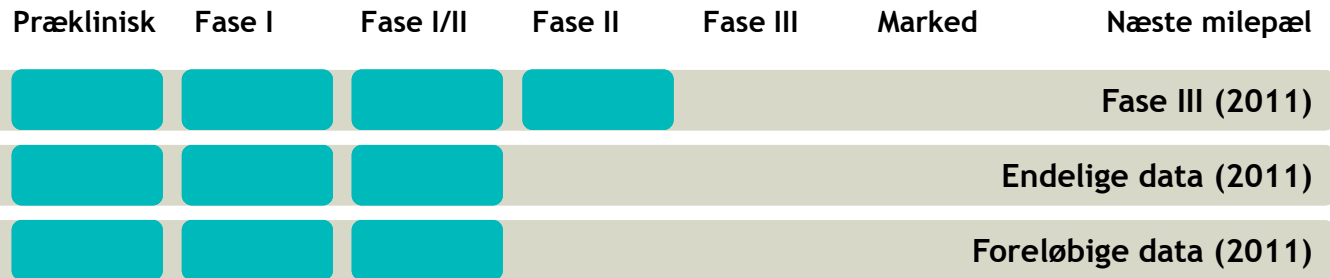
Pipeline

Cancer Vaccines

PROSTVAC™

MVA-BN® PRO

MVA-BN® HER2



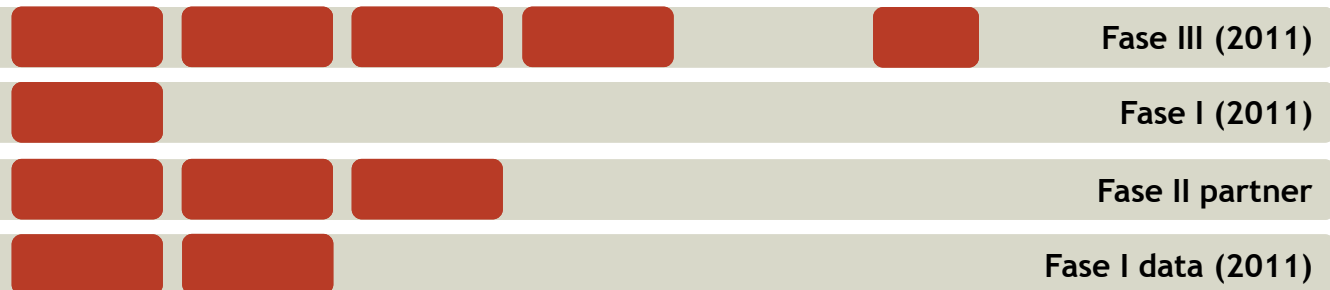
Infectious Diseases

IMVAMUNE®

Miltbrand

HIV

Mæslinger/RSV



Cancer Vaccines

Førende leverandør af terapeutiske vacciner inden for største cancertyper

Førende produkt

PROSTVAC™ - Standard immunterapi til fremskreden prostatacancer

Stærke data i et blockbuster marked
8,5 mdr. forøget overlevelse = 50 % øget levetid

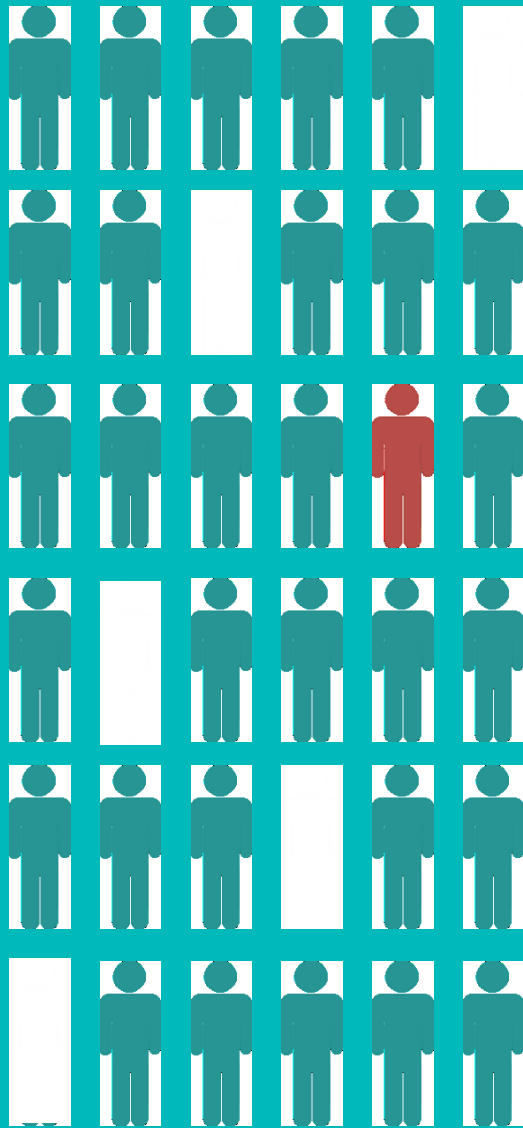
Mål

PROSTVAC™ i fase III og på markedet med partner

Udvide pipelinen med flere mellem-fase projekter

Udvikle nye vaccinerkandidater

		Fase I	Fase I/II	Fase II	Fase III	Næste milepæl
PROSTVAC™	Prostatacancer	█	█	█		Fase III (2011)
MVA-BN® PRO	Prostatacancer	█	█			Endelige data (2011)
MVA-BN® HER2	Brystcancer	█	█			Foreløbige data (2011)



1 ud af 6 mænd
får prostatacancer

1 af 6 af disse dør
af prostatacancer

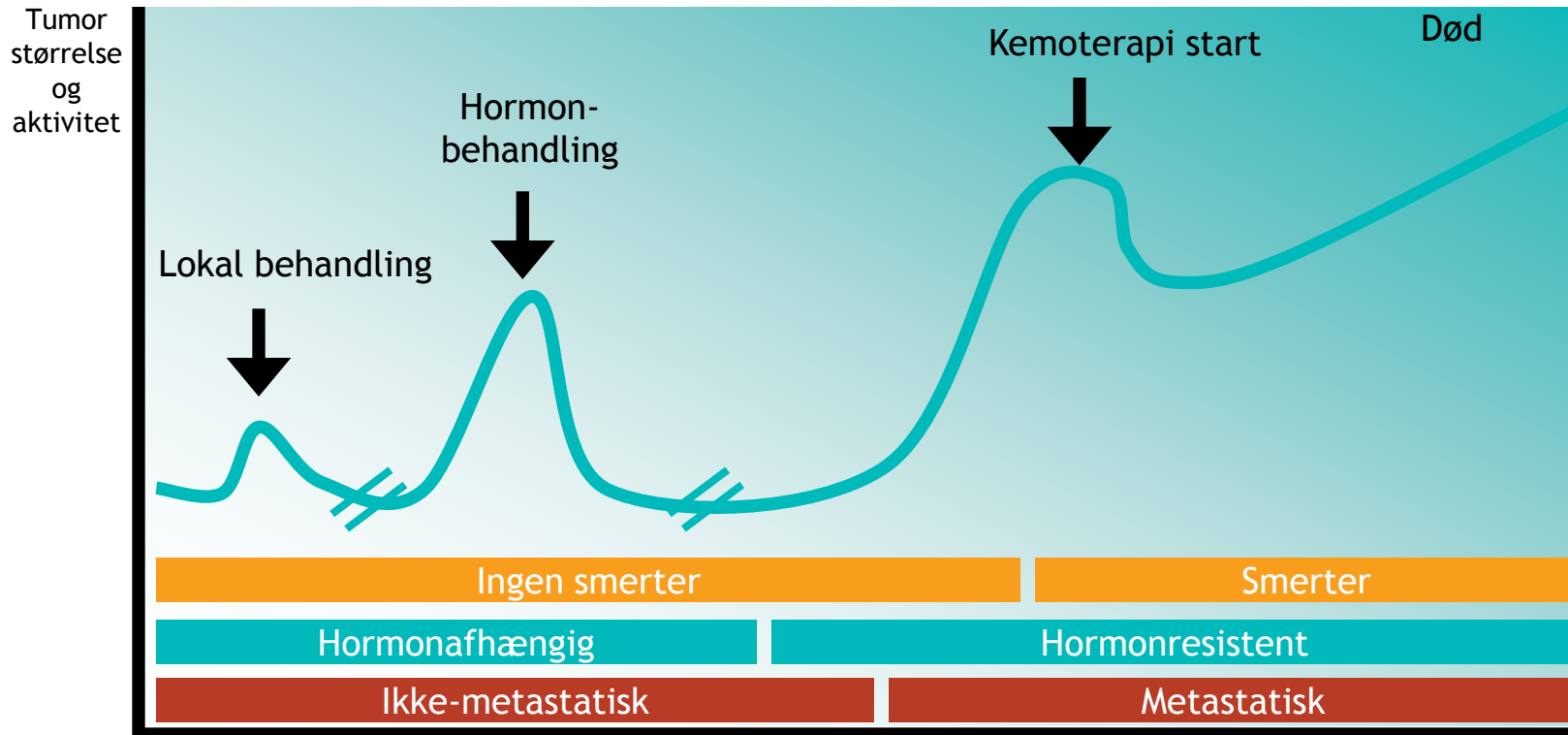
PROSTVAC™

Prostate cancer - high unmet medical need

- Metastatic disease is incurable
- Common cause of death in men
- >250,000 deaths/year (WW)
- Increase in cases (780,000 annually)
- Treated with chemotherapy (limited life-extension and severe side effects)
- Provenge® recently approved as first immunotherapy for this patient population



Udviklingen i prostatacancer



PROSTVAC™

An innovative recombinant therapeutic vaccine

- Subcutaneous injection
- Off-the-shelf vial vaccine that does not require individualised therapy
- Targets a unique cancer cell antigen (PSA)
- And encodes co-stimulatory molecules
- Is a sequentially dosed combination of two different Poxviruses

Phase II results demonstrated extended survival of 8.5 months

- Extended median overall survival of 8.5 months compared to placebo in a Phase 2 randomized, placebo-controlled study that enrolled patients with mCPRC



PROSTVAC™ Phase 2

Multicenter Phase 2

- randomized, placebo-controlled
- double-blind

125 patients enrolled

- 43 sites
- 83 PROSTVAC-VF + GM-CSF
- 41 empty vectors (VVwt-fowlpox) + placebo

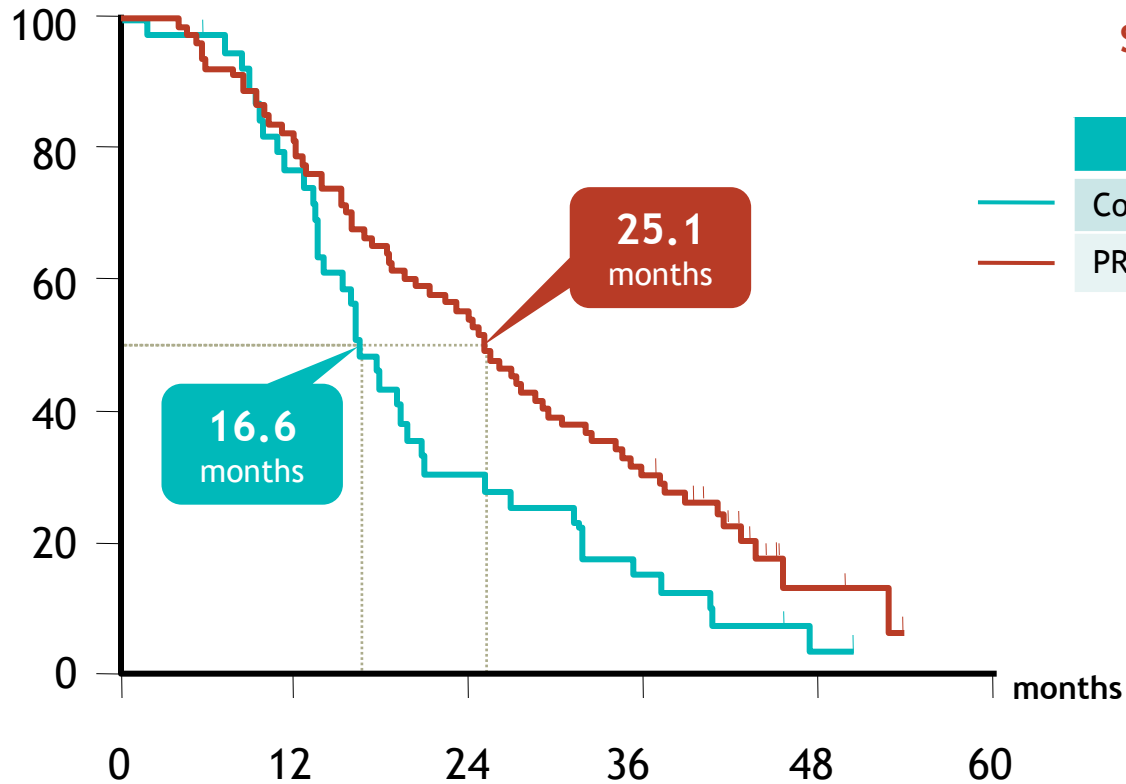
Accrual: November 2003 to July 2005



Overall Survival Analysis of a Phase II Randomized Controlled Trial of a Poxviral-Based PSA-Targeted Immunotherapy in Metastatic Castration-Resistant Prostate Cancer
Journal of Clinical Oncology, 2010, Jan 25

PROSTVAC™ Phase 2 results

survival
(% of patients)



Significantly extended overall survival

	N	Deaths	Median
Control	40	37	16.6
PROSTVAC	82	65	25.1

Δ 8.5 months

Hazard ratio
0.56 (95% CI 0.37–0.85)

p=0.0061

Regulatory progress of PROSTVAC™

End of Phase 2 meeting concluded

- FDA and EMEA endorse the overall Phase 3 plan

Fast Track status granted by the FDA

- Expedited review process
- BLA can be submitted on a rolling basis, allowing the FDA to review sections of the BLA in advance of receiving the complete submission

Special Protocol Assessment (SPA)

- SPA agreement with FDA on Phase 3 protocol received in Dec-2010
- Phase 3 design and endpoints agreed
- A successful Phase 3 outcome could form the primary clinical basis of product approval under a Biologics License Application.

Phase 3 design and endpoints

Phase 3 design (according to SPA)

- Strongly powered, single global, placebo-controlled study
- ~1,200 patients
 - Asymptomatic or minimally symptomatic, metastatic castration-resistant prostate cancer
- Three study arms:
 - PROSTVAC + GM-CSF
 - PROSTVAC + GM-CSF Placebo
 - PROSTVAC Placebo + GM-CSF Placebo

Endpoints

- Primary endpoint is overall survival (OS).
- For the study outcome to be positive, either one or both of the treatment arms must be superior to placebo.
- Each comparison requires 534 deaths with sensitivity for estimated death hazard ratios of 0.82 or less.

PROSTVAC™ has potential

PROSTVAC™ advantages

- Efficacy and safety demonstrated in a rigorous Phase 2 program
- Phase 2 studies show a clinically relevant survival benefit
- Potential application in both early - and late-stage prostate cancer
- Phase 3 in preparation with expected initiation in 2011
- Only off-the-shelf therapeutic vaccine in development for prostate cancer
 - Clear cost and practicality advantages over autologous competitors

Likely to be the second therapeutic vaccine to market

- Riding the wave of the first approved prostate cancer vaccine - opportunity to enter a vaccine-receptive market shaped by the first entrant

PROSTVAC™ has potential

Improved survival benefit and better quality of life

- Compared with current chemotherapies, PROSTVAC™ potentially offers improved survival benefit and better quality of life
- Can potentially be combined with other modalities such as taxotere or abiraterone

Cancer market is occupied by premium products at premium prices

- Avastin® can cost up to US\$100,000/year¹
- Herceptin® can cost up to US\$65,000/year²
- Provenge cost up to US\$93,000 for a full course of treatment

First label in mCRPC

- Subsequent move into early-stage disease supported by study data

¹“The Evidence Gap - Costly Cancer Drug Offers Hope, but Also a Dilemma”, New York Times July 8, 2008

²“Studies Find Trastuzumab (Herceptin) Cost-Effective As Treatment for Women with Early-Stage HER2-Positive Breast Cancer”, ASCO February 16, 2007

Infectious Diseases

Førende leverandør af vacciner mod infektionssygdomme

Førende produkt







IMVAMUNE® - *Næste generation koppevaccine med uovertruffen sikkerhed og effektivitet*

Fuldt finansieret biodefence program og igangværende kontrakter med USA
20 mio. doser ~ USD 505 mio.
+ option 60 mio. doser ~ USD 1,1 mia.

Mål

Succesfulde leverancer af IMVAMUNE® til den amerikanske regering
Opnå nye kontrakter med USA

Udvide pipelinen med flere mellem-fase projekter
Udvikle nye vaccinekandidater

		Fase I	Fase I/II	Fase II	Fase III	Næste milepæl
IMVAMUNE®	<i>Kopper</i>					Fase III (2011)
MVA-BN® Anthrax	<i>Miltbrand</i>					Fase I (2011)
MVA-BN® HIV <i>multiantigen</i>	<i>HIV</i>					Fase II partner
MVA-BN® Measles/RSV	<i>RSV</i>					Fase I data (2011)



IMVAMUNE®

Limitations of current smallpox vaccines



Currently stockpiled vaccines are based on a replicating vaccinia virus:

- DryVax[®] , ACAM2000, LC16m8, Elstree-BN

Side effects

All have been shown to produce some/all of following side effects:

- Encephalitis, generalized vaccinia, inadvertent infection - skin and eyes/self and contacts, myo-pericarditis

25%

25% of the population cannot receive current smallpox vaccines

- Young, elderly, people with a history of atopic disorders (e.g. eczema), HIV or AIDS, cancer patients

IMVAMUNE® advantages

Safety

Based on a non-replicating virus

Far superior safety profile than the old vaccines

More than 3,200 individuals have been vaccinated

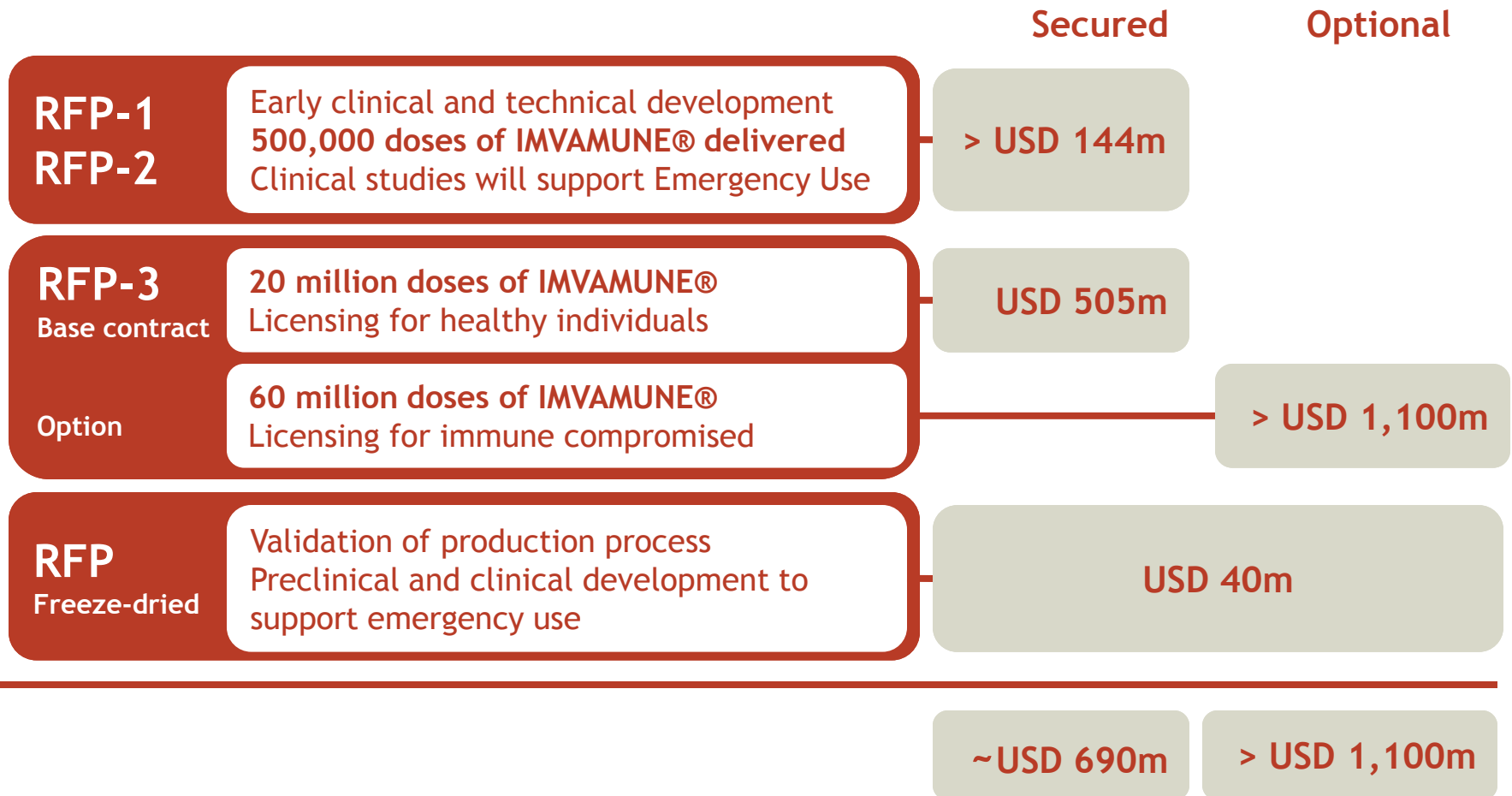
- Well tolerated - even in immune-compromised
- No product-related severe adverse events reported

Efficacy

Induces faster protective immune response

- Protects already after 3-4 days vs. 10-12 days with the traditional vaccines*

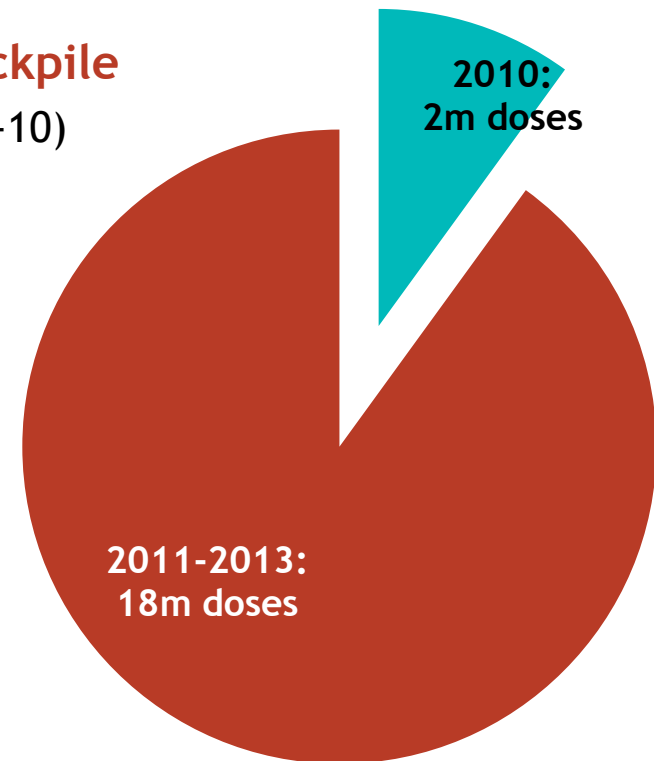
Contracts with the US government



IMVAMUNE® deliveries to the US

Deliveries to the US Strategic National Stockpile

- 1.7m doses delivered and invoiced to date (Nov-10)
- 2m doses will be delivered in 2010
- Remaining 18m doses to be delivered between 2011 and 2013
- Exact delivery schedule is expected to be determined during 2011



Phase III status and next step

Phase III protocols submitted to the FDA awaiting review

- Final clinical and preclinical protocols for Phase III submitted to the FDA
- Once the protocols have been reviewed, a Vaccines Related Biological Product Advisory Committee (VRBPAC) will be scheduled by the FDA to ratify the license strategy. Upon ratification, Phase III can be initiated.

Financial Outlook

2010

Revenue

DKK 325 m

Result (loss) before tax

DKK -450 m

Cash preparedness, year-end

DKK 450 m

All numbers are approximate

Recent highlights

PROSTVAC™ regulatory path outlined

- ✓ SPA agreement with FDA on Phase 3 protocol in place
- ✓ Fast track status granted
- ✓ CRO for Phase 3 engaged - identification of centres

IMVAMUNE® deliveries to the US initiated

- ✓ Deliveries to the US Strategic National Stockpile initiated
- ✓ 2 million doses to be delivered in 2010
- ✓ 18 million doses to be delivered in 2011-2013
- ✓ Phase 3 protocols submitted to the FDA

Future milestones

- PROSTVAC™ Phase 3 initiation
- Commercial partner on PROSTVAC™
- IMVAMUNE® NDS submission to Canada
- Government funding opportunities, current and future projects
- Decision on new pipeline opportunities

The Bavarian Nordic share



BAVA.CO

Institutions, Funds 64%

Private 24%

Non-reg. 12%

No. of shares, 89% free-float	13m
Registered share capital	88%
No. of registered shareholders	17,600
Distribution of reg. shares	DK: 75%, ROW: 25%
Largest shareholders (>5%)	A.J. Aamund A/S, ATP

Share price (8 Feb 2011)	DKK 252.50
High/low 52 weeks	293 / 167
Market cap	DKK 3.3bn
Net free liquidity per share	DKK 25 (30 Sep 2010)
Volume (3m, daily average)	27,000



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