# Interim Results as of 30 September 2012

Q3

13 November 2012



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# Financial Highlights

## Significantly improved financial results

- 6.3 million doses IMVAMUNE® delivered to the SNS during first nine months
- Infectious Disease division further increases profitability
- Nine-months operating profit positive for the group
- Full year financial expectations raised again

| | 9m 2012 | 9m 2011 |
|---|---|---|
| Revenue | DKK 750m | DKK 155m |
| Income before tax | DKK 17m | DKK -333m |



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# Third Quarter Highlights

## Cancer Vaccines

- Preliminary Phase 2 data for CV-301 shows promise in metastatic breast cancer
- PROSPECT Phase 3 study enters into more European countries
- Arduous regulatory process in some EU countries has delayed initiation in these countries – measures implemented to maintain overall schedule

## Infectious Diseases

- IMVAMUNE® deliveries to the U.S. Strategic National Stockpile above target
- Continued, steady improvements in the manufacturing efficiency
- RFP-3 contract further expanded by USD 5m – total value now USD 549m
- U.S. Government has significantly expanded eligible population for IMVAMUNE®
- MVA-BN® platform expansion into veterinary vaccines through another new USG contract that broadens scope of technology

# Cancer Vaccines

PROSTVAC

## Therapeutic vaccine platform for major cancers

| | | PC | Ph1 | Ph 1/2 | Ph 2 | Ph 3 | Next milestone |
|---|---|---|---|---|---|---|---|
| PROSTVAC® | *Prostate cancer* | | | | | | Complete enrolment (2013) |
| CV-301 *breast* | *Breast cancer* | | | | | | Data (2012) |
| CV-301 *lung* | *Lung cancer* | | | | | | Data update (2013) |
| CV-301 *ovarian* | *Ovarian cancer* | | | | | | Data update (2013) |
| MVA-BN® PRO | *Prostate cancer* | | | | | | Data (1H 2013) |
| MVA-BN® HER2 | *Breast cancer* | | | | | | Await CV-301 data |

# 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 flutamide (antihormone) with/without PROSTVAC® (n=65) | Non-metastatic prostate cancer | Time to progression |
| Phase 2 study comparing samarium (radioactive drug) with/without PROSTVAC® (n=68) | Metastatic prostate cancer | 4 month progression free survival |
| Phase 2 study of PROSTVAC® treatment followed by PROSTVAC® and hormonal therapy at disease progression. (n=50) – 19 patients in follow-up | 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

# PROSPECT

## A Global Clinical Study for Metastatic Prostate Cancer


Study recruitment website:

www.continueyourfight.com

For further information:

http://clinicaltrials.gov/ct2/show/NCT01322490



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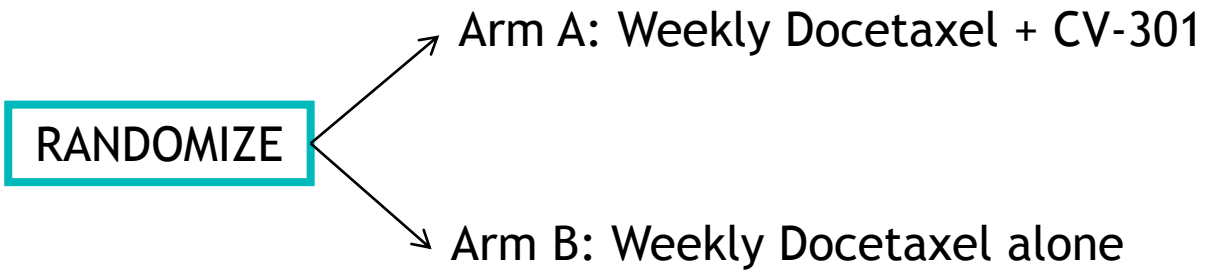
# CV-301 *breast cancer* – ongoing trial

- NCI-funded, open-label Ph2 study (n=48) in metastatic breast cancer
- Docetaxel naïve
- Treatment with Docetaxel with/without CV-301
- Primary endpoint: Progression Free Survival (PFS)
- Enrolment completed




Study Protocol ID: NCT00179309, NCI-6977



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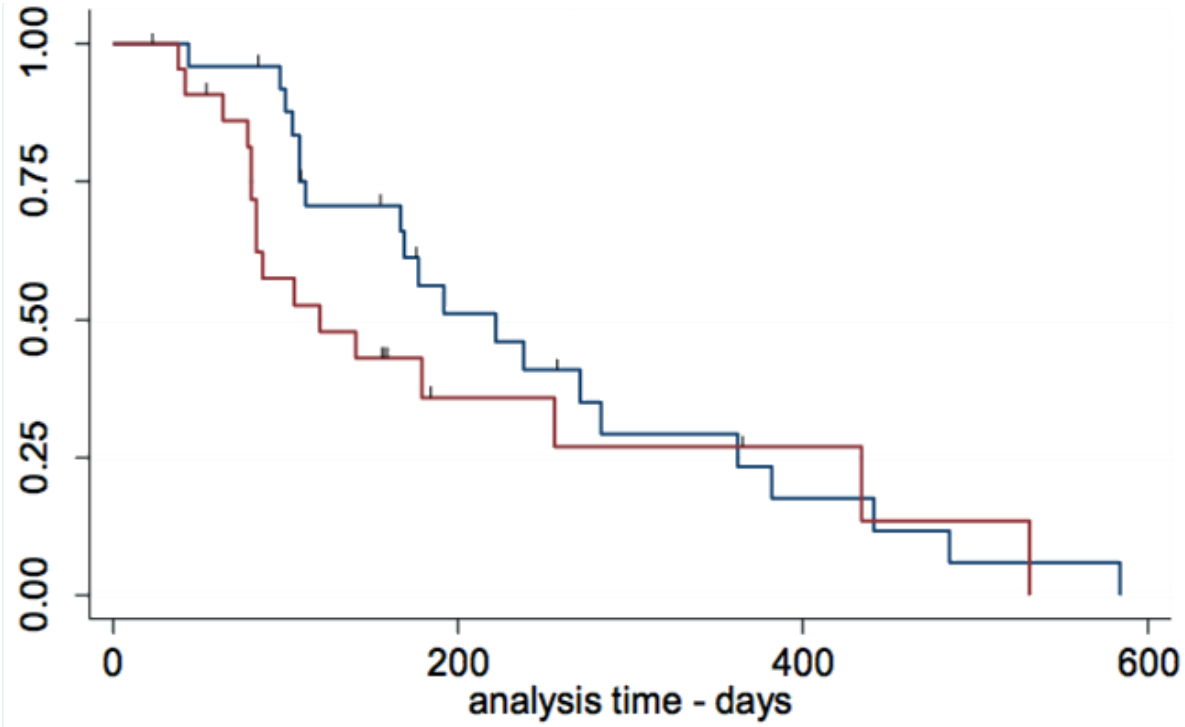
# CV-301 *breast cancer* – preliminary results

## Progression Free Survival




Arm A: 6.6 months
Median cycles - 5

Arm B. 3.8 months
Median cycles - 3

**Hazard ratio**
0.67 (95% CI 0.34–1.31)
**p=0.12**



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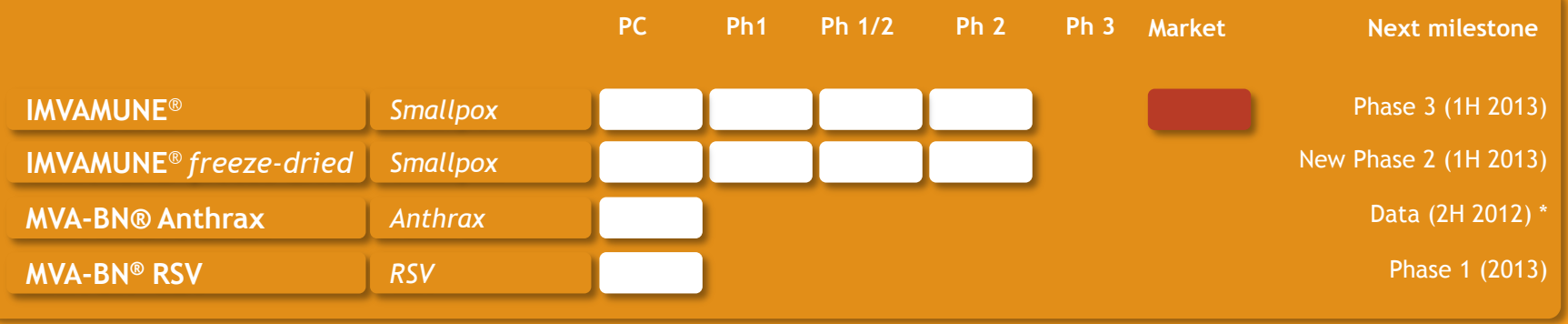
# Cancer Vaccines – Short/Mid-Term Objectives

- Complete enrolment in the PROSPECT Phase 3 trial
- Establish PROSTVAC® partnership
- Report preliminary data from three NCI-funded studies with PROSTVAC®
- Report breast cancer data from CV-301 studies and determine future development strategy

# Infectious Diseases

IMVAMUNE

## Leading supplier of vaccines for biodefense




Sold to government stockpiles under national emergency rules

** Positive preclinical data could support funding of clinical trials of the anthrax vaccine from the U.S. Government*



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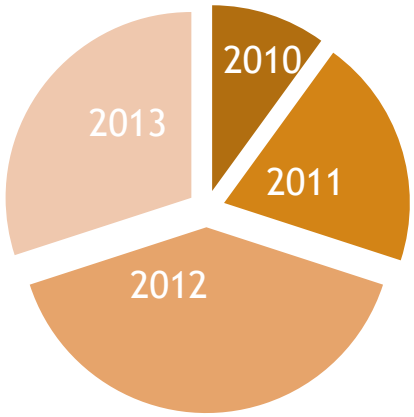
# U.S. Government Contracts

| Year | Contracts with the U.S. Government | Value |
|---|---|---|
| 2003-2004 | Early clinical and technical development of IMVAMUNE®<br>500,000 doses of IMVAMUNE® delivered<br>Clinical studies to support Emergency Use<br>Contract expansion in 2007 | **USD 130m** |
| 2007 | 20 million doses of IMVAMUNE®<br>Licensing for at-risk individuals<br>Development for immune compromised<br>Contract expansions in 2011 and 2012 | **USD 549m** |
| 2009 | Development of freeze-dried version of IMVAMUNE®<br>Validation of production process<br>Preclinical and clinical studies to support advanced development<br>Contract expansion in 2011 | **USD 95m** |
| 2012 | Marburg vaccine<br>Advanced development of an MVA-BN®-based vaccine against Marburg virus | **USD 18m** |
| 2012 | Foot-and-mouth disease<br>Development of a veterinary vaccine against foot-and-mouth disease virus | **USD 1m** |
| | **Total value of contracts awarded to-date** | **USD 793m** |

# IMVAMUNE® Delivery Status

| Deliveries to the U.S. Strategic National Stockpile | |
|---|---|
| Delivered in 2010 | 2m doses ✓ |
| Delivered in 2011 | 4m doses ✓ |
| Delivered in 2012 *as of 30-Sep* | 6.3m doses ✓ |
| *Remains for delivery in 2012-2013* | *7.7m doses* |




# Overview of USG Contracts as of 30 September 2012

| USD million | | P&L | | Cash Flow | |
|---|---|---|---|---|---|
| | Contract value | Revenue recognised | To be recognised | Received | To be received |
| RFP-3 | **549** | 321 | 228 | 346 | 203 |
| RFP-2 | **116** | 115 | 1 | 114 | 2 |
| RFP-1 | **14** | 14 | 0 | 14 | 0 |
| RFP Freeze-dried | **95** | 21 | 74 | 19 | 76 |
| Marburg | **18** | 0 | 18 | 0 | 18 |
| Foot-and-mouth | **1** | 0 | 1 | 0 | 1 |
| **TOTAL** | **793** | **471** | **322** | **493** | **300** |



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# Continued Improvements in IMVAMUNE® Production

- Steady focus on manufacturing efficiency has resulted in a continued increase in the combined performance and output
  - Better utilization of raw materials
  - Consistency in bulk production and fill/finish
  - Improved oversight of sub-contractors
  - Improved release times
  - Overall reduction in resource requirements and staff
- Allows for more doses to be deliveries in 2012 than anticipated
- Will now deliver more than 8 million doses in 2012 (previously 7.5m)
- IMVAMUNE® business remains profitable

# Recent RFP-3 Contract Expansions - Adds USD 37m

## Total contract value now USD 549m

- Awarded additional USD 5m in September
  - To support a study investigating long term storage of frozen bulk vaccine, allowing longer storage and thereby a greater flexibility in the manufacturing process.

- Awarded additional USD 32m in May
  - Mainly to support the expanded Phase 3 trial
  - Contract period extended until 2017

# IMVAMUNE® Phase 3 Program

## US licensing strategy based on two Phase 3 studies, agreed with the FDA:

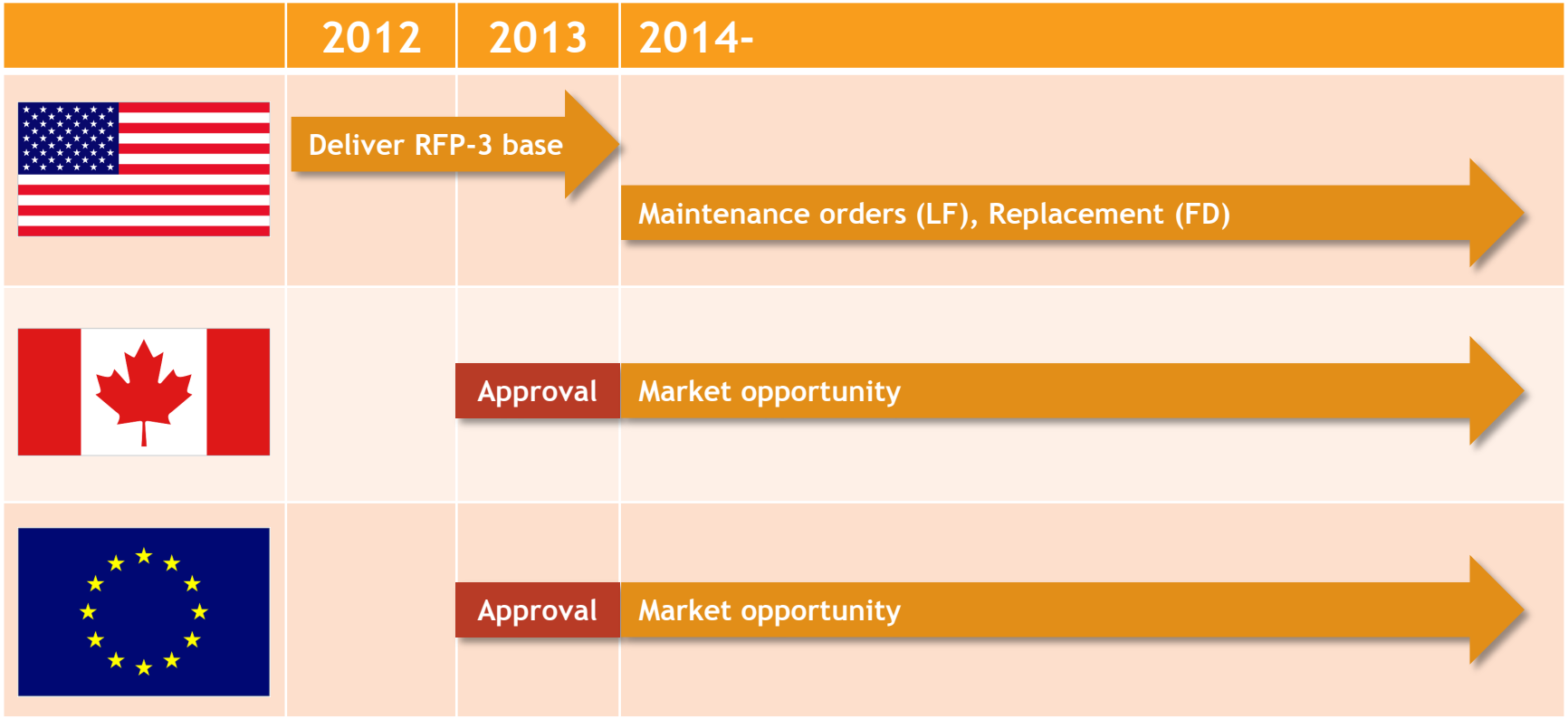
- A lot consistency study in 4,000 healthy individuals
  - Planning on track; clinical trial sites have been selected
  - Expected to be initiated in H1 2013

- A study in 400 military personnel, designed to demonstrate non-inferiority between IMVAMUNE® and the current U.S. licensed smallpox vaccine
  - Selection of a suitable military site has been delayed
  - Study now expected to be initiated in H1 2013. No negative impact on the timing of the Biological License Application (BLA).

# Significant Expansion of Eligible Population

- U.S. Government has significantly expanded the population that is eligible to receive IMVAMUNE® during an emergency:
  - Individuals of all ages with HIV infection or atopic dermatitis (AD)
  - Children, pregnant women, and nursing mothers with HIV or AD are eligible to receive IMVAMUNE®, despite limited clinical data in these specific populations
- Previously, only certain people with HIV were eligible
- BARDA 2010 Broad Agency Announcement highlights need:
  - "*..sufficient quantity to protect 66 M people, comprising those for whom smallpox vaccine is contraindicated and their household contacts (includes 10 M immunocompromised and 28 M atopic dermatitis patients).*"

# IMVAMUNE® - Anticipated Developments




LF: Liquid-frozen
FD: freeze-dried



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# USG Supports MVA-BN® Platform Expansion

## Two new contracts advances the development of new MVA-BN® based vaccines

- Five-year contract valued up to USD 18m awarded by NIAID to support the advanced development of vaccines and technologies that accelerate the immune response for use in post-event settings

- A second contract valued at USD 1 million awarded by DHS for the development of an MVA-BN®-based animal vaccine against Foot-and-mouth disease virus

*NIAID: National Institute of Allergy and Infectious Diseases*
*DHS: U.S. Department of Homeland Security Science and Technology Directorate*

# Infectious Diseases – Short/Mid-Term Objectives

- Deliver 14 million doses of IMVAMUNE® to the U.S. Strategic National Stockpile in 2012-2013 (>8 million in 2012)
- Remain profitable in division
- Secure new IMVAMUNE® orders in the USA
- Initiate pivotal Phase 3 trial of IMVAMUNE®
- Obtain marketing authorisation for IMVAMUNE® in Canada
- Obtain marketing authorisation for IMVANEX® (IMVAMUNE®) in the EU

# Financial Statements

| DKK million | 9m 2012 | 9m 2011 | *FY 2011* |
|---|---|---|---|
| Revenue | 750 | 155 | *524* |
| Production costs | 379 | 194 | *403* |
| **Gross profit** | **371** | **(39)** | ***120*** |
| Research and development costs | 225 | 187 | *262* |
| Distribution and administrative costs | 123 | 108 | *167* |
| **Total operating costs** | **348** | **295** | ***428*** |
| **Income before interest and taxes** | **23** | **(334)** | ***(308)*** |
| Financial income/loss | (6) | 1 | *12* |
| **Income before company tax** | **17** | **(333)** | ***(296)*** |
| Tax | (195) * | 56 | *28* |
| **Net profit for the period** | **(178)** | **(277)** | ***(268)*** |
| | | | |
| Cash preparedness **(end of period)** | **666** | **632** | ***704*** |

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

# Financial Statements – quarter by quarter

| DKK million | Q1 2012 | Q2 2012 | Q3 2012 | 9m 2012 |
|---|---|---|---|---|
| Revenue | 168 | 278 | 304 | 750 |
| Production costs | 92 | 142 | 145 | 379 |
| **Gross profit** | **76** | **136** | **159** | **371** |
| Research and development costs | 68 | 76 | 81 | 225 |
| Distribution and administrative costs | 38 | 41 | 44 | 123 |
| **Total operating costs** | **106** | **117** | **125** | **348** |
| **Income before interest and taxes** | **(30)** | **19** | **34** | **23** |
| Financial income/loss | (5) | 3 | (4) | (6) |
| **Income before company tax** | **(35)** | **22** | **30** | **17** |
| | | | | |
| **IMVAMUNE® doses delivered (thousands)** | **1,437** | **2,300** | **2,592** | **6,329** |

# 2012 Financial Expectations Raised

| | Old | New |
|---|---|---|
| **Revenue** | DKK 900m | **DKK 975m** |
| **Result (loss) before tax** | DKK -150m | **DKK -70m** |
| **Cash preparedness at year-end** | DKK 400m | **DKK 525m** |

***Assumptions***

| | | |
|---|---|---|
| IMVAMUNE® - deliver and recognize | 7.5m doses | >8m doses |
| R&D costs - GROUP | DKK 400m | DKK 370m |
| Infectious Disease Division, EBIT | DKK 230m | DKK 300m |
| Cancer Vaccines Division, EBIT | DKK -280m | DKK -250m |

*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.*

# Anticipated Future Milestones

## CANCER VACCINES

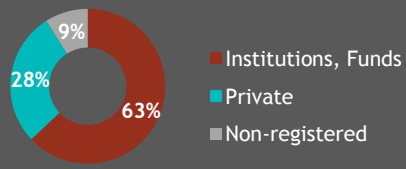
- PROSTVAC® Ph3 complete enrolment (2013)
- Data from PROSTVAC® NCI studies
  - Phase 2 PSA progression combo with hormones
  - Phase 2 non-metastatic PC, combo with flutamide
  - Phase 2 mCRPC combo with samarium
- CV-301 Ph2 data in metastatic breast cancer (4Q 2012)
- MVA-BN® PRO final Ph1/2 data (1H 2013)

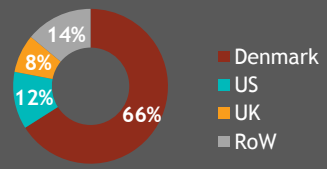
## INFECTIOUS DISEASES

- Deliver 14m doses of IMVAMUNE® to US government in 2012-2013
- IMVAMUNE® Ph3 initiation (1H 2013)
- IMVAMUNE® licensure in Canada (1H 2013)
- IMVANEX® (IMVAMUNE®) licensure in Europe (2013)
- Anthrax Ph1 funding and initiation
- RSV Ph1 initiation (2013)
- Government funding opportunities, current and future projects



| | |
|---|---|
| Share price (09 Nov 2012) | DKK 51 |
| High/low 52 weeks | 61 / 35 |
| Market cap | DKK 1.3bn |
| Net free liquidity per share | DKK 21 (30 Sep 2012) |
| Volume (3m, daily average) | 47,000 |
| No. of shares, 93% free-float | 26m |
| No. of registered shareholders | 21,000 |
| Largest shareholders | ATP (> 10%) |
| | A.J. Aamund A/S (> 5%) |
| | BB Biotech AG (> 5%) |
| | OrbiMed Advisors LLC ( > 5%) |




| | |
|---|---|
| 2012 Annual Report | 7 March 2013 |
| Annual General Meeting | 17 April 2013 |
| 2013 First Quarterly Report (Q1) | 16 May 2013 |
| 2013 Half Year Report (Q2) | 22 August 2013 |
| 2013 Third Quarterly Report (Q3) | 14 November 2013 |

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