# ANNUAL GENERAL MEETING 2019



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**BAVARIAN NORDIC** 



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**7** Election of Auditors.



## WELCOME

GERARD VAN ODIJK CHAIRMAN OF THE BOARD

## **2018 IN REVIEW: OPERATIONALLY ON TARGET**

- Moving towards U.S. licensure of smallpox vaccine after successful completion of Phase 3 and BLA submission to the FDA
- Initiated construction of fill and finish facility
- Expansion of **partnership with U.S. Government** on encephalitis vaccine
- First of three commercial programs under Janssen partnership now in clinical trials
- Successfully completed Phase 2 development of RSV vaccine
- Strong progress in **immuno-oncology** portfolio with 4 new Phase 2 studies initiated
- Results and cash preparedness better than guided





#### THE BAVARIAN NORDIC SHARE



BAVARIAN NORDIC

## **BOARD GOVERNANCE**

- A total of 11 Board meetings and 15 committee meetings held during 2018.
- Board evaluation conducted and facilitated by external consultant. Positive outcome and good input for further development of the Board.





Nominated for election Anne Louise Eberhard, LL.M. (Danish, born 1963)

Extensive finance and risk management experience and board experience from publicly listed companies

<u>Board memberships</u>: FLSmidth A/S, Topdanmark A/S, Finansiel Stabilitet <u>Other positions</u>: Advisory board member of Moneyflow Group ApS and a faculty member and lecturer at Copenhagen Business School, Board Educations.

#### BAVARIAN NORDIC

#### **INVESTING FOR THE FUTURE** RETURNING TO PROFITABILITY

#### Consolidating our leadership position in smallpox vaccines

- U.S. licensure in 2019 will expand commercial opportunities
- Investment in fill and finish facility will expand our manufacturing capabilities and secure future revenues

#### Partnerships which could provide evergreen returns

- U.S. Government (smallpox and other contracts)
- Janssen

#### Applying new tactics in immuno-oncology

• Enhanced vaccines and new routes of administration designed to trigger improved responses and tumor killing

#### Using our platform to improve public health

• Our ability to discover new and life-changing therapies demands that we continue to innovate and generate new opportunities for those in need



## FINANCIALS HENRIK JUUEL EXECUTIVE VICE PRESIDENT & CFO

### **FINANCIAL RESULTS 2018**



2018

- Consistent with previous years, revenues were in line with our guidance
- EBIT and cash preparedness better than guided due to lower expenses and investments
- The net result was a loss of DKK 362 million which is proposed transferred to 2019



		2010
mDKK	guidance	actual
Revenue	500	501
EBIT	(385)	(354)
Cash preparedness at year-end	2,100	2,314

Cash preparedness includes cash, cash equivalents, investments in securities and the aggregate amount of undrawn credit lines.

## **FINANCIAL OUTLOOK 2019**

- Majority of 2019 revenue expected from second tranche of bulk smallpox vaccine contract (50 mUSD)
- R&D costs of approx. 570 mDKK (420 mDKK in P&L)
- Investments in FnF of approx. 270 mDKK (peak year)
- Sale of Priority Review Voucher has not been included in guidance



	2019
mDKK	guidance
Revenue	600
EBIT	(360)
Cash preparedness at year-end	1,600

Cash preparedness includes cash, cash equivalents, investments in securities and the aggregate amount of undrawn credit lines.

## **2018 IN REVIEW** PAUL CHAPLIN CEO AND PRESIDENT

#### **OUR VISION & STRATEGY** INVESTING FOR THE FUTURE



By 2023 we aspire to be a leading and <u>profitable biotech company</u> that through harnessing the power of the immune system will <u>develop</u>, <u>manufacture</u> and <u>commercialize</u> products for infectious disease and cancer

MAINTAIN global leadership of our smallpox vaccine business Finalize development of smallpox vaccine
Secure broader sales

**EXPAND** and rapidly **ADVANCE** the pipeline of infectious disease programs

- Launch RSV vaccine
- Advance partnered programs
- Advance infectious disease pipeline

**ESTABLISH** a broad and deep cancer immunotherapy portfolio

- Explore combination therapies with vaccines and standard
   of care
- Explore more advanced combinations

**EXPAND** the commercial footprint and capabilities

- Take advantage of core manufacturing capabilities and
- capacity
- Build commercial infrastructure to drive profitable growth

#### **INVESTING FOR THE FUTURE** RETURNING TO PROFITABILITY



**Partnerships** 

- Adding value to the pipeline assets R&D investments remain unchanged
- Expanding manufacturing capabilities transitional period of lower revenues
- Investments in Fill and Finish plant will peak in 2019 as construction will be finalized this year
- Financially well prepared for these investments.



BAVARIAN NORDIC

## **ONE PLATFORM - MULTIPLE OPPORTUNITIES**



Unlocking the power of the immune system to improve public health with a focus on high unmet medical needs



#### SMALLPOX INFECTIOUS DISEASE CANCER IMMUNOTHERAPY COMMERCIA

## A GLOBAL LEADER IN SMALLPOX VACCINES

- Strong presence and capabilities in the smallpox vaccine area
- MVA-BN is the only non-replicating approved smallpox vaccine in Europe and Canada
- U.S. government contracts awarded to-date valued at nearly DKK 12 billion

#### THE PAST

- 22 clinical trials completed including two Phase 3 studies
- Approved for emergency use
- 28 million doses stockpiled for immune compromised - now expired
- BLA submitted

#### THE PRESENT

- Bulk vaccine worth > DKK 2 billion produced to-date and stored for future fill and finish
- Approval expected in 2019
- Priority Review Voucher to be sold
- Initiating Phase 3 with freezedried vaccine
- Finalizing construction of fill and finish facility

#### THE FUTURE

- DKK 2 billion in secured future revenue from completion of 13M freeze-dried doses
- 10-year contract with additional procurement options
- Post-approval opportunities beyond stockpiling
  - Military personnel
  - Healthcare workers



JNOTHERAPY

#### OUR COLLABORATION WITH JANSSEN A LONG-TERM VALUE DRIVER

#### 4 license agreements in place

- The combination of Janssen's AdVac + MVA-BN has demonstrated robust and sustained immune responses in humans
- The synergistic benefit of combining our technology has been key to establishing collaborations in blockbuster indications
- Equity investments have made JNJ a major shareholder with ownership of 5.77%





**COMMERCIAL** 

## **RSV - A LARGE UNMET MEDICAL NEED**

Differentiated RSV vaccine ready for Phase 3 after completing two successful Phase 2 studies

### RSV

No approved prophylactic vaccine

#### Influenza

\$5.4B USD global market



Initial target population:

#### Elderly and At-Risk Adults

- ~180,000
   hospitalizations in
   the US per year
- ~14,000 deaths in the US per year
- Similar in the EU



#### BAVARIAN NORDIC

COMMERCIAL

## **BUILDING A BROAD IMMUNOTHERAPY PORTFOLIO**



AstraZeneca

Bristol-Myers Squibb

#### BN vaccine + standard of care (e.g. chemotherapy & radiation)

- Pivotal trial of BN-Brachyury plus radiation ongoing in rare cancer chordoma
- Data expected in 2H19

#### BN vaccine + checkpoint inhibitors

- Three Phase 2 trials of CV301 in combination with checkpoint inhibitors ongoing
- Bladder data expected in 2H19

#### **Next-generation BN vaccines**

- Providing the body with more weapons
- Customizable for type of cancer & delivery
- One construct for multiple targets



**Initiating 2019** 

Roche

COMMERCIAL

## **INVESTING FOR THE FUTURE**

- Fill and finish facility
  - Up to 8M freeze-dried & 40M liquid doses per year
- Expands our manufacturing capability
  - Key driver in securing higher smallpox revenues in the years to come
- Support new partnerships
  - Launch RSV
  - Licensing of pipeline assets
  - Manufacturing for partners/collaborators



#### Project timeline

Mar-18	Nov-18	Jun-19	Oct-19	Jan-20	Oct-20	end 2020
Groundbreaking	Outer building completed	Construction finalized	All equipment installed	Equipment commissioned and qualified	PQ activities completed	Initiation of production

## **2019 PRIORITIES AND GOALS**

**MAINTAIN** global leadership of our smallpox vaccine business

- FDA approval of liquid-frozen MVA-BN
- Award of Priority Review Voucher
- Initiate Phase 3 study of freeze-dried MVA-BN

**EXPAND** and rapidly **ADVANCE** the pipeline of infectious disease programs

**ESTABLISH** a broad and deep cancer immunotherapy portfolio

**EXPAND** the commercial footprint and capabilities

- Finalize **RSV** development plan
- Initiate Phase 1/2a study of HIV vaccine with Janssen
- Initiate Phase 1 dose finding study of equine encephalitis virus vaccine
- Initiate Phase 1 study of intra-tumoral administration of CV301 in solid tumors
- Initiate Phase 1 study of intravenous administration of BN-Brachyury
- Report initial ORR results from CV301 in combination with atezolizumab in bladder cancer
- Report initial ORR results from Phase 2 study of BN-Brachyury in chordoma

• Finalize construction of fill and finish facility



The Board of Directors' report on the Company's activities in the past year.

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The loss for year is proposed transferred to retained earnings (equity)

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Election of Auditors.



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#### **5a** Authorisations to increase the share capital

Proposal to increase and extend the authorisations of the Board of Directors in Article 5a of the Articles of Association, so that the Board of Directors until 30 June 2020 is authorised to increase the share capital of the Company by nominally DKK 32,310,560, corresponding to 10% of the Company's share capital.

## ECTORS

## **5b** Warrants

Proposal to increase and extend the authorisation of the Board of Directors in Article 5b of the Articles of Association, so that the Board of Directors until 31 December 2020 is authorised to issue warrants, which entitle the holders to subscribe for shares in the Company at a nominal value of up to DKK 6,000,000.

Warrants may not be granted to members of the Company's Board of Directors but only to members of the Executive Management and to employees of the Company or the Company's subsidiaries.

#### **5c** Guidelines for incentive remuneration

Proposal to amend the Remuneration Policy including the general guidelines for incentive remuneration of the Board of Directors and the Executive Management.

"The base wage of the Executive Management comprises a fixed annual wage. In addition, the members of the Executive Management may receive non-cash compensation such as education, health insurance coverage, company car, company phone, internet and allowances for reallocation expenses. Members not living in their home country may receive housing allowances or compensation for housing expenses or the Company may provide for living accommodation (provided the market value of the house/apartment at the time of first occupancy by the Executive does not exceed DKK 12 million)."

### **5d** Remuneration

Proposal to approve remuneration of the Board of Directors and the Board Committees for the current financial year.

#### 5e Repurchase of shares

Proposal to authorise the Board of Directors to repurchase own shares.

#### **5f** Change in the Articles of Association

Proposal to align the Danish terminology of the Company's Articles of Association so that the word "ejerbog" (in English "register of shareholders") is used instead of the word "aktiebog". The proposal entails adjustments of Articles 8, 10, 11 and exhibit 1.

#### **5g** Change in the Articles of Association

Proposal to amend Article 10, subsection 4 of the Articles of Association so that the obligation to convene General Meetings by publication in the IT information system of the Danish Business Authority is omitted.



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## 6. ELECTION OF MEMBERS TO THE BOARD OF DIRECTORS

#### Anders G.Pedersen

Deputy chairman since 2014 Member since 2010

Member of the Finance, Risk and Audit *Committee since 2015* 

#### Erik G. Hansen

Member since 2010 Chairman of the Finance, Risk and Audit Committee since Compensation Committee 2015 since 2018

#### Elizabeth M. Anderson

Member since 2017 Member of the Nomination and

#### Gerard van Odijk

Chairman since 2014 Member since 2008

#### Chairman of the Nomination and Compensation Committee since 2015

#### Frank Verwiel

Member since 2016 Member of the Finance, Risk and Audit Committee since 2016

#### Peter Kürstein

Member since 2012 Member of the Nomination and Compensation Committee since 2015

#### Anne Louise Eberhard

Nominated for election as new member





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The Board of Directors proposes that Deloitte is re-elected as the Company's auditor.

### FORWARD-LOOKING STATEMENTS



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 regarding our short-term objectives and opportunities, financial expectations for the full year and financial preparedness as of year end, as well as statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements which may accompany the forward-looking statements. 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.

