

ANNUAL REPORT

2018

1994 **25** 2019

YEARS

OF GREAT ACHIEVEMENTS
IN THE VACCINE SPACE



BAVARIAN NORDIC



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 are expressly qualified by these cautionary statements and any other cautionary 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.

DELIVERING ON OUR STRATEGY

KEY HIGHLIGHTS FOR 2018

- Reported positive clinical results confirming Bavarian Nordic as the **global leader in smallpox and RSV vaccine** development
- **BLA for MVA-BN smallpox** was accepted with priority review
- Initiated construction of a **fill and finish facility** expanding our manufacturing capabilities & securing higher future revenues. Investment supported through U.S. Government award of USD 44 million
- Made significant progress with our immunotherapy assets with the **initiation of 4 proof-of-concept Phase 2 studies**
- Brought new innovative ideas to expand the pipeline with the announcement of **new immunotherapy strategies** to treat cancer patients with the first clinical trials expected in 2019.
- Vaccine platform was recognised with the award of a \$36 M contract from the U.S. DoD to develop a vaccine against **equine encephalitis virus** - another biological threat
- Significant progress with Janssen partnership - initiated Phase 1/2a for therapeutic HPV

OUR VISION & STRATEGY

INVESTING FOR THE FUTURE

By 2023 we aspire to be a leading and profitable biotech company that through harnessing the power of the immune system will develop, manufacture and commercialize 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

A GLOBAL LEADER IN SMALLPOX VACCINES

MVA-BN - a non-replicating smallpox vaccine for the general population, including those for whom replicating smallpox vaccines are contraindicated, such as all people with HIV or skin allergies and their household contacts

- MVA-BN is the only **non-replicating approved smallpox vaccine** in Europe and Canada
- We operate the worlds' only **dedicated manufacturing facility** for MVA-based vaccines, currently being expanded with a **fill and finish** facility.
- **28 million** liquid-frozen doses supplied (now expired) to the U.S. for emergency use in people for whom replicating smallpox vaccines are contraindicated

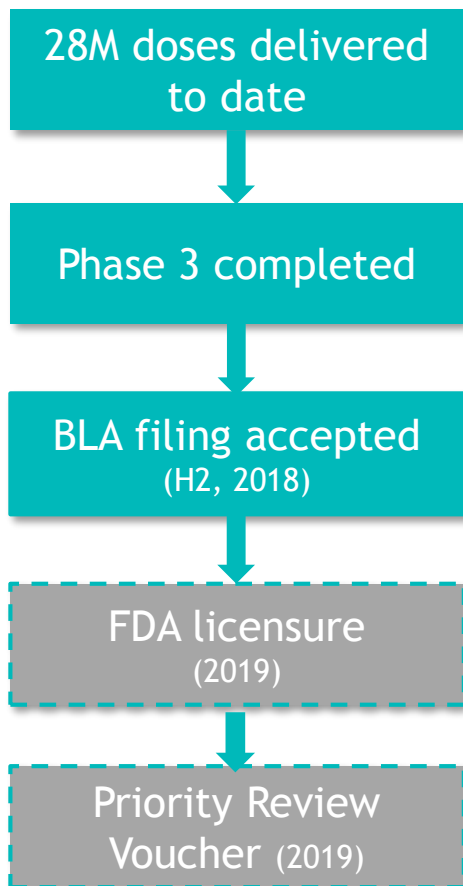
Phase 3 results: MVA-BN vs. ACAM2000 (current approved, replicating vaccine):

- Peak neutralizing antibodies induced by MVA-BN were two-fold higher than those stimulated by ACAM2000. This met the co-primary endpoint of non-inferiority and even showed a statistically superior immune response.
- Immune responses were shown to be non-inferior after a single MVA-BN vaccination - at a time when ACAM2000 is reported to have induced a protective response.
- No serious adverse events related to MVA-BN were reported, and the frequency of Grade 3 or higher related adverse events was less in MVA-BN (1.2%) in comparison to ACAM2000 (10.3%).

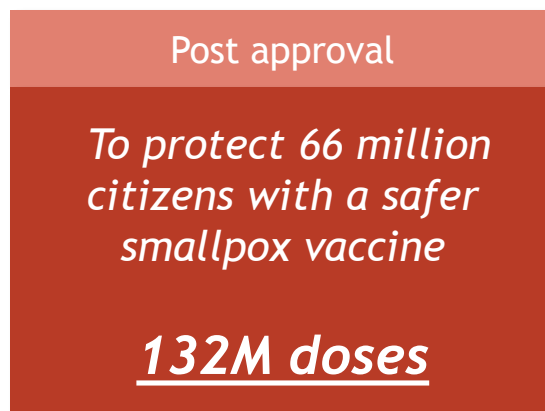
MVA-BN PARTNERSHIP WITH U.S. GOVERNMENT

USD 1.8 BILLION ALREADY AWARDED TO DATE

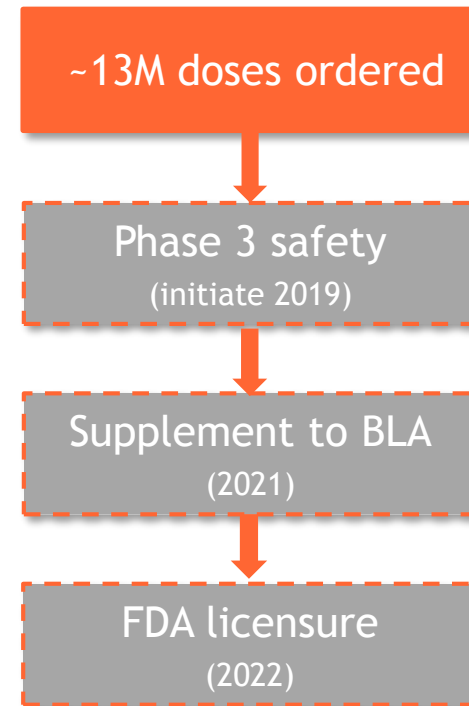
Liquid-frozen



U.S. strategic long-term stockpiling goal



Freeze-dried



A GROWING NEED FOR PREPAREDNESS

FUTURE OPPORTUNITIES FOR MVA-BN

- Recent cases of **human monkeypox** in the U.K. and Israel highlight the need for preparedness plans; update of stockpiles with safest alternatives and **vaccination of first line responders**
 - 3 cases in U.K. and 1 in Israel, all related to current Nigeria outbreak - 1 case of a health care worker
 - U.K. authorities chose IMVANEX* over currently stockpiled, replicating smallpox vaccines for vaccination of healthcare workers
- Post MVA-BN licensure for the general adult population a number of **new opportunities beyond national stockpile**
 - Current recommendation for smallpox vaccination are military personnel in S. Korea
 - Future: All troops entering basic training
 - Future: All active duty military personnel
 - U.S. smallpox vaccination guidelines (2002):
 - 0.5M to up to 10M healthcare workers
 - Other civilians who wish to be vaccinated

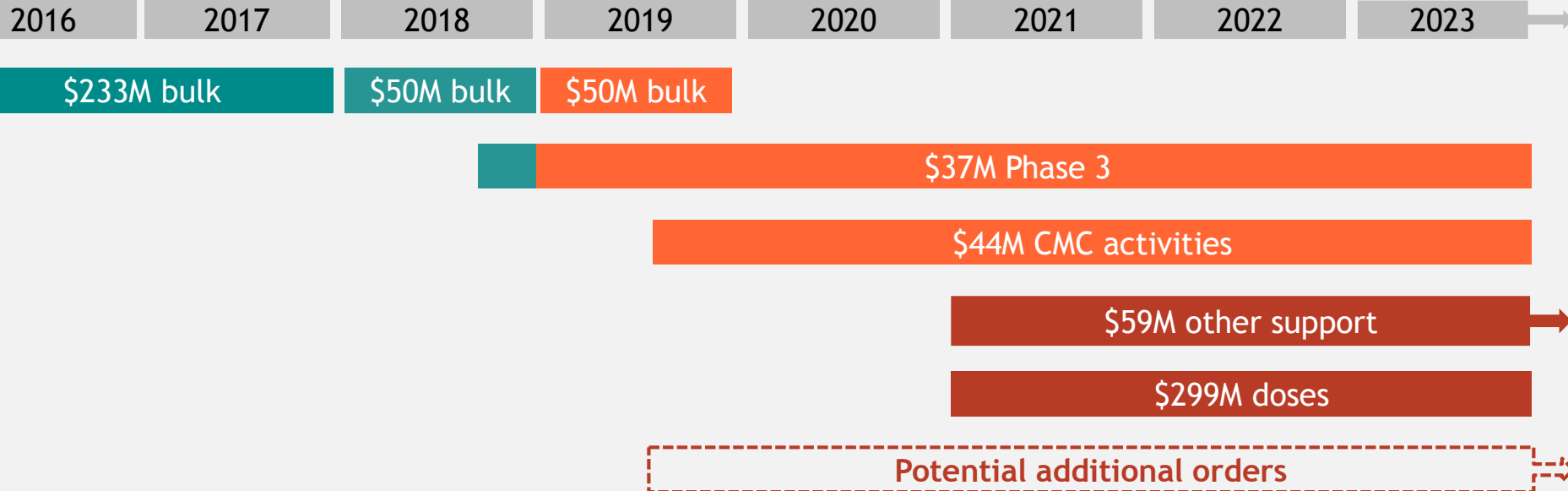
Monkeypox

- Zoonotic disease (transmission from animals to humans), with mortality rate ranging from 1-10%
- Human-to-human transmission
- No approved vaccines, but smallpox vaccines historically showed efficacy in preventing monkeypox

* IMVANEX (MVA-BN) is not approved for the prevention of monkeypox

FREEZE-DRIED MVA-BN CONTRACT WITH USG

RETURNING TO PROFITABILITY



Bulk vaccine



Construction of fill/finish plant



Freeze-dried
MVA-BN

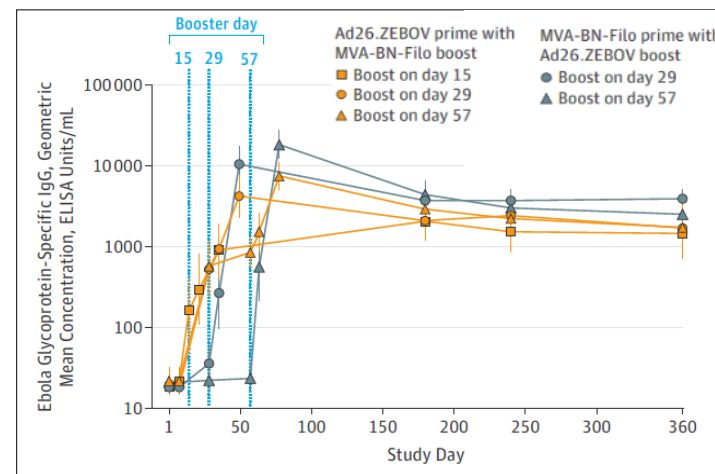
OUR COLLABORATION WITH JANSSEN

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%



MVA-BN Filo (Ebola)

Phase 3 ongoing

MVA-BN HPV

Phase 1/2a ongoing

MVA-BN HIV

Phase 1/2a in 2019

MVA-BN HBV

Potential milestone payments of
~\$1BN + royalties



RSV VACCINE DEVELOPMENT HISTORY

- Development of a vaccine for RSV has been ongoing for >60 years with finite success
- The history of RSV vaccine development is notable for the vaccine-enhanced illness that occurred after a formalin-inactivated RSV (FI-RSV) vaccine was administered to seronegative infants in the 1960s.
- Vaccine approaches using recombinant RSV F protein (with & without adjuvant) have failed in field efficacy trials
 - No correlation of neutralizing antibody titers with protection¹
 - RSV-specific nasal IgA correlated with risk-reduction of PCR-confirmed infection¹
 - T-cells: Abundance of resident CD8 memory cells in the lung before infection correlates with reduced symptoms and viral load²

1. Habibi, MS., et al., *Am J Respir Crit Care Med.* **191**(9):1040-9 (2015)

2. Jozwik, A., et al., *Nature Communications* **6**:10224 (2015)

AT THE FOREFRONT OF RSV VACCINE DEVELOPMENT

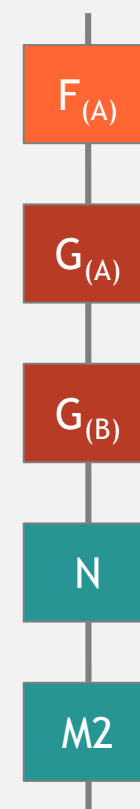
Novel Vaccine Design

- Encodes 5 distinct targets of RSV to stimulate a broad protective immune response (T-cell and antibody response).
- The vaccine is mimicking a natural response to an RSV infection that is believed to induce protection for at least a year.

Competitive Advantages

- Induction of a broad T-cell and antibody response against RSV
- Induction of mucosal immunity
- Durable immune response lasting a year in the majority of subjects
- Based on MVA-BN - live virus adjuvant with a favorable safety profile

MVA-BN RSV



RSV PHASE 3 CONSIDERATIONS

- Ongoing dialogue with the FDA regarding requirements for licensure of MVA-BN RSV
- Current Phase 3 considerations:
 - Phase 3 in 12,000 - 18,000 depending on statistical plan to be finalized with the FDA in 2019
 - Study will start in 2020
 - Potentially could conduct a Phase 3 over 2 RSV seasons including a futility analysis after season 1
 - Estimated Phase 3 trial cost: USD 80-120 M



IND/Reg. authority



Months of vaccination

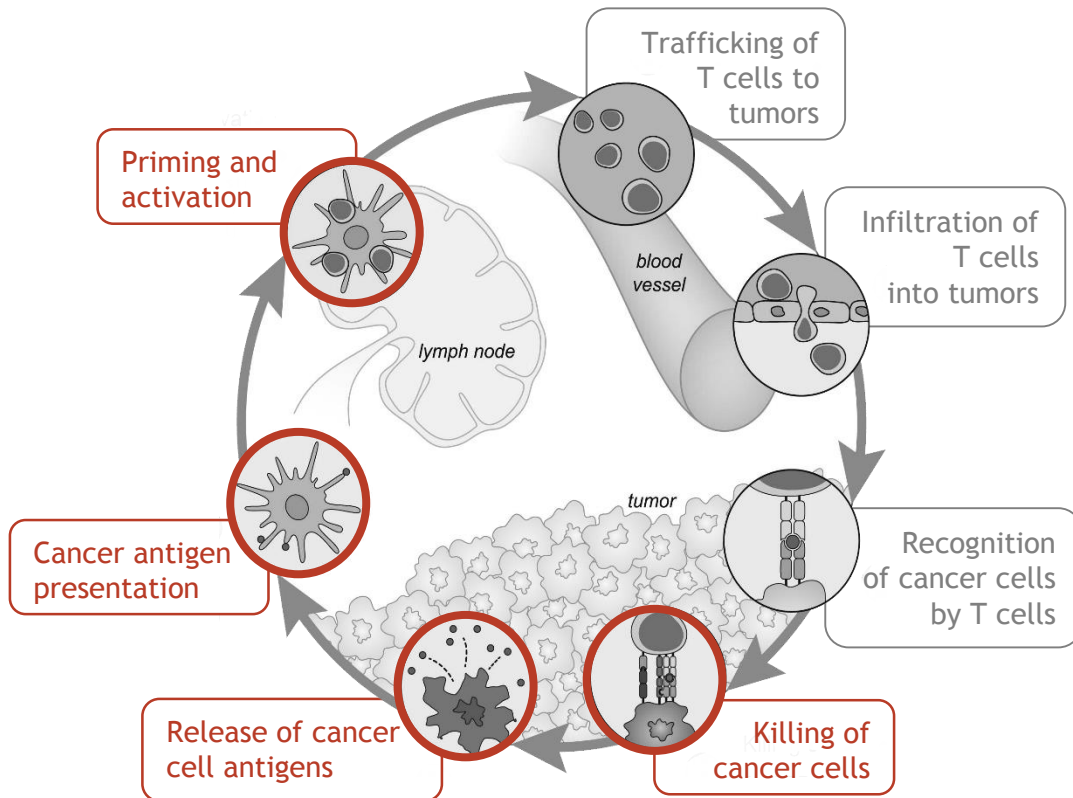


Results

HOW HAS OUR I-O STRATEGY EVOLVED?

Augmented dosing regimen

2 priming doses in 4 different areas (as compared with prior constructs), which appears to **increase the quantity of antigen-specific T cells** in vaccinated patients



Vastly enhanced immunogenicity and improved antigen selection

PROSTVAC induced PSA-specific T cell activation in **less than 30%** of patients

CV301 and **BN-Brachyury** demonstrated T cell activation targeting CEA, MUC-1 and Brachyury in **>90%** of vaccinated patients

Provided the body with more weapons

Combining BN-Brachyury and CV301 with checkpoint inhibitors, radiation and/or chemotherapy is believed to amplify the body's ability to **recognize, infiltrate and kill** cancer cells

BRACHYURY

- NEW FRONTIERS IN TREATING METASTATIC CANCERS

Brachyury

- Tumor-associated antigen that is overexpressed in major solid tumor indications and several ultra-rare orphan cancers
 - Expression is highly correlated with metastatic disease, multi-drug resistance and decreased survival rates
- **BN-Brachyury** vaccine candidate utilizes a prime-boost regimen that has been **optimized to include the gene for brachyury** and other molecules known to increase immune activation
 - Phase 1 data demonstrated that BN-Brachyury vaccine could **safely target** brachyury and **induce brachyury-specific T-cell** responses
 - Ongoing **Phase 2 trial in chordoma**
 - Received orphan drug status from the FDA
 - Potential for **Breakthrough Designation**

PIVOTAL TRIAL ONGOING IN CHORDOMA

ULTRA-ORPHAN CANCER WITH LIMITED TREATMENT OPTIONS

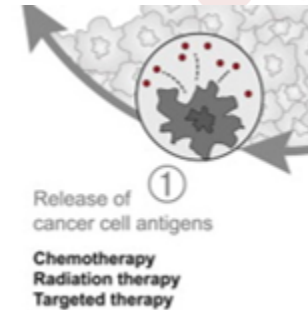
- Multi-site trial to assess the effectiveness of **BN-Brachyury** vaccine and current standard of care, **radiation** therapy, in patients with **advanced chordoma**
- **Radiation** has been shown to inflame the tumor, **releasing cancer antigens**, increasing the **targeting of brachyury**
- Patients will receive **2 primer vaccinations with MVA-BN Brachyury** followed by **boosters** with (fowlpox virus) **FPV-Brachyury** and **radiation** therapy
- Establish if combo therapy results in a **clinically-meaningful ORR**
- **Stage 1 enrollment completed in January 2019**

STAGE 1 (10 patients)

- Only proceed to stage 2 if at least 1 objective response occurs

STAGE 2 (19 patients)

- ORR goal total = 4/29 patients (stage 1 + 2)



Chordoma

- Rare cancer that occurs in the skull base and spine that universally overexpresses brachyury
- 1,000 new cases in the U.S. and E.U. annually
- Historical objective response rate (ORR) with radiation alone <5%

CV301

THREE PHASE 2 COMBINATION TRIALS ONGOING

- **Investigator sponsored** studies and studies that employ adaptive trial designs to provide a **capital-efficient, rapid proof of concept**
- Patients receive **2 priming doses on MVA-BN-CV301** in four different injection sites, followed by **multiple boosters of FPV-CV301** at tapering intervals for the duration of checkpoint inhibitor therapy

Bladder cancer

CV301 + TECENTRIQ
(*atezolizumab*)

Primary Endpoint:
Objective Response Rate
(ORR)

N=68 (27 in stage 1)

Bavarian Nordic-sponsored
trial



Colorectal cancer

CV301 + OPDIVO
(*nivolumab*) & chemotherapy

Primary Endpoint:
Overall Survival (OS)

N=78

Sponsored by Rutgers
University



Bristol-Myers Squibb

Colorectal & Pancreatic

CV301 + IMFINZI
(*durvalumab*)

Primary Endpoint:
Progression Free Survival
(PFS)

N=52 (26 for each disease)

Sponsored by Georgetown
University

AstraZeneca 

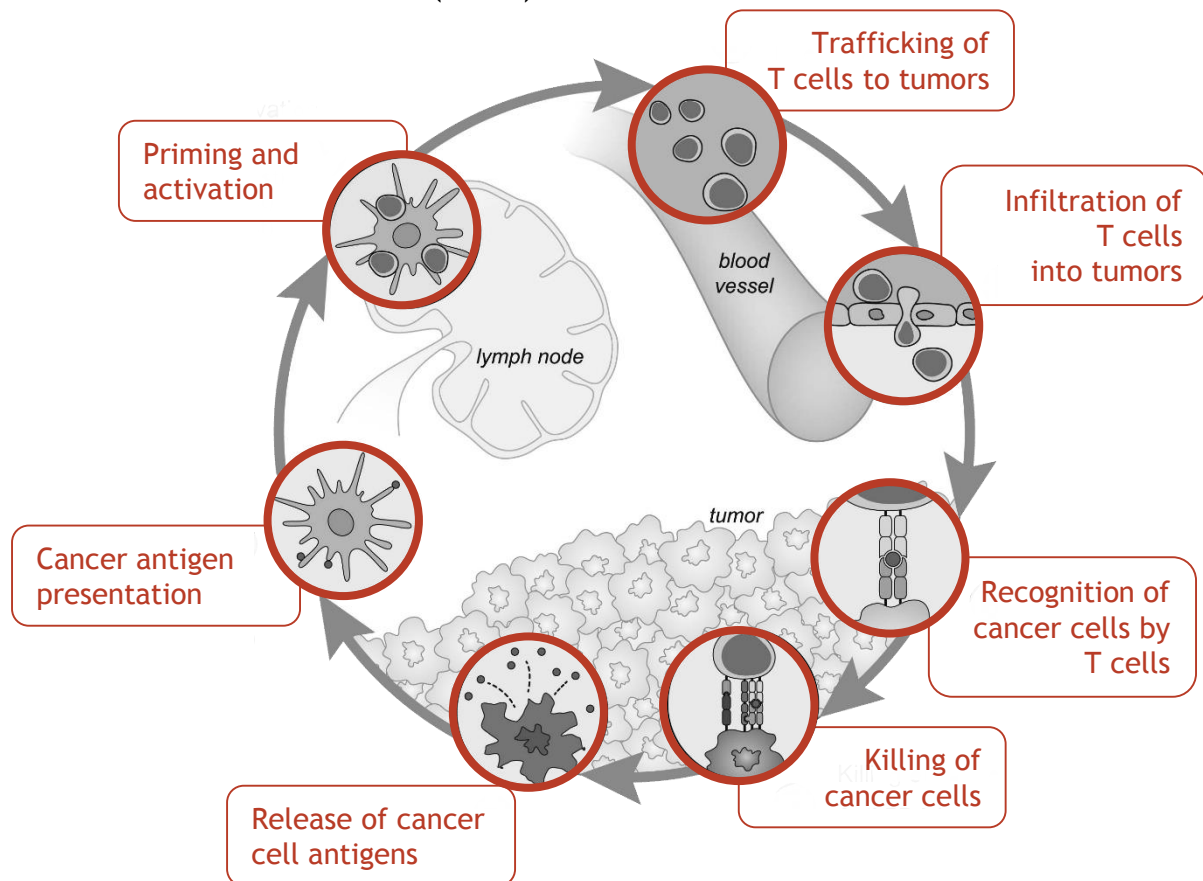
INTRA-TUMORAL AND INTRAVENOUS ADMINISTRATION

Strengthening our immuno-oncology platform

Developing intra-tumoral (IT) and intravenous (IV) administration of cancer immunotherapies as a potent approach to activate both arms of the immune system and alter the suppressive tumor microenvironment (TME)

Preclinical data of IT and IV immunotherapy demonstrate:

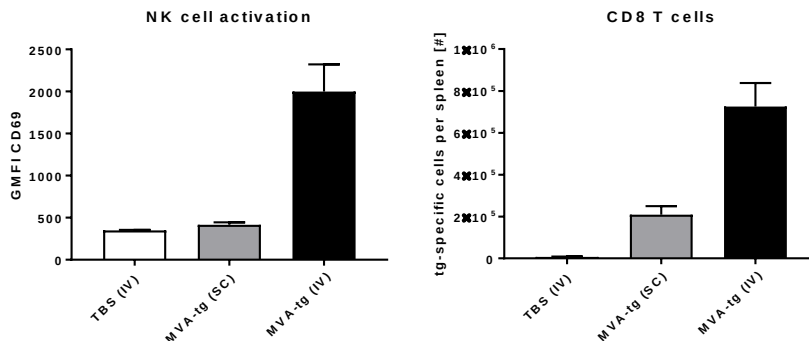
- Strong activation of innate and adaptive immune mechanisms
- Inflammatory responses in the TME
- Tumor-specific T cell recruitment into the tumor tissue
- Control of tumor growth
- Synergies with immune checkpoint blockade



THE BENEFITS OF INTRA-TUMORAL AND INTRAVENOUS ADMINISTRATION

Intravenous administration

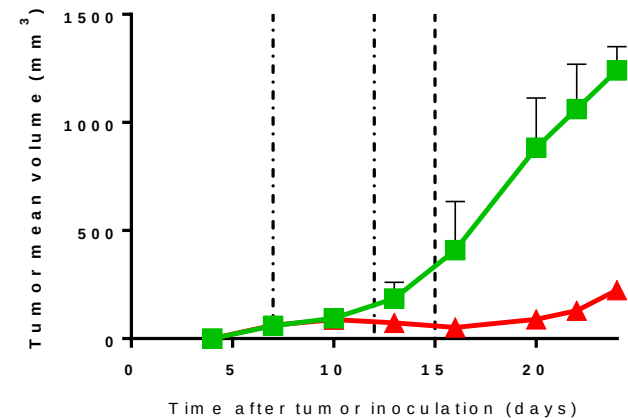
- Improved quantity of T-cell response
- Stimulates NK cell activation and expansion to recognize cancer cells and overcome MHC loss
- Induces systemic cytokine responses
- Elevated responses when vaccine also encodes CD40L



Phase 1 planned with BN-Brachyury in 1H19

Intra-tumoral administration

- ‘Heats’ up the TME by generating intra-tumoral inflammation
- Creates a systemic immune response by activating tumor-antigen specific CD8 T cells



Transgenic melanoma model B16.tg

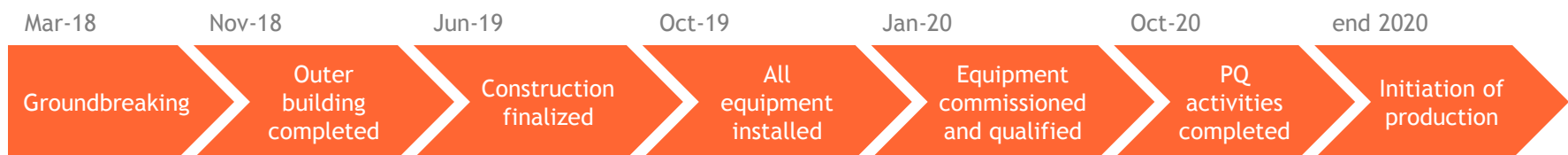
Phase 1 planned with CV301 in 1H19

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

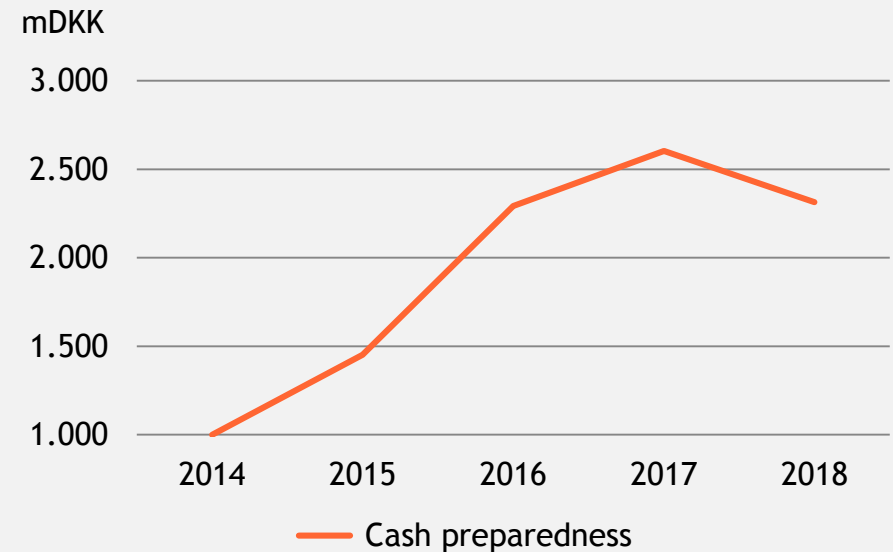
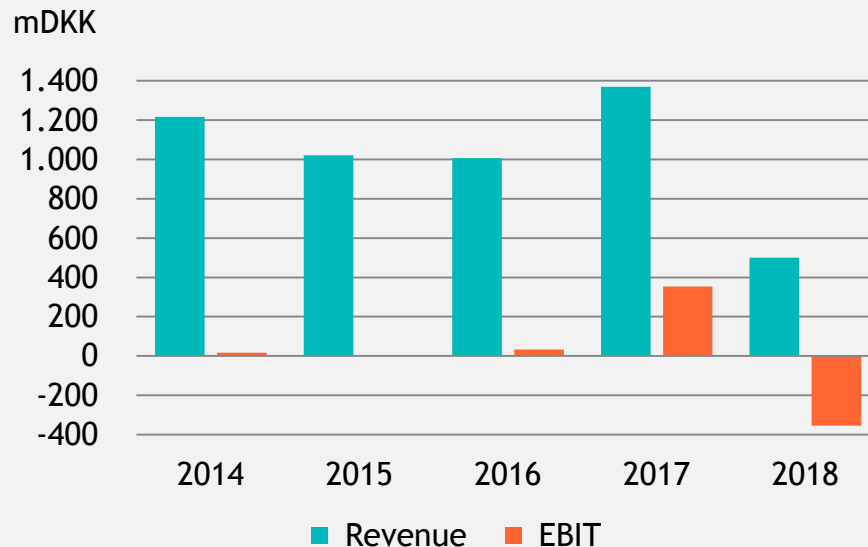
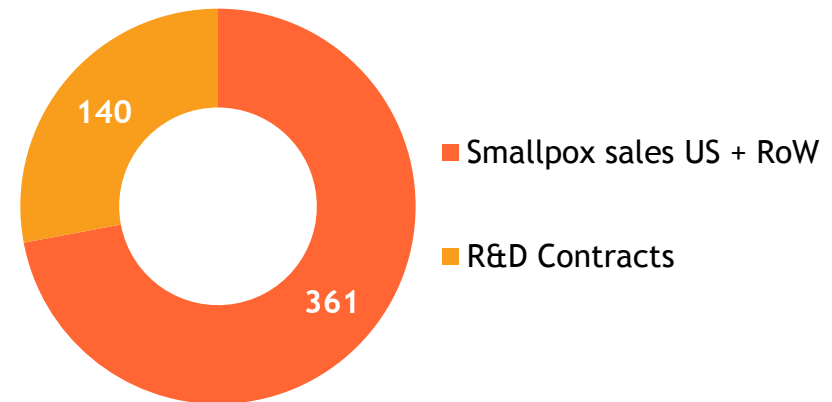


FINANCIAL RESULTS 2018

- Revenue of 501 mDKK - in line with guidance
- EBIT and cash preparedness better than guided due to lower expenses and investments
 - EBIT of (354) mDKK
 - Cash preparedness of 2,314 mDKK

Revenue 2018

mDKK

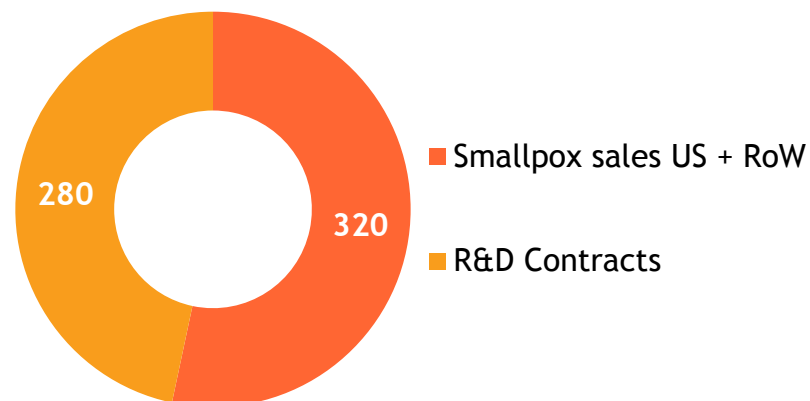


FINANCIAL OUTLOOK 2019

- 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

Revenue 2019

mDKK



		2018		2019	mUSD		
					2018	2019	
mDKK	guidance	actual	guidance		guidance	actual	guidance
Revenue	500	501	600		77	77	92
EBIT	(385)	(354)	(360)		(59)	(54)	(54)
Cash preparedness at year-end	2,100	2,314	1,600		322	355	246

USD / DKK = 6.5

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

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**

ESTABLISH a broad and deep cancer immunotherapy portfolio

- 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

EXPAND and rapidly ADVANCE the pipeline of infectious disease programs

- 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

EXPAND the commercial footprint and capabilities

- Finalize construction of **fill and finish** facility



Q&A

