

Bavarian Nordic

Q3 2021

*Spreading hope,
pioneering vaccines*

12 November 2021



BAVARIAN NORDIC

Disclaimer

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.

2021 highlights YTD



Commercial

Rabies market impacted by COVID-19, particularly in Europe, due to travel restrictions

TBE market adversely affected by limited access to physicians (Germany)

Smallpox/Ebola sales remain unaffected

Guidance maintained at lower end of guided ranges

mDKK	FYE 2021
Revenue	~1,900
EBITDA	~100
Cash	~1,400

Pipeline

COVID-19 encouraging Phase 1 results for booster vaccine candidate, showing strong antibody response, high neutralization capacity against variants and a favorable safety profile. Phase 2 initiated.
Phase 3 funding (800 mDKK) agreement with the Danish Government.

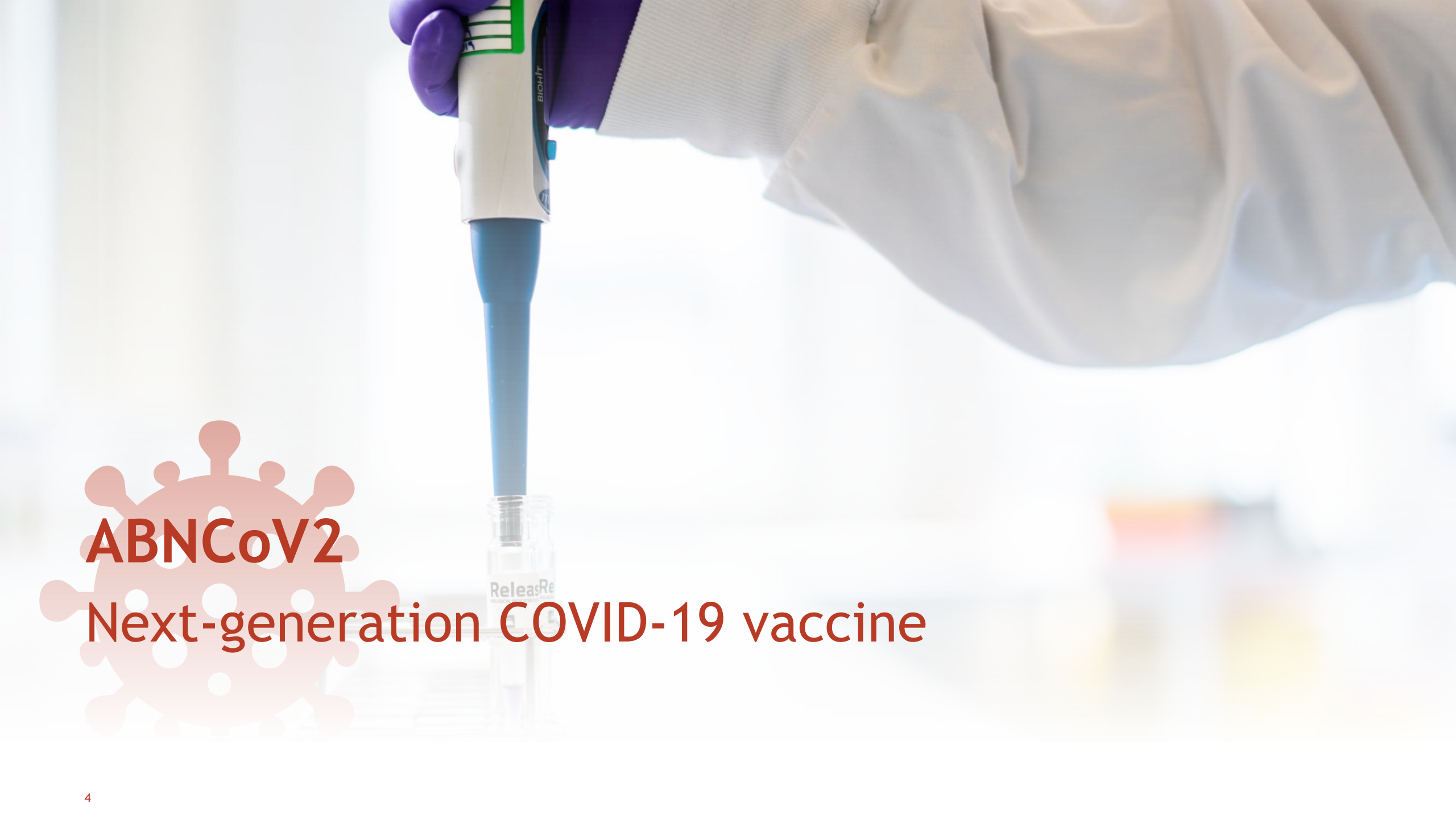
Phase 2 read out in Q4 2021

Phase 3 initiation in 2022 pending Phase 2 results and regulatory discussions

RSV human challenge trial achieved the primary endpoint by demonstrating statistically significant reduction in viral load in vaccinated versus control (placebo) treated volunteers. Vaccine showed 79% efficacy in reducing symptomatic RSV infection

Preparing for Phase 3 in 2022, pending further analysis, regulatory discussions and funding considerations.

Go/no-go decision in Q4 2021



ABNCoV2

Next-generation COVID-19 vaccine

ABNCoV2

- a potential to develop a universal COVID-19 booster vaccine

The vaccine

- Capsid virus like particle (cVLP) based SARS-CoV-2 subunit vaccine
- Licensed from AdaptVac
- ABNCoV2 has shown to be highly immunogenic inducing durable and superior responses to convalescent sera from patients that have recovered from COVID-19, while also providing a favorable safety profile.
- More importantly, Phase 1 data confirms the potential of ABNCoV2 to induce neutralizing antibodies against circulating variants of SARS-CoV2, including the Delta variant.



Funding

- DKK 800 million funding from Danish Ministry of Health to support development through to licensure
- Milestone-based agreement based on achievement of certain milestones related to completion of Phase 2, Phase 3 development and scaling up of production for commercial manufacturing.
- Subject to repayment by delivery of vaccines and royalty payments, however only if EU approval is obtained and royalties only if a certain volume in annual sales is reached.



Phase 2 ongoing

- Phase 2 study ongoing with results anticipated in Q4 2021.



Phase 3 planned for 2022

- Targeting a smaller study to demonstrate non-inferiority to approved COVID-19 vaccine.
- Final study design will depend on Phase 2 results and feedback from regulators, including determining pathway for approval (emergency use or normal authorization).
- Scaling-up manufacturing for Phase 3 and commercial production has been initiated.

2021



Phase 1

2022

Phase 2

Phase 3



Scale-up of manufacturing

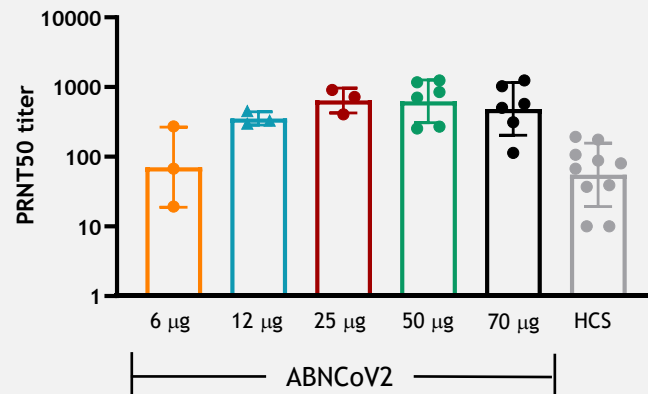
ABNCoV2 Phase 1

First-in-human trial completed - suggests strong antibody response and favorable safety profile

- Phase 1/2 open label, dose-escalation trial assessing the safety and tolerability of two doses of ABNCoV2 (dose ranges from 6-70 µg), formulated with and without adjuvant, in 45 healthy, adult, SARS-CoV-2-naïve volunteers (NCT04839146)
- Study sponsored under a Horizon 2020 EU grant to AdaptVac and the PREVENT-nCoV consortium

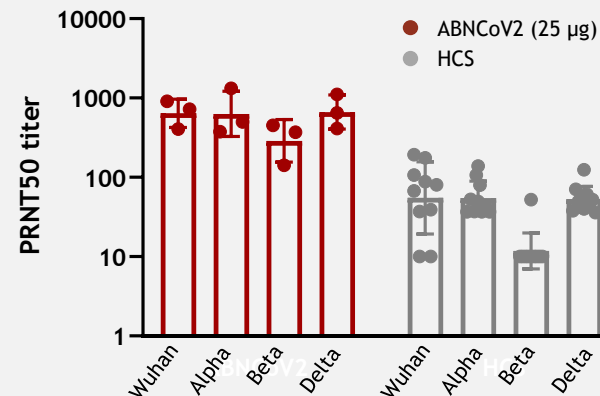
ABNCoV2 induces high neutralization titers

- Dose response: increased titers with higher vaccine doses up to 25 mg, reaching a plateau at higher doses
- Up to 12-fold higher neutralizing antibody titers than seen in human convalescent samples (HCS)



Strong cross neutralisation of variants

- No reduction in neutralization capacity against Alpha or Delta.
- A 2.2-fold reduction is seen against Beta (compared to >10-fold reported for Comirnaty).



Safety profile

- Vaccine was well tolerated across all dose groups with no observed difference in the adverse event profile after first and second vaccination.
- No serious adverse events were reported.
- Safety profile comparable to other vaccines based on recombinant protein-technology.

ABNCoV2 Phase 2

Ongoing trial with data anticipated in Q4 2021 - amended trial design to seek optimal dosing

- Multi-center trial in Germany to evaluate ABNCoV2 as a booster vaccine in individuals with existing immunity.
- Enrolling a total of up to 210 healthy adults.
 - Individuals (n=180) with existing immunity against SARS-CoV-2, acquired through previous disease or from prior immunization with approved COVID-19 vaccines (mRNA and Adeno).
 - Individuals (n=30) with no prior vaccination or disease.
- Trial will also assess neutralizing immune responses against circulating variants of SARS-CoV2.
- Initial results anticipated in Q4 2021 (seropositive group, 100 µg)

Phase 2

Seropositive

Previously infected or fully vaccinated

N = 90

100 µg



Single-shot booster vaccination

✓ Fully enrolled

N = 90

50 µg



Single-shot booster vaccination

• Pending initiation

Seronegative

No existing immunity

N = 30

100 µg



Prime-boost vaccination (days 0, 28)

• Enrolling

MVA-BN RSV

Broad-spectrum vaccine candidate
addressing an unmet medical need



RSV - a blockbuster opportunity

RSV remains a large disease burden in vulnerable populations

No approved prophylactic vaccine

Annual disease burden in the US

	Influenza ¹	RSV ²
Hospitalizations	176,000	177,525
Deaths	13,673	14,000

Our vaccine candidate: **MVA-BN RSV**

Encodes 5 distinct targets of RSV to stimulate a broad protective immune response (T-cell and antibody response) mimicking a natural infection of RSV



Comprehensive clinical data confirms breadth and durability of immune response

Induction of a broad T-cell and antibody response against RSV

Induction of mucosal immunity

Durable immune response lasting longer than an RSV season

Phase 2 in 421 elderly completed, confirming potential as annual booster

Well-tolerated

Phase 1

Safety and immunogenicity of novel modified vaccinia Ankara-vectored RSV vaccine: A randomized phase I clinical trial, Vaccine, 2020 Mar 4;38(11):2608-2619

Phase 2

Broad Antibody and Cellular Immune Response From a Phase 2 Clinical Trial With a Novel Multivalent Poxvirus-Based Respiratory Syncytial Virus Vaccine, J Infect Dis., 2021 Mar 29;223(6):1062-1072.

1) CDC estimate 2019/2020 season: <https://www.cdc.gov/flu/about/burden/2019-2020.html>

2) Falsey AR, Hennessey PA, Formica MA, Cox C, Walsh EE. Respiratory syncytial virus infection in elderly and high-risk adults. New Engl J Med. 2005;352(17):1749-59.

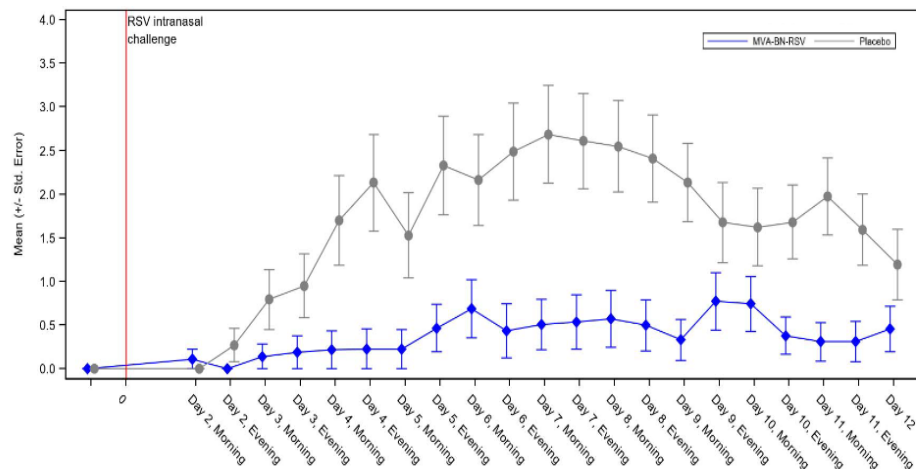
MVA-BN RSV

Human challenge trial achieved its primary endpoint

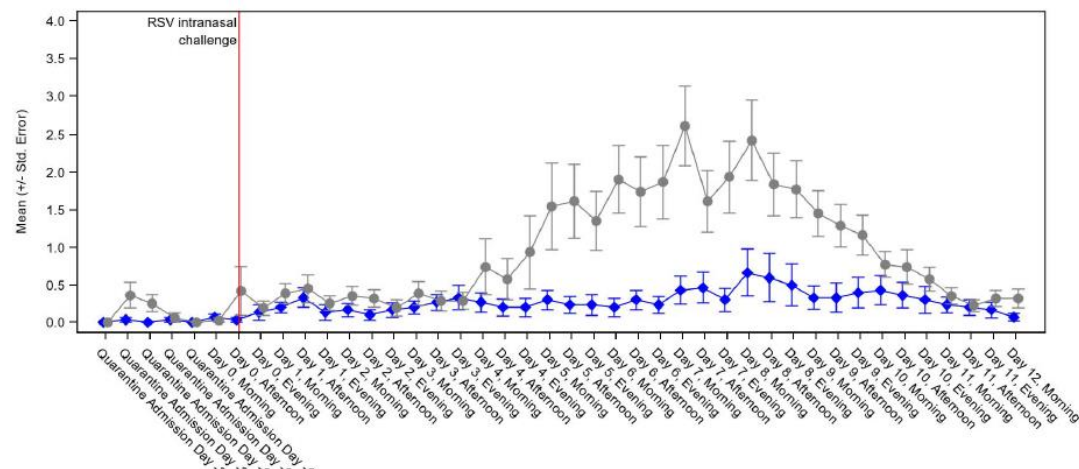
- Randomised, double-blinded, placebo-controlled Phase 2 study assessing the safety, immunogenicity and efficacy of MVA-BN RSV against RSV infection in a virus challenge model in healthy adults (NCT04752644)
- Viral load in vaccine group was significantly lower than placebo, demonstrated by the difference between the area under the curves'
- Up to 79% reduction of symptomatic RSV infections

Viral load (nasal washes, PCR)

qRT-PCR (log10 copies/mL) mean value over time
P-value: 0.017



Total symptom scores (mean value over time)



Immunogenicity

- Data for serum IgG, serum IgA and PRNT (A) very similar to previously reported Phase 2 in elderly
- MVA-BN RSV elicits a substantially higher boost response than the challenge virus (in placebo subjects)

Safety

- No related serious adverse events
- Safety profile overall in line with previous experience from Phase 1 and Phase 2

MVA-BN RSV

Summary



Unique vaccine design targeting both RSV subtypes

Encodes 5 distinct targets of RSV to stimulate a broad protective immune response (T-cell and antibody response) mimicking a natural infection of RSV



Clinical proof-of-concept in elderly population

Phase 1 and Phase 2 concluded, demonstrating favorable safety profile and broad and durable immune responses (T-cells and antibodies) against RSV



Highly efficacious in human challenge trial

Significant reduction in viral load in vaccinated versus control (placebo) treated volunteers
Up to 79% reduction of symptomatic RSV infections



Next steps

Discussion of phase 3 design with regulators based on HCT data and current RSV practice

Executing on our commercial strategy

We set out to:

- stop historical market share loss
- avoid losing ground during transition from GSK
- increase awareness of Bavarian Nordic among HCPs



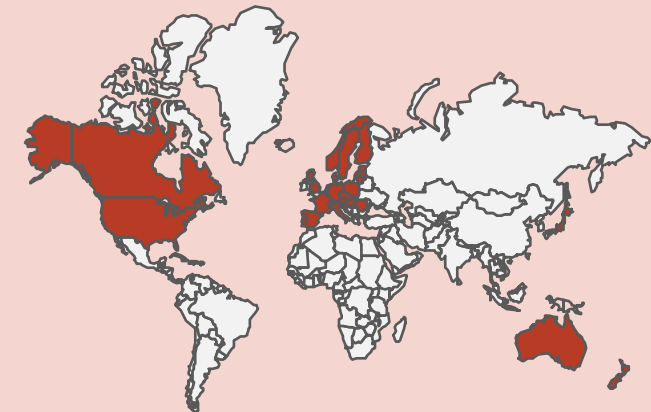
We have today:

- ✓ maintained, or grown, our market share in a difficult market
- ✓ transferred all markets from GSK, except Japan, all in line with plans and in record times
- ✓ increased awareness of Bavarian Nordic



However

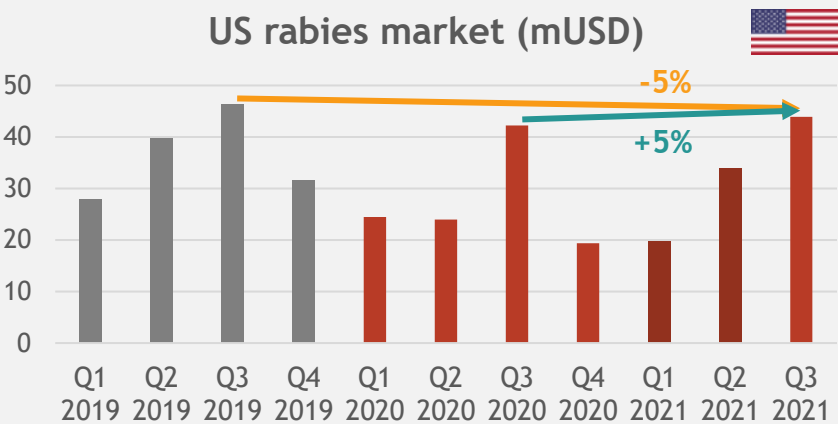
- ..the rabies and TBE markets are still impacted by COVID-19
 - European rabies market reduced by approx. 90% due to lack of travelling to endemic areas
 - US rabies market more resilient as this is an endemic market, but still impacted
 - The largest TBE market, Germany, impacted by lack of access to physicians as their current priority is COVID-19 vaccinations
- ..but smallpox and Ebola markets remain unaffected



Rabies vaccine

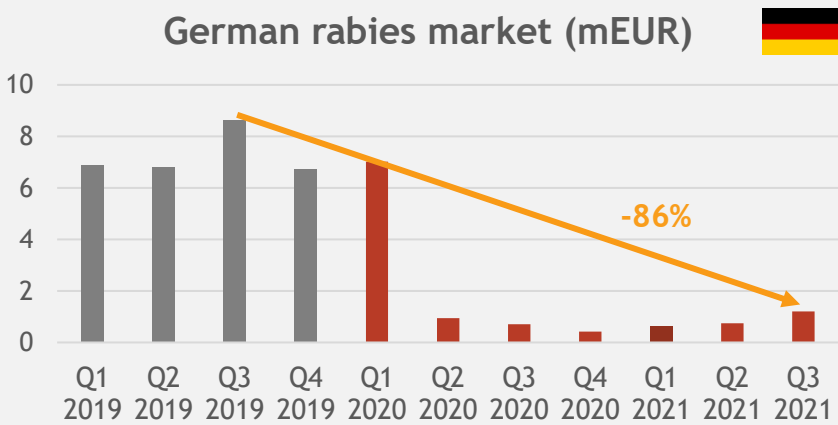
Market development and performance

Rabies market



Both **post-exposure** and **pre-exposure** segments impacted by US lock-down and lack of domestic and international travel.

However, the market remains more resilient than the European market and is approaching pre-covid level.



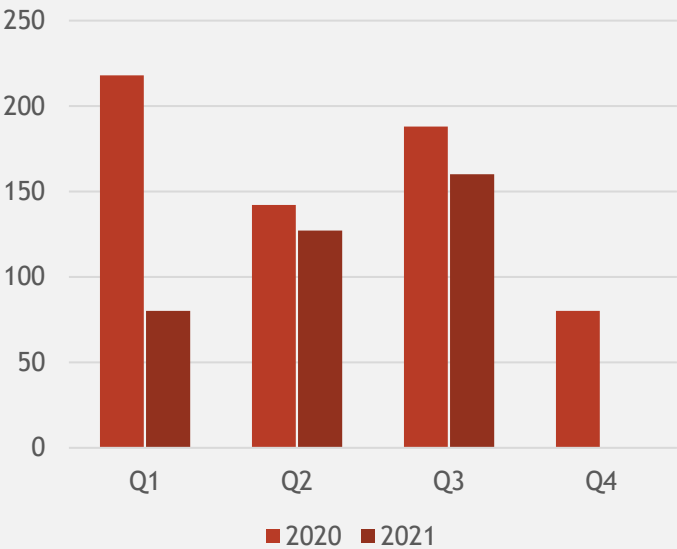
Pre-exposure market eroded during Q2 2020 and continues to suffer from COVID-19 travel restrictions.

Data source: IQVIA

Rabipur/RabAvert sales (mDKK)

Q3 2021	Q3 2020	Growth
160	188	-15%

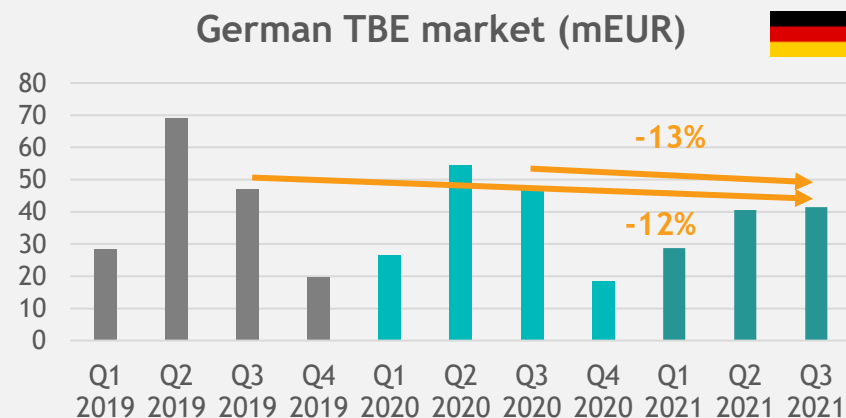
- COVID-19 impact on key markets
- Market share down compared to Q3 2020 due to competitor no longer being out-of-stock, still higher than the pre-stock-out level
- Some inventory fluctuations



TBE vaccine

Market development and performance

TBE market



German market down by 13% compared to Q3 2020, despite signs of growth in Q1. Decline caused by lack of resources for TBE vaccinations as general practitioners were focused on COVID-19 vaccinations.

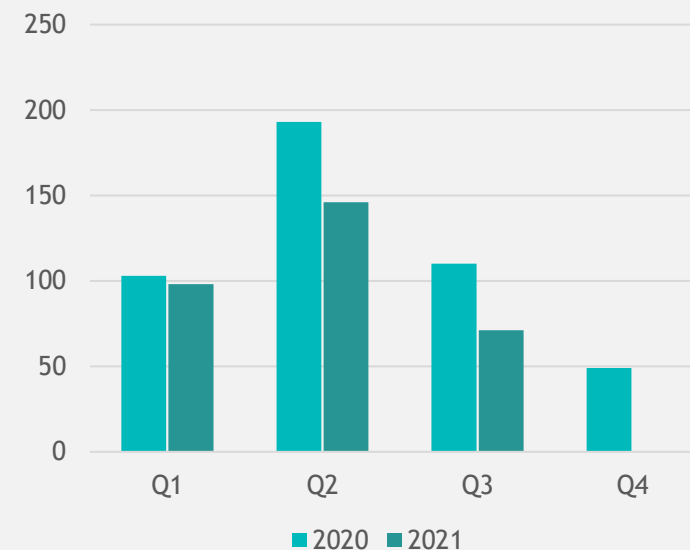


Data source: IQVIA

Encepur sales (mDKK)

Q3 2021	Q3 2020	Growth
71	110	-35%

- Decrease of 35% versus prior year primarily caused by a continued market decline in Germany and inventory movements at wholesalers and partner
- Market share remains stable around 31% in Germany



Profit & Loss

mDKK	Q3 2021	Q3 2020	9M 2021	9M 2020	FY 2020
Revenue	449	558	1,354	1,623	1,852
Production costs	314	246	941	868	1,195
Gross profit	135	313	413	755	657
Research and development costs	75	102	294	226	341
SG&A costs	107	147	361	423	564
Total operating costs	182	249	655	649	905
Other operating income	-	-	-	628	628
EBIT	(47)	64	(242)	734	380
Net financial items	(32)	(37)	(115)	(79)	(98)
EBT	(79)	27	(357)	654	282
Tax	3	1	6	2	4
Net profit for the period	(81)	26	(363)	652	278
EBITDA	52	163	44	1,001	740

Revenue was 1,354 million

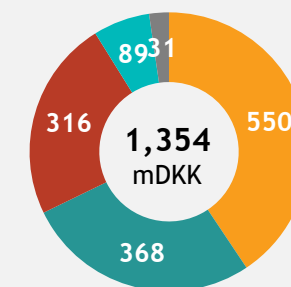
Gross profit impacted by low commercial utilization of plant due to manufacture of RSV clinical trial material and building project and due to inventory write downs caused by COVID-19. YTD inventory write downs of DKK 43 million with the majority in Q3 2021.

R&D costs increase primarily driven by manufacturing of RSV phase 3 material.

SG&A costs slightly lower driven by significantly lower distribution costs, partly offset by higher project costs related to the ongoing transfer project for Rabipur/RabAvert and Encepur.

EBITDA was positive by DKK 44 million. In 2020, EBITDA was positively impacted by the sale of Priority Review Voucher (DKK 628 million)

Revenue 9M 2021
DKK million



- Jynneos
- Rabipur/RabAvert
- Encepur
- Mvabea
- Contract work

Cash flow and Balance Sheet

Selected cash flow figures

mDKK	9M 2021	9M 2020
Cash flow from operating activities	(247)	988
Cash flow from investment activities	(1,356)	(2,051)
Free cash flow	(1,603)	(1,063)
Cash flow from financing activities	1,655	1,331
Net cash flow for the period	52	268

Cash flow from operating activities was negative by DKK 247 million (positive by DKK 988 million), primarily following an increase in trade receivables compared to year-end 2020.

Cash flow from investment activities was negative by DKK 1,356 million (negative by DKK 2,051 million) following net investments in securities of DKK 947 million (net investment of DKK 1,827 million). Cash flow from investment activities also include DKK 307 million (DKK 108 million) of investments in property, plant and equipment related to the ongoing expansion of the drug substance facility for future production of Rabipur/RabAvert and Encepur.

Cash flow from financing activities was a contribution of DKK 1,655 million (DKK 1,331 million), following the proceeds from capital increase through private placement, proceeds from warrant exercise and conclusion of repo transactions.

Selected balance sheet figures

mDKK	Sep-30 2021	Sep-30 2020
Intangible assets	5,162	5,364
Total assets	10,118	9,451
Equity	5,771	5,264
Non-current liabilities	2,034	2,408
Current liabilities	2,313	1,779
Securities, cash and cash equivalents	2,638	2,569
Debt, bank & institutional	(850)	(396)
Net cash*	1,788	2,173

Increase in **equity** largely attributed to the capital increase through a private placement in March 2021, which increased the equity by DKK 1,148 million before costs.

*Deferred consideration to GSK of DKK 2,911 million not included. Book value of the deferred consideration is calculated using NPV and probability weighted milestone payments. Unutilized credit facilities of DKK 243 million not included either.

2021 Outlook

2021 guidance

mDKK	FYE 2021
Revenue	~1,900
EBITDA	~100
Cash position (securities, cash and cash equivalents)	~1,400

Guidance maintained, although in the lower end of the originally expected range, due to continued impact from COVID-19 on the TBE and rabies markets, whereas the smallpox and Ebola business are not expected to be impacted.

Cash at year-end impacted by:

- Continued investments in facility expansion and tech-transfer from GSK during
- Expected capitalization of ABNCoV2 development costs (net of funding)
- Continued milestone payments to GSK
- Draw-down of EUR 30 million existing credit facility with European Investment Bank

All numbers are approximate

2021 activities and milestones

R&D

- Initiate and complete a Phase 2 human challenge trial in RSV
- Continue preparations for initiation of the Phase 3 trial of MVA-BN RSV in older adults in 2022
- Advance the development of the COVID-19 vaccine candidate, ABNCoV2 into Phase 2 and scale-up of manufacturing to phase 3 volume levels
- Advance the development of smallpox MVA-BN freeze-dried formulation
- Further explore intravenous administration of brachyury containing construct within immunotherapy.

Commercial

- Drive profitable growth for Rabipur/RabAvert and Encepur
- Take over physical distribution for Rabipur/RabAvert and Encepur in remaining markets
- Improve awareness and image of Bavarian Nordic with key stakeholders

Manufacturing

- Filling of first commercial vaccine doses in the newly built fill and finish facility
- Completion of construction of new/amended drug substance facility
- Progress the manufacturing technology transfer of Rabipur/RabAvert and Encepur according to plan, including completing qualification of packaging performed at a selected contract manufacturer

Q&A

