



*An open world through **vaccines***

Annual Report 2021

4 March 2022



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.

Bavarian Nordic - a fully integrated vaccine company

*By 2025, we aspire to be one of the largest pure play vaccine companies improving and saving lives by excelling in **R&D innovation, manufacturing and commercialization***

*2022 will be a pivotal year for Bavarian Nordic, with the initiation of **two Phase 3 trials in blockbuster indications***

Investing to fulfill our vision and to bring more life-saving vaccines to the market

800+
employees



4
marketed products:
rabies, TBE,
smallpox, Ebola



Commercial scale
manufacturing and
World-wide distribution
network



Commercial
infrastructure
supporting key
markets in US
and EU



RSV
late-stage vaccine
candidate in
blockbuster
indication



COVID-19
Danish Government
support, reported
positive Phase 2
topline data



Strong financial
position to
execute on
growth strategy



2021

Strong progress on strategic priorities

COVID-19

- Encouraging Phase 1 & 2 results for universal booster vaccine candidate, showing strong antibody response, high neutralization capacity against variants and a favorable safety profile.
- Funding agreement with the Danish Government (800 mDKK)

Commercial & Manufacturing

- Rabies market impacted by COVID-19 in Europe, due to travel restrictions
- TBE market adversely affected by limited access to physicians (Germany)
- Smallpox/Ebola sales unaffected (Canada contract postponed to 2022)
- Expansion of manufacturing site and transfer process continue
- Appointment of Russell Thirsk as EVP, Chief Operating Officer April 1

RSV

- Excellent data from RSV human challenge study reported
- Granted FDA Breakthrough Therapy Designation for MVA-BN RSV

Financials

- In line with, or better than guidance

mDKK	2021A	2021E
Revenue	1,898	1,900
EBITDA	75	70
Cash*	3,217	3,100

* Securities, cash and cash equivalents, repo pledged securities deducted.

End-to-end commercial-scale manufacturing in Denmark

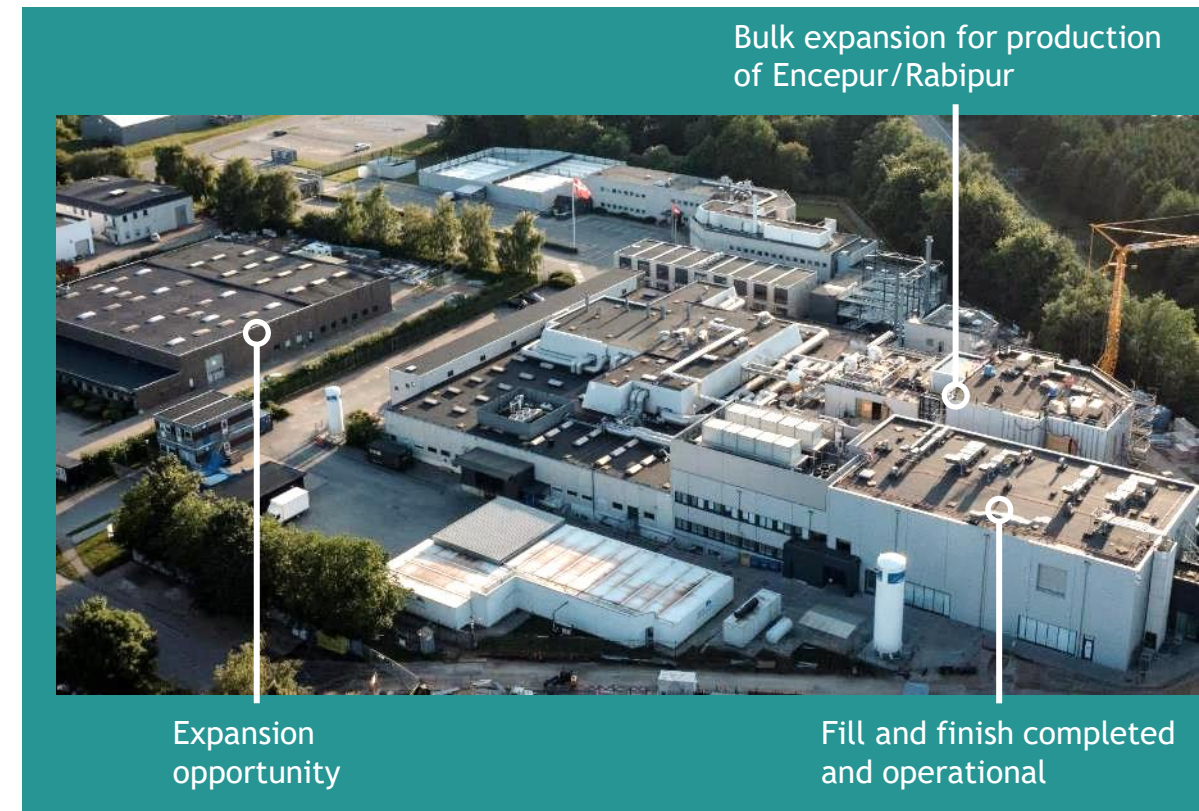
Status - end 2021

- Construction of new bulk facility for Rabies + TBE complete.
- Existing bulk facility closed down from autumn 2021 due to segregation of the two bulk facilities.
- New fill and finish facility completed, and first commercial doses filled and invoiced.
- Rabies and TBE tech transfer project progressed according to plan.

Key activities 2022

- Complete the investment in new bulk facility.
- Re-open existing bulk facility in the autumn after segregation of the two bulk facilities allowing them to operate independently.
- Advance the Rabies and TBE tech transfer project according to plan, including qualification of packaging of both products.
- Fill ABNCoV2 doses for Phase 3 clinical trial.
- Continue implementation of freeze-dried JYNNEOS to unlock future BARDA orders.

All with the goal to expand our end-to-end manufacturing site and secure sufficient flexibility and capacity to support Bavarian Nordic's vision.



2022

A year of significant investments ahead to secure future growth

- A pivotal year with significant investments in R&D and manufacturing
- Launch of two Phase 3 trials: **RSV** and **COVID-19**
- Tech transfer of freeze-dried **JYNNEOS** to support BLA submission
- Complete investments in manufacturing expansion to enable tech transfer of **Rabipur/RabAvert** and **Encepur**
- Financial guidance that reflects the investments

2022 outlook

mDKK

Revenue 1,100 - 1,400

EBITDA (1,300) - (1,000)

Cash and cash equivalents, year-end 1,000 - 1,200

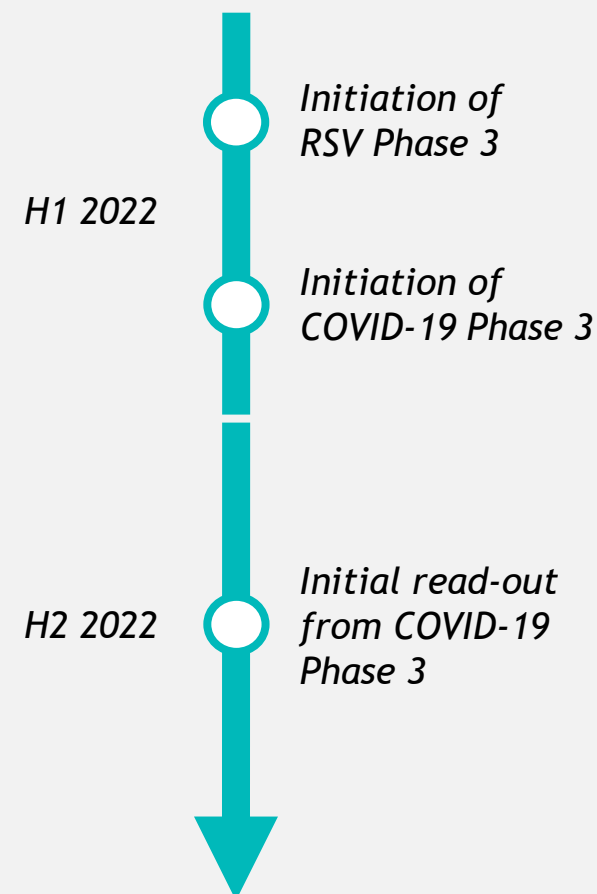
Guided intervals reflect continued uncertainty around COVID-19 impact on TBE and rabies markets.

mDKK

R&D investments 1,950
(incl. capitalized ABNCoV2 investment)

Four-fold increase in normal R&D spend.

Upcoming key milestones





ABNCoV2

Next-generation COVID-19 vaccine

A need for continued advances in COVID-19 vaccine development



Durability of protection from existing COVID-19 vaccines against new circulating variants is sub-optimal/remains unknown. However, approved vaccines has shown to be protective against severe symptoms from Omicron infection.



Ongoing threat of new COVID-19 virus variants combined with continued low global vaccination rates underpins the need for booster vaccines.



Unlikely that COVID-19 can be eliminated and regular booster vaccinations and/or new vaccines will likely be required to reduce the continuing disease burden globally. The market could transition towards a flu-like market with annual boosting of people at risk and the elderly population.



ABNCoV2 Phase 2

Full data confirms high levels of neutralizing antibodies across all study groups

- Vaccination with ABNCoV2 (50µg and 100µg) induces a strong boosting effect in previously vaccinated (mRNA or Adeno).
- Both when used as primary and booster vaccination, ABNCoV2 increased levels of SARS-CoV-2 neutralizing antibodies against the Wuhan variant to levels reported to be highly efficacious (>90%) against SARS-CoV-2¹.
- A similar fold increase was observed for all SARS-CoV-2 variants of concern tested (Wuhan, Alpha, Beta and Delta) following the booster vaccination with ABNCoV2.
- Comparing the induced levels of neutralizing titres by also taking into account the starting titre (pre-booster) and/or the time since the last vaccination, results showed that the higher booster dose of ABNCoV2 trended towards inducing stronger levels of neutralizing titres against SARS-CoV-2.

Phase 2 trial design

Seropositive

Previously infected or fully vaccinated (mRNA or Adeno)

N = 103

100 µg



N = 66

50 µg



Seronegative

No existing immunity

N = 28

100 µg

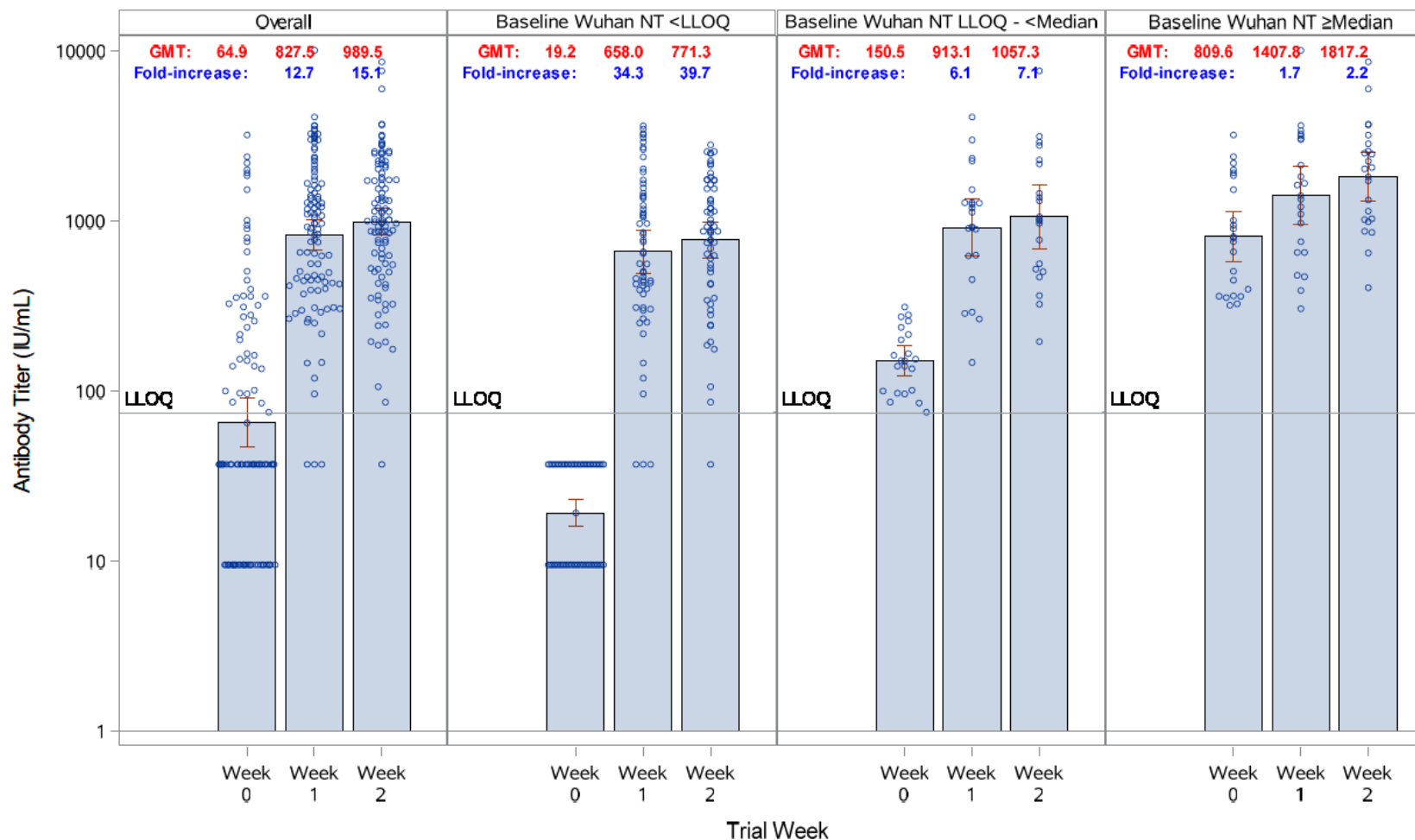


Favorable safety profile

- Vaccine was generally well-tolerated, with no related serious adverse events reported
- No relevant difference in the safety profile between subjects receiving either the low (50 µg) or high dose (100 µg) of ABNCoV2.

ABNCoV2 Phase 2 topline results

Seropositive (100µg) neutralizing antibody titers (Wuhan strain)

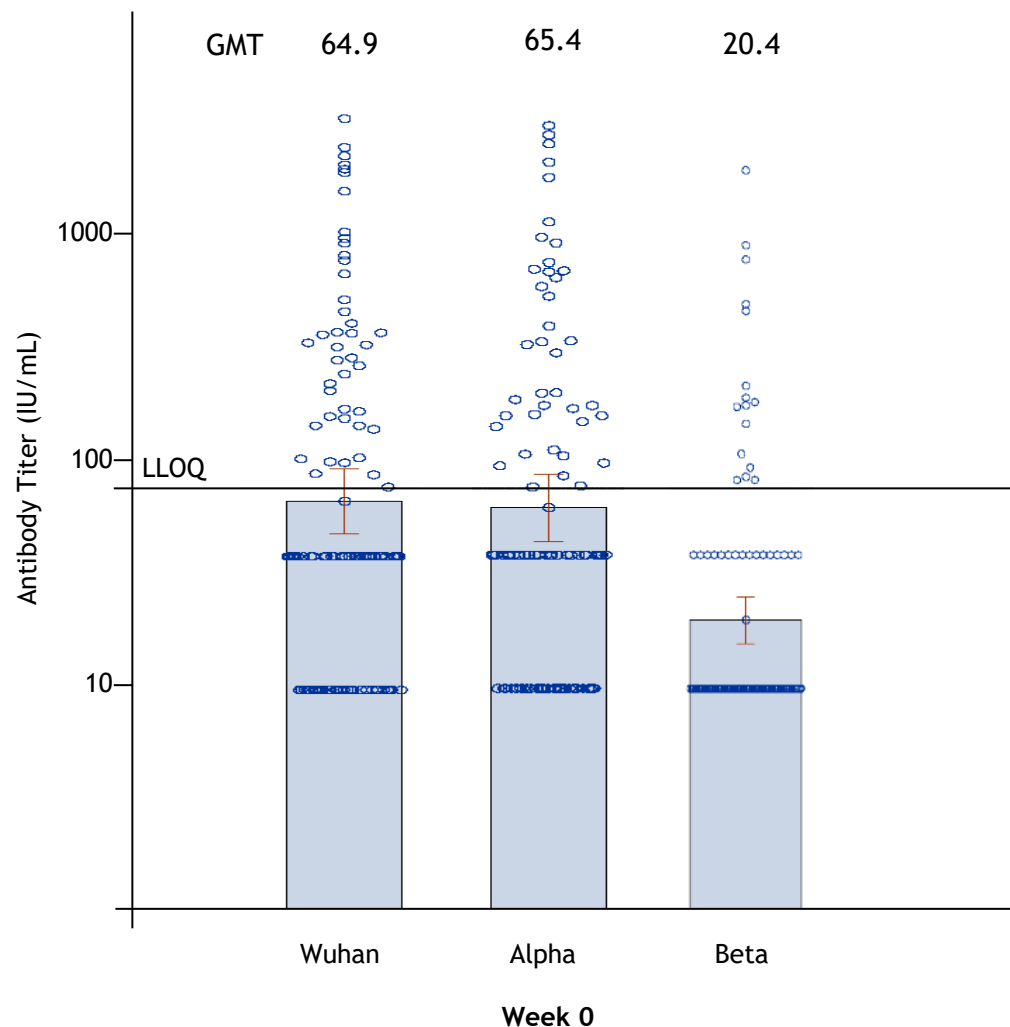


ABNCoV2 induces strong booster effect

- Booster vaccination with ABNCoV2 increased the existing levels of SARS-CoV-2 neutralizing antibodies against the Wuhan variant by 2-40-fold depending on the initial levels of antibodies
- Results determined using a pseudovirion neutralizing assay calibrated with the WHO standard and expressed as International Units (IU)

ABNCoV2 Phase 2 topline results

Seropositive (100µg) baseline antibody titers at week 0 for Wuhan, Alpha and Beta Strains



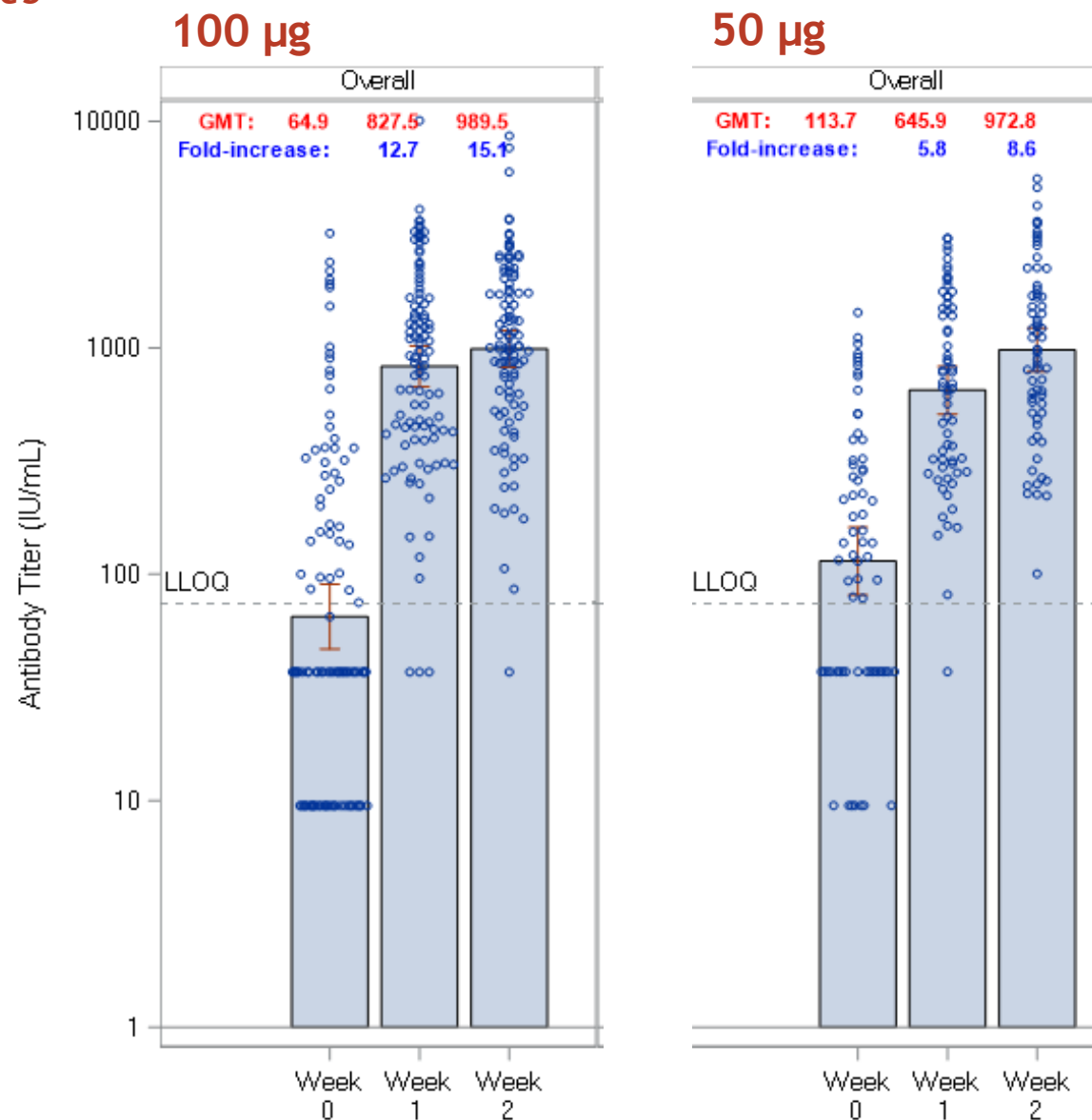
- One hundred and three (3) subjects enrolled (23% ≥ 65 yrs old) that had completed a primary COVID vaccination with either mRNA (67%) or adenoviral (32%) based vaccines or recovered from COVID (1%)
- The majority ($\geq 57\%$) had no detectable antibodies or were below the Lower Level of Quantification (LLOQ) for the Wuhan, Alpha and Beta variants
- The same trend was also observed for the Delta variant using a competitive receptor binding assay
- Neutralizing antibody titers of 100IU (91% efficacy CI 87-94) and 1000IU (96% efficacy CI 94-98).¹

¹ P. B. Gilbert et al., Science 10.1126/science.abm3425 (2021)

ABNCoV2 Phase 2 topline results

Strong booster response for both 50µg and 100µg doses

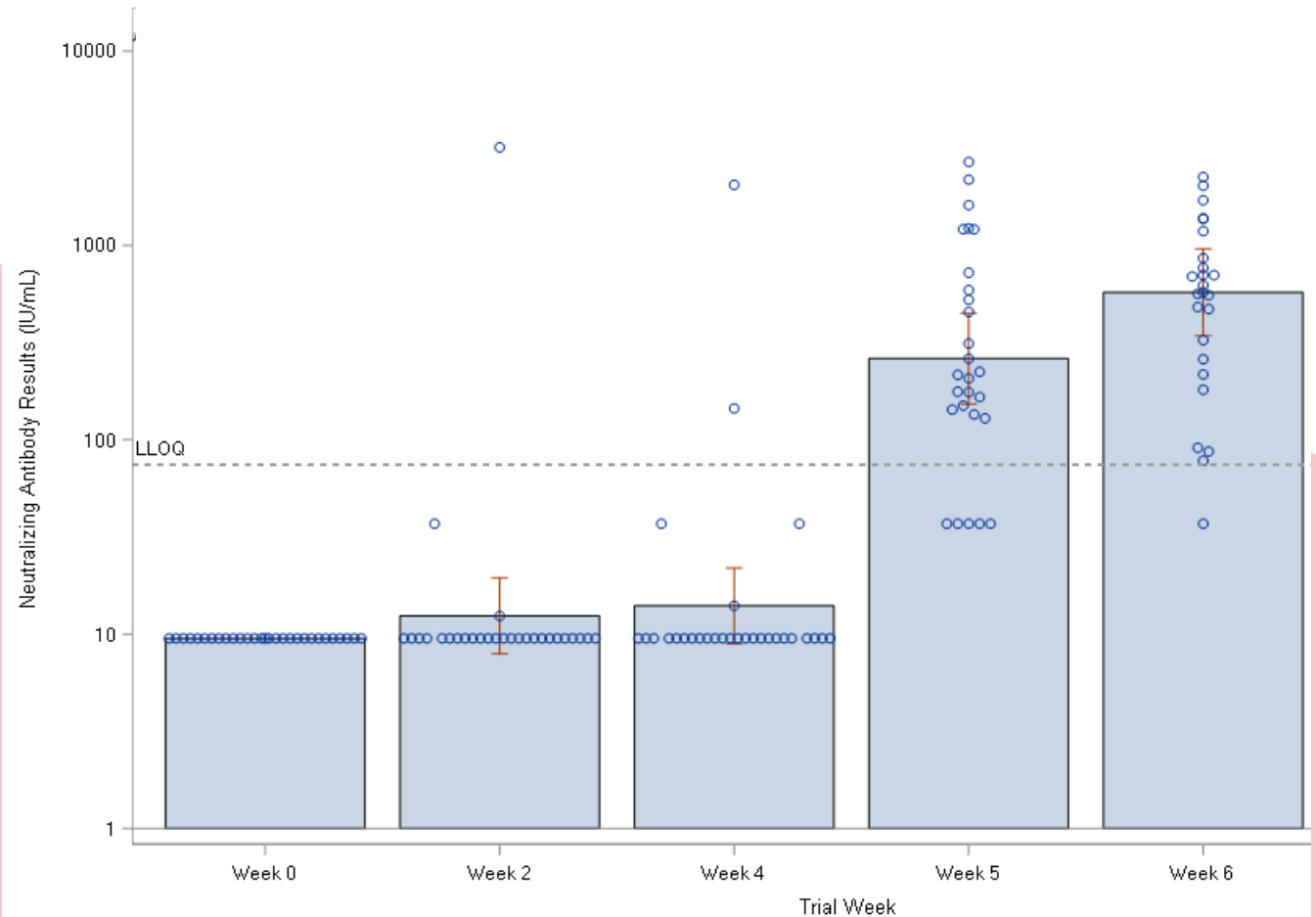
- Similar booster effect with both doses of ABNCoV2
- No difference in the favorable safety profile between doses
- No difference in responses to variants of concern (Wuhan, Alpha, Beta, Delta)
- Sub-analysis from time of vaccination or starting titers indicates a trend towards higher titers for the 100µg dose
- Phase 3 will be conducted using 100µg to maximize the likelihood of success



ABNCoV2 Phase 2 topline results

Seronegative group (100µg) antibody titers (Wuhan strain)

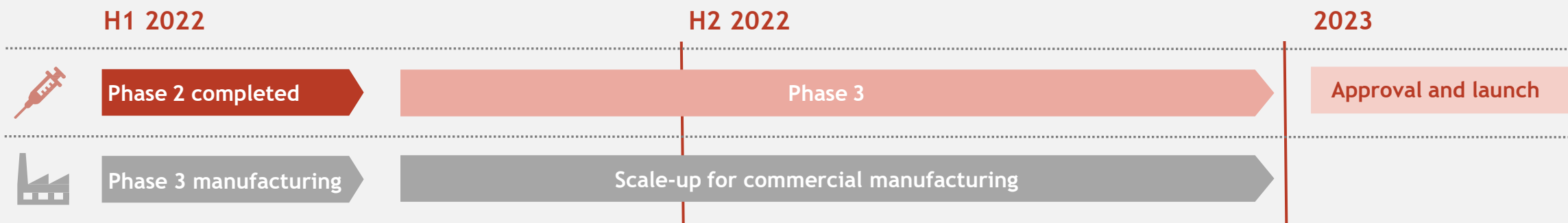
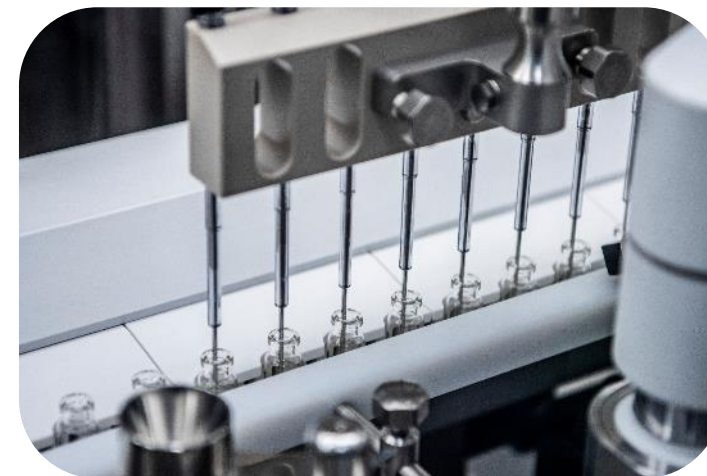
- Confirming excellent data seen in Phase 1 results in a larger study
- Titers in the range of >90% efficacy¹



ABNCoV2 Phase 3

Trial planned for initiation H1 2022

- An overall agreement has been made with regulatory authorities on the trial design.
- Approx. 4,000 seropositive subjects who will receive a booster vaccination with 100µg ABNCoV2 or an mRNA-based vaccine, aiming to demonstrate non-inferiority of ABNCoV2 to the licensed mRNA vaccine.
- Manufacturing of vaccine bulk for the trial has been completed, filling now ongoing at BN's own manufacturing line.
- Trial planned for initiation in H1 2022 and with anticipated completion before year-end.



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

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

Targeted at the elderly population

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

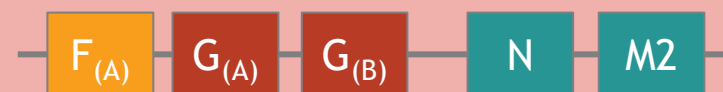
Phase 2 in 421 elderly subjects completed, confirming potential as annual booster

Well-tolerated

Human challenge study achieved primary endpoint and 79% efficacy in reducing symptomatic RSV infections

Annual disease burden in the US in elderly (65+ yrs)

	Influenza ¹	RSV ²
Hospitalizations	171,023	177,525
Deaths	11,945	14,000



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>

16 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.

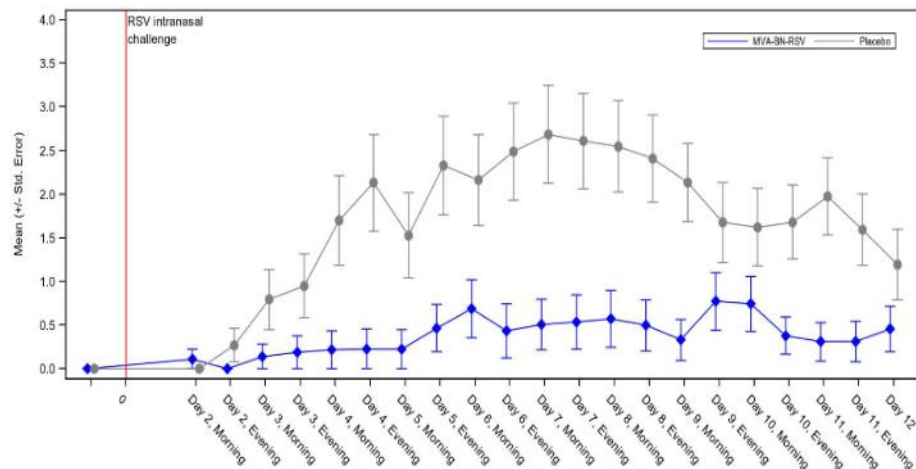
MVA-BN RSV

Human challenge trial achieved its primary endpoint

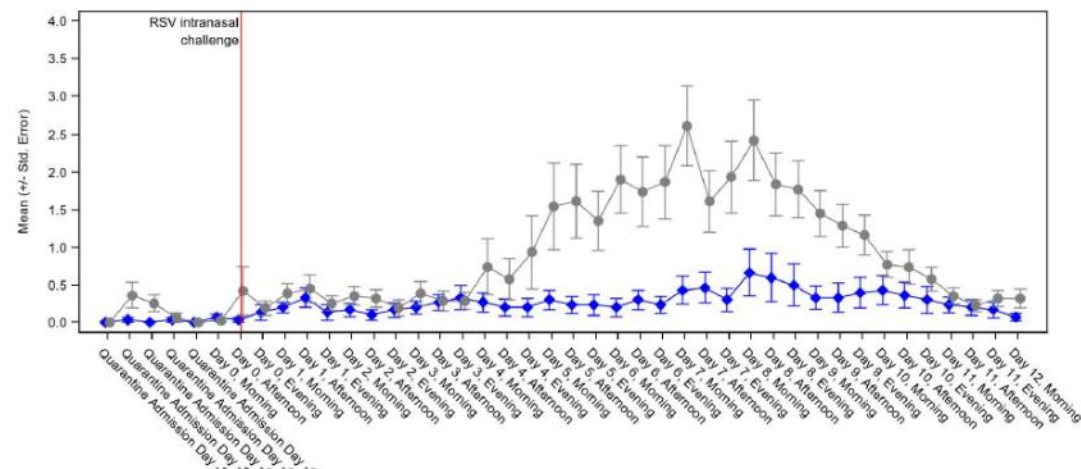
- Randomised, double-blinded, placebo-controlled Phase 2 study assessing the safety, immunogenicity and efficacy of MVA-BN RSV against RSV infection in a virus challenge model in healthy adults (NCT04752644)
- Study achieved the primary endpoint by demonstrating a statistically significant reduction in viral load in vaccinated versus control (placebo) treated volunteers
- Demonstrated up to a 79% efficacy in reducing 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


Phase 3 trial design

- 

Start of trial in H1 2022
Expected to run over the course of one year
- 




Primary endpoint: Occurrence of lower respiratory tract disease (LRTD) events associated with RSV post vaccination
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The Phase 3 trial is expected to enrol 20,000 subjects
- 

Estimated costs: Approx. US\$ 250m, including follow-up phases in 2023 and 2024
- 

Countries
US, Germany (140 sites)

Trial design

Group	Age (years)	Vaccination schedule Day 1	Dose (Inf.U/0.5 mL) IM	
	≥ 60	MVA-BN-RSV	At least 3x10 ⁸ Inf.U	10,000
	≥ 60	Placebo		10,000

Financials and Outlook



Revenue split Q4 and full year

- Total 2021 revenue in line with guidance and 2% above 2020 level
- COVID-19 driven lower FY revenues for Rabipur/RabAvert an Encepur off-set by more resilient smallpox and Ebola business

Revenue distribution, fourth quarter

mDKK	Q4 2021	Q4 2020	Growth
JYNNEOS/IMVANEX	184	60	306%
Rabipur/RabAvert	138	80	73%
Encepur	47	49	-4%
Mvabea	171	0	-
Contract work	4	39	-90%
Total	544	229	138%

Revenue distribution, full year

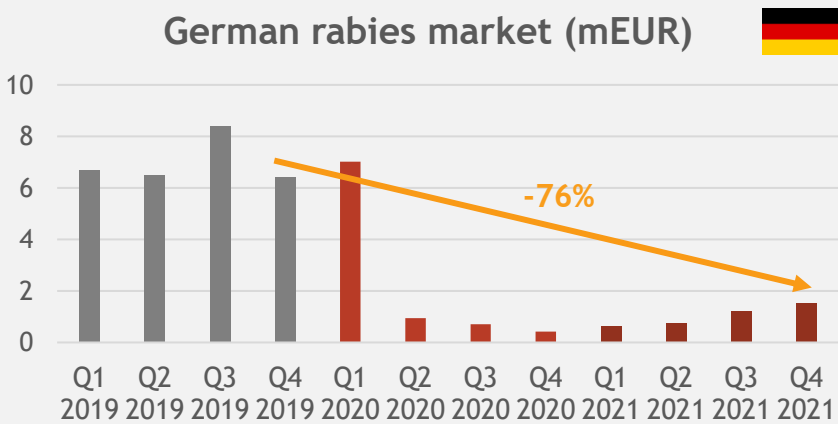
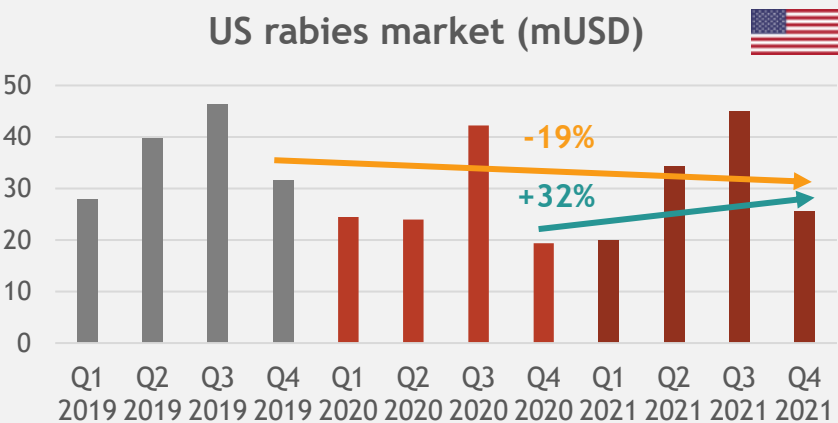
mDKK	FY 2021	FY 2020	Growth
JYNNEOS/IMVANEX	734	541	36%
Rabipur/RabAvert	506	628	-19%
Encepur	363	455	-20%
Mvabea	260	0	-
Contract work	35	162	-78%
Milestone payments	0	67	-
Total	1,898	1,852	2%

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.
Year-over-year growth of 13%.

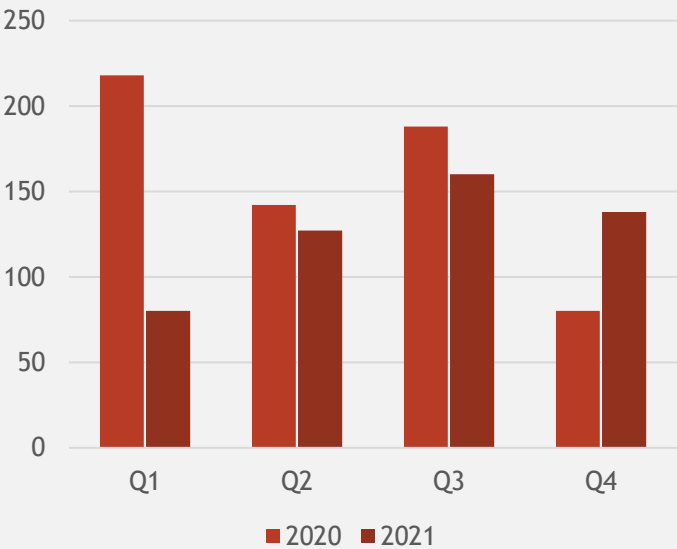
Pre-exposure market eroded during Q2 2020 and has suffered severely from COVID-19 travel restrictions.
Year-over-year decline of 55%, but signs of recovery in 2 HYR.

Data source: IQVIA

Rabipur/RabAvert sales (mDKK)

FY 2021	FY 2020	Growth
506	628	-19%

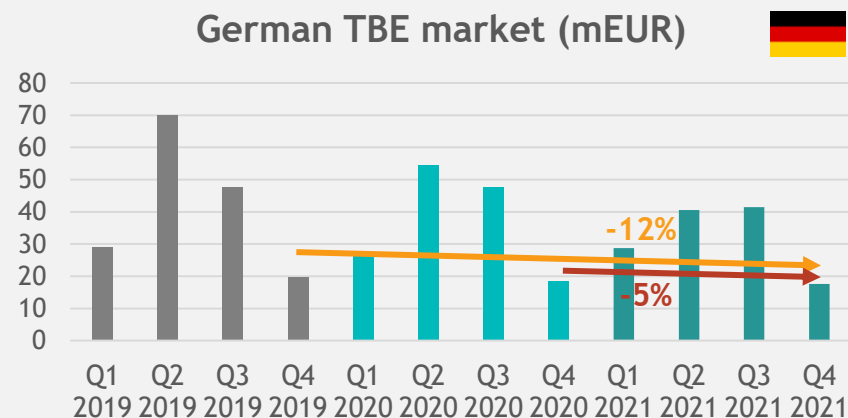
- Continued COVID-19 impact on key markets, but with the US market being the exception
- US market share 70%, down from 75% in 2020 due to competitor no longer being out-of-stock, still higher than the pre-stock-out level
- Some inventory fluctuations



TBE vaccine

Market development and performance

TBE market



German FY market down by 13% compared to 2020. Decline caused by lack of resources for TBE vaccinations as general practitioners were focused on COVID-19 vaccinations.

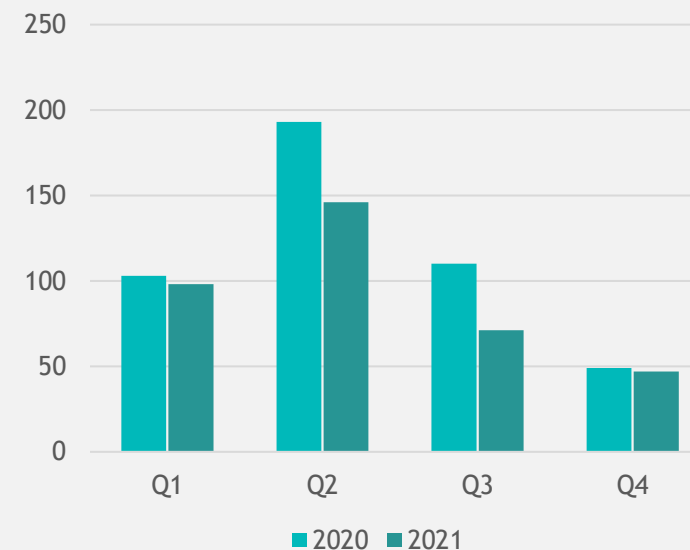


Data source: IQVIA

Encepur sales (mDKK)

FY 2021	FY 2020	Growth
363	455	-20%

- Decrease 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	FY 2021	FY 2020
Revenue	1,898	1,852
Production costs	1,328	1,195
Gross profit	570	657
Research and development costs	399	341
SG&A costs	485	564
Total operating costs	884	905
Other operating income	-	628
EBIT	(314)	380
Net financial items	(141)	(98)
EBT	(454)	282
Tax	10	4
Net profit for the year	(465)	278
EBITDA	75	740

Revenue was DKK 1,898 million, with increase in sale of smallpox and Ebola vaccines off-setting lower sales of Rabipur/RabAvert and Encepur.

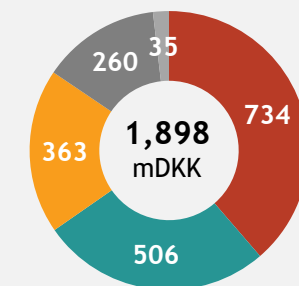
Production costs was impacted by provisions for inventory write-downs caused by COVID-19.

R&D costs increased primarily due to costs related to preparations for RSV Phase 3 trial.

SG&A costs 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 75 million. In 2020, EBITDA was positively impacted by the sale of Priority Review Voucher (DKK 628 million in other operating income)

Revenue 2021
DKK million



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

Cash flow and Balance Sheet

Selected cash flow figures

mDKK	FY 2021	FY 2020
Cash flow from operating activities	(359)	572
Cash flow from investment activities	(2,877)	(1,912)
Free cash flow	(3,235)	(1,340)
Cash flow from financing activities	3,536	1,335
Net cash flow for the period	301	(5)

Cash flow from operating activities totaled a net spend of DKK 359 million primarily driven by a negative net profit and increases in net working capital following substantial revenue recognized in December 2021

Cash flow spend on investment activities totaled DKK 2,877 million and included milestone payments to GlaxoSmithKline, continued investments in manufacturing and tech transfer of Rabipur/RabAvert and Encepur and capitalized costs related to the ABNCoV2 development asset. Net investment in securities is also included.

Cash flow from financing activities was a contribution of DKK 3,536 million split between net proceeds from capital increases DKK 2.8 billion, ABNCoV2 funding from Danish Ministry of Health DKK 160 million, proceeds from warrant exercise DKK 107 million and a repo position of DKK 500 million.

Selected balance sheet figures

mDKK	Dec-31 2021	Dec-31 2020
Intangible assets	5,804	5,291
Total assets	12,089	8,759
Equity	7,375	4,894
Non-current liabilities	2,806	2,912
Current liabilities	1,909	952
Securities, cash and cash equivalents	3,717	1,670
Debt, bank & institutional	(893)	(395)
Net cash*	2,823	1,275

Increase in **equity** largely attributed to two capital increases through private placements in March and December 2021 with combined net proceeds of DKK 2.8 billion and warrant exercise amounted to DKK 107 million.

Intangible assets increase due to ABNCoV2 capitalization of development costs and contingent liabilities also related to ABNCoV2 partly off-set by amortization of product rights for Encepur + Rabipur/RabAvert.

Total assets increase is furthermore driven by higher receivables, prepayments to ABNCoV2 contract manufacturers and increased securities, cash and cash equivalents follow two capital raises in 2021.

*Deferred consideration to GSK of DKK 2,551 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.

2022 Outlook - Investing in pursuit of our vision

Guiding in intervals due to continued uncertainty about COVID-19 impact on TBE and rabies markets

2022 guidance

mDKK	FYE 2022
Revenue	1,100 - 1,400
EBITDA	(1,300) - (1,000)
Cash position (securities, cash and cash equivalents)	1,000 - 1,200

The mid-point of the guidance assumes a partial return to normality for the TBE market and the US rabies market and a slower return to normality for the European rabies business.

Includes only confirmed smallpox vaccine orders with BARDA of approximately DKK 100 million and a previously announced order to Public Health Agency of Canada of DKK 203 million

Due to close-down of the existing bulk plant until end of August 2022, only limited capacity will be available for bulk manufacturing of MVA-based products (smallpox and Ebola) and hence no revenue is expected from Ebola in 2022. The close-down is a planned step in the expansion of the bulk facility to enable future manufacturing of Rabipur/RabAvert and Encepur.

Limited revenue from partner agreements with Valneva and Dynavax

Potential income from RSV partnering is not included

Other assumptions

Research and development costs

- Total investments of approximately DKK 1,950 million, including ABNCoV2 capitalized costs of approximately DKK 700 million.
- Non-capitalized costs amount to approximately DKK 1,250 million of which the RSV project accounts for approximately DKK 850 million.

Cash position

- Milestone payments to GSK relating to the acquisition of Rabipur/RabAvert and Encepur: approx. DKK 600 million
- Capitalization of tech-transfer activities for acquired vaccines: approx. DKK 250 million
- Capitalization of ABNCoV2 development costs: approx. DKK 700 million
- Financial support to ABNCoV2 from the Danish Ministry of Health: approx. DKK 640 million. This represents the full remaining amount under the DKK 800 million funding agreement.
- Other tangible investments: approx. DKK 350 million, including finalization of new bulk facility for future manufacturing of Rabipur/RabAvert and Encepur.
- Net working capital expected to remain approximately unchanged with inventory increase of approx. DKK 250 million largely off-set by expected increase in accounts payable.
- Debt level by year-end of approx. DKK 600 million assumed, excluding repo positions.

Outlook is based on exchange rates of DKK 6.50 per 1 USD and DKK 7.45 per 1 EUR.

2022 strategic objectives

Developing innovative life-saving vaccines

RSV

- Initiate Phase 3 enrollment in first half of 2022.
- Complete enrollment of 20,000 subjects by end of 2022.
- Prepare for commercial launch.

COVID-19

- Initiate enrollment for Phase 3 of ABNCoV2 in the first half of 2022.
- Report Phase 3 data in the second half of 2022.
- Prepare for a regulatory submission by end of 2022.
- Prepare for commercial launch.

Freeze-dried JYNNEOS

- Continue transfer of freeze-dried manufacturing process to Bavarian Nordic.

Best in class vaccine manufacturing

- Progress the manufacturing technology transfer of Rabipur/RabAvert and Encepur according to plan, including completing the qualification of packaging of both products.
- Complete investment in the expansion of the bulk manufacturing facility.

Driven by commercial excellence

- Defend and gain market shares for Rabipur/RabAvert and Encepur in key markets.
- Improve awareness of Bavarian Nordic among key stakeholders.
- Assume marketing and distribution of Ixiaro and Dukoral from Valneva in certain markets.
- Launch Heplisav-B in Germany (in-licensed from Dynavax)

*A pivotal year with significant investments
to fuel our vision to become one of the largest
pure play vaccine companies!*

A close-up, low-angle shot of a complex industrial machine, likely a pharmaceutical tablet press. The foreground is dominated by a long, narrow conveyor belt or tray filled with a dense, uniform grid of small, dark, oval-shaped tablets. The machine's components, including various rollers, guides, and adjustment mechanisms, are visible in the background, creating a sense of depth and precision. The lighting is bright and even, highlighting the metallic surfaces and the texture of the tablets.

Q&A



BAVARIAN NORDIC