Bavarian Nordic

Q3 2020 results | 11 November 2020

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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 forwardlooking 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









Q3: A strong quarter demonstrating successful transition

• Commercial transition successfully on track

- TBE market showing signs of rebound from COVID-19. Encepur Q3 revenue growth of 14% vs LY.
- Rabies EU market hit hard by COVID-19. German market down by 92% vs LY.
- Rabies US market more resilient, but still impacted by COVID-19. RabAvert showing strong growth of more than 30% in Q3 in a declining market.
- Resilient smallpox vaccine business with USG.
- Maintaining our revenue guidance.
- Upgrading EBITDA and year-end cash position as result of operational savings.
- RSV human challenge trial planned for 2021 to provide important efficacy data before the planned Phase 3, which has been postponed by one year to mitigate impact from COVID-19.
- Licensed COVID-19 vaccine show positive results in NHP study confirming the potential of the VLP platform; continued development is pending external funding.



Encepur & Rabipur/RabAvert integration moving forward

2020 accomplishments/milestones

- Commercial infrastructure in place with local teams established in US and EU
- Transfer of marketing and distribution completed in several countries including key markets US and Germany, now covering more than 80% of product revenues
- Distribution and marketing agreement with Valneva for selected EU markets and Canada
- Initiated expansion of bulk manufacturing in preparation for tech transfer of acquired products



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Update on manufacturing expansion

Single-bulk facility transforming into a fully-fledged manufacturing plant

Fill and finish

- Construction completed
- (Validation & qualification completed
- ✓ Ready for first commercial manufacturing



Bulk manufacturing

 Construction work ongoing for expansion of facility to allow for simultaneous bulk manufacturing of multiple products





RSV - de-risking Phase 3 with planned human challenge trial

- Human challenge trial in 2021 will provide efficacy insights ahead of Phase 3
- Postponing Phase 3 study initiation by one year into 2022 due to anticipated COVID-19 impact

Human challenge trial

- Assessing the effect of vaccination with MVA-BN-RSV vaccine, in reducing the RSV viral loads due to the challenge strain when compared to placebo
- Other predefined outcome measures, such as symptoms scores will also be evaluated

Phase 3 in older adults

- Randomized, placebo-controlled trial with an adaptive design enrolling 12,000 -14,000 subjects over two seasons (6,000 for the first season, 6,000-8,000 for the second season)
- After passing the first season threshold there would be a ~75% chance of successfully reaching the efficacy endpoint of the trial
- Estimated costs to determine futility after the first season will be USD 40m. Second season will cost an additional USD 50-70m



COVID-19 vaccine program

- AdaptVac is planning the initiation of a first-in-human study, supported by a Horizon 2020 EU grant. Initial data expected during Q1 2021.
- Bavarian Nordic-sponsored NHP study ongoing with preliminary results confirming AdaptVac's immunogenicity data in mice. Longterm efficacy data from the study are anticipated early in 2021.
- Accelerated development plan including Phase 3 design has been developed, conditioned upon availability of external funding.

COVID-19 vaccine candidate

- Capsid virus like particle (cVLP) based SARS-CoV-2 subunit vaccine
- Designed to fulfil WHO's criteria for a COVID-19 vaccine during outbreak (e.g. single-shot, rapid onset of protection, suitable for all ages)
- Licensed from AdaptVac

Flexible platform adaptive to mutations





NHP study

Preliminary results show that the cVLP vaccine induces high levels of neutralizing antibodies, comparable with the levels detected in the convalescent sera of SARS-CoV2 patients.

The rabies market and COVID-19 impact



• **Post-exposure** market impacted by US lock-down, but still more resilient to COVID-19



• **Pre-exposure** market eroded during Q2 2020 and continuing as result of no travels due to COVID-19

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The TBE market, signs of recovery



- German market is the largest single market and a good proxy for the global market
- Underlying demand for TBE vaccination remains, but market impacted by COVID-19 due to limited access to physicians
- Low market decline in Jul/Aug suggesting the start of a recovery at the end of the vaccination season.



RABIPUR/RABAVERT sales - strong US performance



mDKK

Q3 2020	Q3 2019	Growth	9M 2020	9M 2019	Growth
188	257	-27%	548	692	-21%

- Competitor was out-of-stock in the beginning of the year
- OPost-exposure segment is more resilient and less impacted by COVID-19. US market decline limited to 14% vs LY
- Market share gain in US market (61% in 1Q19 to 79% in 3Q20)
- US revenue growth of more than 30% vs LY
- Pre-exposure (travel) market heavily impacted down by 92% in Germany in (July/August 2020 versus prior year)



* Q4 2019 significantly positively impacted by competitor's out of stock situation; nearly DKK 150 million higher than expected



Sales figures from 2019 have been provided by GSK and are presented for comparison only.

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ENCEPUR sales - Sign of market rebound

mDKK

Q3 2020	Q3 2019	Growth	9M 2020	9M 2019	Growth
110	97	14%	406	484	-16%

- Year-over-year decline was caused by inventory movements in the supply chain and COVID-19 impact in key markets due to limited access to physicians
- Largest market, Germany slightly declined in July/August, but showing signs of recovery
- Market share remains stable around 30%
- Encepur growth of 14% in Q3 vs LY





Sales figures from 2018 and 2019 have been provided by GSK and are presented for comparison only.

Finan

Financial statements						
mDKK	Q3 2020	Q3 2019	9m 2020	9m 2019	FY 2019	
Revenue	558	144	1,623	372	662	Revenue
Production costs	246	93	868	220	355	sale of n
Gross profit	313	51	755	152	308	Other op
Research and development costs	102	91	226	288	409	of Priorit
SG&A costs	147	57	423	162	227	
Total operating costs	249	148	649	450	636	l leevily 6
Other operating income	-	-	628	-	-	Heavily f no costs
EBIT	64	(97)	734	(298)	(328)	
Net financial items	(37)	(1)	(79)	-	(16)	
EBT	27	(98)	654	(298)	(345)	
Tax	-	1	2	3	2	
Net profit for the period	26	(99)	652	(301)	(347)	

(82)

1,001

163

(255)

(271)

ue was DKK 1,623 million, primarily driven by new products and smallpox vaccine

operating income of DKK 628 million from sale rity Review Voucher in Q1

was DKK 1,001 million

frontloaded earnings due to PRV income with s associated

Revenue 9M 2020 DKK million



■ Milestone, Janssen

EBITDA

Cash flow

Selected cash flow figures

mDKK	9m 2020	9m 2019	FY 2019
Cash flow from operating activities	988	(269)	(276)
Cash flow from investment activities	(2,051)	354	(810)
Free cash flow	(1,064)	85	(1,086)
Cash flow from financing activities	1,331	(252)	1,115
Net cash flow for the period	268	(167)	29

Cash flow from operating activities was DKK 988 million (negative by DKK 269 million), with a significant contribution from the sale of the Priority Review Voucher.

Cash flow from investment activities was negative by DKK 2,051 million (positive by DKK 354 million) following net investments in securities of DKK 1,827 million (net sale of DKK 653 million) after sale of the Priority Review Voucher and the completion of the rights issue. Also included are DKK 108 million of investments in property, plant and equipment related to finalization of the fill-and-finish plant and expansion of the bulk facility.

Cash flow from financing activities was a contribution of DKK 1,331 million (negative by DKK 252 million), following the rights issue partly offset by repayment of the bridge loan.

Selected balance sheet figures

Net cash*

mDKK	Sep-30 2020	Dec-31 2019
Intangible assets	5,364	5,484
Total assets	9,451	7,047
Equity	5,264	1,865
Non-current liabilities	2,408	3,134
Current liabilities	1,779	2,047
Securities, cash and cash equivalents	2,569	472
Debt, bank & institutional	(396)	(1,771)

Increase in **equity** largely attributed to the rights issue in March 2020, which increased the equity by DKK 2,824 million before costs.

Strong cash contribution from rights issue generating net proceeds of DKK 2,724 million, DKK 628 million from sale of Priority Review Voucher and milestone payment of USD 10 million from Janssen at EU approval of Ebola vaccine.

Debt as of December 31, 2019 includes a bridge loan of DKK 1,373 million which has been repaid in first quarter 2020 following completion of rights issue.

*Deferred consideration to GSK of DKK 3,184 mDKK not included. Book value calculated using NPV and probability weighted milestone payments. Unutilized credit facilities not included either.

2,173

(1, 299)

Outlook



2020 guidance

mDKK		FYE
	Chg.	2020
Revenue	-	1,900
EBITDA	1	725
Cash position (securities, cash and cash equivalents)	•	1 600

Lower **revenues** from acquired products due to negative COVID-19 impact, particularly on travel segment. However this is offset by resilient business in smallpox vaccines, thus revenue expectations remain unchanged.

EBITDA raised from DKK 675 million to DKK 725 million as result of operational savings, partly due to COVID-19.

Cash at year-end raised from DKK 1,500 million to DKK 1,600 million. Both previous and updated cash guidance includes the EUR 30 million loan from the European Investment Bank as cash, which is currently not drawn upon.

Large cash spend in fourth quarter consists of expected milestone payments to GSK related to marketing authorization transfer (approx. DKK 375 million); negative EBITDA contribution; investments in the range of DKK 130-160 million; inventory build-up of Encepur and Rabipur/RabAvert in the range of DKK 300-350 million.

2020 news flow

Commercial

- ✓ Assume full sales and marketing responsibility for Rabipur/RabAvert and Encepur from GSK
- ✓ Establish a full commercial organization to support Rabipur/RabAvert, Encepur and JYNNEOS for the monkeypox indication
- ✓ Take over physical distribution of Rabipur/RabAvert and Encepur in selected markets
- \div Increase awareness and establish a new market for the monkeypox indication

R&D

- ✓ Continue preparations for initiation of the Phase 3 trial of MVA-BN RSV in the elderly in 2021
- ✓ Advance the Phase 3 trial of smallpox MVA-BN freeze-dried formulation
- ✓ Obtain successful marketing authorization of Ebola vaccine MVA-BN Filo in the EEA (partnered with Janssen)
- ✓ Top-line results from MVA-BN WEV (equine encephalitis) Phase 1 study
- ✓ Explore intra-tumoral/intravenous administration within immunotherapy
- Establish proof-of-concept for BN-Brachyury in chordoma

Manufacturing

- Commence investment in expansion of vaccine bulk manufacturing
- (\checkmark) Complete the qualification and validation of the newly built fill and finish facility
- ✓ Commence the manufacturing technology transfer of Rabipur/RabAvert and Encepur

