# ANNUAL REPORT 2020

12 March 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.*

# 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*

**700+**
employees

+40%
in 2020

**4**
marketed products

- rabies
- TBE
- smallpox
- Ebola

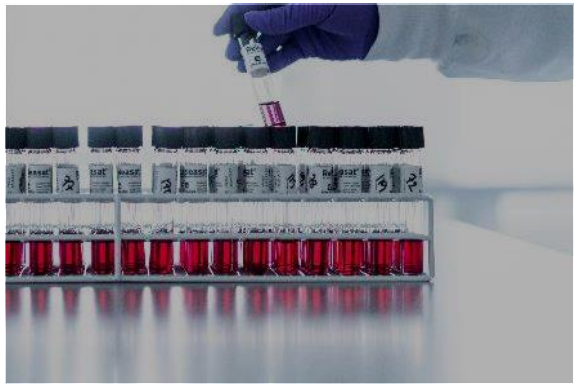
Commercial scale manufacturing facility with inhouse fill and finish being added during 2021

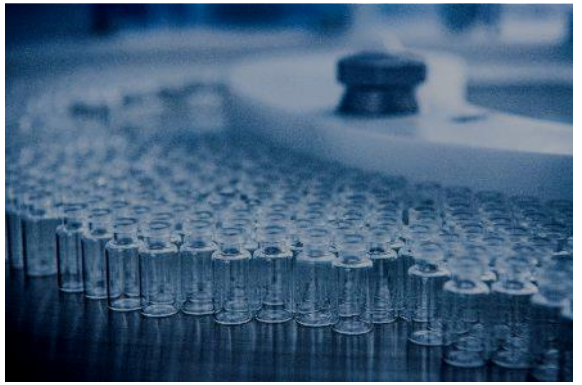
Commercial infrastructure supporting key markets in US and EU

**RSV**
late-stage vaccine candidate in blockbuster indication

**COVID-19**
advancing clinical development

Profitable vaccine business





# 2020 was the first important step in a successful transition

- Strong execution on commercial strategy with successful build-up of presence in key markets
- Market share gains in rabies market, stable for TBE compared to 2019
- COVID-19 impact on markets offset by resilient smallpox business
- Revenue in line with expectations but EBITDA and year-end cash position better than original guidance

| mDKK | 2020A | 2020E |
|---|---|---|
| Revenue | 1,852 | 1,900 |
| EBITDA | 740 | 725 |
| Cash* | 1,670 | 1,600 |

* Securities, cash and cash equivalents

## Key drivers

- Additional smallpox contracts entered with US government and other countries
- RSV program revised with addition of human challenge trial in 2021 (data 3Q21) ahead of planned Phase 3 in 2022
- Addition of fill and finish capabilities combined with continued manufacturing expansions provide strategic flexibility
- Licensed COVID-19 vaccine (VLP) with encouraging preclinical results being advanced into the clinic; BN to accelerate development with larger trial after successful private placement

# Proceeds from private placement accelerates COVID-19 strategy and provides flexibility to grow new opportunities

An accelerated bookbuild offering in March 2021 raised DKK 1.148m via new shares to new and existing, Danish and international institutional investors.

## Use of proceeds:

Funding of a phase 2 clinical study and scale-up of manufacturing to accommodate potential future clinical development to support licensure of the COVID-19 vaccine.

Continued strengthening of the Company's manufacturing capabilities, to increase agility and flexibility with respect to potential opportunities where Bavarian Nordic may produce vaccines on behalf of third parties, e.g., COVID-19 vaccines

Ensuring the strategic flexibility necessary to pursue an active M&A strategy.

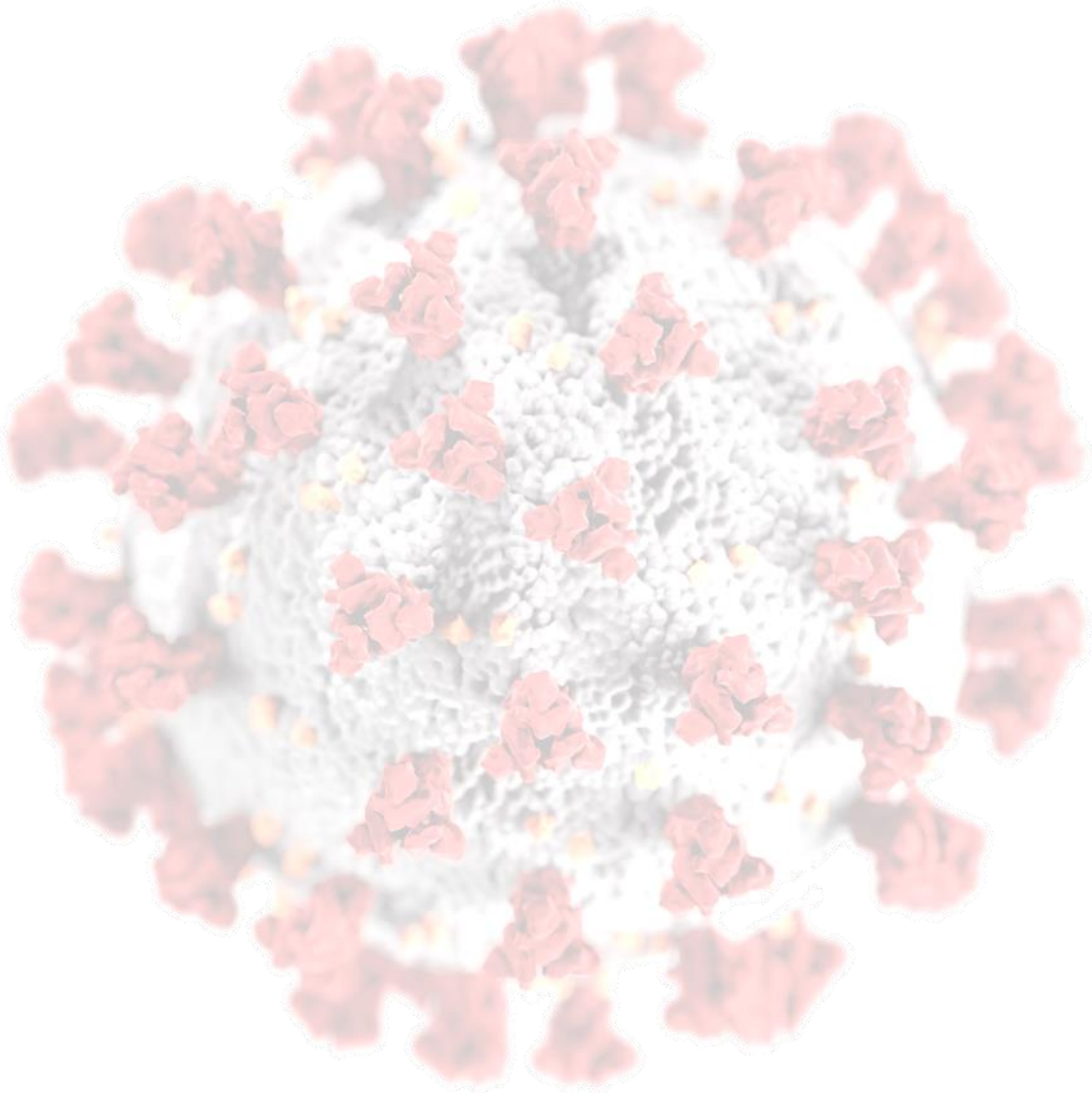
A strengthening of the Company's capital base

# A need for continued advances in COVID-19 vaccine development

Durability and breadth of protection for existing COVID-19 vaccines against new circulating variants remains unknown.

Unlikely that COVID-19 can be eliminated and regular booster vaccinations and/or new COVID vaccines will likely be required to reduce the continuing burden of disease in the worldwide population.

The requirement for billions of COVID-19 vaccine doses has highlighted the complexity and a number of bottlenecks in vaccine production and supply



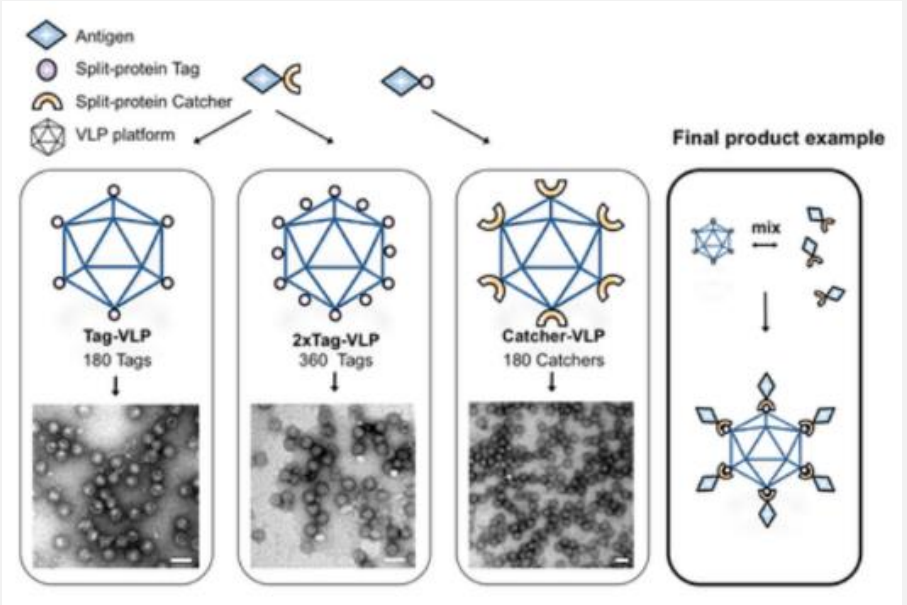
# ABNCoV2 – next generation COVID-19 vaccine candidate

- Our COVID-19 vaccine candidate, **ABNCoV2**, has shown to be highly immunogenic in relevant preclinical models inducing durable responses equivalent to high convalescent sera from patients that have recovered from COVID-19.
- Coupled with the ease of production and the ability to rapidly adapt the vaccine platform to new potentially more deadly variants, ABNCoV2 looks like a highly promising candidate.

## ABNCoV2

- Capsid virus like particle (cVLP) based SARS-CoV-2 subunit vaccine
- Licensed from **AdaptVac**

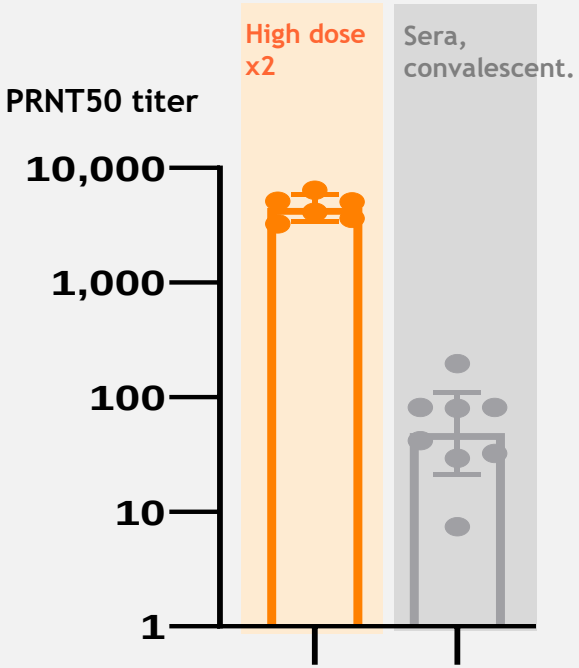
**Flexible platform adaptive to mutations**



# ABNCoV2 preclinical data

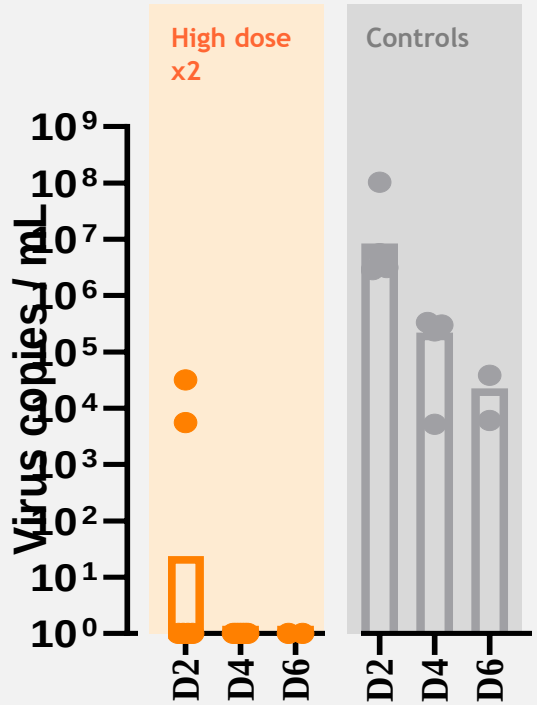
## Neutralizing antibodies

- A single administration of low and high dose with adjuvant, but also the high dose without adjuvant induced SARS-CoV-2 neutralizing antibodies at comparable levels to those measured in convalescent human samples
- A second administration of non-adjuvanted ABNCoV2 led to >50-fold higher titers




## Viral load after challenge

- Following a challenge with SARS-CoV-2, virus load was significantly reduced in all vaccinated groups, compared to non-vaccinated controls, and no virus could be detected at any timepoint in the majority of the subjects vaccinated with two high doses of ABNCoV2.



# Accelerating the clinical development of ABNCoV2

- First-in-human study was initiated by Adaptvac and the PREVENT-nCoV consortium in March 2021, supported by a Horizon 2020 EU grant.
  - Phase 1/2 open label, dose-escalation trial assessing the safety and tolerability of two doses of ABNCoV2, formulated with and without adjuvant, in up to 42 healthy, adult, SARS-CoV-2-naïve volunteers.
  - Initial data expected in Q2 2021

- Bavarian Nordic will invest in a regulatory phase 1/2 clinical trial and scale up manufacturing in preparation for further clinical development towards licensure.
  - Phase 1/2 study expected to start in Q2 2021 in Germany with readout in Q3 2021
  - The study will investigate the ability of ABNCoV2 to boost existing immunity through prior infection or vaccination, to create a more durable immune response that could protect against the current circulating variants of COVID-19.

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

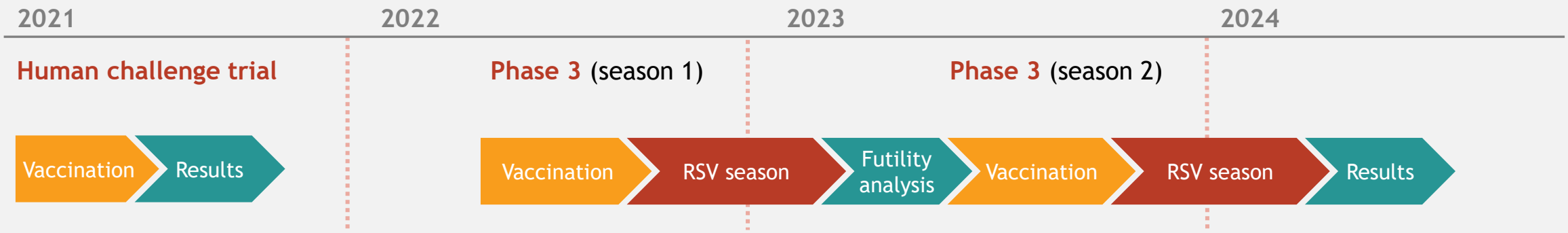
- Human challenge trial in 2021 will provide efficacy insights ahead of Phase 3
- Postponing Phase 3 study initiation by one year into 2022 due to anticipated COVID-19 impact

## 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

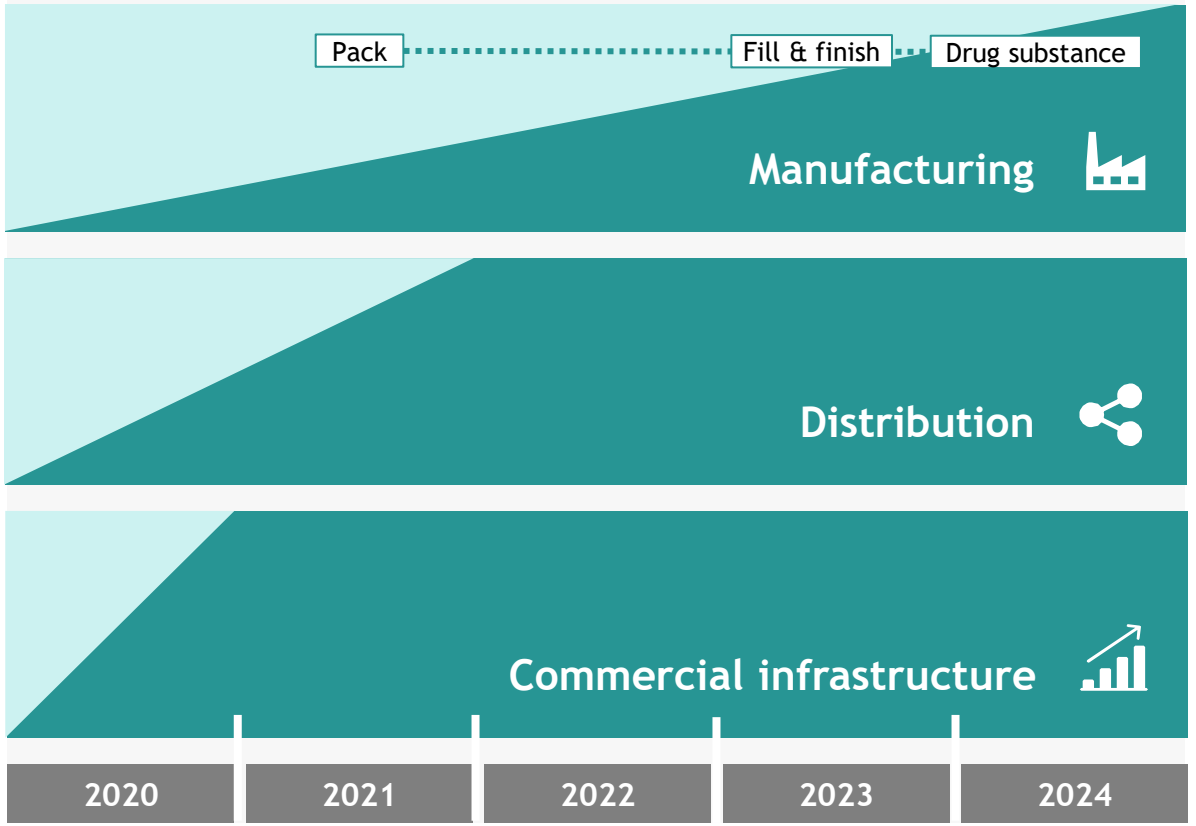


# Encepur & Rabipur/RabAvert integration moving forward

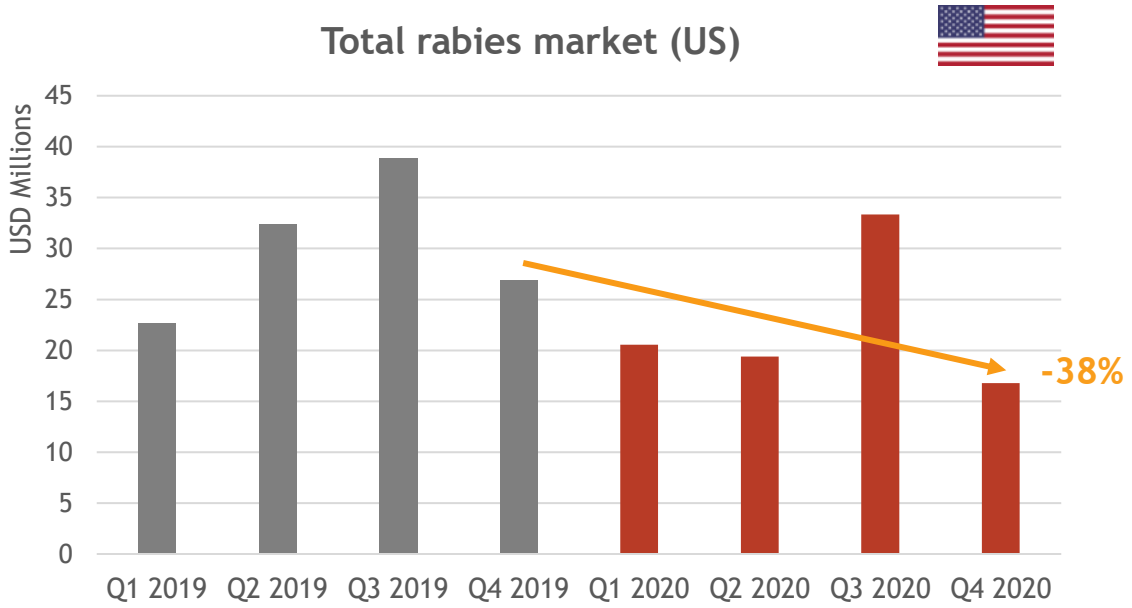
## 2020 accomplishments/milestones

- ✓ Commercial infrastructure in place with local teams established in US and EU
- ✓ Transfer of marketing and distribution completed in 18 countries including key markets US and Germany, now covering more than 90% of total 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

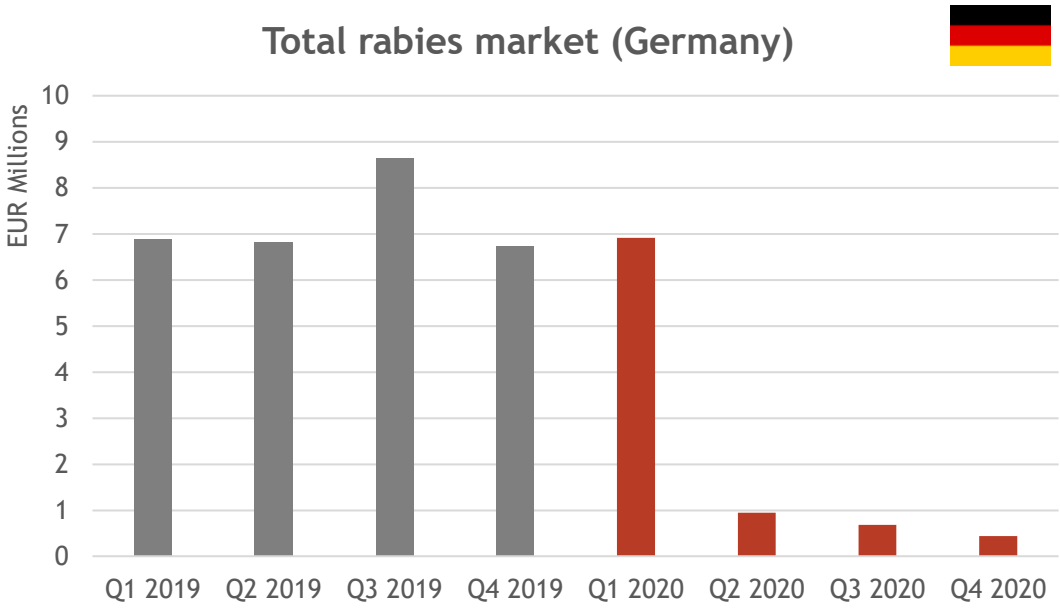
## 5-year transition plan



# The rabies market and COVID-19 impact




- **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.

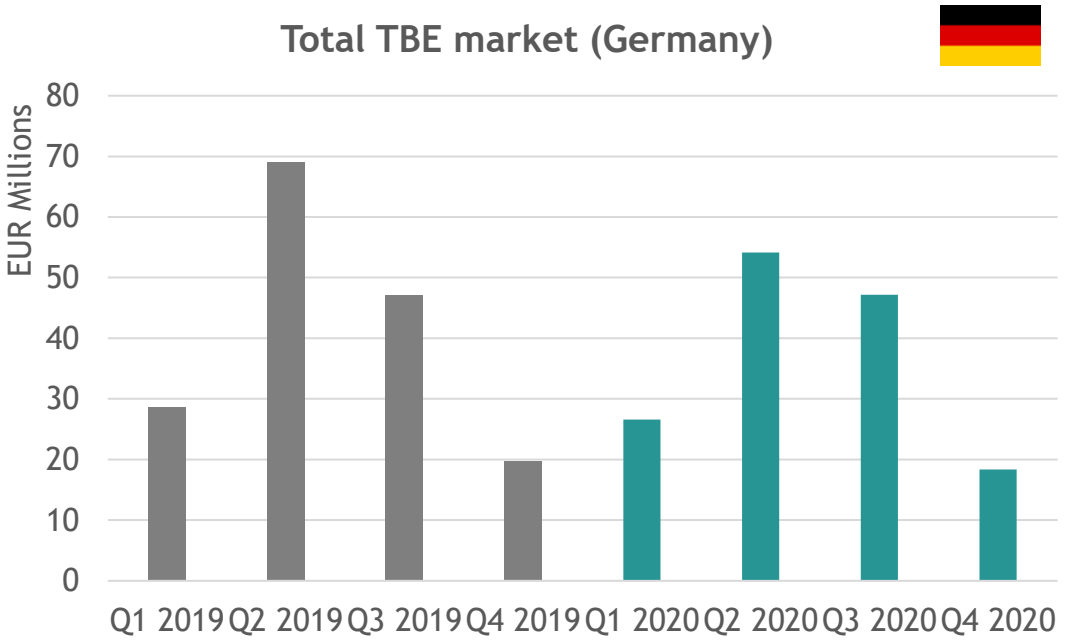



- Pre-exposure market eroded during Q2 2020 and continued throughout the year as result of no travels due to COVID-19



Data source: IQVIA

# The TBE market - *Access to vaccinations is key*




- 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 (either forced or voluntarily)
- Q4 2020 level versus prior year indicating an intact underlying market demand, however Q4 is a low season quarter.

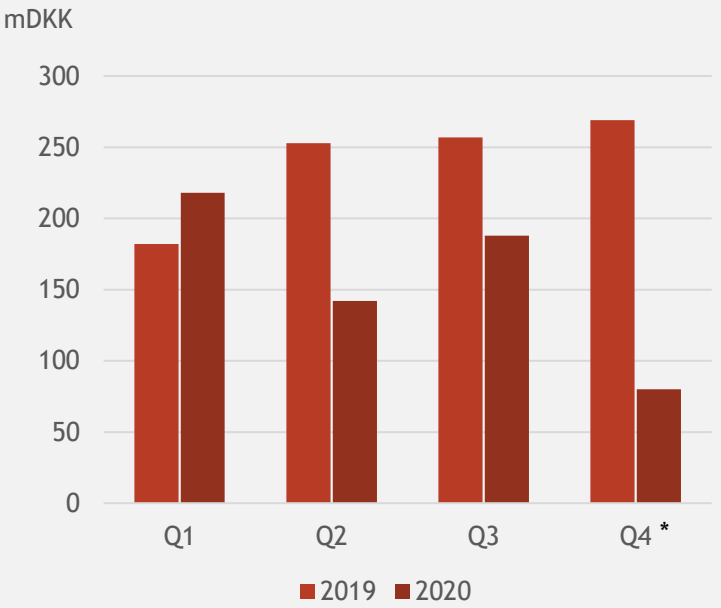
Data source: IQVIA

# RABIPUR/RABAVERT sales – *strong US performance in 2020*

mDKK

| Q4 2020 | Q4 2019 | Growth | FY 2020 | FY 2019 | Growth |
|---|---|---|---|---|---|
| 80 | 269 | -70% | 628 | 960 | -35% |

- Competitor was out-of-stock from Q4 2019 and until recently.
- Post-exposure (US) segment is more resilient and less impacted by COVID-19. Total US market decline in 2020 of approximately 25%. RabAvert full year decline of only 11% due to market share gains.
- Q4 US market share at 70%. Down from 79% in Q3/20 due to competition being back. Market share level still above pre-stockout period.
- US Q4 revenue level significantly below prior year due to extraordinary Q4/19 level.
- Pre-exposure (travel) market heavily impacted - down by 94% in Germany in Q4 versus prior year.




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

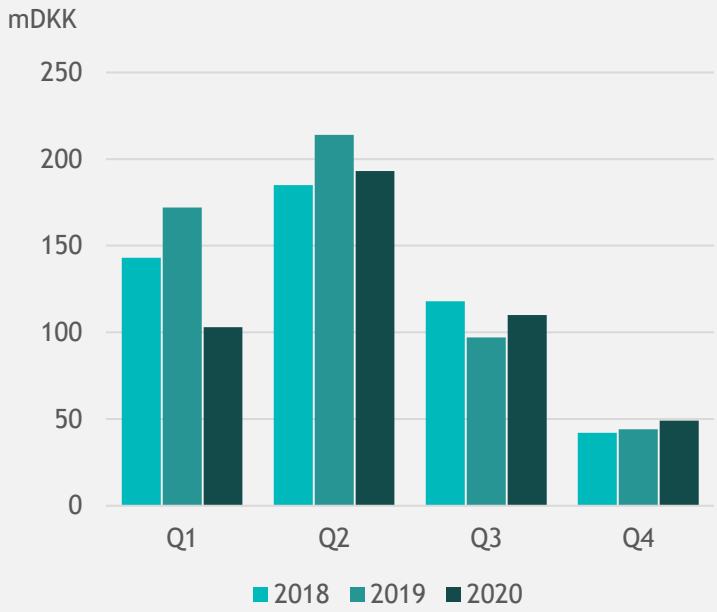

*Sales figures from 2019 have been provided by GSK and are presented for comparison only.*

# ENCEPUR sales – *consolidation of market position*

mDKK

| Q4 2020 | Q4 2019 | Growth | FY 2020 | FY 2019 | Growth |
|---|---|---|---|---|---|
| 49 | 44 | 12% | 455 | 527 | -14% |

- 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 showed negative growth of approximately 6.5% in Q4 versus prior year due to COVID-19 restrictions.
- Market share remains stable around 30%.
- Encepur growth of 12% in Q4 vs LY.





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

# Profit & Loss

| mDKK | FY 2020 | FY 2019 |
|---|---|---|
| Revenue | 1,852 | 662 |
| Production costs | 1,195 | 355 |
| **Gross profit** | **657** | 308 |
| Research and development costs | 341 | 409 |
| SG&A costs | 564 | 227 |
| **Total operating costs** | **905** | 636 |
| Other operating income | 628 | - |
| **EBIT** | **380** | (328) |
| Net financial items | (98) | (16) |
| **EBT** | **282** | (345) |
| Tax | 4 | 2 |
| **Net profit for the year** | **278** | (347) |
| **EBITDA** | **740** | (271) |

**Revenue** was DKK 1,852 million, with increase driven primarily by sale of new products and smallpox vaccine.

Production costs include

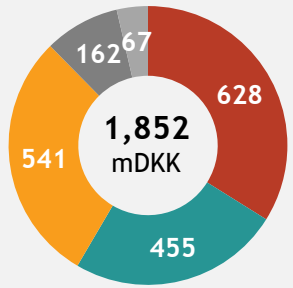
**R&D** costs lower than prior year due to phasing of RSV activities.

**SG&A** costs increase due to commercialization of new products.

**Other operating income** of DKK 628 million from sale of Priority Review Voucher in Q1.

**EBITDA** was DKK 740 million.

**Revenue 2020**
DKK million




- Rabipur/RabAvert
- Encepur
- Smallpox vaccine
- Contract work
- Milestone, Janssen

# Cash flow and Balance Sheet

## Selected cash flow figures

| mDKK | FY 2020 | FY 2019 |
|---|---|---|
| Cash flow from operating activities | 572 | (276) |
| Cash flow from investment activities | (1,912) | (810) |
| **Free cash flow** | **(1,340)** | (1,086) |
| Cash flow from financing activities | 1,335 | 1,115 |
| **Net cash flow for the period** | **(5)** | 29 |

**Cash flow from operating activities** was DKK 572 million (negative by DKK 276 million), with positive contribution from net profit and negative contribution from working capital increase due to inventory build-up.

**Cash flow from investment activities** was negative by DKK 1,912 million (negative by DKK 810 million) following net investments in securities of DKK 1,202 million (net sale of DKK 1,861 million) after sale of the Priority Review Voucher and the completion of the rights issue. Also included are DKK 205 million of investments in property, plant and equipment related to finalization of the fill-and-finish plant and expansion of the bulk facility and milestone payments amounting to DKK 394 million to GSK.

**Cash flow from financing activities** was a contribution of DKK 1,335 million (DKK 1,115 million), following the rights issue partly offset by repayment of the bridge loan.

## Selected balance sheet figures

| mDKK | Dec-31 2020 | Dec-31 2019 |
|---|---|---|
| Intangible assets | 5,291 | 5,484 |
| Total assets | 8,759 | 7,047 |
| Equity | 4,894 | 1,865 |
| Non-current liabilities | 2,912 | 3,134 |
| Current liabilities | 952 | 2,047 |
| Securities, cash and cash equivalents | 1,670 | 472 |
| Debt, bank & institutional | (395) | (1,771) |
| Net cash* | 1,275 | (1,299) |

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 2,823 million (DKK 3,151 million) not included. Book value calculated using NPV and probability weighted milestone payments. Unutilized credit facilities of DKK 244 million not included either.

# 2021 Outlook

## 2021 guidance

| mDKK | FYE 2021 |
|---|---|
| **Revenue** | **1,900 - 2,200** |
| **EBITDA** | **100 - 250** |
| **Cash position (securities, cash and cash equivalents)** | **1,400 - 1,600** |

The guidance intervals reflects the current uncertainty related to COVID-19.

The low end of the **revenue and EBITDA** range reflects a scenario where a lockdown due to COVID-19 continues beyond Q1 in key markets like the US and Germany.

The higher end of the **revenue and EBITDA** range reflects a scenario where a gradual reopening will happen in key markets during Q2 and where travel starts picking up again in Q3 and Q4 of 2021.

The smallpox and Ebola business are not expected to be impacted by COVID-19.

**R&D** spend of approximately DKK 750 million, whereof up to DKK 200 million will be capitalized (ABNCoV2).

**Cash** at year-end impacted by:

- Investment of approximately DKK 650 million in facility expansion and tech-transfer from GSK
- Working capital increases of approximately DKK 300 million (inventories)
- Continued milestone payments to GSK
- Draw-down of EUR 30 million existing credit facility with European Investment Bank
- Investments in COVID-19 program of up to approximately DKK 200 million (capitalized R&D costs)
- Net proceeds of approximately DKK 1,100 million from private placement

## 2021 activities and milestones

### R&D

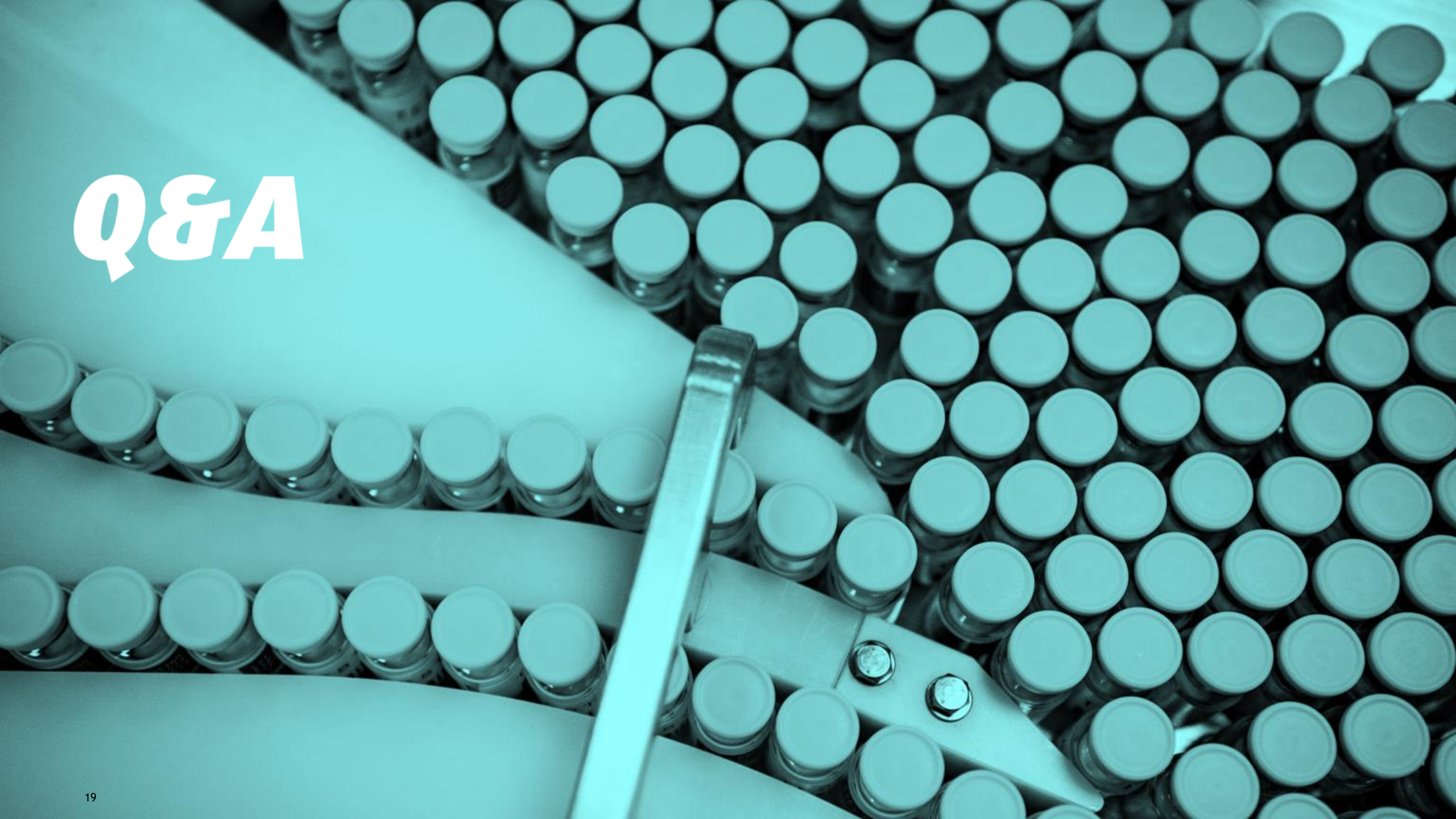
- Initiate and complete a Phase 2 human challenge trial in RSV
- Continue preparations for initiation of the Phase 3 trial of MVA-BN RSV in older adults in 2022
- Advance the development of the COVID-19 vaccine candidate, ABNCoV2 into Phase 2 and scale-up of manufacturing to phase 3 volume levels
- Advance 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