



*An open  
world  
through  
**vaccines***

Q3  
22

Q3 Report | November 9, 2022

# 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.*

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*

# A strong quarter with focus on execution

## Monkeypox

- Expanded vaccine access through additional supply contracts, including HERA (EU) and PAHO (Latin America)
- Increased manufacturing capacity via own facility and through partners
- Significant order book building up for 2023 and beyond, including large US and Canada orders

>70

*countries now has access to our vaccine*

## COVID-19

- Global Phase 3 trial initiated in September with initial data expected early 2023
- Phase 2 six-month follow up data demonstrated durable antibody levels across variants of concern

4,000

*subjects being enrolled*

## RSV

- Global Phase 3 trial enrolling with topline results anticipated mid-2023

20,000

*subjects being enrolled*

## Financials

- All time high quarterly revenue growth driven by strong sales in rabies and monkeypox
- Nearing a break-even result for the year, despite significant investments in R&D (~ DKK 2bn)

DKK 2.8 - 3 bn

*guided revenue for 2022*



# Monkeypox

*Leveraging our technology and manufacturing competencies to improve public health*



## Monkeypox still an emergency

- Infection rates going down in Europe, but outbreak still evolving, in particular in Latin America
- On November 1, WHO maintained the outbreak as a Public Health Emergency of International Concern
- On November 2, the US HHS extended the national Public Health Emergency

**78,599 cases in 110 countries<sup>1</sup>**

## Expanded access to vaccine across affected regions

- Agreements with the European Health Emergency Preparedness and Response Authority (HERA) and the Pan American Health Organization (PAHO) have significantly expanded the worldwide access to our vaccine
- EU member states, PAHO countries and other countries have continued to sign individual supply agreements

**>70**

*countries with access  
to vaccine*

**>3M**

*doses supplied  
worldwide YTD*

## Real-life data demonstrates effectiveness for MVA-BN

- A U.S. retrospective analysis of 5,402 monkeypox cases during outbreak showed 14x higher incidence of monkeypox in unvaccinated persons than in persons vaccinated with 1 dose of MVA-BN<sup>2</sup>
- Israeli study in 1,970 high-risk individuals demonstrated 79% effectiveness after 1 dose of MVA-BN during outbreak<sup>3</sup>

**79%**

*effectiveness after single dose of MVA-BN*

## Scaling up manufacturing capacity

- Reinitiated bulk manufacturing at own site and increased filling capacity
- Tech transfer to US contract manufacturer ongoing to support US government orders



# COVID-19

## ABNCoV2 - a differentiated booster vaccine candidate

### Phase 3 trial ongoing

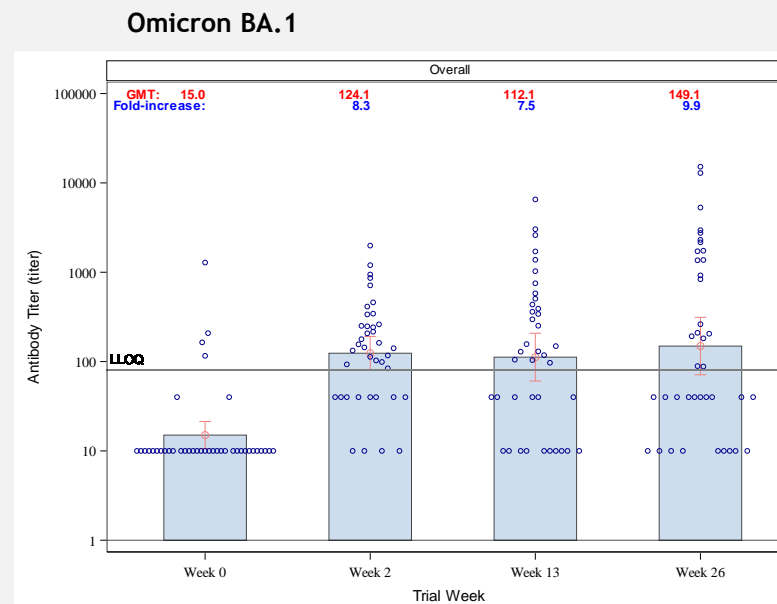
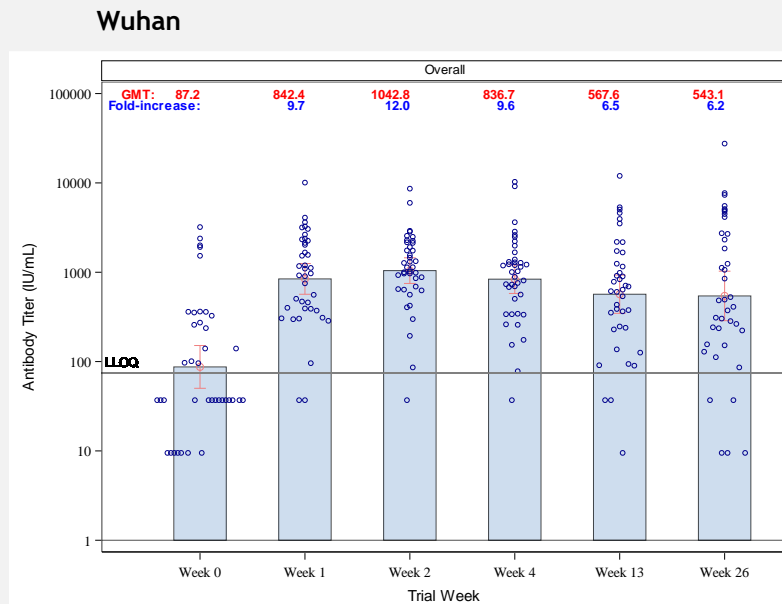
- Global two-cohort study initiated in September
  - Safety arm (US) with 3,000 subjects who will receive a single dose of ABNCoV2
  - Active, controlled arm (Denmark/Belgium) with 1,000 subjects randomized to receive either a single dose of ABNCoV2 or a single booster dose of Comirnaty
- Initial data read-out expected early 2023

4,000

subjects being enrolled

### Phase 2 six-month follow-up data demonstrate durable antibody levels

>90%



- 41/103 subjects were followed for six months post vaccination
- Six months post the booster vaccination with 100ug ABNCoV2, the neutralization antibody titers against Wuhan and the Omicron variant remained high and at levels associated with a greater than 90% efficacy
- Compared to data published for mRNA vaccines, the antibody decay after six months appears less sharp, indicating a potentially longer duration of protection across variants of concern

# RSV

*A global, blockbuster opportunity*

## An large unmet need

- RSV remains a large disease burden in older people and immunocompromised individuals
- Hospitalizations and deaths are comparative to that of influenza
- No approved prophylactic vaccine
- Vaccine market size in major markets estimated to reach USD 4.5 - 6 bn in 2025

## MVA-BN RSV - a differentiated approach

- Candidate vaccine designed to stimulate a broad immune response and protect against severe respiratory disease
- Comprehensive clinical data generated, including a human challenge trial, which demonstrated 79% efficacy in reducing symptomatic RSV infections

## Phase 3 trial ongoing

- Global efficacy study initiated in April 2022
- 20,000 subjects enrolling in the USA and Germany
- Topline data anticipated mid-2023



up to **120k** *annual*  
*hospitalizations among adults 65+ in the US<sup>4</sup>*

**79%**  
*efficacy in reducing symptomatic infections*

**20,000**  
*subjects being enrolled*

# Commercial and Financial Update



## Revenue split Q3 and first nine months

### Strong quarter fueled by monkeypox vaccines and continued rabies market growth

- Continued strong growth in the US rabies market, significantly above pre-COVID level for Q3. European market also sees strong growth, however not fully recovered yet.
- TBE market also seeing growth, but Encepur impacted by temporary stockout during Q3
- Increased smallpox/monkeypox revenue as deliveries have picked up during Q3, continuing into Q4.

#### Revenue distribution, third quarter

mDKK	Q3 2022	Q3 2021	Growth
Rabipur/RabAvert	338	160	111%
Encepur	62	72	-13%
JYNNEOS/IMVANEX/IMVAMUNE	578	214	170%
Mvabea	-	-	-
Sale of third-party products	11	-	-
Milestone payments	-	-	-
Contract work	15	3	345%
<b>Total</b>	<b>1,004</b>	<b>449</b>	<b>124%</b>

#### Revenue distribution, first nine months

mDKK	9m 2022	9m 2021	Growth
Rabipur/RabAvert	689	368	87%
Encepur	275	316	-13%
JYNNEOS/IMVANEX/IMVAMUNE	695	550	126%
Mvabea	30	89	-66%
Sale of third-party products	64	-	-
Milestone payments	83	-	-
Contract work	25	31	-20%
<b>Total</b>	<b>1,860</b>	<b>1,354</b>	<b>37%</b>

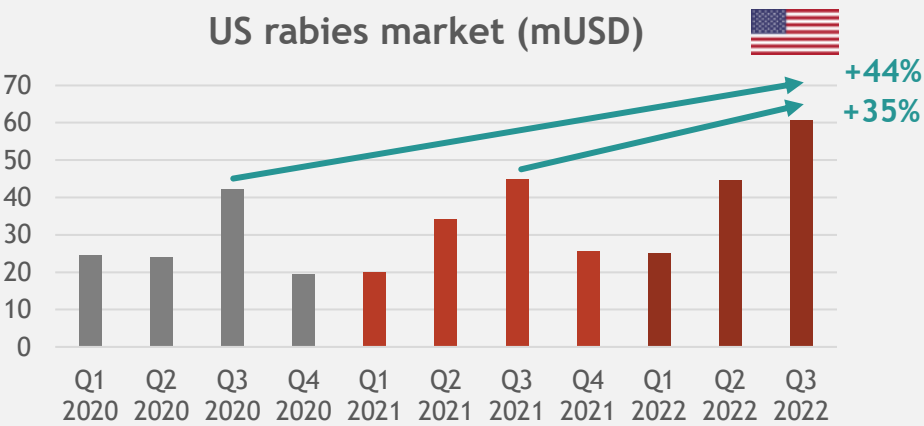


# Rabies vaccine

## Market development and performance

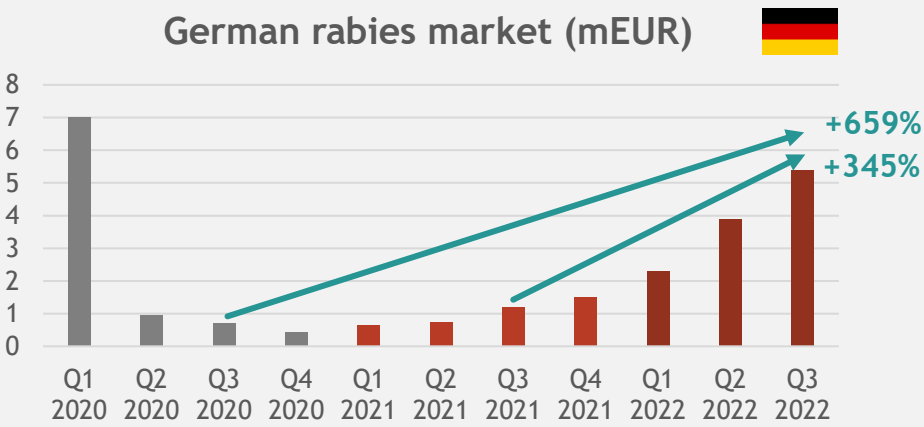


### Rabies market



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

However, the market remained more resilient than the European market and strong 2022 growth has now brought the market level above the 2019 pre-covid level.



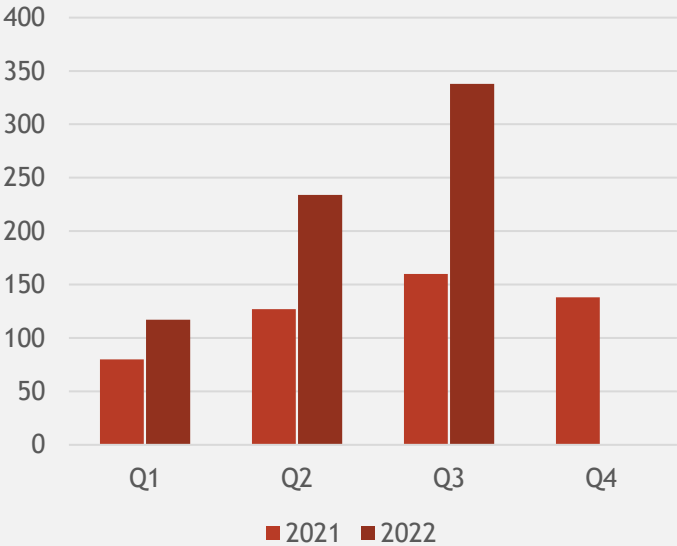
**Pre-exposure** market suffered severely from COVID-19 travel restrictions, but has shown strong signs of recovery over the past quarters. The market size is still below the pre-covid level.

Data source: IQVIA

### Rabipur/RabAvert sales (mDKK)

Q3 2022	Q3 2021	Growth
338	160	111%

- Significant market growth in key markets during Q3
- US market share has improved quarter by quarter in 2022, now at approx. 67% and above the level seen prior to competition facing stockout situation in 2019/2020. German market share remained unchanged at approx. 95%.
- Positive impact from USD exchange rate development

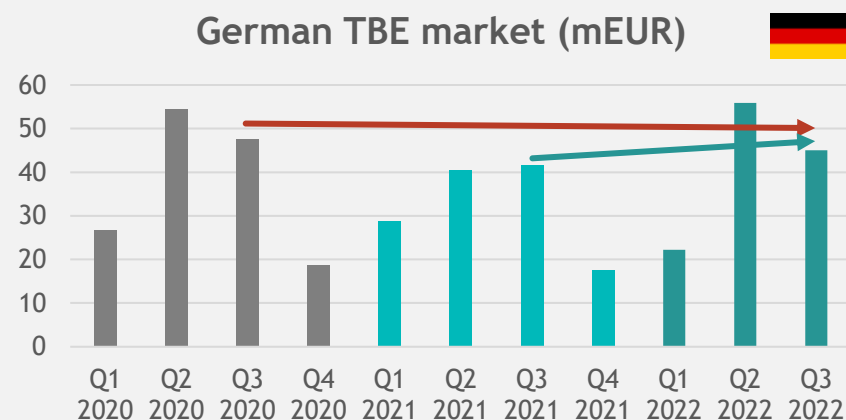


# TBE vaccine

## Market development and performance



### TBE market



-6%  
+8%

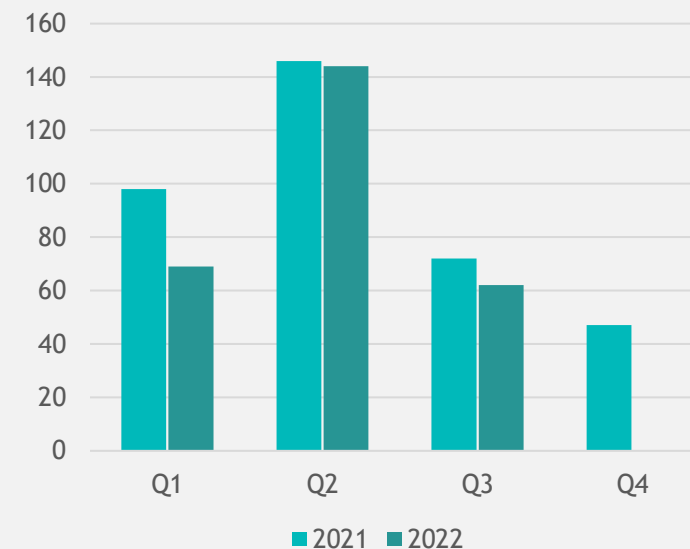
Market still in recovery. Overall YTD growth of 11% in the German market YTD despite decline during September.

Data source: IQVIA

### Encepur sales (mDKK)

Q3 2022	Q3 2021	Growth
62	72	-13%

- A slight decrease versus prior year despite positive market growth, caused by inventory movements at wholesaler and partner level (Valneva) plus a temporary stockout situation in Q3, which has now been resolved.



# Profit & Loss

mDKK	Q3 2022	Q3 2021	9m 2022	9m 2021	FY 2021
Revenue	1,004	449	1,860	1,354	1,898
Production costs	384	314	1,107	941	1,328
<b>Gross profit</b>	<b>620</b>	<b>135</b>	<b>753</b>	<b>413</b>	<b>570</b>
Research and development costs	360	75	650	294	399
SG&A costs	132	107	385	361	485
<b>Total operating costs</b>	<b>492</b>	<b>182</b>	<b>1,035</b>	<b>644</b>	<b>884</b>
<b>EBIT</b>	<b>128</b>	<b>(47)</b>	<b>(282)</b>	<b>(242)</b>	<b>(314)</b>
Net financial items	(109)	(32)	(205)	(115)	(141)
<b>EBT</b>	<b>19</b>	<b>(79)</b>	<b>(487)</b>	<b>(357)</b>	<b>(454)</b>
Tax	7	3	10	6	10
<b>Net profit for the period</b>	<b>12</b>	<b>(81)</b>	<b>(497)</b>	<b>(363)</b>	<b>(465)</b>
<b>EBITDA</b>	<b>226</b>	<b>52</b>	<b>14</b>	<b>44</b>	<b>75</b>

**Revenue** was DKK 1,860 million driven by positive market trends for the rabies and monkeypox business.

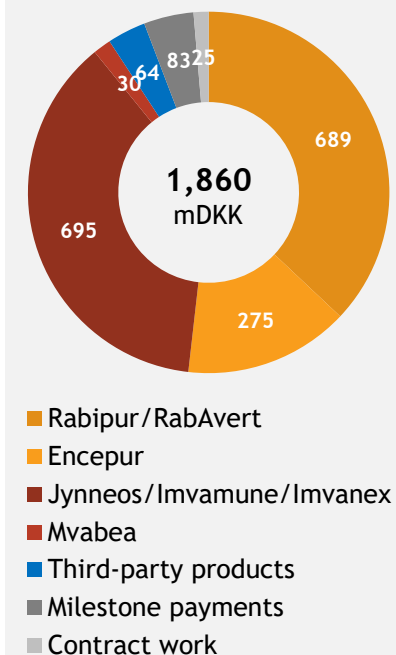
**Production costs** totaled DKK 1,107 million. Increase driven by higher activity in the filling line as well as the reopening of the bulk facility after the planned shut down.

**R&D** costs increased due to initiation of RSV phase 3.

**SG&A** in line with prior year.

**EBITDA** was a profit of DKK 14 million.

**Revenue 9m 2022**  
DKK million



# Cash flow and balance sheet

## Selected cash flow figures

mDKK	9m 2022	9m 2021
Cash flow from operating activities	3	(247)
Cash flow from investment activities	(291)	(1,356)
<b>Free cash flow</b>	<b>(288)</b>	<b>(1,603)</b>
Cash flow from financing activities	405	1,655
<b>Net cash flow for the period</b>	<b>117</b>	<b>52</b>

**Cash flow from operating activities** was positive by DKK 3 million (negative by DKK 247 million). Working capital worsened by DKK 47 million (DKK 344 million) compared to December 31, 2021.

**Cash flow from investment activities** was negative by DKK 291 million (negative by DKK 1,356 million, including DKK 947 million net investment in securities) and includes investments in property, plant and equipment of DKK 295 million (DKK 307 million), mainly related to the expansion of the drug substance facility for future production of Rabipur/RabAvert and Encepur. Investment in other intangible assets amounted to DKK 279 million (DKK 86 million) and includes the ongoing Rabipur/RabAvert and Encepur technology transfer project, the development project for the COVID-19 vaccine and IT system investments. Investment in financial assets relates to prepayments to CMOs for tech transfer and scale up activities of DKK 127 million (DKK 15 million).

**Cash flow from financing activities** was a contribution of DKK 405 million (DKK 1,655 million), primarily from funding received from the Danish Ministry of Health. The net change in cash and cash equivalents was positive by DKK 117 million (positive by DKK 52 million).

## Selected balance sheet figures

mDKK	Sep-30 2022	Sep-30 2021
Intangible assets	5,865	5,162
Total assets	12,295	10,118
Equity	6,958	5,771
Non-current liabilities	3,024	2,034
Current liabilities	2,313	2,313
Securities, cash and cash equivalents	3,242	2,638
Debt, bank & institutional	(892)	(850)
Net cash*	2,350	1,788

Increase in **equity** largely attributed to the capital increase through private placements in December 2021 with proceeds of DKK 1.7 billion.

**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 prepayments to ABNCoV2 contract manufacturers and increased securities, cash and cash equivalents following two capital raises in 2021.

\*Deferred consideration to GSK of DKK 2,561 million not included. Book value of the deferred consideration is calculated using NPV and probability weighted milestone payments.

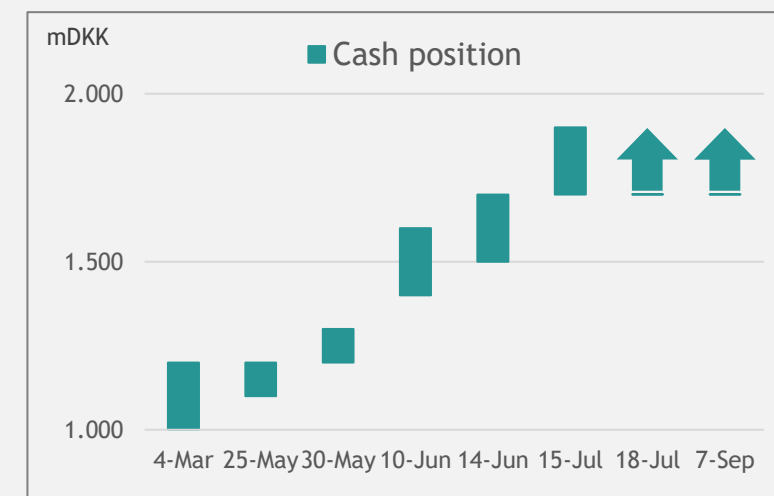
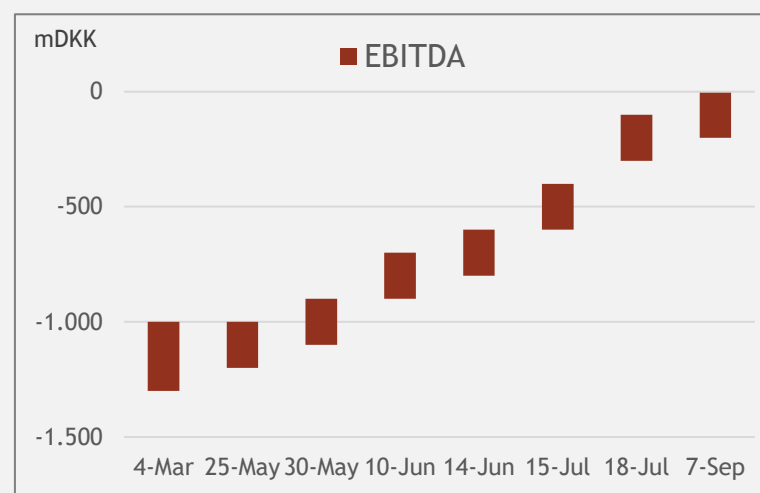
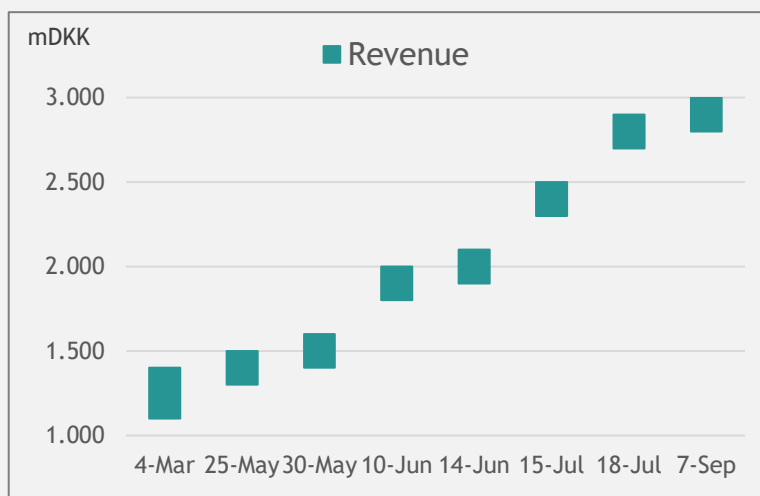


# Financial guidance

- 2022 was designated “an investment year” with nearly DKK 2 billion earmarked for Phase 3 trials in RSV and COVID-19
- Seven guidance adjustments since March resulting from multiple supply contracts for monkeypox vaccine and a strong rabies vaccine business
- Smallpox/monkeypox vaccine orders with existing and new customers have been secured for recognition across 2022 and 2023 and beyond. Guidance is still sensitive to final shipment schedule around the turn of the year.
- Guided cash position by year-end still assumes a debt level of DKK 600 million

mDKK	Original guidance March 4, 2022	Current guidance Sep 7, 2022
Revenue	1,100 - 1,400	2,800 - 3,000
EBITDA	(1,300) - (1,000)	(200) - 0
Cash position *	1,000 - 1,200	> 1,700

## Changes in guidance during 2022



\* Securities, cash and cash equivalents

# References

1. <https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html>, accessed 09-Nov-22
2. Payne AB, Ray LC, Kugeler KJ, et al. Incidence of Monkeypox Among Unvaccinated Persons Compared with Persons Receiving  $\geq 1$  JYNNEOS Vaccine Dose – 32 U.S. Jurisdictions, July 31–September 3, 2022. MMWR Morb Mortal Wkly Rep. ePub: 30 September 2022. DOI: <http://dx.doi.org/10.15585/mmwr.mm7140e3>
3. Arbel R. et al. Effectiveness of a single-dose Modified Vaccinia Ankara in Human Monkeypox: an observational study. Preprint posted on Research Square. September 23rd, <https://doi.org/10.21203/rs.3.rs-1976861/v2>
4. <https://www.cdc.gov/rsv/research/index.html>

# Q&A

