## BAVARIAN NORDIC

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# Bavarian Nordic Q3 2024 Results

Conference Call

November 15, 2024



- Q3 2024 financial highlights
- Travel Health
- Public Preparedness
- Mpox update
- Commercial performance
- Financials
- Guidance 2024
- Q&A





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#### Forward-looking statements

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.

# Q3 2024 financial highlights



## Key highlights to date

- Continued strong growth in Travel Health in Q3 (+21%) and 9M (+18%), primarily driven by rabies and TBE
- Rabipur/RabAvert tech transfer completed, while Encepur tech transfer progressing as planned (expected completion in 2025)
- Commercial presence being expanded into new territories to support 2025 chikungunya launch and ongoing Vivotif and Vaxchora relaunches
- Public Preparedness revenue in line with revised expectations, supported by new orders in Q3
- Several regulatory approvals received in Q3, including WHO prequalification, and label extension for adolescents
- Chikungunya launch preparations intensified with regulatory review underway in the US and Europe (expected launch in H1 2025)
- Guidance 2024 maintained, and sufficient capacity retained with potential for additional capacity for future demand
- For 2025, DKK ~2,400m<sup>\*</sup>) of revenue currently secured from mpox/smallpox orders, including previously announced deferred revenue

\*) This amount assumes 2024 revenue realized at the high end of the guidance. Any lower 2024 Public Preparedness revenue will add to the 2025 order book.

## **Continued strong Travel Health**

## Rabies

- Sales increased 22% in Q3 (11% in 9M), reflecting a strong demand from key markets in the US and Germany
- US: Continued market growth (4% vs. Q3 2023) and increased market share to 79%
- **Germany:** Strong market demand resulting in market growth of 24%, with market share back at 95% (vs. 82% in Q2)
- Tech transfer approved and completed according to plan and budget, expected to result in gross margin improvement in 2026 (full 15-20pp impact in 2027)

## TBE

- Sales increased 36% in Q3 (16% in 9M), supported by market growth
- TBE German market growth of 10% (vs. Q3 2023) and market share of 29% maintained
- Tech transfer progressing as planned and expected to be finalized in 2025

### Cholera and typhoid

- Combined sales for both products grew in the first nine months compared to 2023<sup>1</sup>
- Lower Vivotif sales vs. Q3 2023 explained by a gross-to-net adjustment in August 2024 adjusting for returns from launch supply into the market in 2023

Commercial presence currently being expanded into new territories to support the ongoing relaunch of Vivotif and Vaxchora, and the gradual take-back of Rabipur/RabAvert and Encepur sales and marketing in markets currently managed by Valneva.

<sup>1</sup> 2023 revenue only includes revenue from mid-May 2023 from the time when the acquisition of the vaccines was completed.

Travel Health, revenues by quarter nDKk 800 700 600 500 400 300 200 100 

## Expanding the Public Preparedness business

New contracts in response to the public health crisis

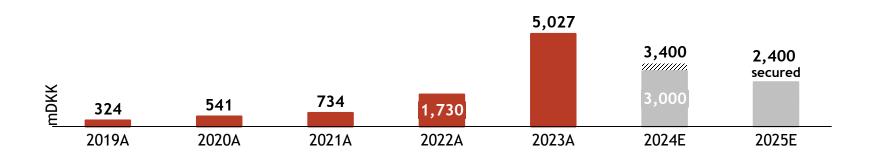
- USD >220m of multi-year orders from the US government for manufacturing of additional bulk vaccine and final vaccine
- 175,420 dose mpox vaccine order from HERA for donation to Africa CDC
- 440,000 dose smallpox/mpox vaccine order from an undisclosed European country
- 1m dose mpox vaccine order from UNICEF

#### US & Germany private market launch

- JYNNEOS launched in the private market in US and Germany
- Strong US sales in Q3 due to public health emergency
- +100,000 doses expected to be sold in the US private market in 2024
- German private market also boosted by the mpox health emergency situation, however still from a low level

#### **Regulatory** approvals

- EMA approval for adolescents (12-17 years)
- WHO prequalification for MVA-BN as the first and only mpox vaccine to receive the approval
- Full approval in Singapore and Mexico, and provisional approval in New Zealand





# Mpox update

## Status and initiatives



# Continued joint efforts in strengthening mpox preparedness

Intensified global collaboration

World Health Organization

AfricaCDC

BARDA

Gavi 🚱

European Commission Nearly 3m MVA-BN doses made available to Africa through donations and agreements

Donations by the EC, the US government and Bavarian Nordic the first to arrive in DRC in September Maximizing manufacturing capacity to meet global demand in short- to mediumterm Ensuring **equitable access** to MVA-BN for all populations

# Regulatory and clinical progress

- MVA-BN currently the only approved non-replicating smallpox/mpox vaccine for adults aged +18 years by the US, the EC, the UK, Canada, Switzerland, Singapore, New Zealand<sup>1</sup> and Mexico<sup>2</sup>
- EMA approval of mpox vaccine for adolescents (12-17 years)
- **CEPI funded clinical trial** initiated in Africa to potentially **expand the approval of MVA-BN to include children** (2-12 years)
- **CEPI co-funded study** initiated in Africa to potentially **expand access to MVA-BN for priority populations**, assessing if vaccination with MVA-BN could reduce mpox risk after a person coming into contact with someone diagnosed with mpox
- MVA-BN study in Africa supported by CEPI and Bavarian Nordic to assess the safety and immunogenicity of MVA-BN in pregnant and breastfeeding women, and infants under 2 years (planned for 2025)



<sup>1</sup> MVA-BN has been given provisional approval by Medsafe, New Zealand Medicines and Medical Devices Safety Authority.

 $^2$  MVA-BN has been fully approved by the Mexican Federal Committee for Protection from Sanitary Risks, COFEPRIS.





## Chikungunya

Intensified preparations for potential US and Europe launch of chikungunya vaccine in H1 2025.

First adolescent chikungunya vaccine candidate **B** regulatory review with EMA and FDA

- EMA:
  - MAA submitted to EMA in June and accepted in July
  - MAA being reviewed under accelerated assessment (expected decision in H1 2025)
- FDA:
  - Rolling BLA submission completed in June
  - BLA with priority review granted in August  $\rightarrow$ shorter review time
  - PDUFA date: February 14, 2025
- Expansion of commercial presence into new territories to support the 2025 chikungunya launch

## **Commercial performance**

## Q3 and 9M 2024

mDKK	Q3 2024	Q3 2023	Growth	9M 2024	9M 2023	Growth
Public preparedness						
JYNNEOS/IMVANEX/IMVAMUNE	525	708	-26%	1,549	2,890	-46%
Travel health						
Rabipur/RabAvert	526	432	22%	1,095	987	11%
Encepur	121	89	36%	449	388	16%
Vivotif	30	54	-44%	128	<b>82</b> <sup>1</sup>	56%
Vaxchora	34	12	183%	67	<b>19</b> <sup>1</sup>	253%
Third-party products	61	52	17%	154	133	16%
	773	639	21%	1,892	1,608	18%
Other revenue	65	30	117%	181	117	54%
Total	1,363	1,376	-1%	3,622	4,615	-22%

- Public Preparedness driven by previously signed contracts with existing customers and new contracts in Q3
- Continued double-digit growth in Travel Health in Q3 (+21%) and 9M (+18%), primarily driven by rabies and TBE
- Initial expectations for combined sales of Rabipur/RabAvert and Encepur exceeded, triggering sales milestone to GSK in Q3
- Vivotif and Vaxchora still in relaunch phase

<sup>1</sup> Includes only revenue from mid-May 2023 from the time when the acquisition of the vaccines was completed.

# Financials in line with expectations

mDKK	Q3 2024	Q3 2023	9M 2024	9M 2023	FY 2023
Revenue	1,363	1,376	3,622	4,615	7,062
Production costs	784	514	2,068	1,626	2,459
Gross profit	580	862	1,565	2,989	4,603
Gross margin	43%	63%	43%	65%	<b>65</b> %
R&D costs	264	980	659	1,782	2,228
SG&A costs	222	208	675	617	872
Total operating costs	486	1,188	1,334	2,399	3,101
EBIT	94	(326)	231	590	1,503
Net financial items	(21)	(8)	(6)	(5)	(20)
EBT	72	(335)	224	585	1,483
Tax	2	6	7	11	8
Net profit for the period	70	(341)	217	574	1,475
EBITDA	250	380	692	1,552	2,615
EBITDA margin	18%	28%	<b>19</b> %	34%	37%

- 9M revenue and EBITDA in line with expectations
- Lower gross margin vs. LY due to delay in rabies bulk production, water damage and idle capacity in factory mainly during Q1
- Lower operating costs vs. LY due to decreased clinical costs, while higher SG&A related to 2023 acquired activities and 2024 chikungunya prelaunch activities
- 19% EBITDA margin in 9M and net profit of DKK 217m

## Cash flow and balance sheet

## Cash flow

mDKK	9M 2024	9M 2023
Cash flow from operating activities	994	534
Cash flow from investment activities	(1,545)	(802)
Free cash flow	(551)	(268)
Cash flow from financing activities	73	723
Net cash flow for the period	(478)	455

- Significant positive cash flow from operating activities, negatively impacted by planned inventory build-up, while positively impacted by a reduction in receivables
- Cash flow from investment activities include placement of cash in securities (DKK 1,048m) and milestone payments to GSK and Emergent BioSolutions (DKK 990m)
- Cash flow from financing activities primarily related to the exercise of warrants

## Balance sheet

mDKK	Sep-30 2024	Sep-30 2023
Intangible assets	6,419	6,535
Total assets	13,949	13,399
Equity	10,685	9,336
Non-current liabilities	184	1,176
Current liabilities	3,079	2,887
Securities, cash and cash equivalents	1,871	1,506
Debt, bank & institutional	(14)	(16)
Net cash	1,858	1,491

- Adequate cash position to pay remaining milestones to GSK and EBS during next 3 quarters while pursuing current strategy
- Deferred consideration of DKK ~1,700m to GSK and Emergent BioSolutions
- Undrawn sustainability-linked loan (SLL) of DKK 1,000m
  retained

# Guidance 2024 maintained

The latest guidance, upgraded in September following additional mpox vaccine orders combined with improved performance in Travel Health, is maintained for the rest of the year.

	Latest guidance	Orig	Original guidance		
Revenue	5,400 - 5,800 mDKK <sup>1</sup>	5,000 - 5,300 mDKK			
EBITDA	1,450 - 1,700 mDKK <sup>1</sup>	1,100 - 1,350 mDKK			
Revenue split	Public Preparedness	Travel Health	Other income		
	<b>3,000 -</b> <b>3,400</b> mDKK	~ <b>2,200</b> mDKK	~200 mDKK		

<sup>1</sup> The guidance range reflects the uncertainty related to logistics and supply timing of deliveries of mpox vaccines dictated by among others the level of preparedness to receive and handle the vaccines in the receiving countries.

#### Key assumptions

- DKK ~850m of R&D costs with chikungunya representing ~50%
- DKK ~100m (previously DKK 240m) negative impact on manufacturing costs due to chikungunya program
- DKK ~1,050m (previously DKK 900m) increase in net working capital due to final inventory buildup before completion of rabies and TBE tech transfers, driven by amongst others higher receivables
- DKK ~100m (previously DKK 300m) of other tangible investments, driven by phasing of CAPEX projects
- Assumption on FX of DKK 6.90/USD and DKK 7.45/EUR

 For 2025, DKK ~2,400m<sup>\*</sup>) of revenue currently secured from mpox/smallpox orders, including previously announced deferred revenue

\*) This amount assumes 2024 revenue realized at the high end of guidance. Any lower 2024 Public Preparedness revenue will add to the 2025 order book.

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