

Bavarian Nordic offentliggør delårsregnskab for de første ni måneder af 2022

KØBENHAVN, Danmark, 9. november 2022 - Bavarian Nordic A/S (OMX: BAVA) offentliggjorde i dag regnskab for de første ni måneder af 2022 samt rapporterede på begivenheder for tredje kvartal 2022.

Administrerende direktør i Bavarian Nordic, Paul Chaplin udtaler: "Vi befinder os i en spændende periode for Bavarian Nordic, hvor vi har fortsat med at udvide vores aktiviteter for at understøtte den globale indsats mod abekopper, samtidig med afviklingen af to globale fase 3-forsøg med vores sen-fase programmer. Det er opmuntrende at se, hvordan vores vacciner virkelig kan gøre en forskel for udsatte befolkningsgrupper og være med til at ændre abekoppeudbruddets gang. Mere end 1 million mennesker har modtaget vores vaccine siden begyndelsen af udbruddet, og antallet vokser dag for dag. Vi har desuden allerede sikret betydelige ordrer for 2023 og fremover. Leveringerne er blevet intensiveret i løbet af de sidste 3 måneder og vil fortsætte ind i fjerde kvartal, efterhånden som vi øger forsyningerne af vores koppe-/abekoppevaccine til mere end 70 lande verden over. Det øgede salg af vores produkter på tværs af porteføljen driver en rekordhøj omsætning, og vi nærmer os et nulresultat målt på EBITDA for 2022."

Finansielle hovedpunkter

- Den samlede omsætning i de første ni måneder var DKK 1.860 mio. bestående af DKK 1.752 mio. fra det kombinerede salg af produkter, DKK 83 mio. fra milepælsbetalinger fra partnere og DKK 25 mio. fra kontraktarbejde.
- Omsætningen i tredje kvartal udgjorde DKK 1.004 mio. bestående af DKK 338 mio. fra salg af Rabipur®/RabAvert®, DKK 62 mio. fra salg af Encepur®, DKK 578 mio. fra salg af JYNNEOS®/IMVANEX®/IMVAMUNE®, DKK 11 mio. fra salg af tredjepartsprodukter og DKK 15 mio. fra kontraktarbejde.
- Resultat af primær drift før afskrivninger og nedskrivninger (EBITDA) i de første ni måneder var DKK 14 mio.
- Likvider udgjorde DKK 2.741 mio. ved udgangen af tredje kvartal.
- De seneste finansielle forventninger til helåret, som udmeldtes den 7. september, fastholdes med en omsætning i intervallet fra DKK 2.800 til 3.000 mio., et driftsresultat før afskrivninger og nedskrivninger (EBITDA) i intervallet fra DKK -200 til 0 mio. og likvider ved årets udgang på mere end DKK 1.700 mio.

DKK mio.	Q3 2022	Q3 2021	9m 2022	9m 2021	2022 forventet
Omsætning	1.004	449	1.860	1.354	2.800 - 3.000
Resultat af primær drift før afskrivninger og nedskrivninger (EBITDA)	226	52	14	44	(200) - 0
Likvider	2.741*	2.182*	2.741*	2.182*	> 1.700

* Fratrullet belånte obligationer

Øvrige begivenheder

Abekopper

- I juli bestilte den amerikanske regering yderligere 5 mio. doser abekoppevaccine til levering i 2022 og 2023. Vaccinerne vil blive påfyldt ved brug af den råvaccine, der er produceret under tidligere kontrakter med den amerikanske regering. Med henblik på at udvide produktionsapparatet og øge forsyningerne vil doserne også blive påfyldt hos en amerikansk kontraktproducent, når produktionsprocessen er blevet overført.
- I juli godkendte Europa-Kommissionen en udvidelse af markedsføringstilladelsen for selskabets koppevaccine, IMVANEX, til også at omfatte beskyttelse mod abekopper.
- I juli modtog Bavarian Nordic godkendelser fra de amerikanske og europæiske tilsynsmyndigheder af færdigvareproduktionen af koppe- og abekoppevaccine på selskabets nye fyldefabrik i Danmark.
- I august indgik Bavarian Nordic en aftale med Pan American Health Organization (PAHO) der muliggør adgang til abekoppevacciner for lande i Latinamerika.
- I september blev Bavarian Nordic tildelt en 10-årig kontrakt til en værdi af op til USD 434 mio. for levering af koppe-/abekoppevaccine til Canada.
- I september indgik Bavarian Nordic yderligere en kontrakt med EU's Myndighed for Kriseberedskab og -indsats på Sundhedsområdet (HERA) på levering af abekoppevacciner til EU's medlemslande.
- Yderligere ordrer på abekoppevaccine blev indgået i løbet af kvartalet med en række regeringer, herunder signifikante ordrer for 2023. Flere end 70 lande har nu adgang til vaccinen.

Respiratorisk syncytialvirus (RSV)

- Rekruttering til det globale fase 3 kliniske forsøg med MVA-BN RSV i ældre forløber planmæssigt.

ABNCoV2 (COVID-19)

- I september påbegyndte Bavarian Nordic et globalt fase 3 klinisk forsøg med COVID-19 boostervaccinekandidaten ABNCoV2. Forsøgets primære endemål er at påvise, at niveauerne af de neutraliserende antistoffer, der fremkaldes af ABNCoV2 mod SARS-CoV-2 (Wuhan wild type), ikke er ringere (non-inferior) end dem, der ses ved vaccination med Comirnaty®.

Øvrige forhold

- I september udnævnte bestyrelsen den tidligere administrerende direktør for GSK's globale vaccineforretning, Luc Debruyne til observatør i bestyrelsen med hensigt at opstille ham til valg til bestyrelsen på den ordinære generalforsamling i marts 2023, hvor han efter bestyrelsens konstituering ventes at overtage formandsposten efter Gerard van Odijk, der fratræder efter at have siddet 15 år i bestyrelsen.

Begivenheder efter rapporteringsperioden

- I oktober indgik Bavarian Nordic sin første bilaterale kontrakt med et land i Latinamerika om levering af abekoppevacciner, hvormed adgangen til vacciner i regionen blev øget ud over den aftale, der tidligere blev indgået med PAHO.
- I oktober indgik selskabet desuden en aftale med Schweiz om levering af abekoppevacciner. Som en del af aftalen vil Bavarian Nordic indsende en ansøgning til Swissmedic med henblik på at understøtte en potentiel markedsføringstilladelse af vaccinen.
- I oktober rapporterede Bavarian Nordic resultater fra en opfølgende analyse foretaget 6 måneder efter vaccination i et fase 2 klinisk forsøg med selskabets COVID-19 boostervaccinekandidat ABNCoV2, som viste, at 6 måneder efter boostervaccination med ABNCoV2 forblev koncentrationen af neutraliserede antistoffer mod Wuhan og omikron i forsøgspersonerne på høje niveauer, der er associeret med mere end 90% effektivitet.

Webcast og telefonkonference

Selskabets ledelse afholder en telefonkonference i dag kl. 14.00 dansk tid for at præsentere delårsregnskabet og besvare eventuelle spørgsmål. Det er muligt at overvære præsentationen via <https://bit.ly/3Mud65F>. For at stille spørgsmål, skal der foretages registrering forud for eventet via <https://bit.ly/3g5j4gR>.

Kontakt

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Om Bavarian Nordic

Bavarian Nordic er et fuldt integreret vaccineselskab, der er fokuseret på udvikling, produktion og kommercialisering af livsvigtige vacciner. Vi er globalt førende inden for koppevacciner, og er mangeårig leverandør til den amerikanske regering af en ikke-replikerende koppevaccine, som er godkendt af de amerikanske sundhedsmyndigheder, også til beskyttelse mod abekopper. Vaccinen er desuden godkendt i Canada og Europa. Vores kommercielle produktportefølje består endvidere af markedsledende vacciner mod rabies og flåtbåren hjernebetændelse. Med udgangspunkt i vores virale vaccineplatform, MVA-BN®, har vi udviklet en bred portefølje af produktkandidater, der sigter mod at forbedre og beskytte liv ved at frigøre immunsystemets egne kræfter. Blandt andet har vi udviklet en ebolavaccine, der er licenseret til Janssen Pharmaceutical Companies of Johnson & Johnson. Vi er desuden engageret i udviklingen af en næstgenerations COVID-19 vaccine. For yderligere information besøg www.bavarian-nordic.com.

Udsagn om fremtiden

Denne meddelelse indeholder fremadrettede udsagn, som er forbundet med risici, usikkerheder og andre faktorer, hvoraf mange er uden for vores kontrol. Dette kan medføre, at faktiske resultater afviger væsentligt fra de resultater, som er omhandlet i ovennævnte fremadrettede udsagn. Fremadrettede udsagn omfatter udsagn vedrørende vores planer, mål, fremtidige begivenheder, præstation og/eller anden information, som ikke er historisk information. Alle fremadrettede udsagn skal udtrykkeligt vurderes i sammenhæng med de forbehold, der er taget eller henvist til i denne erklæring. Vi påtager os ingen forpligtelser til offentligt at opdatere eller revidere udsagn om fremtiden således, at disse afspejler efterfølgende begivenheder eller omstændigheder, undtagen i det omfang dette er foreskrevet ved lov.

Management's Review

Products and pipeline

Our products

We sell and distribute vaccines to over 30 countries globally. During 2022, we have helped to secure access to vaccines in more than 70 countries in emergency response to the global monkeypox outbreak.

Two products were developed using our proprietary platform technology **MVA-BN**.

In recent years, we have expanded our commercial portfolio through acquisitions and partnerships.

PRODUCT	INDICATION	MARKETS
Rabipur®/RabAvert®	Rabies	Marketed globally in 20 countries
Encepur®	Tick-borne encephalitis (TBE)	Marketed in 12 EU countries
JYNNEOS®/IMVAMUNE®/IMVANEX®	Smallpox and Monkeypox	Sold to governments
Mvabea® <i>Licensed to Janssen</i>	Ebola	Approved in the EU, but not commercialized. Janssen has made the vaccine available for high-risk areas in West Africa.
IXIARO® <i>Marketing and distribution agreement with Valneva</i>	Japanese encephalitis	Germany and Switzerland
DUKORAL® <i>Marketing and distribution agreement with Valneva</i>	Cholera	Germany and Switzerland
HEPLISAV-B® <i>Marketing and distribution agreement with Dynavax</i>	Hepatitis-B	Germany

Our pipeline

Late-stage pipeline with two leading product candidates in major indications: **RSV** and **COVID-19**. The latter is supported through a funding agreement with the Danish State.

PRODUCT CANDIDATE	INDICATION	STATUS / MILESTONE
MVA-BN freeze-dried	Smallpox/Monkeypox	Phase 3 completed
MVA-BN RSV	RSV	Phase 3 ongoing
ABNCoV2	COVID-19	Phase 3 ongoing
TAEK-VAC	Cancer	Phase 1/2 study ongoing

Consolidated Key Figures (unaudited)

DKK thousand	1/7 - 30/9 2022	1/7 - 30/9 2021	1/1 - 30/9 2022	1/1 - 30/9 2021	1/1-31/12 2021
Income statements					
Revenue	1,003,565	448,656	1,860,320	1,353,908	1,897,875
Production costs	383,752	313,913	1,107,248	940,555	1,327,560
Sales and distribution costs	50,243	37,575	135,559	135,671	191,783
Research and development costs	360,122	74,511	649,783	293,728	399,159
Administrative costs	81,482	69,641	249,494	225,571	292,920
Income before interest and taxes (EBIT)	127,966	(46,984)	(281,764)	(241,617)	(313,547)
Financial items, net	(108,622)	(31,834)	(205,368)	(115,065)	(140,883)
Income before company tax	19,344	(78,818)	(487,132)	(356,682)	(454,430)
Net profit for the period	12,108	(81,440)	(497,005)	(362,543)	(464,775)
Balance sheet					
Total non-current assets			7,749,236	6,523,564	7,335,630
Securities, cash and cash equivalents			3,241,578	2,638,064	3,716,615
Other current assets			1,304,186	955,896	1,037,024
Total assets			12,295,000	10,117,524	12,089,269
Equity			6,957,830	5,770,699	7,374,667
Non-current liabilities			3,023,692	2,034,090	2,806,044
Current liabilities			2,313,478	2,312,735	1,908,558
Cash flow statements					
Cash flow from operating activities			2,603	(247,117)	(358,500)
Cash flow from investment activities			(290,783)	(1,355,880)	(2,876,946)
- Investment in intangible assets			(275,888)	(86,010)	(575,324)
- Investment in property, plant and equipment			(295,047)	(307,166)	(483,127)
- Net investment in securities			407,092	(947,362)	(1,779,454)
Cash flow from financing activities			404,966	1,655,265	3,536,080
Financial Ratios¹⁾					
EBITDA	226,375	51,581	14,358	43,596	74,764
Earnings (basic) per share of DKK 10			(7.1)	(5.8)	(7.4)
Net asset value per share			98.4	90.1	104.7
Share price at period-end			215	326	269
Share price/Net asset value per share			2.2	3.6	2.6
Number of outstanding shares at period-end (thousand)			70,694	64,065	70,468
Equity share			57%	57%	61%
Number of employees, converted to full-time, at period-end			917	750	759

¹⁾ Earnings per share (EPS) is calculated in accordance with IAS 33 "Earning per share". Other financial ratios have been calculated in accordance with the guidelines from the Danish Society of Financial Analysts.

Reconciliation of EBITDA

Income before interest and tax (EBIT)	127,966	(46,984)	(281,764)	(241,617)	(313,547)
Depreciation and amortization	98,409	98,565	296,122	285,213	388,311
EBITDA	226,375	51,581	14,358	43,596	74,764

Continuing our strong commitment to the global response against monkeypox

At its peak in August, more than 1,000 new cases of monkeypox were reported globally on average every day. Fortunately, this number has declined, which is largely attributed to a positive development in European countries where the outbreak first began. An improved public health response, awareness campaigns and increased vaccine availability have been important tools to control the disease and further spread of the virus in the region, but it is believed that these measures need to be maintained to mitigate the risk of monkeypox becoming endemic.

However, since the peak, the global number of cases has doubled to more than 70,000 cases across more than 100 countries. This is largely driven by new cases in the Americas, which accounts for nearly two thirds of all cases reported to date.

As the sole manufacturer of an approved monkeypox vaccine, we at Bavarian Nordic remain committed to expanding the access to our vaccine around the globe.

During the third quarter, we have entered additional supply agreements with governments and supranational organizations, including the Pan American Health Organization (PAHO), through which countries in Latin America can now obtain the vaccine. More than 70 countries across the Americas, Europe, Asia and Oceania now have access to the vaccine, reflecting our priority to assist as many countries as possible in their initial response to the outbreak, while gradually increasing our supply as more vaccines become available.

The demand led us to reprioritize the production schedule at our manufacturing facilities and seek partnerships to expand the short- to medium term capacity to produce and deliver on incoming orders. Specifically, during the third quarter, we entered an agreement with a U.S. based contract manufacturer, who will assist in filling vials for the U.S. government, thus freeing up capacity at our own fill and finish facility to accommodate orders from other countries.

The investment in our bulk facility will now allow us to manufacture different life-saving vaccines in parallel and allows us to dedicate one part of the facility to the production of our smallpox/monkeypox vaccine.

We have welcomed nearly 50 new employees during the quarter to assist us in scaling up our manufacturing activities and we will continue to expand the organization.

Expedited approvals for faster and broader access to the vaccine

The expansion of our manufacturing capabilities over the past years has primarily been driven by acquired products and our commitments to the U.S. government to supply our smallpox vaccine to the Strategic National Stockpile. Hence, we have established our own fill and finish facility, which had only just started commercial operations when the monkeypox outbreak emerged. To expedite the approval of the facility, we have worked intensively with both U.S. and EU regulatory authorities during the second and third quarters. This required amongst others a rescheduling of a planned pre-approval inspection by the FDA, which was conducted early July with no observations being made. Both the FDA and EMA have subsequently approved the fill and finish line and the process established for the smallpox/monkeypox vaccine.

While our vaccine had already been approved for monkeypox in the U.S. and Canada, the approval in the EU only covered smallpox. Thus, countries within the EU, but also outside, were

providing the vaccines under local exemptions, such as emergency use provisions. Upon recommendation from the Emergency Task Force of the European Medicines Agency (EMA), we worked with the authorities to expedite a review of data to support an extension of the current approval of IMVANEX to include monkeypox. A positive opinion was adopted by EMA's Committee for Medicinal Products for Human Use (CHMP) in July and shortly after, the European Commission formally gave its approval, which is valid in all European Union Member States, as well as in Iceland, Liechtenstein, and Norway.

As part of the supply agreement entered in October with the Swiss authorities, we will submit an application to Swissmedic within three months to support a potential marketing authorization of the vaccine against smallpox and monkeypox in Switzerland in 2023.

Commercial update

Comparative figures for 2021 are shown in brackets. Where market shares are mentioned, these are measured by value.

Q3 sales

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%
Total	1,004	449	124%

Rabipur/RabAvert

Rabipur/RabAvert revenue amounted to DKK 338 million (DKK 160 million) for the third quarter. The 111% growth in revenue versus the prior year was driven by continued and significant market growth in the US and Germany that represent the two largest markets.

The US market continued demonstrating strong growth in Q3 and reached a year-to-date growth rate of 31% versus prior year. RabAvert now has a market share of approximately 67%, slightly above the level seen prior to competition facing a stockout situation during late 2019 and first half of 2020.

Also, the German market continued the strong growth rate demonstrated in previous quarters and reached a year-to-date growth of approximately 344%, however the market has not yet fully recovered from COVID-19 pandemic. Rabipur achieved a market share of 95%, slightly above the 2021 level.

For the first nine months, Rabipur/RabAvert revenue amounted to DKK 689 million (DKK 368 million), i.e. an increase of 87%.

Encepur

Encepur revenue amounted to DKK 62 million (DKK 71 million) for the third quarter, i.e. a decrease of 13% versus prior year.

In Q3 the German market continued the positive growth that started in Q2 2022 after a period of market decline. Year-to-date the German market has grown by 11% versus prior year. The Encepur market share in Germany ended at approximately 29% by end of September, slightly below prior year and explained by a temporary stockout situation that has since been resolved.

For the first nine months, Encepur revenue amounted to DKK 275 million (DKK 316 million), i.e. a decrease of 13% despite the positive growth in the German market and due to country mix, inventory movements at wholesaler and partner level as well as the temporary stockout situation in Q3 and which has now been resolved.

JYNNEOS/IMVANEX/IMVAMUNE

Revenue from sale of JYNNEOS/IMVANEX/IMVAMUNE in the third quarter was DKK 578 million (DKK 214 million), all related to contracts with various governments in response to the global monkeypox outbreak. The order flow has continued during the quarter with additional revenues expected in the fourth quarter of 2022 and beyond.

9m sales

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%
Total	1,860	1,354	37%

For the first nine months, revenue from sale of JYNNEOS/IMVANEX/IMVAMUNE amounted to DKK 695 million (DKK 550 million).

Mvabea (Ebola)

In the third quarter, revenue from Mvabea was DKK 0 million (DKK 89 million).

For the first nine months, Mvabea revenue amounted to DKK 30 million (DKK 89 million), i.e. a decrease of 66%. Revenue in the period is related to the order announced in June 2020.

Third-party products sale

Revenue from sale of third-party products in the third quarter was DKK 11 million (DKK 0 million), which is related to sale of DUKORAL and IXIARO (Valneva products assumed in first quarter 2022) and HEPLISAV-B (Dynavax product assumed in second quarter 2022).

For the first nine months, revenue from sale of third-party products amounted to DKK 64 million (DKK 0 million).

Contract work

Revenue from contract work in the third quarter was DKK 15 million (DKK 3 million), mainly stemming from the remaining activities related to the qualification and validation activities of to the fill-and-finish plant under contracts with the U.S. government.

For the first nine months, revenue from contract work amounted to DKK 25 million (DKK 31 million).

Research & development

Two product candidates have advanced into global Phase 3 clinical trials during 2022, thus representing a pivotal year of R&D investments by Bavarian Nordic.

RSV

A global Phase 3 clinical trial of MVA-BN RSV against respiratory syncytial virus (RSV) was initiated in April in adults ≥ 60 years of age. The study is expected to enroll 20,000 subjects by year-end 2022 with topline results anticipated mid-2023, if the pre-defined number of lower-respiratory tract disease (LRTD) events has occurred.

MVA-BN RSV is based on Bavarian Nordic's proprietary vaccine platform technology, MVA-BN, and incorporates five distinct RSV antigens to stimulate a broad immune response against both RSV subtypes (A and B). In a clinical Phase 2 double-blinded, placebo-controlled human challenge trial, a significant reduction in viral load was reported in vaccinated subjects versus placebo and MVA-BN RSV demonstrated a vaccine efficacy of up to 79% in preventing symptomatic RSV infections.

Based on the preliminary clinical evidence, indicating that the vaccine may demonstrate a substantial improvement over available therapy on a clinically significant endpoint, MVA-BN RSV received special designations from U.S. and EU regulatory authorities earlier in 2022, intended to expedite the development and regulatory review of the product candidate. In February, the U.S. Food and Drug Administration (FDA) granted MVA-BN RSV Breakthrough Therapy Designation for the prevention of RSV in older adults, and in June, the European Medicines Agency (EMA) granted access to its priority medicines (PRIME) scheme for MVA-BN RSV in active immunization for the prevention of LRTD caused RSV in adults ≥ 60 years of age.

As part of the strategy to commercialize the vaccine globally, Bavarian Nordic has entered into a regional license and supply agreement with Nuance Pharma in the first quarter of 2022 on the development and commercialization of MVA-BN RSV for adults in China and selected Asian markets.

COVID-19

In September, the first subject was dosed in the global, double-blind, controlled Phase 3 clinical trial of ABNCoV2, a VLP-based, non-adjuvanted COVID-19 booster vaccine candidate.

The primary endpoint of the trial is to assess non-inferiority of ABNCoV2 compared to Comirnaty® in terms of neutralizing antibodies against the SARS-CoV-2 (Wuhan wild type). Other variants of concern will be assessed as secondary endpoints.

The two-cohort study will enroll approximately 4,000 adult subjects who either previously completed primary vaccination or have already received one booster dose of a licensed COVID-19 vaccine. The first cohort, enrolling in the U.S., will evaluate the safety and tolerability of the vaccine in 3,000 subjects receiving a single 100 µg dose of ABNCoV2. The second cohort, enrolling in Denmark and Belgium, comprises 1,000 subjects, who will be randomized to receive either a single 100 µg dose of ABNCoV2, or a single 30 µg adult booster dose of Comirnaty.

Initial trial results are expected in the early part of 2023, which is a slight delay from the original plan due to a delayed recruitment initiation caused by late regulatory challenges and logistics associated with the comparator vaccine.

The Phase 3 development of ABNCoV2 is largely funded through an agreement with the Danish State to fund up to 800 million DKK in the development of ABNCoV2.

Durable antibody responses, six months after booster vaccination
Encouraging results from the Phase 2 clinical trial were reported in October, demonstrating that six months post the booster vaccination with ABNCoV2, the neutralization antibody titers against Wuhan and the Omicron variant remained high and at levels associated with a greater than 90% efficacy.

Previously reported results from the trial showed, that vaccination with 100ug ABNCoV2 in 103 seropositive subjects was able to demonstrate a strong boosting effect, increasing the existing levels of SARS-CoV-2 neutralizing antibodies against both the Wuhan variant and variants of concern (Alpha, Beta, Delta and Omicron) to levels reported to be highly efficacious ($>90\%$) against SARS-CoV-2¹.

A cohort of 41 subjects were followed for six months post vaccination. From this cohort, two subjects with confirmed COVID-19 disease were excluded from the immune analysis. Six months post vaccination, neutralization titers were six times higher than pre-boost titers against Wuhan and nearly 10 times higher than the pre-boost titers for Omicron BA.1. This represented less than a 50% decline in the peak neutralizing titers after six months and compared to the data published for mRNA vaccines^{2,3,4}, the antibody decay appears less sharp, indicating a potentially longer duration of protection across variants of concern.

Smallpox / monkeypox

A freeze-dried version of JYNNEOS® with improved shelf-life is being developed. The clinical development of this version has been completed and Bavarian Nordic is working to finalize the transfer of the manufacturing process as the last activity to support the submission of a supplement Biologics License Application (BLA) to the FDA to extend the current approval of JYNNEOS for the freeze-dried formulation.

Immuno-oncology

TAEK-VAC, a tumor antibody enhanced therapeutic vaccine, is a novel immuno-oncology candidate employing the MVA-BN technology. A Phase 1/2 open label trial of intravenous administration of the vaccine, was initiated in 2021 in patients with advanced HER2 and brachyury-expressing cancers.

During third quarter, the first stage of the study was completed, confirming the dose for stage 2, which is expected to start during the fourth quarter of 2022. In this stage, two cohorts will initially enroll patients with either chordoma (TAEK-VAC given as monotherapy) or HER2-positive breast cancer (TAEK-VAC in combination treatment with trastuzumab). Once safety of the combination treatment has been established in the second cohort, two further combination treatment cohorts will be opened for recruitment.

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

² Bellusci et al. Antibody affinity and cross-variant neutralization of SARS-CoV-2 Omicron BA.1, BA.2 and BA.3 following third mRNA vaccination

³ Forgacs et al. The Effect of Waning on Antibody Levels and Memory B Cell Recall following SARS-CoV-2 Infection or Vaccination

⁴ Qu et al. Durability of Booster mRNA Vaccine against SARS-CoV-2 BA.2.12.1, BA.4, and BA.5 Subvariants (letter)

Financial review

Financial statements for the period January 1 - September 30, 2022 are un-audited. Comparison figures for the same period 2021 are stated in brackets.

Revenue

Revenue for the period was DKK 1,860 million (DKK 1,354 million). Revenue was composed of DKK 963 million (DKK 684 million) from sales of Rabipur/RabAvert and Encepur, DKK 695 million (DKK 550 million) from sale of MVA-BN smallpox/monkeypox vaccine, DKK 83 million in milestone payments (DKK 0 million) from our RSV partner Nuance, DKK 64 million (DKK 0 million) from sale of third-party products (DUKORAL, IXIARO and HEPLISAV-B), DKK 30 million (DKK 89 million) from sales of Mvabea (Ebola) to Janssen and finally DKK 25 million (DKK 31 million) from contract work. Revenue reported for the three months ended September 30, 2022 was DKK 1,004 million (DKK 449 million).

Production costs

Production costs totaled DKK 1,107 million (DKK 941 million). Costs related directly to revenue amounted to DKK 568 million (DKK 453 million), of which cost of goods sold totaled DKK 554 million (DKK 432 million). Contract costs totaled DKK 14 million (DKK 20 million). Amortization of product rights related to Rabipur/RabAvert and Encepur was recognized as part of the production costs with a total of DKK 205 million (DKK 205 million). Other production costs totaled DKK 334 million (DKK 283 million). The bulk manufacturing facility has just reopened after a year of shutdown due to the expansion of the facility for future production of Rabipur/RabAvert and Encepur. The shutdown resulted in a limited absorption of indirect production costs for the first 3 quarters of 2022. In 2021 other production costs were also impacted by limited absorption of indirect production costs due to the shutdown but also due to production of RSV Phase 3 clinical trial material, which contributed to a low commercial utilization of the manufacturing capacity. In the third quarter of 2022, production costs were DKK 384 million (DKK 314 million).

The year-to-date gross margin was 40.5% (30.5%), whereas the gross margin for Q3 was 61.8% (30.0%) following a substantial change in product mix favoring monkeypox/smallpox vaccines based on Bavarian Nordic's proprietary MVA-BN platform and produced entirely at BN's own facilities.

Sales and distribution costs

Sales and distribution costs totaled DKK 136 million (DKK 136 million) split between costs for distribution of products of DKK 19 million (DKK 13 million) and costs for running the commercial organization and activities of DKK 117 million (DKK 123 million).

Research and development costs

Research and development costs totaled DKK 650 million (DKK 294 million). The increase compared to 2021 relates to RSV spend for the ongoing phase 3 trial. The amount excludes R&D costs of DKK 14 million (DKK 20 million) recognized as production costs, see [note 5](#). Research and development costs of DKK 171 million (DKK 20 million) related to ABNCoV2 were capitalized during the period.

Administrative costs

Administrative costs totaled DKK 249 million (DKK 226 million).

EBIT/EBITDA

Income before interest and tax (EBIT) was a loss of DKK 282 million, compared to a loss of DKK 242 million in the first nine months of 2021.

EBITDA was a gain of DKK 14 million (gain of DKK 44 million). Amortization of product rights related to Rabipur/RabAvert and Encepur amounted to DKK 205 million (DKK 205 million) whereas depreciation on other fixed assets amounted to DKK 91 million (DKK 81 million).

Financial items

Financial items totaled a net expense of DKK 205 million (net expense of DKK 115 million) and consisted of interest expense on debt of DKK 16 million (DKK 13 million), net value adjustment of deferred consideration of DKK 7 million (DKK 88 million) from the acquisition of Encepur and Rabipur/RabAvert and ABNCoV2, net loss on derivative financial instruments DKK 11 million (DKK 0 million), and a net expense from securities (bond portfolio) of DKK 194 million (DKK 28 million), partly offset by net foreign exchange rate gains of DKK 23 million (DKK 12 million) due to increase in USD exchange rate. The negative fair value adjustment on the bond portfolio amounted to DKK 209 million corresponding to a 6% decrease in value as a consequence of the significant increase in the interest levels seen in first nine months of 2022.

The net value adjustment of deferred consideration DKK 7 million (DKK 88 million) consists of three components; Adjustment of deferred consideration due to change in estimated timing of payments of DKK 53 million income (income of DKK 7 million), currency adjustments of DKK 0 million expense (income of DKK 2 million) and unwinding⁵ of the discounting effect related to deferred consideration of DKK 60 million (DKK 97 million), see [note 6](#) and [7](#).

Income before company tax was a loss of DKK 487 million (loss of DKK 357 million).

Tax

Tax on income was DKK 10 million (DKK 6 million) and relates to taxes in subsidiaries. The parent company's taxable income for the full year of 2022 is expected to be negative due to Phase 3 trial costs for both ABNCoV2 and RSV, leading to an effective tax rate close to 0% for the Group as no tax assets will be recognized. Deferred tax asset on the balance sheet remains at DKK 0 million. The Company retains the right to use the tax losses carried forward that was written down in prior year, see [note 14](#) in the Annual Report for 2021.

Net profit

For the first nine months of 2022, Bavarian Nordic reported a net loss of DKK 497 million (net loss of DKK 363 million).

Product rights

Product rights recognized in the balance sheet totaled DKK 4,708 million (DKK 4,913 million as of December 31, 2021) and relates to Rabipur/RabAvert and Encepur.

Acquired rights and development in progress

Acquired rights and development in progress relates to the development of ABNCoV2 and stood at DKK 897 million (DKK 734 million as of December 31, 2021). The asset includes the upfront payment to AdaptVac of DKK 30 million, the net present value of

⁵ The deferred consideration for product rights is measured at net present value and the difference between the net present value and the amounts

due is recognized in the income statement as a financial expense over the period until expected payment date using the effective interest method.

probable future sales/development milestones DKK 596 million and capitalization of development costs for running the completed Phase 2 study and the running Phase 3 study, DKK 271 million. For further description of the asset and the accounting policy see note 16 in the Annual Report for 2021.

The Group has ensured significant financing for the ABNCoV2 development program through the funding obtained from the Danish Ministry of Health. Under the agreement, the Company is entitled to payments of up to DKK 800 million, which are contingent upon reaching a number of predefined milestones under the development project. All payments are potentially subject to repayment, however only upon successful obtainment of marketing authorization and upon reaching certain annual levels of doses sold. As per September 30, 2022, the upfront payment of DKK 80 million and further milestones amounting to DKK 480 million, in total DKK 560 million, have been received and recognized as 'Prepayment and loan from Government'.

Prepayments

Production of drug substance for ABNCoV2 is taking place at a CMO. The CMO produced the drug substance for the clinical trial materials for the Phase 3 and will also produce drug substance for future commercial use. Costs related to the scale up activities are recognized as prepayments and will be recognized as inventory in concurrence with future purchase of products from the CMO. As per September 30, 2022 DKK 150 million has been recognized as non-current prepayments.

Part of the technology transfer of the production and packaging activities for Encepur and Rabipur/RabAvert takes place at CMO's (filling of Encepur, labelling and packing). Costs related to the technology transfer activities are recognized as prepayments and will be recognized as inventory in concurrence with future purchase of services from the CMO's. As per September 30, 2022 DKK 15 million has been recognized as non-current prepayments.

Securities, cash and cash equivalents

Securities, cash and cash equivalents were DKK 3,242 million as of September 30, 2022, including repo pledged securities of DKK 500 million (DKK 3,717 million as of December 31, 2021, including repo pledged securities of DKK 500 million). The net cash position amounts to DKK 2,742 million (DKK 3,217 million as of December 31, 2021).

Cash flow

Cash flow generated by 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).

Equity

The Group's equity as of September 30, 2022 stood at DKK 6,958 million (DKK 7,375 million as of December 31, 2021).

Deferred consideration

Deferred consideration to GlaxoSmithKline for purchase of product rights amounted to DKK 2,561 million, whereas deferred consideration to AdaptVac related to potential future development and sales milestones and tiered royalties amounted to DKK 593 million as per September 30, 2022.

Debt to credit institutions

As of September 30, 2022, debt to credit institutions amounted to DKK 892 million and included the European Investment Bank loan of DKK 372 million, a repo position of DKK 500 million and a mortgage loan of DKK 20 million. Unchanged compared to December 31, 2021, except for mortgage loan which was deducted by DKK 1 million.

Significant risks and uncertainties

Bavarian Nordic faces a number of risks and uncertainties, common for the biotech/pharma industry. These relate to operations, research and development, manufacturing, commercial and financial activities. For further information about risks and uncertainties which Bavarian Nordic faces, refer to page 48-52 "Risk Management" in the 2021 Annual Report.

Outlook for 2022

The financial guidance for the full year has been upgraded seven times since March 2022 as a result of multiple supply contracts being entered since the start of the monkeypox outbreak in May. The most recent guidance, issued on September 7, is maintained at revenues between DKK 2,800 and 3,000 million, EBITDA with a loss between DKK -200 and 0 million and cash and cash equivalents at year-end expected to exceed DKK 1,700 million.

Beyond the additional revenue generated by the monkeypox situation the guidance also reflects the current market conditions and general commercial performance as well as the current exchange rate levels. The cash and cash equivalent guidance still assumes a debt level of DKK 600 million at year-end. Other key assumptions for the guidance remain largely unchanged since the publication of guidance in the 2021 Annual Report.

The monkeypox outbreak has created a broader, global demand for vaccines, and Bavarian Nordic has entered several contracts with both existing and new customers to supply its monkeypox vaccine for both emergency use and long-term stockpiling beyond 2022. The recognition of revenue between 2022 and 2023 from secured contracts is very sensitive to the final delivery schedules. The Company remains in discussions with governments and supranational organizations and expects to sign more contracts for 2023 and beyond.

Financial calendar 2022 and 2023

2022 Annual Report	March 2, 2023
Annual General Meeting*	March 30, 2023
Three-month report (Q1)	May 9, 2023
Half-year report (Q2)	August 23, 2023
Nine-month report (Q3)	November 16, 2023

* Pursuant to Article 12 of the Articles of Association, shareholders who wish to submit a request for proposals for consideration at the annual general meeting must lodge this with the Company no later than Wednesday, February 15, 2023.

Financial statements

Unaudited Condensed Consolidated Income Statements for the Periods Ended September 30, 2022 and 2021 and December 31, 2021

DKK thousand	Note	1/7 - 30/9 2022	1/7 - 30/9 2021	1/1 - 30/9 2022	1/1 - 30/9 2021	1/1-31/12 2021
Revenue	3	1,003,565	448,656	1,860,320	1,353,908	1,897,875
Production costs	4	383,752	313,913	1,107,248	940,555	1,327,560
Gross profit		619,813	134,743	753,072	413,353	570,315
Sales and distribution costs		50,243	37,575	135,559	135,671	191,783
Research and development costs	5	360,122	74,511	649,783	293,728	399,159
Administrative costs		81,482	69,641	249,494	225,571	292,920
Total operating costs		491,847	181,727	1,034,836	654,970	883,862
Income before interest and tax (EBIT)		127,966	(46,984)	(281,764)	(241,617)	(313,547)
Financial income	6	10,034	12,369	90,999	30,994	50,233
Financial expenses	7	118,656	44,203	296,367	146,059	191,116
Income before company tax		19,344	(78,818)	(487,132)	(356,682)	(454,430)
Tax on income for the period		7,236	2,622	9,873	5,861	10,345
Net profit for the period		12,108	(81,440)	(497,005)	(362,543)	(464,775)
Earnings per share (EPS) - DKK						
Basic earnings per share of DKK 10		0.2	(1.3)	(7.1)	(5.8)	(7.4)
Diluted earnings per share of DKK 10		0.2	(1.3)	(7.1)	(5.8)	(7.4)

Unaudited Condensed Consolidated Statements of Comprehensive Income for the Periods Ended September 30, 2022 and 2021 and December 31, 2021

DKK thousand	1/7 - 30/9 2022	1/7 - 30/9 2021	1/1 - 30/9 2022	1/1 - 30/9 2021	1/1-31/12 2021
Net profit for the period	12,108	(81,440)	(497,005)	(362,543)	(464,775)
Items that might be reclassified to the income statement:					
Exchange rate adjustments on translating foreign operations	30,250	3,834	19,915	7,825	10,081
Change in fair value of financial instruments entered into to hedge future cash flows	(2,493)	(3,053)	(25)	(13,839)	(542)
Other comprehensive income after tax	27,757	781	19,890	(6,014)	9,539
Total comprehensive income	39,865	(80,659)	(477,115)	(368,557)	(455,236)

Unaudited Condensed Consolidated Statements of Cash Flow for the Periods Ended September 30, 2022 and 2021 and December 31, 2021

DKK thousand	1/1 - 30/9 2022	1/1 - 30/9 2021	1/1-31/12 2021
Net profit for the period	(497,005)	(362,543)	(464,775)
Adjustment for non-cash items:			
Financial income	(90,999)	(30,994)	(50,233)
Financial expenses	296,367	146,059	191,116
Tax on income for the period	9,873	5,861	10,345
Depreciation, amortization and impairment losses	296,121	285,211	388,310
Share-based payment	33,429	55,381	56,857
Changes in inventories	(111,171)	(32,196)	41,039
Changes in receivables	(153,688)	(213,885)	(364,393)
Changes in current liabilities	217,693	(97,908)	(146,007)
Cash flow from operations (operating activities)	620	(245,014)	(337,741)
Received financial income	18,216	7,323	6,198
Paid financial expenses	(13,824)	(7,630)	(24,383)
Paid company taxes	(2,409)	(1,796)	(2,574)
Cash flow from operating activities	2,603	(247,117)	(358,500)
Investments in products rights	3,595	-	(371,849)
Investments in other intangible assets	(279,483)	(86,010)	(203,475)
Investments in property, plant and equipment	(295,047)	(307,166)	(483,127)
Investments in/disposal of financial assets	(126,940)	(15,342)	(39,041)
Investments in securities	(380,460)	(1,138,549)	(2,115,796)
Disposal of securities	787,552	191,187	336,342
Cash flow from investment activities	(290,783)	(1,355,880)	(2,876,946)
Payment on loans	(1,617)	(1,630)	(2,173)
Proceeds from loans	400,000	456,418	660,000
Repayment of lease liabilities	(16,115)	(14,608)	(19,507)
Proceeds from warrant programs exercised	32,087	100,804	107,183
Proceeds from rights issue	-	-	2,856,596
Proceeds from capital increase through private placement	-	1,148,450	-
Cost related to issue of new shares	(61)	(25,588)	(57,438)
Purchase of treasury shares	(9,328)	(8,581)	(8,581)
Cash flow from financing activities	404,966	1,655,265	3,536,080
Cash flow of the period	116,786	52,268	300,634
Cash as of 1 January	591,820	285,487	285,487
Currency adjustments 1 January	10,040	4,067	5,699
Cash end of period	718,646	341,822	591,820

Unaudited Condensed Consolidated Statements of Financial Position - Assets as of September 30, 2022 and 2021 and December 31, 2021

DKK thousand	Note	30/9 2022	30/9 2021	31/12 2021
Assets				
Product rights		4,708,129	4,981,064	4,912,830
Acquired rights and development in progress		897,233	49,167	733,770
Software		16,352	26,594	22,985
Intangible assets in progress		242,805	105,314	134,371
Intangible assets		5,864,519	5,162,139	5,803,956
Land and buildings		329,491	354,187	345,953
Leasehold improvements		16,357	10,013	10,011
Plant and machinery		236,382	255,972	254,530
Fixtures and fittings, other plant and equipment		215,314	220,828	223,467
Assets under construction		846,457	421,696	578,707
Property, plant and equipment		1,644,001	1,262,696	1,412,668
Right-of-use assets	<u>14</u>	70,613	79,265	75,843
Other receivables		5,310	4,692	4,778
Prepayments		164,793	14,772	38,385
Financial assets		170,103	19,464	43,163
Total non-current assets		7,749,236	6,523,564	7,335,630
Inventories	<u>8</u>	591,214	553,278	480,043
Trade receivables	<u>9</u>	654,282	302,973	381,624
Other receivables	<u>10</u>	26,177	43,215	66,517
Prepayments		32,513	56,430	108,840
Receivables		712,972	402,618	556,981
Securities	<u>15, 16</u>	2,522,932	2,296,242	3,124,795
Cash and cash equivalents		718,646	341,822	591,820
Securities, cash and cash equivalents		3,241,578	2,638,064	3,716,615
Total current assets		4,545,764	3,593,960	4,753,639
Total assets		12,295,000	10,117,524	12,089,269

Unaudited Condensed Consolidated Statements of Financial Position - Equity and Liabilities as of September 30, 2021 and 2020 and December 31, 2020

DKK thousand	Note	30/9 2022	30/9 2021	31/12 2021
Equity and liabilities				
Share capital		706,943	640,651	704,684
Treasury shares		(1,463)	(1,176)	(1,112)
Retained earnings		6,131,979	5,069,631	6,588,908
Other reserves		120,371	61,593	82,187
Equity		6,957,830	5,770,699	7,374,667
Deferred consideration for product rights		2,392,272	1,953,519	2,569,090
Prepayment and loan from Government		564,616	-	160,511
Debt to credit institutions	11	17,280	19,443	18,896
Lease liabilities	14	49,524	61,128	57,547
Non-current liabilities		3,023,692	2,034,090	2,806,044
Deferred consideration for product rights		761,622	957,251	577,667
Debt to credit institutions	11, 15	874,372	830,787	874,373
Lease liabilities	14	23,998	21,059	21,266
Prepayment from customers	12	19,327	50,755	16,904
Trade payables		381,904	222,795	263,611
Company tax		6,663	2,063	3,743
Other liabilities	13	245,592	228,025	150,994
Current liabilities		2,313,478	2,312,735	1,908,558
Total liabilities		5,337,170	4,346,825	4,714,602
Total equity and liabilities		12,295,000	10,117,524	12,089,269

Unaudited Condensed Consolidated Statements of Changes in Equity for the Periods September 30, 2022 and 2021

DKK thousand	Share capital	Treasury shares	Retained earnings	Reserves for currency adjustment	Reserves for fair value of financial instruments	Share-based payment	Equity
Equity as of January 1, 2022	704,684	(1,112)	6,588,908	(30,559)	(1,351)	114,097	7,374,667
Comprehensive income for the period							
Net profit	-	-	(497,005)	-	-	-	(497,005)
Other comprehensive income							
Exchange rate adjustments on translating foreign operations	-	-	-	19,915	-	-	19,915
Change in fair value of financial instruments entered into to hedge future cash flows	-	-	-	-	(25)	-	(25)
Total comprehensive income for the period	-	-	(497,005)	19,915	(25)	-	(477,115)
Transactions with owners							
Share-based payment	-	-	-	-	-	37,580	37,580
Warrant program exercised	2,259	-	39,049	-	-	(9,221)	32,087
Warrant program expired	-	-	5,971	-	-	(5,971)	-
Cost related to issue of new shares	-	-	(61)	-	-	-	(61)
Purchase of treasury shares	-	(716)	(8,612)	-	-	-	(9,328)
Transfer regarding restricted stock units	-	365	3,729	-	-	(4,094)	-
Total transactions with owners	2,259	(351)	40,076	-	-	18,294	60,278
Equity as of September 30, 2022	706,943	(1,463)	6,131,979	(10,644)	(1,376)	132,391	6,957,830

DKK thousand	Share capital	Treasury shares	Retained earnings	Reserves for currency adjustment	Reserves for fair value of financial instruments	Share-based payment	Equity
Equity as of January 1, 2021	584,501	(1,077)	4,246,359	(40,640)	(809)	106,019	4,894,353
Comprehensive income for the period							
Net profit	-	-	(362,543)	-	-	-	(362,543)
Other comprehensive income							
Exchange rate adjustments on translating foreign operations	-	-	-	7,825	-	-	7,825
Change in fair value of financial instruments entered into to hedge future cash flows	-	-	-	-	(13,839)	-	(13,839)
Total comprehensive income for the period	-	-	(362,543)	7,825	(13,839)	-	(368,557)
Transactions with owners							
Share-based payment	-	-	-	-	-	29,818	29,818
Warrant program exercised	4,650	-	119,201	-	-	(23,047)	100,804
Capital increase through rights issue	51,500	-	1,096,950	-	-	-	1,148,450
Cost related to issue of new shares	-	-	(25,588)	-	-	-	(25,588)
Purchase of treasury shares	-	(317)	(8,264)	-	-	-	(8,581)
Transfer regarding restricted stock units	-	218	3,516	-	-	(3,734)	-
Total transactions with owners	56,150	(99)	1,185,815	-	-	3,037	1,244,903
Equity as of September 30, 2021	640,651	(1,176)	5,069,631	(32,815)	(14,648)	109,056	5,770,699

Notes

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|--|---|
| 1. Significant accounting policies | 11. Debt to credit institutions |
| 2. Significant accounting estimates, assumptions and uncertainties | 12. Prepayment from customers |
| 3. Revenue | 13. Other liabilities |
| 4. Production costs | 14. Right-of-use assets and lease liabilities |
| 5. Research and development costs | 15. Transferred financial assets that are not derecognized |
| 6. Financial income | 16. Financial instruments |
| 7. Financial expenses | 17. Warrants |
| 8. Inventories | 18. Significant changes in contingent liabilities and other contractual obligations |
| 9. Trade receivables | 19. Significant events after the balance sheet date |
| 10. Other receivables | 20. Approval of the unaudited condensed consolidated interim financial statements |

1. Significant accounting policies

The interim financial statements are prepared in accordance with IAS 34, Interim Financial Reporting, as adopted by EU and the additional Danish requirements for submission of interim reports for companies listed on Nasdaq Copenhagen. The interim report has not been audited or reviewed by the Company's auditors.

The interim financial statements are presented in Danish Kroner (DKK), which is considered the primary currency of the Group's activities and the functional currency of the parent company.

The accounting policies used in the interim financial statements are consistent with those used in the consolidated financial statements for 2021 and in accordance with the recognition and measurement policies in the International Financial Reporting Standards (IFRS) as adopted by EU.

As of September 30, 2022, the Company has implemented all new or amended accounting standards and interpretations as adopted by the EU and applicable for the 2022 financial year. None of the new or amended standards or interpretations are assessed to have significant impact on the consolidated financial statements.

2. Significant accounting estimates, assumptions and uncertainties

In the preparation of the interim financial statements according to IAS 34, Interim Financial Reporting, as adopted by the EU, Management is required to make certain estimates as many financial statement items cannot be reliably measured but must be estimated. Such estimates comprise judgments made on the basis of the most recent information available at the reporting date. It may be necessary to change previous estimates as a result of changes to the assumptions on which the estimates were based or due to supplementary information, additional experience or subsequent events.

Similarly, the value of assets and liabilities often depends on future events that are somewhat uncertain. In that connection, it is necessary to set out e.g. a course of events that reflects Management's assessment of the most probable course of events.

Further to the significant accounting estimates, assumptions and uncertainties, which are stated in the Annual Report 2021, the Management has not changed significant estimates and judgments regarding recognition and measurement.

DKK thousand	1/7 - 30/9 2022	1/7 - 30/9 2021	1/1 - 30/9 2022	1/1 - 30/9 2021	1/1-31/12 2021
3. Revenue					
MVA-BN smallpox/monkeypox vaccine sale	577,719	213,667	694,503	550,045	733,593
Rabipur/RabAvert	337,931	160,347	688,863	367,537	505,769
Encepur	61,957	71,365	274,976	316,025	363,054
Other product sale	11,366	-	94,101	89,079	260,225
Sale of goods	988,973	445,379	1,752,443	1,322,686	1,862,641
Milestone payments	-	-	83,048	-	-
Contract work	14,592	3,277	24,829	31,222	35,234
Sale of services	14,592	3,277	107,877	31,222	35,234
Revenue	1,003,565	448,656	1,860,320	1,353,908	1,897,875
Total revenue includes: Fair value adjustment concerning financial instruments entered into to hedge revenue	-	-	-	269	(7,072)
4. Production costs					
Cost of goods sold	206,848	108,595	554,073	432,255	539,789
Contract costs	9,229	1,076	13,974	20,305	21,959
Amortization product rights	68,234	68,234	204,701	204,701	492,877
Other production costs	99,441	136,008	334,500	283,294	272,935
Production costs	383,752	313,913	1,107,248	940,555	1,327,560
5. Research and development costs					
Research and development costs occurred in the period Of which:	369,351	75,587	663,757	314,033	421,118
Contract costs recognized as production costs	(9,229)	(1,076)	(13,974)	(20,305)	(21,959)
Research and development costs	360,122	74,511	649,783	293,728	399,159
6. Financial income					
Financial income from bank and deposit contracts	-	1,243	27	1,340	1,739
Interest income from financial assets measured at amortized cost	-	1,243	27	1,340	1,739
Financial income from securities	6,409	2,238	15,312	7,703	11,045
Adjustment of deferred consideration due to change in estimated timing of payments	26,222	446	52,541	6,789	32,185
Currency adjustment deferred consideration	1,001	78	(31)	1,865	1,677
Net gains on derivative financial instruments at fair value through the income statement	(8,921)	940	-	940	-
Net foreign exchange gains	(14,677)	7,424	23,150	12,357	3,587
Financial income	10,034	12,369	90,999	30,994	50,233
7. Financial expenses					
Interest expenses on debt	7,143	4,589	15,614	13,473	18,487
Interest expenses on financial liabilities measured at amortized cost	7,143	4,589	15,614	13,473	18,487
Fair value adjustments on securities	81,921	12,834	209,190	35,830	39,056
Unwinding of the discounting effect related to deferred consideration	17,676	28,867	59,647	96,756	133,573
Net loss on derivative financial instruments at fair value through the income statement	11,916	(2,087)	11,916	-	-
Financial expenses	118,656	44,203	296,367	146,059	191,116

DKK thousand	30/9 2022	30/9 2021	31/12 2021
8. Inventories			
Raw materials and supply materials	163,955	70,490	80,243
Work in progress	300,112	101,774	79,904
Manufactured goods and commodities	252,475	460,344	492,837
Write-down on inventory	(125,328)	(79,330)	(172,941)
Inventories	591,214	553,278	480,043
Write-down on inventory 1 January	(172,941)	(63,537)	(63,537)
Write-down during the period	(6,579)	(76,889)	(171,643)
Use of write-down	45,055	61,096	62,239
Reversal of write-down	9,137	-	-
Write-down end of period	(125,328)	(79,330)	(172,941)
9. Trade receivables			
Trade receivables from smallpox/monkeypox vaccine sale	226,590	-	78,218
Trade receivables from Encepur and Rabipur/RabAvert	391,292	264,621	162,546
Trade receivables from other product sale	-	-	137,731
Trade receivables from contract work	36,400	38,352	3,129
Trade receivables	654,282	302,973	381,624
10. Other receivables			
Receivable VAT and duties	16,873	37,970	55,973
Derivative financial instruments at fair value	1,854	-	191
Interest receivables	7,450	5,245	10,353
Other receivables	26,177	43,215	66,517
11. Debt to credit institutions			
Mortgage	19,457	21,617	21,074
European Investment Bank (loan in DKK)	372,195	372,195	372,195
Security lending (repo transactions)	500,000	456,418	500,000
Debt to credit institutions	891,652	850,230	893,269
12. Prepayment from customers			
Prepayments from customers as of January 1	16,904	74,347	74,347
Prepayments received during the period	2,423	-	33,850
Recognized as revenue during the period	-	(23,592)	(91,293)
Prepayments from customers end of period	19,327	50,755	16,904
13. Other liabilities			
Financial instruments at fair value	17,729	14,762	1,351
Liability relating to phantom shares	11,684	30,413	23,917
Payable salaries, holiday accrual etc.	73,793	85,152	68,491
Gross to net deduction accrual	123,237	74,404	37,134
Other accrued costs	19,149	23,294	20,101
Other liabilities	245,592	228,025	150,994

14. Right-of-use assets and lease liabilities**Right-of-use assets**

DKK thousand	Rent facility	Car leasing	Equipment	Total
Right-of-use assets as of January 1, 2021	73,026	1,742	1,075	75,843
Additions	917	5,879	-	6,796
Modifications	5,326	1,114	-	6,440
Disposals	(8,529)	(1,130)	(46)	(9,705)
Depreciations	(14,780)	(2,112)	(375)	(17,267)
Reversal depreciations	909	-	-	909
Exchange rate adjustments	6,341	1,211	45	7,597
Right-of-use assets as of September 30, 2022	63,210	6,704	699	70,613

Lease liabilities

DKK thousand	30/9 2022
Non-current	49,524
Current	23,998
Lease liabilities	73,522

Amounts included in the income statement

DKK thousand	1/1 - 30/9 2022
Interest expense leases	1,447
Depreciation recognized on right-of-use assets	17,267
Cost recognized for short term leases (less than 12 months)	180
In the first nine months of 2022 the total cash outflow relating to lease was DKKt 17,562 split between interests of DKKt 1,447 and repayment of DKKt 16,115.	

15. Transferred financial assets that are not derecognized

The Company has entered into transactions that transferred ownership of securities to a counterparty, while the Company retains the risks associated with the holding of the securities (repo transactions). As the Company retains all risks, the securities remain in the balance sheet, and the transactions are accounted for as loans received against collateral (securities lending). The transactions involve selling the securities to be repurchased at a fixed price at a later date. Counterparties are entitled to sell the securities or deposit them as collateral for loans.

DKK thousand	30/9 2022	30/9 2021	31/12 2021
Carrying amount of transferred securities	499,355	305,050	498,534
Carrying amount of associated liabilities (repo transactions)	(500,000)	(456,418)	(500,000)
Net position	(645)	(151,368)	(1,466)

16. Financial instruments

Method and assumption to determine fair value

The Group has financial instruments measured at fair value at level 1 and level 2.

Securities (level 1)

The portfolio of publicly traded government bonds and publicly traded mortgage bonds is valued at listed prices and price quotas.

Derivative financial instruments (level 2)

Currency forward contracts, currency option contracts and currency swap contracts are valued according to generally accepted valuation methods based on relevant observable swap curves and exchange rates.

Fair value hierarchy for financial instruments measured at fair value

As of September 30, 2022

DKK thousand	Level 1	Level 2	Total
Securities	2,023,577	-	2,023,577
Transferred securities that are not derecognized	499,355	-	499,355
Derivative financial instruments at fair value through the income statement (currency)	-	2,716	2,716
Financial assets measured at fair value through the income statement	2,522,932	2,716	2,525,648
Derivative financial instruments to hedge future cash flow (currency)	-	(6,524)	(6,524)
Derivative financial instruments to hedge future cash flow (interest)	-	1,854	1,854
Financial assets/liabilities used as hedging instruments	-	(4,670)	(4,670)
Derivative financial instruments at fair value through the income statement (currency)	-	(11,206)	(11,206)
Security lending (repo transactions)	(500,000)	-	(500,000)
Liability relating to phantom shares	-	(11,684)	(11,684)
Financial liabilities measured at fair value through the income statement	(500,000)	(22,890)	(522,890)

As of December 31, 2021

DKK thousand	Level 1	Level 2	Total
Securities	2,626,261	-	2,626,261
Transferred securities that are not derecognized	498,534	-	498,534
Derivative financial instruments at fair value through the income statement (repo)	-	191	191
Financial assets measured at fair value through the income statement	3,124,795	191	3,124,986
Derivative financial instruments to hedge future cash flow (currency)	-	(646)	(646)
Derivative financial instruments to hedge future cash flow (interest)	-	(705)	(705)
Financial assets/liabilities used as hedging instruments	-	(1,351)	(1,351)
Liability relating to phantom shares	-	(23,917)	(23,917)
Financial liabilities measured at fair value through the income statement	-	(23,917)	(23,917)

17. Warrants

Outstanding warrants as of September 30, 2022

	Outstanding as of January 1	Addition during the period	Warrants exercised	Annulled	Terminated	Transferred	Outstanding as of September 30
Corporate Management	743,346	-	-	-	(73,445)	-	669,901
Other Executive Management	418,163	63,157	-	-	-	(174,070)	307,250
Other employees	1,880,363	18,715	(112,612)	(143,504)	(4,216)	(63,429)	1,575,317
Resigned employees	314,612	-	(113,310)	-	(34,074)	237,499	404,727
Total	3,356,484	81,872	(225,922)	(143,504)	(111,735)	-	2,957,195
Weighted average exercise price	219	190	142	240	247	-	222
Weighted average share price at exercise			250				
Numbers of warrants which can be exercised as of September 30, 2022							469,792
at a weighted average exercise price of DKK							181

The total recognized cost of the warrant programs was DKK 29.7 million in the first nine months of 2022 (DKK 22.8 million).

Specification of parameters for Black-Scholes model

DKK	Nov 2017	Nov 2018	Nov 2019	Jan 2020	Nov 2020	Nov 2021	Apr 2022
Average share price	259.50	159.00	154.05	171.20	179.84	307.20	171.35
Average exercise price at grant	303.00	179.60	185.40	197.00	206.82	353.06	190.11
Average exercise price determined at date of rights issue March 30, 2020 (DKK)	239.60	142.00	146.60	155.80	-	-	-
Applied volatility rate	52.4%	53.3%	52.2%	53.0%	39.8%	41.8%	42.3%
Expected life (years)	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Expected dividend per share	-	-	-	-	-	-	-
Risk-free interest rate p.a.	-0.55%	-0.43%	-0.69%	-0.65%	-0.66%	-0.53%	0.39%
Fair value at grant ¹⁾	80	52	45	53	41	76	47

The applied volatility is based on the historical volatility of the Bavarian Nordic share, except for November 2020, November 2021 and April 2022 programs where the volatility is based on the volatility for a peer group.

¹⁾ Fair value of each warrant applying the Black-Scholes model

18. Significant changes in contingent liabilities and other contractual obligations

No significant changes in contingent liabilities and other contractual obligations have occurred since December 31, 2021.

19. Significant events after the balance sheet date

On October 3, Bavarian Nordic announced an agreement with a country in Latin America on the supply of monkeypox vaccines

On October 14, Bavarian Nordic announced a supply agreement for monkeypox vaccines to Switzerland. Under this agreement, Bavarian Nordic will seek regulatory approval of the vaccine with Swissmedic.

On October 17, Bavarian Nordic announced data from a six-month follow-up analysis of subjects in the Phase 2 clinical trial of its COVID-19 booster vaccine candidate, demonstrating durable antibody responses

20. Approval of the unaudited condensed consolidated interim financial statements

The unaudited condensed consolidated interim financial statements were approved by the Board of Directors and Corporate Management and authorized for issue on November 9, 2022.

Statement from the Board of Directors and Corporate Management

The Board of Directors and Corporate Management have, today reviewed and approved the Bavarian Nordic A/S interim report for the period January 1 to September 30, 2022.

The interim report has been prepared in accordance with IAS 34 "Interim Financial Reporting" as adopted by the EU and additional Danish disclosure requirements for interim reports of listed companies, including those of Nasdaq Copenhagen.

In our opinion, the interim report gives a true and fair view of the group's assets and liabilities and financial position as of September 30, 2022, and the results of the group's activities and cash flows for the period January 1 to September 30, 2022.

In our opinion, the management's review provides a true and fair description of the development in the group's activities and financial affairs, the results for the period and the group's financial position as a whole as well as a description of the most important risks and uncertainty factors faced by the group.

Hellerup, November 9, 2022

Corporate Management:



Paul John Chaplin
President & CEO



Henrik Juul
Executive Vice President & CFO

Board of Directors:



Gerard W.M. van Odijk
Chairman of the Board



Anders Gersel Pedersen
Deputy Chairman



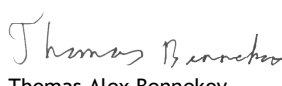
Peter H. Kürstein-Jensen



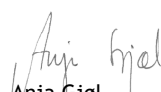
Frank A.G.M. Verwiel



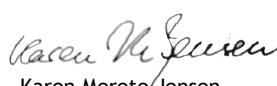
Anne Louise Eberhard



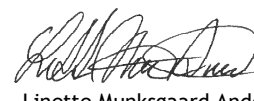
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Employee-elected



Anja Gjøl
Employee-elected



Karen Merete Jensen
Employee-elected



Linette Munksgaard Andersen
Employee-elected