



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Announces Annual Report 2018

COPENHAGEN, Denmark, March 21, 2019 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today its Annual Report for 2018. Below is a summary of business progress, financial performance for the year and financial outlook for 2019 from the report. The full report is attached as a PDF file and can be found on the company's website, www.bavarian-nordic.com.

Delivering on our strategy

Paul Chaplin, President & Chief Executive Officer of Bavarian Nordic said: "We made excellent progress on our pipeline assets and delivered on all our plans in 2018. The Company initiated a number of new studies and reported important clinical data that confirmed Bavarian Nordic as the global leader in smallpox and in RSV vaccine development. This year will be another exciting year, as we continue to invest in our future with the initiation of new clinical studies evaluating new treatment options for cancer patients and the completion of our filling line investment that will secure improved revenues in the years ahead. We look forward to our first vaccine approval in the U.S. that will create new options beyond stockpiling to help the U.S. Government in their preparedness plans for smallpox and also have the real possibility to significantly improve our 2019 guidance if we sell the associated priority review voucher. Everyone in the company is excited about the opportunities ahead, as we continue to develop innovative products to improve public health and return to profitability within the coming years."

Key highlights

- Positive results from a Phase 3 study of **MVA-BN smallpox vaccine** were reported, demonstrating the same efficacy as the current FDA approved replicating smallpox vaccine. We filed a BLA for the vaccine, which was accepted with priority review by the FDA in December, with an anticipated approval in September 2019.
- We initiated the construction of a new **fill and finish facility** to expand our manufacturing capabilities. To support this investment, the U.S. Government awarded USD 44 million for qualification of the facility, as well as transfer and validation of the freeze-drying production.
- Additional positive data for our **RSV vaccine** were reported and confirmed the durability of broad vaccine responses after 1 year that could be rapidly increased following an annual booster vaccination. As Phase 2 clinical development has been completed, discussions with the FDA are ongoing regarding the design of the Phase 3 study to support licensure of the vaccine.
- Significant progress was made with our immunotherapy assets with the initiation of 4 Phase 2 studies, with the first data already expected later this year.
 - Three Phase 2 clinical studies were initiated, evaluating our **CV301** immunotherapy candidate in combination treatment with immune checkpoint inhibitors in three different indications (bladder, colorectal and pancreatic cancer) as part of a broad collaboration with industry and academic partners.
 - Our novel cancer immunotherapy candidate, **BN-Brachyury**, was granted orphan drug designation for the treatment of chordoma cancer by the FDA and we initiated a Phase 2 study in this indication, completing enrolment in the first stage ahead of schedule earlier this year.
- To ensure we continue to bring new innovative ideas to expand the pipeline we also announced **new immunotherapy strategies** to treat cancer patients with the first clinical trials expected in 2019.
- We continued to expand our partnership with the U.S. Government who once again recognized the value of our vaccine platform with the award of a contract from the U.S. Department of Defense to develop a vaccine against **equine encephalitis virus**, which is considered a potential biological threat. The contract has a potential value of USD 36 million and is in addition to the USD 1.8 billion that has already been awarded for MVA-BN as a smallpox vaccine.

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- We made significant progress in our **collaboration with Janssen** with the initiation of a Phase 1/2a clinical trial of the therapeutic HPV vaccine regimen, which is expected to trigger a clinical milestone payment of USD 12.5 million later this year.
- Our executive management was strengthened with the appointment of Henrik Juuel as Chief Financial Officer.

Financial performance

Bavarian Nordic **achieved its planned goals for the year**, while also managing the expenditures better than planned, contributing to a better than guided result and cash preparedness at year-end.

Revenues were DKK 501 million in line with guidance and the result before interest and tax (EBIT) was a loss of DKK 354 million, compared to a guided loss of DKK 385 million.

The cash preparedness at year-end was DKK 2,314 million, compared to a guidance of DKK 2,100 million.

Danish kroner (DKK) is the Company's reporting currency. The USD figures provided below are based upon an assumed exchange rate of DKK 6.52 per 1.00 USD, which was the exchange rate as of December 31, 2018.

2018	DKK million		USD million	
	guidance	actual	guidance	actual
Revenue	500	501	77	77
EBIT	(385)	(354)	(59)	(54)
Cash preparedness, year-end*	2,100	2,314	322	355

Revenue was comprised of DKK 323 million from sale of MVA-BN smallpox bulk drug substance to the U.S. Government, DKK 38 million from the sale of MVA-BN smallpox vaccine to other customers and DKK 140 million from ongoing development contracts, with the majority generated by the Janssen agreements.

Outlook for 2019 - Investing for the future

2019E	DKK million	USD million
Revenue	600	92
EBIT	(360)	(55)
Cash preparedness, year-end*	1,600	246

* Cash preparedness includes cash, cash equivalents, investments in securities and the aggregate amount of undrawn credit lines.

Only signed contracts are included in the revenue expectations for 2019, which are comprised of revenue of approximately DKK 320 million from the MVA-BN smallpox vaccine business and approximately DKK 280 million from contract work. The majority of revenues are dollar-denominated, based on an exchange rate of DKK 6.5 per 1.00 USD.

While the Company anticipates the award of a Priority Review Voucher upon the expected approval of MVA-BN smallpox vaccine by the FDA in 2019, income from the sale of this voucher has not been included in the guidance.

In addition to factors already mentioned, the guidance is based on the continued investment into research and development (R&D) of approximately DKK 570 million, of which DKK 150 million will be recognized as production costs. Also included are the final investments in the new fill and finish facility of approximately DKK 270 million, which will support securing improved revenues from the existing MVA-BN smallpox order in the years to come. With significant R&D investments, we continue to develop our key pipeline assets and will report key data for both BN-Brachyury and CV301, initiate a Phase 3 study for the freeze-dried version of MVA-BN smallpox vaccine, while also preparing to initiate an RSV Phase 3 study in 2020.

Conference call and webcast

The management of Bavarian Nordic will host a conference call today at 2 pm CET (9 am EDT) to present the annual results followed by a Q&A session. A listen-only version of the call can be accessed via <http://www.bavarian-nordic.com/investor/events.aspx?event=5502>. To join the Q&A session, use one of the following dial-in numbers: Denmark: +45 32 72 80 42, UK: +44 (0) 844 571 8892, USA: +1 631 510 7495. Participant code is 6777399.

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About Bavarian Nordic

Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative and safe therapies against cancer and infectious diseases. Using our live virus vaccine platform technology, MVA-BN[®], we have created a diverse portfolio of proprietary and partnered product candidates intended to improve the health and quality of life for children and adults. We supply our MVA-BN[®] non-replicating smallpox vaccine to the U.S. Strategic National Stockpile and other government stockpiles. The vaccine is approved in the European Union (under the trade name IMVANEX[®]) and in Canada (under the trade name IMVAMUNE[®]). In addition to our long-standing collaboration with the U.S. government on the development of MVA-BN and other medical countermeasures, our infectious disease pipeline comprises a proprietary RSV program as well as vaccine candidates for Ebola, HPV, HBV and HIV, which are developed through a strategic partnership with Janssen. Additionally, in collaboration with the National Cancer Institute, we have developed a portfolio of active cancer immunotherapies, designed to alter the disease course by eliciting a robust and broad anti-cancer immune response while maintaining a favorable risk-benefit profile. Through multiple industry collaborations, we seek to explore the potential synergies of combining our immunotherapies with other immune-modulating agents, e.g. checkpoint inhibitors. For more information visit www.bavarian-nordic.com or follow us on Twitter [@bavariannordic](https://twitter.com/bavariannordic).

Forward-looking statements

This announcement 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 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.