UPPDRAGSANALYS

Preparing for the final

Bavarian Nordic redesigning pivotal study

Bavarian Nordic still has a chance to kick off its pivotal phase 3 trial with ABNCoV2 in June, which is the timeline that has been communicated by the company. The study is being redesigned and will no longer be part of governmental booster programs but a separate randomized study on 4 000 patients in EU and US.

The primary endpoint will register the boost of neutralizing antibodies to the Wuhan strain of the COVID-19 virus two weeks after administration of the vaccine, either the ABNCoV2 or Pfizer's Comirnaty. This design gives us good confidence, a 68 percent likelihood, that the candidate will be launched in late 2023.

Mounting competition in COVID-19 prevention

The planned phase 3 study will allow Bavarian Nordic to claim non-inferiority of ABNCoV2, a protein-based vaccine, to the market leader Comirnaty, a mRNA-based vaccine. This may prove to be a marketing challenge. However, the product will have the convenience of being stored in room temperature.

Furthermore, competitive pressure is building up with the approval in EU of Nuvaxovid, the first approved protein-based vaccine, and a few other vaccines down the line. And even more so, the likely approval of efficient Omicron-directed vaccines from Pfizer and Moderna should take the lead in a resurge of vaccinations expected to come in this fall.

Focus on proprietary breast cancer vaccine candidate

We are looking ahead with excitement to more data on the in-house development of ES2B-C001, ExpreS²ion's proprietary therapeutic vaccine candidate for HER2+ metastatic breast cancer. The program has been delayed in preclinical development with about two years and the market is also seeing a lot of competition. Animal safety data in 2023 will be the next milestone and a phase 1 study may start in 2024.

Fair value lowered based on new challenges

ExpreS²ion Biotechnologies holds about a 1 percent stake in the future sales of ABNCoV2 and more importantly a 34 percent stake in AdaptVac, which holds a +10 percent stake in the program.

Mounting competition in the market leads us to lower the anticipated doses sold in 2023-27 to 225 million (260). Regulatory requirements on safety should not be neglected either, as can be seen in other development programs, such as Novavax' and Valneva's.

ExpreS²ion Biotech

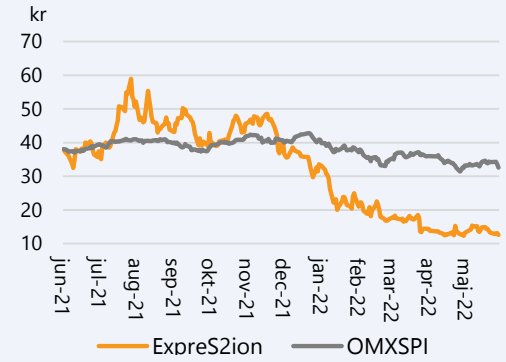
Date	13 juni 2022
Analyst	Sten Westerberg

Facts

Industry	Vaccine Development
Chairman of the Board	Martin Roland Jensen
CEO	Bent U. Frandsen
Year of Listing	2016
Stock List	First North Growth Market
Ticker	EXPRS2
Share price	SEK 14
No. of shares, mln.	37,2
Market cap, SEKm	521
Cash 2022p, SEKm	113

Web site www.expres2ionbio.com

Share price development last year



Source: Refinitiv

Forecasts & Key ratios, SEKm

	2020	2021	2022p	2023p
Revenues	15	14	10	51
EBIT	-29	-48	-82	-55
Net income	-36	-44	-86	-58
Earnings per share	-1,8 kr	-1,5 kr	-2,7 kr	-1,8 kr
Dividend	0 kr	0 kr	0 kr	0 kr
Revenue growth	11%	-10%	-31%	431%
Cash	107	139	113	55
New share issue	133	83	73	0

Source: Company, Analysguiden

We are lowering the fair value of our base scenario for ExpreS²ion to SEK 30 (39), a consequence of both dilution and trimming of ABNCoV2 and ES2B-C001 valuation.

Struggling with the COVID fatigue

Bavarian Nordic has been considering the final design of its phase 3 study with ABNCoV2 for some time longer than we initially anticipated. However, we still see a decent chance for the Danish vaccine company to start enrolment in its pivotal study in June, which is the timeline set by the company.

Initially Bavarian Nordic aimed at a study making ABNCoV2 a part of different governmental COVID-19 booster programs. This solution provided a way of circumventing the ban for including commercially approved vaccines in a clinical phase 3 study since the approved mRNA vaccines are sold to mainly governmental agencies and could not be purchase directly from its manufacturers. This situation threatened to block the inclusion of a comparator vaccine in the Bavarian Nordic study.

The study, which will include 4 000 patients, is planned to be carried out in US and EU and was about to be kicked off while experiencing challenges to find suitable sites where patients could be enrolled. According to the Bavarian Q1 teleconference EU has now opened up for selling the Pfizer vaccine directly to Bavarian Nordic, making it possible to redesign the study.

Two-week study duration

The current design of the study, as released on clinicaltrials.gov, aims at a two-week duration after the administration of a single boost vaccination. Patients will be randomized 3:1 to receive either 100 µg ABNCoV2 or Pfizer's mRNA-based vaccine Comirnaty.

Patients will have received vaccination with a mRNA vaccine either three or six months before being included in the Bavarian study. Two weeks after the administration of the vaccine geometric mean titres (GMT) of neutralizing antibodies to the Wuhan strain will be measure as the primary endpoint of the study.

The only secondary endpoint extending beyond two weeks is the safety and tolerability check, which is carried on day 8 and day 29. The safety control is then ongoing until February 2023, which is the final endpoint of the study.

This short study duration speaks in favour of the Bavarian Nordic guidance that topline data from the study will be released already in the second half of this year. This would also allow for a rolling submission to regulatory agencies before year-end. We expect the regulatory duration to be 10-12 months, allowing for a launch of the vaccine late in 2023.

The study aims at proving non-inferiority to Comirnaty. Since it is unlikely to include any data on superior antibody titres or superior antibody duration, we do not expect ABNCoV2 to obtain an fast-track review, which has been the case with the mRNA vaccines.

Potential risks to the guided timeline

It is our understanding that regulations regarding the handling of the Covid-19 vaccine programs are complex and the process of finding 4 000 patients to the phase 3 study may be cumbersome. The current vaccination rate in EU and US is dropping rapidly, which also sets up a hurdle to recruitment at least during the summer period. Taking this 'COVID fatigue' into consideration, a traditional randomized study may need more time than 4-5 months to recruit all patients.

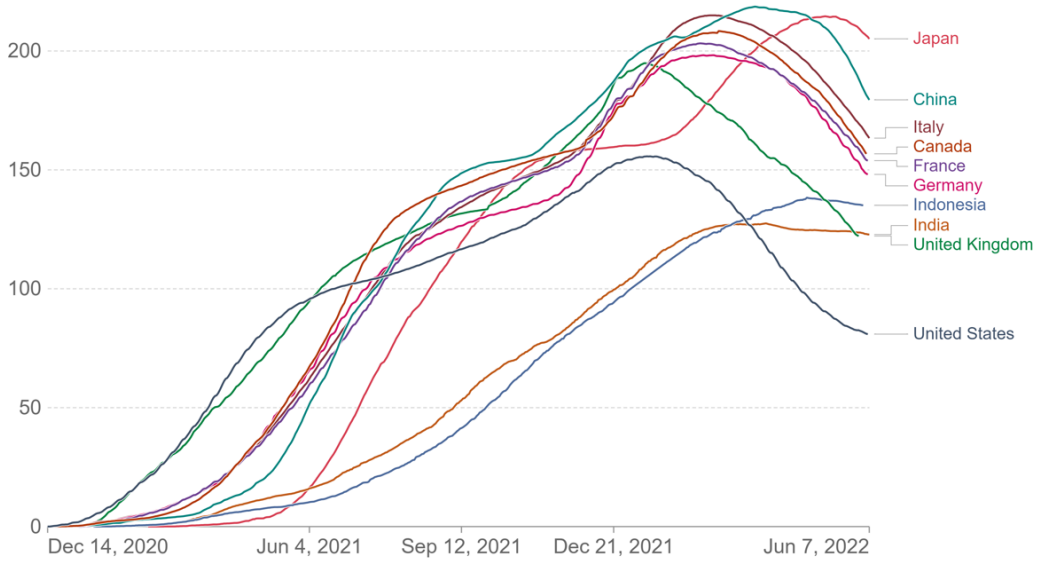
We see chances of ABNCoV2 reaching non-inferiority to Comirnaty as high as 80 percent, based on clinical data on the Wuhan strain which has been presented in phase 2. This speaks in favour of a rolling submission to regulatory agencies before year-end. However, the regulatory risk that ensues cannot be neglected. In the case of ABNCoV2, regulators may have difficulties reaching a firm view on safety based on the 3 000-patient sample. For example, the most comparable vaccine to ABNCoV2, Nuvaxovid, faced a rigorous safety review at the FDA, in spite of already being approved in EU. It also included an FDA Panel discussion, which arrived at a favourable conclusion on June 7.

Nuvaxovid (NVX-CoV2373) has been tested in more than 50 000 individuals and is likely to be used primarily as a booster vaccine. It is a protein-based vaccine, just as ABNCoV2, and has other structural similarities to ABNCoV2. It differs in respect to that it is making use of an adjuvant, MATRIX M, while ABNCoV2 is unadjuvanted, solely depending on the VLP technology to raise an immune response to the mounted antigen.

Nuvaxovid contains 5 µg per dose of the Wuhan spike protein compared to 100 µg of the ABnCoV2. To this Nuvaxovid adds 50 µg per dose of the MATRIX M adjuvant.

We have increased the regulatory risk for ABNCoV2 to 85 percent likelihood of passing FDA and EMA compared to a previous very optimistic 95 percent. Our compounded likelihood of approval upon initiation of the phase 3 trial is 68 percent, compared to previously 71 percent.

No of doses/100 inhabitants, rolling12 month basis



Source: Our World In Data, based on official data

Slow uptake of Nuvaxovid in EU

Whereas Nuvaxovid has not yet receive approval in the US, it was recommended for approval by the European regulatory agency EMA in December last year. In Q1 Novavax reports to have shipped 42 million doses globally on a revenue of USD 586m. This suggests an average price per dose of USD 14, markedly below Pfizer's and Moderna's.

We believe that this price includes high portion of sales in low-income countries, such as Indonesia and India.

As for the distribution in national vaccination programs, the uptake has been slow in EU. A report in April suggested only 100 000 doses had been administered in spite of inventories being at 47 million with 55 million more to be delivered this year. Most of the doses were administered to unvaccinated individuals, sceptics to the dominating mRNA vaccines. Only a small part of the doses went to boosting already vaccinated individuals.

In total Novavax is committed to deliver 2 billion doses worldwide in 2022, of which more than half are related to GAVI agreement in exchange for development support. In ExpreS²ion Biotechnologies recent prospect the company estimates that more than 500 million dose is a possible market share for ABNCoV2 over a longer period. In our base scenario we have assumed ABNCoV2 can sell 225 million doses in the period of 2023-27. In an endemic scenario, where COVID-19 will move on to become a seasonal flu, accumulated vaccination numbers are likely to be substantially higher.

Pfizer / Moderna continue to dominate

On June 8 Moderna presented phase 2/3 data on its new bivalent vaccine booster candidate, aimed at protection to both the concerned Omicron strains as well as the original Wuhan strain. Currently approved mRNA vaccines are based on Wuhan data.

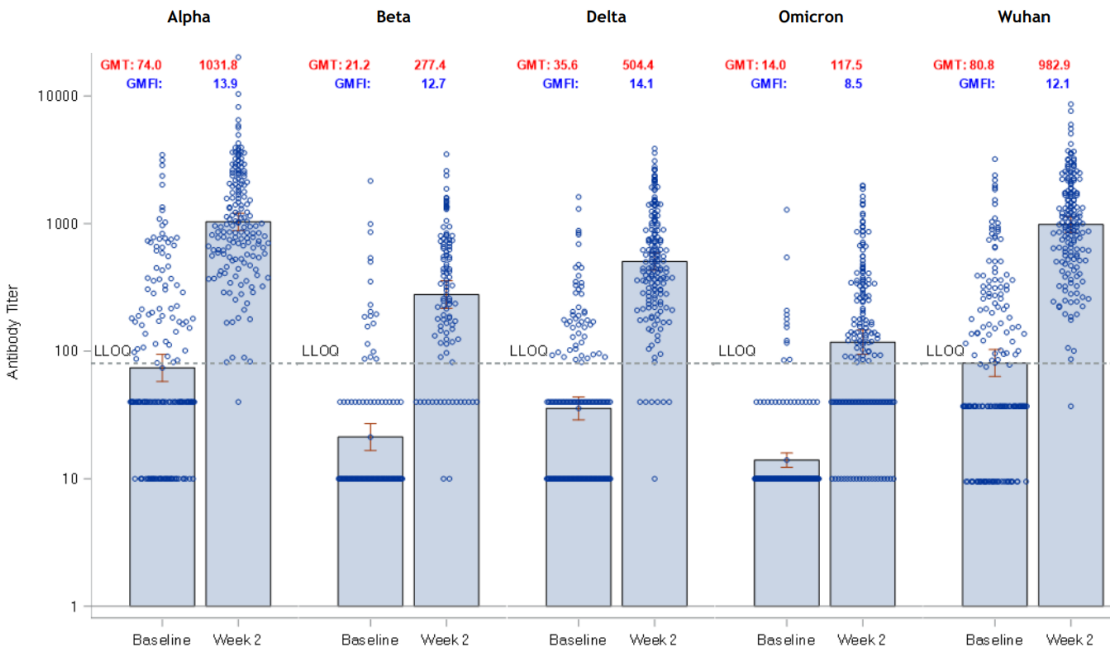
A 50-µg booster dose of the Moderna bivalent candidate mRNA-1273.214 met all pre-specified endpoints, including superior neutralizing antibody response (GMT) against the Omicron variant one month after administration when compared to the currently approved vaccine. The side effect profile was comparable to a booster dose of the approved vaccine.

Among seronegative (healthy) participants one month after administration of the Moderna bivalent candidate mRNA-1273.214, neutralizing antibody titers against Omicron was 2 372, compared to GMT for the currently sold vaccine of 1 473. The new candidate appears to almost double protection to the Omicron strain compared to the currently sold vaccine.

The Moderna numbers compare favorably to the ABNCoV2 data after two weeks which can be seen in the diagram below. As shown in the diagram below, ABNCoV2 recorded a GMT of 117 after two weeks. However, it is notoriously difficult to compare different studies of different vaccines, partly because the baseline values differ substantially depending and patient population and design settings.

We expect that updated Omicron vaccines from Pfizer and Moderna would continue to dominate in an expected resurge of vaccinations in high-risk populations in the coming autumn and winter seasons.

Antibody levels with ABNCoV2 in phase 2 study results



Source: Bavarian Nordic

Breast cancer candidate delayed

ExpreS²ion Biotechnologies still has some way to carry its in-house program for a breast cancer vaccine ES2B-C001 before entering a clinical phase 1 trial. In 2020 it was expected that the program would be ready for a CTA, Clinical Trial Application, in the first half of 2022. This CTA has for various reasons been pushed into 2024, a delay that has been seen in many oncology programs during the corona pandemic.

In 2020 the program was developed by AdaptVac and called AV001. In the option deal which ExpreS²ion struck with AdaptVac in February 2020 described AV001, later to be ES2B-C001, as having shown proof-of-concept in animal testing on mice in an article published 2018 by researchers at the University of Bologna. However, this study was based on a non-proprietary tag catcher method and had to be redone with a proprietary tag catcher system developed by AdaptVac.

These new proof-of-concept studies in animals have been published recently in two separate articles.

ES2B-C001 is developed as a therapeutical vaccine for patients with HER2 positive breast cancer, having progressed after initial treatment with the standard anti-HER2 therapy Avastin (trastuzumab). In published research ES2B-C001 has demonstrated a strong tumor-growth inhibiting effect in a mice model and when blood serum from vaccinated mice was applied to cultures of HER2-positive human breast cancer tumors. ES2B-C001 has also shown successful results in HER2-transgenic preventive as well as therapeutic tumor mice models, where ES2B-C001 demonstrated effective inhibition of tumor development compared to control groups.

According to the recently published prospect, two weeks after the inoculation of tumor cells, the first vaccine administrations were given. ES2B-C001 formulated in an adjuvant was found to totally block tumor development, whereas the control group progressively expanded with lung metastases and subcutaneously growing local tumors. Additionally, ES2B-C001 without adjuvant was found to inhibit, but not prevent, tumor development.

Capital raise invested in ES2B-C001

The recent capital raise of net SEK 60 million will be invested in carrying out toxicological studies in non-human primates to complement the previous toxicological studies in mice. This was a requirement of the Danish Medicines Agency, DKMA, resulting from a meeting held with the agency in February. A dose range will be established in the monkey study. Also, there will be further investments in scaling manufacturing capacity ahead of the clinical trial in 2024-25, another costly procedure in vaccine development.

Competitive landscape in HER2+ breast cancer

About 15-20 percent of all breast cancers are HER2+, which makes any new treatment to a potential blockbuster. We note that there are several ongoing vaccine studies on HER2+ breast cancer. Clinicaltrails.gov lists 19 ongoing clinical trials when screening its data base. One of these is a 598-patient phase 3 trial, FLAMINGO-01, sponsored by Texas-based Greenwich Lifesciences, which is not yet recruiting. This competitive landscape needs to be looked into in order to understand the potential advantages of ExpreS²ion Biotechnologies lead program ES2B-C001.

We also note that in the second line setting of females with metastatic relapsing breast cancer after failing first line treatment with generic trastuzumab, AstraZeneca/Daiichi scored a recent success with its phase 3 program Enhertu. In the 557-patient study, those taking Enhertu survived for 23.9 months, as compared with 16.8 months for those who received standard chemotherapy. This is considered a very positive result in a difficult to treat patient setting and Enhertu is expected to change the current standard-of-care in second-line HER2+ breast cancer.

Potential launch of ES2B-C001 in 2029-30

We currently see a potential for ES2B-C001 to reach the market in 2029-30, a delay compared to a previously 2027-28. We have assigned the program a 14 percent chance of reaching the market. We estimate that including the current capital raise of SEK 60 million, management has invested some SEK 100 million in ES2B-C001 and that this is reflected in our current valuation of SEK 185m. This corresponds to SEK 5 / share, if we assume that ExpreS²ion will not have to a new shares issue in 2024.

Financial discussion and scenarios

In our previous report we estimated that AdaptVac would receive a milestone payment of EUR 15m from Bavarian Nordic upon initiation of the phase 3 study, rendering a SEK 20m income to ExpreS²ion Biotechnologies. We are withdrawing this assumption for conservative reasons and expect no payments to ExpreS²ion Biotechnologies from AdaptVac this year.

The distribution of milestone payments which AdaptVac will receive from Bavarian Nordic is a source of uncertainty in the valuation of ExpreS²ion Biotechnologies. ExpreS²ion is a minority holder in Adaptvac and is not in control of future dividend payments. We expect only a minor part of these to be paid as dividend to the shareholders of AdaptVac in the 2022-24. The lion part is likely to stay in operations of AdaptVac, an assumption which may prove to be wrong.

Bavarian Nordic has booked a liability of DKK 596 million, or EUR 75 million, as a net present value of future development and sales milestone to be paid to AdaptVac, a lower number than the total value at EUR 136 million of the milestones presented in the 2020 deal with Adaptvac. We expect the EUR 75 million to be paid to AdaptVac in the course of 2022-24 and the remainder is yet to be concluded depending on the sales performance of beyond 2024.

We expect AdaptVac to receive a 11 percent royalty on sales of ABNCoV2. Out of this revenue stream we expect ExpreS²ion to catch 10 percent, i.e., about 1 percent share of sales of ABNCoV2. On top of this ExpreS²ion is entitled to receive EUR 2 mln in commercial milestones from AdaptVac, which we expect to occur in 2023-24. This may still be enough to be able to take ES2B-C001 into clinical development in 2024, but a new share issue in 2024 cannot be ruled at that point in time.

Value of the AdaptVac holding

Our NPV calculation of AdaptVac ends up at SEK 1,6bn out of which ExpreS²ion Biotechnologies holds 34 percent after having swapped its initial 50 percent holding for the exclusive license of ES2B-C001 in 2021. The control of AdaptVac lies with NextGen Vaccines, holding the remaining 66 percent of AdaptVac.

In a valuation of the AdaptVac holding we expect 85 percent of the cash pile which may end up in AdaptVac on the commercialization of ABNCoV2 to be distributed to its shareholders in 2027. This is a rough way of getting to a value to include in ExpreS²ion Biotechnologies and it may prove wrong. However, to include a 100 percent at this point in time is not possible in our view, since we expect AdaptVac to make us of some of its cash in other projects.

On the other hand, in a possible future floating of AdaptVac it may prove that the stock market will assign a higher value to the AdaptVac technology. At this point in time, we value ExpreS²ion's holding at 12,5 SEK/share, which is on top of the 6,4 SEK/share coming from the royalty stream.

Sum-of-The-Parts valuation of ExpreS²ion Biotech

	Project value (MSEK)	Value / share (SEK)	Peak sales (MEUR)	LOA*	WACC	Share of NPV	Comments
ES2B-C001	186	5,0	2 052	14%	14%	100%	
Royalty, ABNCoV2	238	6,4	4 591	68%	9%	100%	11% of Adaptvac
Adaptvac holding	464	12,5		68%	9%	34%	of DCF value
Platform	65	1,7	1,4	100%	7%	100%	cash flow based
Malaria project	110	3,5	175	21%	14%	10%	of consortium
Indigo (influenza)	30	0,6	952	5%	12%	8%	of consortium
Sum	1 093	30	*based on the no. of shares by end of 2022, mln*				*37,2*
**) Likelihood of approval*			*based on the no. of shares by end of 2024, mln*				*37,2*

Forecasts by Analysguiden

The swapping of ABNCoV2 for ES2B-C001

In February 2021 ExpreS²ion exercised its right to the option of licensing ES2B-C001 by swapping 16 percentage points of its 50 percent holding in AdaptVac with the other shareholder in AdaptVac, NextGen Vaccines Aps. In light of the delay and the recent new share issue, which will finance preclinical development of ES2B-C001, we are still not convinced that this deal was favorable to the ExpreS²ion shareholders. A 16 percent stake in AdaptVac in our valuation is worth about SEK 220 million, compared to our current valuation of ES2B-C001 at SEK 185 million. However, this relationship may change should the project proceed to a phase 1 study in 2024.

ExpreS²ion exposure to ABNCoV-2, three scenarios

	Slow scenario	Main scenario	Strong scenario	Comments
Aggregated sales , EURm	2 000	4 591	10 000	225 mln doses sold in main scen
EUR per dosis	17	17	17	Our assumption
Adaptvac royalty from Bavarian	7%	10%	13%	Single digit to double digit
ExpreS²ions royalty from Adaptvac	11%	11%	11%	Double digit number
royalty of vaccine net sales	*0,8%*	*1,1%*	*1,4%*	
ExpreS²ion revenues, EURm	15	50	143	Over period 2023-2027
in SEKm	*162*	*530*	*1 502*	
Milestone from Adaptvac, SEKm	20	20	20	EUR 2m in 2023
ExpreS²ion revenues, SEKm	182	550	1 522	
SEK/share	4,9	14,8	40,9	
Tax rate	18%	18%	18%	Assuming full taxation
Likelihood of Approval (LOA)	68%	68%	68%	100% phase 1/2, 75 % phase 3
Risk-adjusted after tax, SEK/share	2,7	8,3	22,8	Not discounted, see SoTP

Forecasts by Analysguiden, price inflation of 1 percent included in main scenario

A bull scenario value at SEK 60

Our base scenario for ABNCoV2 is based on conservative assumptions given the competitive landscape, but even more so on the non-inferiority claim to Comirnaty. In a more positive scenario with data showing long-lasting protection to the virus we see the fair value of ExpreS²ion Biotechnologies at least doubling to SEK 60. We expect longevity data to start being published by the end of 2023 giving a possible boost to sales in 2024-25. The aggregated sales of ABNCoV2 would then surge to some EUR 10bn, more than double of our main scenario at EUR 4.6bn.

In a negative scenario, where ABNCoV2 is not able to show non-inferiority to Wuhan protection in the phase 3 trial, the project will be dropped and the share price should fall below a level at 5 SEK per share, corresponding to our undiluted valuation of the preclinical asset ES2B-C001.

Assumptions in Net Present Valuation of ExpreS²ion Biotech

SEKm	2020	2021	2022p	2023p	2024p	2025p	2026p	2027p	2030p
Operating income	15	14	10	51	83	99	13	14	14
ABNCoV-2	*0*	*0*	*0*	*32*	*74*	*86*	*88*	*89*	*0*
ES2B-C001				*0*	*-3*	*0*	*73*	*0*	*131*
platform/services	*11*	*5*	*10*	*19*	*12*	*13*	*13*	*14*	*14*
EBIT	-29	-48	-82	-55	-23	-23	3	4	
Cash	107	139	113	55	31	8			

ABNCoV-2 (EURm)	2020	2021	2022p	2023p	2024p	2025p	2026p	2027p	2030p
Net sales			0	350	893	1 094	1 116	1 138	
EUR/dosis			*17*	*17*	*18*	*18*	*18*	*18*	
No. of doses, mln total of 225			*0*	*10*	*40*	*50*	*62*	*63*	
ExpreS²ion milestones, EURm		0	1	0	0	0	0	0	
Royalty, MEUR			0	2	7	12	12	13	
Royalty rate				*0,6%*	*0,8%*	*1,1%*	*1,1%*		
Expres2ion revenues, SEKm		0	11	20	72	126	129	131	
Risk-adjusted		*1,00*	*1,00*	*0,80*	*0,68*	*0,68*	*0,68*	*0,68*	
Risk adjusted revenues, NPV (SEKm)			0,0	13,8	49,1	85,9	87,6	89,4	

WACC	9%
NPV, royalty (SEKm)	238
NPV/share, SEK	6,4
LOA	68%

ES2B-C001 (SEKm)	2020	2021	2022p	*Licens*	2024p	2025p	2026p	2027p	2030p
Costs, preclinical / clinical	-7	-36	-24	-20	-14	0	-50	0	-75
incl milestones to Adaptvac	*-3,5*	*-3,5*	*-3,5*	*0*	*-14*	*0*	*-50*	*0*	*-75*
Sales, EURm								0	946
Milestones, licensing partner 550 MEUR				0	0	0	100	0	150
Royalty 15%								*0*	*142*
Expres2ion revenues, SEKm				0	-14	0	970	0	2902
Risk-adjusted	*1,00*	*0,85*	*0,64*	*0,64*	*0,29*	*0,16*	*0,14*	*0,14*	*0,14*
Risk adjusted revenues, NPV (SEKm)				0	-3	0	73	0	131

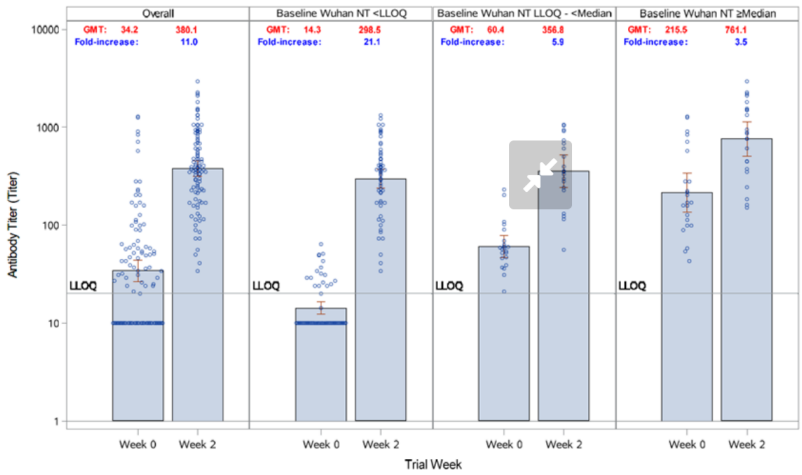
WACC	14%
Net present value (SEKm)	186
NPV/share, SEK	5,0
LOA	14%

Solid phase 2 data pave the way

Bavarian Nordic repeated solid results for its vaccine candidate ABNCoV2 in recently released topline numbers from the phase 2 study arm of the 100-µg dose. This is a non-randomized, non-controlled study, and in contrast to the COUGH-1 study, we no longer find support for a superior effect of ABNCoV2 over the marketed mRNA vaccines Comirnaty and Spikevax. This should not come as a surprise, as we argue below.

Results for the three virus variants Wuhan (the wild type), Alpha and Beta are supporting the strong antibody responses (2- to 40-fold higher levels compared to Wuhan baseline) two weeks after the shot, which also may be necessary in order to show non-inferiority to a marketed vaccine in the phase 3 trial. As for the currently dominating Delta variant a slightly less potent booster effect was recorded, a 4 to 21-fold increase in levels of neutralizing antibodies (highlighted in blue in graph below). These levels still qualify for a highly potent immunization to the virus.

ABNoV2 immunization to SARS CoV2 Delta variant



Source: Bavarian Nordic

We note that Bavarian Nordic used a different technology, a receptor binding assay, for testing the immunization to the Delta variant, possibly due to a shortage of the standard PRNT50 test. It is not clear to us if and to what extent this different assay has had an impact on the absolute numbers. At least it makes comparisons to other vaccines even more difficult than already is the case in a non-controlled study.

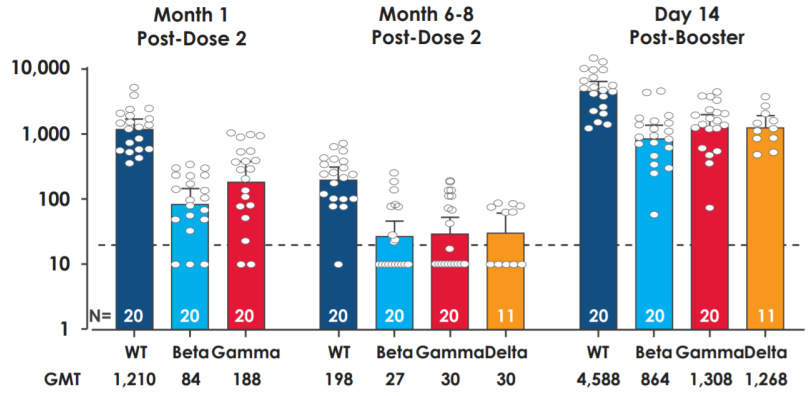
Moderna's Spikevax 50 µg dose has shown equally strong immunization boost to Delta as to Beta and Gamma (see below). These relative computations of increases of antibody levels have to be made carefully as they are entirely dependent on the baseline values, which makes it very difficult to compare this phase 2 trial to other phase 2 trials. In general, we believe that Bavarian Nordic has set itself a difficult

comparison, with a shorter interval down to 90 days after the prime vaccination.

ABNCoV2 vaccination grade below 96 percent

However, when looking at the absolute levels of neutralizing antibodies in subjects infected with the Delta variant, the currently dominating variant, they are trending well below the 1 000-mark (see graph above). This mark believed to correspond to a 96 percent vaccination effect. In Moderna phase 2 data we still read the mean titers as being well above the 1 000 mark, corresponding to a vaccination grade above 96 percent (see graph below). Again, the ABNCoV2 values for the Delta variant are retrieved with a different assay than the 50 percent neutralizing titer assay which is the standard in the industry.

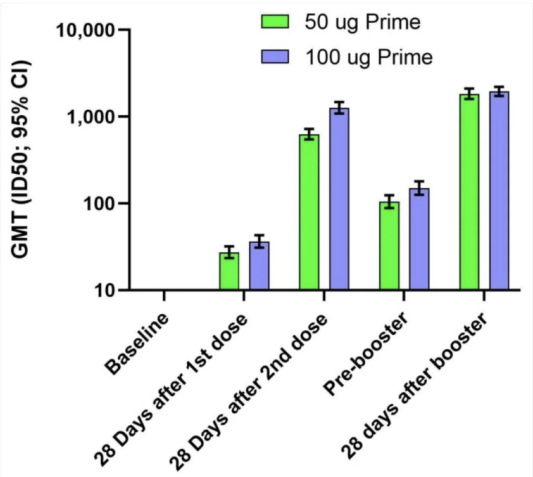
Moderna shows 23 to-40-fold antibody increase



Source: Moderna study 201B, CDC presentation, October 21

Both Moderna and Pfizer claims higher neutralizing titers one month after the booster dose compared to one month after the prime vaccination. Pfizer-BioNTech Comirnaty (BNT162b2) booster dose at 30 µg shows a 99,5 percent seroresponse rate one month after the booster injection. The mean neutralizing antibody titers with Comirnaty were 2 455 at that point, substantially higher than seen in the Bavarian Nordic trial, but again based on a different assay for measuring the immunization boost.

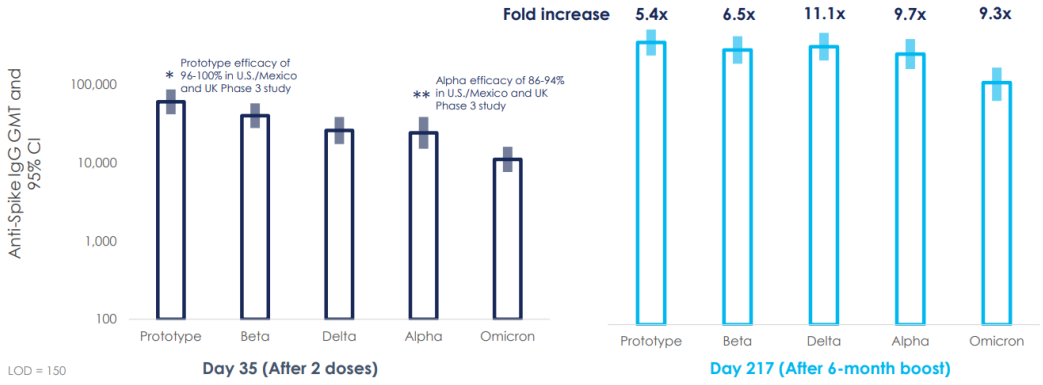
Strong reneutralization with Moderna 50 µg boost



Source: Chu, L.(2021). Immune Memory Response After a Booster Injection of mRNA-1273

In the chart above we show data from another Moderna study of the booster properties of Spikevax to Wuhan and Delta strains. Participants immunized 6-8 months earlier with a primary series of two doses of 50 or 100 µg of mRNA-1273 were administered a booster injection of 50 µg of mRNA-1273. A single booster dose of Spikevax was shown to result in a geometric mean fold rise (GMFR) of 13,0 (95% CI: 11.04, 15.29) in neutralizing antibodies from pre-booster compared to 28 days after the booster dose.

Booster responses to Nuvaxovid (Novavax)



Källa: Novavax investor presentation

The Danish financing agreement

In August last year Bavarian Nordic entered a funding agreement, valued at up to DKK 800 million, with the Danish Ministry of Health to provide the full financing of ABNCoV2 development towards approval. The agreement included an upfront payment of DKK 80 million in October, in addition to payments of up to DKK 720 million. The additional payments are contingent upon reaching a number of predefined milestones including among others completion of the ongoing phase 2 trial, phase 3 development milestones and milestones related to upscaling of manufacturing for clinical and commercial production of the vaccine.

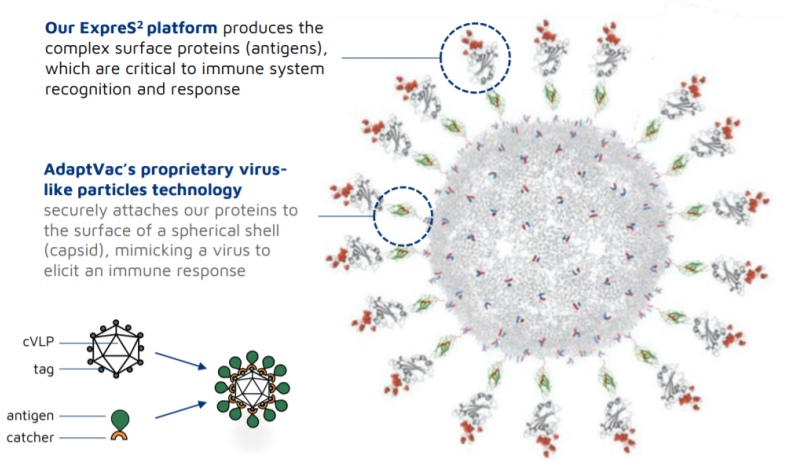
All payments are potentially subject to repayment, however only upon successful marketing authorization of the vaccine by the European Commission. Repayment may occur via supply of vaccines and royalty payments from the sale of the vaccine to other customers. Royalty payments are only triggered upon reaching a certain volume in sales. The Danish Ministry of Health could be entitled to an additional, capped royalty payment if the sales reach a certain threshold.

We are surprised by the size of the financing, which in our mind is economical for being a phase 3 financing, which also includes investment in manufacturing capacity.

Summary of the ABNCoV2 technology

We classify ABNCoV2 as a combined protein subunit antigen technology, provided by ExpreS²ion, coupled with a capsid Virus Like Particle (cVLP), provided by the AdaptVac platform. The capsid-like particle is coated with 60-80 particles of the recombinant RBD protein fragment. After exposure to the ABN vaccine, mice serum was tested for antibodies to the receptor binding domain of SARS-CoV-2. Researchers have shown in a Nature article that RBD proteins glued to the CLP had a 3-4-fold higher immunogenicity compared to soluble RBD proteins injected without being mounted to the capsid-like particle, a strong rationale for the technology behind the ABNCoV2 cVLP vaccine.

Schematic figure of cVLP expression and construct



Source: Company presentation

Potential advantages with ABNCoV2

ABNCoV-2 has the potential to be a very potent COVID-19 vaccine. The readouts from preclinical animal data suggests an equal or stronger activity of neutralizing antibodies after two dosages compared to most other published preclinical animal data, also from currently approved

COVID-19 vaccines, such as Pfizer-BioNTech's, Moderna's, and AstraZeneca-Oxford's vaccines.

Preclinical evidence in mice of the potency for ABNCoV2 opens for a possibility of single shot dosing, even if the schedule in the first clinical study makes use of double dosing. It is also speculated that the capsid-based antigen display induces long-lived plasma T-cells, thus potentially conferring immunity for decades, as seen with the HPV vaccines, which are also based on a VLP construct. This would be a differentiating factor to other recombinant proteins, which run the risk of not eliciting long-lasting T-cell response.

An additional advantage with the technology being used by AdaptVac and ExpreS²ion is that it would be relatively easy to replace the current vaccine RBD antigen in the event that the SARS-CoV-2 virus should acquire mutations in the RBD domain and thereby reducing the efficacy of an existing vaccine. Another advantage being mentioned by the authors of the Nature article is that the vaccine does not contain any viral material and cannot infect the human cell.

Summary of potential advantages

- Potent immunogenicity by neutralizing antibodies, also to newer SARS variants of concern,
- No genetic content in the vaccine may confer better safety,
- One single shot administration may be enough in booster indication,
- Long-lasting response with the cVLP adjuvant,
- Stable storage in room temperature, easy to handle

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Responsible analyst:

Sten Westerberg