First human data reassuring

ANALYSGUIDEN

av Aktiespararna

First human data expected to be satisfactory

Prospects for the COVID-19 vaccine candidate ABNCoV-2 has improved markedly following the DKK 1.1 billion new share issue by Bavarian Nordic in March. The first clinical study, COUGH-1, has performed an interim analysis, as expected, pointing to a good safety profile in the first 18 health volunteers treated with the vaccine. Final data from all 42 patients, including immunological in vitro responses, is now expected in late July.

Meanwhile Bavarian Nordic has announced its intention to start a second phase 1/2 study of ABNCoV-2 later in Q2, including some 200 patients previously treated with another vaccine or displaying antibodies to the virus. The vaccine will be investigated as a booster to currently approved vaccines, a position expected to be of importance in the continued fight against the virus. Further funding is required before the project can enter final phase 3 later this year.

Need for new vaccines to be reflected in prices

We are raising our assumptions for the ABNCoV-2 vaccine candidate both on expected pricing as well as chances of successfully reaching the market. Vaccine development is considered the least hazardous area of therapeutical development, which together with the ample documentation of the vaccine target, lead us to raise our probability of approval to 41 percent. Our previous pricing of 10 EUR per dose is raised to 15 EUR per dose, at a slight premium to the expected pricing of the Novavax vaccine. We also raise our estimate for total number of doses to 700 million, still well below the projected number of Novavax doses, reflecting a belief that ABNCoV-2 may be positioned as a booster vaccine on top of first-and second-line products.

Fair value raised to SEK 49 / share

In our brushed-up approach we have substantially raised our valuation of Expres²ion's 34 percent holding in AdaptVac. We value AdaptVac at SEK 2.0bn, based on the future revenue slew from Bavarian Nordic. The holding in AdaptVac corresponds to SEK 21 per share in Expres²ion. Our sum of the parts amounts to SEK 49 / share, double that of our latest report. A more bullish view on the share price would assume that we raise our forecast of distributed doses to a +1 billion, which we find it too early to include as a base case.

ExpreS²ion Biotech

Date	22 april 2021
Analyst	Sten Westerberg
Facts Industry Chairman of the Board CEO Year of Listing Stock List Ticker Chare price	Vaccine Development Martin Roland Jensen Bent U. Frandsen 2016 First North Growth Market EXPRS2
No. of shares 2021, mln.	31,5
Market cap, SEKm	1 292
Net cash 2021, SEKm	121

Web site

www.expres2ionbio.com

Share price development – 1y



Forecasts & Key ratios, SEKm

	2019	2020	2021p	2022p
Revenues	14	15	23	54
EBIT	-18	-29	-70	-57
Net income	-17	-36	-73	-61
Earnings per share	-0,5 kr	-1,1 kr	-2,3 kr	-1,9 kr
Dividend	0 kr	0 kr	0 kr	0 kr
Revenue growth	55%	9%	12%	131%
EBIT margin	-129%	-188%	-300%	-106%
Cash	5	107	121	60
New share issues	8	140	87	0
P/E ratio	neg	neg	neg	neg

Source: Bolaget, Analysguiden

Investment case

A continued need for new vaccines

The need for new COVID-19 vaccines continues to spur development of a number of clinical late-stage candidates. The recent stumbling of adenovirus-based products, notably AstraZeneca and J&J, underscores the importance of allowing new vaccine platforms, such as AdaptVac's VLP technology, to complement the current supply. It is also reported by the mRNA-based manufacturers that there may be need for a third dose in order to obtain durable immune responses from these products, as well as a repeated shot every 6 or 12 months.

This urge for new vaccines is best expressed by looking into the WHO database, showing a continued flow of new candidates entering clinical trials. On April 16 88 candidates had entered clinical development, up from 64 in late January when we published our latest report on ExpreS²ion Biotechnologies.

Likelihood of approval raised to 41 percent

Vaccine development is considered the least hazardous area for development of new therapeutical agents. The general rule is that 1 vaccine in 3 entering clinical development make it to the market compared to 5 in 100 for oncology programs, considered the most difficult area of drug development. Given the well-documented nature of the target spike protein of SARS-CoV-2, we believe chances for success are even higher for ABNCoV-2, where Adaptvac and ExpreS²ion Biotechnologies stand to gain royalty and milestones. We raise our raise our likelihood of a successful launch to 41 percent from a previous assumption of 25 percent.

Sum of the parts raised to SEK 49 / share

With the entry of Bavarian Nordic as sponsor of a phase 2 study we have seen remounting momentum for the ABNCoV-2 vaccine candidate. In our new approach we assume ABNCoV-2 to be distributed in 700 million doses over a 5–6-year period at a price of EUR 15, suggesting a positioning as a booster to available vaccines.

Assuming that Bavarian Nordic can achieve full funding of a phase 3 program, we value AdaptVac at SEK 2.0bn, corresponding to SEK 21 per share in ExpreS²ion Biotechnologies. The 34 percent holding in AdaptVac becomes the lion part of ExpreS²ion in a SOTP approach, further supported by SEK 10 per share in royalties to ExpreS²ion paid by AdaptVac. In our modelling of the company, we arrive at a sum-of-the-parts of 49 SEK per share, of which ABNCoV-2 is making up SEK 31.

No safety signal in interim analysis

The first clinical trial of the ABNCoV2 vaccine candidate, COUGH-1, started on March 8 and is a 1/2 open label, dose-escalation trial assessing the safety and tolerability of two doses of ABNCoV2, formulated with and without adjuvant, in up to 42 SARS-CoV-2-naïve, non-infected, volunteers. No elderly above 65 will be included.

Sponsor of the study is Radhoud University Medical Centre, one of the members of the PREVENT-nCoV consortium which is funded by a Horizon 2020 EU grant promoting the first clinical essay. The other members in the consortium are AdaptVac, ExpreS²ion Biotechnologies, Leiden University Medical Center (LUMC), Institute for Tropical Medicine (ITM) at University of Tübingen, the Department of Immunology and Microbiology (ISIM) at University of Copenhagen, and the Laboratory of Virology at Wageningen University.

Six different doses will be tested, of which the first three low-dose groups, including 18 patients, already have been treated with "no untoward safety signal" registered so far. The last three high-dosing groups, including 24 patients, are expected to start in May. Final headline data, including in vitro induction of immune responses, will be released in July, slightly delayed from a previous communication by Bavarian Nordic pointing to end of June.

Considering the low-risk profile of vaccine development, especially in the early stages, and the well-documented target spike protein of the SARS-CoV2 virus, we see very low likelihood for negative safety signals in phase 1/2 (5 percent). We assign a 41 percent likelihood of approval.

Bavarian Nordic to finance next study

Bavarian Nordic has decided to move the ABNCoV-2 project forward by investing in a second phase 1/2 clinical trial, involving some 200 patients previously vaccinated or infected. Bavarian will also scale up manufacturing to phase 3 volume levels in preparation for further clinical development towards licensure. We estimate that both these measures will cost DKK 200m each, i.e., 36 percent of the cash raised in Bavarian Nordic's latest new share issue.

The Bavarian lead phase 1/2 study will investigate the ability of ABNCoV2 to boost existing immunity from prior infection or vaccination, to create a more durable immune response that could provide better protection against the current circulating variants of COVID-19. We understand this design as a means of exploring a role for ABNCoV-2 as a booster to existing regimens, but do not exclude other indications in a future phase 3 program later this this year. Many physicians expect COVID-19 to remain spreading in society for

years to come as another infectious disease that needs to be managed. This would create a need for booster vaccines to maintain or broaden the protection against this disease.

Continued search for third-party funding

In parallel with the phase 2 study Bavarian Nordic will continue to seek funding to further progress the candidate towards licensure. Possible third-party funding for a phase 3 program which has been discussed is a national or EU financed public vehicle. Industrial collaborations with other manufacturers could also be a possible way forward. We estimate the cost of a full-scale phase 3 program to EUR 200-400m, excluding further investments in commercial manufacturing capacity, which may amount to just as much. The ongoing clinical program of Novavax involves over 50 000 patients at a total cost of more than USD 2bn, including a major component of public financing. We do not expect that this size will be mandatory for future phase 3 programs, as the vaccines become more of second- or third-line or booster oriented.

Financial discussion and valuation

In our updated sum-of-the parts approach to a valuation of ExpreS²ion Biotechnologies we have substantially raised the value of its partner company AdaptVac, in which ExpreS²ion holds 34 percent of the shares. The DCF value of royalties and milestones paid by Bavarian Nordic in our de-risked main scenario amounts to an aggregated pre-tax EUR 7.4bn over 2022-27.

ExpreS²ion revenues from ABNCoV-2, three scenarios

	Slow	Main	Strong	
	scenario	scenario	scenario	Comments
Aggregated sales , EURm	5 000	10 733	15 000	696 mln doses sold in main scen
EUR per dosis	15	15	15	Our assumption
Adaptvac royalty from Bavarian	7%	10%	13%	Single digit to double digit
ExpreS ² ions royalty from Adaptvac	11%	11%	11%	Double digit number
royalty of vaccine net sales	0,8%	1,1%	1,4%	
ExpreS ² ion revenues, EURm	39	118	215	Over period 2022-2026
in SEKm	389	1 192	2 166	
Milestone from Adaptvac, SEKm	20	20	20	EUR 2m in 2021-22
ExpreS ² ion revenues, SEKm	409	1 212	2 186	
SEK/share	13,0	38,4	69,3	
Tax rate	18%	18%	18%	Assuming full taxation
Likelihood of Approval (LOA)	41%	41%	41%	67% phase 1/2, 65 % phase 3
Risk-adjusted after tax, SEK/share	4,4	12,9	23,3	Not discounted, see SoTP

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

Discounted after tax and a 41 percent chance of a positive outcome the valuation of AdaptVac ends at EUR 2.0bn, of which Expres2ion holds 34 percent or SEK 21 per share. In principle, we include two different components of revenue streams from ABNCoV-2:

- The low-single digit royalty (estimated at 1.1 percent) and milestones on commercial sales of ABNCoV2 vaccine
- The 34 percent holding in AdaptVac, which may be realized in different ways, such as a stock market floating

In the table above, we show that ExpreS²ion's royalties per share from Bavarian Nordic's commercial sales can amount to SEK 38 / share in our de-risked main scenario. Risk-adjusted and after tax, income sinks to SEK 13 / share. To this value should be added ExpreS²ion's stake in AdaptVac of 21 SEK / share. If our scenario materializes, AdaptVac will turn into a large money bag of milestones and royalties from Bavarian Nordic.

In our main scenario, we expect ExpreS²ion to receive 1.1 percent of total vaccine net sales as royalty, which is a product of the two royalty rates we have adopted in the table above. For AdaptVac's part, we believe that the royalty extends between 7-13 percent. AdaptVac's agreement with Bavarian entitles to milestones corresponding to a maximum of EUR 136 million, but only EUR 2 million of these are shipped down to ExpreS²ion in our model.

	Project value	Value / share	Peak sales	Sha o			e		
	(MSEK)	(SEK)	(MEUR)	LOA*	WACC	NPV	Comments		
ES2B-C001	339	10,8	1 171	10%	14%	100%			
Royalty, ABNCoV2	324	10,4	10 733	41%	10%	100%	11% of Adaptvac		
Adaptvac holding	675	21,5		41%	10%	34%	of DCF value		
Platform	100	3,2	2,2	100%	7%	100%	cash flow based		
Malaria project	90	2,9	175	21%	14%	10%	of consortium		
Indigo (influenza)	30	0,6	952	5%	12%	8%	of consortium		
Sum	1 559	49	based on th	e no. of sh	ares by en	d of 202	1. mln 31.3		

Sum-of-The-Parts valuation of ExpreS²ion Biotech

based on the no. of shares by end of 2021, mln 1 559 31,3 49

*) Likelihood of approval

Forecasts by Analysguiden

ExpreS²ion holds 34 percent of ownership in AdaptVac with the Danish academic group NextGen Vaccines ApS holding the remaining majority stake in AdaptVac. NextGen is a spin-out from the University of Copenhagen's Institute of Immunology and Molecular Biology, controlled by a handful of researchers at this institution.

In our update we maintain a value of SEK 11 per share in the breast cancer vaccine candidate ES2B-C001, which is estimated to enter a clinical trial in first half of 2023. ES2B-C001 can become an important value driver in the longer run, but in the short run muck of the focus will be on the COVID-19 vaccine and the continued efforts to finance a phase III program, assuming the phase II part is

successful. We assign a 67 percent chance for a positive outcome of the two phase 2 studies which are underway.

Assumptions in Net Present Valuation of ExpreS²ion Biotech

SEKm	2019	2020	2021p	2022p	2023p	2024p	2025p	2026p	2027p	2030p
Sales	11	15	23	54	169	180	158	21	22	22
ABNCoV-2	14	0	23	29	405 118	173	70	36	0	0
FS2B-C001		Ū	U	55	331	-2	68	-2	95	85
platform/services	14	11	12	15	19	- 18	20	21	22	22
EBIT	-18	-29	-70	-57	411	145	128	5	7	
Cash	5	107	121	60	467	611	738			
ABNCoV-2 (EURm)		2020	2021p	2022p	2023p	2024p	2025p	2026p	2027p	2030p
Net sales				909	3 709	3 784	1 544	787	0	
EUR/dosis				15	15	15	16	16		
No. of doses, mln total of 6	596		1	60	242	245	99	50		
Exprestion milestones, EURM			I	I	0	0	0	0		
Royalty, MEUR				7	29	42	17	9	0	
Royalty rate				0,8%	0,8%	1,1%	1,1%	1,1%		
Expres2ion revenues, SEKm			10	81	288	420	172	87	0	0
Risk-adjusted			1,00	0,70	0,41	0,41	0,41	0,41	0,41	
Risk adjusted revenues, NPV (S	EKm)			29,0	118,5	172,6	70,4	35,9	0,0	
WACC	10%									
NPV, AV001 (SEKm)	324									
NPV/share, SEK	10,4									
LOA	41%									
ES2B-C001 (SEKm)		2020	2021p	2022p	Licens	2024p	2025p	2026p	2027p	2030p
Costs, preclinical / clinical		-7	-46	-54	-20	-14	0	-50	0	-75
incl milestones to Add	aptvac	-3,5	-3,5	-3,5	0	-14	0	-50	0	-75
Sales, EURm									147	921
Milestones, licensing partner	975 M	IEUR			75	0	100	0	200	200
Royalty 10%									15	92
Expres2ion revenues, SEKm					765	-14	1020	-50	998	2904
Risk-adjusted		1,00	0,75	0,56	0,56	0,23	0,11	0,10	0,10	0,10
Risk adjusted revenues, NPV (S	EKm)				331	-2	68	-2	95	85
WACC	14%									
Net present value (SEKm)	339									
NPV/share, SEK	10,8									
LOA	10%									

Summary of Adaptvac 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 prospectus

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 Human Papilloma Virus 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 responses by T-cells.

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 thus cannot infect or replicate in the human cell.

Summary of potential advantages

- Potent immunogenicity by neutralizing antibodies,
- No genetic content in the vaccine may confer better safety,
- One single shot administration may be enough,
- Long-lasting response with the cVLP adjuvant,
- Easy to handle compared to some other vaccines

COVID-19 vaccines sorted after technology platform

Protein subunit	28	32%
Viral Vector (non-replicating)	13	15%
DNA	10	11%
Inactivated Virus	12	14%
RNA	12	14%
Viral Vector (replicating)	4	5%
Virus Like Particle	4	5%
VVr + Antigen Presenting Cell	2	2%
Live Attenuated Virus	2	2%
VVnr + Antigen Presenting Cell	1	1%
	88	

Source: WHO, as of April 16

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