Funding still pending

First efficacy data for ABNCoV2

The first clinical efficacy data for the vaccine candidate ABNCoV2 were recently presented from COUGH-1, a Phase 1/2 study in healthy volunteers initiated earlier this year. ABNCoV2 showed a strong in vitro neutralizing effect on the SARS-CoV2 virus in comparison to blood of convalescent patients recently recovered from the infection.

The consortium behind the product, PREVENT-nCoV, stated in its press release that ABNCoV2 showed up to 12 times higher titers of neutralizing antibodies compared to the convalescent patients not receiving ABNCoV2. This effect is markedly stronger than what has been seen in similar studies with the approved mRNA vaccines.

Bavarian Nordic seeks funding of phase 3 trial

In July last year, commercial rights to ABNCoV2 were sold to the Danish vaccine company Bavarian Nordic. Bavarian Nordic does not intend to finance phase 3 on its own and has since sought funds in the range of DKK 2-3 billion. Among other parties, the company is in discussion with the Danish Government about reaching a tax-funded solution to the Phase 3 investment. No outcome has yet been presented from the negotiations, which may be contingent on more phase 2 data.

Proprietary portfolio moving along

Meanwhile ExpreS²ion is advancing its proprietary portfolio of vaccines. In May a lead candidate in the breast cancer vaccine program (ES2B-C001) was selected for studies in animal models. In July a phase 1b malaria prevention study was started. These projects may overtime become important value drivers for the company.

Fair value at SEK 55 / share (49)

Although initial clinical data look promising, competition from other vaccine candidates is stiffening with more than 100 projects in clinical development, according to the WHO. We maintain our forecast of a 41 percent likelihood of Bavarian Nordic succeeding in reaching the market with ABNCoV2, provided that phase 3 funding can be found. Our sales forecast is 650 million doses sold during the period 2023-27. In this report we raise our assumption of price per dose to EUR 20 from previous EUR 15, which has a positive impact on ExpreS²ion's fair value by SEK 6 to SEK 55, still leaving some upside in the near-term news flow.

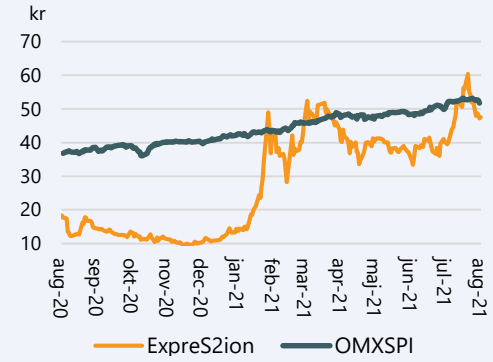
ExpreS²ion Biotech

Date	23 augusti 2021
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 50
No. of shares 2021, mln.	31,5
Market cap, SEKm	1 575
Cash 2021, SEKm	144
Web site	www.expres2ionbio.com

Kursutveckling senaste året



Source: Refinitiv

Forecasts & Key ratios, SEKm

	2019	2020	2021p	2022p
Revenues	14	15	13	22
EBIT	-18	-29	-47	-49
Net income	-17	-36	-50	-53
Earnings per share	-0,5 kr	-1,1 kr	-1,6 kr	-1,7 kr
Dividend	0 kr	0 kr	0 kr	0 kr
Revenue growth	55%	7%	12%	65%
Cash	5	107	144	92
New shares, mln	8	14	4	0
P/E ratio	neg	neg	neg	neg
Dividend yield	0%	0%	0%	0%

Source: Bolaget, Analysguiden

Investment case

Continued need for new vaccines

The need for new vaccines against COVID-19 continues to spur the development of a large number of candidates in clinical development. The recent setbacks for adenovirus-based products from AstraZeneca and J&J underscore the importance of using new technology platforms, such as AdaptVac's VLP technology, to complement the current range of mainly mRNA-based vaccines. Increasingly, the need for a third dose of vaccination against SARS-CoV2 is discussed and it is proposed in the US that certain risk populations should be vaccinated continuously every 8-12 months.

However, competition is intense and new vaccine candidates are constantly entering phase 3 studies. As illustrated by the WHO database as of August 17, 112 projects had started clinical development or reached the market, up from 88 projects in April when we published our latest report on ExpreS²ion Biotechnologies.

Strong antiviral effect in phase 1/2

Recently, first efficacy data were presented from COUGH-1, a study with the vaccine candidate ABNCoV2 on forty-five healthy volunteers. The study was primarily a safety study and showed that ABNCoV2 did not cause any unexpected side effects. Among secondary endpoints the *in vitro* antivirus effect in blood infected with SARS-CoV2 was examined. Blood tests with the vaccine candidate ABNCoV2 showed 12 times higher levels of neutralizing antibodies against the virus compared to levels in convalescent patients. The currently approved mRNA vaccines have shown a lower antivirus effect, up to 4.1 times, compared to blood from convalescent patients.

Just as importantly, blood samples showed high levels of cross-variant in vitro neutralization, in particular of delta and beta variants.

New pricing assumptions, fair value SEK 55 (49)

We have assumed that the chances for Bavarian Nordic to develop ABNCoV2 are relatively good, just over 40 percent, which of course assumes full phase 3 funding. The early clinical preparations have been slightly delayed and competition for second-line vaccine boosters is stiffening. We keep our forecasts mostly unchanged except for price per dose, which is raised to EUR 20 (15). Fair value of ExpreS²ion Biotechnologies is increased to SEK 55 (49).

Strong efficacy signal in phase 1/2

The consortium PREVENT-nCoV recently presented efficacy data from the COUGH-1 study, the first human study with the vaccine candidate ABNCoV2. Forty-five healthy volunteers aged up to 65 years were treated at a Dutch center with two doses of six different strengths (6-70 µg) of ABNCoV2 either with or without adjuvans. The primary endpoint of the study was to investigate the safety, or reactogenicity, of the substance. The substance did not cause any severe side effects in these patients and it can thus be said that outcome was positive, admitting Bavarian Nordic to move forward with its plans to start a full-scale Phase 2 study.

In addition to safety, a secondary endpoint of the study was to investigate antiviral activity of the vaccine candidate. This part of the trial has also been described as a phase 2a. Blood samples of the healthy volunteers was infected in test tubes (in vitro) with the SARS-CoV2 virus and neutralizing antibodies generated by the immune reaction to ABNCoV2 showed strong ability to kill off the virus. The measure used to detect antiviral efficacy is the titer of antibodies able to neutralize at least 50 percent of viruses present in a solution, so-called plaque reduction neutralization test (PRNT).

ABNCoV2 beats human immune system

The consortium reported that the concentration of antibodies in ABNCoV2-exposed blood was 12 times higher than the concentration seen in a control of blood from convalescent COVID patients. These control patients may consist of a mixture of unvaccinated and vaccinated, but may also vary between symptomatic, asymptomatic or hospitalized individuals, making comparisons to other trials highly difficult. Both Pfizer and Moderna have cited 3 to 4 times higher neutralizing effect of their commercially available strengths compared to blood in convalescent patients. This surrogate measure, PRNT, is considered to provide good guidance of the vaccination effect in a Phase 3 study. Phase 3 studies with Pfizer and Moderna later provisionally approved vaccines conveyed a 90-95 percent vaccination grade (prevention of COVID-19).

Even if it is difficult to compare studies using PRNT, which can consist of different assays, we believe that the reported 12 times efficacy to convalescent blood indicates that ABNCoV2 is a highly effective substance for vaccination against the SARS virus.

Competitor reports 10-fold activity in phase 2

We note that Medicago and GlaxoSmithKline recently reported that their substance, based on a different VLP technology, generated 10 times higher antibody titers compared to blood from convalescent patients in the phase 2 part. This compound is currently in a 30 000-participant phase 3 study. However, for many reasons we would like

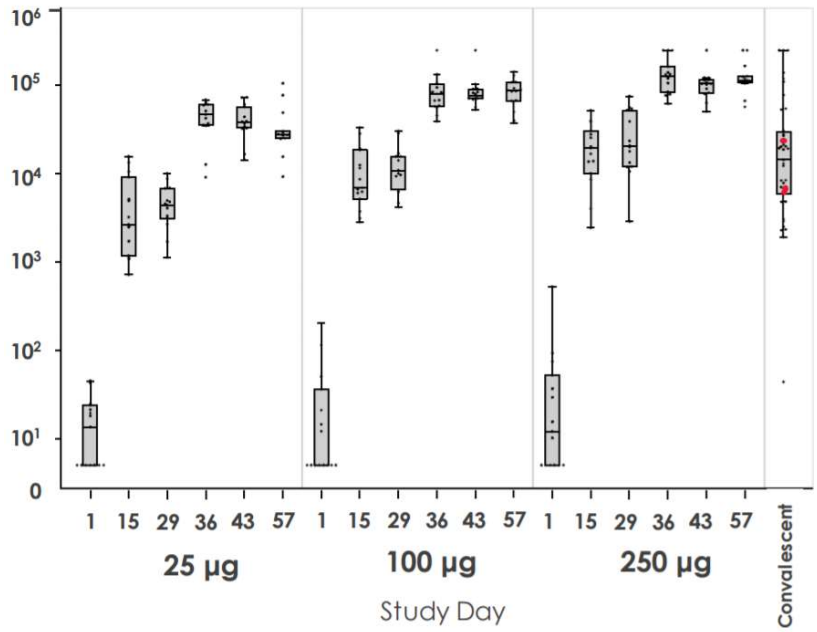
to caution comparisons of data between early studies in this area. The Medicago construct is based on a plant derivate and potentially less stable than a bacteria-based vaccine, such as AdaptVac's.

Final results expected later this year

Sponsor of the COUGH-1 study was Radboud University Medical Centre, one of the members of the PREVENT-nCoV consortium which is funded by a Horizon 2020 EU grant. 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.

Full results from the COUGH-1 study are expected later this year. Among other things, we will look in the final results for how different types of T cells, such as Th cells (CD4+) and antigen-specific CD8+, reacted to the exposure to ABNCoV2. It is a general belief among researchers that this indication may provide guidance on the duration of the antibody response to the virus. The final result may also facilitate comparison to the data on neutralizing antibodies presented by the mRNA and Novavax vaccines in similar studies.

Moderna's Phase 1 data vs convalescent patients



Source: Moderna, phase 1 interim analysis (July 15, 2020)

By comparison, the interim analysis published by Moderna on 15 July last year of data from an ongoing Phase 1 study can be mentioned. The table above shows data on three different dose strengths of Moderna's substance mRNA-1273. Longed out on the right, the stack for convalescent patients is shown, i.e. patients recovered from COVID-19 without a vaccine. The strength of 100 µg was later selected for phase 3 dose and is now the dose commercially available.

This strength showed at day 43 a 4.1-fold level of neutralizing antibodies compared to samples from the convalescent patients.

In Pfizer's Phase 1 study, BNT162b2, later named Comirnaty, showed concentrations of 1.7-4.1 times the levels in recovered COVID-19 patients without vaccines, i.e. on par with Moderna's Phase 1 data. The dose strength then selected for phase 3 trial had, as far as we can assess, 3.3 times higher levels of neutralizing antibodies than recovered blood.

Bavarian Nordic to finance phase 2 study

As from now Bavarian Nordic will take full responsibility for the development of ABNCoV2. Bavarian will conduct a Phase 2 study and has received go-ahead from the German Regulatory Authority (BfArM). The study will include 150 adults immune to the SARS-CoV2 virus either after vaccination or previous disease. Another 60 patients with no prior vaccination or disease will be studied in a second arm. The first arm will investigate ABNCoV2 as a booster of already vaccinated individuals, which is the most likely indication to go for in a future phase 3 study. Initial results will be presented in the fourth quarter of this year.

Bavarian Nordic will also start to scale up production volumes in preparation of phase 3 clinical development in several thousand patients. We estimate that both of these measures will cost DKK 200 million each, i.e. 36 percent of the cash raised in Bavarian Nordic's latest rights issue in March this year.

Means to fund phase 3 still lacking

More importantly, in parallel with preparations for the Phase 2 study, Bavarian Nordic continues to seek funding for a pivotal Phase 3 program. We estimate that a Phase 3 study of the booster effect with ABNCoV2 needs to include 4,000-5,000 individuals, corresponding to a cost of 200-300 million EUR.

It is known that Bavarian Nordic is in negotiations with the Danish Government to find third party to fund a Phase 3 program. Other possible sources of funding could be an EU-funded Phase 3 program. According to the European Commission's website, funds equivalent to EUR 350 million have so far been allocated to the development of new COVID vaccines, including vaccines from BioNTech Curevac and Immunic. However, we are not aware of the EU funding an entire phase 3 program.

It is possible that a third-party investor likes to see the full phase 2 data package before assigning financing a phase 3 trial, in which case an announcement of a partner still may have to wait for some more time. In many other phase 3 programs with COVID-vaccines the sponsor simply has rolled over seamlessly from phase 2 in accordance with the fast-track procedures. What is particular to ABNCoV2 is the

fact that the phase 2 sponsor, Bavarian Nordic, has declared that it will not finance the phase 3 on its own.

Another source of funding would be CEPI, the Coalition for Epidemic Preparedness Innovations, which was launched in 2017 to develop vaccines to stop future epidemics. However, CEPI has recently more focused on vaccine development outside the Western Economies.

We estimate the cost of a Phase 3 program at approximately EUR 200 million, excluding additional investments in manufacturing capacity, an investment that may amount to similar amounts. Bavarian Nordic would thus avoid the kind of phase 3 investments made by companies such as Novavax, with 50,000 patients at a total cost of more than USD 2 billion, covered by CEPI grants and new share issues.

Financial discussion and valuation

Prior to the recently released Phase 1 data, we had assumed a 95 percent probability of a successful outcome and the initiation of subsequent Phase 2 study. The only major adjustment in this report is that we increase our assumption of price per dose to 20 EUR from the previous 15 EUR. We believe that an effective booster vaccine should not have any difficulty pricing itself at least in line with the current mRNA vaccines. We have also pushed the potential launch of the vaccine in to early 2023.

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	339	10,8	1 171	10%	14%	100%	
Royalty, ABNCoV2	404	12,9	13 685	41%	10%	100%	11% of Adaptvac
Adaptvac holding	779	24,9		41%	10%	34%	of DCF value
Platform	67	2,1	1,5	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	1 729	55	*based on the no. of shares by end of 2021, mln*				*31,3*

**) Likelihood of approval*

Forecasts by Analysguiden

The new dose pricing assumption for ABNCoV2 leads us to raise fair value of ExpreS²ion Biotechnologies to SEK 55 per share from previous SEK 49. In our view a forecasted sale of 650 million doses of ABNCoV2 during 2023-27 should be seen as a realistic scenario for a strong booster vaccine with limited upside at this point in time. In other words, the stock is approaching its fair value but there are still triggers that could send the stock above our 55 SEK in the short term. We see primarily three short-term triggers:

1. Today's announcement that Bavarian Nordic has received German approval to start a phase 2 study,
2. More interim data from the phase 1/2 trial,
3. Bavarian Nordic reaching agreement on third-party funding for a phase 3 program, approximately EUR 200-300 million

Discounted after tax and a 41 percent chance for ABNCoV2 to reach approval the valuation of AdaptVac ends at SEK 2.3bn, of which ExpreS²ion holds 34 percent or SEK 25 per share. In this valuation we have only included the potential cash pile from ABNCoV2, but not assigned a value to Adaptvac's technology platform. In principle, we include two different components of potential revenue streams from ABNCoV2:

- 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 below, we show that ExpreS²ion's royalties per share from Bavarian Nordic's commercial sales can amount to SEK 49 / 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 25 SEK / share. If our scenario materializes, AdaptVac will turn into a large money bag of milestones and royalties from Bavarian Nordic.

ExpreS²ion exposure to ABNCoV-2, three scenarios

	Slow scenario	Main scenario	Strong scenario	Comments
Aggregated sales , EURm	6 000	13 685	19 000	663 mln doses sold in main scen
EUR per dosis	20	21	21	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	46	151	272	Over period 2023-2027
in SEKm	*467*	*1 520*	*2 744*	
Milestone from Adaptvac, SEKm	20	20	20	EUR 2m in 2021-22
ExpreS²ion revenues, SEKm	487	1 540	2 764	
SEK/share	15,5	49,2	88,3	
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	5,2	16,5	29,6	Not discounted, see SoTP

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

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.

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 focus will remain on the COVID-19 vaccine and efforts to finance a phase 3 program.

Assumptions in Net Present Valuation of ExpreS²ion Biotech

SEKm	2019	2020	2021p	2022p	2023p	2024p	2025p	2026p	2027p	2030p
Operating income	14	15	13	20	484	239	175	14	15	15
ABNCoV-2		*0*	*5*	*10*	*134*	*230*	*94*	*72*	*18*	*0*
ES2B-C001					*331*	*-2*	*68*	*-2*	*95*	*85*
platform/services	*14*	*11*	*5*	*10*	*19*	*12*	*13*	*14*	*15*	*15*
EBIT	-18	-29	-47	-91	426	196	145	3	4	
Cash	5	107	144	49	472	666	810			

ABNCoV-2 (EURm)	2020	2021p	2022p	2023p	2024p	2025p	2026p	2027p	2030p
Net sales			0	4 204	5 045	2 058	1 575	803	
EUR/dosis			*20*	*20*	*21*	*21*	*21*	*21*	
No. of doses, mln total of 663			*0*	*206*	*245*	*99*	*75*	*38*	
ExpreS²ion milestones, EURm		1	1	0	0	0	0	0	
Royalty, MEUR			0	32	55	23	17	4	
Royalty rate			*#DIV/0!*	*0,8%*	*1,1%*	*1,1%*	*1,1%*		
Expres2ion revenues, SEKm		10	10	327	560	229	175	45	0
Risk-adjusted		*1,00*	*0,70*	*0,41*	*0,41*	*0,41*	*0,41*	*0,41*	
Risk adjusted revenues, NPV (SEKm)			0,0	133,9	229,5	93,7	71,7	18,3	

WACC	10%
NPV, AV001 (SEKm)	404
NPV/share, SEK	12,9
LOA	41%

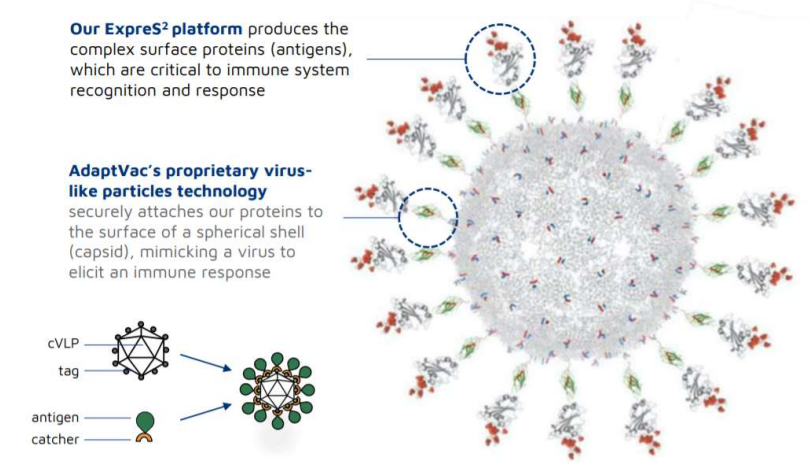
ES2B-C001 (SEKm)	2020	2021p	2022p	*Licens*	2024p	2025p	2026p	2027p	2030p
Costs, preclinical / clinical	-7	-6	-54	-20	-14	0	-50	0	-75
incl milestones to Adaptvac	*-3,5*	*-3,5*	*-3,5*	*0*	*-14*	*0*	*-50*	*0*	*-75*
Sales, EURm								147	921
Milestones, licensing partner 975 MEUR				75	0	100	0	200	200
Royalty 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 (SEKm)				331	-2	68	-2	95	85

WACC	14%
Net present value (SEKm)	339
NPV/share, SEK	10,8
LOA	10%

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 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, 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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