UPPDRAGSANALYS

Broadening the portfolio

Acquisition of preclinical breast cancer vaccine

ExpreS²ion Biotech broadens its portfolio by acquiring full ownership of AV001, a preclinical project to develop a breast cancer vaccine. The proposed new share issue should cover development costs up to phase 2b. At the same time, the corona vaccine is making rapid headway, knocking on the door of a phase 3 study within two quarters. In conjunction, ExpreS²ion Biotechnologies and Adaptvac separate their structures in a settlement over AV001, currently under development by Adaptvac. ExpreS²ion assumes full control of AV001 and at the same time reduces its holding in Adaptvac by 16 percentage points to 34 percent.

Royalty on the PREVENT-nCoV vaccine

Adaptvac's deal with Bavarian Nordic in July over the vaccine candidate developed in the PREVENT-nCoV consortium shows that ExpreS²ion's royalty rate at the launch of the vaccine ends up in low single-digit numbers, between 1-2 percent according to our calculation. The project is advancing very rapidly towards a phase 1/2a study starting during the last quarter of the year. The Phase 2b / 3 study can then start already during the first quarter of next year, even before publishing the results of the first study.

Dilution offset by new prospects

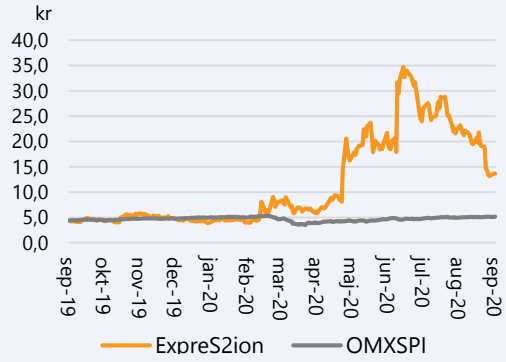
In the short term, the ExpreS²ion share price is likely to be hampered by the new share issue and subscription rights, but new information about the financing of Bavarian's phase 3 study can quickly change that conditions. A setback for any of the most advanced candidates, now 30 vaccines in clinical trials, could also affect the landscape facing Bavarian Nordic. A launch of the company's covid vaccine, which is based on a technology not in use by the most advanced participants in this race, may be possible as early as the end of next year.

To reflect new conditions in the corona vaccine race, as well as Bavarian Nordics chances of receiving external funding of a phase 3 trial, we are raising our peak sales potential of the vaccine, assigning a 26 percent chance of approval under an accelerated development pathway. Our summation of the company's project NPV values ends up at SEK 24, of which the engagement in the corona vaccine accounts for SEK 10 (royalties and 34 percent holding in Adaptvac). After the proposed financing of a clinical program for AV001 we include 8 SEK/share in the SoTP.

ExpreS²ion Biotech

Date	3 september 2020
Analyst	Sten Westerberg
Facts	
Industry	Drug 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	13,5 kr
No. of shares 2021, mln.	30,9
Market cap, SEKm	417
Net cash 2021, SEKm	89
Enterprise value (EV)	328
Web site	www.expres2ionbio.com

Share price development, -1y



Source: Refinitiv

Forecasts & Key ratios, SEKm

	2018	2019	2020p	2021p
Revenues	9	14	15	27
EBIT	-18	-18	-46	-54
Net income	-17	-17	-26	-58
Earnings per share	-0,5 kr	-0,5 kr	-0,8 kr	-1,9 kr
Dividend	0 kr	0 kr	0 kr	0 kr
Revenue growth	12%	56%	12%	78%
EBIT margin	-206%	-130%	-297%	-196%
Cash	6	5	93	89
New share issues	19	8	134	55
P/E ratio	neg	neg	neg	neg
Dividend yield	0%	0%	0%	0%

Source: Bolaget, Analysguiden

Investment case

Deal with Adaptvac reduces portfolio risk

ExpreS²ion is broadening its portfolio by exercising an option from its partner Adaptvac to take control of full rights to the preclinical project AV001, a therapeutic breast cancer vaccine. The large exposure in the valuation that the company previously had to Adaptvac's corona vaccine decreases and AV001 becomes an almost equally important part of our Sum-of-The-Parts–valuation. The listed entity ExpreS²ion Biotech Holding AB holds 100 percent of ExpreS²ion Biotechnologies ApS, the operative entity based in Horsholm, Denmark.

To enable this reallocation of the company, the Board proposes a new share issue of SEK 131 million with preference for shareholders to be subscribed for during October at SEK 12. The offer includes two warrants for free, TO4 and TO5, which during the next year can bring in an additional SEK 22-80 million depending on the share price development.

Reduced ownership in Adaptvac

In order to exercise its option, ExpreS²ion pays a fee of SEK 3.5 million. The bulk payment is made by the transfer of 16 percentage points of its ownership in Adaptvac to the other shareholders of Adaptvac. We interpret this transaction as being done without any cash consideration to ExpreS²ion. Following the transaction, ExpreS²ion will own 34 percent of the shares in Adaptvac compared to the previous 50 percent.

After the July agreement between Adaptvac and Bavarian Nordic, the responsibility for further development of the PREVENT-nCoV corona vaccine will be transferred to Bavarian Nordic, an integrated vaccines company with majority of its commercial operations in US. A Phase 1/2a study is expected to begin already in the fourth quarter of this year. As early as the first quarter of 2021, Bavarian expect to advance the project to large Phase 3 studies. This ultra-rapid drug development has been made possible by the governmental vaccine demand against the corona virus, which keep the world economy in a choke hold. Decisive in the short term will be how Bavarian Nordic solves the financing of the large phase 3 study, which we estimate can cost up to USD 400 million. An application for support from CEPI, Coalition for Epidemic Preparedness Innovations, has been submitted, but other avenues for soft financing are also open.

Minor increase in Sum of the parts

We are raising our sales assumptions and the likelihood of approval (LOA) of the PREVENT-nCoV project. We see the AV001 advancing towards clinical trials and becoming an important value driver in the long term. These adjustments compensate by a small margin the close

to doubling in number of shares following the proposed new share issue. Our summation of the various project values in the company amounts to SEK 24 in a 'base case', SEK 1 higher than our previous Sum-of-The-Parts.

New share issue creates new focus

ExpreS²ion Biotech's proposed new share issue and the management's intention to exercise the AV001 option creates a new focus in the company. AV001 is emerging as an important value driver alongside the covid-19 vaccine and we believe that the proceeds gives the company the possibility to bring AV001 up to clinical phase 2b. At present, the partner Adaptvac owns the full rights to AV001 and ExpreS²ion's ownership in the project is indirect via the company's shareholding in Adaptvac.

ExpreS²ion made it clear early on that it was investigating the possibility of financing an acquisition of the full rights to AV001. With the Adaptvac agreement, which we expect to enter into force this year, ExpreS²ion will reduce its ownership in Adaptvac to 34 percent from the previous 50 percent. ExpreS²ion will also pay SEK 3.5 million to exercise the option and will pay minor milestones to Adaptvac as AV001 advances in clinical development.

The company also proposes a new share issue with preference for shareholders of SEK 131 million with a subscription period in October this year. The issue is fully guaranteed and corresponds to a subscription price of SEK 12 per share. Linked to the new share issue, two warrants will be distributed, TO4 and TO5, which together in 2021 can bring in between SEK 22-80 million. With the proceeds, the company will have resources to:

- Invest in preclinical and clinical trials for AV001, where we expect the funds to be sufficient to complete at least Phase 2a;
- Continue to cover the costs of ExpreS²ion 's contribution to the PREVENT-nCoV consortium (covid-19), including the company's optimization of the vaccine antigen,
- Move forward one or more of the projects for an influenza vaccine,
- Promote one or more of the company's clinical projects for vaccination against malaria,
- Strengthen the company's opportunities to invest in various activities both internally and with Adaptvac.

Clarity about PREVENT-nCoV

The financial data released regarding ExpreS²ion's involvement in the PREVENT-nCoV consortium strengthens a picture of a continued large commercial commitment. The responsibility for the project falls at the Danish vaccine company Bavarian Nordic with the agreement that Adaptvac and Bavarian entered into on 22 July.

We had expected that the agreement would bring a minor milestone to ExpreS²ion as well, but instead the compensation will almost exclusively be paid for as royalty, when the vaccine is approved for sale. If all goes well in clinical studies, approval may be possible as

late 2021 or early 2022, reflecting the accelerated avenues for vaccine development allowed for during the ravaging covid-19 pandemic. We had expected that the agreement would bring a smaller milestone also to ExpreS²ion, but instead the compensation will for the most part be paid as royalty, when the vaccine is approved for sale.

Commercial outcome ExpreS²ion, different scenarios

	Weak scenario	Main scenario	Strong scenario	Comments
Aggregated sales , EURm	3 000	5 807	9 000	Total amount of doses >500m
EUR per dosis	12	12	12	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 from vaccine sales	*0,8%*	*1,1%*	*1,4%*	
ExpreS²ion revenues, EURm	23	64	129	Over period 2022-2026
in SEKm	*231*	*639*	*1 287*	
Milestone from Adaptvac, SEKm	20	20	20	EUR 2m in 2021-22
ExpreS²ion revenues, SEKm	251	659	1 307	
SEK/share	8,1	21,3	42,3	
Tax rate	21%	21%	21%	Assuming full taxation
Likelihood of Approval (LOA)	26%	26%	26%	40 % phase 1/2, 65 % phase 3
Risk-adjusted after tax, SEK/share	1,7	4,4	8,7	Not discounted, see SoTP

Forecasts by Analysguiden

Royalty-driven model

In the table above, we show that ExpreS²ion's cash flow per share from PREVENT-nCoV can amount to SEK 21 / share in our derisked main scenario. Risk-adjusted and after tax, income amounts to SEK 4.4 / share. To this value must be added ExpreS²ion's stake in Adaptvac, which will be 34 percent after the exercise of the AV-001 option. If our scenario materializes, Adaptvac will turn into a large bag of money derived from milestones and royalties from Bavarian Nordic. In this situation, we expect that Adaptvac in 2024 will be able to distribute 75 percent of the company's cash position, which by then estimate at approximately SEK 4 billion.

In our main scenario, we expect ExpreS²ion to receive 1.1 percent of total vaccine 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 to ExpreS²ion, which is a weaker outcome than what we outlined in the previous report. On the positive side, it is noticeable that our assumption of the likelihood of approval in the current corona landscape and after the Bavarian deal is substantially improved. We estimate the chances of an approved vaccine (LOA) to be 26 percent when the clinical phase 1 study begins in last quarter of this year. The final phase 3 study, involving 10,000s of patients, is planned to start during the first quarter of 2021 and be run in parallel with a phase 2 safety study.

Preclinical data "at least on par" with competitors

The company's report in June on the preclinical results sounds very positive, which is reflected in the Bavarian deal. After immunization in mice with the VLP displayed ExpreS²ion antigen or Receptor Binding Domain, high-level antigen-specific antibody responses were measured after even a single vaccination. The mice's ability to neutralize the virus was reported to be "at least on par" with published preclinical data on other COVID-19 vaccines.

Bavarian has commented that they expect Adaptvac's vaccine to work just as well in on young people as on old people, which is not something all vaccines can achieve. We also note that the vaccine so far has not been boosted by an added adjuvant, a kind of trigger substance that is often added to a vaccine to set off an initial reaction of the immune system.

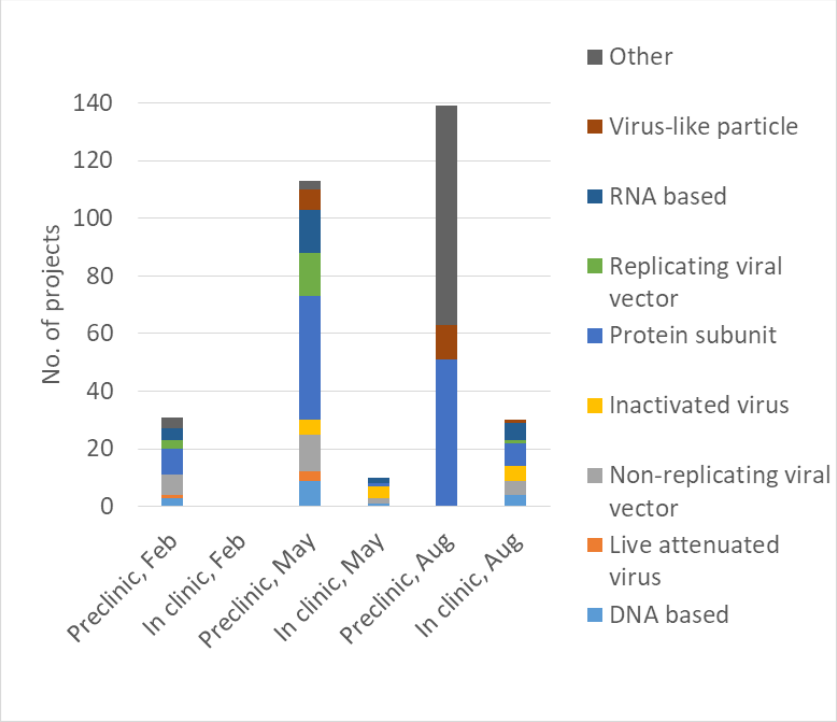
Decision on phase 3 financing close

In order for Bavarian to be able to initiate a very costly phase 3 study, the company has said that it is seeking a grant support from CEPI, the global network Coalition for Epidemic Preparedness Innovations. A Phase 3 study on large patient groups can be expected to cost $ 300-500 million, which Bavarian is unlikely to invest out of its own cash.

CEPI has currently granted money to nine different vaccine-developing pharmaceutical companies, both for clinical trial and ramp up of manufacturing. Another nine candidates have applied in a second round and it remains to be seen if Bavarian Nordic is included in this group. We expect a decision from CEPI already this September, but it is important to emphasize that support for phase 3 development of a vaccine may come from other sources both within CEPI and from other public or private investors, such as pharmaceutical companies.

CEPI's goal is to help end the acute phase of the corona pandemic in 2021 and therefore emphasizes the importance of speed in clinical development. It is possible to speculate that this accelerated development path may result in vaccines taking the safe road before the unsafe, i.e. do not become as effective as an ordinary influenza should be. It is also possible to speculate that the probability of success in these projects is slightly higher than for the average vaccine.

WHO register increase in number of tested corona projects



Source: WHO

30 vaccine projects in clinical testing

In the table above, we show the WHO's current data as of August 22 on the number of corona vaccine projects that are under development. Since May, when ten projects were in the clinical phase, the number in the clinical phase has risen to 30, of which six have begun decisive phase 3 trials. In May, no projects with phase 3 status were specified. This ultra-rapid advance towards several ready-made vaccines is unparalleled in the history of drug development.

One of the 30 projects that went into clinical trials in June is based on the VLP technology, a technology also applied by Adaptvac. The company in early clinical testing is the Canadian entity Medicago. However, the WHO describes Adaptvac's technology as a 'protein subunit' platform, which makes a comparison with VLPs more uncertain. The projects are sorted by the type of technology platform used to produce antigen, the vaccine's most active ingredient.

CEPI emphasizes speed in its prioritization

Bluntly, vaccine development can be described on the basis of two axes: one denoting speed, another effect. A third axis with product safety could make this diagram three-dimensional. The global network Coalition for Epidemic Preparedness Innovations (CEPI) emphasizes in its reports that speed is important at this stage. CEPI identifies DNA and RNA based platforms as the fastest for developing a vaccine. With this yardstick, US based Moderna and the Pfizer-led consortium would be best ones placed to develop a vaccine with their respective RNA platforms. Both companies are in phase 3 together along with another competing project, AstraZeneca's ChAdOx1-S.

In addition to these three competitors, there are three Chinese projects, all of which are based on inactivated viruses, i.e. viruses no longer capable of replicating its DNA. A disadvantage of DNA and RNA-based platforms, as well as inactivated viruses, is that the final product, the finished vaccine, contains genetic material, which can increase the risk of side effects and the development of resistance. We believe that this ensures that other platforms, such as VLP mounted antigens, which may need a little more time in development, will also have a fair chance to be approved in order to broaden the supplied vaccine range.

AV001 in preclinical phase

AV001 is being developed in preclinical tests to treat HER2-positive breast cancer in women. Patients with this form of breast cancer have tumors that express elevated levels of the protein Epidermal Growth Factor Receptor 2 (HER2). About 20 percent of all breast cancers are HER2-positive. This form is also one of the more aggressive forms and responds poorly to traditional anti-hormonal treatment.

The outlook for these patients improved significantly in 1998 when Genentech received approval for its Herceptin (trastuzumab) antibody therapy. Nearly half of the patients receiving Herceptin respond to treatment. Nevertheless, poor prospects remain for a large proportion of HER2-positive patients and this medical need is in focus for the AV001 project.

The commercial potential of a therapeutic vaccine against HER2-positive breast cancer is huge. For the time being, we expect that AV001 in its first stage will be developed as a second line therapy for patients who do not respond to generic trastuzumab. Several products are being developed to enter the market, but these consist of antibodies or small-molecule compounds of the tyrosine kinase inhibitor type. We do not know of a therapeutic vaccine that is being developed actively in late clinical stage, while a few previous trials have been aborted.

AV001 is in preclinical phase and it remains to perform proof-of-concept animal studies on mice. If the project meets the set criteria, phase 1 / 2a trials on humans can be initiated during the first half of 2022.

Financial discussion and triggers

The proposed rights issue entails a recast of ExpreS²ion Biotechnologies. It ends the cash constraints and allows for creating value in the AV001 project. This new situation compensates for the slightly weaker outcome of the Bavarian deal, at least in comparison with our assumptions.

The risk in the company is diluted over two major assets, PREVENT-nCoV and AV001. In the short term, however, the focus on the covid vaccine rally will dominate. During the fourth quarter of this year, Adaptvac, now owned by ExpreS²ion to 34 percent, is expected to begin phase 1 / 2a studies, which are funded within the framework of the original PREVENT-nCoV consortium. Already during the first quarter of next year, Bavarian Nordic's plan is to start phase 3 studies, provided that the company has obtained financing. A positive note from CEPI in September granting Bavarian funding for its Phase 3 study would mark an important milestone. However, we assume that Bavarian Nordic, while CEPI is evaluating the all candidates, also will inquire other possible sources of funding.

If and when the vaccine begins a clinical trial, we believe that the chances of approval exceed the ordinary 5-10 percent that is generally assumed for early-stage pharmaceutical assets. We argue that solid preclinical data as well as a derisked development path could be a good start for an early stage vaccine and project a 26% probability that Bavarian Nordic will be able to reach the market.

Sum-of-The-Parts valuation

	Project value (MSEK)	Value / share (SEK)	Peak sales (MEUR)	LOA	WACC	Share of NPV	Comments
AV001 (breast cancer)	253	8,2	1 171	10%	14%	100%	
Royalty, PREVENT	121	3,9	5 807	26%	10%	100%	12% av Adaptvac roy
Adaptvac, dividend	251	6,1		26%	10%	75%	utdelas 2024
Platform	120	3,9	2,6	100%	7%	100%	av intäkterna
Malaria project	40	1,3	175	12%	14%	10%	av konsortiet
Indigo (influenza)	30	0,6	952	5%	12%	8%	av konsortiet
Summering	562	24,0					
No. of shares:	*30,9 mln by end of 2021*						

The valuation of ExpreS²ion's 34% holding in Adaptvac has been included as a future dividend of 75 percent of the cash that Adaptvac would accumulate by 2024 if the vaccine reaches the market. At that time, the cash pile may amount to SEK 4 billion. However, the valuation of Adaptvac holdings is surrounded by various uncertainties, partly because we are not aware of the company's agreements with other parties in the consortium.

Our summation of the values in the individual projects amounts to SEK 24, corresponding to the upper part of the range of the subscription price for TO5, which starts running in September next year. By that time, data from the phase 1 / 2a study are published and allow PREVENT-nCoV to be compared with competing projects.

A triggers in the short term, in addition to information about Bavarian's funding of the phase 3 study, is the start of phase 1 / 2a, which is expected during the last quarter of the year. It is also likely that news flow from the most advanced vaccines in phase 3 will start

to have some impact on the Bavarian as well as the ExpreS2ion share price. In the short term, we do not expect any miracles from the share price, as the new issue will be subscribed for at SEK 12 in October, but after this fully guaranteed issue, we expect a return to the SEK 20 mark.

Assumptions in Net Present Valuation of ExpreS²ion Biotech

SEKm	2019	2020p	2021p	2022p	2023p	2024p	2025p	2026p	2027p	2030p
Sales	13,8	15,4	27,4	61,1	341,8	72,2	112,7	25,2	26,4	26,4
PREVENT-nCoV		*0*	*10*	*43*	*49*	*52*	*28*	*7*	*0*	*0*
AV001					*271*	*-2*	*61*	*-2*	*86*	*77*
platform/services	*14*	*12*	*14*	*18*	*22*	*22*	*24*	*25*	*26*	*26*
EBIT	-18,1	-24,1	-57,1	-22,3	291,9	28,3	82,8	6,3	7,9	
Cash	5	93	89	66	357	384	466			

PREVENT-nCoV	2020p	2021p	*Lansering*	2023p	2024p	2025p	2026p	2027p	2030p
Sales, EURm			1 515	1 560	1 393	883	455	0	
EUR/dosis			*11*	*11*	*12*	*12*	*12*		
No. of doses, mln total of 502			*135*	*136*	*119*	*74*	*37*		
ExpreS²ion milestones, EURm		1	1	0	0	0	0		
Royalty, MEUR			13	19	20	11	3	0	
Royalty rate			*0,8%*	*1,2%*	*1,4%*	*1,2%*	*0,6%*		
Expres2ion revenues, SEKm		10	137	187	201	106	27	0	0
Risk-adjusted		*1,00*	*0,40*	*0,26*	*0,26*	*0,26*	*0,26*	*0,26*	
Risk adjusted revenues, NPV (SEKm)			33,1	48,7	52,2	27,6	7,1	0,0	

WACC	10%
NPV, AV001 (SEKm)	121
NPV/share, SEK	3,9
LOA	26%

AV001 - SEKm	2020p	2021p	2022p	*Licens*	2024p	2025p	2026p	*Lansering*	2030p
Costs, preclinical / clinical	-7	-46	-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	875	2904
Risk-adjusted	*1,00*	*0,75*	*0,53*	*0,53*	*0,21*	*0,12*	*0,10*	*0,10*	*0,10*
Risk adjusted revenues, NPV (SEKm)				271	-2	61	-2	86	77

WACC	14%
Net present value (SEKm)	253
NPV/share, SEK	8,2
LOA	10%

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Responsible analyst:

Sten Westerberg