

ExpreS2ion Biotech

expreS2ion
BIOTECH

Market: Nasdaq First North Sweden

Ticker: EXPRS2

Share price (SEK): 0.90

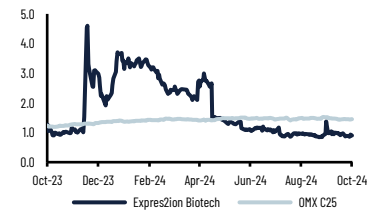
Market cap (SEK): 74.9m

Net cash (SEK): 97m (Q2'24)

Enterprise value (SEK): N/A

Note*: includes gross proceeds from rights issue of around SEK 30m

Share information*



Ytd -57.5% 1 year: -29.4%
1 month: -23.2% 3 year: -97.8%

Note: *We apply the closing price from 19 October 2024
Index rebased to October 2023. Source: S&P Capital IQ

Financials

(SEKm)	2022	2023	2024E*
Revenue	6.2	8.8	8.0*
Revenue growth	-58.0%	43%	N/A
Research & Development	-71.3	-51.4	N/A
EBIT	-127.6	-106.0	-27.0*
Cash flow from operations	-99.6	-100.1	N/A
Cash position	110.9	57.6	N/A

Note: *) One analyst estimate

Pipeline

Product Candidate	Phase I	Phase II	Phase III
HER2 cVLP (Breast cancer)	CTA submitted		
Cytomegalovirus* (CMV)	Pre-clinical		
Hemagglutinin* (Influenza)	Pre-clinical		
Malaria Blood stage** (RH5.1)	Completed	ongoing	

Note: *Collaboration agreements; CMV collaboration with Evaxion Biotech, ExpreS2ion has right to license; Influenza collaboration with University of Copenhagen. **Project is conducted by the University of Oxford under a Clinical License Agreement

Company description

ExpreS2ion Biotech is a Nasdaq First North Listed biotechnology company with operations in Denmark, with a vaccine technology platform with applications in proprietary, and partner/customer-driven assets (drug candidates). ExpreS2ion's lead, and self-owned candidate, ES2B-C001, is a HER2+ therapeutic vaccine for breast cancer, currently preparing for Phase I trials in early 2025. ExpreS2ion leverages its proprietary ExpreS2 platform for protein expression to support ongoing collaborations in vaccine development across diseases such as CMV, malaria, influenza, and Nipah virus.

The company previously contributed to the successful development of a Phase III validated COVID-19 booster vaccine, licensed by Bavarian Nordic, in partnership with AdaptVac, of which ExpreS2ion owns 34%. AdaptVac's capsid virus-like particle (cVLP) technology forms the foundation of these vaccine efforts, ensuring safe and effective vaccine production.

Investment case

Although not a one-product company, the huge shareholder value creation lies in the progression of its ES2B-C001 breast cancer vaccine candidate, given its unmet need within HER2+ breast cancer therapy, and very large addressable market at around USD 10bn^[1] annually based on current treatments.

The ES2B-C001 vaccine targets the HER2+ protein, associated with a more aggressive, higher recurrence, and higher mortality rate disease. The ES2B-C001 vaccine targets multiple HER2+ epitopes sites vs existing therapies (1-2 epitopes) of the HER2-ECD. Existing monoclonal therapies have been associated with resistance, (which pre-clinical data has overcome), and additional adverse cardiac effects. An elongation of progression free survival (PFS) or reduced cardiac effects would offer a significant advantage.

From a valuation perspective, a DCF-modelling approach is considered appropriate. Based on the assumptions discussed on pages 2 and 3, the model suggests a market-implied probability of success (POS) of around 3%, which compares to an average historical likelihood of a phase I pipeline project attaining marketing approval of around 7%. Our bear and bull case indicate a POS of 5.5% and 1.5%, respectively. Our valuation includes a small value to the technology platform and ExpreS2ion's 34% ownership of AdaptVac, but currently excludes other early-stage pipeline candidates and also excludes cash. As the lion's share of the valuation is derived from a single candidate, assumptions are detrimental to the implied value.

Source 1: <https://www.globaldata.com/store/report/her2-breast-cancer-market-analysis/>

Key investment reasons

The breast cancer vaccine candidate ES2B-C001 offers two notable advantages over typical early-stage candidates. First, its ExpreS2 protein and AdaptVac cVLP virus platforms, have been validated in a large-scale Phase III trial via the ABNCoV2 COVID-19 vaccine. Second, ES2B-C001's polyclonal approach targets multiple epitopes and when combined with the proven cVLP platform, may overcome issues of limited durability due to triggering a greater immune response. This reduces "me-too" competition risk and eases market access if marketing authorization is achieved.

The HER2+ protein targeted by the ES2B-C001 candidate also plays a role in other cancer types, such as HER2-low breast cancer and HER2+ gastro-esophageal junction cancer (GEJ). While ExpreS2ion's vaccine is too early phase to attribute value to possible wider uses it highlights additional platform potential down the road.

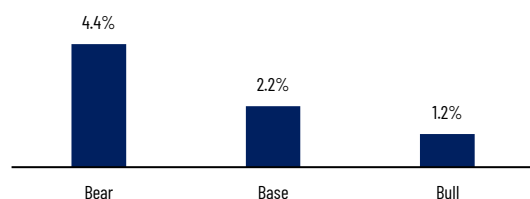
Having assigned a CRO and filed a Clinical Trial Application (CTA) in August, the company expects its Phase I trials to commence in Q1 2025, which should increase the likelihood of value-adding study data/news flow over the following 12-20 months. Clearance of the trial application expected in Q4 2024 is the next upcoming milestone, which could further de-risk the timeline.

Key investment risks

Drug development is generally high-risk, and ExpreS2ion's primary pipeline candidate is currently in the early phases. Investing in the company, therefore, requires patience and high risk appetite.

Despite having a healthy cash position with runway into 2025, there is a risk of further capital raises, in addition to the current TO 10 and TO 11 warrant programs, before potentially reaching a partnership agreement in 2026/2027. The capital and runway situation depends on the development in the share price and, therefore, short-term news flow since funding via the two warrant programs is based on a price set at a discount to the market price in the two-weeks preceding the subscription periods. Shortfalls in the capital raised by the warrant programs may be counteracted by a bridge loan or grants. However, if the funding gap is significant a further dilutive capital raise may be necessary.

PoS - Bear/Base/Bull Scenarios



Appendix – Discussion of assumptions in DCF-model

The model

This one-pager does not aim to set a price target for ExpreS2ion Biotech shares but instead offers investment perspectives using a simplified Discounted Cash Flow (DCF) model. Through scenario simulations, the model estimates the degree to which ExpreS2ion Biotech's current market capitalization reflects the implied probability of success (PoS) for its ES2B-C001 breast cancer vaccine. The DCF model projects future cash flows based on key assumptions aligned with management's assumptions, where possible. See more below.

Despite its early stage the majority of ExpreS2ion's value comes from in its ES2B-C001 HER2+ vaccine pipeline candidate, as it addresses an unmet need in a very large breast cancer market. Additional value lies in ExpreS2ion's technology platform for developing hard-to-express proteins, its 34% stake in AdaptVac, with its cVLP vaccine platform. We isolate the market-implied POS for ES2B-C001, by subtracting the NPV (net present value) of the technology platform and Adaptvac of around SEK 0.5/share from the market value (adjusted for warrants), resulting in a residual market-implied value for ES2B-C001. Additional value lies in ExpreS2ion's collaboration/partner vaccine candidates (influenza, Nipah virus, and CMV), however are currently excluded from our model due to their early stage. The recent Serum Institute of India partnership for the Phase II RH5.1 malaria project is expected to yield low single-digit royalties if approved, however, we currently focus solely on the ES2B-C001 candidate. The probability of success for ES2B-C001 can be benchmarked against the average historical phase I to full marketing approval success rate of around 7%, according to biostatistics.

Market size and market growth

The ES2B-C001 vaccine candidate addresses the HER2+ protein, expressed in 20-25% of all breast cancer incidences and with an annual market size of around USD 10.4 billion^[1]. Breast cancer incidence is rising annually due to aging populations and demographic changes, with an estimated growth of 3.2% in 2024-2030 and 1.6% in 2030-2040^[2], which guides our market growth expectations. Unhealthy western lifestyles may exacerbate this rate. We assume that ExpreS2ion patent protection will expire in 2041, reflecting a 25-year period after AdaptVac's cVLP 2016 patent filing, and expect revenues to decline post-expiry due to competition and price reductions. We, therefore, model a terminal growth rate of -25% to appropriately discount the patent expiry.

Market share and revenue

ExpreS2ion Biotech forecasts significant market potential for its therapeutic ES2B-C001 HER2+ vaccine based on strong pre-clinical trial efficacy data and lack of alternatives to resistance against existing monoclonal antibody therapies. ExpreS2ion expects peak market ES2B-C001 revenues of around EUR 2.8bn, reflecting a peak market share of around 20%, based on our model assumptions; also the peak market share applied in our base case. We anticipate a linear market share development over a 5-year period from a base-case scenario launch date of 2032. We adjust the launch date by +/- one year in our bear and bull scenarios to reflect funding-based accelerations or delays to the development process. We also model milestone revenues as clinical trial milestones are met, for the periods 2026-launch, as we assume a partnership will be entered following phase I. This may extend to after Phase II if management deems appropriate.

Source 1: <https://www.globaldata.com/store/report/her2-breast-cancer-market-analysis/>
Source 2: <https://gco.iarc.who.int/en>



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Investment Case
One-pager

Discount rate

The model uses a discount rate of 15% reflecting the generally high level of investment risk and uncertainty typically associated with forecasting future cash flows from biotech companies. The development of an early-stage drug candidate within the challenging oncology sector validates that there is significant uncertainty. The model, therefore, uses the widely accepted discount rate of 15% within the industry.

Probability of successful launch (PoS)

Based on historical data from Biostatistics research containing 5,764 pipeline projects, across all medical indications, the average historical likelihood of a Phase I pipeline project passing through to launch is around 7%. ExpreS2ion may justify a higher PoS due to the successful validation of its cVLP platform in Bavarian Nordic's Phase III trial for its COVID-19 booster and the strong pre-clinical data. However, the typically lower PoS in oncology could counterbalance this. A lower-than-average PoS suggests that the market perceives a lower-than-average likelihood of ExpreS2ion Biotech to successfully launch its ES2B-C001 HER2+ vaccine. Alternatively, a lower PoS may suggest that the market expects further dilutive capital or that challenging funding conditions reduce the likelihood of clinical progression/completion. Overall a below-average POS suggests that clinical progression, and moving toward full marketing authority for ES2B-C001, could correspond to a potential value increase for ExpreS2ion Biotech.

EBIT-margin, milestones, and royalty rates

According to the S&P Capital IQ Financial System, five-year average EBIT margins within major pharmaceutical and biotech companies are approximately 30%. Looking at biotech companies specifically, the five-year average is approximately 50%, reflecting a generally more focused business model that is often based on higher economies of scale and partnership or out-licensing deals, which is also the strategy for ExpreS2ion Biotech. We have assumed a royalty rate of 10% will be attained during partnership, which is a common level for partnerships following Phase I completion when we expect a partnership to be initiated. In addition to ExpreS2ion 10% royalty, we assume AdaptVac will receive a 3% royalty due to its cVLP technology, of which ExpreS2ion will receive 34%. Therefore, our base case is for ExpreS2ion to receive an 11% royalty, which is considered comparable to industry standards for products representing a novel approach, with large market potential. We also assume back-loaded milestones of around SEK 1.0bn at development intervals up to and including launch.

Capital increases

It is assumed that existing cash, the post-Q2 2024 rights issue, and T0 10 and T0 11 warrant programs will provide sufficient financing until 2026 when a partnership can be agreed after phase I results. However, this assumption relies on fully subscribed warrant programs, including share price appreciation by around 2.0x ahead of the T0 11 warrant programs in Sept 2025. Shortfalls in the capital raised by the warrant programs may be counteracted by a bridge loan; however, if the funding gap is significant, a further dilutive capital raise may be necessary. The current share count stands at 83.6 million, which we anticipate rising to 143.7m following the conclusion of both rights issues. ExpreS2ion will propose a 1:40 reverse stock split at an EGM on 21.10.2024, however, with no impact on capital reserves, or market value.

Appendix – Results and Conclusion

Scenarios

Based on the previously mentioned assumptions regarding market size and growth, level of profitability, royalty rates, market share, and discount rate, different scenarios can be simulated to assess how much the market is implicitly discounting the successful likelihood of launch of the ES2B-C001 HER2+ breast cancer therapeutic vaccine. As illustrated, the model has simulated the implicit likelihood in 3 scenarios: a bear-, base- and bull-case scenario using the indicated level of peak market share levels as the main differentiator. Accordingly, the remaining criteria discussed are assumed to be the same in all scenarios.

Base case scenario

In the base case scenario, the model uses the indicated market size of USD 10.4bn for the ES2B-C001 breast cancer therapeutics market. The assumptions of moderately declining CRO revenues, moderate but faster-growing grant revenues for the technology platform, and 50% EBIT margin post-launch are constant across all three scenarios. The model assumes an estimated peak market share of 20% for ES2B-C001, a royalty rate of 10% for ExpreS2ion, and 3% for AdaptVac,. Based on this, the market currently implicitly assumes there is a 2.2% probability of successful launch (PoS) for ES2B-C001 for ExpreS2ion. This compares to a historical average level of success of approximately 6.9% respectively for drug and vaccine projects across all types of indications.

Bear case scenario

In the bear case scenario, the model uses an estimated peak market share of 15% for the ES2B-C001 vaccine, and with a lower royalty rate of 7.5% for ExpreS2ion and 2% for AdaptVac. Based on this, the market currently implicitly attributes a 4.4% probability of successful launch (PoS) for the ES2B-C001 vaccine for ExpreS2ion.

Bull case scenario

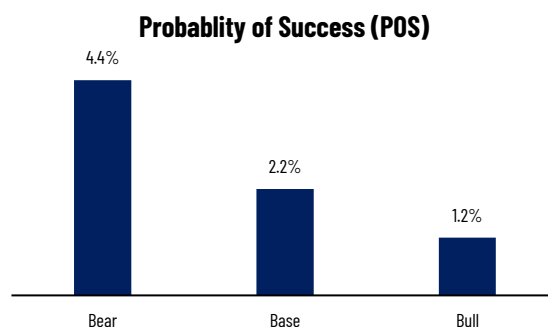
In the bull case scenario, the model uses an estimated peak market share of 25% for the ES2B-C001 vaccine, and with a higher royalty rate of 12.5% for ExpreS2ion and 3% for AdaptVac. Based on this, the market currently implicitly attributes a 1.2% probability of successful launch (PoS) of the ES2B-C001 vaccine for ExpreS2ion.

Conclusion

The three examples of simulations all suggest a relatively low level of market confidence for ExpreS2ion Biotech to successfully launch their ES2B-C001 HER2+ breast cancer vaccine candidate (through partnership). This means that the value potential of the vaccine candidates is only partly reflected in the share price but can be substantially altered if the vaccine candidate progresses through clinical trials and is approved and launched (by partners).

A low POS is common for biotech companies still in their developing phase as statistical risk relating to clinical trials exists. A low POS can also reflect that the market assesses there is a likelihood that ExpreS2ion Biotech will need to raise additional capital.

An interesting perspective is that the current market implied POS, based on our model assumptions lies below the historical benchmark POS at this stage of 6.9% for all three scenarios. This may suggest that the market expects additional funding risk, as our model assumes adequate funding up to 2026 via existing warrant programs. Alternatively, it could suggest risks surrounding securing a partnership at our assumed levels of royalty, or other risks regarding the clinical process.



Note: Probability of success (PoS) model based on general market assumptions and HC Andersen Capital assumptions.