RhoVac

Company update

On the home straight

Pharma & biotech

RhoVac's Phase IIb BRaVac trial has been fully enrolled since September 2021. According to the latest guidance, key results are expected in May or June 2022, which is the most significant catalyst of the investment case so far. The BRaVac trial is investigating RV001, a tissue-agnostic cancer immunotherapy now known as onilcamotide, in prostate cancer patients with localised disease who have relapsed after treatment with curative intent. There is a lack of treatment options in this stage and patients would typically be offered a 'watchful waiting' approach even though there already are signs of the cancer reappearing, so the unmet need is high. Our valuation has increased slightly to SEK1.71bn or SEK89.5/share (from SEK84.9/share previously) after rolling the model forward.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/20	6.0	(46.9)	(2.06)	0.0	N/A	N/A
12/21	10.2	(62.1)	(2.83)	0.0	N/A	N/A
12/22e	5.9	(38.9)	(1.64)	0.0	N/A	N/A
12/23e	0.0	(45.0)	(2.36)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

Next steps after the readout

With regards to the next steps after the readout, management has consistently guided that its strategy is to develop RV001 to proof-of-concept stage and then to seek a partnership agreement or sale. In other words, if the data are promising, the goal is to seek some form of reward for shareholders. For this reason, RhoVac had planned a budget sufficient until the readout. This is still the case, but in February 2022, management decided to propose a preferential rights (extended to all shareholders) issue of a convertible loan of c SEK25m in order to secure runway following the readout, so that it could plan the appropriate next steps. The loan is guaranteed and the board will decide whether to approve it on 4 March.

RV001 is tissue-agnostic

Although the ongoing BRaVac trial is investigating RV001 in one indication, the read-across potential to other cancer types is significant, as the target, RhoC protein, is tissue-agnostic, but crucial for the metastatic process. There is potential to expand RV001's use not only in other settings in prostate cancer, but also to other types of cancer that tend to metastasise (ie malignant cancers). To this end, recently RhoVac conducted a market research project to assess other potential opportunities, which will also prepare the management for any potential negotiation if the readout is positive.

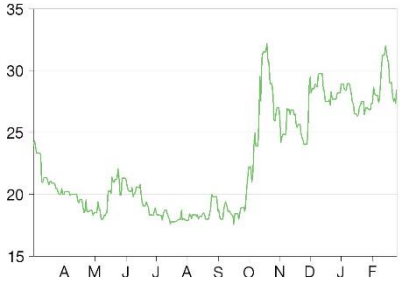
Valuation: SEK1.71bn or SEK89.5/share

Our RhoVac valuation is higher SEK1.71bn or SEK89.5/share due to rolling the model forward, which was partially offset by a lower cash position (SEK29.6m at end-FY21). Our valuation is based solely on RV001 in prostate cancer in a specific setting. Given BRaVac is a Phase IIb proof-of-concept trial, the upcoming readout will be a binary event, so it is a high risk, high reward event, typical for biotechs in this stage. A detailed review of the investment case is in our Outlook report.

28 February 2022

Price	**SEK28.40**
Market cap	**SEK540m**
Net cash (SEKm) at end-FY21	29.6
Shares in issue	19.0m
Free float	85%
Code	RHOVAC
Primary exchange	Spotlight Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	5.2	18.3	13.8
Rel (local)	10.8	38.9	7.6
52-week high/low	SEK32.20	SEK17.54	

Business description

RhoVac is an immunotherapy company listed on the Spotlight stock market in Sweden, with a 100%-owned subsidiary in Denmark. It is developing a peptide-based immunotherapy, RV001, which aims to train the immune system to specifically target cancer cells with metastatic potential. This is a novel approach that could have utility across a range of cancer settings.

Next events

Phase IIb BRaVac study results	May/June 2022
Updates on partnering process	2022

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Edison profile page

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The BRaVac study: Key readout approaching

The lead product, RV001, contains a 20 amino acid peptide fraction of the RhoC protein, which is used as a tissue-agnostic cancer immunotherapy. RhoC is a promising target since it is overexpressed in cancer cells with metastatic potential compared with healthy cells across multiple cancer types. RV001 is expected to prevent or limit metastasis by activating T-cells against cells with metastatic potential. This preventive concept differentiates RhoVac from most of the other drug developers in oncology.

RV001 is positioned to target prostate cancer patients with localised disease who have relapsed after treatment with curative intent (ie radical prostatectomy or radiotherapy). A relapse in these patients is known as biochemical recurrence/biochemical failure. Practically the only approach currently used for these patients is 'watchful waiting'. As an example, the FDA has agreed that RhoVac can use placebo in the control arm in the currently ongoing BRaVac study, a sign that the regulator agrees there is no other option than just waiting. If there was a viable intervention, it would be unethical to use placebo and RhoVac would have been asked to use standard-of-care treatment as the control instead. The lack of available therapy for these patients is also the reason for the FDA granting RhoVac Fast Track Designation in this indication.

The ongoing lead study BRaVac is a double-blind, placebo-controlled Phase IIb study (in at least 180 patients) evaluating RV001 in men with biochemical recurrence following radical prostatectomy or radiotherapy. Since the end of September 2021, RhoVac's Phase IIb BRaVac trial has been fully enrolled. The **primary endpoint** is time to PSA progression (doubling), or clinical recurrence or death. Patients with biochemical failure will be included in the study if they:

- have had biochemical recurrence where their PSA level reaches ≥0.2ng/mL; and
- have PSA doubling time from baseline of between three and 12 months.

During the study, patients' PSA will be measured to calculate doubling time. RhoVac is aiming to reduce the PSA progression rate (in other words, the doubling time should increase) by 50% compared with the placebo group, an outcome that would be interesting to urologists. PSA progression is a good endpoint for this group of patients in a Phase II trial, mainly because it allows RhoVac to perform a relatively small and fast study. Feedback from both the EMA and FDA was positive on the endpoints. Other studies in the same group of patients are also using PSA endpoints in Phase II stage, for example nivolumab (Bristol-Myers Squibb) and olaparib (AstraZeneca). PSA is known to be a reliable measure of disease progression/metastasis in prostate cancer, especially after the prostate is surgically removed. PSA can only emanate from metastatic prostate cells, making it an ideal proxy for metastatic activity,

Large market opportunity and no competition

Prostate cancer is a common cancer in men over the age of 50. The National Cancer Institute estimates that 248,530 patients in the United States were diagnosed with prostate cancer in 2021 and there were c 34,130 deaths recorded from the disease in the United States during 2021. In our model we assume a treatment price of $50k per patient per year in the United States (30% discount in Europe) with peak sales of $1.8bn reached in five years (Exhibit 1; detailed assumptions are in our last Outlook report).

Virtually the only approach used for the group of patients at which RV001 is targeted in the ongoing Phase IIb trial is so-called 'watchful waiting'. As a result, in this specific patient population RV001 as a monotherapy would have no competition. Overall, the best-selling prostate cancer drugs in 2020

were branded hormone drugs targeting advanced disease, ie Xtandi (enzalutamide, Astellas) with sales of $4.3bn and Zytiga (abiraterone acetate, Janssen Biotech) with sales of $2.5bn (source: EvaluatePharma).

Valuation

Our RhoVac valuation is slightly higher at SEK1.71bn or SEK89.5/share compared to SEK1.62bn or SEK84.9 per share, due to rolling the model forward, which offsets the lower cash position (SEK29.6m at end-FY21). We make no other changes to our model ahead of the BRaVac trial readout. There is a clear rationale for RV001 to be expanded in other settings, but for now we include a single asset in a single indication in our valuation given the management's strategy is to focus on partnering or trade sale (although any such event would likely be reflected in the economics of the deal; see below for more details on our approach regarding the licensing deal benchmark use in our rNPV model).

Exhibit 1: Sum-of-the-parts RhoVac valuation

Product	Launch	Peak sales (US$m)	Unrisked NPV (SEKm)	Technology probability (%)	rNPV (SEKm)	rNPV/share (SEK)
RV001 – prostate cancer	2027	1,775	6,033.5	20%	1,675.8	88.0
Net cash, last reported			29.6	100%	29.6	1.6
Valuation			**6,063.1**		**1,705.4**	**89.5**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations.

Positive Phase IIb study scenarios

In Exhibit 2 below we provide a sensitivity analysis that looks at the potential effect on our valuation of a successful Phase IIb outcome, by rolling forward our model to several future dates during 2022 when the BRaVac data might become available. Assuming the data are positive, we would expect to increase the technological success probability to 40% from our current 20%. Because a successful Phase IIb outcome would also be the first clinical proof-of-concept, we believe this would increase RV001's potential in other indications (read-across effect). For this reason we would reflect a larger portion of comparable deal economics in our rNPV model (only 40% of the comparable deal economics is reflected at the moment in our rNPV model, as explained in a previous report). There are no historical comparators as to how much this portion should increase in the case of a positive readout, so we will review the totality of data.

Exhibit 2: Phase IIa BRaVac trial read-out sensitivity analysis on RV001's rNPV (SEK/share)

		Deal economics adjustment				
	rNPV	10%	20%	40%	80%	100%
Readout timing	**May 2022**	101.50	117.07	148.21	210.47	241.61
	June 2022	102.53	118.25	149.70	212.59	244.04
	July 2022	103.52	119.40	151.15	214.66	246.41
	August 2022	104.56	120.60	152.67	216.82	248.89

Source: Edison Investment Research

Financials

With its FY21 results, RhoVac reported revenue of SEK10.2m, which was the allocated portion of the EU Horizon 2020 grant. The operating loss in FY21 was SEK61.9m versus SEK47.5m a year ago, reflecting the continued R&D uplift as new patients were being enrolled into the BRaVac study in the first part of the year. In addition, the company recognised SEK7.5m in tax credits in FY21. We do not make any changes to our P&L estimates; however, we will review them after the BRaVac data are out and RhoVac decides on the next steps.

The reported end-FY21 cash position was SEK29.6m with no interest-bearing debt. RhoVac will still receive the remaining part of the EU Horizon 2020 grant (c SEK4m). We expect the current cash on hand, the pre-payments and expected proceeds from the grant should be sufficient to fund the remainder of the BRaVac trial.

However, to ensure a sufficient runway to prepare for the next steps after the readout, management decided to propose a preferential rights (extended to all shareholders) issue of a convertible loan amounting to SEK25m. The loan is guaranteed by RhoVac's largest shareholder M2 Asset Management. The participants will have the option to convert the loan after the readout (expected in May or June 2021) at a price of SEK40/share. Fully converted, the shares issued would correspond to 3.2 % of total shares post issue. The convertibles carry an annual interest rate of 10% of their nominal value and the term is one year. We do not yet include the convertible loan in our valuation model. The board will decide whether to proceed with the issue on 4 March.

Exhibit 3: Financial summary

SEK000s	2020	2021	2022e	2023e
Year end 31 December	Local GAAP	Local GAAP	Local GAAP	Local GAAP
PROFIT & LOSS				
Revenue	6,012	10,191	4,000	0
Cost of Sales	0	0	0	0
Gross Profit	6,012	10,191	4,000	0
Research and development	(45,974)	(63,781)	(45,000)	(45,000)
EBITDA	(47,468)	(61,856)	(41,000)	(45,000)
Operating Profit (before amort. and except.)	(12,857)	(20,148)	(47,468)	(61,856)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(47,468)	(61,856)	(41,000)	(45,000)
Net Interest	(468)	(220)	148	0
Profit Before Tax (norm)	(47,936)	(62,076)	(40,852)	(45,000)
Profit Before Tax (reported)	(47,936)	(62,076)	(40,852)	(45,000)
Tax	7,744	7,503	7,700	0
Profit After Tax (norm)	(40,192)	(54,573)	(33,152)	(45,000)
Profit After Tax (reported)	(40,192)	(54,573)	(33,152)	(45,000)
Average Number of Shares Outstanding (m)	19.0	19.0	19.0	19.0
EPS - normalised (SEK)	(2.06)	(2.83)	(1.64)	(2.36)
EPS - normalised and fully diluted (SEK)	(2.06)	(2.83)	(1.64)	(2.36)
EPS - (reported) (SEK)	(2.06)	(2.83)	(1.64)	(2.36)
Dividend per share (SEK)	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	0	0	0	0
Intangible Assets	0	0	0	0
Tangible Assets	0	0	0	0
Investments	0	0	0	0
Current Assets	101,947	55,830	17,994	10,323
Stocks	0	0	0	0
Debtors	14,619	15,886	7,671	0
Cash	77,524	29,621	0	0
Other	9,804	10,323	10,323	10,323
Current Liabilities	(7,147)	(14,134)	(7,100)	(5,950)
Creditors	(7,147)	(14,134)	(7,100)	(5,950)
Short term borrowings	0	0	0	0
Long Term Liabilities	0	0	(2,349)	(40,828)
Long term borrowings	0	0	(2,349)	(40,828)
Other long-term liabilities	0	0	0	0
Net Assets	94,800	41,696	8,545	(36,455)
CASH FLOW				
Operating Cash Flow	(53,838)	(56,713)	(39,819)	(38,479)
Net Interest	(468)	0	148	0
Tax	3,808	7,576	7,700	0
Capex	0	0	0	0
Acquisitions/disposals	0	0	0	0
Financing	0	0	0	0
Other	(1,521)	1,234	0	0
Dividends	0	0	0	0
Net Cash Flow	(52,019)	(47,903)	(31,970)	(38,479)
Opening net debt/(cash)	(129,543)	(77,524)	(29,621)	2,349
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(77,524)	(29,621)	2,349	40,828

Source: RhoVac accounts, Edison Investment Research

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