EDISON

RhoVac

Company update

Limited impact from COVID-19 pandemic

Pharma & biotech

According to the latest update from RhoVac, the COVID-19 pandemic has had limited impact on it to date. No patients have dropped out of the ongoing Phase IIb BRaVac study with RV001, a cancer immunotherapy targeting RhoC, in prostate cancer. The company expects full recruitment will be delayed by only three months to end-2020. RhoVac added that the delay is manageable within the existing budget, so we do not expect it to have a significant effect on the investment case. The company is expanding its R&D activities in the US, which will position it for timely interactions with the FDA. Our valuation is marginally higher at SEK925m or SEK48.6/share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/18	0.0	(20.2)	(1.95)	0.0	N/A	N/A
12/19	6.0	(35.9)	(2.25)	0.0	N/A	N/A
12/20e	0.0	(59.4)	(2.71)	0.0	N/A	N/A
12/21e	0.0	(59.6)	(3.13)	0.0	N/A	N/A

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

US sites to recruit more patients than planned

There is an unexpected benefit of the recruitment delay in the European countries. Originally, the BRaVac trial design focused on Europe alone and the investigational new drug (IND) application to the FDA was to be filed later. Given that recruitment has been delayed, the US can now be a source of patients alongside Europe, resulting in more patients being recruited overseas than initially planned. In general, it is advisable to have a presence in the US as soon as possible in drug development as the FDA typically asks for data from a meaningful sample of US patients to initiate regulatory approval discussions.

All clinical trial sites should be enrolling patients soon

The BRaVac trial is testing RV001, a cancer immunotherapy targeting RhoC, for prostate cancer patients who have experienced biochemical failure after curative intent therapy. Sites in all six European countries and the US are either enrolling patients or about to start. The primary endpoint is time to prostate-specific antigen (PSA) progression, defined as the time from randomisation to the doubling of PSA from the baseline value. Key interim results are expected in Q421, while follow-up data should be ready in Q422.

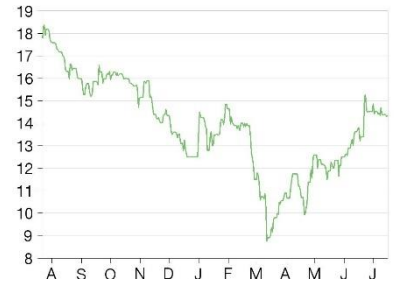
Valuation: SEK925m or SEK48.6/share

Our RhoVac valuation is marginally higher at SEK925m or SEK48.6/share. We maintain the assumptions in our risk-adjusted NPV model. Our valuation is based on RV001 in prostate cancer only, specifically in patients with biochemical recurrence following radical prostatectomy or radiotherapy. Noteworthy near-term news flow includes first patient enrolment in the US (July/August), filing for fast-track designation (August/September), completion of patient enrolment (end-2020), initiation of exploratory preclinical studies in other cancers (end-2020), and the publication of the full article with data from the Phase I/II study (likely in Q320).

20 July 2020

Price	**SEK14.44**
Market cap	**SEK275m**
Net cash (SEKm) at end Q120	124.7
Shares in issue	19.0m
Free float	85%
Code	RHOV
Primary exchange	Spotlight Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	9.4	35.0	(16.1)
Rel (local)	6.9	24.1	(8.0)
52-week high/low	SEK18.38	SEK8.75	

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 study fully enrolled	end-2020
Interim results from the Phase IIb study	H121
Start of exploratory clinical study in other cancer indications	H220
Updates on partnering process	H220/21

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Edison profile page

Operational update

Limited impact from COVID-19 pandemic: Only three-month delay to full recruitment, no patients have dropped out

Addressing the impact of the COVID-19 pandemic, RhoVac has pointed out that not a single patient has dropped out of the Phase II BRaVac trial. Furthermore, clinical trial sites in Germany started enrolling patients in April when the pandemic was peaking. Clinical trial sites in six European countries and the US will be recruiting patients, of which Denmark, Finland and Germany already are, while the US, Belgium and Sweden should start in coming weeks. Originally, RhoVac anticipated full enrolment by end September, while the current target is the end of December. The company stated that the modest delay is manageable within the existing budget, so we do not see any significant effect on the investment case.

There is an unexpected benefit of the delay of recruitment in European countries. Originally, the BRaVac trial design focused on Europe and the IND was to be filed with the FDA later. The US can now be a source of patients alongside Europe, resulting in more patients being recruited overseas than initially planned. When CEO Anders Månsson came on board in May 2019, he argued for inclusion of sites in the US. The FDA typically asks for data from a meaningful sample of US patients to initiate regulatory approval discussions. So, although such expansion adds to the costs of the trial, in general, it is advisable to have a presence in the US as soon as possible in drug development.

Next step: Fast-track designation

The FDA approved the IND in February 2020 and RhoVac indicated that as a next step it will apply for fast-track designation in August. The requirements for this designation are that the drug is meant to treat an important disease and that the drug addresses an unmet need. Prostate cancer is one of the most prevalent malignancies and there is no treatment available for the specific indication that RhoVac is initially targeting, ie prevention of cancer metastases after curative intent therapy of the local tumour. 'Watchful waiting' is common practice in this setting, and since there is a significant risk of recurrence, waiting without knowing what will happen can very negatively affect the mental health of the patients and their families. The FDA has agreed that RhoVac can use placebo in the control arm, which is another sign that the regulator agrees there is no other option than just waiting. Should there be 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. So, all in all, we believe there is a good chance that the application will be approved.

The benefits of Fast track designation include more frequent meetings and written correspondence with the FDA, potential for accelerated approval or priority review if additional criteria are met, and rolling review, which means a company can submit completed sections of its new drug application (NDA) for review by the FDA, rather than waiting until every section of the application is completed.

Near-term newsflow

Near-term newsflow includes:

- First patient enrolled in the BRaVac trial in the US in **July/August**;
- filing for Fast track designation in **August/September;**
- completion of patient enrolment **by the end of 2020**;
- initiation of exploratory preclinical studies in other cancers by **end-2020**; and
- the publication of the full article with data from the completed Phase I/II study, likely **in Q320**.

The article publication is particularly interesting, as this will be a peer-reviewed article, a form of external validation. It should also contain a more detailed background description of the science, as well as some additional data. The full results of the Phase I/II study have already been published via a press release, so we do not expect substantial modifications to our R&D model, but RhoVac mentioned the article will contain indicative PSA data as well as in-depth analysis of RV001's pharmacodynamics.

With regards to background on the target RhoC (and as a reminder), a comprehensive third-party review article on this target was published in July 2019 for the first time to our knowledge (Thomas et al, 'RhoC: a fascinating journey from a cytoskeletal organizer to a Cancer stem cell therapeutic target'). In cancer, RhoC is responsible for enhanced migration, invasion and metastasis. Existing data show that it is essential for cancer metastasis, which is how RhoVac is developing its vaccine (prevention of prostate cancer spreading). We have reviewed this article in detail in our January 2020 report.

With regards to exploratory preclinical studies in other cancers that the company aims to initiate this year, RhoVac has a clear strategy to complete the ongoing Phase IIb trial and then to out-license the asset. To increase the attractiveness of RV001's data package, however, the company plans to conduct one or more small exploratory preclinical and potentially clinical trials in other cancer indications.

Three high-profile advisory board members joined this year

On the personnel front, it is worth mentioning that RhoVac has been ramping up its scientific advisory board. This year alone three new experts have joined the board. Anne J Ridley, PhD, is the professor of cell biology and head of School of Cellular and Molecular Medicine, University of Bristol, UK. Prof Ridley has 30 years of research experience in cancer, specifically in tumour progression, inflammation, cell migration and the Rho family of GTPases to which RhoC belongs.

Prof Ridley joined the board in February, while Prof Emeritus Per-Anders Abrahamsson and Prof Klaus Brasso joined in June. Per-Anders-Abrahamsson is former head of operations at the Urological Clinic, Skåne University Hospital SUS and research group head at the Faculty of Medicine, Department of Clinical Sciences, at Lund University. Prof Brasso is an expert in prostate cancer and the principle investigator in RhoVac's ongoing Phase IIb BRaVac study.

The three new advisors joined Professor Per thor Straten, who is co-founder of RhoVac and a long-time scientific advisor. He has extensive research experience in immunotherapy, specifically therapeutic cancer vaccines. With these four scientific advisers, RhoVac now covers both the scientific and clinical sides of RV001 development.

Financials and valuation

Q120 operating costs were SEK9.7m, up from SEK6.2m in Q119 due to more intensive R&D activities as the BRaVac study is gaining pace. Grant income of SEK2.4m and tax credits of SEK1.6m meant that the Q120 net loss of SEK6.1m was largely in line with SEK5.7m booked in Q119.

The reported end-Q120 cash position was SEK125m with no interest-bearing debt. However, RhoVac will also receive the remaining part of the grant of c SEK13m and expects around SEK18m in tax credits during the duration of the BRaVac trial. These expected amounts in addition to prepaid expenses of SEK16m (current asset on the balance sheet) mean that the total expected funding is around SEK172m, which is more than sufficient to complete the ongoing Phase IIb study. We maintain our financial estimates.

Our RhoVac valuation is marginally higher at SEK925m or SEK48.6/share compared to the previous SEK889.5m or SEK46.7/share due to rolling the model forward, which offset the lower cash position (SEK130m at end-Q419). We maintain the assumptions in our risk-adjusted NPV model. Our valuation is based on RV001 in prostate cancer only, specifically in patients with biochemical recurrence following radical prostatectomy or radiotherapy.

According to our model, a successful Phase IIb outcome would result in RhoVac's rNPV increasing to SEK2.05bn or SEK108/share (not including the net cash estimate). This would include setting the probability of success at 40% as a Phase III-ready asset and changing the date of the valuation to the start of 2022, but leaving all other inputs unchanged.

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	888	3,636.3	15%	800.3	42.0
Net cash, last reported			124.7	100%	124.7	6.5
Valuation			**3,760.9**		**925.0**	**48.6**

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

Exhibit 2: Financial summary

SEK'000s	2018	2019	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	0	5,979	0	0
Cost of Sales	0	0	0	0
Gross Profit	0	5,979	0	0
Research and development	(19,154)	(38,570)	(60,000)	(60,000)
EBITDA	(20,148)	(36,325)	(60,000)	(60,000)
Operating Profit (before amort. and except.)	(20,148)	(36,325)	(60,000)	(60,000)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(20,148)	(36,325)	(60,000)	(60,000)
Net Interest	(64)	382	577	363
Profit Before Tax (norm)	(20,212)	(35,943)	(59,423)	(59,637)
Profit Before Tax (reported)	(20,212)	(35,943)	(59,423)	(59,637)
Tax	2,936	3,837	7,900	0
Profit After Tax (norm)	(17,276)	(32,106)	(51,523)	(59,637)
Profit After Tax (reported)	(17,276)	(32,106)	(51,523)	(59,637)
Average Number of Shares Outstanding (m)	8.9	14.3	19.0	19.0
EPS - normalised (SEK)	(1.95)	(2.25)	(2.71)	(3.13)
EPS - normalised and fully diluted (SEK)	(1.95)	(2.25)	(2.71)	(3.13)
EPS - (reported) (SEK)	(1.95)	(2.25)	(2.71)	(3.13)
Dividend per share (SEK)	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	100.0	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	2,848	3,021	3,021	3,021
Intangible Assets	2,848	3,021	3,021	3,021
Tangible Assets	0	0	0	0
Investments	0	0	0	0
Current Assets	20,372	149,928	98,028	38,228
Stocks	0	0	0	0
Debtors	240	14,391	14,391	14,391
Cash	16,060	129,543	77,643	17,843
Other	4,071	5,994	5,994	5,994
Current Liabilities	(4,380)	(12,574)	(12,574)	(12,574)
Creditors	(4,380)	(12,574)	(12,574)	(12,574)
Short term borrowings	0	0	0	0
Long Term Liabilities	(596)	(624)	(624)	(624)
Long term borrowings	0	0	0	0
Other long-term liabilities	(596)	(624)	(624)	(624)
Net Assets	18,245	139,751	87,851	28,051
CASH FLOW				
Operating Cash Flow	(17,097)	(43,309)	(60,000)	(60,000)
Net Interest	(64)	(1,834)	200	200
Tax	2,229	2,986	7,900	0
Capex	0	0	0	0
Acquisitions/disposals	0	0	0	0
Financing	21,756	154,715	0	0
Other	(191)	925	0	0
Dividends	0	0	0	0
Net Cash Flow	6,632	113,483	(51,900)	(59,800)
Opening net debt/(cash)	(9,428)	(16,060)	(129,543)	(77,643)
HP finance leases initiated	0	0	0	0
Other	(0)	0	0	0
Closing net debt/(cash)	(16,060)	(129,543)	(77,643)	(17,843)

Source: RhoVac accounts, Edison Investment Research

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