EDISON

# RhoVac

R&D update

## Fast Track designation granted by FDA

Pharma & biotech

**Following the submission of an application in September, the US FDA has now granted Fast Track designation to RhoVac's lead drug RV001. Although we had expected this, it indicates a third-party validation for RhoVac and its ongoing clinical programme. Importantly, this designation should make RV001 more appealing to potential partners, given it eases some of the regulatory processes ahead. Other developments include the news that RhoVac's Phase I/II data have been published in a peer-reviewed article, which gave some additional details. The COVID-19 pandemic continues to cause delays, but the BRaVac study timelines still fit within the existing budget. Our valuation is SEK64.2/share (vs SEK61.8/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) | (1.55) | 0.0 | N/A | N/A |
| 12/20e | 12.0 | (37.4) | (2.19) | 0.0 | N/A | N/A |
| 12/21e | 8.0 | (41.6) | (2.61) | 0.0 | N/A | N/A |

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

## Fast Track designation benefits

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 Biologic License Application (BLA) for review by the FDA, rather than waiting until the full application is complete.

## Phase I data published in a peer-reviewed article

RhoVac obtained another form of external validation when a peer-reviewed article with the Phase I/II results was published in the *Journal Of ImmunoTherapy of Cancer* (JITC) in November. Full results had previously been published via a press release, but this publication also included some new PSA data as well as in-depth analysis of the pharmacodynamic results (more details below).

## COVID-19-related delays covered with existing funds

The COVID-19 pandemic's second wave is causing delays with clinical trials across the board. In October, RhoVac issued an update on the recruitment into its Phase IIb BRaVac prostate cancer trial, which has continued to be adversely affected by the ongoing pandemic. Based on current estimates, full recruitment into the trial is now expected during Q221 (from Q420), which pushes out the expected timing for key interim data to early-2022 (from Q421), but still within the existing budget.

## Valuation: SEK1.22bn or SEK64.2/share

Our RhoVac valuation is higher at SEK1.22bn or SEK64.2/share due to rolling the model forward and a lower cash position (SEK97.5m at end-Q320). The slight delay in expected interim data from the Phase IIb trial does not affect our valuation, given this is primarily focused on the licensing potential, which we still expect could happen during 2022.

**27 November 2020**

| | |
|---|---|
| **Price** | **SEK18.8** |
| **Market cap** | **SEK357m** |
| Net cash (SEKm) at end-Q320 | 97.5 |
| Shares in issue | 19.0m |
| Free float | 84% |
| Code | RHOV |
| Primary exchange | Spotlight Stockholm |
| Secondary exchange | N/A |

### Share price performance


| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | 5.2 | 3.6 | 30.6 |
| Rel (local) | (6.7) | (2.6) | 36.4 |
| 52-week high/low | SEK20.75 | 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 BRaVac study fully enrolled | Q221 |
| Phase IIb BRaVac interim results | Early-2022 |
| Start of exploratory clinical study in other cancer indications | H220 |
| Updates on partnering process | 2021/22 |

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## Published article provides granular Phase I/II review

Information about the Phase I/II study of RV001 and the results that have been released so far can be found in our outlook report published in October 2020. The Phase I/II clinical study included 22 patients who had previously undergone radical prostatectomy. These patients received injections subcutaneously with RV001 for a total of 30 weeks.

After a long-term follow up of the 21 evaluable patients, 18 (86%) had shown a robust, polyfunctional CD4+ T cell response during vaccination, with three HLA-class II epitopes identified relating to RV001. CD8+ response was observed in one patient (1/21 or 5%) and this was restricted to one HLA class-I epitope. These immunological effects were durable, with responses detectable for at least 10 months post vaccination.

Prostate-specific antigen (PSA) doubling time – the time it takes for the PSA level to double – versus pre-study levels is considered an effective surrogate endpoint for a clinical effect in prostate cancer. Despite the trial not being designed to investigate clinical response, PSA levels were still monitored throughout the course of the Phase I/II study. Only two patients had measurable levels of PSA at the base line, so the PSA doubling is not evaluable in other patients. The investigators saw that in these two patients the PSA doubling time increased during the course of the study (in one patient from 1.3 to 2.1 years and in the second patient from 1.95 to 3.8 years). This would imply a clinical response to treatment. Although the results from these two patients are anecdotal (only two cases), the fact that both patients had delayed progression is intriguing, in our view. In the ongoing Phase IIb BRaVac trial, the inclusion criteria are designed to recruit patients with measurable PSA levels at the base line. A clearer picture on PSA doubling time will come from this trial, which is powered to show this effect as the primary endpoint.

Overall, we view the Phase I/II results as positive, as RV001 looks to be a very safe treatment and elicits a long-lasting immune response in a large majority of patients. So, RV001 appears to do what it was designed for. The question of whether this CD4 biased immune activation induced by RV001 can translate into clinical efficacy will be addressed in a controlled Phase IIb trial. There is an ongoing debate in the scientific community about the extent to which CD4+ and CD8+ are involved in the anti-cancer response. The authors of the article published in the JITC in November argued that ‘CD4 T cells are crucial for CD8 T cell activation and expansion, as well as for the generation and maintenance of CD8 T cell memory; They also display a range of antitumoral effects, such as secretion of tumour necrosis factor and interferon-γ activation of macrophages or natural killer cells and direct cytotoxicity’.

## Financials and valuation

Operating costs in the first nine months of 2020 (9M20) were SEK37.5m vs SEK41.9m a year ago. The Phase IIb BRaVac study started recruiting patients in November 2019, so in 2020 and 2021 we expect stable cash burn. Our operating cost estimates for 2020 and 2021 are SEK50m. Tax credits in 9M20 were SEK6.8m versus SEK6.7m in 9M19. The reported end-Q320 cash position was SEK97.5m with no interest-bearing debt. Our estimates are unchanged.

Our RhoVac valuation (Exhibit 1) is higher at SEK1.22bn or SEK64.2/share, versus SEK1.18bn or SEK61.8/share, due to rolling the model forward, which offset the lower cash position. Detailed assumptions for our risk-adjusted net present value (rNPV) model can be found in our most recent Outlook note.

**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 | 5,432.7 | 15% | 1,225.8 | 59.1 |
| Net cash, last reported | | | 97.5 | 100% | 97.5 | 5.1 |
| **Valuation** | | | **5,530.2** | | **1,223.2** | **64.2** |

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

To model a **successful Phase IIb outcome**, as an indicative scenario we have set the model to a future date (1 January 2022) and increased the technological success probability to 40% from 15%. 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. This would allow us to reflect a larger portion of comparable deal economics (which are currently set only at 40%, as explained in our last published outlook report). There are no historical comparators as to how much this portion should increase, so we will review the totality of data (RhoVac may also conduct preclinical studies in other indications in parallel to the Phase IIb trial). Exhibit 2 provides a sensitivity analysis.

**Exhibit 2: Valuation per share sensitivities in positive Phase IIb study scenarios**

| Comparable licensing deal value adjustment | 60% | 80% | 100% |
|---|---|---|---|
| Valuation per share (SEK) | 184 | 215 | 245 |

Source: Edison Investment Research

## Exhibit 1: Financial summary

| SEK000s | 2018 | 2019 | 2020e | 2021e |
|---|---|---|---|---|
| Year-end 31 December | Local GAAP | Local GAAP | Local GAAP | Local GAAP |
| **PROFIT & LOSS** | | | | |
| Revenue | 0 | 5,979 | 12,000 | 8,000 |
| Cost of Sales | 0 | 0 | 0 | 0 |
| Gross Profit | 0 | 5,979 | 12,000 | 8,000 |
| Research and development | (19,154) | (38,570) | (50,000) | (50,000) |
| EBITDA | (20,148) | (36,325) | (37,997) | (41,992) |
| Operating Profit (before amort. and except.) | (20,148) | (36,325) | (38,000) | (42,000) |
| Intangible Amortisation | 0 | 0 | 0 | 0 |
| Exceptionals | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 |
| Operating Profit | (20,148) | (36,325) | (38,000) | (42,000) |
| Net Interest | (64) | 382 | 577 | 363 |
| Profit Before Tax (norm) | (20,212) | (35,943) | (37,423) | (41,637) |
| Profit Before Tax (reported) | (20,212) | (35,943) | (37,423) | (41,637) |
| Tax | 2,936 | 3,837 | 7,900 | 0 |
| Profit After Tax (norm) | (17,276) | (32,106) | (29,523) | (41,637) |
| Profit After Tax (reported) | (17,276) | (32,106) | (29,523) | (41,637) |
| Average Number of Shares Outstanding (m) | 8.9 | 14.3 | 19.0 | 19.0 |
| EPS - normalised (ore) | (195.00) | (155.00) | (219.00) | (261.00) |
| EPS - normalised and fully diluted (SEK) | (1.95) | (2.25) | (1.55) | (2.19) |
| EPS - (reported) (SEK) | (1.95) | (2.25) | (1.55) | (2.19) |
| Dividend per share (SEK) | 0.0 | 0.0 | 0.0 | 0.0 |
| Gross Margin (%) | N/A | 100.0 | 100.0 | 100.0 |
| 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 | 119,431 | 77,239 |
| Stocks | 0 | 0 | 0 | 0 |
| Debtors | 240 | 14,391 | 14,391 | 14,391 |
| Cash | 16,060 | 129,543 | 99,046 | 56,854 |
| 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 | 109,254 | 67,062 |
| **CASH FLOW** | | | | |
| Operating Cash Flow | (17,097) | (43,309) | (37,997) | (41,992) |
| Net Interest | (64) | (1,834) | 200 | 200 |
| Tax | 2,229 | 2,986 | 7,900 | 0 |
| Capex | 0 | 0 | (600) | (400) |
| 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 | (30,497) | (42,192) |
| Opening net debt/(cash) | (9,428) | (16,060) | (129,543) | (99,046) |
| HP finance leases initiated | 0 | 0 | 0 | 0 |
| Other | (0) | 0 | 0 | 0 |
| Closing net debt/(cash) | (16,060) | (129,543) | (99,046) | (56,854) |

Source: RhoVac's accounts, Edison Investment Research

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