EDISON

RhoVac

Q219 update

Funded to execute Phase IIb study as planned

Pharma & biotech

The past few months have been transformative for RhoVac. The company completed a large rights issue, published final follow-up results from its Phase I/II trial with RV001 in prostate cancer and is about to enrol the first patient to a new controlled efficacy Phase IIb trial. On the corporate side of the business, a new CEO was appointed, bringing a wealth of business development expertise, a strategic fit given RhoVac's priorities over the next two to three years. The recently received EU Horizon 2020 grant of €2.5m will not only provide a financial support from the EU Commission, but we also view it as a form of external validation. We have increased our valuation to SEK885.1m or SEK46.5/share (vs SEK37.2/share previously).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	0.0	(12.9)	(1.34)	0.0	N/A	N/A
12/18	0.0	(20.2)	(1.95)	0.0	N/A	N/A
12/19e	0.0	(49.6)	(3.47)	0.0	N/A	N/A
12/20e	0.0	(59.4)	(3.12)	0.0	N/A	N/A

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

Final Phase I/II study follow-up results

On 4 July 2019, RhoVac released long-term follow-up results of the Phase I/II trial with RV001. In this study, safety and immunological response were assessed at three, six, nine and 12 months. Positive results after the three- and six-month follow-ups have been reported previously. The July announcement was the final 12-month update, which confirmed that treatment with RV001 was safe and elicited a longstanding immune response. RhoVac is now running a larger Phase IIb study to explore efficacy in the same patient group. The trial is expected to enrol the first patient imminently. Most of the study centres are in Europe, but RhoVac confirmed it will open several US centres. The final data are expected in H221.

New CEO appointed

RhoVac announced on 2 September 2019 it had appointed Anders Månsson as the new CEO. Former CEO, Anders Ljungqvist, will continue working as chief operating officer. Mr Månsson joined RhoVac in May 2019 as deputy CEO and chief business officer. We believe his expertise is a good fit strategically because RhoVac's areas of focus over the next three years will be executing the ongoing Phase IIb study and business development activities, with the ultimate goal of finding a suitable partner for the late-stage development of RV001.

Valuation: SEK885.1m or SEK46.5/share

We have increased our valuation of RhoVac to SEK885.1m or SEK46.5/share from SEK708m or SEK37.2/share previously. This was mainly due to rolling our model forward and a higher probability of success (15% vs 10% previously), which we have increased as the rights issue has removed the previous funding risk for the Phase IIb trial. The enrolment of the first patient to the Phase IIb study and Phase I/II data publication in a peer-reviewed article are some of the potential R&D newsflow in the near term. According to our model, a successful Phase IIb outcome would result in an increase in RhoVac's rNPV to SEK2.0bn or SEK107.1/sh.

18 September 2019

Price	**SEK15.82**
Market cap	**SEK301m**

Net cash (SEKm) at end Q219	174.5
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	(2.9)	(17.4)	(61.8)
Rel (local)	(9.4)	(19.8)	(58.9)
52-week high/low	SEK42.2	SEK15.2	

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

Initiation of Phase IIb study	Q319
Q319 results	15 November 2019

Analyst

Jonas Peciulis +44 (0)20 3077 5728

healthcare@edisongroup.com

Edison profile page

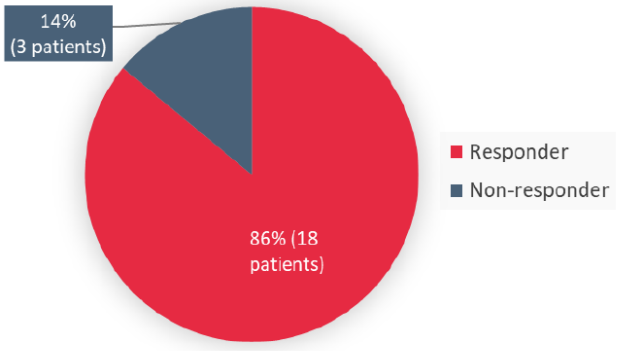
R&D update

Phase I/II final follow-up

On 4 July 2019, RhoVac released long-term follow-up results of the Phase I/II trial with RV001. The 22 prostate cancer patients who were enrolled to the trial received 11 subcutaneous injections over 30 weeks. The primary objective was to evaluate safety and tolerability, while the secondary objective looked at immune response. The patients were monitored for 12 months. Treatment-related reactions and immunological response (measured by IFNγ ELIspot analysis) were assessed at three, six, nine and 12 months (positive findings after the three- and six-month follow-ups had already been reported). The July announcement was the final update on patient follow-up in the Phase I/II trial. In summary:

- All 22 patients completed the follow-up and no treatment-related adverse reactions were observed. In total 21 patients were evaluable for immune activation.
- As reported previously, 18 out of 21 patients (86%) showed significant treatment-related immunological response after treatment with RV001. This significant response was maintained in the same 18 patients at three-, six- and nine-month follow-up. At the 12-month point, 17 patients still showed significant immunological response.

Exhibit 1: Phase I/II follow-up results



Follow up Time Point	% Responding
3 months post-vacc.	86%
6 months post-vacc.	86% (90%)*
9 months post-vacc.	86% (90%)*
12 months post vacc.	81% (86%)*

*One patient developed RV001 specific response 6 months after end of treatment

Source: RhoVac

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 immune activation will translate into clinical efficacy will be addressed in a controlled trial that is already underway. RhoVac should publish the Phase I/II results in a peer-reviewed article in the near future.

Phase IIb first patient to be enrolled imminently

Following publication of positive initial Phase I/II data, RhoVac has designed a larger Phase IIb study to explore efficacy in the same patient group (Exhibit 2). The trial is expected to enrol the first patient any time now. Most of the study centres are in Europe, but RhoVac has confirmed it plans to open several US centres. The therapy will be administered as 12 subcutaneous injections over several months and final data are expected in H221. Exhibit 2 summarises the trial design.

Exhibit 2: Planned Phase IIb trial design	
Summary design	A Phase II, double-blind, placebo-controlled study of RV001V in adult males with biochemically relapsed prostate cancer following definitive local therapy (eg prostatectomy, radiotherapy)
Objective	To investigate whether a vaccination regimen with multiple subcutaneous administrations of RV001 0.1mg/mL (RV001V) can reduce prostate-specific antigen (PSA) progression compared to the control group
Number of patients	150 (will enrol 180 in order to have 150 evaluable patients)
Treatment groups	Experimental treatment arm: RV001 (12 subcutaneous vaccinations: priming period of six vaccinations – one every two weeks, then a boosting period of five vaccinations – one vaccination every four weeks, then final vaccination given six months after the 11th vaccination) Control: placebo (same dosing as RV001)
Endpoints	Primary endpoint: time to documented PSA progression or clinical recurrence, death of any cause Secondary endpoints: safety and tolerability, time to subsequent antineoplastic therapy, disease-free survival Exploratory endpoints: relationship between immune-response and anti-tumour efficacy, identification of predictive biomarkers, metastasis-free survival
Key inclusion criteria	Biochemical recurrence within three years of radical prostatectomy (PSA ≥0.2ng/mL, PSA doubling time >3 months and <12 months, history of Gleason 7 (4+3) or higher) or definitive radiotherapy (same definitions except PSA >nadir + 2ng/mL)
Key exclusion criteria	No distant metastasis or locoregional recurrence No castration-resistant prostate cancer Not receiving androgen-deprivation therapy PSA>10ng/mL
Clinical trial sites	Denmark and other European countries
Sponsor	RhoVac
Timelines	Study start: Q319 Study duration (approximate): two years (one-year enrolment, one-year follow-up) Expected data readout: H221

Source: RhoVac

New CEO

On the corporate side of the business, RhoVac announced on 2 September 2019 that Anders Månsson had been appointed as the new CEO. Former CEO Anders Ljungqvist will continue working as chief operating officer. Mr Månsson joined RhoVac in May 2019 as deputy CEO and chief business officer. He has extensive experience in the pharmaceutical and biotech industries and has worked in senior positions in major pharmaceutical companies in Sweden, Denmark, the UK and Switzerland. His focus was on sales and marketing, as well as on business development including distribution, licence agreements, divestments and acquisition agreements worth over several billion SEK. In recent years, he also held a number of board positions in biotech/life science companies and was the CEO of a stem cell company in Lund.

We believe Mr Månsson's expertise is a good fit strategically because RhoVac's areas of focus over the next three years will be executing the ongoing Phase IIb study and business development activities, with the ultimate goal of finding a suitable partner for the late-stage development and global launch of RV001. The fact that former CEO and co-founder Anders Ljungqvist is staying on as COO is also very positive as RhoVac will maintain the expertise it has accumulated in RV001 technology.

Significant EU grant received

On 22 August 2019, RhoVac announced that the EU Commission had granted it €2.5m from the EU framework programme Horizon 2020. Over the next 36 months, RhoVac will receive grant payments to support the Phase IIb trial with RV001 in prostate cancer and RhoVac's business development activities. This is substantial support for RhoVac, bearing in mind that the recently completed rights issue amounted to SEK181m, which is expected to be sufficient to fund budgeted activities until 2022. In addition to the financial benefit, we view the grant as a form of external validation, since proposed business plans and technology are subject to scrutiny by the EU Commission.

Financials and valuation

RhoVac reports no income, while the operating spend was SEK30.1m in H119, up from SEK7.9m in H118, mainly because of the preparations and initiation of the Phase IIb study. We already expected operating expenditure to increase as the Phase IIb accelerates after the right issue. Our previous operating loss estimates were SEK37m and SEK50m for 2019 and 2020 respectively, which we now revise to SEK50m and SEK60m.

RhoVac received SEK5.1m in tax credits in H119. In June 2019, it completed a rights issue raising a total of SEK180.9m gross (SEK166.2m net). In total, 9,523,551 shares were issued (a 100% increase in the number of shares outstanding) at a price of SEK19/share (vs SEK34.9/share on the day before the announcement). The rights issue was guaranteed by commitments from a group of investors. The newly raised funds should be sufficient to fund RhoVac's operations for the next three years. With its H119 report, RhoVac reported SEK68.8m in cash and no debt. SEK105.7m was booked in receivables, as the rights issue was completed in July 2019.

We have increased our valuation of RhoVac to SEK885.1m or SEK46.5/share from SEK708m or SEK37.2/share previously. This was mainly due to rolling our model forward and increasing the success probability to 15% from 10%. As we discussed in our initiation report, we had assumed a somewhat more conservative success probability prior to the rights issue, as the project required substantial funding commitments. Now the rights issue has been successfully resolved, funding risk is lower and we increased the success probability to our standard 15% (Phase II to approval for oncology projects). We maintain all other assumptions in our risk-adjusted NPV model as published in our recent initiation report. 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 SEK2.04bn or SEK107.1/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 3: 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	3,272.3	15%	710.6	37.3
Net cash at end-H119			174.5	100%	174.5	9.2
Valuation			**3,446.8**		**885.1**	**46.5**

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

Exhibit 4: Financial summary

SEK'000s	2017	2018	2019e	2020e
December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	0	0	0	0
Cost of Sales	0	0	0	0
Gross Profit	0	0	0	0
Research and development	(12,243)	(19,154)	(50,000)	(60,000)
EBITDA	(12,857)	(20,148)	(50,000)	(60,000)
Operating Profit (before amort. and except.)	(12,857)	(20,148)	(50,000)	(60,000)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(12,857)	(20,148)	(50,000)	(60,000)
Net Interest	(5)	(64)	382	577
Profit Before Tax (norm)	(12,861)	(20,212)	(49,618)	(59,423)
Profit Before Tax (reported)	(12,861)	(20,212)	(49,618)	(59,423)
Tax	1,911	2,936	0	0
Profit After Tax (norm)	(10,950)	(17,276)	(49,618)	(59,423)
Profit After Tax (reported)	(10,950)	(17,276)	(49,618)	(59,423)
Average Number of Shares Outstanding (m)	8.2	8.9	14.3	19.0
EPS - normalised (SEK)	(1.34)	(1.95)	(3.47)	(3.12)
EPS - normalised and fully diluted (SEK)	(1.34)	(1.95)	(3.47)	(3.12)
EPS - (reported) (SEK)	(1.34)	(1.95)	(3.47)	(3.12)
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	2,342	2,848	2,848	2,848
Intangible Assets	2,342	2,848	2,848	2,848
Tangible Assets	0	0	0	0
Investments	0	0	0	0
Current Assets	13,598	20,372	161,245	101,822
Stocks	0	0	0	0
Debtors	1,141	240	240	240
Cash	9,428	16,060	150,762	91,339
Other	3,029	4,071	10,243	10,243
Current Liabilities	(2,177)	(4,380)	(28,616)	(28,616)
Creditors	(2,177)	(4,380)	(28,616)	(28,616)
Short term borrowings	0	0	0	0
Long Term Liabilities	(505)	(596)	(613)	(613)
Long term borrowings	0	0	0	0
Other long term liabilities	(505)	(596)	(613)	(613)
Net Assets	13,258	18,245	134,864	75,441
CASH FLOW				
Operating Cash Flow	(13,853)	(17,097)	(31,918)	(60,000)
Net Interest	(6)	(64)	382	577
Tax	1,945	2,229	0	0
Capex	0	0	0	0
Acquisitions/disposals	0	0	0	0
Financing	1,182	21,756	166,237	0
Other	(241)	(191)	0	0
Dividends	0	0	0	0
Net Cash Flow	(10,973)	6,632	134,701	(59,423)
Opening net debt/(cash)	(20,401)	(9,428)	(16,060)	(150,762)
HP finance leases initiated	0	0	0	0
Other	0	(0)	0	(0)
Closing net debt/(cash)	(9,428)	(16,060)	(150,762)	(91,339)

Source: RhoVac's accounts, Edison Investment Research

General disclaimer and copyright

This report has been commissioned by RhoVac and prepared and issued by Edison, in consideration of a fee payable by RhoVac. Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

The Investment Research is a publication distributed in the United States by Edison Investment Research, Inc. Edison Investment Research, Inc. is registered as an investment adviser with the Securities and Exchange Commission. Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1,185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia