more pessimistic bear scenario, the corresponding figure is SEK 7 per share.

# **Clear Focus on Increased Shareholder Value**

#### Continued Development of RP101 and RP501

ANALYSGUIDEN

av Aktiespararna

As expected, Redwood Pharma reported no sales during Q1 and the operating result amounted to SEK -4.3 million (-4.4). In connection with the transfer of the company's listing to Nasdaq First North, a successful rights issue was carried out which gave the company a cash position of SEK 28 million. To maximize the value of RP101 for dry eye disease (DED) in postmenopausal women, Redwood Pharma continues to explore strategic alternatives with potential partners. Furthermore, Redwood Pharma has now officially established RP501 as a separate project for the treatment of milder forms of eye dryness based on the IntelliGel platform.

#### Significant Market for the Treatment of Dry Eyes

With 344 million people worldwide suffering from dry eyes, the market potential for Redwood Pharma's ophthalmic drugs is significant. RP101 for the treatment of DED in postmenopausal women is, after positive phase 2 results, well positioned for continued development in a pivotal phase 3 trial. In December 2020, US clinical contract research organization Ora, Inc. presented additional findings regarding RP101. RP101 showed a statistically significant effect on corneal damage, with a difference of 0.70 compared to the control group on day 90. This is very interesting considering that Xiidra, to which Novartis recently acquired the rights in a deal worth up to USD 5.3 billion, showed an improvement of less than 0.10 after three months of treatment.

#### **Potential For RP501 as a Non-Prescription Product**

The company's other program, RP501, is intended to treat milder forms of dry eye disease in a broader patient population consisting of both men and women. Since OTC products generally have a lower price point, the sales potential for RP501 is lower, at the level of USD 50 million per year. For the company, however, the it has the advantage that it can be developed relatively quickly and reach the market to generate revenue within two to three years.

#### **Reiterating Our SEK 14 Target Price**

With continued positive clinical results, we see great potential in the company's share price. We assume that a launch of RP101 will take place in 2025, and that the drug will reach top sales of EUR 500 million. We reiterate our target price of SEK 14 for Redwood Pharma. In our more optimistic bull scenario, we see the potential for a value of SEK 28 per share, and in our

# **Redwood Pharma**

Company Update	
Date	7 June 2021
Analyst	Thomas Nilsson
Basic Facts	
Industry	Health Care
Chairman	Gunnar Mattsson
CEO	Martin Vidaeus
Listed Since	2016
Exchange	Nasdaq First North
Ticker	REDW
Share Price	SEK 6,67
Shares Outstanding, m	20,7
Market Cap, MSEK	138
Net Debt, MSEK	-28
Enterprise Value, MSEK	110
Website	www.redwoodpharma.se

#### **Share Price Development**



Source: NasdagOMX

#### **Financials, MSEK**

	2019	202E	2021E	2022E
Revenue	0	0	0	0
EBITDA	-16	-15	-14	-14
Operating Profit	-16	-15	-14	-14
Pretax Profit	-16	-15	-14	-14
Net Income	-16	-15	-14	-14
EPS	-1,07 kr	-1,03 kr	-0,68 kr	-0,68 kr
Dividend	0,00 kr	0,00 kr	0,00 kr	0,00 kr
Revenue Growth	n/a	n/a	n/a	n/a
EBITDA margin	n/a	n/a	n/a	n/a
Operating Margin	n/a	n/a	n/a	n/a
Net Debt/Equity	-0,7	-0,4	-0,9	-0,6
Net Debt/EBITDA	n/a	n/a	n/a	n/a
P/E	n/a	n/a	n/a	n/a
EV/EBIT	n/a	n/a	n/a	n/a
EV/Sales	n/a	n/a	n/a	n/a
Dividend Yield	0,0%	0,0%	0,0%	0,0%

Source: Company reports, Analysguiden

### **Investment Case**

#### Significant Market for Dry Eye Drugs

The dry eye drug market currently stands at USD 5.4 billion and is expected to grow to USD 7.2 billion by 2025, according to a report by TMR. <sup>1</sup> This market research firm also affirms there is potential for a number of blockbusters, i.e., drugs that reach a billion dollars or more in annual sales. Redwood Pharma's commercial strategy is to undertake early development of new innovative drugs and then to enter licensing agreements with major pharmaceutical companies that have the resources to market globally. In the spring of 2020, Redwood Pharma published successful results from the clinical phase 2 trial of RP101. In addition to ongoing discussions with potential partners, the company plans for preparatory studies for a future phase 3 trial of RP101. Furthermore, Redwood Pharma has now officially established RP501 as a separate development project for the treatment of mild dry eye based on IntelliGel. This is in line with the company's ambition to develop new products to meet the needs of different patient groups with dry eyes.

#### **RP101 Has Blockbuster Potential**

In the US alone, some 4 million women who have experienced menopause suffer from moderate to severe chronic dry eye disease, and in Europe the corresponding figure is 6 million. With RP101, Redwood Pharma initially targets this large segment with a biologically active pharmaceutical substance. A new in-depth study published in December 2020 showed additional strengths of RP101. It was concluded that RP101 showed statistically significant efficacy of treatment in relation to corneal damage. RP101 showed a significant (p=0.0463) improvement of 0.70 when compared to the control group on day 90. These results are encouraging when considering that Xiidra, which received FDA approval largely due to inferior corneal staining, showed an improvement of just under 0.10 (p=0.0007) after three months of treatment in a larger phase 3 study. It should however be noted that the patient groups in these two studies were not identical. It is also worth noting that Novartis acquired the rights to Xiidra from Takeda in a deal worth up to USD 5.3 billion. In our model, we forecast peak sales of EUR 500 million for RP101 in 2031, which is approximately half the USD 1.2 billion in sales that Xiidra is expected to reach in 2025.

The market for dry eye disease drugs is expected to grow to USD 7,2 billion in 2025

RP101 showed a better effect on corneal damage than Novartis' drug Xiidra, which was acquired in a deal worth up to USD 5.3 billion

<sup>&</sup>lt;sup>1</sup> <u>https://www.asdreports.com/market-research-report-562474/dry-eye-disease-diagnostics-treatment-market</u>

#### **Corneal Staining a Possible New Endpoint for RP101**

In the phase 2 study of RP101, the sustained-release platform IntelliGel was used as a placebo. The challenge in developing drugs to treat dry eye disease is finding significant effect in relation to placebo, as the symptoms are due to an instability in the tear film. As soon as water is added to the eye, the patient gets better. One option here is to continue looking at corneal staining which is the endpoint that was used when Novartis' Xiidra was approved. One then looks at different regions of the cornea. In the in-depth analysis conducted by Ora, Inc. on RP101, it looked even stronger than Xiidra in terms of the effect of the treatment on corneal staining.

#### OTC Drug RP501 Can Reach the Market in Two Years

In the phase 2 clinical trial of RP101, Redwood Pharma found not only that the drug is safe and effective. It was also concluded that the drug delivery platform IntelliGel in and of itself was able to provide relief to patients affected by mild dry eye disease. Redwood Pharma believes that RP501 has the potential to become a non-prescription product in the US and Europe. RP501 also extends the possibility of more potential partnerships as the product is likely to be marketed through non-pharmaceutical channels. As a non-prescription product, RP501 will not have the same potential as RP101 in terms of sales. In the context of ophthalmic OTC products, annual sales of USD 50 million are considered a success. On the positive side, however, RP501 could start generating revenue for Redwood Pharma within two to three years, as compared to RP101, which is not expected to be launched until 2025.

#### **Successful Rights Issue**

In February 2021, Redwood Pharma carried out a successful rights issue which provided the company with SEK 29 million. The funds will be used for in-depth studies of RP101 and development work on the RP501 project. Ahead of an upcoming pivotal phase 3 trial of RP101, Redwood Pharma plans to conduct preparatory studies regarding medical compatibility with contact lenses, as well as further clinical studies regarding tolerability during intensive use of IntelliGel.

#### **Reiterating SEK 14 Target Price**

We see great sales potential in RP101 and forecast peak sales of EUR 500 million in 2031. This is approximately half the USD 1.2 billion that Novartis' Xiidra is expected to reach in 2025. RP101 is not expected to be launched until 2025, but in 2021 a potential partnership agreement could be a possible positive share price trigger. As CE marking is a less cumbersome process, RP501 will require less investment and the product is expected to reach the market within two to three years. We reiterate our SEK 14 target price for Redwood Pharma.

As a non-prescription product, RP501 could reach the market within two to three years, whereas RP101 is not expected to be launched until 2025 at the earliest

We forecast peak sales of EUR 500 million for RP101 by 2031

# **Operational Update**

#### **Developments In Q1 2021**

As expected, Redwood Pharma did not report any revenue during the first quarter of the year, and the operating result came in at SEK -4.3 million (-4.4). During the quarter, the company carried out a successful rights issue that provided the company with approximately SEK 29 million. The funds will be used to further the development of RP101 and RP501. After the end of the quarter, Redwood Pharma transferred its listing to Nasdaq First North Growth Market as of April 14<sup>th</sup>. The company reports that the ongoing Covid-19 pandemic to some extent has affected the business development side regarding RP101 negatively, as people have had to work remotely.

#### **Phase 2 Results Published in Advances in Therapy**

The results of Redwood Pharma's Phase 2 study of RP101 have now been published in the medical journal Advances in Therapy. They have also been presented as a scientific poster at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO). The forum where Redwood Pharma's principal investigator presented these results was well attended and attracted great interest from representatives from the pharmaceutical industry, big pharma, and academics. RP101, Redwood Pharma's most advanced program, is now moving towards the next phase of clinical trials following positive data from the completed phase 2 trial. The goal is to generate the data required for market approval from the European Medicines Agency EMA and the US FDA.

#### **RP101 Towards a Pivotal Larger Clinical Trial**

Redwood Pharma is developing a low-dose, estrogen-based local eye treatment for post-menopausal women suffering from dry eye disease (DED). With 10 million postmenopausal women in Europe and the US suffering from dry eye disease in its target group, RP101 has significant sales potential. An optimized trial design will now be developed to demonstrate the therapeutic significance of the active drug, RP101, compared to the carrier IntelliGel. This work is based on Redwood Pharma's results and insights from the phase 2 trial, combined with a better understanding of how the carrier IntelliGel acts in patients. To prepare for these additional necessary clinical trials, the company has engaged Ora, Inc., a leading ophthalmological clinical contract research organization. Ora has been involved in the development of as many as 80% of all approved DED therapies in the United States and has worked extensively with global regulatory authorities. To maximize the value of RP101, Redwood Pharma continues to explore strategic options with potential development partners. The company will also seek to hold meetings with regulatory authorities to present and receive support for the proposed project strategy and design of future clinical trials.

The presentation of phase 2 results for RP101 attracted great interest at the Association for Research in Vision and Ophtalmology (ARVO)

Redwood Pharma is working on an optimized trial design for the pivotal clinical trial of RP101

#### **RP501 Moving Closer to Commercialization**

RP501 is derived from the results of the phase 2 study of RP101, in which the carrier IntelliGel independently proved effective by reducing both objective and subjective efficacy measures. While RP101 will be evaluated by the authorities as a prescription drug, RP501 is intended to be registered as a medical device with lighter regulatory requirements. Redwood Pharma believes that RP501 may be an excellent first-line therapy for the treatment of mild eve dryness in both men and women. In the work of bringing RP501 further to the market, regulatory expertise and clinical contract research laboratories have been engaged. The company is also evaluating which business model is most suitable for the RP501, whether to commercialize the product by itself or finding a partner. With regard to both RP101 and RP501, Redwood Pharma will perform additional studies with IntelliGel in patients with contact lenses. This is an important target group that has not been included in previous studies. It is estimated that about 20% of patients with dry eye also wear contact lenses. It is the company's assessment that a future partner will want to see this type of study result.

Redwood Pharma believes that RP501 may be an excellent first-line therapy for the treatment of mild eye dryness in both men and women

With regard to both RP101 and RP501, Redwood Pharma will perform additional studies with IntelliGel in patients with contact lenses

## Valuation

#### **Base Case Scenario**

In our valuation approach, we are building a base case scenario on RP101 reaching peak sales of approximately EUR 500 million five years after the expected launch in 2025. This is about half of the USD 1.2 billion that Novartis' Xiidra is expected to reach in 2025. The discount rate of 12.8% is based on a risk-free interest rate of 0%, a beta value of 1.3, a risk premium of 6.8%, and an additional small-cap premium of 4.0%. These numbers are derived from a PwC risk premia study from 2020 and the beta value is an average for biotech companies, according to Damodaran Online.

#### We Model a 45% Probability of Launch in 2025

As RP101 completed phase 2 in March 2020 and Redwood Pharma is preparing for a pivotal phase 3 study, we have chosen to use publicly available industry statistics to model RP101's chance of reaching the market. We estimate the probability of a successful launch to be 45%.

#### **Reiterating Our SEK 14 Target Price**

Since RP101 has reached furthest in development, we base our valuation of Redwood Pharma on this drug candidate. Of the 10 million women in Europe and the US who are eligible for treatment with RP101, we assume that 3%, or 300,000, will be treated with the drug by 2031. This would result in sales of just over SEK 5 billion for RP101, which assuming a 15% royalty rate would revenues of SEK 766 million for Redwood Pharma. In our base case scenario, this leads to a target price of SEK 14.

### Valuation of Redwood Pharma, Three Scenarios

	Bear Case	Base Case	Bull Case
RP101 Launch Year	2025	2025	2025
US Postmenopausal Women with Dry Eye Disease, m	4,0	4,0	4,0
EU Postmenopausal Women with Dry Eye Disease, m	6,0	6,0	6,0
% of all Patients Prescribed RP101	1,50%	3,00%	6,00%
Number of Patients Prescribed RP101	0,2	0,3	0,6
US Price per Patient per Annum, EUR	2 400	2 400	2 400
EU Price per Patient per Annum, EUR	1 200	1 200	1 200
Forecast US Sales in 2031, MEUR	144	288	576
Forecast EU Sales in 2031, MEUR	108	216	432
Forecase RP101 Sales in 2031, MSEK	2 553	5 106	10 211
Redwood Pharma Royalty Rate	15%	15%	15%
Estimated RP101 Royalties in 2031, MSEK	383	766	1 532
Operating Margin	35%	35%	35%
Operating Profit in 2031, MSEK	134	268	536
Net Income, MSEK	106	213	426
EPS in 2031 (20,7m)	5,1 kr	10,3 kr	20,6 kr
2031 P/E-Multiple	10	10	10
Fair Value per Share in 2013	51 kr	103 kr	206 kr
Discounted to 2021 Using a 13% Discount Rate	15 kr	30 kr	61 kr
RP101 Probability of Launch	45%	45%	45%
Risk Adjusted NPV per Share	7 kr	14 kr	28 kr

Source: Analysguiden

# **Company Description**

#### Background

Redwood Pharma develops ophthalmic drugs for areas with great medical needs. The company focuses on early clinical development and will move projects to a licensing deal with larger pharmaceutical companies no later than after phase 2 clinical trials. The company's first project, RP101, is a biologically active drug for chronic dry eye disease among women after menopause. The drug uses the licensed drug delivery platform IntelliGel, which controls the release of the active substance. Chronic or severe dry eye disease is something that affects 7% of all women after menopause.<sup>2</sup> In the United States alone, 4 million women who have experienced menopause suffer from moderate to severe chronic dry eye disease, and in Europe the corresponding figure is 6 million.

#### Allergan, Novartis and Santen Among the Key Players

Several companies are currently working actively with research and development in this area, and there are a number of drug candidates in clinical development. In the market for ophthalmic drugs, the three largest companies have a combined market share of over 50%. These three companies are Allergan, Novartis, and Santen Pharmaceutical.

#### **Positive Phase 2 Results for RP101**

In March 2020, Redwood Pharma presented the initial results of the phase 2 study of RP101. The drug candidate showed significant efficacy against the patient's baseline in several subjective and objective endpoints. The primary endpoint, which was the production of tear fluid according to the Schirmer test, showed a rapid improvement after 14 days while maintaining efficacy throughout the study until day 90. This is much faster than what has been achieved by other products on the market. Tear fluid production increased by up to 150%.

 $<sup>^{\</sup>rm 2}$  Frost & Sullivan – US Ophthalmic Disease Markets, 2006

Major Shareholders	
Avanza Pension	11,1%
Martin Vidaeus	5,8%
Formue Nord Markedsneutral A/S	4,9%
Jan Petersen	4,1%
Hans Ageland	2,0%

Source: Spotlight Stock Market

### **Income Statement (MSEK)**

	2016	2017	2018	2019	2020	2021E	2022E
Net Sales	0	0	0	0	0	0	0
Operating Costs	-9	-19	-14	-16	-15	-14	-14
EBITDA	-9	-19	-14	-16	-15	-14	-14
Depreciation	0	0	0	0	0	0	0
EBITA	-9	-19	-14	-16	-15	-14	-14
Amortization	0	0	0	0	0	0	0
Operating Profit (EBIT)	-9	-19	-14	-16	-15	-14	-14
Extraordinary Items	0	0	0	0	0	0	0
EBIT Excluding Extraordinary Items	-9	-19	-14	-16	-15	-14	-14
Net Financial Items	0	0	0	0	0	0	0
Pretax Profit	-9	-19	-14	-16	-15	-14	-14
Taxes	0	0	0	0	0	0	0
Minority Interests	0	0	0	0	0	0	0
Net Income	-9	-19	-14	-16	-15	-14	-14

### Balance Sheet (MSEK)

	2016	2017	2018	2019	2020	2021E	2022E
ASSETS							
Property, Plant & Equipment	0	0	0	0	0	0	0
Other Fixed Assets	0	0	0	0	0	0	0
Goodwill	0	0	0	0	0	0	0
Other Intangible Assets	1	1	6	6	6	8	10
Other Fixed Assets	0	0	0	0	0	0	0
Total Fixed Assets	1	1	6	6	6	8	10
Inventory	0	0	0	0	0	0	0
Accounts Payable	0	0	0	0	0	0	0
Other Current Assets	0	0	0	0	0	1	2
Cash and Cash Equivalents	13	8	11	8	7	22	8
Total Current Assets	13	8	11	8	7	23	10
TOTAL ASSETS	14	9	17	14	13	31	20

# Equity and Liabilities (MSEK)

	2016	2017	2018	2019	2020	2021E	2022E
Equity	12	3	13	12	7	25	14
Minority Interests	0	0	0	0	0	0	0
Total Equity	12	3	13	12	7	25	14
Long-Term Interest-Bearing Debt	0	0	0	0	0	0	0
Other Long-Term Liabilities	0	0	0	0	0	0	0
Total Long-Term Liabilities	0	0	0	0	0	0	0
Short-Term Interest-Bearing Debt	0	0	0	0	0	0	0
Accounts Payable	0	3	0	1	0	1	1
Other Short-Term Liabilities	2	3	4	1	6	5	5
Total Current Liabilities	2	6	4	2	6	6	6
TOTAL EQUITY AND LIABILITIES	14	9	17	14	13	31	20

### **Cash Flow Statement (MSEK)**

	2016	2017	2018	2019	2020	2021E	2022E
CF Before Changes in Working Capital	-9	-19	-14	-16	-15	-14	-14
Changes in Working Capital	1	4	-2	-2	4	0	0
Other Items	0	0	0	0	0	0	0
Cash Flow From Operating Activities	-7	-15	-16	-18	-11	-14	-14
Cash Flow From Investing Activities	-1	0	-5	0	0	0	0
Free Cash Flow	-8	-15	-21	-18	-11	-14	-14
Cash Flow From Financing Activities	21	10	24	15	9	29	0
Cash Flow for the Period	13	-5	3	-3	-2	15	-14
Cash and Cash Equivialents	13	8	11	8	7	22	8
Net Debt (Net Cash)	-13	-8	-11	-8	-3	-22	-8

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#### **Analyst:**

Thomas Nilsson

