Accelerated Development of RP501 for Dry Eyes

RP501 Can Reach the Market Within 2 years

As expected, Redwood Pharma reported no revenue during H1 2021. Operating profit amounted to SEK -11 million (-8) and the company's cash position amounted to SEK 22 million at the end of the period. In October, a strategic change was announced in the form of accelerated development of RP501 for dry eyes. While RP101 continues to be a clinically proven, unique drug candidate for postmenopausal women, there will be an increased focus on RP501, which can generate revenue in the near future. RP501 is intended to treat milder forms of dry eyes in a wider patient population with both men and women. As OTC products have a lower price level, the sales potential for RP501 is lower, at the level of USD 50 million per geographical region. Redwood Pharma has assessed that RP501 can reach the market within 2 years and that the company's cash at hand is sufficient to obtain a CE mark in the EU.

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. RP101 has shown significant effect on corneal damage, with a greater difference than the ophthalmic drug Xiidra, for which Novartis acquired the rights in a deal worth up to USD 5.3 billion. In our valuation model, we estimate RP101 could reach peak sales of EUR 500 million.

Target Price Adjusted to SEK 10

RP501 can reach the market within two years and thus generate revenues in the near future. With the accelerated development of RP501, we have now included it with RP101 in our sum-of-the-parts valuation. As the company will not invest more resources in the RP101 program at present, we have reduced the probability of a launch of RP101 in 2026. Overall, our changed assumptions mean that in our base case scenario our new target price is SEK 10 (previously SEK 14).

Redwood Pharma

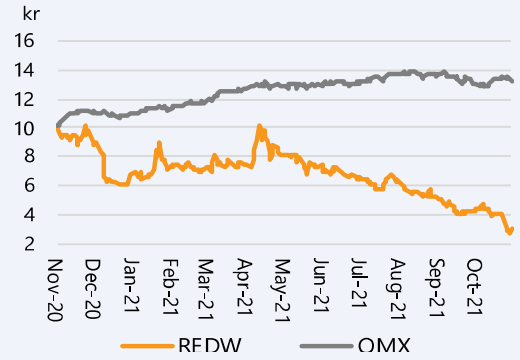
Company Update

Date	15 November 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 2,90
Shares Outstanding, m	20,7
Market Cap, MSEK	60
Net Debt, MSEK	-22
Enterprise Value, MSEK	38
Website	www.redwoodpharma.se

Share price development



Source: NasdaqOMX

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	-1,1 kr	-1,0 kr	-0,7 kr	-0,7 kr
Dividend	0,0 kr	0,0 kr	0,0 kr	0,0 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	n/a	n/a	n/a	n/a
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

Source: Company reports, Analysguiden

Operational Update

Accelerated Development of RP501 for Dry Eyes

In October, a strategic change was announced in the form of accelerated development of RP501 for dry eyes (Dry Eye Disease, DED). While RP101 continues to be a clinically proven, unique drug candidate for postmenopausal women, there will now be an increased focus on RP501, which can generate revenues in the near future. RP501 has significant commercial potential as a next generation first-line therapy for the majority of all those suffering from dry eyes, which includes both men and women of all ages. According to a report from Transparency Market Research, the global market was valued at USD 2.3 billion in 2019 and is expected to grow to USD 2.9 billion by 2030. For an OTC-product such as RP501, USD 50 million in sales in a geographical region would be considered a success if achieved. A successful launch of RP501 could in and of itself move Redwood Pharma to profitability.

OTC-product RP101 can start generating revenue within two to three years

Promising Results with RP501 in Clinical Trials

Regular eye drops are quickly removed from the front of the eye and must therefore be applied frequently. This has led to a need for products that stay on the eye for a longer period of time and reduces the number of times they need to be administered throughout the day. RP501 (IntelliGel) was used as a drug carrier and placebo control in the phase 2 clinical trial of RP101 completed in 2020. Data from this study showed that RP501, when administered twice daily, improved both symptoms and objective measurement points, even in patients with severe DED. In this study, RP501 showed improved tear fluid production as measured by the Schirmer test. The goal is to offer RP501 as an easy-to-use alternative to regular eye drops for more than 340 million people suffering from dry eyes.

RP501 is intended as an alternative for the more than 340 million people suffering from dry eyes

Upcoming Steps in the Development of RP501

The company has worked with clinical and regulatory consultants to map the regulatory pathways, and identify and start the activities needed to reach approvals in Europe and the US. Lab tests have been completed which have shown that RP501 is compatible with contact lenses, which is important as approximately 20% of those suffering from mild dry eye in Europe and the US use them. Redwood Pharma has now decided to increase the pace of the development work related to RP501. Among other things, a decision has been made to proceed with a clinical trial in order to provide support for future medical device applications in Europe and the US. This study is not as resource intensive as the previous phase 2 study with RP101. The next steps in the development of RP501 include:

RP501 is compatible with contact lenses used by 20% of those with mild eye dryness

- Adoption of a regulatory strategy for Europe and the US
- Complementary *in vitro* tests to obtain regulatory approval
- Clinical trial for additional tests in people suffering from dry eyes, including those with contact lenses

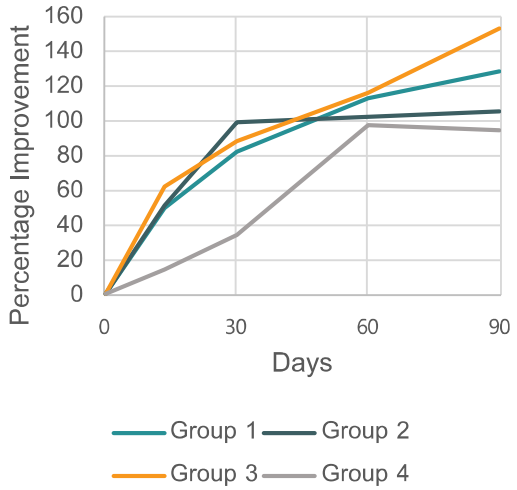
The company estimates that cash at hand will be sufficient to obtain a CE mark in the EU. Redwood Pharma is now working on establishing a budget for the work of achieving regulatory approval for RP501 in the US. RP501 is to be seen as an extension of the RP101 program and is based on the results from the phase 2 study of RP101 and the investment made by the shareholders in connection with this.

RP101 Ready for Pivotal Phase 3 Trial

The results of Redwood Pharma's phase 2 study of RP101 were published in the medical journal Advances in Therapy in H1 2021. 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. Although RP101 did not reach the primary endpoint of Schirmer tests when compared to the IntelliGel vehicle, it showed safety and efficacy in a number of important objective and subjective benchmarks against both the baseline and the drug carrier IntelliGel, which was used as placebo control. The primary measure of effectiveness, the production of tear fluid according to the Schirmer test, showed a rapid onset already after 14 days with maintained effect throughout the study until day 90. This is significantly earlier than with other available treatments. Tear fluid production increased by up to 150%, as shown in the following chart. In the phase 2 study of RP101, the carrier IntelliGel was used as a placebo, which in itself is a water-carrying system. The outcome for the patients who only received IntelliGel is shown as group 4 in the same chart. These data support RP101 for the treatment of DED in postmenopausal women and have formed the basis of the design of the pivotal study required for market approval.

RP101 increased tear fluid production by 150% after 90 days of treatment

Highest Dose Increased Tear Production by 150%



Source: Redwood Pharma, Schirmer test RP101

Discussions With Potential Partners Regarding RP101

Since the phase 2 results were presented, Redwood Pharma has had discussions with a large number of larger, and some more specialized, pharmaceutical companies regarding the development of RP101. If Redwood Pharma finds a partner with whom it enters a licensing agreement for RP101, the drug can reach the market four years later. RP101's unique mechanism of action could make the program the first hormone therapy for dry eyes that targets the underlying biological mechanisms in and around the eye. The process of finding a suitable partner continues to require patience and perseverance from Redwood Pharma and its shareholders. At present, however, it has not been possible to find a satisfactory agreement with a partner to take the program further. The company's assessment is that RP101 can be a significant commercial therapy that can help many women after menopause who suffer from chronic DED, where there is a great medical need. Until an agreement is found with a partner for RP101, however, the focus will be on accelerating the development of RP501. RP501 has significant potential as first-line therapy for the majority of all people suffering from dry eyes, which includes both men and women of all ages. There is also additional potential to develop new products based on the IntelliGel platform, which has been clinically tested and has the ability to deliver drugs to the front of the eye.

If Redwood Pharma finds a partner for RP101, the drug can reach the market in 4 years

Target Price Adjusted After Change of Strategy

As expected, Redwood Pharma reported no revenue in H1 2021 and operating profit came in at SEK -11 million (-8). The cash position at the end of the period amounted to SEK 22 million. During Q2, the company changed its listing from Spotlight Stock Market to Nasdaq First North Growth Market in order to increase visibility among larger investors. As the company intends to invest the majority of its resources in the development of RP501, we have chosen to revisit our valuation model. The positive thing about the accelerated development program for RP501 is that this OTC-product can reach the market within two years, and thus generate revenue in the near future. We have therefore included RP501 together with RP101 in our sum-of-the-parts valuation. As the company will not invest more resources in the RP101 program at present, we have reduced the probability of a launch of RP101 in 2026. Overall, our changed assumptions mean that the new target price in our base case scenario is SEK 10 (previously SEK 14).

As RP101 will be allocated fewer resources, we adjust our target price to SEK 10

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. [1] 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.

The market for dry eye drugs is expected to grow to USD 7.2 billion in 2025

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

[1] https://www.asdreports.com/market-research-report-562474/dry-eye-disease-diagnostics-treatment-market

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.

RP101 has shown better results than Xiidra acquired by Novartis in a deal worth USD 5.3bn

Källa: Novartis

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 2026.

For an OTC-product like RP501, USD 50m in a geographic region is considered successful

Target Price Adjusted to SEK 10

With the accelerated development of RP501, we now include it with RP101 in our sum-of-the-parts valuation. As the company will not invest more resources in the RP101 program at present, we have reduced the probability of a launch of RP101 in 2026. Our new target price is SEK 10 (previously SEK 14).

Valuation

RP501 Included in Sum of the Parts Valuation

OTC-product RP501 can reach the market within 2 years

As Redwood Pharma has made a strategic decision to accelerate the development of RP501, we have chosen to now include this drug candidate in our sum-of-the-parts valuation. With continued successful development, RP501 could reach the market within 2 years, and for this type of OTC-product, USD 50 million in sales in a geographic region is considered a success. In our base case scenario, we assume that this level of sales will be reached five years after launch in both Europe and the US.

RP101 Can Reach Peak Sales of 500 MEUR

As RP501 is now prioritized, we have lowered the probability of launching RP101 in 2026

In our base case scenario, we assume RP101 can reach peak sales of EUR 500 million five years after launch. This is approximately half of the USD 1.2 billion in revenue that Novartis' Xiidra is expected to generate in 2025. Of the 10 million women in Europe and the US currently eligible for treatment with RP101, we assume that 3%, or 300,000, could be treated with the drug in 2031. This would result in sales of just over SEK 5 billion for RP101, which with a 15% royalty would give Redwood Pharma revenues of SEK 766 million. As the company now prioritizes the development of RP501, we have chosen to lower the probability of launching RP101 in 2026 by 50% to 23% (previously 45%).

Target Price Adjusted After Change of Strategy

Target price adjusted to SEK 10

With the accelerated development of RP501, we now include it with RP101 in our valuation model. As the RP101 program will be allocated less resources, we have reduced the probability of a launch of RP101 in 2026. Our new target price is SEK 10 (previously SEK 14).

Valuation of Redwood Pharma, Three Scenarios

	Bear Case	Base Case	Bull Case
Risk Adjusted NPV Per Share, RP101	3,4 kr	6,9 kr	13,8 kr
Risk Adjusted NPV Per Share, RP501	1,5 kr	3,0 kr	4,4 kr
Risk Adjusted NPV per Share, Redwood Pharma	5 kr	10 kr	18 kr

Source: Analysguiden

Valuation of RP101, Three Scenarios

	Bear Case	Base Case	Bull Case
RP101 Launch Year	2026	2026	2026
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
Forecast 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	23%	23%	23%
Risk Adjusted NPV per Share	3,4 kr	6,9 kr	13,8 kr

Källa: Analysguiden

Valuation of RP501, Three Scenarios

	Bear Case	Base Case	Bull Case
RP501 Launch Yeat	2024	2024	2024
Forecast US Sales in 2029, MUSD	25,0	50,0	75,0
Forecast European Sales in 2029, MUSD	25,0	50,0	75,0
Forecast Sales in 2029, MSEK	433	866	1 299
Redwood Pharma Royalty Rate	15%	15%	15%
Estimated RP501 Royalties in 2029, MSEK	65	130	195
Operating Margin	35%	35%	35%
Operating Profit in 2029, MSEK	23	45	68
Net Income, MSEK	18	36	54
EPS in 2029 (20,7m)	0,9 kr	1,7 kr	2,6 kr
2029 P/E-Multiple	10	10	10
Fair Value Per Share in 2029	8,7 kr	17,4 kr	26,2 kr
Discounted to 2021	3,3 kr	6,6 kr	9,8 kr
RP501 Probability of Launch	45%	45%	45%
Risk Adjusted NPV per Share	1,5 kr	3,0 kr	4,4 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. 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.[2] 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. While RP101 continues to be a clinically proven, unique drug candidate for postmenopausal women, there will be an increased focus on RP501, which can generate revenue in the near future. RP501 is intended to treat milder forms of dry eyes in a wider patient population with both men and women of all ages.

Allergan, Novartis and Santen Among 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.

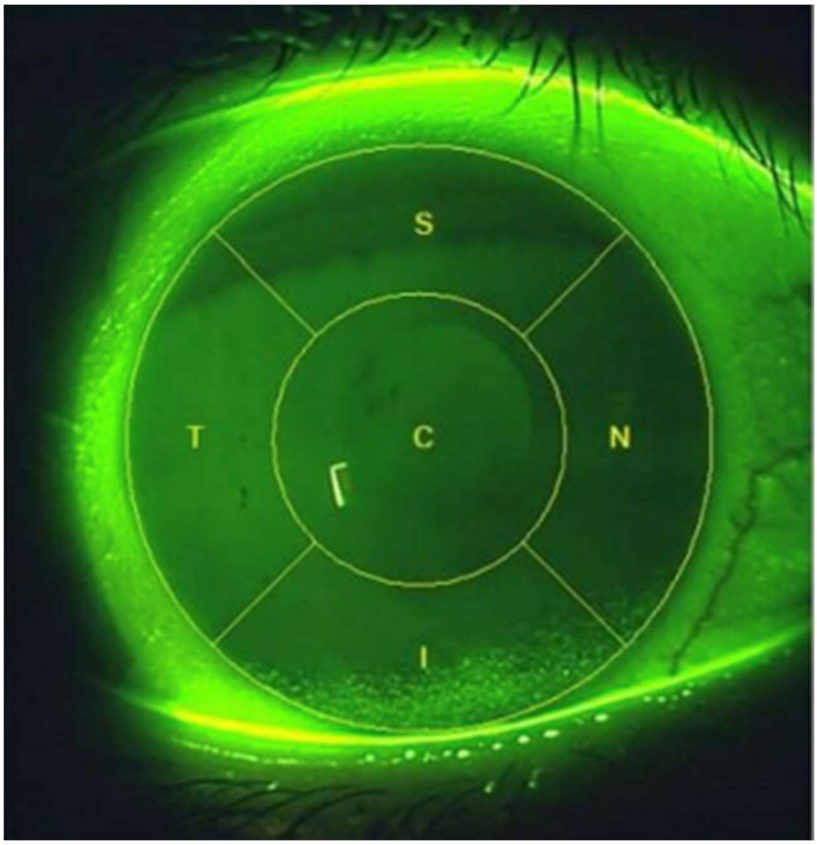
Positive Phase 2 Results for RP101

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%.

[2] Frost & Sullivan – US Ophthalmic Disease Markets, 2006

Corneal Staining a Possible New Endpoint for RP101

In the phase 2 study of RP101, the carrier IntelliGel which was used as placebo control, is in itself a water-carrying system. The challenge in DED is often to show a significant effect when compared to placebo as the symptoms are due to an instability in the tear film. As soon water is added, the patient gets better. An alternative is to study so-called corneal staining which is the endpoint used when Novartis' Xiidra was approved. In the in-depth analysis performed by Ora, Inc. on RP101, it showed better effect than Xiidra in terms of the effect of the treatment on corneal damage.



Source: A Novel Scale for Describing Corneal Staining, Woods et al.

C (central zone), S (superior zone), N (nasal zone), I (inferior zone), T (temporal zone)

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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