Cyxone AB

Sweden / Biotechnology
Nasdaq First North
Bloomberg: CYXO SS
ISIN: SE0007815428

Q1/20 results & pipeline update

RATING	**BUY**
PRICE TARGET	**SEK 12.70**
Return Potential	87.0%
Risk Rating	Speculative

PIPELINE DEVELOPMENT SLIGHTLY DELAYED, BUT POTENTIAL INTACT

Cyxone published Q1/20 results and provided an update on the R&D pipeline. Preparations for the next steps with the two main R&D programmes, Rabeximod for rheumatoid arthritis (RA) and T20K for multiple sclerosis (MS) have progressed, although with some delay. Management's decision to order fresh active material to produce Rabeximod pushes back the initiation of the Phase IIb trial to Q1/21 (previously: H1/20). The company is also conducting additional tests to optimise the T20K Phase Ib trial design. Although time-consuming, we view these actions as vital to maximise the upcoming trials' chances of success. On 1. June, Dr Tara Heitner took over as new CEO from Mr Skanung (CFO) who acted as interim CEO. Dr Heitner has extensive experience from previous board and senior management positions in the pharma and biotech field. We view this step as positive. She will provide Cyxone with a sharper business development focus, and we expect that the drug candidates will benefit from her experience in terms of future successful closing of partnering deals. On 10 June, Cyxone added a therapeutic programme against COVID-19 to its pipeline. The new programme is a collaboration with the inventor, Dr Kalev Kask. The company has so far disclosed only limited information on this early-stage programme and so we have not included it in our valuation. We have updated our SOTP pipeline valuation model to take account of the new development timelines of the two lead programmes. We arrive at a new price target of SEK 12.70 (old: SEK 13.50). We reiterate our Buy rating.

Rabeximod's Phase IIb study in moderate to severe RA to start in Q1/21 (FBe: Q2/20) In November last year the company appointed a UK contract research organisation (CRO) to carry out animal studies lasting six months to investigate toxicity during long-term treatment with Rabeximod. In December, management commissioned the service provider Aptuit (a subsidiary of the German biotech company Evotec) to conduct encapsulation of the active ingredient. (p.t.o)

FINANCIAL HISTORY & PROJECTIONS

	2017	2018	2019	2020E	2021E	2022E
Revenue (SEK m)	0.00	0.00	0.03	0.03	0.03	178.03
Y-o-y growth	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT (SEK m)	-8.82	-31.78	-35.17	-42.78	-47.52	129.92
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income (SEK m)	-8.82	-31.78	-35.17	-42.78	-47.52	129.92
EPS (diluted) (SEK)	-0.50	-1.41	-0.86	-0.87	-0.89	2.26
DPS (SEK)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (SEKm)	-11.37	-43.49	-36.22	-40.98	-45.86	131.39
Net gearing	n.a.	n.a.	-86.1%	-71.7%	-71.8%	-96.7%
Liquid assets (SEK m)	33.36	38.72	61.76	20.77	16.57	147.97

RISKS

Risks include, but are not limited to development, regulatory, competition and financing risks.

COMPANY PROFILE

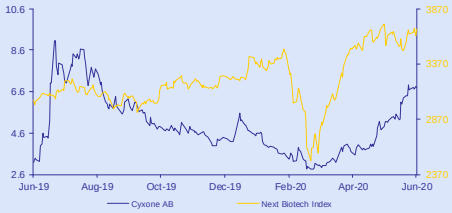
Cyxone AB is a Swedish biotech company focused on the research and development of new drugs to treat autoimmune diseases. The company's proprietary discovery technology is generating drug candidates which belong to a new class of drugs called Cyclotides. Cyxone currently has one drug in a phase I trial for multiple sclerosis and a second drug at the phase II stage for rheumatoid arthritis.

MARKET DATA

	As of 25 Jun 2020
Closing Price	SEK 6.79
Shares outstanding	49.08m
Market Capitalisation	SEK 333.26m
52-week range	SEK 2.85 / 9.07
Avg. Volume (12 Months)	420,578

Multiples	2019	2020E	2021E
P/E	n.a.	n.a.	n.a.
EV/Sales	10592.2	9380.8	9380.8
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

	As of 31 Mar 2020
Liquid Assets	SEK 51.83m
Current Assets	SEK 52.72m
Intangible Assets	SEK 11.29m
Total Assets	SEK 64.97m
Current Liabilities	SEK 3.41m
Shareholders' Equity	SEK 61.55m

SHAREHOLDERS

Accequa AB	12.2%
Avanza Pension	6.6%
Jan Ivar Nordqvist	4.2%
OxyPharma AB	3.9%
Others	73.2%

Analyst: Christian Orquera, Tel. +49 30 80 93 96 93

Cyxone had granulated material for the Phase IIb trial which it purchased during the acquisition of Rabeximod's IP from Oxypharma. But during the preparation process for encapsulation, Aptuit analysed this material. Based on the results, Cyxone decided to use newly manufactured material. We understand that the existing material may be too old, which could potentially affect its quality.To avoid putting the performance of the drug at risk in the clinical trial, Cyxone ordered new material from its provider. Given typical industry production timelines in the range of 3-6 months, we believe Aptuit will not be able to encapsulate the material until Q3 or early Q4 2020. After manufacture, the capsules will undergo a series of feasibility studies to ensure compliance with quality and patient safety requirements.

In parallel, the company applied last year to two of up to eight target regulatory authorities in selected European countries (including Poland, Estonia, Ukraine, and Georgia) for permission to initiate the Phase IIb study. The applications were successful in the first and more significant stage in which the corresponding Ethics Committees (ECs) gave their approval. Once the ECs approve, the company is required to submit samples of the final product including packaging, labelling, and additional standard documentation to obtain final approval from the regulatory authority in each country. The delay in availability of the encapsulated final product means that the company cannot submit samples and so final approval will also be delayed. The company intends to file for approval in the remaining six countries once it is able to deliver product samples. It is not advisable to make the EC's wait too long for the samples and the subsequent initiation of the trial. According to current management guidance, the final approvals will be obtained in Q1/21 at which point patient recruitment will also start (previous guidance: Q2/20). Cyxone already has two reputable clinical research organisations (CROs) in place which will carry out the clinical trials. EGeen Inc. and Sourcia will jointly be responsible for Eastern and Western Europe.

The company is conducting additional analysis in preparation for the oral Phase Ib study of T20K in MS Cyxone successfully completed the Phase I safety study of T20K administered as i.v. infusion in August 2019. Shortly afterwards, the company started approaching clinicians and experts in the MS field to share the data and obtain feedback which can be valuable for designing the upcoming Phase Ib trial with an oral formulation. Management confirmed that the drug candidate had met with interest. The company also proceeded to conduct further in-vitro and in-vivo investigations into how the substance dissolves and is absorbed in the gastrointestinal tract, how long it remains in circulation and whether it accumulates in any specific organ. This information is intended to support the company's decision on the most appropriate type of oral formulation to be used in the Phase Ib study. We believe this data will also strengthen the application dossier, and assist the currently ongoing process of defining an optimal clinical trial design. During H2/20, we anticipate that the company and their CRO QPS (Custom-Built Research) will together approach the regulatory authorities in the Netherlands to discuss the trial design. We expect filing and initiation of the Phase Ib study in H1/21. In addition, Cyxone's partner, the University of Vienna, filed a new patent application for extended protection of T20K in MS.

Further patent applications filed Besides the patent filing for T20K mentioned above, on 10 June the company conducted four additional undisclosed patent filings based on recent innovations. These patents are related to manufacturing and formulation processes. We believe these patents can potentially strengthen both lead drug candidates' IP.

Agreement with the inventor Kalev Kask to develop a COVID-19 treatment allows pipeline expansion Dr Kask is a biotech executive, inventor and entrepreneur who has extensive expertise in drug development and an attractive investor network in the US where he is based. On 10 June, Dr Kask and Cyxone decided to jointly develop a treatment for COVID-19 based on Dr Kask's invention. As part of the agreement, Cyxone will cover the costs related to filing of patents and development of the programme and will pay

undisclosed royalties on net revenues in case of successful commercialisation of the drug. In exchange, the company will own all future IP rights to the product. The deal also gives Dr Kask (either himself or an investor designated by him) the option to buy up to 4.9m Cyxone shares (~10% of the total) until 1 October 2020 at a subscription price starting at SEK 4.45. If the option is exercised, the stock placement could provide Cyxone with funds of up to SEK 21.8m. The final subscription price will be determined and approved by the board at the time of the placement in compliance with market conditions. The investment will also be subject to US laws.

New CEO provides Cyxone with a stronger business development focus On 20 May, Cyxone appointed Dr Tara Heitner as the new CEO of the company. She took up her position on 1. June 2020. She has more than 20 years of experience in academia as well as in the biopharmaceutical industry, including senior management business development and CEO positions at highly innovative biotech companies. She brings to Cyxone a strong international business network built during her international career working across North America, Europe and Asia. In our view, with this personnel change, the company intends to transition the focus from technology and drug development towards business development and commercialisation which includes paving the way to close partnering deals for the products after achieving the upcoming development milestones. We recall that Kjell Stenberg, the previous CEO, stepped down in November last year. Mr Ola Skanung, CFO of the company, took up the role for an interim period.

FY/19 RESULTS – COMPANY SWITCHED FROM CAPITALISING TO EXPENSING DEVELOPMENT COSTS

FY/19 financial statement Cyxone generated revenue and other income of SEK 27k (FBe: SEK 48k). In 2020, management decided to switch from capitalising to expensing development expenses. We view this change as positive, as it aligns better with standard industry practice. The company applied the new policy to the FY/19 financial report. To provide comparable figures, the company also restated the FY/18 financial statement under the assumption that this principle has always been applied. These measures led to higher operating expenses due to the expensing of development costs. The company did not provide figures for FY/19 based on the previous accounting policy. In FY/19, EBIT reported under the new policy was SEK -35.2m which represents a cost increase of only SEK 3.4m compared to the previous period (FY/18: SEK -31.8m). Under the previous accounting policy, we were projecting a Y-o-Y cost increase of SEK 5.0m (up from SEK -15.4m in FY/18 to SEK -20.4m in FY/19E). Net income for the period came in at SEK -35.2m (FY/18: SEK -31.8m). We give an overview of the main P&L positions in figure 1.

Figure 1: P&L FY/19 reported figures vs. FB estimates and FY/18 (KPIs)

in SEK'000	FY/19	FY/19E	Delta	FY/18	Delta
Revenue & other income	27	48	-	1	-
EBIT	-35,165	-20,462	n.m.	-31,783	n.m.
margin	*n.m.*	*n.m.*	-	*n.m.*	-
Net income	-35,165	-20,436	n.m.	-31,783	n.m.
margin	*n.m.*	*n.m.*	-	*n.m.*	-

**FY/18 and FY/19 figures were reported under the new policy of expensing development costs, FY/19E were projected based on the previous policy of capitalising them.*

Source: First Berlin Equity Research, Cyxone AB

Q1/20 RESULTS

P&L Cyxone reported sales and other income of SEK 0 (Q1/18: SEK 48k). The company achieved EBIT of SEK -10.1m (Q1/19: SEK -6.8m). In particular other external operating expenses at SEK 8.6m were substantially higher than in the previous period (Q1/19: SEK 5.2m) due chiefly to higher development activity. Net income came in at SEK -10.2m (Q1/19: SEK -6.8m).

Revising forecasts following FY/19 and Q1/20 results, as well as the accounting policy change In the light of the sales and cost performance achieved in FY/19 and Q1/20, we have fine-tuned our financial projections. Our new forecasts reflect the recent accounting policy change. We have also assessed pipeline progress to adjust our milestone forecasts. We thus pushed back the SEK 89m out-licensing milestone for Rabeximod (after completion of Phase IIb) to FY/22E (previously: FY/20). We left the timing of the SEK 89m out-licensing milestone for T20K unchanged in FY/22E. We have summarised the main changes in figure 2 below.

Figure 2: Changes to our forecasts (KPIs)

	2020E			2021E			2022E		
in SEK'000	old	new	Delta	old	new	Delta	old	new	Delta
Sales	50	30	*-40.0%*	50	30	*-40.0%*	50	30	*-40.0%*
Milestone & Upfront payments	89,000	0	*-100.0%*	0	0	-	89,000	178,000	*100.0%*
EBIT	-63,757	-42,781	-	-31,455	-47,522	-	59,079	129,922	*119.9%*
Margin (%)	-	-	-	-	-	-	-	-	-
Net income	-63,797	-42,781	-	-31,419	-47,522	-	59,108	129,921	*119.8%*
EPS diluted (SEK)	-1.33	-0.87	-	-0.59	-0.87	-	1.01	2.16	*119.8%*

Source: First Berlin Equity Research estimates

Balance sheet Following the successful series-3 warrants conversion in September 2019, which provided net funds of SEK 59.3m, Cyxone has sufficient funds to bring Rabeximod and T20K through Phase IIb and Phase Ib respectively. The end-March cash position was a healthy SEK 51.8m (FY/19: SEK 61.8m). Patent, licenses and similar rights declined slightly to SEK 11.3m from SEK 11.7m in 2019 due to depreciation. This position chiefly includes the patent right expenses and fees for T20K as well as the acquired product Rabeximod. We recall that this position was adjusted under the new accounting principles implemented as of 31 December 2019. The full investment in the purchased drug candidate Rabeximod is now reported under the patents position instead of allocating part of it to a separate intangible asset position called “capitalised development cost”. This value is depreciated over the useful patent lifetime. Also, the “capitalised development costs” position which amounted to SEK 29.9m at the end of 2018 has been removed from the balance sheet since year-end 2019 (also retroactively for FY/2018).

Cash flow Net operating cash flow came in at SEK -9.9m (Q1/19: SEK -8.6m). Cash flow from investment activities amounted to SEK 0 (Q1/19: SEK -27k). As in Q1/19, there was no financing cashflow in Q1/20.

Buy rating reiterated at lower price target The company’s announcements on the appointment of Dr Tara Heitner as the new CEO, the addition of the COVID-19 programme, as well as the five new patent filings are good news. However, a slight positive effect from rolling forward our valuation model is more than cancelled out by the negative impact of the delay in the pipeline development and of the upfront payments we were expecting from potential licensing and partnering agreements. Our SOTP valuation model now yields a price target of SEK 12.70 (previously SEK 13.50). We stick to our Buy recommendation.

VALUATION MODEL

Figure 3: Sum-of-the-parts valuation model

Compound	Project[1)]	Present Value (SEKM)	Patient Pop (K)	Treatment Cost (SEK)	Market Size (SEKM)	Market Share (%)	Peak Sales (SEKM)	PACME Margin[2)] (%)	Discount Factor (%)	Patent Life[3)] (years)	Time to Market (years)
Rabeximod	RA	SEK 483.9M	470K	106,800	50,196.0M	9%	8,461.5M	16%	21.5%	9	5
T20K	MS	SEK 240.6M	850K	213,600	181,560.0M	5%	12,711.4M	18%	21.5%	9	7
PACME PV		SEK 724.5M			231,756.0M		21,172.8M				
Costs PV[4)]		SEK 180.4M									
NPV		SEK 544.1M									
Milestones PV		SEK 82.4M									
Net cash (pro-forma)		SEK 86.2M									
Fair Value		SEK 712.7M									
Share Count (fully diluted)		56,117K									
Price Target		SEK 12.70									

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining patent life after the point of approval

4) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research

INCOME STATEMENT

All figures in SEK '000	2017	2018	2019	2020E	2021E	2022E
Revenue & other income	**0**	**1**	**27**	**30**	**30**	**30**
Upfront & milestone payments	**0**	**0**	**0**	**0**	**0**	**178,000**
Total revenue & other income	**0**	**1**	**27**	**30**	**30**	**178,030**
Personnel Costs	2,287	2,231	5,252	5,515	5,570	5,626
Other external costs	6,515	28,597	28,010	35,292	39,880	40,279
Depreciation & Amortization	22	956	1,794	1,864	1,957	2,055
Operating income (EBIT)	**-8,824**	**-31,783**	**-35,165**	**-42,781**	**-47,522**	**129,922**
Net financial result	0	0	0	0	0	0
Pre-tax income (EBT)	**-8,824**	**-31,784**	**-35,165**	**-42,781**	**-47,522**	**129,921**
Income taxes	0	0	0	0	0	0
Net income / loss	**-8,824**	**-31,784**	**-35,165**	**-42,781**	**-47,522**	**129,921**
Diluted EPS	**-0.50**	**-1.41**	**-0.86**	**-0.87**	**-0.87**	**2.16**
Ratios						
EBIT-Margin on total revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBITDA margin on total revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net Margin on total revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Expenses as % of Revenues						
Personnel Costs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Other external costs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Y-Y Growth						
Total revenue & other income	n.a.	n.a.	n.a.	12.9%	0.0%	n.a.
Operating income	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income/ loss	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

BALANCE SHEET

All figures in SEK '000	2017	2018	2019	2020E	2021E	2022E
Assets						
Current Assets, Total	**33,499**	**39,268**	**62,420**	**21,501**	**17,369**	**148,851**
Cash and Cash Equivalents	33,357	38,715	61,756	20,771	16,565	147,968
Accounts Receivable & others	142	553	664	730	803	884
Non-Current Assets, Total	**7,565**	**13,498**	**12,696**	**11,131**	**9,674**	**8,419**
Capitalised development costs*	6,554	0	0	0	0	0
Other intangibles (patents, licenses)	1,011	13,498	11,741	10,176	8,719	7,464
Other Assets	0	0	955	955	955	955
Total Assets	**41,064**	**52,766**	**75,115**	**32,632**	**27,043**	**157,270**
Shareholders' Equity & Debt						
Current Liabilities, Total	**3,932**	**5,121**	**3,378**	**3,677**	**3,959**	**4,265**
Accounts Payable	3,079	4,026	1,694	1,711	1,797	1,887
Other current liabilities	853	1,095	1,684	1,965	2,162	2,378
Longterm Liabilities, Total	**0**	**0**	**0**	**0**	**0**	**0**
Shareholders Equity	**37,132**	**47,645**	**71,737**	**28,956**	**23,084**	**153,005**
Total Consolidated Equity and Debt	**41,064**	**52,766**	**75,115**	**32,632**	**27,043**	**157,270**
Ratios						
Current ratio (x)	8.52	7.67	18.48	5.85	4.39	34.90
Quick ratio (x)	8.52	7.67	18.48	5.85	4.39	34.90
Net gearing	n.a.	n.a.	-86.1%	-71.7%	-71.8%	-96.7%
Book value per share (€)	2.09	2.12	1.75	0.59	0.43	2.66
Net debt	-33,357	-38,715	-61,756	-20,771	-16,565	-147,968
Equity ratio	90.4%	90.3%	95.5%	88.7%	85.4%	97.3%

**The company stopped capitalising development costs at the financial statement of FY/19; FY/18 figures were also adjusted retroactively.*

CASH FLOW STATEMENT

All figures in SEK '000	2017	2018	2019	2020E	2021E	2022E
Net income	**-8,824**	**-31,784**	**-35,165**	**-42,781**	**-47,522**	**129,921**
Interest, net	0	0	0	0	0	0
Tax provision	0	0	0	0	0	0
EBIT	**-8,824**	**-31,783**	**-35,165**	**-42,781**	**-47,522**	**129,922**
Depreciation and amortization	22	956	1,794	1,864	1,957	2,055
EBITDA	**-8,802**	**-30,827**	**-33,371**	**-40,917**	**-45,564**	**131,977**
Changes in working capital & others	3,426	778	-1,854	232	209	209
Cash interest net	0	0	-1	0	0	0
Other Adjustments	0	0	0	0	0	0
Operating cash flow	**-5,376**	**-30,049**	**-35,226**	**-40,685**	**-45,355**	**132,186**
CapEx	-5,990	-13,444	-991	-300	-500	-800
Free cash flow	**-11,366**	**-43,493**	**-36,216**	**-40,985**	**-45,855**	**131,386**
Cash flow from investing	**-5,990**	**-13,444**	**-991**	**-300**	**-500**	**-800**
Debt Financing, net	0	0	0	0	0	0
Equity Financing, net	23,125	48,851	59,257	0	41,650	0
Cash flow from financing	**23,125**	**48,851**	**59,257**	**0**	**41,650**	**0**
Net cash flows	**11,759**	**5,358**	**23,041**	**-40,985**	**-4,205**	**131,386**
Cash, start of the year	21,598	33,357	38,715	61,756	20,771	16,565
Cash, end of the year	**33,357**	**38,715**	**61,756**	**20,771**	**16,565**	**147,968**

Y-Y Growth						
Operating Cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Free cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBITDA/share	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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Anschrift:
First Berlin Equity Research GmbH
Mohrenstr. 34
10117 Berlin
Germany

Vertreten durch den Geschäftsführer: Martin Bailey

Telefon: +49 (0) 30-80 93 9 680
Fax: +49 (0) 30-80 93 9 687
E-Mail: info@firstberlin.com

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First Berlin Equity Research GmbH

Authored by: Christian Orquera, Analyst
All publications of the last 12 months were authored by Christian Orquera.

Company responsible for preparation: First Berlin Equity Research GmbH, Mohrenstraße 34, 10117 Berlin

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PRICE TARGET DATES

Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

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ASSET VALUATION SYSTEM

First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

RISK ASSESSMENT

The First Berlin categories for risk assessment are low, average, high and speculative. They are determined by ten factors: Corporate governance, quality of earnings, management strength, balance sheet and financial risk, competitive position, standard of financial disclosure, regulatory and political uncertainty, strength of brandname, market capitalisation and free float. These risk factors are incorporated into the First Berlin valuation models and are thus included in the target prices. First Berlin customers may request the models.

RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	30 October 2018	SEK2.09	Buy	SEK13.50
...	↓	↓	↓	↓
2	3 December 2018	SEK2.17	Buy	SEK13.50
3	1 July 2019	SEK3.32	Buy	SEK13.50
4	6 September 2019	SEK5.75	Buy	SEK13.50
5	Today	SEK6.79	Buy	SEK12.70

INVESTMENT HORIZON

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

UPDATES

At the time of publication of this financial analysis it is not certain whether, when and on what occasion an update will be provided. In general First Berlin strives to review the financial analysis for its topicality and, if required, to update it in a very timely manner in connection with the reporting obligations of the analysed company or on the occasion of ad hoc notifications.

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Legally required information regarding

- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
- **sensitivity of valuation parameters**

can be accessed through the following internet link: https://firstberlin.com/disclaimer-english-link/

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Marie-Curie-Straße 24-28, 60439 Frankfurt am Main

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