

Cardiol Therapeutics Inc.

Canada, USA, Germany / Biotechnology
 Nasdaq, US; TSX, Canada; FSE, Germany
 Bloomberg: CRDL US
 ISIN: CA14161Y2006

Pipeline update

RATING
BUY

PRICE TARGET
USD 3.60

Return Potential 239.6%
 Risk Rating High

TRIALS FOR TWO LEAD CARDIOLRX INDICATIONS > 50% RECRUITED

Cardiol Therapeutics (Cardiol) has completed >50% of patient recruitment for CardiolRx™'s two lead indications, acute myocarditis (AM) and recurrent pericarditis (RP). Enrolment of the planned 100 patients for the ongoing international phase II trial in AM is progressing rapidly. Enrolment of the planned 25 patients for the ongoing phase II pilot study in RP has taken some time to gain traction. However, we now expect enrolment to progress faster leading to 100% completion within the next few weeks. We anticipate the company will report topline results in early Q2 2024 and meet with the FDA shortly thereafter to obtain approval for immediate initiation of a phase III trial. The announcement of this data would be a major near-term catalyst for the stock. We continue to see Cardiol as an attractive investment opportunity. We reiterate our Buy recommendation and price target of USD 3.60 (€3.30).

Rapidly progressing proof-of-concept international phase II study in AM patients; >50% enrolment rate achieved in January 2024 The ongoing phase II study (ARCHER) investigating the safety, tolerability, and efficacy of CardiolRx™ in 100 AM patients at major cardiac centres in North America, Latin America, Europe, and Israel is in our view on track to achieve 100% recruitment in early Q3 2024 and to publish headline results in H2 2024. The company has completed enrolment at >35 clinical sites and recruitment is ahead of schedule. The primary endpoints of the trial, which will be evaluated after 12 weeks of double-blind therapy, consist of the following cardiac magnetic resonance (CMR) imaging measures: left ventricular function (global longitudinal strain) and myocardial fibrosis (extra-cellular volume fraction).

Phase II RP study gaining momentum; >50% enrolment rate achieved in November 2023 Cardiol has raised the number of sites participating in the pilot phase II RP study (MAVERIC-Pilot) in the US to a total of 8, all of which are actively enrolling patients. These sites include the prestigious Cleveland Clinic, the Massachusetts General Hospital, and the Mayo Clinic. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2020	2021	2022	2023E	2024E	2025E
Revenue (CAD m)	0.00	0.08	0.00	0.00	0.00	0.00
Y-o-y growth	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT (CAD m)	-20.69	-38.66	-41.34	-27.00	-24.00	-19.00
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income (CAD m)	-20.64	-31.64	-30.93	-25.00	-23.55	-18.85
EPS (diluted) (CAD)	-0.69	-0.73	-0.49	-0.39	-0.35	-0.26
DPS (CAD)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (CADm)	-9.17	-23.55	-27.30	-21.48	-19.10	-15.10
Net gearing	-105.7%	-110.0%	-113.9%	-118.0%	-138.7%	-157.6%
Liquid assets (CAD m)	14.03	83.90	59.47	37.93	18.78	13.62

RISKS

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

COMPANY PROFILE

Founded in 2017, Cardiol Therapeutics Inc is a Canadian biotech company focused on the research and development of new drugs to treat heart diseases. The lead drug candidate, CardiolRx™ (cannabidiol) oral solution, is undergoing a US phase II multi-centre open-label pilot study in 25 patients with recurrent pericarditis and a multi-national phase II study in 100 patients with acute myocarditis.

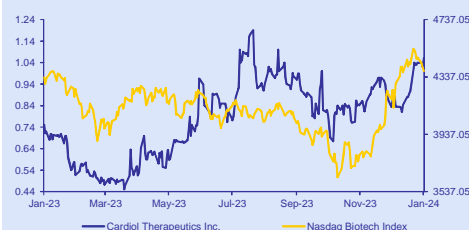
MARKET DATA

As of 18 Jan 2024

Closing Price USD 1.06
 Shares outstanding 64.10m
 Market Capitalisation USD 67.94m
 52-week Range USD 0.45 / 1.19
 Avg. Volume (12 Months) 159,603

Multiples	2022	2023E	2024E
P/E	n.a.	n.a.	n.a.
EV/Sales	n.a.	n.a.	n.a.
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Sep 2023

Liquid Assets CAD 40.54m
 Current Assets CAD 42.45m
 Intangible Assets CAD 0.23m
 Total Assets CAD 43.05m
 Current Liabilities CAD 8.03m
 Shareholders' Equity CAD 34.87m

SHAREHOLDERS

MMCAP International Inc 5.2%
 Management and Directors 4.4%
 Advisorshares Investments LLC 1.7%
 Mirae Asset Global Investments Co Ltd 1.7%
 Freefloat & others 86.9%



We expect Cardiol to complete 100% patient enrolment within the next few weeks. According to the study design, the assessment period for the primary endpoint of patient-reported pericarditis pain using an 11-point numeric rating scale (NRS) is 8 weeks. We therefore see the company on track to publish the topline results in early Q2 2024 and meet with the FDA shortly after to share the new findings and request permission to immediately initiate a phase III trial. We note that the lead investigator in Cardiol's RP phase II study is Dr Allan L. Klein (Cleveland Clinic), who also led the pivotal trial of rilonacept (Arcalyst®), the first and only FDA-approved therapy to treat RP (approved in March 2021). He is therefore a pericarditis expert who knows how to successfully run a trial which meets FDA registration requirements.

Additional preclinical evidence supports cannabidiol's positive effect on diastolic heart failure (DHF)'s underlying inflammation and fibrosis Cardiol is developing CRD-38, a novel subcutaneously administered formulation (SUBQ) of cannabidiol targeting the inflammation and fibrosis typically associated with DHF. This formulation is intended to improve cannabidiol's bioavailability in the blood compared to the current oral formulation, thus enabling more cannabidiol to reach the heart. The company's partner TecSalud presented new preclinical data at the Heart Failure Society of America Annual Scientific Meeting 2023. The data demonstrated that CRD-38 SUBQ slowed increases in body weight and heart weight, and prevented increases in key cardiac inflammatory and remodelling markers (e.g. BNP, IL-10 and VAT/SAT ratio) in a model of heart failure with preserved ejection fraction (i.e. left ventricle ejection fraction $\geq 50\%$). Left ventricle (LV) ejection fraction (EF) is defined as the percentage of blood volume the heart's LV can eject with each heart contraction divided by the volume of blood when the LV is maximally filled. This encouraging data validates the results of the company's previous preclinical work investigating CRD-38 SUBQ's cardioprotective effect on DHF (see: "Cardioprotective effect of cannabidiol in a non-ischemic model of heart failure", Lozano et al., 2020; "Cannabidiol inhibits and also promotes reversal of mechanisms leading to cardiac fibrosis", Krishnamoorthi et al., 2022). At the present preclinical development stage, we estimate the company will require an additional 6-12 months to lock the final formulation and prepare to enter clinical development.

P&L KPI OVERVIEW OF 9M/23 RESULTS

9M 2023 financial results roughly as expected The company reported EBIT of CAD -21.8m (FBe: CAD -22.0m; 9M 2022: CAD -32.2m). The substantial OPEX decline YoY chiefly reflects lower administrative and R&D expenses for the two ongoing phase II clinical trials of CardiolRx™ in RP and AM compared to significant OPEX for the large LANCER study during 9M 2022. Thanks to a solid cash position and the high interest rate level, the company recorded strong positive net interest income of CAD 1.6m (FBe: CAD 450k; 9M/22: CAD 653k). The other financial result came in at CAD -325k (FBe: CAD 0; 9M/22: CAD 8.2m) chiefly due to a non-cash change in derivative liabilities of CAD -390k (FBe: CAD 0; 9M/22: CAD 4.7m) in connection with the quarterly revaluation of warrants. Derivative liabilities rose from CAD 420k at YE 2022 to CAD 810k at the end of September 2023. The warrants are exercisable at a price of USD 3.75 p/s, expire in November 2024 and are currently out of the money. The net loss was CAD -20.5m (FB: CAD-21.6m; 9M/22: CAD -23.4m).

Table 1: P&L 9M/23 reported figures vs FB estimates and 9M/22 (KPIs)

in CAD'000	9M/23	9M/23E	Delta	9M/22	Delta
Revenue	0	0	-	0	-
EBIT	-21,757	-22,000	-	-32,241	-
margin	-	-	-	-	-
Net interest income	1,590	450	-	653	-
Financial gain on foreign exchange & derivative lias.	-325	0	-	8,172	-
Net income	-20,491	-21,550	-	-23,416	-

Source: First Berlin Equity Research, Cardiol Therapeutics Inc



Revising net financial result forecasts following 9M 2023 results In light of the strong financial result due to the ongoing high-interest rate environment, we have increased our 2023-2025 net interest forecast. These changes lead to higher net income. We have summarised the main changes for 2023-2025 in table 2 below.

Table 2: Change to our FY 2023-2025 financial forecasts (KPIs)

Figures in CAD'000	2023E			2024E			2025E		
	old	new	Delta	old	new	Delta	old	new	Delta
Revenue	0	0	-	0	0	-	0	0	-
EBIT	-27,000	-27,000	-	-24,000	-24,000	-	-19,000	-19,000	-
Net interest income	500	2,000	300.0%	300	450	50.0%	100	150	50.0%
Financial gain on foreign exchange & derivative lias.	0	0	-	0	0	-	0	0	-
Net income	-26,500	-25,000	-	-23,700	-23,550	-	-18,900	-18,850	-

Source: First Berlin Equity Research estimates

9M 2023 cash flow Operating cash flow amounted to CAD -18.7m (9M/22: CAD -14.7m) and was negatively impacted by high working capital due to a cash outflow for receivables/accrued liabilities of CAD -2.2m related to R& and clinical D trials expenses (9M/22: CAD 2.8m). The cash position declined by CAD 18.9m to CAD 40.5m (YE 2022: CAD 59.5m) and is sufficient to fund operations into 2026.



VALUATION MODEL

Buy rating and price target confirmed Cardiol's 9M 2023 financial results were roughly as expected and the company is well financed to execute its development strategy. We expect positive data from the ongoing pilot phase II study of CardiolRx™ in the RP indication in early Q2 2024, which could lead to the start of the phase III study shortly thereafter and trigger share price appreciation. In the AM indication, patient recruitment is progressing quite rapidly, which is also encouraging news. Our sum-of-the-parts valuation model still yields a price target for Cardiol of USD 3.60 (€3.30). We reiterate our Buy rating.

Table 3: "Sum-of-the-parts" valuation model

Compound	Project ¹⁾	Present Value	Patient Pop (K)	Treatment Cost (USD)	Market Size (USDM)	Market Share (%)	Peak Sales (USDM)	PACME Margin ²⁾ (%)	Discount Factor (%)	Market Exclusivity ³⁾ (years)	Time to Market (years)
CardiolRx™	RP - US	USD 171.2M	40K	52,000	2,080.0M	18%	474.3M	30%	17.0%	7	4
CardiolRx™	AM - US	USD 89.2M	54K	52,000	2,808.0M	18%	652.1M	20%	17.0%	7	6
CardiolRx™	AM - EU	USD 34.0M	72K	18,000	1,296.0M	18%	322.9M	20%	17.0%	7	6
PACME PV		USD 294.4M			6,184.0M		1,449.3M				
Costs PV⁴⁾		USD 63.6M									
NPV		USD 230.8M									
Milestones PV		USD 0.0M									
Net cash (proforma)		USD 42.9M									
Fair Value		USD 273.7M									
Share Count (proforma)		75,948K									
Price Target		USD 3.60									
Price Target		EUR 3.30	(based on EUR-USD exchange rate of 1.09)								

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)

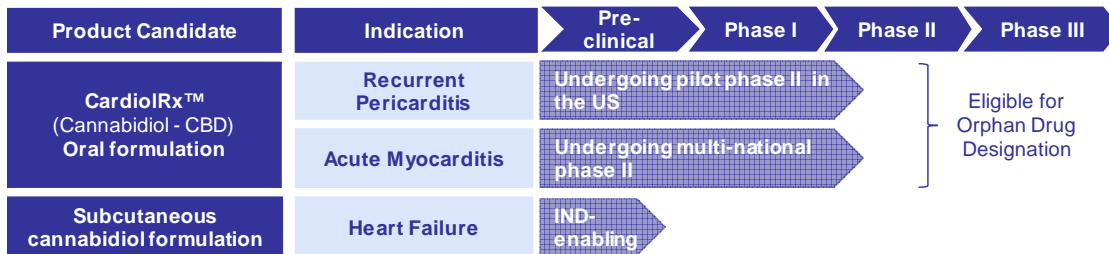
3) Remaining market exclusivity after the point of approval

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



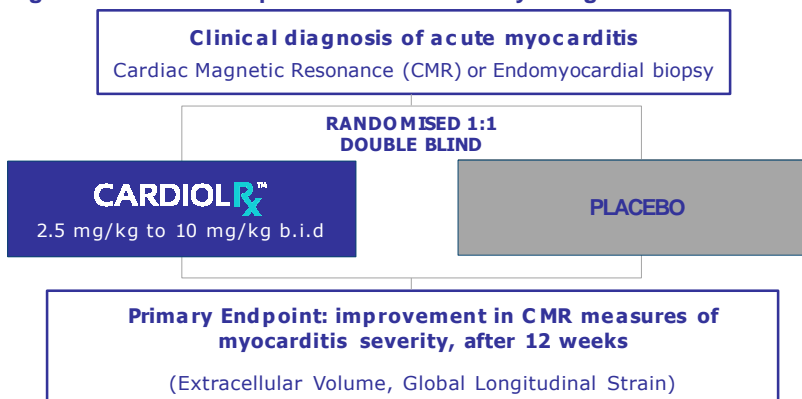
CARDIOL'S R&D PIPELINE AND DESIGN OF ONGOING STUDIES

Figure 1: Snapshot of the R&D pipeline focusing on cardiac diseases



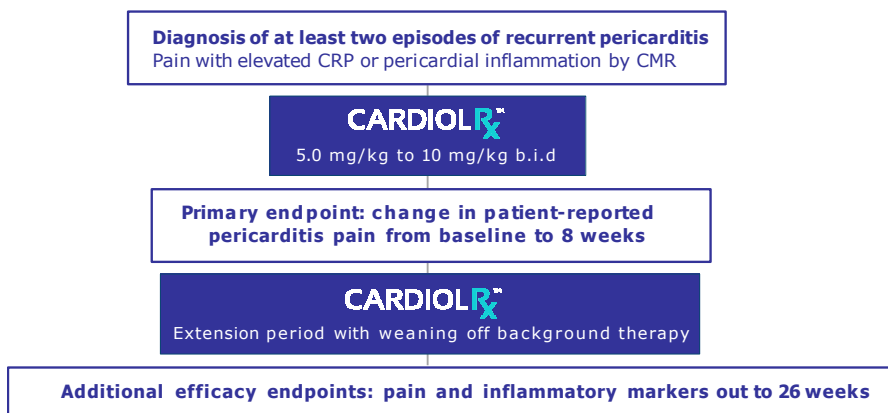
Source: First Berlin Equity Research, Cardiol Therapeutics Inc

Figure 2: CardiolRx™ phase II ARCHER study design



Source: First Berlin Equity Research, Cardiol Therapeutics Inc

Figure 3: Overview of the pilot phase II recurrent pericarditis study design



Source: First Berlin Equity Research, Cardiol Therapeutics Inc



INCOME STATEMENT

All figures in CAD '000	2020	2021	2022	2023E	2024E	2025E
Revenue	0	79	0	0	0	0
Cost of goods sold	0	0	0	0	0	0
Gross profit	0	79	0	0	0	0
General & Administrative	-10,088	-27,873	-22,374	-16,000	-14,000	-11,000
Research & Development	-10,603	-10,870	-18,962	-11,000	-10,000	-8,000
Total operating expenses (OPEX)	-20,690	-38,744	-41,336	-27,000	-24,000	-19,000
Operating income (EBIT)	-20,690	-38,664	-41,336	-27,000	-24,000	-19,000
Net financial result	42	1,998	4,000	2,000	450	150
Non-operating income/expenses	7	5,029	6,406	0	0	0
Pre-tax income (EBT)	-20,641	-31,638	-30,931	-25,000	-23,550	-18,850
Income taxes	0	0	0	0	0	0
Net income / loss	-20,641	-31,638	-30,931	-25,000	-23,550	-18,850
Diluted EPS (CAD)	-0.69	-0.73	-0.49	-0.39	-0.35	-0.26
Ratios						
EBIT Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBITDA Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Expenses as % of OPEX						
Sales & Marketing	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
General & Administrative	48.8%	71.9%	54.1%	59.3%	58.3%	57.9%
Research & Development	51.2%	28.1%	45.9%	40.7%	41.7%	42.1%
Y-Y Growth						
Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	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 CAD '000	2020	2021	2022	2023E	2024E	2025E
Assets						
Current Assets, Total	14,950	87,140	61,438	39,302	20,049	14,692
Cash and cash equivalents	14,025	83,899	59,470	37,935	18,782	13,619
Accounts receivables	220	407	480	460	450	420
Inventories	18	0	0	0	0	0
Other current assets	687	2,834	1,488	908	817	653
Non-Current Assets, Total	943	736	591	437	311	220
Property plant and equipment	479	356	296	227	185	179
Intangible assets	464	379	295	210	126	41
Total Assets	15,893	87,876	62,029	39,740	20,359	14,912
Shareholders' Equity & Debt						
Current Liabilities, Total	2,518	11,565	9,805	7,572	6,800	6,262
Accounts payable	2,466	4,859	9,334	7,100	6,745	6,205
Derivative liabilities	0	6,661	420	420	0	0
Other current liabilities	52	45	50	52	55	57
Longterm Liabilities, Total	105	73	22	18	14	11
Other liabilities	105	73	22	18	14	11
Shareholders Equity	13,270	76,238	52,202	32,150	13,546	8,639
Total Consolidated Equity and Debt	15,893	87,876	62,029	39,740	20,359	14,912
Ratios						
Current ratio (x)	5.94	7.53	6.27	5.19	2.95	2.35
Quick ratio (x)	5.93	7.53	6.27	5.19	2.95	2.35
Net gearing	-105.7%	-110.0%	-113.9%	-118.0%	-138.7%	-157.6%
Book value per share (€)	0.44	1.76	0.84	0.50	0.20	0.12
Net debt	-14,025	-83,899	-59,470	-37,935	-18,782	-13,619
Equity ratio	83.5%	86.8%	84.2%	80.9%	66.5%	57.9%



CASH FLOW STATEMENT

All figures in CAD '000	2020	2021	2022	2023E	2024E	2025E
Net income	-20,641	-31,638	-30,931	-25,000	-23,550	-18,850
Interest, net	-42	-1,998	-4,000	-2,000	-450	-150
Tax provision	0	0	0	0	0	0
Non-operating items	-7	-5,029	-6,406	0	0	0
EBIT	-20,690	-38,664	-41,336	-27,000	-24,000	-19,000
Depreciation and amortisation	230	220	220	213	207	201
EBITDA	-20,461	-38,444	-41,116	-26,787	-23,793	-18,799
Derivative liability	0	-4,916	-6,241	0	-420	0
Share & warrant based payments	2,910	12,694	6,894	4,000	4,000	3,000
Changes in working capital	8,316	77	5,748	-1,632	-252	-344
Cash interest net	42	1,998	4,000	2,000	450	150
Other adjustments	63	5,052	3,495	1,000	1,000	1,000
Operating cash flow	-9,129	-23,540	-27,220	-21,419	-19,015	-14,993
CapEx	-41	-13	-75	-60	-80	-110
Free cash flow	-9,170	-23,553	-27,295	-21,479	-19,095	-15,103
Other investments	0	0	0	0	0	0
Cash flow from investing	-41	-13	-75	-60	-80	-110
Debt Financing, net	0	0	0	0	0	0
Equity Financing, net	16,345	93,489	0	0	0	10,000
Other financing activities	-50	2,785	-54	-56	-58	-60
Cash flow from financing	16,295	93,438	-54	-56	-58	9,940
Net cash flows	7,125	69,885	-27,349	-21,535	-19,153	-5,163
Cash, start of the year	6,956	14,025	83,899	59,470	37,935	18,782
Impact of exchange rates on cash	-56	-11	2,920	0	0	0
Cash, end of the year	14,025	83,899	59,470	37,935	18,782	13,619

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.

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Anschrift:

First Berlin Equity Research GmbH
Friedrichstr. 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

Amtsgericht Berlin Charlottenburg HR B 103329 B

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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, Friedrichstraße 69, 10117 Berlin

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Person responsible for forwarding or distributing this financial analysis: Martin Bailey

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PRICE TARGET DATES

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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	11 April 2023	USD0.51	Buy	USD3.60
2	24 May 2023	USD0.68	Buy	USD3.60
3	30 August 2023	USD0.98	Buy	USD3.60
4	Today	USD1.06	Buy	USD3.60

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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