Cardiol Therapeutics Inc.

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

H1 2023 results

RATING	**BUY**
PRICE TARGET	**USD 3.60**
Return Potential	266.3%
Risk Rating	High

CARDIOLRX IN RP COULD SURPRISE POSITIVELY IN Q4 2023

Cardiol Therapeutics has published its H1 2023 financial report. Overall figures were in line with our expectations. The company reported EBIT of CAD -14.1m (FBe: CAD -14.3m; H1 2022: CAD -19.0m). The net loss came in at CAD -14.6m (FBe: CAD -14.0m; H1 2022: CAD -15.4m). The cash position declined by CAD 14.6m to CAD 44.9m (YE 2022: CAD 59.5m) but is sufficient to fund operations into 2026. Importantly, both CardiolRx's core programmes in recurrent pericarditis (RP) and acute myocarditis (AM) are on track. At a recent US investor conference, management confirmed that all 8 US clinical sites for RP are actively recruiting and we expect 50% of the total planned patient recruitment will be completed in the next few weeks. We thus believe there is a good chance that Cardiol could positively surprise investors ahead of the full trial results due early next year. Similar to Kiniksa Pharmaceuticals' approval process for its approved drug Rilonacept (Arcalyst), if efficacy results for the first 50% or ~12 patients are positive, we expect management to meet with the FDA in Q4 2023. The aim of the meeting will be to gain permission (as received by Kiniksa) to immediately initiate a phase III trial. The ensuing announcement of the start (in early 2024) of a phase III study would be a great catalyst for the stock. Regarding the ongoing multinational AM study, management mentioned that it has completed enrolment of >35 clinical sites (plan: 25-35) and recruitment is progressing ahead of schedule. We anticipate Cardiol achieving 50% recruitment in early 2024, 100% recruitment in early Q3 2024 and headline results in H2 2024 (FBe: H2 2024 - H1 2025), which is good news. Last but not least, following positive share price development, Cardiol announced that on 7 August 2023 the firm had regained compliance with the minimum bid price requirement under Nasdaq Listing Rules for continued listing on Nasdaq Stock Exchange. We continue to believe that Cardiol is substantially undervalued. We reiterate our Buy recommendation and price target of USD 3.60 (€3.30).

(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	-26.50	-23.70	-18.90
EPS (diluted) (CAD)	-0.69	-0.73	-0.49	-0.41	-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	-19.68	-19.73	-15.37
Net gearing	-105.7%	-110.0%	-113.9%	-121.7%	-143.6%	-162.4%
Liquid assets (CAD m)	14.03	83.90	59.47	39.74	19.95	14.52

RISKS

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

COMPANY PROFILE

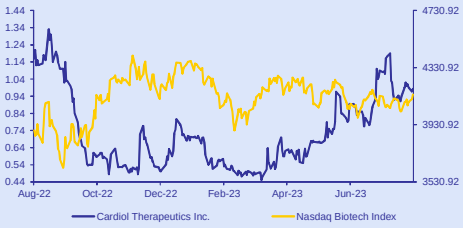
Founded in 2017, Cardiol Therapeutics Inc is a Canadian biotech company focused on the research and development of new drugs to treat heart diseases. The lead drug candidate, CardiolRx™ (cannabidiol) oral solution, is undergoing a US phase II mutli-centre open-label pilot study in 25 patients with recurrent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

MARKET DATA

As of 29 Aug 2023	
Closing Price	USD 0.98
Shares outstanding	64.10m
Market Capitalisation	USD 63.00m
52-week Range	USD 0.45 / 1.33
Avg. Volume (12 Months)	172,628

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 Jun 2023	
Liquid Assets	CAD 44.94m
Current Assets	CAD 46.65m
Intangible Assets	CAD 0.25m
Total Assets	CAD 47.17m
Current Liabilities	CAD 8.42m
Shareholders' Equity	CAD 38.75m

SHAREHOLDERS

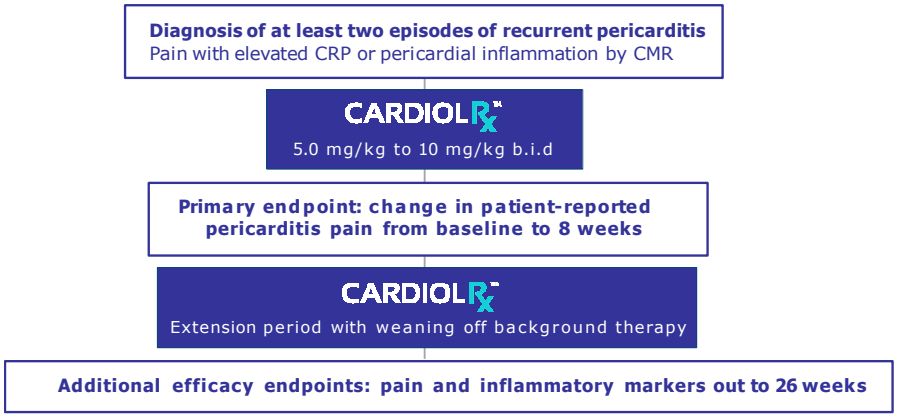
MMCAP International Inc	5.2%
Management and Directors	4.4%
Advisorshares Investments LLC	1.7%
Mirae Asset Global Investments Co Ltd	1.7%
Freefloat & others	86.9%

Analyst: Christian Orquera, Tel. +49 (0)30 - 80 93 96 90

OVERVIEW OF CARDIOL'S TWO ONGOING CLINICAL TRIALS

I) US phase II pilot trial in 25 recurrent pericarditis (RP) patients – primary endpoint is the change over 8 weeks in patient-reported pericarditis pain intensity Cardiol is currently conducting a US, open-label, multi-centre phase II pilot trial to assess the efficacy, safety and tolerability of oral CardiolRx™ in 25 RP patients. The primary efficacy endpoint is the change from baseline over 8 weeks in patient-reported pericarditis pain intensity using an 11-point numeric rating scale (NRS). Secondary endpoints include the NRS pain score after 26 weeks of treatment and changes in circulating levels of C-reactive protein (a relevant marker of inflammation).

Figure 1: Overview of the pilot phase II recurrent pericarditis study design

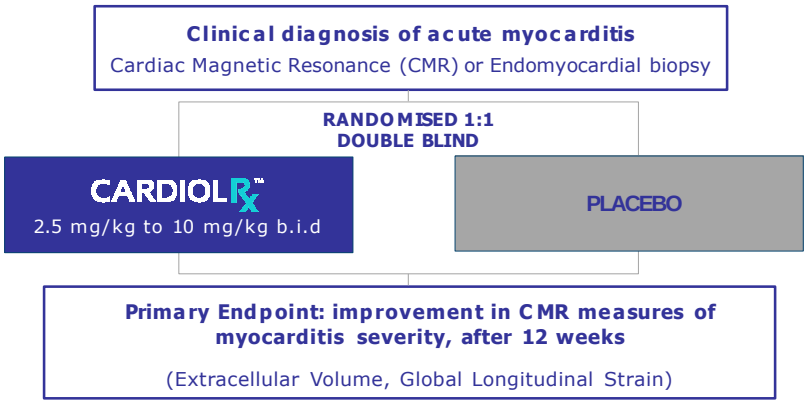


Source: First Berlin Equity Research, Cardiol Therapeutics Inc

Pilot phase II study started in December 2022 – headline data should be available in early 2024, but earlier positive surprise is likely On 17 January 2023, the company enrolled the first patient in the CardiolRx™ pilot study at the Cleveland Clinic, and a total of 8 leading US clinical sites, including the Mayo Clinic, are currently actively enrolling patients (5-10 were planned). At a recent US investor conference, management confirmed that patient recruitment is on track and we expect recruitment of 50% of the total planned RP patients will be completed in the next few weeks. We continue to expect that key results will be available in early 2024. However, we believe there is a good chance that Cardiol will positively surprise investors ahead of the full results. Similar to Kiniksa Pharmaceuticals' approval process for its approved drug Rilonacept (Arcalyst®), if efficacy results for the first 50% or ~12 patients are positive, Cardiol will meet with the FDA in Q4 2023 to share the new findings and request permission to immediately initiate a Phase III trial (as granted by the FDA to Kiniksa). This would mean that Cardiol could announce the start of the Phase III study before YE and begin in early 2024.

II) Proof of concept multi-national phase II study in 100 acute myocarditis (AM) patients – primary endpoint is improvement in myocarditis severity assessed by cardiovascular magnetic resonance imaging (CMR) after 12 weeks Cardiol is conducting a phase II proof of concept study (named ARCHER) to investigate the safety, tolerability, and efficacy of CardiolRx™ in 100 AM patients at major cardiac centres in North America, Latin America, Europe, and Israel. The first patient was enrolled in August 2022. The study will split the patients into two randomised arms of 50 patients each. Each arm will receive b.i.d. (twice daily) doses of either CardiolRx™ or placebo. 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). The secondary endpoint is left ventricular ejection fraction, also measured by CMR (see figure 2 overleaf).

Figure 2: CardiolRx™ phase II *ARCHER* study design



Source: First Berlin Equity Research, Cardiol Therapeutics Inc

The ongoing phase II study could be completed in H2 2024 As of February 2023 15 leading cardiac centres across the US (8), Canada (2) and Israel (5) were recruiting patients for the study. The company had been targeting a total of 25-35 clinical sites; recently management announced at an investor conference that it has completed enrolment of >35 clinical sites and recruitment is progressing ahead of schedule. We anticipate Cardiol achieving 50% enrolment in early 2024, 100% enrolment in early Q3 2024 and headline results in H2 2024 (FBe: H2 2024 - H1 2025), which is good news.

P&L KPI OVERVIEW OF H1/23 RESULTS

H1 2023 financial results as anticipated The company reported EBIT of CAD -14.1m (FBe: CAD -14.3m; H1 2022: CAD -19.0m). OPEX declined YoY chiefly due to lower administrative and R&D expenses for CardiolRx's two ongoing phase II clinical trials in recurrent pericarditis (RP) and acute myocarditis (AM) compared to significant R&D expenses for the large LANCER study running in H1 2022. The reported strong positive net interest income of CAD 1.1m (FBe: CAD 250k; H1/22: CAD 264k) was offset by a foreign exchange loss of CAD 752k (FBe: CAD 0; H1/22: gain of CAD 319k) due to fluctuation of the USD against the CAD and a non-cash change in derivative liabilities of CAD 783k (FBe: CAD 0; H1/22: gain of CAD 3.0m) due to quarterly revaluation of warrants. Derivative liabilities increased from CAD 420k at YE 2022 to CAD 1.2m at the end of June 2023. The warrants are exercisable at a price of USD 3.75 p/s within three years and are currently out of the money. The net loss amounted to CAD -14.6m (FB: -14.0; H1/22: CAD -15.4m).

Table 1: P&L H1/23 reported figures vs FB estimates and H1/22 (KPIs)

in CAD'000	H1/23	H1/23E	Delta	H1/22	Delta
Revenue	0	0	-	0	-
EBIT	-14,101	-14,300	-	-19,021	-
margin	-	-	-	-	-
Net interest income	1,075	300	-	263	-
Financial gain in foreign exchange & derivative liab.	-1,535	0	-	3,313	-
Net income	-14,561	-14,000	-	-15,444	-

Source: First Berlin Equity Research, Cardiol Therapeutics Inc

H1 2023 cash flow Operating cash flow came in at CAD -15.3m (H1/22: CAD -13.0m) and was negatively impacted by high WC due to a cash outflow for receivable/accrued liabilities of CAD -2.2m related to R&D and clinical trials expenses (H1/22: CAD 2.8m). The cash position declined by CAD 14.6m to CAD 44.9m (YE 2022: CAD 59.5m) and is sufficient to fund operations into 2026.

VALUATION MODEL

Buy rating and price target confirmed Cardiol's H1 2023 financial results were as expected. The lead drug candidate CardiolRx™ is on track in the RP indication. However, a positive surprise following positive preliminary data for 50% or ~12 patients in Q4 2023 could lead to an earlier than expected start to the phase III study. In the AM indication, enrolment of centres and patient recruitment seem to be progressing faster than anticipated, which is good news. We believe investors also welcomed the recent announcement that Cardiol has regained compliance with the minimum bid price requirement under Nasdaq Listing Rules for continued listing on Nasdaq Stock Exchange. Following the positive financial results and the encouraging pipeline outlook, 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 2: "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 PV[4]		USD 63.8M									
NPV		USD 230.6M									
Milestones PV		USD 0.0M									
Net cash (proforma)		USD 48.2M									
Fair Value		USD 278.8M									
Share Count (proforma)		78,307K									
Price Target		USD 3.60									
Price Target		EUR 3.30	(based on EUR-USD exchange rate of 1.08)								

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

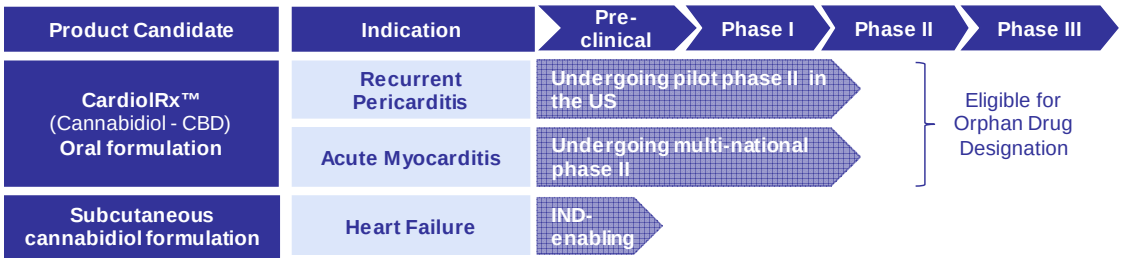
2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of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

Figure 3: Snapshot of the R&D pipeline focusing on cardiac diseases



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	500	300	100
Non-operating income/expenses	7	5,029	6,406	0	0	0
Pre-tax income (EBT)	**-20,641**	**-31,638**	**-30,931**	**-26,500**	**-23,700**	**-18,900**
Income taxes	0	0	0	0	0	0
Net income / loss	**-20,641**	**-31,638**	**-30,931**	**-26,500**	**-23,700**	**-18,900**
Diluted EPS (CAD)	**-0.69**	**-0.73**	**-0.49**	**-0.41**	**-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**	**41,103**	**21,214**	**15,591**
Cash and cash equivalents	14,025	83,899	59,470	39,736	19,948	14,518
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**	**41,541**	**21,525**	**15,812**
Shareholders' Equity & Debt						
Current Liabilities, Total	**2,518**	**11,565**	**9,805**	**8,873**	**7,615**	**6,861**
Accounts payable	2,466	4,859	9,334	8,401	7,561	6,805
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**	**32,650**	**13,896**	**8,939**
Total Consolidated Equity and Debt	**15,893**	**87,876**	**62,029**	**41,541**	**21,525**	**15,812**
Ratios						
Current ratio (x)	5.94	7.53	6.27	4.63	2.79	2.27
Quick ratio (x)	5.93	7.53	6.27	4.63	2.79	2.27
Net gearing	-105.7%	-110.0%	-113.9%	-121.7%	-143.6%	-162.4%
Book value per share (€)	0.44	1.76	0.84	0.50	0.20	0.12
Net debt	-14,025	-83,899	-59,470	-39,736	-19,948	-14,518
Equity ratio	83.5%	86.8%	84.2%	78.6%	64.6%	56.5%

CASH FLOW STATEMENT

All figures in CAD '000	2020	2021	2022	2023E	2024E	2025E
Net income	**-20,641**	**-31,638**	**-30,931**	**-26,500**	**-23,700**	**-18,900**
Interest, net	-42	-1,998	-4,000	-500	-300	-100
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	5,000	4,000	3,000
Changes in working capital	8,316	77	5,748	-331	-737	-561
Cash interest net	42	1,998	4,000	500	300	100
Other adjustments	63	5,052	3,495	2,000	1,000	1,000
Operating cash flow	**-9,129**	**-23,540**	**-27,220**	**-19,618**	**-19,650**	**-15,260**
CapEx	-41	-13	-75	-60	-80	-110
Free cash flow	**-9,170**	**-23,553**	**-27,295**	**-19,678**	**-19,730**	**-15,370**
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 financiing 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**	**-19,734**	**-19,788**	**-5,430**
Cash, start of the year	6,956	14,025	83,899	59,470	39,736	19,948
Impact of exchange rates on cash	-56	-11	2,920	0	0	0
Cash, end of the year	**14,025**	**83,899**	**59,470**	**39,736**	**19,948**	**14,518**

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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The production of this recommendation was completed on 30 August 2023 at 14:40

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

INFORMATION PURSUANT TO SECTION 85 (1) SENTENCE 1 OF THE GERMAN SECURITIES TRADING ACT [WPHG], TO ART. 20 (1) OF REGULATION (EU) NO 596/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF APRIL 16, 2014, ON MARKET ABUSE (MARKET ABUSE REGULATION) AND TO ART. 37 OF COMMISSION DELEGATED REGULATION (EU) NO 2017/565 (MIFID) II.

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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.

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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	Today	USD0.98	Buy	USD3.60

INVESTMENT HORIZON

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- **key sources of information in the preparation of this research report**
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