Cardiol Therapeutics Inc.

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

Q1 2023 results

RATING	**BUY**
PRICE TARGET	**USD 3.60**
Return Potential	429.9%
Risk Rating	High

Q1 RESULTS AS EXPECTED; PIPELINE ON TRACK

Cardiol Therapeutics has published its Q1/23 financial report and business update, which was roughly in line with our expectations. The company reported no revenue (FBe and Q1/22: CAD 0) and EBIT of CAD -7.8m (FBe: CAD -7.4m; Q1/22: CAD -9.8m). OPEX was largely driven by administrative and R&D expenses for CardiolRx™'s two ongoing phase II clinical trials in recurrent pericarditis (RP) and acute myocarditis (AM). Robust net interest income of CAD 546k (FBe: CAD 125k; Q1/22: CAD 72k) and a foreign exchange gain and change in derivative liability totalling CAD 151k (FBe: 0; Q1/22: CAD 762k), meant that the net result came in at CAD -7.1m (FBe: CAD -7.3m; Q1/22: CAD -9.0m). Due mainly to the operating performance and high cash outflow for working capital (particularly accounts receivable/accrued liabilities amounting to CAD 2.6m relating to R&D and clinical trials expenses), operating cash flow was CAD -9.9m (Q1/22: CAD -10.4m). The net change in cash was CAD -10.0m (Q1/22: CAD -10.4m), leading to a cash position of CAD 49.5m (FY/22: CAD 59.5m). These funds should be sufficient to fund the company into 2026. CardiolRx™'s lead indication is RP (inflammation of the sac protecting the heart), for which the company is conducting a phase II open-label pilot US study in 25 patients. We anticipate headline efficacy results in early 2024. CardiolRx™'s second lead indication, AM (heart muscle inflammation), is undergoing a multi-national phase II study in 100 patients. We believe recruitment in both studies is progressing according to plan. CardiolRx™ is a blockbuster drug candidate with a combined sales potential of >USD 1.4bn in the two lead indications of RP and AM, according to our estimates. Still, the stock is trading roughly at the level of its net cash position, thereby placing no value on CardiolRx™. In our view, this is unwarranted. We thus see Cardiol as an attractive investment opportunity for investors. We have updated the cash position in our sum-of-the-parts valuation model, which still yields a USD 3.60 (€3.30) price target. We reiterate our Buy recommendation. **(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	-0.34	-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

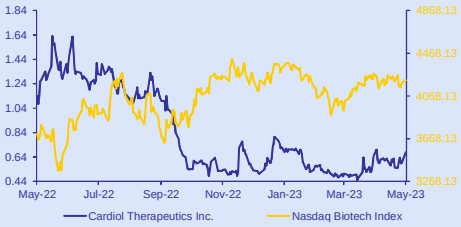
Founded in 2017, Cardiol Therapeutics Inc is a Canadian biotech company focused on the research and development of new drugs to treat heart diseases. The lead drug candidate, CardiolRx™ (cannabidiol) oral solution, is undergoing a US phase II mutli-centre open-label pilot study in 25 patients with recurrent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

MARKET DATA

As of 23 May 2023	
Closing Price	USD 0.68
Shares outstanding	64.10m
Market Capitalisation	USD 43.55m
52-week Range	USD 0.45 / 1.63
Avg. Volume (12 Months)	160,272

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 31 Mar 2023	
Liquid Assets	CAD 49.47m
Current Assets	CAD 52.11m
Intangible Assets	CAD 0.27m
Total Assets	CAD 52.69m
Current Liabilities	CAD 7.12m
Shareholders' Equity	CAD 45.56m

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%

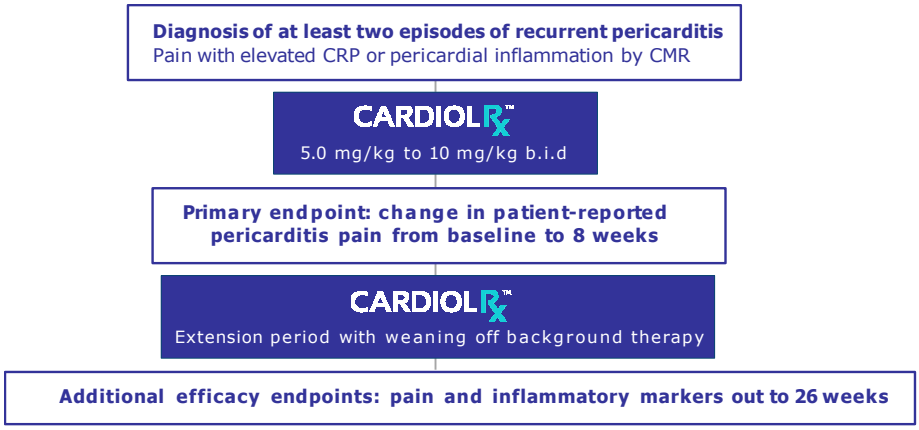
Analyst: Christian Orquera, Tel. +49 (0)30 - 80 93 96 90

OVERVIEW OF CARDIOL'S TWO ONGOING CLINICAL TRIALS

We provide a brief overview of the two ongoing trials for the lead drug candidate CardiolRx™. For more details on CardiolRx™, RP, AM or Cardiol Therapeutics, please see our comprehensive initiating coverage report of 11 April 2023.

I) US phase II pilot trial in 25 RP patients 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 patients will be treated for 8 weeks with twice-a-day (BID) drug doses escalating from 5 mg/kg at the beginning of the study to 10.0 mg/kg towards the end of the treatment period. Then, the patients will undergo a 26-week extension treatment period with progressive weaning of concomitant background therapy, including corticosteroids, to investigate CardiolRx™'s activity as a stand-alone drug. 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



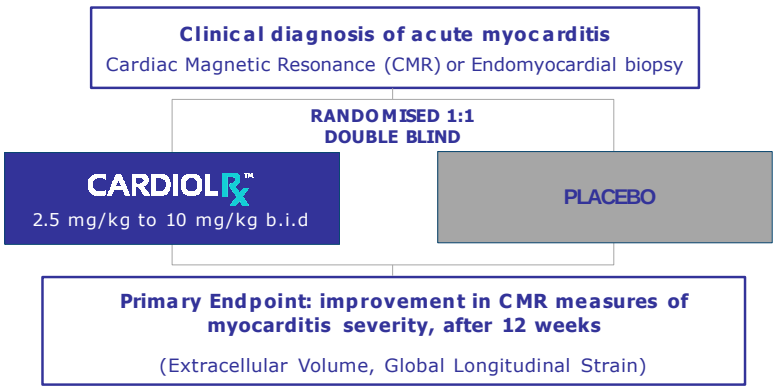
Source: First Berlin Equity Research, Cardiol Therapeutics Inc

Pilot phase II study started in December 2022; headline data should be available in early 2024 On 17 January 2023, the company enrolled the first patient into the CardiolRx™ pilot study at the Cleveland Clinic. Further US centres are being set up. We expect to see headline results in early 2024.

II) Proof of concept multi-national phase II study in 100 AM patients 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, Europe, and Israel. The first patient was enrolled in August 2022.

Primary endpoint – improvement in myocarditis severity assessed by cardiovascular magnetic resonance imaging (CMR) The study will split the patients into two randomised arms of 50 patients each. Each arm will receive BID (twice daily) doses of either CardiolRx™ or placebo, escalating weekly over four weeks from 2.5 mg/kg to 10 mg/kg of bodyweight. 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

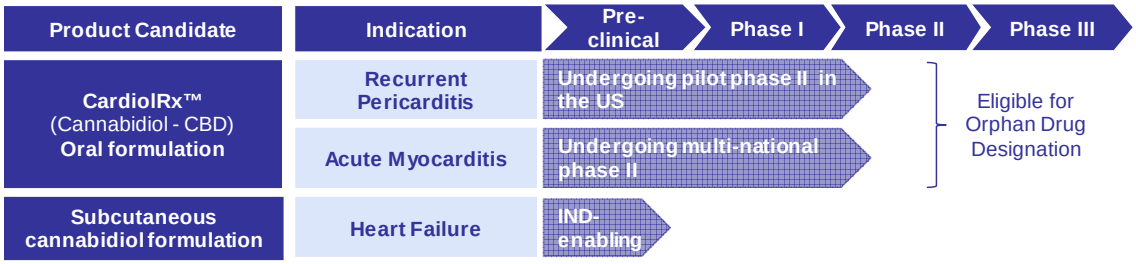


Source: First Berlin Equity Research, Cardiol Therapeutics Inc

The ongoing phase II study could be completed by H2 2024 or H1 2025 As of February 2023 15 leading cardiac centres across the US (8), Canada (2) and Israel (5) were recruiting patients for the study. Additional centres are scheduled to join the study over the coming months.

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

P&L KPI OVERVIEW OF Q1/23 RESULTS

Table 1: P&L Q1/23 reported figures vs FB estimates and Q1/22 (KPIs)

in CAD'000	Q1/23	Q1/23E	Delta	Q1/22	Delta
Revenue	0	0	-	0	-
EBIT	-7.786	-7.400	-	-9.788	-
margin	-	-	-	-	-
Net interest income	546	125	-	72	-
Financial gain in foreign exchange & derivative liab.	151	0	-	762	-
Net income	-7.089	-7.275	-	-8.954	-
margin	-	-	-	-	-

Source: First Berlin Equity Research, Cardiol Therapeutics Inc

VALUATION MODEL

Buy rating and price target confirmed Cardiol's Q1/23 financial results came in roughly as expected. The lead drug candidate CardiolRx™ is on track in both lead RP and AM indications and prospects for the respective ongoing clinical studies are promising. Following the positive financial results and the pipeline progress, our sum-of-the-parts valuation model still yields a price target for Cardiol of USD 3.60. 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 51.0M									
Fair Value		USD 281.6M									
Share Count (proforma)		79,219K									
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

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**	**-0.34**	**-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 24 May 2023 at 12:30

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

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The present financial analysis is based on the author's own knowledge and research. The author prepared this study without any direct or indirect influence exerted on the part of the analysed company. Parts of the financial analysis were possibly provided to the analysed company prior to publication in order to avoid inaccuracies in the representation of facts. However, no substantial changes were made at the request of the analysed company following any such provision.

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	Today	USD0.68	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/

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