Cardiol Therapeutics Inc.

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

Pipeline news

RATING	**BUY**
PRICE TARGET	**USD 3.60**
Return Potential	104.5%
Risk Rating	High

ORPHAN DRUG DESIGNATION & PHASE II ENROLMENT IN RP IN THE US COMPLETE

Cardiol Therapeutics (Cardiol) announced that the FDA has granted Orphan Drug Designation (ODD) in the US for its lead drug candidate CardiolRx™ for the treatment of pericarditis, including recurrent pericarditis (RP). Importantly, the FDA's decision was based on pre-clinical data as well as initial clinical data from the ongoing RP phase II study. This is excellent news, as in our view it indicates that the undisclosed data from the phase II study that was reported to the FDA is in all likelihood favourable. Based on this encouraging news, we see our positive assessment of CardiolRx™'s prospects in RP confirmed. The ODD will provide the company with attractive benefits, including seven years of market exclusivity. In addition, the company announced the completion of patient enrolment in the phase II RP study and confirmed that topline results are expected to be published in Q2 2024. We reiterate our Buy recommendation and price target of USD 3.60 (€3.30).

CardiolRx™ obtained ODD in pericarditis – implications for the ongoing RP and acute myocarditis (AM) studies Based on a combination of preclinical data and initial clinical data from the ongoing phase II open-label pilot US study (MAvERIC-Pilot) in RP in 25 patients, Cardiol applied for an ODD in RP. Encouragingly, the FDA granted an ODD for the broader indication of pericarditis. This is excellent news in four respects: 1) As noted above, we believe that the grant of the ODD is an indication that the initial phase II data provided to the FDA is in all likelihood favourable, thus increasing, in our view, the probability that the overall RP phase II study will deliver positive results; 2) ODD will offer seven years of market exclusivity, exemptions from certain FDA fees, protocol assistance, a potentially shorter waiting time for drug approval, and tax credits for qualified clinical trials; 3) the FDA's decision to grant ODD in pericarditis increases the chances of market expansion. Pericarditis has a broader patient population than RP. Based on statistics provided by the American Heart Association, ~160k patients p.a. suffer from acute pericarditis in the US and ~25% of them, or ~40k people, are affected by RP. (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

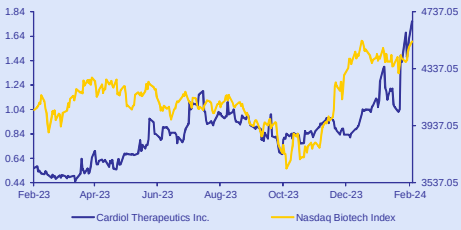
Founded in 2017, Cardiol Therapeutics Inc is a Canadian biotech company focused on the research and development of new drugs to treat heart diseases. The lead drug candidate, CardiolRx™ (cannabidiol) oral solution, is undergoing a US phase II mutli-centre open-label pilot study in 25 patients with recurrent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

MARKET DATA

As of 26 Feb 2024	
Closing Price	USD 1.76
Shares outstanding	64.10m
Market Capitalisation	USD 112.81m
52-week Range	USD 0.45 / 1.76
Avg. Volume (12 Months)	200,167

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%

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

While we expect that Cardiol will conduct a phase III study in RP, and if successful obtain a registration in RP, because of the broader designation a potential strategic partner might find that a more attractive opportunity as it already has market exclusivity for the full indication. In addition, there is a chance that the product will benefit from off-the-label prescribing in pericarditis; and 4) As the underlying causes of RP and AM is inflammation, a positive result in the ongoing RP study increases the chances of obtaining a positive result in the ongoing international AM phase II study.

Recruitment of the pilot phase II study in RP completed – topline results expected in Q2 2024 The company announced the completion of enrolment of the targeted 25 patients, and the countdown to the publication of the topline results of this study has begun. 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 expect that the company will report positive topline data from the full study in RP as early as the second half of April 2024. Management has guided that topline data will be reported in Q2 2024. This could lead to the FDA giving an immediate go ahead for the start of the phase III study. Secondary endpoints of the phase II study include the NRS pain score after 26 weeks of treatment and changes in circulating levels of C-reactive protein, a relevant marker of inflammation (see RP study design in figure 2 overleaf). The study will also assess freedom from pericarditis recurrence. Assuming a successful phase III trial and approval of the drug candidate, we expect CardiolRx™ to achieve peak sales of >USD 400m five years after market launch.

VALUATION MODEL

Buy rating and price target confirmed Following excellent news on the achievement of orphan drug designation for pericarditis and the completion of recruitment for CardiolRx™ in the ongoing pilot phase II study for RP, we see a positive outlook for the upcoming major milestone of topline data of this programme in the second half of April or early May. 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 1: "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	3
CardiolRx™	AM - US	USD 89.2M	54K	52,000	2,808.0M	18%	652.1M	20%	17.0%	7	5
CardiolRx™	AM - EU	USD 34.0M	72K	18,000	1,296.0M	18%	322.9M	20%	17.0%	7	5
PACME PV		USD 294.4M			6,184.0M		1,449.3M				
Costs PV[4)]		USD 63.6M									
NPV		USD 230.8M									
Milestones PV		USD 0.0M									
Net cash (proforma)		USD 43.1M									
Fair Value		USD 273.9M									
Share Count (proforma)		76,118K									
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

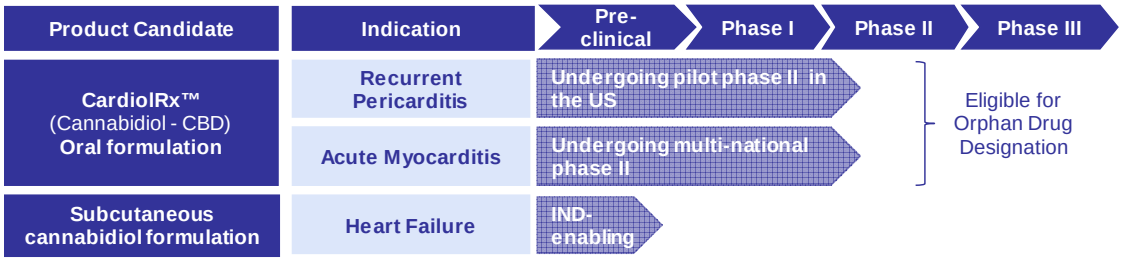
2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of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

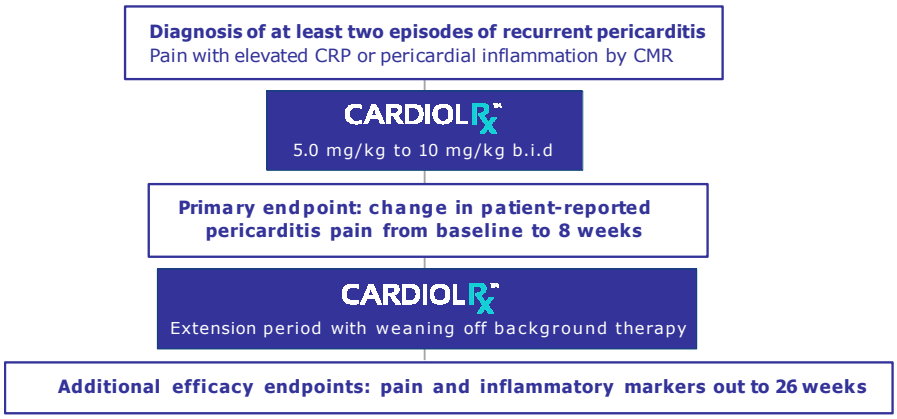
CARDIOL'S R&D PIPELINE AND DESIGN OF ONGOING STUDIES

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



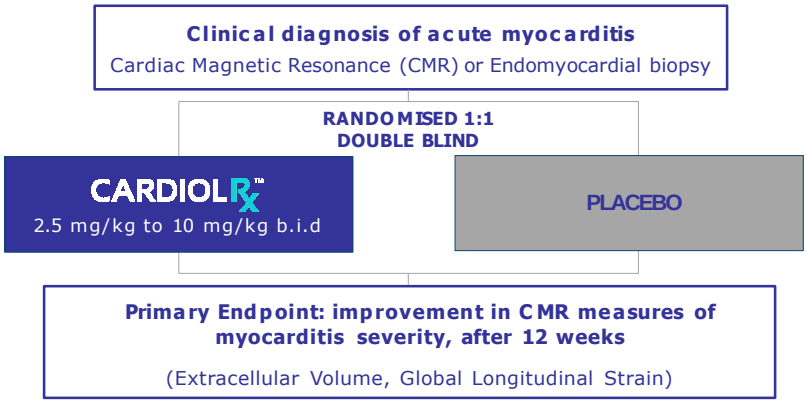
Source: First Berlin Equity Research, Cardiol Therapeutics Inc

Figure 2: Overview of the phase II MAvERIC-Pilot recurrent pericarditis study design



Source: First Berlin Equity Research, Cardiol Therapeutics Inc

Figure 3: CardiolRx™ phase II *ARCHER* acute myocarditis 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 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**	**-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

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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

The production of this recommendation was completed on 27 February 2024 at 13:50

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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- The author, First Berlin, or a company associated with First Berlin holds an interest of more than five percent in the share capital of the analysed company;

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PRICE TARGET DATES

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

AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

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	24 May 2023	USD0.68	Buy	USD3.60
3	30 August 2023	USD0.98	Buy	USD3.60
4	19 January 2024	USD1.06	Buy	USD3.60
5	Today	USD1.76	Buy	USD3.60

INVESTMENT HORIZON

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