Jason Wittes, Managing Director, (646) 716-3612
jwittes@roth.com

Sales (800) 933-6830, **Trading** (203) 861-9060

COMPANY NOTE | EQUITY RESEARCH | November 19, 2024

Healthcare: Biotechnology **Company Update**

Cardiol Therapeutics, Inc. | CRDL-$1.79-NASDAQ | *Buy*

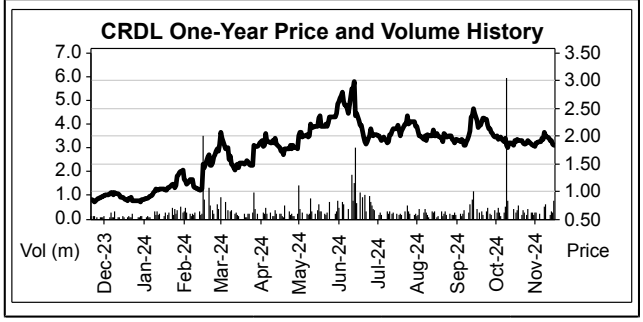
Stock Data	
52-Week Low - High	$0.81-$2.97
Shares Out. (mil)	81.60
Mkt. Cap.(mil)	$147.23
3-Mo. Avg. Vol.	443,080
12-Mo.Price Target	$10.00
Cash (mil)	C$28.6
Tot. Debt (mil)	C$0.0

Rev (C$M)

Yr Dec	— 2023—	— 2024E—	— 2025E—
		Curr	Curr
1Q	0.0A	0.0A	0.0E
2Q	0.0A	0.0A	0.0E
3Q	0.0A	0.0A	0.0E
4Q	0.0A	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E

EPS C$

Yr Dec	— 2023—	— 2024E—		— 2025E—	
		Curr	Prev	Curr	Prev
1Q	(0.11)A	(0.14)A	(0.14)A	(0.12)E	(0.10)E
2Q	(0.12)A	(0.10)A	(0.10)A	(0.12)E	(0.10)E
3Q	(0.09)A	(0.18)A	(0.11)E	(0.12)E	(0.11)E
4Q	(0.12)A	(0.10)E	(0.10)E	(0.11)E	(0.10)E
YEAR	(0.44)A	(0.51)E	(0.44)E	(0.46)E	(0.41)E



CRDL: 18 Week Extension Shows Remarkable Durability in Recurrent Pericarditis

Yesterday, at the American Heart Association Scientific Sessions, CRDL provided detailed results for its Phase II MAvERIC study evaluating CardiolRX in recurrent pericarditis (topline was announced in June) including new data on patients in the 18-week extension cohort, which showed remarkable durability of the 8-week results, all the more impressive since patients were taken off heavy steroid and pain drug regimens. This bodes particularly well for upcoming Phase III and II/III trials.

Summary Finding:

- Reduction in pain was maintained throughout the duration of the trial with a mean reduction of 4.3, from 5.8 at baseline to 1.5 at week 26.
- CRP levels for the entire group of patients were reduced from 2.0 mg/dL at baseline to 0.74 and 0.55 at weeks 8 and 26, respectively, with a median time to CRP normalization of 21 days.
- Freedom from recurrence was maintained in 71% (17/24) of patients during the EP when CardiolRx was continued and patients were weaned off baseline medications. For those patients experiencing a recurrence, the median time to an episode was 7.7 weeks during the EP.
- Number of pericarditis episodes per year was markedly reduced from 5.8 prior to the study to 0.9 during the study.
- Median time to resolution or near resolution of pain (defined as a score of ≤ 2) was rapid and was observed just 5 days following initiation of CardiolRx treatment, despite patients being only midway through dose escalation from 5mg/kg to 10 mg/kg.
- As previously announced, the primary endpoint of patient-reported pericardial pain on an 11-point numerical rating scale from 0-10 showed a mean reduction of 3.7, from 5.8 at baseline (range of 4 to 10) to 2.1 (range of 0 to 6) at week 8.

Based on these results, the company plans to commence Phase II/III by year-end, evaluating CardiolRx in recurrent pericarditis patients following cessation of IL-1 blockers, which with 6-month expected enrollment and 5-month follow-up should read out by year-end 2025. This is a year before we expect to see results from the planned Phase III for recurrent pericarditis scheduled to enroll in 1H 2025 (following an end of Phase 2 meeting with the FDA in early 2025), but it also may be enough to support an orphan drug approval. With the recent equity raise, the company has enough cash on hand to fund operations through mid-2026.

Phase II MAvERIC

This is designed as a 25-patient multicenter open label pilot study to assess the safety and tolerability of CardiolRx during the resolution of a pericarditis recurrence. The trial is designed to evaluate improvements in objective measures (change in baseline NRS score improvements) and assess the feasibility of weaning concomitant background therapy while taking CardiolRx.

The primary efficacy endpoint is the change from baseline to 8 weeks, in patient-reported pericarditis pain using an 11-point numeric rating scale ("NRS"). The NRS is a validated clinical tool employed across multiple conditions with acute and chronic pain, including previous studies of recurrent pericarditis. While there is no control, a 2-point reduction in NRS score is considered significant and in Arcalyst/Rilonacept's RHAPSODY trial study, which MAvERIC was closely modeled after, there was a 3.8-point reduction. Secondary endpoints include the NRS score after 26 weeks (which 89% of patients opted for) of treatment, and changes in circulating levels of C-reactive protein, a commonly used clinical marker of inflammation. Importantly, the study will also assess freedom from pericarditis recurrence.

Exhibit 1: MAvERIC Trial Design

Source: CRDL Website

Key inclusion criteria include:

- Male or female patients aged ≥18 years
- Diagnosis of at least 2 episodes of recurrent pericarditis
- At least 1 day with pericarditis pain score ≥4 on the 11-point NRS within the prior 7 days
- C-reactive protein level (CRL) ≥1.0 mg/dL, or evidence of pericardial inflammation assessed by delayed pericardial hyperenhancement on cardiac magnetic resonance imaging
- Currently receiving non-steroidal anti-inflammatory drugs (NSAIDs), colchicine or corticosteroids for treatment of pericarditis (in any combination) in stable doses

As mentioned, the trial itself closely follows the design used by Kiniksa for its RHAPSODY trial, with patients enrolled for 8 weeks with an 18-week extension in which patients are weaned off concomitant therapies and as revealed from the patient demographics, these patients had a heavy drug burden including high doses of steroids and pain medications.

Exhibit 2: MAvERIC Patient Demographic and Clinical Characteristics at Baseline

Characteristic	n=27
Age	mean 52.7; median 54.0 (24.0-77.0)
Sex	female 18 (66.7%); male 9 (33.3%)
Race / Ethnicity	White 27 (100%) / non-Hispanic or Latino 27 (100%)
Medications used to treat pericarditis – no. (%)	NSAID 21 (77.8 %); colchicine 23 (85.2%); glucocorticoid 11 (40.7%)
Number of previous episodes of pericarditis – no. (%)	2-episodes 9 (33.3%); 3-episodes 9 (33.3%); ≥4-episodes 9 (33.3%)
Duration of disease – yr (mean)	2.69 years
Pain score according to the NRS scale 0-10 (mean)	5.8 (maximum in prior week)
C-reactive protein – mg/dL (mean; (SD))	2.0 (4.9)
Manifestation of pericarditis in qualifying episode – no. (%)	Pericardial effusion 21 (77.8%); pericardial rub 4 (14.8%); ST-segment elevation or PR depression 5 (18.5%)

Source: CRDL November 2024 Investor Presentation

Primary Endpoint HRS reduction at 8-weeks (previously reported topline results):

Cardiol Therapeutics' Phase II MAvERIC-Pilot study showed that CardiolRx materially reduced pericarditis pain and inflammation in patients with recurrent pericarditis. Over an 8-week treatment period, patients reported a mean pain reduction of 3.7 points (from 5.8 to 2.1) on an 11-point scale, and 80% of patients with a baseline CRP ≥1mg/dL had a normalization of CRP (≤0.5 mg/dL). The mean CRP decreased from 5.71 mg/dL at baseline to 0.31 mg/dL in 8 weeks. While there is no control to compare it to, both measures are clinically meaningful. As mentioned, a 2-point reduction in NRS is considered clinically meaningful as was the reduction in CRP. Rilonacept is considered a much more aggressive drug, and while direct comparisons between trials are not possible, it is nonetheless encouraging that the reduction in NRS scores was like what was seen in RHAPSODY at 8 weeks in a similarly designed trial.

Exhibit 3: Previous Episodes of Pericarditis in MAvERIC-Pilot Patients at Baseline

# Previous Episodes of Pericarditis	CardiolRx™ (N = 27)
2 episodes	9 (33%)
3 episodes	9 (33%)
4 episodes	4 (15%)
>4 episodes	5 (19%)

Prior recurrences is a strong predictor of future recurrences as 20-40% of pts. with ≥2 recurrences can expect subsequent episodes:

(i) Klein A et al. US Database Study of Clinical Burden and Unmet Need in Recurrent Pericarditis. J Am Heart Assoc. 2021;10(15):e01895

(ii) Cremer PC et al. Complicated Pericarditis: Understanding Risk Factors and Pathophysiology to Inform Imaging and Treatment. J Am Coll Cardiol. 2016;68(21):2311-2328. doi:10.1016/j.jacc.2016.07.785

Source: CRDL Presentation June 2024

Exhibit 4: MAvERIC-Pilot Study Topline Efficacy Data (Primary and Secondary Endpoints)

Primary Endpoint

Change in patient-reported pericarditis pain using NRS* from baseline to 8 weeks

n=27	Baseline	Week 8	Difference†
Mean	5.8	2.1	-3.7
Range	4.0 - 10.0	0.0 - 6.0	

*Numerical rating scale (NRS) is a validated 11-point instrument used to assess patient-reported pericarditis pain. Zero represents 'no pain at all' whereas the upper limit of 10 represents 'the worst pain ever possible'.

†Negative value indicates an improvement in NRS pericarditis pain.

Source: CRDL Presentation June 2024

Secondary Endpoint

Percentage of patients with CRP normalization[#] at 8 weeks (for patients with CRP ≥1.0 mg/dL at baseline).

Number of Patients with CRP ≥1.0 mg/dL at Baseline	10 (of 27)
Number of Patients with CRP ≤0.5 mg/dL at Week 8	8
Percentage of Patients with CRP Normalization at Week 8	80.0%

[#] CRP normalization defined as CRP ≤0.5 mg/dL.

C-reactive Protein (CRP)

Change in CRP for those patients with ≥1 mg/dL at BL.

	Baseline	Week 8	Difference[§]
Mean	5.71	0.31	-5.39

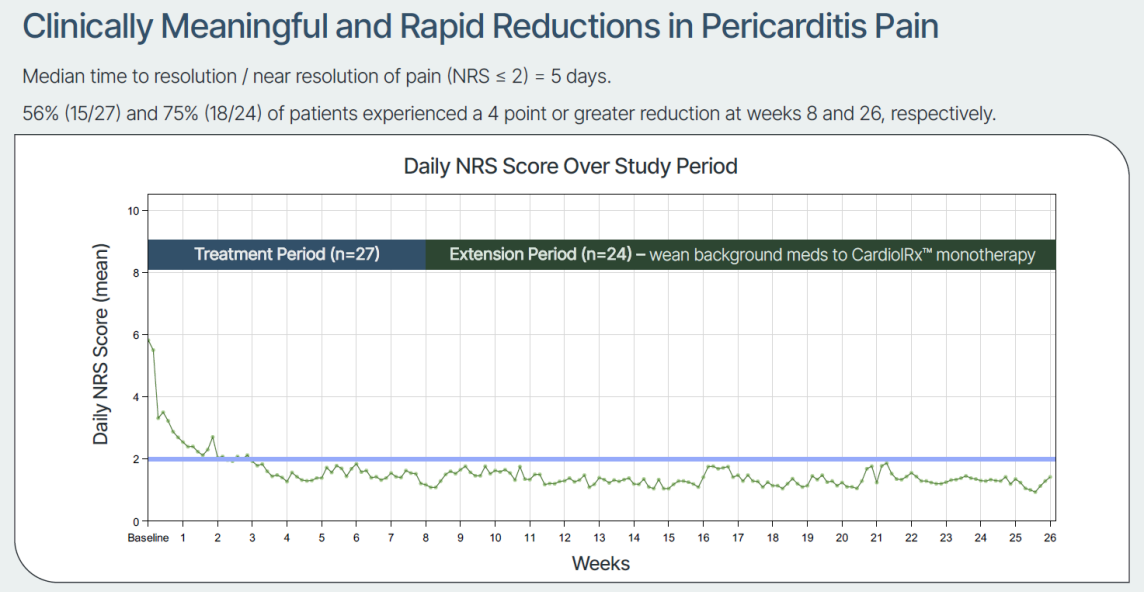
[§]Negative value indicates an improvement in CRP.

Source: CRDL Presentation June 2024

CardiolRx was shown to be safe and well tolerated with eighty-nine percent of patients (24/27) progressing to the EP and overall study drug compliance reported at 95%.

Extended results showed remarkable durability with clinically meaningful reductions in NRS scores and CRP levels. All the more impressive since patients were taken off a heavy drug regime of steroids and pain medications during the 18-week extension. In addition, median time to resolution/near resolution (NRS</= 2) occurred within 5 days, halfway through the dose escalation period (see above).

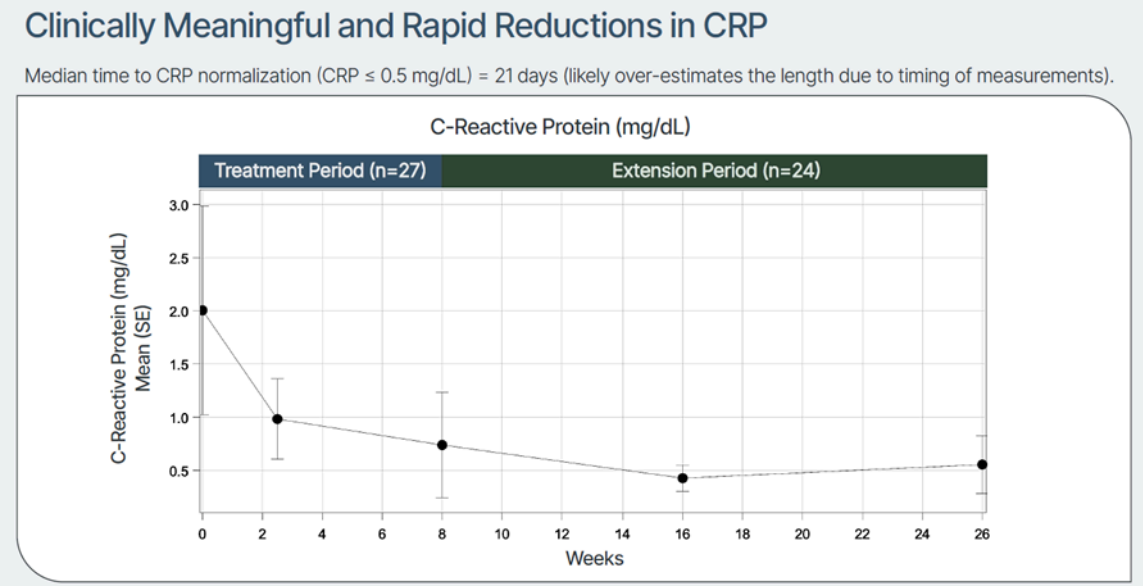
Exhibit 5: Daily NRS Scores through 26 weeks



Source: CRDL Presentation November 2024

CRP levels for the entire group of patients were reduced from 2.0 mg/dL at baseline to 0.74 and 0.55 at weeks 8 and 26, respectively, with a median time to CRP normalization of 21 days.

Exhibit 6: Mean CRP Scores through 26 weeks



Source: CRDL Presentation November 2024

Freedom from recurrence was maintained in 71% (17/24) of patients during the EP when CardiolRx was continued, and patients were weaned off baseline medications. For those patients experiencing a recurrence the median time to an episode was 7.7 weeks during the EP. Number of pericarditis episodes per year was markedly reduced from 5.8 prior to study to 0.9 during the study.

Exhibit 7: Reduction in Events

CardiolRx™ (n=27)		rilonacept (n=86)	
Events per Year of Pericarditis Prior to the Study	Events per Year of Pericarditis During the Study	Events per Year of Pericarditis Prior to the Study	Events per Year of Pericarditis During the Study
5.8	0.9	4.4	0.15

When Weaned to CardiolRx™ Monotherapy, Freedom From Recurrence During the Extension Period was Maintained in 71% of Patients (17/24) (Median time to Recurrence = 7.7 weeks)

Source: CRDL Investor Presentation November 2024

VALUATION

Our 12-month price target is $10, based on a sum-of-the-parts valuation using 3x sales multiple on risk-adjusted peak sales and 9% WACC, consistent with industry norms. We attribute $9 to CardiolRx for recurrent pericarditis (assumes $609M sales in 2033, 60% probability of success), $1 to CardiolRx (assumes $132 million sales in 2033, 40% probability of success) for acute myocarditis, and ~$0 to forward-year cash.

Product	Indication	Sales (M)	Probab. of Approval	Prob-adj Sales (M)	Year	Sales Multiple	Discount Periods	Discount Rate	Total Value (M)	Shares	Value/Share
CardiolRx	Recurrent Pericarditis	$ 592	60%	$ 355	2032	3	7	9%	$ 660	78	$ 9
CardiolRx	Acute Myocarditis	$ 132	40%	$ 53	2033	3	8	9%	$ 79	78	$ 1
~FY1 cash									$ (2.34)	78	$ (0)
										Price Target:	$ 10

Impediments to our price target include failure to reach clinical endpoints and delays in clinical progress or regulatory approval times, as well as slower potential revenues due to pricing, competitive pressures or adoption.

RISKS

Clinical risk. CRDL's clinical staged products could fail to deliver statistically significant results in clinical trials, substantially reducing the value of CRDL's product candidates and therefore our price target.

Regulatory risk. Even if successful in the clinic, CRDL's products could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce CRDL's value and therefore our price target.

Financing risk. CRDL will need additional capital to fund its operations, and such financing may not occur, or it could be substantially dilutive to existing investors.

Competitive risk. For any current or future approved CRDL products, they may not be well adopted in a competitive marketplace, which would adversely affect CRDL's value and therefore our price target.

High stock price volatility. This issue is common among small-cap biotechnology companies with relatively low trading volumes.

COMPANY DESCRIPTION

Cardiol Therapeutics, Inc. is a clinical-stage life sciences company focused on the research and clinical of anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease. Its lead product candidate, CardiolRx, is a pharmaceutically manufactured oral cannabidiol formulation that is being clinically developed for use in heart diseases. The firm is conducting clinical studies to evaluate the efficacy and safety of CardiolRx in diseases affecting the heart: a Phase II multi-national, randomized, double-blind, placebo-controlled trial (the "ARCHER" trial) in acute myocarditis; and a Phase II multi-center open-label pilot study in recurrent pericarditis. It is also involved in developing a novel subcutaneously administered drug formulation of cannabidiol intended for use in heart failure. The company was founded by David Elsley, Eldon Smith, and Anthony Bolton on January 19, 2017 and is headquartered in Oakville, Canada. (source: FactSet)

Cardiol Therapeutics Inc.

Jason Wittes, Managing Director, Senior Research Analyst jwittes@roth.com

Income Statement

(Fiscal Year Ending December 31; Canadian Dollar in Millions, except per share data)

	2022A	2023A				2023A	2024E				2024E	2025E				2025E	2026E				2026E
	Year	Q1A	Q2A	Q3A	Q4A	Year	Q1A	Q2A	Q3A	Q4E	Year	Q1E	Q2E	Q3E	Q4E	Year	Q1E	Q2E	Q3E	Q4E	Year
Revenues:																					
CardiolRx - Recurrent Pericarditis	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CardiolRx - Acute Myocarditis	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total revenues	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Operating expenses:																					
Cost of goods solds																					
Selling, general and administrative	22.4	3.7	2.8	5.1	4.0	15.6	5.1	5.0	10.4	5.1	25.6	5.2	5.2	5.3	5.3	20.9	5.4	5.4	5.5	5.5	21.8
Research and development	19.0	4.1	3.5	2.6	4.0	14.2	3.3	2.7	3.8	4.0	13.8	4.2	4.4	4.6	4.8	18.1	5.1	5.3	5.6	5.9	21.9
Total operating expenses	**41.3**	**7.8**	**6.3**	**7.7**	**8.0**	**29.8**	**8.4**	**7.7**	**14.1**	**9.1**	**39.4**	**9.3**	**9.6**	**9.9**	**10.2**	**39.0**	**10.5**	**10.8**	**11.1**	**11.4**	**43.7**
Income (loss) from operations	**(41.3)**	**(7.8)**	**(6.3)**	**(7.7)**	**(8.0)**	**(29.8)**	**(8.4)**	**(7.7)**	**(14.1)**	**(9.1)**	**(39.4)**	**(9.3)**	**(9.6)**	**(9.9)**	**(10.2)**	**(39.0)**	**(10.5)**	**(10.8)**	**(11.1)**	**(11.4)**	**(43.7)**
Interest Income	1.2	0.5	0.5	0.5	0.4	2.0	0.4	0.3	0.2	0.2	1.1	0.2	0.2	0.2	0.2	0.8	0.0	0.0	0.0	0.0	0.8
Gain (loss) on foreign exchange	2.8	0.1	(0.8)	0.7	(0.6)	(0.7)	0.6	0.2	(0.1)	(0.1)	0.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Change in derivative liability	6.2	0.1	(0.9)	0.4	0.6	0.2	(1.8)	0.7	1.4	1.4	1.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Income	0.2	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Income (loss) before taxes	**(30.9)**	**(7.1)**	**(7.5)**	**(5.9)**	**(7.6)**	**(28.1)**	**(9.2)**	**(6.6)**	**(12.7)**	**(7.7)**	**(36.2)**	**(9.1)**	**(9.4)**	**(9.7)**	**(10.0)**	**(38.2)**	**(10.5)**	**(10.8)**	**(11.1)**	**(11.4)**	**(42.9)**
Income tax expense (benefit)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income (loss)	**(30.9)**	**(7.1)**	**(7.5)**	**(5.9)**	**(7.6)**	(28.1)	**(9.2)**	**(6.6)**	**(12.7)**	**(7.7)**	**(36.2)**	**(9.1)**	**(9.4)**	**(9.7)**	**(10.0)**	**(38.2)**	**(10.5)**	**(10.8)**	**(11.1)**	**(11.4)**	**(42.9)**
Net income (loss) per share:																					
Basic	(0.49)	(0.11)	(0.12)	(0.09)	(0.12)	(0.44)	(0.14)	(0.10)	(0.18)	(0.10)	(0.51)	(0.12)	(0.12)	(0.12)	(0.11)	(0.46)	(0.11)	(0.13)	(0.12)	(0.14)	(0.51)
Diluted	(0.49)	(0.11)	(0.12)	(0.09)	(0.12)	(0.44)	(0.14)	(0.10)	(0.18)	(0.10)	(0.51)	(0.12)	(0.12)	(0.12)	(0.11)	(0.46)	(0.11)	(0.13)	(0.12)	(0.14)	(0.51)
Weighted-average shares - basic	62.5	64.1	64.1	64.5	64.5	64.5	67.26	68.75	69.84	78.54	71.10	79.13	79.72	80.32	91.41	82.65	92.10	83.27	92.79	83.89	83.65
Weighted-average shares - diluted	62.5	64.1	64.1	64.5	64.5	64.5	67.26	68.75	69.84	78.54	71.10	79.13	79.72	80.32	91.41	82.65	92.10	83.27	92.79	83.89	83.65

Source: Company and Roth Estimates.

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Disclosures:

Shares of Cardiol Therapeutics, Inc. may be subject to the Securities and Exchange Commission's Penny Stock Rules, which may set forth sales practice requirements for certain low-priced securities.

Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services**shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

			IB Serv./Past 12 Mos. as of 11/19/2024	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**345**	**72.78**	**107**	**31.01**
Neutral [N]	**79**	**16.67**	**6**	**7.59**
Sell [S]	**2**	**0.42**	**0**	**0**
Under Review [UR]	**48**	**10.13**	**1**	**2.08**

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Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH Capital does not publish research or have an opinion about this security.

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