

# With an effective anti-inflammatory and anti-fibrotic agent, Cardiol Therapeutics is focused on our hearts

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*Trialing cannabidiol-based therapies for pericarditis and myocarditis while developing new therapies for heart failure – Cardiol is well-capitalized to achieve corporate milestones into 2026*

Two very serious heart conditions are pericarditis and myocarditis. Both involve heart infection and can occur after having a flu, Covid-19, or other infection typically occurring in otherwise healthy young adults or in immune suppressed individuals (such as those undergoing cancer chemotherapy). 'Pericarditis' is an infection in the sack around the heart and 'myocarditis' is an infection in the heart's muscle tissue.

In a 2023 InvestorIntel interview, David Elsley [stated](#) that acute myocarditis,

*“is a leading cause of sudden cardiac death in people under the age of 30 and there is currently no accepted standard of care for that condition. Furthermore, the current treatments come at an exceptionally high cost. The market is wide open for a more cost-effective solution for both conditions.”*

David's company is working to develop and prove via clinical trials the effectiveness of their therapies used to combat recurrent pericarditis and acute myocarditis, and ultimately to prevent both inflammatory and fibrotic heart disease, as well as

developing novel therapies for heart failure. The company is using ‘cannabidiol’ based therapies because cannabidiol has been shown to be a very effective anti-inflammatory and anti-fibrotic agent.

The Company is [Cardiol Therapeutics Inc.](#) (NASDAQ: CRDL | TSX: CRDL) (“Cardiol”).

**The market opportunity for pericarditis and myocarditis is very significant. There is an opportunity for new medicines that can be proven effective and come at a lower cost to the current very expensive options**

### Recurrent Pericarditis: Market Opportunity

Unmet Medical Need: An oral drug targeting the inflammatory process for patients intolerant to treatment, colchicine resistant, or corticosteroid dependent.

#### Current Pharmacotherapy

- First-line conventional treatment: NSAIDs or aspirin with or without colchicine<sup>(1)</sup>.
- Second-line therapy for patients with continued recurrence and inadequate response: corticosteroids (despite safety issues and difficulty tapering or discontinuation<sup>(1)</sup>).
- One FDA-approved therapy: >\$150,000/year (rilonacept) primarily used for ≥3 recurrences.

#### Cases/year (United States) & Impact

- 160,000 (based on 40/100,000<sup>(2)</sup>) annual prevalence; includes 38,000 with a recurrence.
- \$20 – \$30k average hospitalization costs and 6 – 8-day length of stay<sup>(3)</sup>.
- 30%<sup>(3)</sup> experience a recurrence ≤ 18 months; up to 50% with a recurrent episode experience more recurrences<sup>(4)</sup>.

Source: [Cardiol Therapeutics company presentation](#)

## Cardiol Therapeutics and their two heart disease therapies CardiolRx™ and CRD-38

Cardiol is a clinical-stage life sciences company focused on the research and clinical development of anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease.

Cardiol's lead drug candidate is [CardiolRx™](#) (cannabidiol) oral solution. CardiolRx™ is pharmaceutically manufactured under cGMP to meet the highest standards for product purity, consistency, and stability. A Phase I safety and pharmacokinetic study of single and multiple ascending doses of CardiolRx™ was completed and demonstrated that CardiolRx™ was safe and generally well tolerated at all dose levels, with no serious adverse events reported. CardiolRx™ is eligible for FDA orphan drug and EMA orphan medicine designations for recurrent pericarditis and acute myocarditis. The [US orphan drug program](#) offers an accelerated path to development for new drugs to treat rare diseases with reduced cost of development via tax incentives and exemption from user fees. Once developed the new drug is typically offered a 7 year plus period of exclusivity to assist the companies to recoup their development costs.

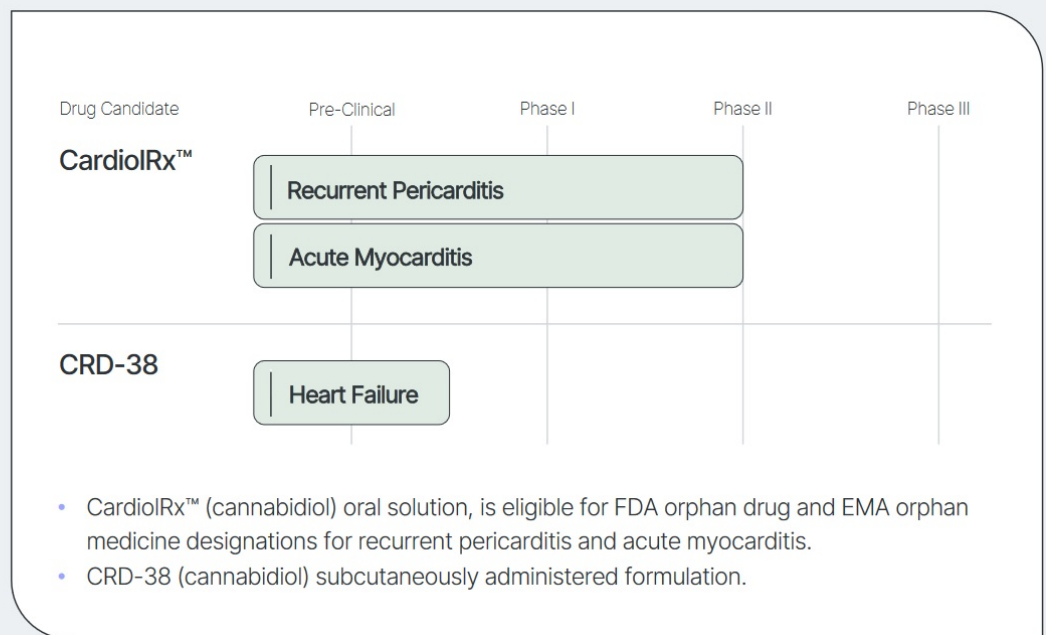
Cardiol's other product undergoing development is [CRD-38](#), which is a novel subcutaneously administered drug formulation of cannabidiol intended for use in heart failure. Cardiol [state](#):

*“Our research collaborators have shown that cannabidiol, when administered subcutaneously, is effective in a pre-clinical model of heart failure.”*

**Cardiol's two key products in their pipeline**

## Product Pipeline

Developing drug candidates that attenuate multiple inflammatory signaling pathways, including inhibiting activation of the NLRP3 inflammasome, known to play an important role in the inflammation and fibrosis associated with pericarditis, myocarditis, and heart failure.



Source: [Cardiol Therapeutics company presentation](#)

Cardiol currently has two clinical trials for CardiolRx™ in the early stages:

1. A Phase II U.S multi-center open-label pilot study in **recurrent pericarditis** (inflammation of the pericardium), which is associated with symptoms including debilitating chest pain, shortness of breath, and fatigue, and results in physical limitations, reduced quality of life, emergency department visits, and hospitalizations. The Study seeks to evaluate the tolerability, safety, and efficacy of CardiolRx™ in patients with recurrent pericarditis.
2. A Phase II multi-national, randomized, double-blind, placebo-controlled trial (the ARCHER trial) in **acute myocarditis**, an important cause of acute and fulminant heart failure in young adults and a leading cause of sudden cardiac death in people less than 35 years of age.

Cardiol's game plan is [stated](#) as:

*“We plan to pursue the development of CardiolRx™ as an orphan drug for the treatment of these heart conditions under the U.S. Orphan Drug Designation program and the European Medicine Agency’s orphan medicine product program.”*

## **CardiolRx™ (cannabidiol) oral solution**

**CardiolRx™ (cannabidiol) oral solution is in clinical development for use in the treatment of heart disease. CardiolRx™ attenuates multiple inflammatory signaling pathways, including inhibiting activation of the NLRP3 inflammasome, which is known to play an important role in the inflammation and fibrosis associated with pericarditis, myocarditis, and heart failure.**



Source: [Cardiol Therapeutics website](#)

Cardiol lists its next 3 major milestones over the next 1-2 years as:

1. Complete Phase II U.S. study in recurrent pericarditis with CardiolRx™.
2. Complete patient enrollment in the global ARCHER trial in acute myocarditis with CardiolRx™.
3. Advance the development of a subcutaneously administered formulation intended for use in heart failure.

The outcome of these two clinical trials will be a key factor in determining the potential success of CardiolRx™ and for Cardiol Therapeutics as a company. Furthermore, the development and potential future success of CRD-38 in treating heart failure will also be one to follow closely, especially given that heart failure is a huge global market.

## Closing remarks

Cardiol is debt free with [\\$49.5 million in cash](#) as of the end of Q1, 2023. This means they are well-capitalized to achieve their corporate milestones into 2026. To watch a great CEO interview you can click the [link here](#). The interview gives more details about the current Company activities and the next steps ahead.

Cardiol Therapeutics trades on a market cap of [C\\$70 million](#). One to watch in 2023 and beyond.