

# Cardiol Furthers Clinical Trials to Advance Disruptive Cannabidiol-Based Therapies for Heart Disease

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Heart disease continues to be a leading cause of death globally. According to [Cardiol Therapeutics Inc.](#) (NASDAQ: CRDL | TSX: CRDL) ("Cardiol"), there is a prevalence of [160,000](#) cases per year of pericarditis and 46,000 cases per year of myocarditis in the USA. Globally heart failure affects more than [64 million](#) people with health costs [in excess of US\\$100 billion](#). In other words, this is a huge industry ideally suited for disruptive new therapies. Of course, getting FDA approval is a major challenge all new drug companies face and investors need to be mindful of this risk.

## Cardiol Therapeutics Inc.

Cardiol Therapeutics 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.

## CardiolRx™ and CRD-38

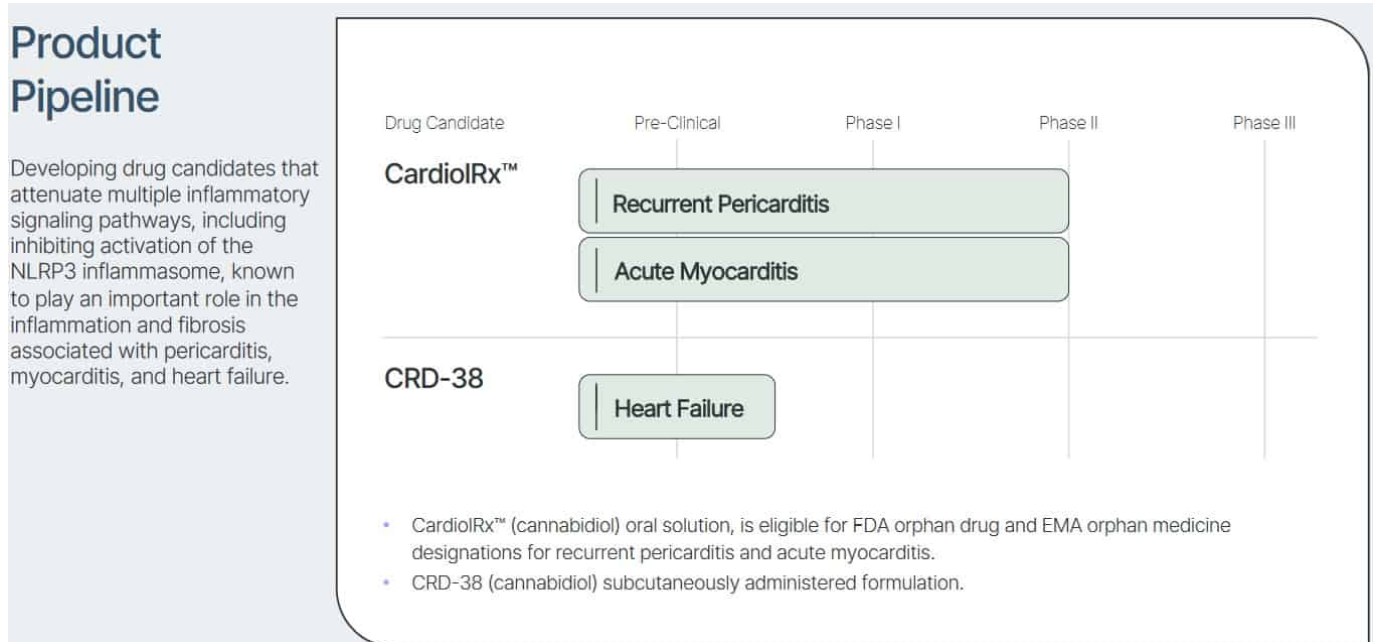
Cardiol's lead drug candidate is CardiolRx™ (cannabidiol) oral solution. It is recognized that 'cannabidiol' inhibits the activation and progression of inflammation and fibrosis associated with:

- Myocarditis, inflammation and damage of the heart muscle known as the myocardium;
- Pericarditis, inflammation of the thin membrane around the heart known as the pericardium; and,
- Heart failure.

CardiolRx™ is currently being evaluated in a Phase II multinational study (the ARCHER trial) to evaluate its safety and tolerability as well as its impact on myocardial recovery, in patients presenting with acute myocarditis.

Cardiol's other product undergoing development is CRD-38. It is a novel subcutaneously administered drug formulation of cannabidiol intended for use in heart failure.

## FIGURE 1: Cardiol Therapeutics product pipeline and stage of development



Source: [Cardiol Therapeutics company presentation](#)

## Latest update on Cardiol Therapeutics

As [announced](#) on March 29, 2023, Cardiol is advancing its Phase

II open-label clinical trial investigating the safety, tolerability, and efficacy of CardiolRx™ in patients with recurrent pericarditis.

Cardiol is also advancing its ARCHER Trial – a Phase II multinational, randomized, placebo-controlled clinical trial evaluating the safety and efficacy of CardiolRx™ in patients with acute myocarditis.

Cardiol also reported that, in 2022, it had presented at the American Heart Association 2022 scientific sessions and at the Annual Scientific Meeting of the Heart Failure Society of America. These presentations highlighted data on the cardioprotective effects of CardiolRx™ in a model of acute pericarditis and pre-clinical study results demonstrating CardiolRx™ inhibits and promotes reversal mechanisms leading to cardiac fibrosis.

## **Next steps over the next 12-24 months**

Cardiol lists its next 3 major milestones 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.

## **Cardiol has an extensive and very experienced team – Board, Management, and Advisers**

Cardiol has a strong board and management team led by President

and CEO [David Elsley](#) (MBA), Chief Medical Officer and Head of Research & Development [Andrew Hamer](#) (MBChB), and Chief Operating Officer [Bernard Lim](#) (MIET, CEng (UK)). Members of the Scientific Advisory Board are shown [here](#).

David Elsley founded Vasogen Inc., a biotechnology company focused on the research and commercial development of novel therapeutics for the treatment of heart failure and other inflammatory conditions. Cardiol's website [states](#):

*“Mr. Elsley managed and directed Vasogen’s growth from start-up to an organization employing over 250 people with operations and R&D programs in Canada, the United States and Europe. He established the research and development infrastructure, partnerships, manufacturing capability, and corporate quality systems necessary to advance two anti-inflammatory therapies from concept to completion of international multi-center pivotal phase III clinical trials involving 2,500 patients. Vasogen went public on the TSX and the Nasdaq, raising over \$200 million to support corporate development and reached a market capitalization of over US\$ 1 billion.”*

*Note: Investors should note that Vasogen later had various [setbacks](#), the stock declined and was [taken over in 2009](#).*

## **FIGURE 2: Cardiol Therapeutics highlights**

## Developing Novel Therapeutic Approaches for Patients with Underserved Heart Disease



### Leadership

Experienced Management team, Board of Directors, and Scientific Advisory Board, with extensive expertise in developing therapeutics for inflammatory heart disease.



### Broad Exclusivity Protection

Comprehensive intellectual property portfolio. Eligible to pursue FDA orphan drug and EMA orphan medicine designations for CardiolRx™.



### Scientific Rationale

Compelling evidence demonstrating the anti-inflammatory and anti-fibrotic properties of CardiolRx™ in myopericardial diseases.



### Innovative Research

Advancing the development of CRD-38, a novel proprietary subcutaneously administered pharmaceutical intended for use in heart failure.



### Lead Asset in Clinical Development

CardiolRx™, oral drug candidate, in Phase II trials for recurrent pericarditis and acute myocarditis.



### Strong Financial Position

CAD\$59.5 million in cash Y/E 2022, debt-free, and well-capitalized to achieve corporate milestones into 2026.

Source: [Cardiol Therapeutics company presentation](#)

## Closing remarks

Cardiol continues to work to further prove the effectiveness of its two drug candidates CardiolRx™ and CRD-38, whilst also presenting results at various leading U.S heart scientific sessions and conferences.

The next 2 years will be focused on Phase II clinical trials, so investors will need some patience. Cardiol's experienced management team and high cash levels help reduce risk, but FDA approval remains a significant hurdle.

As of December 31, 2022, Cardiol stated that they had cash and cash equivalents of [C\\$59.5 million](#), enough capital to achieve corporate milestones and fund operations into 2026.

That's a huge cash buffer and very attractive considering Cardiol Therapeutics' market cap of just [US\\$39 million](#) ([C\\$53 million](#)) and a negative Enterprise Value ("EV").

Definitely worth putting Cardiol Therapeutics on your watch list. Stay tuned.