

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

written by InvestorNews | July 31, 2023

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.

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## 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**

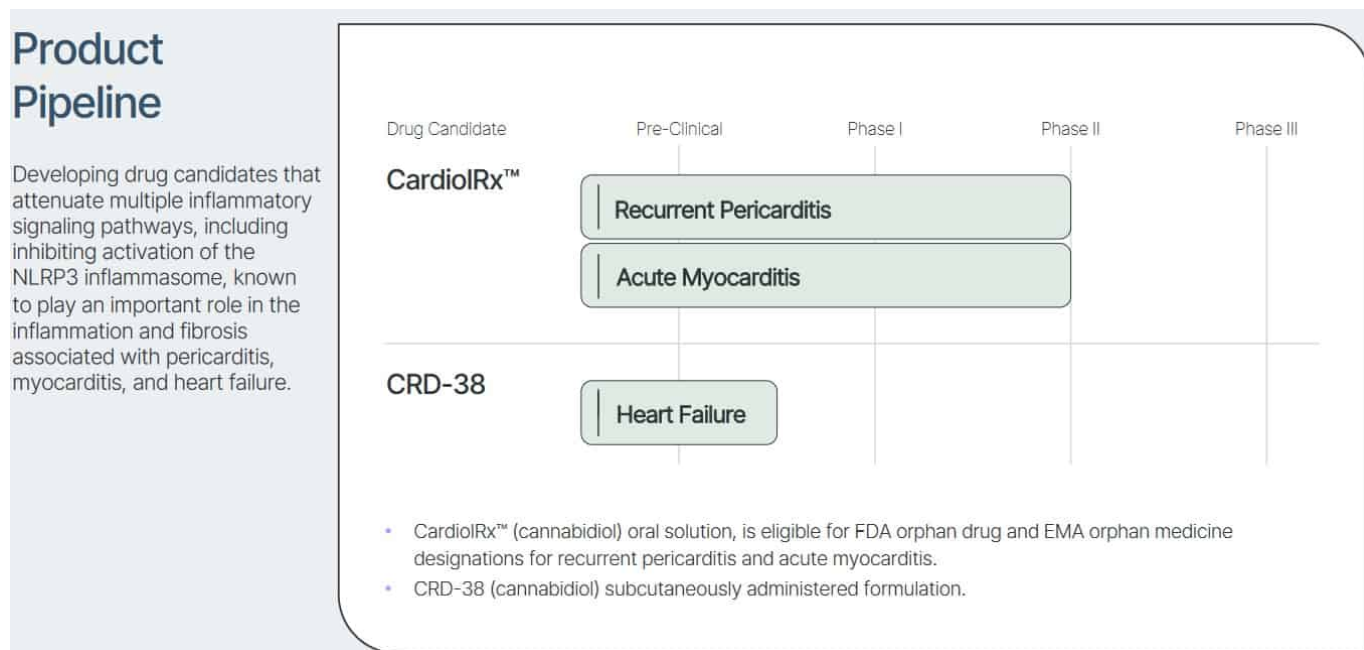
Cardiol's lead drug candidate is CardiolRx™ (cannabidiol) oral solution. It is recognized that 'cannabidiol' inhibits the activation and progression of inflammation and fibrosis associated with:

- 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 multi-national 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 multi-national, 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](#).

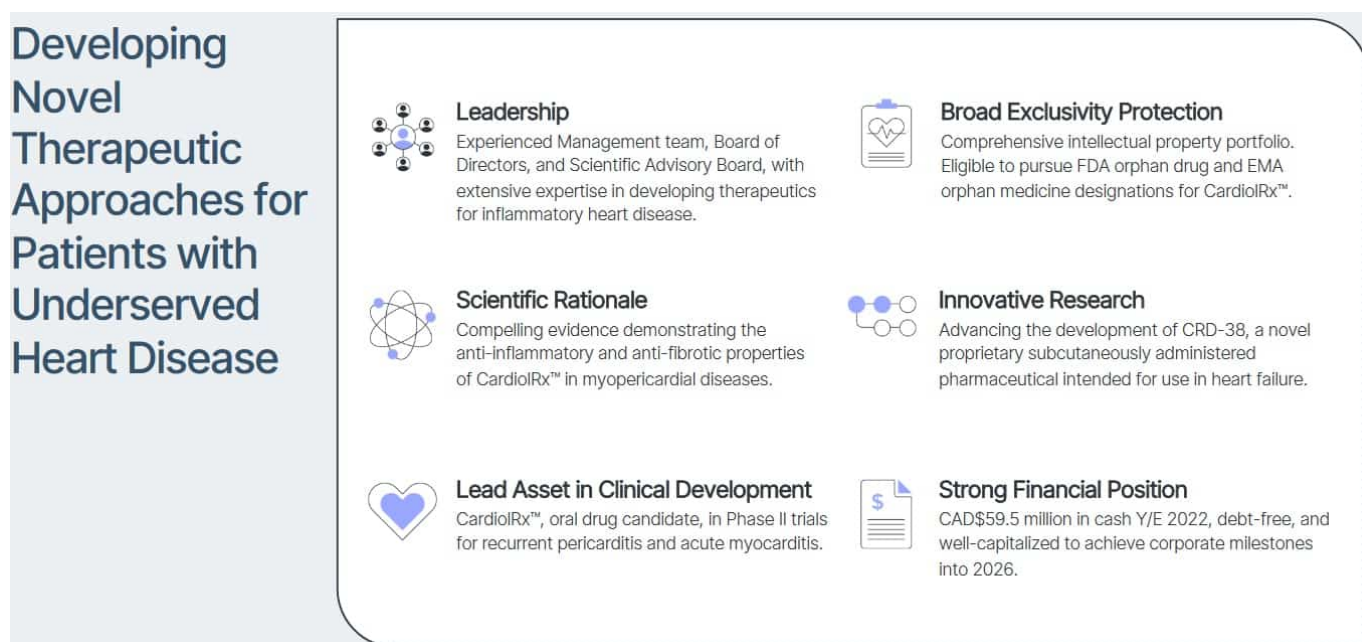
David Elsley founded Vasogen Inc., a biotechnology company focused on the research and commercial development of novel therapeutics for the treatment of heart failure and other inflammatory conditions. Cardiol's website [states](#):

*“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



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.

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## David Elsley of Cardiol Therapeutics talks about their global Phase II clinical trials for the treatment of heart diseases

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In this InvestorIntel interview, Chris Thompson talks to [Cardiol Therapeutics Inc.](#)'s (NASDAQ: CRDL | TSX: CRDL) CEO, President and Director David Elsley about Cardiol's therapies for the treatment of heart diseases. Currently targeting recurrent pericarditis and acute myocarditis, David discusses how these two forms of heart diseases generally affect younger populations who are otherwise healthy.

David tell Chris that there is no currently no FDA-approved therapy on the market for acute myocarditis, and only one FDA approved treatment for recurrent pericarditis which “costs upwards of \$200,000 per patient per year.” Currently in Phase II clinical trials, David discusses how Cardiol is developing CardiolRx™ as an “orphan drug” for the treatment of acute myocarditis and recurrent pericarditis. He tells Chris that the current global Phase II trial is “the largest clinical program ever to be undertaken in acute myocarditis.” He goes on to provide an update on Cardiol’s new formulation in the pipeline for the treatment of heart failure.

To access the full InvestorIntel interview, [click here](#).

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### **About Cardiol Therapeutics Inc.**

Cardiol Therapeutics Inc. (NASDAQ: CRDL) (TSX: CRDL) 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 diseases. The Company’s lead product candidate, CardiolRx™ (cannabidiol), is a pharmaceutically manufactured oral solution formulation that is being clinically developed for use in heart diseases. It is recognized that cannabidiol inhibits activation of the inflammasome pathway, an intracellular process known to play an important role in the inflammation and fibrosis associated with myocarditis, pericarditis, and heart failure.

Cardiol has received Investigational New Drug Application authorization from the United States Food and Drug Administration to conduct clinical studies to evaluate the efficacy and safety of CardiolRx™ in two diseases affecting the heart: (i) 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; and (ii) a Phase II 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.

Cardiol is also developing a novel subcutaneously administered drug formulation of cannabidiol intended for use in heart failure – a leading cause of death and hospitalization in the developed world, with associated healthcare costs in the United States exceeding \$30 billion annually.

To learn more about Cardiol Therapeutics Inc., [click here](#)

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If you have any questions surrounding the content of this interview, please contact us at +1 416 792 8228 and/or email us direct at [info@investorintel.com](mailto:info@investorintel.com).

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# Cardiol Therapeutics is concerned with affairs of the heart

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One thing I really enjoy about writing for InvestorIntel is all the random learning I get from reading MD&As of the various companies I write about. Some of it is very informative, some of it is fascinating and some of it is just plain entertaining.

Today's company falls into the first two categories, at least for me, as it sent me down a bit of a rabbit hole on cardiovascular disease (CVD). Coming from a long family history of unfortunate events related to the heart and its functions, I'm always keen to understand more about the prevention and cure of various heart maladies.

You may or may not be curious about which specific diseases we are dealing with today, but I'm going to tell you anyway – acute myocarditis and recurrent pericarditis, two underserved diseases affecting the heart. Acute myocarditis is an inflammatory condition of the heart muscle (myocardium) characterized by chest pain, impaired cardiac function, atrial and ventricular arrhythmias, and conduction disturbances. While recurrent pericarditis refers to inflammation of the pericardium (the membrane or sac that surrounds the heart) that follows an initial episode (frequently resulting from a viral infection). Perhaps that's too much information but it's important to understand if you have any interest in today's company.

That company is [Cardiol Therapeutics Inc.](#) (NASDAQ: CRDL | TSX: CRDL), 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 diseases. The Company's lead product candidate, CardiolRx™, is a pharmaceutically manufactured oral cannabidiol formulation that is being clinically developed for use in heart diseases. Cardiol has received Investigational New Drug Application authorization from the United States Food and Drug Administration to conduct clinical studies to evaluate the efficacy and safety of CardiolRx™ in the two aforementioned diseases affecting the heart: (i) 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; and (ii) a Phase II 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.

Now that we've covered a small encyclopedia worth of medical terminology, let's get down to the business catalysts behind Cardiol. In early October the Company [announced data](#) that was presented at The Annual Scientific Meeting of the Heart Failure Society of America (is it just me or does this seem like an awful name for a society?). The study results demonstrate the active pharmaceutical ingredient in CardiolRx™ inhibits and also promotes the reversal of mechanisms known to play a role in the occurrence and development of fibrotic CVD. Cardiol is currently advancing its Phase II ARCHER trial, designed to assess CardiolRx™ in acute myocarditis. The Company has received regulatory clearance in multiple jurisdictions and is expected to enroll 100 patients at major cardiac centers in North America, Europe, Latin America, and Israel. The primary endpoints of the trial will be evaluated after 12 weeks of double-blind therapy. Concurrent with the ARCHER trial, the Company is also undertaking a Phase II pilot study in recurrent pericarditis. Cardiol's study is expected to enroll 25 patients at major clinical centers specializing in pericarditis in the U.S.

But now, possibly the most interesting thing about Cardiol, is the fact that it is trading at or even below its current cash value. The Company ended Q2/22 with working capital of C\$62 million and currently has a market cap of just over C\$50 million. With a quarterly burn rate of roughly C\$6.5 million, that suggests the cash value alone in Cardiol is somewhere in

the neighborhood of C\$54 million give or take, which is C\$0.06/share or 8% higher than yesterday's close. Regardless of what the back of the envelope math says, the Company itself has [stated](#) that its cash runway now extends into 2026. That is plenty of time to see the ARCHER trial through to completion as well as the pilot study in recurrent pericarditis.

It appears Cardiol has plenty of available resources to make something happen over the coming weeks and months.