Cardiol Therapeutics' Cannabidiol Formulation Reduced Inflammation—Phase II Topline Data Ignites the Race to Treat Acute Myocarditis

written by Tracy Hughes | August 6, 2025

A single-digit p-value has rarely carried such freight. Cardiol Therapeutics Inc. (NASDAQ: CRDL | TSX: CRDL) this morning unveiled topline data from its Phase II **ARCHER** trial showing that its oral cannabidiol formulation **CardiolRx™** showed a notable improvement in left-ventricular (LV) extracellular volume (ECV) – a magnetic-resonance proxy for myocardial edema and scarring – just enough to flirt with statistical significance (p = 0.0538) versus placebo after 12 weeks of therapy in acute myocarditis patients. Equally telling, their drug coaxed meaningful improvements over placebo in multiple pre-specified cardiac magnetic resonance imaging endpoints, including a significant reduction in LV mass, while preserving the pristine safety profile the company first advertised in pericarditis.

Acute myocarditis, often viral, has long been a therapeutic desert: no FDA-approved drugs, seven-day average hospital stays and a 4–6% in-hospital mortality rate, with the threat of sudden cardiac death stalking otherwise healthy adults under 35. Against that backdrop, even a near-miss p-value can resonate.

"The results offer exciting new insights into the treatment of acute myocarditis and strongly support advancing the clinical development of this novel therapeutic approach for inflammatory

cardiac conditions, including myocarditis and heart failure," **Dr. Dennis M. McNamara**, Chair of the ARCHER trial's steering committee, said after thanking the 109 patients who volunteered across four continents.

Dr. Leslie T. Cooper, Jr. of the Mayo Clinic, the trial's co-chair, added "ARCHER was an important, well-designed, and well-executed clinical trial," noting the findings "reinforce our hypothesis that pharmaceutically manufactured cannabidiol can attenuate myocardial inflammation and edema" — language that nudges Cardiol's program from hypothesis to early validation.

CEO **David Elsley** seized the moment: "We now look forward to integrating the ARCHER findings into our broader clinical strategy," he said, highlighting the support to continue advancements of CardiolRx™ and a novel sub-q drug formulation, CRD-38, as potential treatments for inflammatory cardiac disorders.

Cardiol's pipeline already has momentum. In April the company randomized the first patient into **MAVERIC**, a pivotal Phase III study testing CardiolRx™ in recurrent pericarditis, a market now dominated by Kiniksa's injectable interleukin-1 (IL-1), **rilonacept**. MAVERIC's design—an oral cannabinoid formulation stepping in as patients taper off expensive IL-1 blockers—aims to prove CardiolRx™ can keep relapses at bay without systemic immunosuppression.

That competitive calculus matters. Since rilonacept won FDA approval in 2021 and launched for recurrent pericarditis, it instantly became the only approved therapy for the disease—and a pricey, weekly injection at that. (U.S. Food and Drug Administration) Not to mention, it has achieved over $1 billion in cumulative sales despite only 5.5% of the 38,000 patients with recurrent pericarditis in the U.S. being on treatment as of

end Q2 2025. Cardiol is betting physicians will welcome an oral alternative that targets upstream pathways associated with NLRP3 inflammasome activation (and the subsequent release of proteins called cytokines that are responsible for the inflammation) and is not an immunosuppressant associated with infection risk.

Investors will parse ARCHER's p-value, but cardiologists will study the tapestry: coherence across ECV, LV mass and other strain measures suggests biological effect, not statistical accident. Regulatory eyes will look for a confirmatory trajectory into a broader clinical development strategy.

Should CardiolRx™ clear that bar, the company plans to follow with **CRD-38**, a novel subcutaneously administered cannabidiol drug formulation aimed at heart-failure with preserved ejection fraction, stretching its therapeutic pipeline into a multibillion-dollar arena.

For now, today's topline data gives Cardiol credible proof of concept in a field starved for options, and a competitive narrative that pits a convenient oral formulation against biologic injectables in the race to calm an inflamed heart.