

Cardiol Therapeutics Inc.: Form 6-K - Filed by newsfilecorp.com UNITED STATESSECURITIES AND EXCHANGE COMMISSIONWashington, D.C. 20549 FORM 6-K REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934 For the month of September 2024 Commission File Number: 001-40712 Cardiol Therapeutics Inc. (Translation of registrant's name into English) 602-2265 Upper Middle Road East, Oakville, Ontario, Canada L6H 0G5(Address of principal executive offices) Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F. [X] Form 20-F  [ ] Form 40-F Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): [ ] Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): [ ] SUBMITTED HEREWITH Exhibits Exhibit A Description A 99.1 A News Release dated September 10, 2024 - Cardiol Therapeutics Announces Completion of the MAVERIC Phase II Study in Recurrent Pericarditis with Results to be Presented at the American Heart Association Scientific Sessions 2024 SIGNATURES Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized. A CARDIOL THERAPEUTICS INC. A (Registrant) A A Date: September 10, 2024 By: /s/ Chris Waddick A A Chris Waddick A Title: Chief Financial Officer Cardiol Therapeutics Inc.: Exhibit 99.1 - Filed by newsfilecorp.com Cardiol Therapeutics Announces Completion of the MAVERIC Phase II Study in Recurrent Pericarditis with Results to be Presented at the American Heart Association Scientific Sessions 2024 A Full clinical data will be reported in an oral presentation at the premier global event for advancements in cardiovascular science and medicine on November 18, 2024 Toronto, ON - September 10, 2024 - Cardiol Therapeutics Inc. (NASDAQ: CRDL) (TSX: CRDL) ("Cardiol" or the "Company"), 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, today announced the data from its Phase II open-label MAVERIC-Pilot study investigating the impact of CardiolRx, a small molecule drug candidate administered to patients with symptomatic recurrent pericarditis will be reported in an oral presentation as part of the Laennec Clinician-Educator Award & Lecture that runs from 9:45 a.m. to 11:00 a.m. Central Time, on Monday, November 18th, 2024, at the American Heart Association Scientific Sessions 2024. Dr. S. Allen Luis, Co-Director, Pericardial Diseases Clinic and Associate Professor of Medicine, Department of Cardiovascular Medicine at the Mayo Clinic, will present on behalf of the MAVERIC-Pilot investigators. "Having recently reported the positive primary endpoint data from the MAVERIC-Pilot study demonstrating that oral administration of our small molecule CardiolRx, a drug candidate administered to patients with symptomatic recurrent pericarditis pain and inflammation at 8 weeks, we are delighted that the data has been accepted for oral presentation in such a prestigious session of the American Heart Association Scientific Sessions 2024, the premier global event for advancements in cardiovascular science and medicine," said David Elsley, Cardiol Therapeutics' President and Chief Executive Officer. "We extend our thanks and gratitude to the patients and our clinical research collaborators whose participation in this important study have served to support our objective of developing a more accessible and non-immunosuppressive therapeutic option for thousands of patients suffering from this chronic inflammatory heart disease." "The MAVERIC-Pilot study was designed to investigate the impact of our novel therapy CardiolRx, a drug candidate administered to patients with the debilitating symptoms of recurrent pericarditis," said Andrew Hamer, Cardiol Therapeutics' Chief Medical Officer and Head of Research & Development. "Having reached the important milestone of concluding the study, we now look forward to reporting the full clinical results from MAVERIC-Pilot that will include additional endpoints including freedom from pericarditis recurrence during the 18-week Extension Period, 26-week pericarditis pain score and inflammatory marker levels, and safety and tolerability outcomes. We anticipate the totality of the results will support and further inform our plans to advance to a Phase III trial of CardiolRx, a drug candidate administered to patients with symptomatic recurrent pericarditis pain and inflammation at 8 weeks, in this inflammatory heart disease that is associated with symptoms that adversely affect quality of life, mental health, and physical activity." MAVERIC-Pilot Study Design The MAVERIC-Pilot study evaluated CardiolRx, a drug candidate administered to 27 adult participants (â‰¥18 years) with symptomatic recurrent pericarditis (â‰¥2 recurrences), with or without a raised level of C-reactive protein ("CRP"), at eight clinical sites across the United States. The study Chairman is Allan L. Klein, MD, Director of the Center of Pericardial Diseases and Professor of Medicine, Heart and Vascular Institute, at the Cleveland Clinic. The study design consisted of an 8-week treatment period ("TP") followed by an 18-week extension period ("EP"). Patients with pericarditis chest pain with a numerical rating scale ("NRS") pain score â‰¥4 together with either an elevated level of CRP (â‰¥1mg/dL) or evidence of pericardial inflammation assessed by cardiac imaging were enrolled. CardiolRx, a drug candidate administered to stable doses of baseline therapy for recurrent pericarditis (non-steroidal anti-inflammatory drugs, colchicine, and/or corticosteroids, in any combination). In the first 10 days of the TP, CardiolRx, a drug candidate administered to was up-titrated to 10 mg/kg twice daily, or the maximum tolerated dose. Throughout the TP, patients continued receiving baseline therapy for recurrent pericarditis but were weaned off this during the EP to assess pericarditis recurrence. The primary efficacy endpoint is the change, from baseline to 8 weeks, in patient-reported pericarditis pain using the NRS. Secondary endpoints include NRS pain score at 26 weeks, and freedom from pericarditis recurrence during the EP. Secondary CRP endpoints of interest include change from baseline to 26 weeks, and for patients with CRP â‰¥1 mg/dL at baseline, the time to CRP normalization, as well as the percentage of patients with normalized CRP at both 8 and 26 weeks. Recurrent Pericarditis 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). Patients may have multiple recurrences. Symptoms include debilitating chest pain, shortness of breath, and fatigue, resulting in physical limitations, reduced quality of life, emergency department visits, and hospitalizations. Significant accumulation of pericardial fluid and scarring can progress to life-threatening constriction of the heart. The only FDA-approved therapy for recurrent pericarditis, launched in 2021, is costly and is primarily used as a third-line intervention. On an annual basis, the number of patients in the United States having experienced at least one recurrence is estimated at 38,000. Approximately 60% of patients with multiple recurrences (>1) still suffer for longer than two years, and one third are still impacted at five years. Hospitalization due to recurrent pericarditis is often associated with a 6-8-day length of stay and cost per stay is estimated to range between \$20,000 and \$30,000 in the United States. About Cardiol Therapeutics 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 disease. The Company's lead small molecule drug candidate, CardiolRx, a drug candidate administered to (cannabidiol) oral solution, is pharmaceutically manufactured and in clinical development for use in the treatment of heart disease. It is recognized that cannabidiol inhibits activation of the inflammasome pathway, an intracellular process known to play an important role in the development and progression of 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 ("US FDA") to conduct clinical studies to evaluate the efficacy and safety of CardiolRx, a drug candidate administered to in two

diseases affecting the heart: (i) a Phase II multi-center open-label pilot study in recurrent pericarditis (the MAvERIC-Pilot study; NCT05494788), an inflammatory disease 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; and (ii) a Phase II multi-national, randomized, double-blind, placebo-controlled trial (the ARCHER trial; NCT05180240) 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. The US FDA has granted Orphan Drug Designation to CardiolRx<sup>®</sup> for the treatment of pericarditis, which includes recurrent pericarditis. Cardiol is also developing CRD-38, a novel subcutaneously administered drug formulation 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. For more information about Cardiol Therapeutics, please visit [cardiolrx.com](http://cardiolrx.com). Cautionary statement regarding forward-looking information: This news release contains "forward-looking information" within the meaning of applicable securities laws. All statements, other than statements of historical fact, that address activities, events, or developments that Cardiol believes, expects, or anticipates will, may, could, or might occur in the future are "forward-looking information". Forward looking information contained herein may include, but is not limited to, statements relating to the Company's focus on developing anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease, the molecular targets and mechanism of action of the Company's product candidates, the Company's intended clinical studies and trial activities and timelines associated with such activities, including for primary efficacy endpoint and secondary endpoints, the Company's plans to report in an oral presentation the impact of CardiolRx<sup>®</sup> administered to patients with symptomatic recurrent pericarditis at the American Heart Association Scientific Sessions 2024, the Company's intention to report the full clinical results from the MAvERIC-Pilot study, the Company's anticipation that the totality of the results of the MAvERIC-Pilot study will support and further inform its plans to advance to the Phase III trial of CardiolRx<sup>®</sup>, and the Company's plan to advance the development of CRD-38, a novel subcutaneous formulation of cannabidiol intended for use in heart failure. Forward-looking information contained herein reflects the current expectations or beliefs of Cardiol based on information currently available to it and is based on certain assumptions and is also subject to a variety of known and unknown risks and uncertainties and other factors that could cause the actual events or results to differ materially from any future results, performance or achievements expressed or implied by the forward-looking information, and are not (and should not be considered to be) guarantees of future performance. These risks and uncertainties and other factors include the risks and uncertainties referred to in the Company's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission and Canadian securities regulators on April 1, 2024, as well as the risks and uncertainties associated with product commercialization and clinical studies. These assumptions, risks, uncertainties, and other factors should be considered carefully, and investors should not place undue reliance on the forward-looking information, and such information may not be appropriate for other purposes. Any forward-looking information speaks only as of the date of this press release and, except as may be required by applicable securities laws, Cardiol disclaims any intent or obligation to update or revise such forward-looking information, whether as a result of new information, future events, or results, or otherwise. For further information, please contact: Trevor Burns, Investor Relations +1-289-910-0855 [trevor.burns@cardiolrx.com](mailto:trevor.burns@cardiolrx.com)