



2265 Upper Middle Road East, Suite 602  
Oakville, ON L6H 0G5, Canada

## Cardiol Therapeutics Announces Filing of 2020 Year-end Financial Statements and MD&A

**Oakville, ON – April 1, 2021 – Cardiol Therapeutics Inc. (TSX: CRDL) (OTCQX: CRTPF) (FSE: CT9) (“Cardiol” or the “Company”)**, a clinical-stage biotechnology company focused on developing innovative anti-inflammatory therapies for the treatment of cardiovascular disease, today filed its audited Financial Statements and Management’s Discussion and Analysis for the year ended December 31, 2020. Both are available under the Company’s profile on SEDAR at [www.sedar.com](http://www.sedar.com) and on the Company’s website at [www.cardiolrx.com](http://www.cardiolrx.com).

David Elsley, President and Chief Executive Officer of Cardiol, commented: “2020 was a very exciting year for Cardiol Therapeutics. We made extraordinary progress in our research and clinical development programs, while significantly strengthening our financial position. We are particularly excited about the progress made across our research and development programs supporting the development of CardiolRx™, our pharmaceutically produced extra-strength oral formulation of cannabidiol and lead drug candidate for the treatment of acute inflammatory heart disease.

Notably, receiving Investigational New Drug (“IND”) approval from the FDA for our Phase II/III study in hospitalized COVID-19 patients with prior history of, or risk factors for cardiovascular disease (“CVD”), has presented a unique opportunity to investigate the impact of the cardioprotective properties of CardiolRx on a composite endpoint consisting of one or more of several common significant adverse outcomes in this patient population, including all-cause mortality, requirement for ICU admission and/or ventilatory support, as well as cardiovascular complications, including the development of heart failure, acute myocardial infarction, myocarditis, stroke, or new sustained or symptomatic arrhythmia. We believe successful outcomes from this study will support an emergency use authorization and/or a new drug application and will provide invaluable clinical data with respect to the therapeutic potential of CardiolRx™ in the treatment of other inflammatory heart diseases, including acute myocarditis and heart failure.

Based on the large body of experimental evidence of the anti-inflammatory and cardioprotective properties of cannabidiol in models of cardiovascular disease, we also believe CardiolRx has the potential to offer a breakthrough therapy for acute myocarditis that would be eligible for designation as an orphan drug. Acute myocarditis is an inflammatory condition of the heart, usually resulting from viral infection, and currently represents a leading cause of sudden cardiac death in children and otherwise healthy young adults. In support of our plans to file an IND application with the FDA for an international Phase II clinical trial in acute myocarditis, we

initiated and completed a Phase I double-blind, placebo-controlled, randomized study designed to assess safety, tolerability, and pharmacokinetics of single, followed by multiple day ascending doses of CardiolRx administered orally to 51 healthy adult subjects. As we anticipated, CardiolRx was shown to be well tolerated with no serious adverse events reported in the study.

We also made significant progress in the development of a novel subcutaneous (“SC”) formulation of cannabidiol that we believe represents an entirely new approach to the delivery of this important medicine for the treatment of chronic inflammatory heart disease. The first experimental data from Cardiol-sponsored research utilizing a SC cannabidiol formulation were accepted for presentation at the American College of Cardiology’s 69th Annual Scientific Session & Expo together with the World Congress of Cardiology, held virtually from March 28 – 30, 2020. The study found that cannabidiol administered SC significantly reduced hypertrophy and produced a dose-dependent reduction of key inflammation markers, decreases in fibrosis, and lower BNP expression in an experimental model of non-ischemic heart failure. These data support our long-standing view concerning the anti-inflammatory, anti-fibrotic, and cardioprotective properties of pharmaceutically produced cannabidiol, and serve as an encouraging scientific foundation for our plans to clinically develop a SC formulation of cannabidiol for the treatment of chronic heart failure, which remains a leading cause of death and hospitalization in North America, with associated annual healthcare costs in the U.S. alone exceeding \$30 billion.

In parallel with advancing important research and clinical development programs focused on inflammatory heart disease, we are also developing an attractive commercial opportunity for our high purity cannabidiol formulation by addressing poorly served segments of the \$575 million medicinal cannabinoid market in Canada, particularly patients who should not take THC. Through an exclusive supply agreement with *Medical Cannabis by Shoppers™*, a subsidiary of *Shoppers Drug Mart Inc.*, in late 2020 we commercially introduced Cortalex™, a THC-free (<10ppm) extra-strength cannabidiol formulation with an initial focus on conducting soft launch activities to test the consumer experience and responsiveness to product attributes and pricing. Cortalex addresses the growing demand from paediatricians and family physicians for a cannabidiol formulation that does not contain THC, particularly for patients under the age of 25 where THC has been linked to a detrimental impact on brain development. It is also a concern in older individuals, who might already have chronic diseases that limit coordination or cognitive function and who also wish to avoid any risk of intoxication. During 2021, the Company intends to execute a marketing program specifically designed to increase awareness of Cortalex amongst thought leaders in pediatric and geriatric medicine.

I believe the proposed acquisition of GW Pharma for US\$7.2 billion in early 2021, together with the 2020 acquisition of MyoKardia for US\$13 billion, underscores the potential value proposition for enterprises focused on cannabidiol-based medicines and on the development of new treatments for cardiovascular disease. With a robust research and development pipeline, world-class R&D collaborators, and an experienced management team, we are well positioned to build a leadership position in the development of therapies to address the underlying inflammatory component in heart disease.”

*Highlights during the 2020 Fiscal Period*

- In April 2020, the Company announced that data submitted by its international research collaborators were accepted for presentation at the American College of Cardiology's 69th Annual Scientific Session & Expo together with the World Congress of Cardiology, held virtually from March 28 – 30. The study found that Cardiol's cannabidiol formulation significantly reduced hypertrophy and produced a dose- dependent reduction of key inflammation markers, decreases in fibrosis, and lower BNP expression. These findings confirm the anti-inflammatory and anti-fibrotic activity as well as illustrating the cardio-protective action of Cardiol's cannabidiol formulation in a model of heart failure.
- In May 2020, the Company announced the filing of a new patent application covering the use of cannabidiol to improve the outcome of patients with COVID-19. This new patent application includes the administration of cannabidiol to reduce the severity of disease in COVID-19 patients with pre-existing cardiovascular conditions, and the prevention of development of cardiovascular complications.
- In June 2020, the Company announced the completion of its short form prospectus offering by issuing 6,900,000 common share units at \$2.50 per unit for gross proceeds of \$17,250,000. Each unit consisted of one common share and one-half of one common share purchase warrant. Each whole warrant is exercisable into one common share at the price of \$3.25 per share for a period of two years from closing, subject to accelerated expiry if, at any time, the volume weighted average trading price of the common shares is equal to or greater than \$4.50 for any ten consecutive trading day period.
- In June 2020, the Company announced that it appointed Steven Grasso as Business Advisor to the Company. Over his 27-year career, Steven has worked closely with some of the largest mutual funds, pension funds, insurance companies, and hedge funds in the world directly from the floor of the New York Stock Exchange. Steven is perhaps best known for being a CNBC market analyst and is a regular on CNBC's popular "Fast Money" show. As Business Advisor, Mr. Grasso will assist with raising Cardiol's profile within the U.S. investment community through his extensive network of connections with institutional investors, analysts, and investment banks. His relationships with the senior management of many of the largest pharmaceutical and biotechnology companies in the world will also be of assistance to the Company in achieving its commercial and business development objectives.
- In September 2020, the FDA approved the Company's IND application to commence a Phase II/III, double-blind, placebo-controlled clinical trial investigating the efficacy and safety of CardiolRx™ in 422 hospitalized COVID-19 patients with a prior history of, or risk factors for, CVD. The trial will take place at major centers in the United States and internationally, where the prevalence of COVID-19 remains high. The composite primary efficacy endpoint will be the difference between the active and placebo groups in the percentage of patients who develop, during the first twenty-eight days following randomization and first dose of study medication, one or more of several common significant adverse outcomes.

The Company's Phase II/III study was designed and will be overseen by an independent Steering Committee, consisting of international thought leaders in inflammatory heart disease: Dr. Dennis McNamara (Co-Chair), Professor of Medicine and Director of the Center for Heart Failure Research, University of Pittsburgh; Dr. Leslie Cooper (Co-Chair), Chair of the Mayo Clinic Enterprise Department of Cardiovascular Medicine and Chair of the Department of Cardiovascular Medicine, Mayo Clinic; Dr. Arvind Bhimaraj, Medical

Director, Advanced Heart Failure, Mechanical Circulatory Support and Heart Transplant Programs, Houston Methodist Hospital; Dr. Barry Trachtenberg, Director, Cardio-Oncology and Cardiac Amyloid Programs, Associate Director, Mechanical Circulatory Support Program, Houston Methodist Hospital; Dr. Wilson Tang, Director of the Center for Clinical Genomics, Research Director, and staff cardiologist in the Section of Heart Failure and Cardiac Transplantation Medicine, Cleveland Clinic; Dr. Peter Liu, Chief Scientific Officer and Vice President of Research, University of Ottawa Heart Institute; Dr. Carsten Tschöpe, Vice Director of the Dept. of Cardiology, Charité University Medicine Berlin, Germany; Dr. Matthias Friedrich, Professor of Medicine and Chief, Cardiovascular Imaging, McGill University Health Centre; and Dr. Guilherme Oliveira, Professor of Medicine and Chairman of Cardiovascular Sciences at the University of South Florida Health Morsani College of Medicine.

- In October 2020, the Company commercially introduced Cortalex™, a THC-free (<10ppm) extra-strength oral cannabidiol (CBD) formulation to address the growing demand from paediatricians and family physicians for a cannabidiol formulation that does not contain THC, particularly for patients under the age of 25 where THC has been linked to a detrimental impact on brain development. THC exposure is also a concern in older individuals who might already have chronic diseases that limit coordination or cognitive function and who also wish to avoid any risk of intoxication. Available exclusively at *Medical Cannabis by Shoppers™* online portal, a subsidiary of *Shoppers Drug Mart Inc.*, Cortalex™ is the first pharmaceutically produced CBD formulated for people who should not take THC.
- In December 2020, Cardiol announced the appointment of the contract research organization (“CRO”) Worldwide Clinical Trials (Worldwide) to initiate its Phase II/III trial in high-risk patients hospitalized with COVID-19. Worldwide has extensive experience in conducting clinical research focused on cardiovascular disease and has been the CRO for several international COVID-19 clinical programs. With a global footprint, Worldwide employs over 1900 professionals and provides drug development expertise from early phase to late-stage clinical development, post-approval, and real-world evidence studies; delivering high quality clinical programs designed to support regulatory approvals in multiple jurisdictions.
- In December 2020, the Company announced the completion of its Phase I double-blind, placebo-controlled, randomized study designed to assess safety, tolerability, and pharmacokinetics of single, followed by multiple day ascending doses of CardiolRx administered orally to 52 healthy adult subjects, both in the fasting and fed states. The study results are expected to form an integral part of the Company’s planned IND application with the FDA for an international Phase II clinical trial in acute myocarditis.

#### *Highlights Subsequent to Year-End*

- In January 2021, the Company announced the formation of the Data Safety Monitoring Committee and the Clinical Endpoint Committee for the Company’s Phase II/III trial in high-risk patients hospitalized with COVID-19 at clinical centers throughout the United States.
- In February and March 2021, the Company received total proceeds of \$11,075,936 on the exercise of warrants and stock options.

- In March 2021, the Company announced that it submitted an application to list the Company's common shares on The Nasdaq Capital Market.
- In March 2021, the Company announced that it had appointed Dr. Andrew Hamer as the new Chief Medical Officer following the retirement of Dr. Eldon Smith.

### **About Cardiol Therapeutics**

Cardiol Therapeutics Inc. (TSX: CRDL) (OTCQX: CRTPF) (FSE: CT9) is a clinical-stage biotechnology company focused on the research and clinical development of innovative anti-inflammatory therapies for the treatment of cardiovascular disease (“CVD”). The Company’s lead product, CardiolRx™, is a pharmaceutically produced oral cannabidiol formulation that is currently entering a Phase II/III outcomes study in hospitalized patients testing positive for the COVID-19 virus. This potentially registrational trial is designed to evaluate the efficacy and safety of CardiolRx as a cardioprotective therapy to reduce mortality and major cardiovascular events in COVID-19 patients who have a prior history of, or risk factors for, CVD, and to investigate the influence CardiolRx has on key markers of inflammatory heart disease.

Cardiol is also planning to file an investigational new drug (“IND”) application for a Phase II international trial that will investigate the anti-inflammatory and anti-fibrotic properties of CardiolRx in patients with acute myocarditis, which remains the most common cause of sudden cardiac death in people under 35 years of age. In addition, Cardiol is developing a subcutaneous formulation of CardiolRx and other anti-inflammatory therapies for the treatment of chronic heart failure – a leading cause of death and hospitalization in North America, with associated annual healthcare costs in the U.S. alone exceeding \$30 billion.

Cardiol recently commercialized Cortalex™ ([cortalex.com](http://cortalex.com)) in the Canadian market. Cortalex is a pharmaceutically produced cannabidiol formulation, developed for patients who wish to avoid tetrahydrocannabinol (“THC”) or for whom THC exposure is not recommended. 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 Canadian securities laws. All statements, other than statements of historical fact, that address activities, events, or developments that Cardiol Therapeutics Inc. (“Cardiol” or the “Company”) believes, expects, or anticipates will, may, could or might occur in the future are “forward-looking information.” Forward-looking information contained herein may include, statements relating to the Company’s plans for clinical trials and its development of innovative anti-inflammatory therapies for the treatment of cardiovascular disease, and comments relating to Cardiol’s strategy and comparisons to other pharmaceutical companies. Forward-looking information contained herein reflects the current expectations or beliefs of Cardiol based on information currently available to it and is 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 Information Form dated March 30, 2020, including the risks*

*and uncertainties associated with product commercialization and clinical studies. These risks, uncertainties and other factors should be considered carefully, and investors should not place undue reliance on the forward-looking information. Any forward-looking information speaks only as of the date on which it is made 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:**

David Elsley, President & CEO +1-289-910-0850

[david.elsley@cardiolrx.com](mailto:david.elsley@cardiolrx.com)

Trevor Burns, Investor Relations +1-289-910-0855

[trevor.burns@cardiolrx.com](mailto:trevor.burns@cardiolrx.com)