

CARDIOL THERAPEUTICS INC.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2020

# MANAGEMENT'S DISCUSSION AND ANALYSIS

# Introduction

The following management's discussion and analysis ("MD&A") of the financial condition and results of the operations of Cardiol Therapeutics Inc. (the "Corporation" or "Cardiol") constitutes Management's review of the factors that affected the Corporation's financial and operating performance for the three and nine months ended September 30, 2020 (the "2020 Fiscal Period"). This MD&A was written to comply with the requirements of National Instrument 51-102 – Continuous Disclosure Obligations. This discussion should be read in conjunction with the financial statements for the years ended December 31, 2019 and 2018 and the unaudited condensed interim financial statements for the three and nine months ended September 30, 2020 ("Financial Statements"), together with the respective notes thereto. Results are reported in Canadian dollars, unless otherwise noted. The Financial Statements and the financial information contained in this MD&A are prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board and interpretations of the IFRS Interpretations Committee. In the opinion of Management, all adjustments (which consist only of normal recurring adjustments) considered necessary for a fair presentation have been included.

This MD&A is dated November 10, 2020. All dollar amounts in this MD&A are reported in Canadian dollars, unless otherwise stated. Unless otherwise noted or the context indicates otherwise, the terms "we", "us", "our", "Cardiol" or the "Corporation" refer to Cardiol Therapeutics Inc.

This MD&A is presented current to the date above unless otherwise stated. The financial information presented in this MD&A is derived from the Financial Statements. This MD&A contains forward-looking statements that involve risks, uncertainties, and assumptions, including statements regarding anticipated developments in future financial periods and our plans and objectives. There can be no assurance that such information will prove to be accurate, and readers are cautioned not to place undue reliance on such forward-looking statements. See "Forward-Looking Statements" and "Risk Factors".

# Forward-Looking Information

This MD&A contains forward-looking information that relates to the Corporation's current expectations and views of future events. In some cases, this forward-looking information can be identified by words or phrases such as "may", "might", "will", "expect", "anticipate", "estimate", "intend", "plan", "indicate", "seek", "believe", "predict", or "likely", or the negative of these terms, or other similar expressions intended to identify forward-looking information. Statements containing forward-looking information are not historical facts. The Corporation has based this forward-looking information on its current expectations and projections about future events and financial trends that it believes might affect its financial condition, results of operations, business strategy, and financial needs. The forward-looking information includes, among other things, statements relating to:

- our marketing, and sale of a pharmaceutically produced pure cannabidiol oil as a *Cannabis Act* product line;
- the ability of our nanotherapeutics to deliver cannabinoids and other anti-inflammatory drugs to inflamed tissue in the heart;
- our development of proprietary cannabidiol formulations for near-term commercialization;
- our ability to develop new formulations;
- the successful development and commercialization of our current product candidates and the addition of future products;
- our expectation of a significant increase in the market and interest for pure pharmaceutical cannabidiol products that are tetrahydrocannabinol ("THC") free (<10 ppm);</li>
- the expected growth in the size of the market for cannabidiol in Canada, the United States ("U.S."), and internationally;
- our intention to build a pharmaceutical brand and cannabidiol products focused on addressing heart disease with a particular focus on heart failure;
- the expected medical benefits, viability, safety, efficacy, and dosing of cannabidiol;

- patents, including, but not limited to, our ability to have patents issued covering our drugs, drug candidates, and processes, as well as successfully defending oppositions and legal challenges;
- our expectation of a near-term revenue opportunity from the sale of pure cannabidiol products;
- our competitive position and the regulatory environment in which we operate;
- statements with respect to the acceleration of the broad recognition of Cardiol's true market potential;
- our financial position; our business strategy; our growth strategies; our operations; our financial results; our dividends policy; our plans and objectives; and
- expectations of future results, performance, achievements, prospects, opportunities, or the market in which we operate.

In addition, any statements that refer to expectations, intentions, projections, or other characterizations of future events or circumstances contain forward-looking information. Forward-looking information is based on certain assumptions and analyses made by the Corporation in light of the experience and perception of historical trends, current conditions, and expected future developments and other factors we believe are appropriate, and are subject to risks and uncertainties. Although we believe that the assumptions underlying these statements are reasonable, they may prove to be incorrect, and we cannot assure that actual results will be consistent with this forward-looking information. Given these risks, uncertainties, and assumptions, prospective investors should not place undue reliance on this forward-looking information. Whether actual results, performance, or achievements will conform to the Corporation's expectations and predictions is subject to a number of known and unknown risks, uncertainties, assumptions, and other factors, including those listed under "Risk Factors", which include:

- the inherent uncertainty of product development;
- our requirement for additional financing;
- our negative cash flow from operations;
- our history of losses;
- dependence on success of the sale of our pharmaceutically produced pure cannabidiol oil as a *Cannabis Act* product line and our early-stage product candidates which may not generate revenue;
- reliance on Management, loss of members of Management or other key personnel, or an inability to attract new Management team members;
- our ability to successfully design, commence, and complete clinical trials, including the high cost, uncertainty, and delay of clinical trials and additional costs associated with any failed clinical trials;
- potential negative results from clinical trials and their adverse impacts on our future commercialization efforts;
- our ability to establish and maintain commercialization organizations in the U.S., Mexico, and elsewhere;
- our ability to receive and maintain regulatory exclusivities, including Orphan Drug Designations, for our drugs and drug candidates;
- delays in achievement of projected development goals;
- management of additional regulatory burdens;
- unpredictable and volatile market price for our Class A common shares and the common share purchase warrants of the Corporation (the "Warrants");
- failure to protect and maintain and the consequential loss of intellectual property rights;
- third-party claims relating to misappropriation by our employees of their intellectual property;
- reliance on third parties to conduct and monitor our pre-clinical studies and clinical trials;
- our product candidates being subject to controlled substance laws which may vary from jurisdiction to jurisdiction;
- changes in laws, regulations, and guidelines relating to our business, including tax and accounting requirements;
- our reliance on current early-stage research regarding the medical benefits, viability, safety, efficacy, and dosing of cannabinoids;
- claims for personal injury or death arising from the use of products and product candidates produced by us;

- uncertainty relating to market acceptance of our product candidates;
- our lack of experience in commercializing any products;
- the level of pricing and reimbursement for our products and product candidates, if approved;
- our dependence on Dalton Chemical Laboratories, Inc. operating as Dalton Pharma Services ("Dalton") and other contract manufacturers;
- unsuccessful collaborations with third parties;
- business disruptions affecting third-party suppliers and manufacturers;
- lack of control in future prices of our product candidates;
- our lack of experience in selling, marketing, or distributing our products;
- competition in our industry;
- our inability to develop new technologies and products and the obsolescence of existing technologies and products;
- unfavorable publicity or consumer perception towards cannabidiol;
- product liability claims and product recalls;
- expansion of our business to other jurisdictions;
- fraudulent activities of employees, contractors, and consultants;
- our reliance on key inputs and their related costs;
- difficulty associated with forecasting demand for products;
- operating risk and insurance coverage;
- our inability to manage growth;
- conflicts of interest among our officers and Directors;
- managing damage to our reputation and third-party reputational risks;
- relationships with customers and third-party payors and consequential exposure to applicable anti-kickback, fraud, and abuse and other healthcare laws;
- exposure to information systems security threats;
- the risk that Mr. Grasso's profile will not accelerate the broad recognition Cardiol's true market potential;
- no dividends for the foreseeable future;
- future sales of common shares by existing shareholders causing the market price for the common shares to fall;
- the issuance of common shares in the future causing dilution; and
- the impact of the recent novel coronavirus ("COVID-19") pandemic on our operations.

If any of these risks or uncertainties materialize, or if assumptions underlying the forward-looking information prove incorrect, actual results might vary materially from those anticipated in the forward-looking information.

Information contained in forward-looking information in this MD&A is provided as of the date of this MD&A, and we disclaim any obligation to update any forward-looking information, whether as a result of new information or future events or results, except to the extent required by applicable securities laws. Accordingly, potential investors should not place undue reliance on forward-looking information.

# Overview

On December 20, 2018, the Corporation completed its initial public offering (the "IPO") on the Toronto Stock Exchange (the "TSX"). As a result, the common shares commenced trading on the TSX under the symbol "CRDL" and the Warrants commenced trading under the symbol "CRDL.WT". On May 30, 2019, the Corporation also began trading on the OTCQX Best Market under the symbol "CRTPF".

The Corporation is a clinical-stage biotechnology company focused on developing innovative therapies for inflammatory heart disease. The Corporation recently received approval from the U.S. Food and Drug Administration ("FDA") for its Investigational New Drug (IND) application to commence a Phase II/III, double-blind, placebo-controlled clinical trial investigating the efficacy and safety of its lead product, CardiolRx<sup>™</sup>, in hospitalized COVID-19 patients with a prior history of, or risk factors for, cardiovascular

disease. CardiolRx is an ultra-pure, high concentration cannabidiol oral formulation that is pharmaceutically produced, manufactured under cGMP, and THC-free (<10 ppm).

Cardiol is also planning a Phase II international trial of CardiolRx in acute myocarditis, a condition caused by inflammation in heart tissue, which remains the most common cause of sudden cardiac death in people less than 35 years of age and is developing a proprietary subcutaneous cannabidiol formulation for the treatment of inflammation in the heart that is associated with the development and progression of heart failure. Heart failure is the leading cause of death and hospitalization in North America, with associated annual healthcare costs in the U.S. alone exceeding \$30 billion.

While advancing important clinical trials in inflammatory heart disease, Cardiol is generating a near-term revenue opportunity in the growing Canadian medical cannabinoid market, currently exceeding \$600 million annually, with its recently launched commercial product, Cortalex<sup>™</sup>, <u>www.cortalex.com</u>, the first THC-free extra-strength formulation of cannabidiol oil available across Canada exclusively online at *Medical Cannabis by Shoppers*<sup>™</sup> https://cannabis.shoppersdrugmart.ca.

The Corporation has research programs focused on developing proprietary therapeutics to treat heart failure underway at international centers of excellence, including the University of Alberta, the Houston Methodist DeBakey Heart & Vascular Center, and TecSalud del Tecnológico de Monterrey ("TecSalud"). Cardiol has also established an exclusive manufacturing arrangement with Dalton Pharma Services, a Health Canada approved, FDA registered and inspected, current Good Manufacturing Practice ("cGMP") manufacturer of pharmaceuticals, including cannabinoids, for supplying finished pharmaceutically manufactured cannabidiol products to support the Corporation's research and commercial development programs.

Cardiol has an Exclusive Supply Agreement with Noramco, Inc. ("Noramco") to support Dalton's manufacturing program with large scale supply of pure pharmaceutical cannabidiol. During the period, the Exclusive Supply Agreement was assigned to Purisys, LLC ("Purisys"), an affiliate of Noramco headquartered in Athens, Georgia. This assignment had no impact on Cardiol's rights under the Exclusive Supply Agreement.

Based on Cardiol making certain minimum purchases, Purisys shall not sell pharmaceutical cannabidiol to any third party for use in the production of products in Canada and Mexico (the "Territory"), or to any third party for delivery of products of any kind into the Territory. Notwithstanding this restriction, Purisys shall have the right to sell pharmaceutical cannabidiol to third parties outside Canada for use in products that are approved as prescription medicines by the Therapeutic Products Directorate of Health Canada for delivery into Canada.

Effective upon entering into a supply agreement with Shoppers Drug Mart on March 17, 2020, (see "Operations Highlights – During the 2020 Fiscal Period" below), the Exclusive Supply Agreement was amended such that Cardiol's exclusive rights for products sold to retail pharmacies in the Territory, such as Shoppers Drug Mart, were no longer conditional upon Cardiol meeting any minimum purchase requirements.

Cardiol brings together a wealth of research and development experience, advanced manufacturing capabilities, and a Management team and Board of Directors comprising business and thought leaders with extensive industry experience and expertise in commercializing proprietary drugs.

# **Operations Highlights**

# During the 2020 Fiscal Period

(i) In February 2020, the Corporation granted 109,300 stock options to certain employees and consultants of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$3.54 and expires on February 23, 2025. The options vest 50% on grant and 50% twelve months from the grant date.

(ii) In March 2020, the Corporation announced that it signed a supplier agreement to become a medical cannabidiol supplier to *Shoppers Drug Mart* ("Shoppers"), Canada's largest pharmacy retailer. Under the terms of the agreement, the Corporation will supply Cardiol's pharmaceutical cannabidiol products to Shoppers for sale in all provinces and territories in Canada through Shoppers' online store, *Medical Cannabis by Shoppers*<sup>™</sup>. Manufactured under cGMP and THC free (<10 ppm), Cardiol's products are designed to be the most consistent pharmaceutical cannabidiol formulations available. Shoppers also has the right to purchase all future products available from Cardiol's product line, subject to any and all regulations.

(iii) In April 2020, the Corporation announced that data submitted by its international research collaborators were accepted for presentation at the American College of Cardiology's ("ACC") 69th Annual Scientific Session & Expo together with the World Congress of Cardiology, held virtually from March 28-30.

The effects of Cardiol's pharmaceutically produced cannabidiol formulation were assessed in a model of non-ischemic heart failure. Heart failure was induced by four weeks of infusion of angiotensin II, a substance that produces hypertension, cardiac enlargement, and subsequent heart failure. Two dosages of Cardiol's cannabidiol formulation (or placebo) were administered by subcutaneous injection every three days for four weeks. In addition, the effects of CBD on angiotensin-induced hypertrophy (cell enlargement) and expression of B-type Natriuretic Peptide ("BNP") in a cardiac cell line ("H9c2") were assessed. BNP is a substance released from stretched heart cells which is a widely used clinical indicator of the severity of heart failure.

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 of Cardiol's cannabidiol formulation in a model of heart failure. Moreover, the data show that cannabidiol reduced the amount of BNP released, thereby confirming the role of Cardiol's cannabidiol formulation as a cardioprotective therapy.

(iv) In April 2020, the Corporation announced that data describing Cardiol's nanotechnology approach to drug delivery were submitted by the Corporation's international research collaborators and accepted for presentation at the ACC's 69th Annual Scientific Session & Expo together with the World Congress of Cardiology, held virtually from March 28-30.

Results from this study, conducted at the Houston Methodist DeBakey Heart & Vascular Center, showed that there was a greater than 100-fold increase in uptake of Cardiol's nanoparticles in heart failure hearts compared with control hearts in a pre-clinical model of non-ischemic heart failure. The nanoparticles localized within the diseased hearts, predominantly in areas of fibrosis. Fibrosis is an important component of the pathology of heart failure and is primarily responsible for the stiffening and reduced function of the heart muscle. Moreover, the nanoparticles accumulated within the cytoplasm of the cultured fibroblasts. This evidence of Cardiol's nanoparticles preferentially accumulating intracellularly in fibroblasts shows potential for the successful delivery of anti-fibrotic drugs, such as cannabidiol, to the diseased region of the heart.

Cardiol's proprietary nanotechnology is designed to enable the distribution of water insoluble drugs within the blood (aqueous) circulation, improve pharmacokinetics, and facilitate drug accumulation in the failing heart. Cardiol's nanoparticles are based on a patented family of biocompatible and biodegradable amphiphilic block co-polymers made from polyethylene glycol (PEG) and polycaprolactone (PCL). Both PEG and PCL have a long history of safe use in humans.

(v) In May 2020, the Corporation announced the filing of a new patent application covering the use of cannabidiol (CBD) to improve the outcome of patients with COVID-19. This new patent application includes the administration of CBD to reduce the severity of disease in COVID-19 patients with pre-existing cardiovascular conditions, and to prevent the progression of such conditions.

COVID-19, a disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is primarily a respiratory disease. However, an increasing number of reports indicate that COVID-19 patients are at higher risk of developing cardiovascular complications. Furthermore, patients with underlying cardiovascular disease ("CVD") are more likely to develop severe cases of COVID-19 and have a worse prognosis. A recent study published in the *Journal of the American Medical Association Cardiology* showed that 35% of hospitalized COVID-19 patients had underlying CVD. In this study, patients with underlying CVD and myocardial injury had a significantly higher rate of mortality than patients without these complications.

There is a growing body of experimental evidence that CBD reduces cardiac and vascular inflammation, oxidative stress, and cardiac dysfunction. Pre-clinical research in a model involving cardiac injury demonstrated that Cardiol's pharmaceutically produced (cGMP) cannabidiol has a cardioprotective effect, resulting in a reduction of fibrosis, cardiac hypertrophy (enlargement of the heart), and the cardiac remodelling marker BNP (See (iii) above).

(vi) In June 2020, the Corporation announced the completion of its short form prospectus offering (the "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 Class A 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.

(vii) In June 2020, the Corporation announced that it appointed Steven Grasso as Business Advisor to the Corporation. Steven Grasso began his career on the floor of the New York Stock Exchange in 1993. He joined Stuart Frankel & Co. as an institutional sales trader in 1999. As Director of Institutional Sales for Stuart Frankel & Co., 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 Stock Exchange. Over his 27-year career, Steven has actively participated in various Stock Exchange committees ranging from allocating new listings to designated market makers to developing standardized tests that the floor community uses for continuing education. Steven closely follows the Washington D.C./Markets connection, using his extensive Capitol Hill and SEC relationships to better inform his clients on policy changes and regulation.

Steven is perhaps best known for being a CNBC market analyst and is a regular on CNBC's popular "Fast Money" show, which airs daily during the business week and has an average daily viewership that currently exceeds 250,000. Mr. Grasso also speaks at many traders' conferences across the country on a regular basis, as well as business round tables with many influential leaders of industry where he addresses a broad range of market related issues, including the effects of regulation and the political process on equities.

As Business Advisor, Mr. Grasso will assist with raising Cardiol's profile within the U.S. investment community. Steven has the ability to provide important introductions to investors, analysts, investment banks, and other key investment industry participants. He also has an extensive network of connections with senior management of many of the largest pharmaceutical and biotechnology companies in the world, which will be of assistance to the Corporation in achieving its commercial and business development objectives.

(viii) In October 2020, the Corporation announced the commercial introduction of Cortalex, a THC-free (<10 ppm) extra-strength (100 mg/mL concentration) oral cannabidiol (CBD) formulation. Cortalex is now available across Canada exclusively at *Medical Cannabis by Shoppers™* online portal, a subsidiary of *Shoppers Drug Mart Inc.*, and is the first pharmaceutically produced CBD specifically formulated for the large number of patients who should not be exposed to THC.

# **Clinical Highlights**

# Phase I study

Cardiol received a No Objection Letter from Health Canada to conduct a Phase I study of the Corporation's pharmaceutically produced high concentration, pure cannabidiol formulation. The Corporation initiated the study in August 2020 and expects end results of the study in Q4 2020. This timeline could be affected by the current COVID-19 pandemic (see "Risk Factors - COVID-19 pandemic" below).

The Phase I study is designed to measure the pharmacokinetics (blood levels of drug) following single and multiple doses of the Corporation's extra strength 100mg/mL concentration pharmaceutical cannabidiol formulation in 52 healthy subjects, both in the fasting and fed states. The study will also measure standard safety parameters at escalating doses to help select the optimal dosing levels for the Corporation's planned international Phase II study in acute myocarditis, an inflammatory form of heart failure that represents a leading cause of sudden cardiac death in children and young adults.

# Phase II/III study – COVID-19

In September 2020, the FDA approved the Corporation's Investigational New Drug (IND) application to commence a Phase II/III, double-blind, placebo-controlled clinical trial investigating the efficacy and safety of CardiolRx, a pharmaceutically produced extra strength cannabidiol formulation, in 422 hospitalized COVID-19 patients with a prior history of, or risk factors for, cardiovascular disease (CVD). The trial will take place at major centers in the United States and internationally, where the prevalence of COVID-19 remains high.

Cardiol expects to initiate the Phase II/III clinical trial in Q4, 2020.Cardiol's Phase II/III trial has been designed to assess the efficacy, safety, and tolerability of CardiolRx in preventing cardiovascular complications in hospitalized patients, with a confirmed diagnosis of COVID-19 within the previous 24 hours, and who have pre-existing CVD and/or significant risk factors for CVD. 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, a composite endpoint consisting of one or more of several common 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.

Patients with COVID-19 primarily present with respiratory symptoms which can progress to bilateral pneumonia and serious pulmonary complications. It is now recognized that the impact of COVID-19 is not limited to the pulmonary system. Individuals with pre-existing CVD or who have risk factors for CVD (such as diabetes, hypertension, obesity, abnormal serum lipids, or age greater than 64) are at significantly greater risk of developing serious disease from COVID-19 and experience greater morbidity. Moreover, such COVID-19 patients are at significant risk of developing cardiovascular complications (such as acute myocardial infarction, cardiac arrhythmias, myocarditis, stroke, and heart failure) during the course of their illness, and which are frequently fatal, with an estimated 30 – 40% of patients who die from COVID-19 doing so from cardiovascular complications. A strategy to prevent or limit the number or severity of these cardiovascular complications is likely to considerably improve outcomes from this disease.

The rationale for using cannabidiol to treat patients with COVID-19 is based on extensive pre-clinical investigations by Cardiol and others in models of cardiovascular inflammation which have demonstrated that CBD has impressive anti-inflammatory and anti-fibrotic activity, as well as anti-ischemic, and anti-arrhythmic action, and that it improves myocardial function in models of heart failure. In pre-clinical models of cardiac injury, cannabidiol was shown to be cardio-protective by reducing cardiac hypertrophy, fibrosis, and the production of certain re-modelling markers, such as cardiac B-type Natriuretic Peptide (BNP), which is typically elevated in patients with heart failure. These data were accepted for presentation at the American College of Cardiology's 69th Annual Scientific Session held virtually on March 28 – 30, 2020.

The study was designed and will be overseen by an independent Steering Committee, consisting of international thought leaders in inflammatory heart disease. Members of the Steering Committee include:

# Dennis M. McNamara, MD (Chair)

Dr. Dennis McNamara is a Professor of Medicine at the University of Pittsburgh. He is also the Director of the Center for Heart Failure Research at the University of Pittsburgh Medical Center. Dr. McNamara received his undergraduate/graduate education at Yale University, New Haven, Connecticut, and Harvard Medical School, Boston, Massachusetts, respectively. He completed his internship, residency, and cardiology fellowship at Massachusetts General Hospital in Boston. McNamara's current research interests include etiology and pathogenesis of dilated cardiomyopathies; inflammatory syndromes of cardiovascular disease; myocardial recovery in recent onset non-ischemic primary cardiomyopathy; etiology and management of peripartum cardiomyopathy; and genetic modulation of outcomes in cardiovascular disease.

# Leslie T. Cooper, Jr., MD (Co-Chair)

Dr. Leslie T. Cooper, Jr., is a general cardiologist and the chair of the Mayo Clinic Enterprise Department of Cardiovascular Medicine, as well as chair of the Department of Cardiovascular Medicine at the Mayo Clinic in Florida. Dr. Cooper's clinical interests and research focus on clinical and translational studies of rare and undiagnosed cardiomyopathies, myocarditis, and inflammatory cardiac and vascular diseases, such as giant cell myocarditis, cardiac sarcoidosis, eosinophilic myocarditis, and Takayasu's arteritis. He has published over 130 original peer-reviewed papers, as well as contributing to and editing books on myocarditis. In addition to his clinical and research work, Dr. Cooper is a fellow of the American College of Cardiology, the American Heart Association, the European Society of Cardiology Heart Failure Association, the International Society for Heart and Lung Transplantation, and the Society for Vascular Medicine and Biology. He is also the founder and former president of the Myocarditis Foundation and continues to serve on its Board of Directors.

# Arvind Bhimaraj, MD

Dr. Arvind Bhimaraj is a specialist in Heart Failure and Transplantation Cardiology and is Assistant Professor of Cardiology, Institute for Academic Medicine, at Houston Methodist and at Weill Cornell Medical College, NYC. He has been Co-Director of the Heart Failure Research Laboratory at Houston Methodist since 2016. His area of focus is anti-fibrotic mechanisms and how to promote recovery of a damaged heart. Dr. Bhimaraj was a Heart Failure Fellow at the Cleveland Clinic from July 2010 to September 2011. Dr. Bhimaraj also specializes in Interventional Cardiology, is board certified in Cardiovascular Disease, and the author of numerous cardiovascular publications.

# Barry Trachtenberg, MD

Dr. Barry H. Trachtenberg is a cardiologist specializing in heart failure and cardiac transplantation. He is also the director of the Michael DeBakey Cardiology Associates Cardio-Oncology program, an evolving field devoted to prevention and management of cardiovascular complications of cancer therapies such as chemotherapy and radiation. His clinical experience includes heart failure and heart transplantation, mechanical support pumps, and cardio-oncology. He has contributed to multiple publications related to advanced heart failure, cardiac transplantation, regenerative therapies, and ventricular assist devices. Dr. Trachtenberg is a member of the American Heart Association, the International Society for Heart and Lung Transplantation, the Heart Failure Society of America, and the International CardiOncology Society of North America.

# Wai Hong Wilson Tang, MD

Dr. Wai Hong Wilson Tang is the Advanced Heart Failure and Transplant Cardiology specialist at the Cleveland Clinic in Cleveland, Ohio. Dr. Tang is also the Director of the Cleveland Clinic's Center for Clinical Genomics; Research Director, and staff cardiologist in the Section of Heart Failure and Cardiac

Transplantation Medicine in the Sydell and Arnold Miller Family Heart & Vascular Institute at the Cleveland Clinic. He attended and graduated from Harvard Medical School in 1996, having over 23 years of diverse experience, especially in Advanced Heart Failure and Transplant Cardiology. Dr. Tang is affiliated with many hospitals including the Cleveland Clinic and cooperates with other doctors and physicians in medical groups including The Cleveland Clinic Foundation.

# Peter Liu, MD

Dr. Peter Liu is the Chief Scientific Officer and Vice President, Research, of the University of Ottawa Heart Institute, and Professor of Medicine and Physiology at the University of Toronto and University of Ottawa. He was the former Scientific Director of the Institute of Circulatory and Respiratory Health at the Canadian Institutes of Health Research, the major federal funding agency for health research in Canada. Prior to that role, he was the inaugural Director of the Heart & Stroke/Lewar Centre of Excellence in Cardiovascular Research at University of Toronto. Dr. Liu received his MD from the University of Toronto, and postgraduate training at Harvard University. His laboratory investigates the causes and treatments of heart failure, the role of inflammation, and the identification of novel biomarkers and interventions in cardiovascular disease. Dr. Liu has published over 300 peer-reviewed articles in high impact journals and received numerous awards in recognition of his research and scientific accomplishments.

# Carsten Tschöpe, MD

Dr. Carsten Tschöpe is Professor of Medicine and Cardiology. Vice Director of the Department of Internal Medicine and Cardiology, Charité Hospital, Freie Universität Berlin. He received his doctorate in medicine in 1993 and has over 140 peer - reviewed publications, including overview and book articles, and 120 international original articles. His research interests include inflammatory cardiomyopathy, diabetic cardiopathy, and ischemic cardiopathy. He also includes diastolic dysfunction, endothelial dysfunction, peptide systems, and experimental and clinical studies in cardiology and stem cells in his research studies. For his outstanding research work, Dr. Tschöpe was awarded the prestigious Arthur Weber Prize by the German Cardiac Society – Cardiovascular Research.

# Matthias Friedrich, MD

Dr. Matthias Friedrich is Full Professor with the Departments of Medicine and Diagnostic Radiology at the McGill University in Montreal and Chief, Cardiovascular Imaging at the McGill University Health Centre. He is also Professor of Medicine at Heidelberg University in Germany. Dr. Friedrich earned his MD at the Friedrich-Alexander-University Erlangen-Nürnberg, Germany. He completed his training as an internist and cardiologist at the Charité University Medicine Center, Humboldt University in Berlin. Dr. Friedrich founded one of the first large Cardiovascular Magnetic Resonance centres in Germany at the Charité Hospital in Berlin. After his move to Canada, from 2004 to 2011, he was Director of the Stephenson Cardiovascular MR Centre at the Libin Cardiovascular Institute of Alberta and Professor of Medicine within the Departments of Cardiac Sciences and Radiology at the University of Calgary, Canada. From 2011 to 2015, he directed the Philippa and Marvin Carsley Cardiovascular MR Centre at the Montreal Heart Institute and was Michel and Renata Hornstein Chair in Cardiac Imaging at the Université de Montréal.

# Phase II study – Acute myocarditis

Cardiol is planning a Phase II clinical program in acute myocarditis utilizing its pharmaceutically produced, pure cannabidiol formulation. Cardiol's acute myocarditis program is being designed by an independent Steering Committee comprising thought leaders in cardiology from North America and Europe. The IND filing for the Phase II trial is planned in Q1, 2021. This timeline could be affected by the current COVID-19 pandemic (see "Risk Factors - COVID-19 pandemic" below).

Acute myocarditis is characterized by inflammation in the heart muscle (myocardium). It has many causes but the most common is a viral infection. In a proportion of patients, the inflammation in the heart persists and causes decreased heart function with symptoms and signs of heart failure. In some cases, this becomes progressive and leads to a chronic dilated cardiomyopathy, which is the most common reason for heart transplantation.

Since people with acute myocarditis have heart failure, its treatment is based on standard-of-care recommendations for heart failure. This includes diuretics, ACE inhibitors, angiotensin receptors blockers, beta blockers, and aldosterone inhibitors. For those with a fulminant presentation, intensive care is often required, with the use of inotropic medications (to increase the force of the heart muscle contraction) and, occasionally, heart-lung bypass or ventricular assist devices. There is otherwise no specific treatment for acute myocarditis. Although some patients have responded to therapy with immuno-suppressive therapy (azathioprine) added to steroids, the data are not conclusive enough to be the recommended therapy. Immune-modulation therapy with immune globulin has been trialed but without clear success.

A number of published studies have shown that cannabidiol has anti-inflammatory activities in a range of experimental inflammatory pathologies. In particular, cannabidiol has been shown to reduce vascular inflammation and inflammation in the heart in a model of myocarditis. The Corporation's studies in an experimental model of heart failure have confirmed the anti-inflammatory activity, as well as a prominent anti-fibrotic action of cannabidiol. Increasing fibrosis leads to progression of the heart dysfunction. Based upon this evidence, cannabidiol has the potential to offer therapeutic benefits in the treatment for myocarditis.

Acute myocarditis is a rare disease but is still a significant cause of acute heart failure and death in younger individuals and remains the most common cause of sudden cardiac death in people under 35 years of age. The most recent data from the 'Global Burden of Disease Study' suggests that the prevalence of myocarditis is approximately 22/100,000 persons (estimated U.S. patient population of 73,000), qualifying the condition as an orphan disease in the U.S. and in Europe.

Based on the large body of experimental evidence of the impressive anti-inflammatory activity of cannabidiol in models of cardiovascular disease, Cardiol believes that there is a significant opportunity to develop a therapy for acute myocarditis that would be eligible for designation as an Orphan Drug. As a comparison, the U.S. orphan drug program was successfully utilized to accelerate the first FDA approval of cannabidiol for the treatment of seizures associated with two rare and severe forms of epilepsy, Dravet syndrome and Lennox-Gastaut syndrome.

Members of Cardiol's Acute Myocarditis Steering Committee are included above under "Phase II/III study – COVID-19."

# Outlook

The Corporation expects that the current working capital of \$21,598,494 will be sufficient to fund operations and capital requirements for more than 12 months.

During the next 12 months, the Corporation expects the following key drivers of shareholder value. These timelines could be affected by the current COVID-19 pandemic (see "Risk Factors - COVID-19 pandemic" below).

- 1. Initiate and complete enrollment of 422 patients in International Phase II/III COVID-19 trial examining the cardioprotective properties of CardioIRx;
- 2. Submit IND application to the FDA and commence an international Phase II acute myocarditis trial led by highly distinguished Steering Committee;
- 3. Expand market awareness of Cortalex, the Corporation's commercial cannabidiol product, amongst physicians as well as consumers in the >\$600 million Canadian cannabinoid medical market;
- 4. Complete development of a subcutaneous cannabidiol formulation of CardiolRx for treatment of chronic heart failure, a leading cause of death and hospitalization in North America;

5. Up list to NASDAQ with the goal of significantly increasing U.S. investor awareness.

# Use of IPO Proceeds

The Corporation may reallocate the net IPO proceeds from time to time depending upon our growth strategy relative to market and other conditions in effect at the time. Until we expend the net IPO proceeds, we will hold them in cash and/or invest them in short-term, interest-bearing, investment-grade securities.

A comparison between the projected use of proceeds for the two-year period subsequent to closing the IPO, as disclosed in the Corporation's prospectus dated December 14, 2018 and spending from January 1, 2019 to September 30, 2020 is as follows:

Use of Proceeds	Amount	Spent	Remaining
Cardiol CTX product series and acute myocarditis:			
Basic science, preclinical studies, and a Phase I clinical program <sup>(1)</sup>	1,700,000	1,323,126	376,874
Phase II clinical trial program <sup>(1)</sup>	2,500,000	106,977	2,393,023
Glioblastoma Multiforme:			
Fund the development of immunotherapy in combination with cannabinoids for its target indication of Glioblastoma Multiforme	1,100,000	-	1,100,000
Market introduction, distribution, and marketing of a pharmaceutically manufactured commercial cannabidiol oil product:			
Direct-to-consumer sales expenditure, including website development and marketing to third-party partners and logistics	1,500,000	334,861	1,165,139
Prescription sales expenditure, including physician information, creative developments, and producing material samples	2,000,000	271,544	1,728,456
Other:			
Exclusivity payment to Noramco (USD \$3.0 million) <sup>(2)</sup>	3,900,000	3,900,000	-
100,000 payment expected to be made on the initiation of a Phase II program, to Meros	100,000	-	100,000

- 1. Spending includes basic science, pre-clinical studies, and preparations for the initiation of a clinical trial program in inflammatory heart disease.
- 2. Exclusivity payment made in December 2018.

# Use of Offering Proceeds

The Corporation may reallocate the net Offering proceeds from time to time depending upon our growth strategy relative to market and other conditions in effect at the time. Until we expend the net Offering proceeds, we will hold them in cash and/or invest them in short-term, interest-bearing, investment-grade securities.

A comparison between the projected use of proceeds for the two-year period subsequent to closing the Offering, as disclosed in the Corporation's prospectus dated May 26, 2020 and spending from June 4, 2020 (Offering closing date) to September 30, 2020 is as follows:

Use of Proceeds	Amount	Spent	Remaining
Clinical Trials (Phase I and Phase II/III)	6,400,000	686,116	5,713,884
Pre-clinical studies	900,000	72,447	827,553
Product Development	1,100,000	31,396	1,068,604
Marketing & Business Development	900,000	-	900,000

# **Summary of Quarterly Results**

The Corporation's quarterly information in the table below is prepared in accordance with IFRS.

	Total		Profit or (Loss)	Total
	Revenue		Per Share <sup>(9)</sup>	Assets
Three Months Ended	(\$)	Total (\$)	(\$)	(\$)
September 30, 2020 <sup>(1)</sup>	nil	(4,401,243)	(0.13)	24,455,341
June 30, 2020 <sup>(2)</sup>	nil	(3,624,518)	(0.13)	27,421,000
March 31, 2020 <sup>(3)</sup>	nil	(2,948,647)	(0.11)	13,351,298
December 31, 2019 <sup>(4)</sup>	nil	(3,058,709)	(0.12)	15,502,865
September 30, 2019 <sup>(5)</sup>	nil	(3,491,816)	(0.13)	18,303,737
June 30, 2019 <sup>(6)</sup>	nil	(3,642,636)	(0.14)	20,535,419
March 31, 2019 <sup>(7)</sup>	nil	(3,490,862)	(0.14)	22,914,147
December 31, 2018 <sup>(8)</sup>	nil	(9,073,590)	(0.58)	24,684,773

Note:

- (1) Net loss of \$4,401,243 included research and development of \$1,900,839, administration of \$849,330, share-based compensation of \$620,277, investor relations and promotions of \$463,418, and salaries and benefits of \$480,459.
- (2) Net loss of \$3,624,518 included share-based compensation of \$1,070,188, research and development of \$818,059, administration of \$714,185, salaries and benefits of \$648,861, and investor relations and promotions of \$216,865.
- (3) Net loss of \$2,948,647 included share-based compensation of \$748,693, administration of \$679,545, research and development of \$584,253, salaries and benefits of \$511,531, and investor relations and promotions of \$447,372.
- (4) Net loss of \$3,058,709 included administration of \$885,240, research and development of \$1,031,020, share-based compensation of \$588,746, salaries and benefits of \$447,933, and investor relations and promotions of \$267,916, which was partially offset by other income of \$219,000.
- (5) Net loss of \$3,491,816 included research and development of \$1,237,727, administration of \$815,102, share-based compensation of \$551,977, investor relations and promotions of \$459,473, and salaries and benefits of \$459,037.
- (6) Net loss of \$3,642,636 included share-based compensation of \$867,906, administration of \$813,674, research and development of \$748,481, investor relations and promotions of \$688,290, and salaries and benefits of \$541,488.
- (7) Net loss of \$3,490,862 included share-based compensation of \$1,257,658, investor relations and promotions of \$665,738, administration of \$598,856, research and development of \$512,745, and salaries and benefits of \$385,434.
- (8) Net loss of \$9,073,590 included change in derivative liability of \$5,635,573, share-based compensation of \$895,960, administration of \$731,852, salaries and benefits of \$577,675, listing expense of \$397,528, investor relations and promotions of \$355,291, research and development of \$281,098, and accretion and interest on convertible debentures of \$268,900.
- (9) Basic and fully diluted.

# **Discussion of Operations**

# Three months ended September 30, 2020, compared to the three months ended September 30, 2019

For the three months ended September 30, 2020, the Corporation's net loss was \$4,401,243, compared to a net loss of \$3,491,816 for the three months ended September 30, 2019. The increase in net loss of \$909,427 is a result of the following:

- Research and development increased to \$1,900,839 for the three months ended September 30, 2020, compared to \$1,237,727 for the three months ended September 30, 2019. During the three months ended September 30, 2020, the Corporation incurred increased research and development costs related to basic science, pre-clinical studies, and clinical studies. Research and development costs in the quarter included one-time development costs of approximately \$450,000 and Phase I study costs of approximately \$577,000.
- Share-based compensation increased to \$620,277 for the three months ended September 30, 2020, compared to \$551,977 for the three months ended September 30, 2019. The increase is the result of the timing of the vesting of certain stock options granted during the three months ended September 30, 2020 and in prior periods.
- Gain/loss on foreign exchange decreased to a loss of \$13,819 for three months ended September 30, 2020, compared to a gain of \$30,887 for the three months ended September 30, 2019. The increase is the result of fluctuations in the U.S. dollar against the Canadian dollar.

# Nine months ended September 30, 2020, compared to the nine months ended September 30, 2019

For the nine months ended September 30, 2020, the Corporation's net loss was \$10,974,408, compared to a net loss of \$10,625,314 for the nine months ended September 30, 2019. The increase in net loss of \$349,094 is a result of the following:

- Research and development increased to \$3,303,151 for the nine months ended September 30, 2020, compared to \$2,498,953 for the nine months ended September 30, 2019. During the nine months ended September 30, 2020, the Corporation incurred increased research and development costs related to basic science, pre-clinical studies, and clinical studies.
- Share-based compensation decreased to \$2,439,158 for the nine months ended September 30, 2020, compared to \$2,677,541 for the nine months ended September 30, 2019. The decrease is the result of the timing of the vesting of certain stock options in the prior period versus during the nine months ended September 30, 2020.
- Salaries and benefits increased to \$1,640,851 for nine months ended September 30, 2020, compared to \$1,385,959 for the nine months ended September 30, 2019. The increase is mainly the result of additional employees hired in the year ended 2019 due to the increased level of operations.
- Investor relations and promotions decreased to \$1,127,655 for the nine months ended September 30, 2020, compared to \$1,813,501 for the nine months ended September 30, 2019. During the nine months ended September 30, 2019, the Corporation incurred higher costs on investor relations and promotion as a result of being a newly listed public company, partially offset in the nine months ended September 30, 2020 by costs related to the Corporation's subsequent launch of Cortalex.

# **Capital Management**

The Corporation manages its capital to ensure sufficient financial flexibility to achieve the ongoing business objectives including research activities, funding of future growth opportunities, and pursuit of acquisitions.

The Corporation monitors its capital structure and makes adjustments according to market conditions in an effort to meet its objectives given the current outlook of the business and industry in general. The Corporation may manage its capital structure by issuing new shares, repurchasing outstanding shares, adjusting capital spending, or disposing of assets. The capital structure is reviewed by Management and the Board of Directors on an ongoing basis.

The Corporation considers its capital to be total equity, comprising share capital, warrants, contributed surplus, and the equity portion of convertible debentures less accumulated deficit which at September 30, 2020, totalled \$22,472,803 (December 31, 2019 – \$14,672,037).

The Corporation manages capital through its financial and operational forecasting processes. The Corporation reviews its working capital and forecasts its future cash flows based on operating expenditures, and other investing and financing activities. The forecast is updated based on activities related to its research programs. Selected information is provided to the Board of Directors.

The Corporation is not currently subject to any capital requirements imposed by a lending institution or regulatory body. The Corporation expects that its capital resources will be sufficient to discharge its liabilities as of the current statement of financial position date.

# **Off-Balance-Sheet Arrangements**

As of the date of this MD&A, the Corporation does not have any off-balance-sheet arrangements that have, or are reasonably likely to have, a current or future effect on the results of operations or financial condition of the Corporation, including, and without limitation, such considerations as liquidity and capital resources.

# Liquidity and Financial Position

At September 30, 2020, Cardiol had \$16,546,580 in cash and cash equivalents (December 31, 2019 – \$6,956,203).

At September 30, 2020, accounts payable and accrued liabilities were \$1,816,796 (December 31, 2019 – \$640,076). The Corporation's cash and cash equivalents balances as at September 30, 2020 and December 31, 2019 are sufficient to pay these liabilities.

The Corporation currently has no operating revenues and therefore must utilize its funds from financing transactions to maintain its capacity to meet ongoing operating activities.

As of September 30, 2020, December 31, 2019, and to the date of this MD&A, the cash resources of Cardiol are held with one Canadian chartered bank. The Corporation has no variable interest rate debt and its credit and interest rate risk is minimal. Accounts payable and accrued liabilities are short-term and non-interest-bearing.

# For the 2020 Fiscal Period

Cash and cash equivalents used in operating activities were \$6,596,534 for the nine months ended September 30, 2020. Operating activities were affected by a net loss of \$10,974,033 offset partially by the net change in non-cash working capital balances of \$1,670,576 and non-cash adjustments of \$2,707,298. Non-cash adjustments mainly consisted of \$2,439,158 for share-based compensation. Non-cash working capital was mainly the result of a decrease in other receivables of \$641,301 and an increase in accounts payable and accrued liabilities of \$1,176,720, partially offset by an increase in prepaids of \$325,118.

Cash and cash equivalents used in investing activities were \$27,104 for the nine months ended September 30, 2020. This pertained to the purchase of property and equipment.

Cash and cash equivalents provided by financing activities were \$16,214,015 for the nine months ended September 30, 2020, as a result of issuance of units, net of share issuance costs and proceeds from warrants exercised.

# Use of Working Capital

As of September 30, 2020, Cardiol's working capital was \$21,598,494. Based on current projections, Cardiol believes that this amount is sufficient to meet its planned development activities for more than 12 months.

The Corporation has material commitments and obligations for cash resources set out below.

Contractual Obligations	Total (\$)	Up to 1 year (\$)	1 – 3 years (\$)	4 – 5 years (\$)	After 5 years (\$)
Amounts payable and	1,816,796	1,816,796	Nil	Nil	Nil
other liabilities					
Office lease <sup>(1)</sup>	387,379	103,761	212,136	71,482	Nil
Consulting agreements	736,680	736,680	Nil	Nil	Nil
Contract research	974,398	974,398	Nil	Nil	Nil
Total	3,915,253	3,631,635	212,136	71,482	Nil

Note:

(1) The Corporation has leased premises from third parties.

#### **Related-Party Transactions**

(a) The Corporation entered into the following transactions with related parties:

# For the 2020 Fiscal Period

- (i) Included in research and development expense is \$589,370 and \$1,009,490 for the three and nine months ended September 30, 2020 (three and nine months ended September 30, 2019 \$673,658 and \$1,037,621) paid to a company, Dalton Chemical Laboratories, Inc. operating as Dalton, that is related to a director (Peter Pekos). Mr. Pekos is also the President and CEO of Dalton. As at September 30, 2020, \$618,214 (December 31, 2019 \$76,784) was owed to this company and this amount was included in accounts payable and accrued liabilities and \$nil and \$35,040 (December 31, 2019 \$65,973 and \$35,040) was paid to this company and was included in prepaid expenses and inventory, respectively. Cardiol entered into an exclusive master services agreement with Dalton for the exclusive supply of pharmaceutical cannabidiol, and Cardiol has subcontracted the manufacturing of its drug product candidates to Dalton.
- (ii) Included in administration is \$nil for the three and nine months ended September 30, 2020 (three and nine months ended September 30, 2019 \$60,000 and \$170,000) for corporate advisory services, paid to a company (Fission Creative Solutions Inc., formerly known as Punchcast Inc.) formerly related through a former director (Terry Lynch). Fission Creative Solutions Inc. is controlled by a son of Terry Lynch. As at September 30, 2020, \$nil (December 31, 2019 \$20,000) is included in prepaid expenses.

(b) Key management personnel are those persons having authority and responsibility for planning, directing, and controlling the activities of the Corporation directly or indirectly, including any Directors (executive and non-executive) of the Corporation. Remuneration of Directors and key management personnel of the Corporation, except as noted in (a) above, was as follows:

	Three months ended		Nine months ended		
	September 30, 2020 (\$)	September 30, 2019 (\$)	September 30, 2020 (\$)	September 30, 2019 (\$)	
Salaries and benefits	339,369	281,375	1,141,957	854,209	
Share-based payments	135,559	245,501	504,760	1,323,603	
	474,928	526,876	1,646,717	2,177,812	

As at September 30, 2020, \$122,500 (December 31, 2019 – \$2,005) was owed to key management personnel and this amount was included in accounts payable and accrued liabilities.

# Critical Accounting Judgments, Estimates, and Assumptions

The preparation of the Financial Statements requires Management to make certain estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities at the date of the Financial Statements and reported amounts of expenses during the reporting period. Actual outcomes could differ from these estimates. The Financial Statements include estimates that, by their nature, are uncertain. The impacts of such estimates are pervasive throughout the Financial Statements and may require accounting adjustments based on future occurrences. Revisions to accounting estimates are recognized in the period in which the estimate is revised and future periods if the revision affects both current and future periods. These estimates are based on historical experience, current and future economic conditions, and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

# Critical accounting estimates

Significant assumptions about the future that Management has made that could result in a material adjustment to the carrying amounts of assets and liabilities, in the event that actual results differ from assumptions made, relate to, but are not limited to, the following:

- the inputs used in the Black-Scholes valuation model that are based on unobservable assumptions at the time of issuance of the equity instruments (volatility) in accounting for share-based payment transactions. Share-based payments are valued on the date of grant;
- the estimate of the percentage of completion of certain research and development agreements.
- the valuation of the income tax non-current asset would increase if there was virtual certainty that the tax benefit of net operating losses could be applied to future periods' taxable income.
- intangible assets are comprised of the exclusive global license. Intangible assets are initially stated at cost, less accumulated amortization and accumulated impairment losses. Intangible assets with finite useful lives are amortized over their estimated useful lives. The exclusive global license's useful life is 9 years.

# Critical accounting judgments

- Management applied judgment in determining the functional currency of the Corporation as Canadian dollars;
- Management's assessment that no indicators of impairment exist for intangible assets, based on the facts and circumstances that existed during the period; and
- Management's assessment of the impact the novel coronavirus (COVID-19) pandemic will have on operations (see "Risk Factors – COVID-19 pandemic" below).

# Share Capital

Other than as described below, as of the date of this MD&A, there are no equity or voting securities of the Corporation outstanding, and no securities convertible into, or exercisable or exchangeable for, voting or equity securities of the Corporation.

As of the date of this MD&A, the outstanding capital of the Corporation includes 32,856,291 issued and outstanding common shares, 1,020,000 Meros Special Warrants convertible automatically into common shares (upon the Corporation achieving the Meros Milestone) for no additional consideration pursuant to the Meros License Agreement, 400,000 common shares issuable to Dalton if Dalton meets certain performance objectives, and stock options and warrants as shown below:

Expiry date	Exercise price (\$)	Options outstanding	Options exercisable
March 9, 2021	3.04	50,000	37,500
October 29, 2021	3.28	90,000	90,000
November 24, 2021	3.34	50,000	50,000
June 22, 2022	2.58	500,000	500,000
August 19, 2022	2.58	50,000	25,000
August 19, 2022	2.50	75,000	-
September 8, 2022	3.25	100,000	100,000
September 30, 2022	3.05	75,000	-
October 15, 2024	3.23	110,000	36,667
December 2, 2024	4.08	60,000	-
December 5, 2024	3.69	60,000	15,000
February 23, 2025	3.54	107,800	54,650
August 16, 2025	5.00	200,000	200,000
August 19, 2025	2.12	100,000	-
August 30, 2025	5.00	580,000	393,330
October 7, 2025	2.90	35,000	-
January 2, 2026	4.30	150,000	150,000
January 24, 2026	5.34	60,000	20,000
April 1, 2026	5.77	140,000	46,667
April 4, 2026	5.42	60,000	20,000
Total		2,652,800	1,738,814

# Stock Options

# Warrants

Expiry date	Exercise price (\$)	Warrants outstanding
December 20, 2020	6.50	3,374,544
June 4, 2022	3.25	3,441,195
June 4, 2022 <sup>(1), (2)</sup>	2.50	256,409
August 31, 2022	4.00	824,000
Total		7,896,148

(1) Exercisable into one Class A common share and one-half of one common share purchase warrant. Each additional whole warrant is exercisable into one common share at the price of \$3.25 per share until June 4, 2022.

(2) Subsequent to September 30, 2020, 37,591 warrants were exercised for gross proceeds of \$93,978. As a result, an additional 18,795 warrants, exercisable into one common share at the price of \$3.25 per share until June 4, 2022, were granted.

# **Financial Instruments**

#### Recognition

The Corporation recognizes a financial asset or financial liability on the statement of financial position when it becomes party to the contractual provisions of the financial instrument. Financial assets are initially measured at fair value and are derecognized either when the Corporation has transferred substantially all the risks and rewards of ownership of the financial asset, or when cash flows expire. Financial liabilities are initially measured at fair value and are derecognized when the obligation specified in the contract is discharged, cancelled, or expired.

A write-off of a financial asset (or a portion thereof) constitutes a derecognition event. A write-off occurs when the Corporation has no reasonable expectations of recovering the contractual cash flows on a financial asset.

# **Classification and Measurement**

The Corporation determines the classification of its financial instruments at initial recognition. Financial assets and financial liabilities are classified according to the following measurement categories:

- those to be measured subsequently at fair value, either through profit or loss ("FVTPL") or through other comprehensive income ("FVTOCI"); and
- those to be measured subsequently at amortized cost.

The classification and measurement of financial assets after initial recognition at fair value depends on the business model for managing the financial asset and the contractual terms of the cash flows. Financial assets that are held within a business model whose objective is to collect the contractual cash flows, and that have contractual cash flows that are solely payments of principal and interest on the principal outstanding, are generally measured at amortized cost at each subsequent reporting period. All other financial assets are measured at their fair values at each subsequent reporting period, with any changes recorded through profit or loss or through other comprehensive income (which designation is made as an irrevocable election at the time of recognition).

After initial recognition at fair value, financial liabilities are classified and measured at either:

• amortized cost;

- FVTPL, if the Corporation has made an irrevocable election at the time of recognition, or when required (for items such as instruments held for trading or derivatives); or
- FVTOCI, when the change in fair value is attributable to changes in the Corporation's credit risk.

The Corporation reclassifies financial assets when and only when its business model for managing those assets changes. Financial liabilities are not reclassified.

Transaction costs that are directly attributable to the acquisition or issuance of a financial asset or financial liability classified as subsequently measured at amortized cost are included in the fair value of the instrument on initial recognition. Transaction costs for financial assets and financial liabilities classified at fair value through profit or loss are expensed in profit or loss.

The Corporation's financial asset consists of cash and cash equivalents and interest receivable, which are classified and measured at amortized cost. The Corporation's financial liabilities consist of accounts payable and accrued liabilities and convertible debt, which are classified and measured at amortized cost.

# Fair Value

The Corporation provides information about its financial instruments measured at fair value at one of three levels according to the relative reliability of the inputs used to estimate the fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The three levels of the fair value hierarchy are as follows:

- Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2: inputs other than quotes prices included in Level 1 that are observable for the asset or liability, either directly (i.e., as prices) or indirectly (i.e., derived from prices)
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs)

The Corporation has no financial instruments measured at fair value.

# Financial Instrument Risks

The Corporation's activities expose it to a variety of financial risks: credit risk, liquidity risk, and market risk (including interest rate and foreign currency risk). These financial risks are in addition to the risks set out under "Risk Factors".

Risk management is carried out by the Corporation's Management team under policies approved by the Board of Directors. The Board of Directors also provides regular guidance for overall risk management.

There were no changes to credit risk, liquidity risk, or market risk for the 2020 Fiscal Period.

# Credit risk

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation. The Corporation's financial instruments that are exposed to concentrations of credit risk relate primarily to cash and cash equivalents and interest receivable.

The Corporation mitigates its risk by maintaining its funds with large reputable financial institutions, from which Management believes the risk of loss to be minimal. Interest receivable relates to guaranteed investment certificates and cash balances held with large reputable financial institutions. The Corporation's Management considers that all the above financial assets are of good credit quality.

# Liquidity risk

Liquidity risk is the risk that the Corporation encounters difficulty in meeting its obligations associated with financial liabilities. Liquidity risk includes the risk that, as a result of operational liquidity requirements, the Corporation will not have sufficient funds to settle a transaction on the due date; will be forced to sell financial assets at a value which is less than what they are worth; or may be unable to settle or recover a financial asset. Liquidity risk arises from accounts payable and accrued liabilities and commitments. The Corporation limits its exposure to this risk by closely monitoring its cash flow.

# Market risk

Market risk is the risk of loss that may arise from changes in market factors, such as interest rates and foreign exchange rates.

# (a) Interest rate risk

The Corporation currently does not have any short-term or long-term debt that is variable interest bearing and, as such, the Corporation's current exposure to interest rate risk is minimal.

# (b) Foreign currency risk

Foreign exchange risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in the foreign exchange rates. The Corporation enters into foreign currency purchase transactions and has assets that are denominated in foreign currencies and thus is exposed to the financial risk of earnings fluctuations arising from changes in foreign exchange rates and the degree of volatility of these rates. The Corporation does not currently use derivative instruments to reduce its exposure to foreign currency risk.

The Corporation holds balances in U.S. dollars which could give rise to exposure to foreign exchange risk. Sensitivity to a plus or minus 10% change in the foreign exchange rate of the U.S. dollar against the Canadian dollar would affect the reported loss and comprehensive loss by approximately \$52,000 (December 31, 2019 - \$152,000).

# **Commitments and Contingency**

(i) The Corporation has leased premises from third parties. The minimum committed lease payments as at September 30, 2020, which include the lease liability payments, are as follows:

Fiscal year	
2020	\$ 25,940
2021	103,761
2022	105,780
2023	107,222
2024	44,676
Total	\$ 387,379

(ii) The Corporation has signed various agreements with consultants to provide services. Under the agreements, the Corporation has the following remaining commitments.

# Fiscal year

2020	\$736,680
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(iii) Pursuant to the terms of agreements with various other contract research organizations, the Corporation is committed for contract research services for 2020 and 2021 at a cost of approximately \$974,398.

# **Breakdown of Expensed Research and Development**

	Three months ended		Nine mon	ths ended
	September 30, 2020 (\$)	September 30, 2019 (\$)	September 30, 2020 (\$)	September 30, 2019 (\$)
Contract research	1,526,779	635,263	2,440,257	1,236,012
Wages	105,833	67,807	289,142	161,269
Supplies	157,217	124,545	349,036	505,820
Regulatory	111,010	410,112	224,716	595,852
	1,900,839	1,237,727	3,303,151	2,498,953

# **Breakdown of Operating Expenses**

	Three months ended		Nine mon	ths ended
	September 30,	September 30,	September 30,	September 30,
	2020 (\$)	2019 (\$)	2020 (\$)	2019 (\$)
Administration	849,330	815,102	2,243,060	2,227,632
Depreciation of equipment	36,236	18,404	107,816	37,089
Amortization of intangible assets	21,111	21,111	63,333	63,333
Accretion and interest on				621
convertible debentures	-	-	-	
Investor relations and promotions	463,418	459,473	1,127,655	1,813,501
Salaries and benefits	480,459	459,037	1,640,851	1,385,959
Transfer agent and regulatory	39,113	21,152	146,721	132,535
Share-based compensation	620,277	551,977	2,439,158	2,677,541
	2,509,944	2,346,256	7,768,594	8,338,211

# **Breakdown of Intangible Assets**

	As at September 30, 2020 (\$)	As at December 31, 2019 (\$)
Exclusive global license agreement	767,228	767,228
Accumulated amortization	(282,427)	(219,094)
Carrying value	484,801	548,134

# **Internal Controls Over Financial Reporting**

In accordance with National Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings, Management is responsible for establishing and maintaining adequate Disclosure Controls and Procedures ("DCP") and Internal Control Over Financial Reporting ("ICFR"). Management has designed DCP and ICFR based on the 2013 Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), with the objective of providing reasonable assurance that the Corporation's financial reports and information, including the Corporation's Financial Statements and MD&A were prepared in accordance with IFRS.

The CEO and CFO have concluded that the design of DCP and ICFR were adequate to provide such assurance as at September 30, 2020.

# Limitations of Controls and Procedures

The Corporation's Management, including the CEO and CFO, believes that any DCP or ICFR, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, they cannot provide absolute assurance that all control issues and instances of fraud, if any, within the Corporation have been prevented or detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by unauthorized override of the control. The design of any control system also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Accordingly, because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

# **Risk Factors**

An investment in the securities of the Corporation is highly speculative and involves numerous and significant risks. Such investment should be undertaken only by investors whose financial resources are sufficient to enable them to assume these risks. Prospective investors should carefully consider the risk factors that have affected, and which in the future are reasonably expected to affect, the Corporation and its financial position. Please refer to the section entitled "Risks and Uncertainties" in the Corporation's MD&A for the financial year ended December 31, 2019 (available on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>).

# **COVID-19** pandemic

The recent novel coronavirus (COVID-19) pandemic has impacted and could further impact our expected timelines, operations and the operations of our third-party suppliers, manufacturers, and CROs as a result of quarantines, facility closures, travel and logistics restrictions, and other limitations in connection with the outbreak. While we expect this to be temporary, there is uncertainty around its duration and its broader impact.

The Corporation has ensured that all of its employees work under conditions that comply with federal and provincial public health recommendations. In addition, the Corporation's clinical and regulatory activities have not, for the time being, significantly slowed down despite the COVID-19 crisis. These activities are now performed by Cardiol's employees from their home offices. However, the extent of any delays in the clinical activities will be a result of the ultimate effect that this crisis has on factors such as availability of physicians, clinics, and enrolment.

The Corporation's planned timing of its commercial launch of Cortalex pharmaceutical CBD has not been impacted by the COVID-19 crisis. The crisis has also not materially impacted the Corporation's third-party suppliers and manufacturers.

The current COVID-19 pandemic is a rapidly evolving crisis and it is difficult for the Corporation to accurately assess the impact of the current COVID-19 pandemic on the Corporation's business. Cardiol will continue to actively monitor the situation to assess the impact of the current COVID-19 pandemic on the Corporation's business and take appropriate measures to diminish such impacts.