



**CARDIOL THERAPEUTICS INC.
MANAGEMENT'S DISCUSSION AND ANALYSIS
THREE AND NINE MONTHS ENDED
SEPTEMBER 30, 2023**

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 of the Corporation's ("Management") review of the factors that affected the Corporation's financial and operating performance for the three and nine months ended September 30, 2023 (the "2023 Fiscal Period"). This discussion should be read in conjunction with the consolidated financial statements for the years ended December 31, 2022, 2021, and 2020 and the unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2023 ("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 derived from the Financial Statements prepared in accordance with International Accounting Standard 34, Interim Financial Reporting. Accordingly, they do not include all of the information required for full annual financial statements required by International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") and Interpretations issued by the International Financial Reporting Interpretations Committee ("IFRIC"). 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 9, 2023. 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", the "Company" or the "Corporation" refer to Cardiol Therapeutics Inc.

This MD&A is presented current to November 9, 2023 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", "could", "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 anticipated cash needs, and the need for additional financing;
- our development of our product candidates for use in basic research, clinical studies, and commercialization;
- our ability to develop new routes of administration of our product candidates, including parenteral, for use in basic research, clinical studies, and commercialization;
- our ability to develop new formulations of our product candidates for commercialization;
- the successful development and commercialization of our current product candidates and the addition of future products and product candidates;
- the ability for our product delivery technologies to deliver our product candidates to inflamed and/or fibrotic tissue;
- our intention to build a pharmaceutical brand and our products focused on addressing inflammation and fibrosis in heart disease, including acute myocarditis, recurrent pericarditis, and heart failure;
- the expected medical benefits, viability, safety, efficacy, effectiveness, and dosing of our product candidates;
- patents and intellectual property, including, but not limited to, our (a) ability to procure, defend, and/or enforce our intellectual property relating to our products, product formulations, routes of administration, product candidates, and associated uses, methods, and/or processes, and (b) freedom to operate;
- our competitive position and the regulatory environment in which we operate;

- the molecular targets and mechanism of action of our product candidates;
- our financial position; our business strategy; our growth strategies; our operations; our financial results; our dividend 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. The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. The forward-looking statements are based on our beliefs, assumptions and expectations of future performance, taking into account the information currently available to us. These statements are only predictions based upon our current expectations and projections about future events. 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 including basic research and clinical trials;
- our requirement for additional financing;
- our negative cash flow from operations;
- our history of losses;
- dependence on the success of 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, initiate, execute, and complete clinical trials, including the high cost, uncertainty, and delay of clinical trials and additional costs associated with any failed clinical trials;
- the uncertainty our investigational products will have a therapeutic benefit in the clinical indications we are pursuing;
- potential equivocal or negative results from clinical trials and their adverse impacts on our future commercialization efforts;
- our ability to receive and maintain regulatory exclusivities, including Orphan Drug Designations/Approvals, for our products and product candidates;
- delays in achievement of projected development goals;
- management of additional regulatory burdens;
- volatility in the market price for our securities;
- failure to protect and maintain and the consequential loss of intellectual property rights;
- third-party claims relating to misappropriation by the Corporation 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 early-stage research regarding the medical benefits, viability, safety, efficacy, and dosing of our product candidates;
- claims for personal injury or death arising from the use of our products and product candidates;
- uncertainty relating to market acceptance of our product candidates;
- our lack of experience in commercializing any products, including selling, marketing, or distributing our products;
- securing third-party payor reimbursement for our products and product candidates;
- the level of pricing and reimbursement for our products and product candidates, if approved;
- our dependence on contract manufacturers;
- unsuccessful collaborations with third parties;
- business disruptions affecting third-party suppliers and manufacturers;
- lack of control in future production and selling prices of our product candidates;
- 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 our products;
 - 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 our products;
 - operating risk and insurance coverage;
 - our inability to manage growth;
 - conflicts of interest among the officers and directors ("Director") of the Corporation;
 - 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;
 - no dividends for the foreseeable future;
 - future sales of common shares and warrants by existing shareholders causing the market price for the common shares and warrants to fluctuate;
 - the issuance of common shares in the future causing dilution;
 - our operations could be adversely affected by events outside of our control;
 - our ability to remediate any material weakness in our internal control over financial reporting;
 - global geo-political events, and the responses of governments having a significant effect on the world economy; and
 - failure to meet regulatory or ethical expectations on environmental impact, including climate change.

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

Information contained in forward-looking information in this MD&A is provided as of November 9, 2023, 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 on the Toronto Stock Exchange (the "TSX"). As a result, the common shares commenced trading on the TSX under the symbol "CRDL". On May 12, 2021, warrants arising from a "bought deal" short form prospectus offering that closed on the same date, commenced trading on the TSX. These warrants trade under the symbol "CRDL.WT.A". On August 10, 2021, the Corporation's common shares commenced trading on The Nasdaq Capital Market under the symbol "CRDL".

The Corporation is a clinical-stage life sciences company focused on the research and clinical development of anti-inflammatory and anti-fibrotic therapies for the treatment of heart diseases. The Corporation's lead drug candidate, CardiolRx™ (cannabidiol) oral solution, is pharmaceutically manufactured and is currently in clinical development for use in the treatment of two heart diseases. It is recognized that cannabidiol inhibits activation of the inflammasome pathway, an intracellular process known to play an important role in the development and progression of inflammation and fibrosis associated with myocarditis, pericarditis, and heart failure.

The Corporation has received Investigational New Drug Application ("IND") application authorization from the United States ("U.S.") Food and Drug Administration ("FDA") to conduct a Phase II open-label pilot study designed to evaluate the tolerance, safety, and efficacy of CardiolRx in patients with recurrent pericarditis (the "MAVERIC-Pilot" study). MAVERIC-Pilot will also assess the improvement in objective measures of disease, and during an extension period, assess the feasibility of weaning concomitant background therapy including corticosteroids, while taking CardiolRx. Pericarditis refers to inflammation of the pericardium (the membrane or sac that surrounds the heart) that follows an initial episode (frequently resulting from a viral infection). Patients may have multiple recurrences. Symptoms include debilitating chest pain, shortness of breath, and fatigue, resulting in physical limitations, reduced quality of life, emergency department visits, and hospitalizations. The only FDA-approved therapy for recurrent pericarditis, launched in 2021, is extraordinarily costly and is primarily used as a third-line intervention. The number of cases of patients

seeking and receiving treatment for recurrent pericarditis annually in the U.S. is estimated at 38,000. Hospitalization due to recurrent pericarditis is often associated with a 6-8-day length of stay and cost per stay is estimated to range between US\$20,000 and US\$30,000 in the U.S.

The Corporation has also received IND authorization from the FDA to conduct a Phase II multi-national, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of CardiolRx in acute myocarditis (the "ARCHER" trial). Myocarditis is an acute inflammatory condition of the heart muscle (myocardium) characterized by chest pain, impaired cardiac function, atrial and ventricular arrhythmias, and conduction disturbances. Although the symptoms are often mild, myocarditis remains an important cause of acute and fulminant heart failure and is a leading cause of sudden cardiac death in people under 35 years of age. Although viral infection is the most common cause of myocarditis, the condition can also result from administration of therapies used to treat several common cancers, including chemo-therapeutic agents and immune checkpoint inhibitors. There are no FDA-approved therapies for acute myocarditis which affects an estimated 46,000 people in the U.S. per year. Patients hospitalized with acute myocarditis experience an average seven-day length of stay and a 4 - 6% risk of in-hospital mortality, with average hospital charge per stay estimated at US\$110,000 in the U.S. Severe cases frequently require ventricular assist devices or extracorporeal oxygenation and may necessitate heart transplantation.

The Corporation is planning to pursue the development of CardiolRx as an Orphan Drug for the treatment of recurrent pericarditis and acute myocarditis. The U.S. Orphan Drug Designation program was created to provide the sponsor of a drug or biologic significant incentives, including seven-year marketing exclusivity and exemptions from certain FDA fees, to develop treatments for diseases that affect fewer than 200,000 people in the U.S. Products with Orphan Drug Designation also frequently qualify for accelerated regulatory review. The program was successfully utilized to support the first FDA approval of another form of oral cannabidiol solution for the treatment of seizures associated with rare pediatric epilepsy syndromes. The European Commission's European Medicines Agency ("EMA") has a similar orphan medicine product program for rare diseases.

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

Operations Highlights

During the 2023 Fiscal Period

(i) In January 2023, the Corporation announced the first patient has been enrolled in the Corporation-sponsored Phase II open-label pilot study investigating the tolerance, safety, and efficacy of CardiolRx™ in patients with recurrent pericarditis. See "Phase II Open Label Pilot Study – Recurrent Pericarditis (MAVERIC-Pilot)".

(ii) In March 2023, the Corporation announced study results from one of its international collaborating research centers demonstrating that its pharmaceutically manufactured cannabidiol significantly prevents cardiac dysfunction and the development of fibrosis and cardiomyocyte hypertrophy in a pre-clinical model of heart failure and reduces expression of key inflammatory and fibrotic markers.

The studies were presented by researchers from Instituto Tecnológico y de Estudios Superiores de Monterrey, Mexico ("TecSalud") at the American College of Cardiology's 72nd Annual Scientific Session together with World Congress of Cardiology ("ACC.23/WCC"). TecSalud is one of the Corporation's international collaborating research centers working towards the common goal of developing therapies to advance the treatment of heart diseases.

The poster entitled "Cannabidiol Therapy for Chronic Heart Failure Prevents Cardiac Pathological Remodeling in a Non-ischemic Cardiomyopathy Murine Model" was presented on March 4th within the "Heart Failure and Cardiomyopathies: Basic and Translational Science 1" session of ACC.2023/WCC. This work builds upon existing knowledge by confirming cannabidiol's cardioprotective properties and, in this model, its ability to reduce inflammation and prevent hypertrophy and fibrosis in heart tissue. This work also furthers the understanding of cannabidiol's ability to improve cardiac function and, in isolated cardiomyocytes, improve calcium handling and mitochondrial health.

A second poster entitled "Abnormal Mitochondrial Calcium Content in Angiotensin-Induced Hypertrophy is Ameliorated by Cannabidiol Mimicking PPAR-γ Activation" was presented on March 5th within the "Heart Failure and Cardiomyopathies: Basic and Translational Science 8" session of ACC.2023/WCC. This poster presented data related to the role of cannabidiol in mitochondrial calcium dynamics in hypertrophic cells. Cannabidiol was able to prevent hypertrophy-induced mitochondrial calcium overload and prevent hypertrophy-induced increase of several

mitochondrial function markers such as reactive oxygen species and calcium uptake. In addition, this work suggests that cannabidiol's effects may rely on PPAR- γ activation, which in turn can inhibit NF- κ B, a transcription factor that regulates pro-inflammatory and pro-hypertrophic genes. Together, these findings further clarify cannabidiol's mode of action in combatting cardiac hypertrophy.

(iii) In August 2023, the Corporation announced that it received notice on August 7, 2023 from The Nasdaq Stock Market LLC ("Nasdaq") stating the Corporation had regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.

(iv) In September 2023, the Corporation announced that all collaborating research centers have been initiated and are eligible to enroll patients in ARCHER, the Corporation's Phase II, multi-center, international, double-blind, randomized, placebo-controlled trial. See "Phase II Trial – Acute Myocarditis (ARCHER)".

(v) During the 2023 Fiscal Period, the Corporation granted 600,000 stock options to certain consultants of the Corporation. Each option allows the holder to acquire one common share of the Corporation at exercise prices between \$0.75 and US\$1.00 with expiry dates between April 10, 2025 and June 25, 2028. Of the options granted 200,000 vest one-fourth every three months from the grant date, 80,000 vested on September 30, 2023 and 320,000 expired subsequent to September 30, 2023. During the 2023 Fiscal Period, the Corporation granted 2,100,000 restricted share units ("RSUs") to certain consultants of the Corporation. The common shares underlying the RSUs cannot be traded until February 1, 2024. Of the RSUs granted, 500,000 vested as of September 30, 2023, 385,000 RSUs vested and 60,000 RSUs expired subsequent to September 30, 2023 and 385,000 RSUs will vest on each of November 30, 2023, December 31, 2023, and January 31, 2024. During the 2023 Fiscal Period, the Corporation granted 2,000,000 performance share units ("PSUs") to certain consultants of the Corporation. Grants of PSUs require completion of certain performance criteria specific to each grant. These PSUs have an expiry date of June 30, 2024.

Subsequent to September 30, 2023

(i) Subsequent to September 30, 2023, the Corporation announced positive study results from one of its international collaborating research centers demonstrating that subcutaneously administered cannabidiol, the active pharmaceutical ingredient in Cardiol's novel CRD-38 subcutaneous ("SUBQ") formulation, slowed increases in body weight and heart weight, and prevented increases in key cardiac inflammatory and remodeling markers in a model of heart failure with preserved ejection fraction ("HFpEF").

The study was presented by researchers from TecSalud at the Heart Failure Society of America Annual Scientific Meeting 2023 ("HFSA2023").

The poster entitled "Cannabidiol As A Potential Treatment For Heart Failure With Preserved Ejection Fraction" was presented on October 7th within the "ePoster Viewing Session III" of HFSA2023. This work was performed using a model of HFpEF that is induced using a combination of high-fat diet and hypertension that leads to an increase in heart weight to tibia length ratio, and an increase in markers for inflammation and cardiac remodeling. Cannabidiol administered SUBQ was associated with significantly lower BNP (a cardiac stress marker raised in heart failure patients), IL-10 (a promotor of fibrosis in HFpEF), and visceral adipose tissue (VAT) to subcutaneous adipose tissue (SAT) ratio.

The ratio of VAT/SAT holds critical significance in the context of heart failure. Visceral adipose tissue, the fatty tissue stored around internal organs, is metabolically active and releases inflammatory factors contributing to systemic inflammation. In contrast, subcutaneous adipose tissue, found beneath the skin, has a less detrimental impact. An imbalance in this ratio with excessive visceral adipose tissue is associated with a higher risk of cardiovascular disease, including heart failure. Visceral fat accumulation increases cardiac strain, promotes hypertension, and dysregulates lipid metabolism. Additionally, it can lead to obesity-related comorbidities such as diabetes. Managing this ratio could play an important role in preventing and treating heart failure.

Together these new findings expand the understanding of the cardioprotective effects of CRD-38 and suggest new therapeutic potential in HFpEF, which remains a leading cause of death and hospital admissions in the United States and throughout the developed world, with associated healthcare costs in the US exceeding US\$30 billion annually.

(ii) Subsequent to September 30, 2023, the Corporation announced that it received a notice (the "Notice") from the Nasdaq Stock Market LLC ("Nasdaq"), stating that the Corporation is not in compliance with the minimum bid price requirement ("Minimum Bid Requirement") of USD\$1.00 per share under the Nasdaq Listing Rule 5550(a)(2) based upon the closing bid price of the Corporation's common shares for the 30 consecutive business days prior to the date

of the Notice.

The Notice has no immediate effect on the listing or trading of the common shares on Nasdaq, and the Corporation's operations are not affected by the receipt of the Notice. Under Nasdaq Listing Rule 5810(c)(3)(A), the Corporation has 180 calendar days from the date of the Notice, or until April 16, 2024, to regain compliance with the Minimum Bid Requirement, during which time the common shares will continue to trade on Nasdaq. If at any time before April 16, 2024, the bid price of the common shares closes at or above USD\$1.00 per share for a minimum of 10 consecutive business days, the Corporation will regain compliance with the Minimum Bid Requirement. If the Corporation does not regain compliance with the Minimum Bid Requirement by April 16, 2024, the Corporation may be eligible, upon satisfaction of certain Nasdaq listing requirements, for an additional period of 180 calendar days that would further extend the period of time to regain compliance to October 14, 2024, or the common shares may be subject to delisting from Nasdaq.

This notice does not have any impact on the Corporation's TSX listing.

Phase II Open Label Pilot Study – Recurrent Pericarditis (MAVERIC-Pilot)

Pericarditis refers to inflammation of the pericardium (the membrane or sac that surrounds the heart), frequently resulting from a viral infection. Recurrent pericarditis is the reappearance of symptoms after a symptom-free period of at least four to six weeks following the initial acute episode of pericarditis. Patients may have multiple recurrences. Symptoms include debilitating chest pain, shortness of breath, and fatigue, resulting in physical limitations, reduced quality of life, emergency department visits, and hospitalizations. Causes of pericarditis can include infection (e.g., tuberculosis), systemic disorders such as autoimmune and inflammatory diseases, cancer, and post-cardiac injury syndromes. Pericarditis (and its recurrences) are symptomatic events, the diagnosis of which is based on meeting two of four criteria: chest pain; pericardial friction rub; electrocardiogram changes; and new or worsening pericardial swelling. Elevation of inflammatory markers such as C-reactive protein ("CRP"), and evidence of pericardial inflammation by an imaging technique (computed tomography scan or cardiac magnetic resonance) may help the diagnosis and the monitoring of disease activity. Although generally self-limited and not life threatening, pericarditis is diagnosed in 0.2% of all cardiovascular in-hospital admissions and is responsible for 5% of emergency room admissions for chest pain in North America and Western Europe.

Recurrent pericarditis appears in 15% to 30% of acute cases and usually within 18 months. Furthermore, up to 50% of patients with a recurrent episode of pericarditis experience more recurrences. Standard first-line medical therapy consists of non-steroidal anti-inflammatory drugs or aspirin with or without colchicine. Corticosteroids such as prednisone are second-line therapy in patients with continued recurrence and inadequate response to conventional therapy. The only FDA-approved therapy for recurrent pericarditis, launched in 2021, is a costly and potent subcutaneously injected interleukin-1 inhibitor with immunosuppressive effects. It is generally used as a third-line intervention in patients with a third or fourth recurrence.

The number of cases of patients seeking and receiving treatment for recurrent pericarditis annually in the U.S. is estimated at 38,000. Hospitalization due to recurrent pericarditis is often associated with a 6-8-day length of stay and cost per stay is estimated to range between US\$20,000 and US\$30,000 in the U.S.

In May 2022, the Corporation announced the FDA has authorized the Corporation's IND to commence a Phase II open-label pilot study designed to evaluate the tolerance, safety, and efficacy of CardiolRx in patients with recurrent pericarditis. MAVERIC-Pilot will also assess the improvement in objective measures of disease, and during an extension period, assess the feasibility of weaning concomitant background therapy including corticosteroids, while taking CardiolRx. Recurrent pericarditis is a rare disease in the U.S., thereby making CardiolRx eligible for orphan drug status under the FDA's Orphan Drug Designation program.

Cardiol's study is expected to enroll 25 patients at major clinical centers in the U.S. specializing in pericarditis. The study protocol has been designed in collaboration with thought leaders in pericardial disease. The trial's primary efficacy endpoint is the change, from baseline to eight weeks, in patient-reported pericarditis pain using an 11-point numeric rating scale ("NRS"). The NRS is a validated clinical tool used across multiple conditions with acute and chronic pain, including previous studies of recurrent pericarditis. Secondary endpoints include the pain score after 26 weeks of treatment, and changes in high sensitivity CRP. Importantly, the study will also assess freedom from pericarditis recurrence.

The MAVERIC-Pilot study was designed with the support of an independent Advisory Committee and key trial investigators, consisting of international thought leaders in cardiovascular disease, including:

- **Study Chair: Allan Klein, MD, CM** – Director, Center for the Diagnosis and Treatment of Pericardial Diseases, and Professor of Medicine, Heart, Vascular and Thoracic Institute, Cleveland Clinic;
- **Antonio Abbate, MD** – Ruth C. Heede Professor of Cardiology, School of Medicine, and Department of Medicine, Division of Cardiovascular Medicine - Heart and Vascular Center, University of Virginia;
- **Allen Luis, MBBS, PhD** – Co-Director of the Pericardial Diseases Clinic, Associate Professor of Medicine, Department of Cardiovascular Medicine, at Mayo Clinic Rochester Minnesota;
- **Paul Cremer, MD** – Departments of Medicine and Radiology, Northwestern University, and Multimodality Cardiac Imaging and Clinical Trials Unit, Bluhm Cardiovascular Institute;
- **Stephen Nicholls** – Program Director, Victorian Heart Hospital, Director, Monash Victorian Heart Institute, and Professor of Cardiology, Monash University, Melbourne; and
- **Stefano Toldo, PhD** – Associate Professor of Medicine, Department of Medicine, Cardiovascular Medicine at University of Virginia.

It is anticipated that patient recruitment will be completed during Q1 2024. Cardiol has budgeted additional costs to complete this study to be approximately \$3 million. If Cardiol determines that MAVERIC-Pilot meets its objectives, it currently expects to undertake the next steps of its clinical development program, which would consist of a larger clinical study, the details of which will be determined in conjunction with regulatory agencies. The total cost and timeline to complete this clinical development program cannot be determined at this stage as this will depend on a variety of factors. The Corporation may involve a commercial partner from the pharmaceutical industry, to fund the late-stage clinical development and commercialization of CardiolRx for the treatment of recurrent pericarditis.

Phase II Trial – Acute Myocarditis (ARCHER)

Myocarditis is an acute inflammatory condition of the heart muscle (myocardium) characterized by chest pain, impaired cardiac function, atrial and ventricular arrhythmias, and conduction disturbances. Although the symptoms are often mild, myocarditis remains an important cause of acute and fulminant heart failure and is a leading cause of sudden cardiac death in people under 35 years of age. Although viral infection is the most common cause of myocarditis, the condition can also result from administration of therapies used to treat several common cancers, including chemotherapeutic agents and immune checkpoint inhibitors.

In a proportion of patients, the inflammation in the heart persists and causes decreased heart function with symptoms and signs of heart failure, and as such 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). Severe cases frequently require ventricular assist devices or extracorporeal oxygenation and may necessitate heart transplantation. There are no FDA-approved therapies for acute myocarditis. Patients hospitalized with acute myocarditis experience an average 7-day length of stay and a 4 - 6% risk of in-hospital mortality, with average hospital charge per stay estimated at US\$110,000 in the U.S.

Data from multiple sources, including the 'Global Burden of Disease Study', reports that the number of cases per year of myocarditis range from approximately 10 to 22/100,000 persons (estimated U.S. patient population of 33,000 to 73,000), qualifying the condition as a rare disease in the U.S. and in Europe. Cardiol believes that there is a significant opportunity to develop a therapy for acute myocarditis that may be eligible for designation as an orphan drug under the FDA's Orphan Drug Designation and the European Medicines Agency programs.

In August 2021, Cardiol received IND authorization from the FDA to conduct a Phase II clinical trial of CardiolRx in acute myocarditis - the *ARCHER* trial. *ARCHER* has also received regulatory clearance in other jurisdictions, and is expected to enroll 100 patients at major cardiac centers in North America, Europe, Latin America and Israel. The trial has been designed in collaboration with an independent steering committee comprising distinguished thought leaders in heart failure and myocarditis from international centers of excellence. The primary endpoints of the trial, which will be evaluated after 12 weeks of double-blind therapy, consist of the following cardiac magnetic resonance imaging measures: left ventricular function (global longitudinal strain) and myocardial edema/fibrosis (extra-cellular volume), each of which has been shown to predict long-term prognosis of patients with acute myocarditis.

Members of the Steering Committee include:

- **Chair: Dennis M. McNamara, MD** – Professor of Medicine at the University of Pittsburgh. He is also the Director of the Heart Failure/Transplantation Program at the University of Pittsburgh Medical Center;

- **Co-Chair: Leslie T. Cooper, Jr., MD** – 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;
- **Arvind Bhimaraj, MD** – Specialist in Heart Failure and Transplantation Cardiology and Associate Professor of Cardiology, Institute for Academic Medicine at Houston Methodist and at Weill Cornell Medical College, NYC;
- **Wai Hong Wilson Tang, MD** – 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;
- **Peter Liu, MD** – 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;
- **Carsten Tschöpe, MD** – Professor of Medicine and Cardiology and Vice Director of the Department of Internal Medicine and Cardiology, University Medicine Berlin;
- **Matthias Friedrich, MD** – Full Professor within the Departments of Medicine and Diagnostic Radiology at McGill University in Montreal, and Chief, Cardiovascular Imaging at the McGill University Health Centre;
- **Yaron Arbel, MD** – Cardiologist and Director of the CardioVascular Research Center (CVRC) at the Tel Aviv "Sourasky" Medical Center;
- **Edimar Bocchi, MD** – Serves as the Head of Heart Failure Clinics and Heart Failure Team at Heart Institute (Incor) of Hospital das Clinicas of São Paulo University Medical School, Associate Professor of São University Medical School, São Paulo, Brazil; and
- **Mathieu Kerneis, MD, PhD** – Interventional cardiologist at Pitié Salpêtrière Hospital (Sorbonne University).

It is anticipated that patient recruitment will be completed during Q3 2024. Cardiol has budgeted additional costs to complete this study to be approximately \$8 million. If Cardiol determines that the Phase II study meets its objectives, it currently expects to undertake the next steps of its clinical development program, which would consist of a larger clinical study, the details of which will be determined in consultation with regulatory agencies. The total cost and timeline to complete this clinical development program cannot be determined at this stage as this will depend on a variety of factors. The Corporation may involve a commercial partner from the pharmaceutical industry, to fund the late-stage clinical development and commercialization of CardiolRx for the treatment of acute myocarditis.

Scientific Advisory Board

The Corporation has established a Scientific Advisory Board comprised of distinguished thought leaders in cardiovascular medicine. These individuals will lend their expertise in cardiovascular research and provide invaluable guidance to the Corporation's research and clinical programs. The Scientific Advisory Board members include:

Paul M. Ridker, MD, MPH

Dr. Ridker is director of the Center for Cardiovascular Disease Prevention, a translational research unit at Brigham and Women's Hospital (BWH), Boston. A cardiovascular medicine specialist, he is also the Eugene Braunwald Professor of Medicine at Harvard School of Medicine (HMS). Dr. Ridker received his medical degree from HMS and then completed an internal medicine residency and a cardiology fellowship at BWH. Dr. Ridker is board certified in internal medicine. His clinical interests include coronary artery disease and the underlying causes and prevention of atherosclerotic disease. Dr. Ridker is the author of over 900 peer-reviewed publications and reviews, 64 book chapters, and six textbooks related to cardiovascular medicine. His primary research focus has involved inflammatory mediators of heart disease and the molecular and genetic epidemiology of hemostasis and thrombosis, with particular interests in biomarkers for coronary disease, "predictive" medicine, and the underlying causes and prevention of atherosclerotic disease. Notably, Dr. Ridker has been the Principal Investigator or Study Chairman of several large international trials that have demonstrated the role of inflammation in the genesis and management of coronary artery disease. He was included in TIME magazine's list of 100 most influential people of 2004, and between the years 2000 and 2010, Dr. Ridker was among the ten most often cited researchers in cardiovascular medicine worldwide. Amongst many other honors, he received the American Heart Association Distinguished Scientist Award in 2013, gave the Braunwald Lecture of the American College of Cardiology in 2019, was awarded the Gotto Prize for Atherosclerosis Research from the International Atherosclerosis Society in 2021, and is an elected Member of the National Academy of Medicine (USA).

Bruce McManus, PhD, MD

Dr. McManus is Professor Emeritus, Department of Pathology and Laboratory Medicine, the University of British Columbia. He has served as CEO, Centre of Excellence for Prevention of Organ Failure (PROOF Centre), Director, UBC Centre for Heart Lung Innovation, and Scientific Director, Institute of Circulatory and Respiratory Health, CIHR. Dr. McManus received BA and MD degrees (University of Saskatchewan), an MSc (Pennsylvania State University), and a PhD (University of Toledo). He pursued post-doctoral fellowships at the University of California, Santa Barbara (Environmental Physiology) and at the National Heart, Lung, and Blood Institute, Bethesda, MD (Cardiovascular & Pulmonary Pathology), and residency training at the Peter Bent Brigham Hospital, Harvard University (Internal Medicine and Pathology). Dr. McManus' investigative passion relates to mechanisms, consequences, detection and prevention of injury and aberrant repair in inflammatory diseases of the heart and blood vessels. He has had a longstanding interest in the diagnosis and management of acute viral myocarditis. His life's scholarship is reflected in more than 400 original peer-reviewed publications, over 60 chapters, and several books. He is an extraordinary mentor. Dr. McManus has been widely appreciated for his research, mentoring, and leadership contributions to the health sciences. Amongst many awards and honors, Dr. McManus received the prestigious Max Planck Research Award in 1991, was elected a Fellow of the Royal Society of Canada in 2002, was appointed a Member of the Order of Canada in 2018, and to the Order of British Columbia the following year.

Joseph A. Hill, MD, PhD

Dr. Hill is Professor of Internal Medicine and Molecular Biology, Chief of Cardiology at UT Southwestern Medical Center, Dallas, TX, and Director of the Harry S. Moss Heart Center. Dr. Hill holds both the James T. Willerson, MD, Distinguished Chair in Cardiovascular Diseases, and the Frank M. Ryburn Jr. Chair in Heart Research. He graduated from Duke University with MD and PhD degrees in 1987. His PhD dissertation research was in the field of cardiac ion channel biophysics. Dr. Hill then worked for five years as a postdoctoral fellow at the Institut Pasteur in Paris studying central and peripheral nicotinic receptors. He next completed an internal medicine internship and residency, as well as a clinical cardiology fellowship, at the Brigham and Women's Hospital, Harvard Medical School. He served on faculty at the University of Iowa for five years before moving in 2002 to the UT Southwestern. Dr. Hill's research examines molecular mechanisms of structural, functional, metabolic, and electrophysiological remodeling in cardiac hypertrophy and heart failure. He has served on many NIH panels and committees and delivered numerous invited lectures in the U.S. and around the world. Dr. Hill has received many recognitions and awards, including election to the Association of American Professors and the 2018 Research Achievement Award from the International Society for Heart Research. For the past six years, Dr. Hill has been the Editor-in-Chief of the prestigious American Heart Association journal *Circulation*.

Outlook

During the next 12 - 24 months, the Corporation expects to achieve the following corporate milestones:

- Complete Phase II MAVERIC-Pilot study in recurrent pericarditis with CardiolRx;
- Complete Phase II ARCHER trial in acute myocarditis with CardiolRx;
- Advance development of a subcutaneously administered formulation;

The Corporation expects that the September 30, 2023 working capital of \$34,419,445 will be sufficient to fund operations and capital requirements, associated with achieving these corporate milestones, into 2026.

Use of Offering Proceeds

The Corporation may reallocate the net offering proceeds that it obtained from the April 2021 and November 2021 Offerings (as defined below) 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 November 2021 Offering, as disclosed in the Corporation's prospectus dated November 3, 2021 (the "November 2021 Offering"), and spending from November 5, 2021 (offering closing date) to September 30, 2023 is as follows (figures in the below "Amount" column are translated to CAD from USD at a rate of 1.35):

Use of Proceeds	Amount	Spent	Remaining
LANCER Study	5,400,160	5,400,160	-
Phase II Clinical Trials in Acute Myocarditis	4,320,128	1,936,037	2,384,091
Subcutaneous Development	3,240,096	595,786	2,644,310
Development of Additional Orphan Program	4,320,128	2,192,538	2,127,590
Discovery Research	10,800,320	1,082,783	9,717,537

Summary of Quarterly Results

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

Three Months Ended	Total	Profit or (Loss)		Total
	Revenue (\$)	Total (\$)	Per Share ⁽⁹⁾ (\$)	Assets (\$)
September 30, 2023 ⁽¹⁾	nil	(5,930,185)	(0.11)	43,053,024
June 30, 2023 ⁽²⁾	nil	(7,471,754)	(0.12)	47,169,272
March 31, 2023 ⁽³⁾	nil	(7,089,336)	(0.11)	52,685,268
December 31, 2022 ⁽⁴⁾	nil	(7,515,018)	(0.12)	62,028,518
September 30, 2022 ⁽⁵⁾	nil	(7,972,047)	(0.13)	68,358,729
June 30, 2022 ⁽⁶⁾	nil	(6,489,488)	(0.10)	74,264,968
March 31, 2022 ⁽⁷⁾	nil	(8,954,095)	(0.14)	79,432,326
December 31, 2021 ⁽⁸⁾	nil	(6,257,462)	(0.11)	87,876,128

Note:

- Net loss of \$5,930,185 included general and administration of \$5,079,140 and research and development of \$2,576,751. This is partially offset by a gain on foreign exchange of \$667,548, interest income of \$515,538, a change in derivative liability of \$392,881, and other income of \$149,739.
- Net loss of \$7,471,754 included research and development of \$3,479,385, general and administration of \$2,835,264, change in derivative liability of \$856,893, and loss on foreign exchange of \$828,909. This is partially offset by interest income of \$528,697.
- Net loss of \$7,089,336 included research and development of \$4,127,696 and general and administration of \$3,658,440. This is partially offset by interest income of \$545,927.
- Net loss of \$7,515,018 included research and development of \$5,617,948, general and administration of \$3,477,065, and a loss on foreign exchange of \$528,314. These are partially offset by a change in derivative liability of \$1,523,662 and interest income of \$584,647.
- Net loss of \$7,972,047 included general and administration of \$8,130,743 and research and development of \$5,089,423. These are partially offset by the gain on foreign exchange of \$2,970,896, and change in derivative liability of \$1,723,442.
- Net loss of \$6,489,488 included general and administration of \$4,825,039 and research and development of \$4,407,182. These are partially offset by the gain on foreign exchange of \$1,689,797, and change in derivative liability of \$861,600.
- Net loss of \$8,954,095 included general and administration of \$5,940,952, research and development of \$3,847,527, and a loss on foreign exchange of \$1,370,444. These are partially offset by the gain on the change in derivative liability of \$2,132,517.
- Net loss of \$6,257,462 included general and administration of \$9,569,839 and research and development of \$3,527,834. These are partially offset by the gain on the change in derivative liability of \$4,916,304 and a gain on foreign exchange of \$1,876,987.

9. Basic and fully diluted.

Discussion of Operations

Nine months ended September 30, 2023, compared to the nine months ended September 30, 2022

For the nine months ended September 30, 2023, the Corporation's net loss was \$20,491,275, compared to a net loss of \$23,415,629 for the nine months ended September 30, 2022. The decrease in net loss of \$2,924,354 is a result of the following:

- Research and development decreased to \$10,183,832 for the nine months ended September 30, 2023, compared to \$13,344,132 for the nine months ended September 30, 2022. During the nine months ended September 30, 2023, the Corporation incurred research and development costs related to basic science, pre-clinical studies, and clinical studies, specifically relating to the Phase II acute myocarditis trial and Phase II Open-Label Pilot Study of recurrent pericarditis.
- General and administration expenses decreased to \$11,572,844 for the nine months ended September 30, 2023, compared to \$18,896,733 for the nine months ended September 30, 2022. The decrease was a result of a reduction in corporate communications spending and share-based compensation, as well as a general re-allocation of resources to focus on research and development activities.
- The net loss for the nine months ended September 30, 2023, is increased by the loss on the change in derivative liability, based on the revaluation as at September 30, 2023, of \$389,931, compared to the gain on the change in derivative liability for the nine months ended September 30, 2022 of \$4,717,559.
- The net loss is increased by a loss on foreign exchange during the nine months ended September 30, 2023 of \$84,569, compared to a gain on foreign exchange during the nine months ended September 30, 2022 of \$3,290,249. This is mainly the result of the revaluation of funds held in USD.
- The net loss is decreased by interest income during the nine months ended September 30, 2023 of \$1,590,162, compared to interest income during the nine months ended September 30, 2022 of \$652,985. The increase is the result of an increase in interest rates.

Three months ended September 30, 2023, compared to the three months ended September 30, 2022

For the three months ended September 30, 2023, the Corporation's net loss was \$5,930,185, compared to a net loss of \$7,972,047 for the three months ended September 30, 2022. The decrease in net loss of \$2,041,862 is a result of the following:

- Research and development decreased to \$2,576,751 for the three months ended September 30, 2023, compared to \$5,089,423 for the three months ended September 30, 2022. During the three months ended September 30, 2023, the Corporation incurred research and development costs related to basic science, pre-clinical studies, and clinical studies, specifically relating to the Phase II acute myocarditis trial and Phase II Open-Label Pilot Study of recurrent pericarditis.
- General and administration expense decreased to \$5,079,140 for the three months ended September 30, 2023, compared to \$8,130,743 for the three months ended September 30, 2022. The decrease was a result of a reduction in corporate communications spending and share-based compensation, as well as a general re-allocation of resources to focus on research and development activities.
- The net loss for the three months ended September 30, 2023, is decreased by the gain on the change in derivative liability, based on the revaluation as at September 30, 2023, of \$392,881, compared to the gain on the change in derivative liability for the three months ended September 30, 2022 of \$1,723,442.
- The net loss is decreased by the gain on foreign exchange during three months ended September 30, 2023 of \$667,548. compared to a gain on foreign exchange during three months ended September 30, 2022 of \$2,970,896. This is mainly the result of the revaluation of funds held in USD.

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, and contributed surplus, less accumulated deficit, which at September 30, 2023 totaled \$34,870,776 (December 31, 2022 – \$52,201,588).

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 and reviewed with the Board of Directors of the Corporation.

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, 2023, Cardiol had \$40,540,136 in cash and cash equivalents (December 31, 2022 – \$59,469,868).

At September 30, 2023, accounts payable and accrued liabilities were \$7,191,210 (December 31, 2022 – \$9,334,158). The Corporation's cash and cash equivalents balances as at September 30, 2023 and December 31, 2022 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, 2023, December 31, 2022, 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 2023 Fiscal Period

Cash and cash equivalents used in operating activities were \$18,715,681 for the nine months ended September 30, 2023. Operating activities were affected by a net loss of \$20,491,275 and the net change in non-cash working capital balances of \$(2,084,255), and partially offset by other non-cash adjustments of \$3,859,849. Non-cash adjustments mainly consisted of \$3,144,014 for share-based compensation and \$389,931 for change in derivative liability. Non-cash working capital was mainly the result of a decrease in accounts payable and accrued liabilities of \$2,142,948.

Cash and cash equivalents used in investing activities were \$53,606 for the nine months ended September 30, 2023 as a result of the purchase of property and equipment.

Cash and cash equivalents used in financing activities were \$41,532 for the nine months ended September 30, 2023, as a result of the payment of lease liability.

Use of Working Capital

As of September 30, 2023, Cardiol's working capital was \$34,419,445. Based on current projections, Cardiol believes that this amount is sufficient to fund operations and capital requirements, associated with achieving corporate milestones, into 2026, described in the "Outlook" section above.

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

	Total	Up to 1 year	1 – 3 years	4 – 5 years	After 5 years
Contractual Obligations	(\$)	(\$)	(\$)	(\$)	(\$)
Amounts payable and other liabilities	7,191,210	7,191,210	Nil	Nil	Nil
Office lease ⁽¹⁾	518,238	80,416	214,444	214,444	8,934
Consulting agreements	760,207	357,895	402,312	Nil	Nil
Contract research	709,950	668,524	41,426	Nil	Nil
Total	9,179,605	8,298,045	616,756	214,444	8,934

Note:

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

Related Party Transactions

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

- i. Included in research and development expense is \$169,034 and \$906,843 for the three and nine months ended September 30, 2023 (three and nine months ended September 30, 2022 - \$706,896 and \$1,409,428) paid to a company, Dalton Chemical Laboratories, Inc. operating as Dalton ("Dalton"), that is related to a Director (Peter Pekos). Mr. Pekos is also the CEO of Dalton. As at September 30, 2023, \$280,328 (December 31, 2022 - \$985,022) was owed to this company and this amount was included in accounts payable and accrued liabilities and \$1,800 (December 31, 2022 - \$9,413) was paid to this company and was included in prepaid expenses. Cardiol entered into an exclusive master services agreement with Dalton for the manufacturing of its pharmaceutical cannabidiol.

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, except as noted in (a) above, was as follows:

	Three months ended	Three months ended	Nine months ended	Nine months ended
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
	(\$)	(\$)	(\$)	(\$)
Salaries and benefits	536,320	497,017	2,240,796	1,866,635
Share-based payments	248,870	1,225,099	779,880	2,072,878
	785,190	1,722,116	3,020,676	3,939,513

As at September 30, 2023, \$nil (December 31, 2022 - \$nil) 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 were based on unobservable assumptions when the Corporation was private at the time of issuance of the equity instruments (share price and volatility) in accounting for share-based payment transactions;
- The valuation of the derivative liability;
- 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; and
- 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 nine years.

Critical accounting judgments

- Management applied judgment in determining the functional currency of the Corporation as Canadian dollars;
- Management applied judgment in determining the Corporation's ability to continue as a going concern. The Corporation has incurred significant losses since inception. Management determined that a material going concern uncertainty does not exist due to the sufficient working capital to support their planned expenditure levels. Future financing may come from product sales, licensing arrangements, research and commercial development partnerships, government grants, and/or corporate finance arrangements; and
- Management's assessment that no impairment exists for intangible assets, based on the facts and circumstances that existed during the period.

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 65,113,946 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, warrants, performance share units, and restricted share units as shown below:

Warrants

<u>Expiry date</u>	<u>Exercise price (\$)</u>	<u>Warrants outstanding</u>
May 12, 2024	4.60	3,453,178
November 5, 2024	3.75 ⁽¹⁾	8,175,000
Total		11,628,178

(1) Exercise price denoted in USD.

Stock Options

Expiry date	Exercise price (\$)	Options outstanding	Options exercisable
February 23, 2025	3.54	20,000	20,000
April 10, 2025	0.75	100,000	50,000
August 19, 2025	2.12	100,000	100,000
August 30, 2025	5.00	80,000	80,000
April 1, 2026	5.77	60,000	60,000
September 10, 2026	1.00 ⁽¹⁾	100,000	-
December 8, 2026	3.59	325,000	108,333
January 11, 2027	2.18	220,000	73,333
March 14, 2027	2.07	60,000	20,000
May 12, 2027	1.46	100,000	33,334
September 12, 2027	1.61	207,500	69,168
June 25, 2028	1.00 ⁽¹⁾	80,000	80,000
Total		1,452,500	694,169

(1) Exercise price denoted in USD.

Performance Share Units

The Corporation has 2,000,000 outstanding performance share units ("PSUs") subject to vesting conditions specific to each grant.

Restricted Share Units

The Corporation has 3,883,220 outstanding restricted share units ("RSUs") subject to vesting conditions specific to each grant. Of the outstanding RSUs, 1,775,707 have fully vested as of the date of this MD&A.

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 has 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 accounts receivable, which are classified and measured at amortized cost. The Corporation's financial liabilities consist of accounts payable and accrued liabilities, and lease liability, which are classified and measured at amortized cost, and derivative liabilities which are classified and measured at FVTPL.

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); and
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The Corporation's derivative liabilities are measured at fair value Level 3. No other financial instruments are 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 2023 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 accounts 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 as well as receivables. 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 \$3,194,000 (December 31, 2022 - \$4,414,000).

Commitments and Contingency

(i) The Corporation has leased premises from third parties. The minimum committed lease payments as at September 30, 2023, which include the lease liability payments, are as follows:

Fiscal year	
2023	26,805
2024	80,416
2025	107,222
2026	107,222
2027	107,222
2028	89,351
Total	\$ 518,238

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

Fiscal year	
2023	357,895
2024	402,312
Total	\$ 760,207

(iii) Pursuant to the terms of agreements with various other contract research organizations, the Corporation is committed for contract research services for 2023 and 2024 at a cost of approximately \$668,524 and \$41,426, respectively.

Breakdown of Expensed Research and Development

	Three months ended September 30, 2023	Three months ended September 30, 2022	Nine months ended September 30, 2023	Nine months ended September 30, 2022
	(\$)	(\$)	(\$)	(\$)
Contract research	1,915,913	4,423,368	7,568,799	11,563,771
Wages	437,472	365,905	1,413,479	940,965
Supplies	112	-	534,284	17,041
Regulatory	112,677	108,056	360,801	367,077
Share-based compensation	95,577	192,094	291,469	455,278
	2,576,751	5,089,423	10,183,832	13,344,132

Breakdown of Intangible Assets

	As at September 30, 2023	As at December 31, 2022
	(\$)	(\$)
Exclusive global license agreement	767,228	767,228
Accumulated amortization	(535,759)	(472,426)
Carrying value	231,469	294,802

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. There have been no changes in internal controls over financial reporting for the quarter ended September 30, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As a result of a material weakness in ICFR with respect to certain share-based compensation paid to consultants, as at September 30, 2023, the Corporation concluded that its DCP and ICFR were not effective. This material weakness did not result in any changes to previously reported financial results and has no material impact on the Corporation’s financial results. Management has also concluded that the September 30, 2023 unaudited condensed interim consolidated financial statements present fairly, in all material respects the Corporations’ financial results.

The Corporation has developed a plan to remediate this material weakness. This plan includes the following:

- When applicable, engaging external advisors with appropriate technical accounting knowledge and experience in the application of IFRS to assist with the evaluation and documentation of accounting for complex transactions; and
- Implementing additional controls related to accounting for complex transactions.

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 "Risk Factors" in the Corporation's MD&A for the financial year ended December 31, 2022 (available on SEDAR at www.sedar.com and EDGAR at www.sec.gov). The following updated risk factor is also relevant to prospective investors:

The Corporation may lose its listing on the Nasdaq if it does not regain compliance with Nasdaq Listing Rule 5550(a)(2).

On October 19, 2023, the Corporation received the Notice from the Nasdaq stating that the Corporation is not in compliance with the Minimum Bid Requirement of US\$1.00 per share under the Nasdaq Listing Rule 5550(a)(2) based upon the closing bid price of the Corporation's common shares for 30 consecutive business days prior to the notice.

The Notice has no immediate effect on the listing or trading of the common shares on Nasdaq, and the Corporation's operations are not affected by the receipt of the Notice. Under Nasdaq Listing Rule 5810(c)(3)(A), the Corporation has 180 calendar days from the date of the Notice, or until April 16, 2024, to regain compliance with the Minimum Bid Requirement, during which time the common shares will continue to trade on Nasdaq. If at any time before April 16, 2024, the bid price of the common shares closes at or above USD\$1.00 per share for a minimum of 10 consecutive business days, the Corporation will regain compliance with the Minimum Bid Requirement. If the Corporation does not regain compliance with the Minimum Bid Requirement by April 16, 2024, the Corporation may be eligible, upon satisfaction of certain Nasdaq listing requirements, for an additional period of 180 calendar days that would further extend the period of time to regain compliance to October 14, 2024, or the common shares may be subject to delisting from Nasdaq.

We are monitoring the bid price of our common shares and are considering various strategies available to us to regain compliance with the Minimum Bid Requirement; however, we cannot be sure that we will be able to regain and/or maintain compliance with this listing standard or that we will otherwise be in compliance with other Nasdaq listing standards. If we fail to regain and/or maintain compliance with the Minimum Bid Requirement or to meet other applicable continued listing standards of Nasdaq in the future, and Nasdaq elects to delist our common shares, the market price and liquidity of our common shares could be negatively impacted and our ability to raise additional capital could be reduced. The Notice does not have any impact on the Corporation's TSX listing.