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**CARDIOL THERAPEUTICS INC.  
MANAGEMENT'S DISCUSSION AND ANALYSIS  
THREE AND NINE MONTHS ENDED  
SEPTEMBER 30, 2024**

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## 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. and its subsidiary (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, 2024 (the "2024 Fiscal Period"). This discussion should be read in conjunction with the consolidated financial statements for the years ended December 31, 2023, 2022, and 2021, and the unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2024 ("Financial Statements"), together with the respective notes thereto. 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 11, 2024. 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. and its subsidiary.

This MD&A is presented current to November 11, 2024, 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 testing, research, pre-clinical studies, clinical studies, and commercialization;
- our ability to develop new routes of administration of our product candidates, including parenteral, for use in testing, research, pre-clinical studies, clinical studies, and commercialization;
- our ability to develop new formulations of our product candidates for use in testing, research, pre-clinical studies, clinical studies, and commercialization;
- the successful development and commercialization of our current product candidates and the addition of future products and product candidates;
- the ability of 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 testing, research, pre-clinical studies, 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, if approved;
- 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 in multiple jurisdictions, including Orphan Drug Designations/Approvals, for our 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 future products and product candidates, if approved;
- uncertainty relating to market acceptance of our product candidates, if approved;
- our lack of experience in commercializing any products, including selling, marketing, or distributing pharmaceutical products;
- securing third-party payor reimbursement for our product candidates, if approved;
- the level of pricing and reimbursement for our 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, if approved;
- 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 any products for which we receive marketing authorization;
- 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 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 by existing shareholders causing the market price for the common shares to fluctuate;
- the issuance of common shares in the future causing dilution;
- events outside of our control could adversely affect our operations;
- 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 11, 2024, 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 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.

Cardiol has received Investigational New Drug Application authorization from the United States Food and Drug Administration ("US FDA") to conduct clinical studies to evaluate the efficacy and safety of CardiolRx™ in two diseases affecting the heart: recurrent pericarditis and acute myocarditis. The MAVERIC Program in recurrent pericarditis, an inflammatory disease of the pericardium which is associated with symptoms including debilitating chest pain, shortness of breath, and fatigue, and results in physical limitations, reduced quality of life, emergency department visits, and hospitalizations, comprises the Phase II MAVERIC-Pilot study (the "MAVERIC-Pilot" study; NCT05494788), the Phase II/III MAVERIC-2 trial, and the planned Phase III MAVERIC-3 trial. The ARCHER trial (the "ARCHER" trial; NCT05180240) is a Phase II study in acute myocarditis, an important cause of acute and fulminant heart failure in young adults and a leading cause of sudden cardiac death in people less than 35 years of age. The U.S. FDA has granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis, which includes recurrent pericarditis.

Cardiol is also developing CRD-38, a novel subcutaneously administered drug formulation intended for use in heart failure – a leading cause of death and hospitalization in the developed world, with associated healthcare costs in the United States exceeding \$30 billion annually<sup>1</sup>.

## Operations Highlights

### During the 2024 Fiscal Period

(i) In January 2024, the Corporation announced it had exceeded 50% patient enrollment for ARCHER. See "Phase II Trial – Acute Myocarditis (ARCHER)".

(ii) In January 2024, the Corporation announced that it received notice on January 23, 2024, from The Nasdaq Stock Market LLC 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.

(iii) In February 2024, the Corporation announced that the FDA has granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis, which includes recurrent pericarditis.

(iv) In February 2024, the Corporation announced completion of patient enrollment in MAVERIC-Pilot. See "Phase II Open Label Pilot Study - Recurrent Pericarditis (MAVERIC-Pilot)".

(v) In May 2024, the Corporation announced its Phase II ARCHER trial was the subject of an oral presentation at the World Congress on Acute Heart Failure 2024 in Lisbon, Portugal, at the annual congress of the Heart Failure Association of the European Society of Cardiology ("ESC").

The trial design, rationale, and blinded baseline data on the first 50 patients randomized into ARCHER were presented by Univ.-Prof. Dr. med. Carsten Tschöpe from the Berlin Institute of Health – Charité, on behalf of the ARCHER Study Group, an independent steering committee comprising distinguished thought leaders in heart failure and myocarditis from international centers of excellence who contributed to the design and execution of ARCHER. Concurrent with the presentation the journal *ESC Heart Failure*, which is dedicated to advancing knowledge about heart failure worldwide, accepted the manuscript describing the rationale and design of the ARCHER trial and it was published in June 2024.

(vi) In June 2024, the Corporation reported positive topline 8-week clinical data from its Phase II open-label MAVERIC-Pilot study investigating the impact of CardiolRx™ administered to patients with symptomatic recurrent pericarditis. The data showed a marked reduction in the primary efficacy endpoint of patient-reported pericarditis pain at the end of the 8-week treatment period ("TP"), as well as normalization of inflammation – as measured by C-reactive protein ("CRP") – in 80% of patients with elevated CRP at baseline.

MAVERIC-Pilot study enrolled 27 patients diagnosed with symptomatic recurrent pericarditis. Each patient had a high disease burden as reflected in the mean baseline pericarditis pain score of 5.8 out of 10, and by the number of previous episodes of pericarditis: 9 patients (33%) with 2 previous episodes; 9 (33%) with 3; 4 (15%) with 4; and 5 (19%) with >4.

Summary of topline findings include:

- Primary endpoint of patient-reported pericardial pain on an 11-point numerical rating scale ("NRS") showed a mean reduction of 3.7, from 5.8 at baseline (range of 4 to 10) to 2.1 (range of 0 to 6) at 8 weeks. NRS is a validated instrument used to assess patient-reported pericarditis pain. Zero represents 'no pain at all', whereas the upper limit of 10 represents 'the worst pain ever possible'.
- Eight of the ten patients (80%) with a baseline CRP =1mg/dL had a normalization of CRP (=0.5 mg/dL) at 8 weeks. The mean CRP decreased from 5.7 mg/dL at baseline to 0.3 mg/dL at 8 weeks. CRP is a commonly used clinical marker of inflammation, and in combination with the NRS score, is used by clinicians to assess clinical response and determine a recurrence.
- Eighty-nine percent of patients (24/27) have progressed from the TP into the extension period ("EP") of the study, defined as the additional 18-week period of CardiolRx™ treatment that follows the TP.
- CardiolRx™ was shown to be generally well tolerated.

(vii) In September 2024, the Corporation announced the completion of the MAVERIC-Pilot with results to be presented in an oral presentation as part of the Laennec Clinician-Educator Award & Lecture that runs from 9:45 a.m. to 11:00 a.m. Central Time, on Monday, November 18th, 2024, at the American Heart Association Scientific Sessions 2024. Dr. S. Allen Luis, Co-Director, Pericardial Diseases Clinic and Associate Professor of Medicine, Department of Cardiovascular Medicine at the Mayo Clinic, will present on behalf of the MAVERIC-Pilot investigators.

(viii) In September 2024, the Corporation announced that it had achieved its target patient enrollment of 100 patients for the ARCHER trial.

#### **Subsequent to September 30, 2024**

(i) In October 2024, the Corporation successfully closed a public offering of 9,703,125 common shares, at a price of US\$1.60 per common share, for gross proceeds of US\$15,525,000.

(ii) In October 2024, the Corporation announced plans to expand the MAVERIC clinical development program and advance CardiolRx™ into a late-stage clinical trial ("MAVERIC-2") to evaluate the impact of CardiolRx™ in recurrent pericarditis patients following cessation of interleukin-1 ("IL-1") blocker therapy. See "Phase II/III Trial – Recurrent Pericarditis (MAVERIC-2)".

#### ***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<sup>2</sup>.

Recurrent pericarditis appears in 15% to 30% of patients following the acute index episode 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 blocker with immunosuppressive effects. It is generally used as a third-line intervention in patients with persistent underlying disease, multiple recurrences, and an inadequate response to conventional therapy<sup>2</sup>.

On an annual basis, the number of patients in the U.S. having experienced at least one recurrence is estimated at 38,000. Approximately 60% of patients with multiple recurrences (>1) still suffer for longer than two years, and one third are still impacted at five years. Hospitalization due to recurrent pericarditis is often associated with a 6-8-day length of stay and cost per stay is estimated to range between US\$20,000 and US\$30,000 in the U.S.<sup>2</sup>.

In May 2022, the Corporation announced that the FDA 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., and in February 2024, the FDA granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis, which includes recurrent pericarditis.

The MAVERIC-Pilot study, designed to enroll 25 patients, enrolled 27 patients at eight major clinical centers in the U.S. specializing in pericarditis. The primary efficacy endpoint of the study 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;
- **Study Lead Investigator: Allen Luis, MBBS, PhD** – Co-Director of the Pericardial Diseases Clinic, Associate Professor of Medicine, Department of Cardiovascular Medicine, at Mayo Clinic Rochester Minnesota;
- **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;
- **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.

In June 2024, the Corporation reported positive topline 8-week clinical data from its MAVERIC-Pilot study. The data showed a marked reduction in the primary efficacy endpoint of patient-reported pericarditis pain at the end of the 8-week treatment period (“TP”), as well as normalization of inflammation – as measured by CRP – in 80% of patients with elevated CRP at baseline.

MAVERIC-Pilot study enrolled 27 patients diagnosed with symptomatic recurrent pericarditis. Each patient had a high disease burden as reflected in the mean baseline pericarditis pain score of 5.8 out of 10, and by the number of previous episodes of pericarditis: 9 patients (33%) with 2 previous episodes; 9 (33%) with 3; 4 (15%) with 4; and 5 (19%) with >4.

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- Primary endpoint of patient-reported pericardial pain on an 11-point numerical rating scale (“NRS”) showed a mean reduction of 3.7, from 5.8 at baseline (range of 4 to 10) to 2.1 (range of 0 to 6) at 8 weeks. NRS is a validated instrument used to assess patient-reported pericarditis pain. Zero represents ‘no pain at all’, whereas the upper limit of 10 represents ‘the worst pain ever possible’.
- Eight of the ten patients (80%) with a baseline CRP =1mg/dL had a normalization of CRP (=0.5 mg/dL) at 8 weeks. The mean CRP decreased from 5.7 mg/dL at baseline to 0.3 mg/dL at 8 weeks. CRP is a commonly used clinical marker of inflammation, and in combination with the NRS score, is used by clinicians to assess clinical response and determine a recurrence.
- Eighty-nine percent of patients (24/27) progressed from the TP into the extension period (“EP”) of the study, defined as the additional 18-week period of CardiolRx™ treatment that follows the TP.
- CardiolRx™ was shown to be generally well-tolerated.

In September 2024, the Corporation announced the completion of the MAVERIC-Pilot with results to be presented in an oral presentation as part of the Laennec Clinician-Educator Award & Lecture that runs from 9:45 a.m. to 11:00 a.m. Central Time, on Monday, November 18th, 2024, at the American Heart Association Scientific Sessions 2024. Dr. S. Allen Luis, Co-Director, Pericardial Diseases Clinic and Associate Professor of Medicine, Department of Cardiovascular Medicine at the Mayo Clinic, will present on behalf of the MAVERIC-Pilot investigators.

Cardiol currently expects to undertake the next steps in its clinical development program, which would consist of a larger clinical study, the details of which will be determined in conjunction with its external clinical advisors and 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/III Trial – Recurrent Pericarditis (MAVERIC-2)***

MAVERIC-2 is a randomized, double-blind, placebo-controlled Phase II/III trial in approximately 110 patients. Patients with stable disease who are receiving IL-1 blocker treatment will be randomly assigned to receive either CardiolRx™ or placebo following planned cessation of the IL-1 blocker. The primary clinical objective of the trial will be to assess the impact of CardiolRx™ versus placebo on freedom from a new episode of recurrent pericarditis. Other clinical endpoints of interest include time to a new episode of pericarditis recurrence and change in patient-reported pericarditis chest pain score and the inflammatory marker C-reactive protein (“CRP”).

IL-1 is a key pro-inflammatory cytokine in the pathophysiology of recurrent pericarditis. It is generated downstream following activation of the NLRP3 inflammasome and amplifies the autoinflammatory response characteristic of the disease. IL-1 blockers (rilonacept or anakinra) target and negate the activity of IL-1, but given their expense and immunosuppressant risks, they are generally prescribed as a third-line intervention in difficult-to-treat patients. There is a growing body of evidence indicating pericarditis recurrence rates are as high as seventy-five percent and onset is rapid following cessation of IL-1 blocker therapy. Currently, many patients who discontinue IL-1 blocker therapy and subsequently suffer a recurrence require rescue treatment with further administration of these biologics, potentially leading to IL-1 blocker dependence.

CardiolRx™ has been shown experimentally to inhibit assembly and activation of the NLRP3 inflammasome and the subsequent generation of IL-1, and the topline findings from MAVERIC-Pilot show CardiolRx™ has led to marked reductions in pericarditis pain. This evidence provides the rationale for undertaking MAVERIC-2, as CardiolRx™ may have therapeutic potential to prevent recurrences following discontinuation of IL-1 blockers, which would address an unmet need in a growing subset of patients dependent on long-term IL-1 blocker therapy.

The Corporation expects to initiate MAVERIC-2 during Q4 2024.

### ***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<sup>3</sup>.

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 pharmacological treatment is based on conventional therapy 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.<sup>3</sup>.

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 European Union. 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 Orphan Medicine programs<sup>3</sup>.

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. In May 2024, the Corporation announced that the ARCHER trial had exceeded 85% of its patient enrollment objective. ARCHER 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** – Clinical Professor in Cardiology, Head of the Cardiomyopathy Unit, Department of Cardiology, Angiology and Intensive Care, Campus Virchow, German Heart Center (DHZC) at Charité, 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).

In May 2024, the ARCHER trial was the subject of an oral presentation at the World Congress on Acute Heart Failure 2024 in Lisbon, Portugal, at the annual congress of the Heart Failure Association of the ESC. The trial design, rationale, and blinded baseline data on the first 50 patients randomized into ARCHER were presented by Univ.-Prof. Dr. med. Carsten Tschöpe from the Berlin Institute of Health – Charité, on behalf of the ARCHER Study Group, an independent steering committee comprising distinguished thought leaders in heart failure and myocarditis from international centers of excellence who contributed to the design and execution of ARCHER. Concurrent with the presentation the journal *ESC Heart Failure*, which is dedicated to advancing knowledge about heart failure worldwide, accepted the manuscript describing the rationale and design of the ARCHER trial and it was published in June 2024.

In September 2024, the Corporation announced that it has achieved its target patient enrollment of 100 patients for the ARCHER trial. The Corporation expects to report topline data in Q1 2025. Cardiol has budgeted costs to complete this study to be approximately \$3 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 its external clinical advisors and 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 Chair 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 eight years, Dr. Hill has been the Editor-in-Chief of the prestigious American Heart Association journal *Circulation*.

## Outlook

During the next 12 - 18 months, the Corporation expects to achieve the following corporate milestones:

- Report full results from the Phase II MAVERIC-Pilot study evaluating CardiolRx™ in recurrent pericarditis on Monday, November 18th, 2024, at the American Heart Association Scientific Sessions 2024;
- Complete Phase II ARCHER trial in acute myocarditis with CardiolRx™ and report topline data in Q1, 2025;
- Initiate and complete the Phase II/III MAVERIC-2 study evaluating CardiolRx™ in pericarditis patients dependent on IL-1 blocker therapy;
- Initiate the Phase III MAVERIC-3 trial of CardiolRx™ in pericarditis;
- Advance the development of CRD-38.

The Corporation expects that the November 11, 2024, cash and cash equivalents of \$34,035,996 will be sufficient to fund operations and capital requirements associated with achieving these corporate milestones, into Q2, 2026.

## 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 <sup>(9)</sup>	Assets
	(\$)		(\$)	(\$)
September 30, 2024 <sup>(1)</sup>	nil	(12,728,484)	(0.18)	17,519,645
June 30, 2024 <sup>(2)</sup>	nil	(6,590,873)	(0.10)	26,312,660
March 31, 2024 <sup>(3)</sup>	nil	(9,179,632)	(0.14)	31,126,280
December 31, 2023 <sup>(4)</sup>	nil	(7,637,017)	(0.12)	36,700,508
September 30, 2023 <sup>(5)</sup>	nil	(5,930,185)	(0.11)	43,053,024
June 30, 2023 <sup>(6)</sup>	nil	(7,471,754)	(0.12)	47,169,272
March 31, 2023 <sup>(7)</sup>	nil	(7,089,336)	(0.11)	52,685,268
December 31, 2022 <sup>(8)</sup>	nil	(7,515,018)	(0.12)	62,028,518

### Notes:

1. Net loss of \$12,728,484 included general and administration of \$10,389,712, research and development of \$3,750,688, and a loss on foreign exchange of \$142,033. These are partially offset by a change in derivative liability of \$1,352,085, and interest income of \$201,864.
2. Net loss of \$6,590,873 included general and administration of \$5,031,702, and research and development of \$2,709,644. These are partially offset by a change in derivative liability of \$691,047, a gain on foreign exchange of \$152,017, and interest income of \$307,409.
3. Net loss of \$9,179,632 included general and administration of \$5,082,552, research and development of \$3,322,929, and change in derivative liability of \$1,808,603. These are partially offset by the gain on foreign exchange of \$628,935, interest income of \$377,294, and other income of \$28,223.
4. Net loss of \$7,637,017 included general and administration of \$3,988,373, research and development of \$4,040,455, and a loss on foreign exchange of \$628,148. These are partially offset by interest income of \$448,303, and a change in derivative liability of \$571,656.
5. 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.
6. 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. These are partially offset by interest income of \$528,697.

7. Net loss of \$7,089,336 included research and development of \$4,127,696, and general and administration of \$3,658,440. These are partially offset by interest income of \$545,927.
8. 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.
9. Basic and fully diluted.

## **Discussion of Operations**

### **Nine months ended September 30, 2024, compared to the nine months ended September 30, 2023**

For the nine months ended September 30, 2024, the Corporation's net loss was \$28,498,989, compared to a net loss of \$20,491,275 for the nine months ended September 30, 2023. The increase in net loss of \$8,007,714 is a result of the following:

- Research and development decreased to \$9,783,261 for the nine months ended September 30, 2024, compared to \$10,183,832 for the nine months ended September 30, 2023. During the nine months ended September 30, 2024, the Corporation incurred research and development costs related to basic science, pre-clinical studies, and clinical studies, specifically relating to the ARCHER and MAVERIC-Pilot, in the amount of \$4,082,761 and \$1,866,829, respectively. This compares to \$3,704,637 and \$1,565,878, respectively, relating to ARCHER and MAVERIC-Pilot for the nine months ended September 30, 2023.
- General and administration expenses increased to \$20,503,966 for the nine months ended September 30, 2024, compared to \$11,572,844 for the nine months ended September 30, 2023. The increase was a result of an increase in non-cash share-based compensation.
- The net loss for the nine months ended September 30, 2024, is partially offset by a gain on the change in derivative liability, based on the revaluation as at September 30, 2024, of \$234,529, compared to the loss on the change in derivative liability for the nine months ended September 30, 2023, of \$389,931.
- The net loss is partially offset by a gain on foreign exchange during the nine months ended September 30, 2024, of \$638,919, compared to a loss on foreign exchange during the nine months ended September 30, 2023, of \$84,569. This is mainly the result of the revaluation of funds held in USD.
- The net loss is partially offset by interest income during the nine months ended September 30, 2024, of \$886,567, compared to interest income during the nine months ended September 30, 2023, of \$1,590,162. The decrease is the result of a decrease in cash balance.

### **Three months ended September 30, 2024, compared to the three months ended September 30, 2023**

For the three months ended September 30, 2024, the Corporation's net loss was \$12,728,484, compared to a net loss of \$5,930,185 for the three months ended September 30, 2023. The increase in net loss of \$6,798,299 is a result of the following:

- Research and development increased to \$3,750,688 for the three months ended September 30, 2024, compared to \$2,576,751 for the three months ended September 30, 2023. During the three months ended September 30, 2024, the Corporation incurred research and development costs related to basic science, pre-clinical studies, and clinical studies, specifically relating to the ARCHER and MAVERIC-Pilot, in the amount of \$1,306,814 and \$660,377, respectively. This compares to \$1,156,460 and \$527,591, respectively, relating to ARCHER and MAVERIC-Pilot for the three months ended September 30, 2023.
- General and administration expense increased to \$10,389,712 for the three months ended September 30, 2024, compared to \$5,079,140 for the three months ended September 30, 2023. The increase was a result of an increase in non-cash share-based compensation.

- The net loss for the three months ended September 30, 2024, is partially offset by the gain on the change in derivative liability, based on the revaluation as at September 30, 2024, of \$1,352,085, compared to the gain on the change in derivative liability for the three months ended September 30, 2023, of \$392,881.
- The net loss included a loss on foreign exchange during the three months ended September 30, 2024, of \$142,033, compared to a gain on foreign exchange during the three months ended September 30, 2023, of \$667,548. This is mainly the result of the revaluation of funds held in USD.
- The net loss is partially offset by interest income during the three months ended September 30, 2024, of \$201,864, compared to interest income during the three months ended September 30, 2023, of \$515,538. The decrease is the result of a decrease in cash balance.

## **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, 2024, totaled \$10,431,375 (December 31, 2023 – \$28,246,507).

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 Capital Resources**

At September 30, 2024, Cardiol had \$15,885,018 in cash and cash equivalents (December 31, 2023 – \$34,931,778).

At September 30, 2024, accounts payable and accrued liabilities were \$6,918,639 (December 31, 2023 – \$8,041,485). The Corporation's cash and cash equivalents balances as at September 30, 2024, and December 31, 2023, 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. Future financing may come from product sales, licensing arrangements, research and commercial development partnerships, government grants, and/or corporate finance arrangements.

We expect to continue to incur substantial losses as we continue our research and development efforts. We continue to manage our research and development plan to ensure optimal use of our existing resources as we expect to fund our operations and capital requirements, associated with achieving our corporate milestones, with existing working capital (See "Outlook"). We expect to continue to incur additional costs associated with operating as a public company. Factors that may affect our anticipated cash usage, but are not limited to, expansion of our clinical trial programs, the timing of

patient enrollment in our clinical trials, the actual costs incurred to support each clinical trial, the number of treatments each patient will receive, the timing of research and development activity with our clinical trial research collaborations, and other factors described in the "Risk Factors" section.

As of September 30, 2024, December 31, 2023, 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 are minimal. Accounts payable and accrued liabilities are short-term and non-interest bearing.

#### For the 2024 Fiscal Period

Cash and cash equivalents used in operating activities were \$19,467,574 for the nine months ended September 30, 2024. Operating activities were affected by a net loss of \$28,498,989 and the net change in non-cash working capital balances of \$(1,921,976), and partially offset by other non-cash adjustments of \$10,953,391. Non-cash adjustments mainly consisted of \$11,130,090 for share-based compensation, \$(234,529) for change in derivative liability and \$(286,123) for unrealized foreign exchange gain on cash. Non-cash working capital was mainly the result of a decrease in accounts payable and accrued liabilities of \$1,746,589.

Cash and cash equivalents used in investing activities were \$15,131 for the nine months ended September 30, 2024 as a result of the purchase of property and equipment.

Cash and cash equivalents provided by financing activities were \$149,822 for the nine months ended September 30, 2024, as a result of the proceeds from stock options exercises.

#### Use of Working Capital

As of September 30, 2024, Cardiol's working capital was \$10,327,648. Based on current projections, Cardiol believes that this amount is sufficient to fund operations and capital requirements, associated with achieving corporate milestones, into 2026, as described in the "Outlook" section above.

The Corporation has material commitments and obligations for cash resources set out below. The Corporation has no commitments for capital expenditures.

<b>Contractual Obligations</b>	<b>Total (\$)</b>	<b>Up to 1 year (\$)</b>	<b>1 – 3 years (\$)</b>	<b>4 – 5 years (\$)</b>	<b>After 5 years (\$)</b>
Amounts payable and other liabilities	6,918,639	6,918,639	Nil	Nil	Nil
Office lease <sup>(1)</sup>	437,822	107,222	214,444	116,156	Nil
Consulting agreements	290,456	218,130	72,326	Nil	Nil
Contract research	2,392,810	1,994,005	398,805	Nil	Nil
<b>Total</b>	<b>10,039,727</b>	<b>9,237,996</b>	<b>685,575</b>	<b>116,156</b>	<b>Nil</b>

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, paid to a company, Dalton Chemical Laboratories, Inc. operating as Dalton ("Dalton"), that was previously related to a Director (Peter Pekos). As at December 31, 2023 - \$416,792 was owed to this company and this amount was included in accounts payable and accrued liabilities. Cardiol has 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 September 30, 2024	Three months ended September 30, 2023	Nine months ended September 30, 2024	Nine months ended September 30, 2023
Salaries and benefits	\$ 567,797	\$ 536,320	\$ 2,372,536	\$ 2,240,796
Share-based payments	2,175,162	248,870	2,450,893	779,880
	<b>\$ 2,742,959</b>	<b>\$ 785,190</b>	<b>\$ 4,823,429</b>	<b>\$ 3,020,676</b>

As at September 30, 2024, \$nil (December 31, 2023 - \$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 valuation of performance share units;
- 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 whether performance conditions on share-based awards were market or non-market, and whether the fair value of the goods or services provided by certain non-employees could be reliably measured;
- Management applied judgment in determining the Corporation's ability to continue as a going concern. The Corporation has incurred significant losses since its 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 81,603,422 issued and outstanding common shares; 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:

#### Stock Options

<b>Expiry date</b>	<b>Exercise price (\$)</b>	<b>Options outstanding</b>	<b>Options exercisable</b>
February 23, 2025	3.54	20,000	20,000
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	1.35 <sup>(1)</sup>	25,000	25,000
December 8, 2026	3.59	325,000	216,667
January 11, 2027	2.18	220,000	146,667
March 1, 2027	2.56	350,000	175,000
May 12, 2027	1.46	70,000	46,667
September 12, 2027	1.61	207,500	138,334
<b>Total</b>		<b>1,457,500</b>	<b>1,008,335</b>

<sup>(1)</sup> Exercise price denoted in USD.

#### Performance Share Units

The Corporation has 200,000 outstanding performance share units ("PSUs") subject to vesting conditions specific to each grant.

#### Restricted Share Units

The Corporation has 5,057,869 outstanding restricted share units ("RSUs") subject to vesting conditions specific to each grant. Of the outstanding RSUs, 2,280,368 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 assets consist 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 2024 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 \$1,056,000 (December 31, 2023 - \$2,770,000).

## Commitments and Contingency

(i) The Corporation has leased premises from third parties. The minimum committed lease payments as at September 30, 2024, which include the lease liability payments, are as follows:

<b>Fiscal year</b>	
2024	\$ 26,805
2025	107,222
2026	107,222
2027	107,222
2028	89,351
<b>Total</b>	<b>\$ 437,822</b>

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

<b>Fiscal year</b>	
2024	\$ 218,130
2025	72,326
<b>Total</b>	<b>\$ 290,456</b>

(iii) Pursuant to the terms of agreements with various other contract research organizations, the Corporation is committed for the following contract research services:

<b>Fiscal year</b>	
2024	\$ 967,116
2025	1,298,663
2026	127,031
<b>Total</b>	<b>\$ 2,392,810</b>

### Breakdown of Expensed Research and Development

	<b>Three months ended September 30, 2024</b>	<b>Three months ended September 30, 2023</b>	<b>Nine months ended September 30, 2024</b>	<b>Nine months ended September 30, 2023</b>
Contract research	\$2,276,089	\$1,915,913	\$6,860,413	\$7,568,799
Wages	360,011	437,472	1,399,604	1,413,479
Supplies	-	112	3,612	534,284
Regulatory	142,162	127,677	467,633	375,801
Share-based compensation	972,426	95,577	1,051,999	291,469
	<b>\$3,750,688</b>	<b>\$2,576,751</b>	<b>\$9,783,261</b>	<b>\$10,183,832</b>

### Breakdown of Intangible Assets

	<b>As at September 30, 2024</b>	<b>As at December 31, 2023</b>
Exclusive global license agreement	\$ 767,228	\$ 767,228
Accumulated amortization	(767,228)	(556,870)
<b>Carrying value</b>	<b>\$ -</b>	<b>\$ 210,358</b>

### 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 DCP and ICFR were adequately designed and operating effectively to provide such assurance as at September 30, 2024.

### 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 is also 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.

There have been no changes in internal controls over financial reporting for the quarter ended September 30, 2024, that

have materially affected, or are reasonably likely to materially affect, the Corporation's ICFR.

### **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, 2023 (available on SEDAR+ at [sepdarplus.ca](http://sepdarplus.ca) and EDGAR at [www.sec.gov](http://www.sec.gov)).

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