

# CARDIOL THERAPEUTICS INC. MANAGEMENT'S DISCUSSION AND ANALYSIS THREE AND SIX MONTHS ENDED JUNE 30, 2025

# 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 six months ended June 30, 2025 (the "2025 Fiscal Period"). This discussion should be read in conjunction with the consolidated financial statements for the years ended December 31, 2024, and 2023, and the unaudited condensed interim consolidated financial statements for the three and six months ended June 30, 2025 ("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 and International Accounting Standard as issued by the International Accounting Standards Board (IASB) and Interpretations (collectively "IFRS Accounting Standards"). 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 August 13, 2025. 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 August 13, 2025, 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 includes certain "forward looking information" within the meaning of applicable Canadian securities legislation (collectively, "Forward-Looking Information"). 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 or references to future periods. All information other than historical facts, included in this MD&A that address activities, events or developments that the Corporation expects or anticipates will or may occur in the future, including such things as future business strategy, competitive strengths, goals, expansion and growth of the Corporation's business, operations, plans and other such matters is intended to identify forward-looking information. Statements containing forward-looking information are not historical facts.

The Corporation has based the 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, but not limited to, 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 it believes are appropriate and are subject to risks and uncertainties. Although we believe that the assumptions underlying these statements are reasonable, they may prove to be incorrect, and we cannot assure that actual results will be consistent with this forward-looking information. Given these risks, uncertainties, and assumptions, prospective investors should not place undue reliance on this forward-looking information. Whether actual results, performance, or achievements will conform to the Corporation's expectations and predictions is subject to a number of known and unknown risks, uncertainties, assumptions, and other factors, including those listed under "*Risk Factors*", which include:

- the inherent uncertainty of product development 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 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 the common shares;
- 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 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;
- 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;

- delays in the timing of regulatory authority decision-making, actions, and meetings as a result of workforce realignment, and potentially significant reductions in workforce or other resources, including at the United States Food and Drug Administration ("U.S. FDA") and other U.S. federal agencies;
- 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;
- inability to expand our business to other jurisdictions;
- fraudulent activities of employees, contractors, and consultants;
- our reliance on key inputs and their related costs;
- difficulty associated with forecasting demand for products;
- · operating risk and insurance coverage;
- our inability to manage growth;
- · conflicts of interest among our officers and directors;
- managing damage to our reputation and third-party reputational risks;
- relationships with customers and third-party payors and consequential exposure to applicable anti-kickback, fraud, and abuse and other healthcare laws;
- exposure to information systems security threats;
- 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.

Although the Corporation has attempted to identify important factors that could cause actual actions, events, or results to differ materially from those described in forward-looking information, there may be other factors that cause actions, events, or results not to be as anticipated, estimated, or intended. There can be no assurance that forward-looking information will prove to be accurate, as actual results and future events could differ materially from those anticipated. The Corporation does not undertake to update forward-looking information if circumstances or management estimates, assumptions, or opinions should change, except as required by applicable law. The reader is cautioned not to unduly rely on forward-looking information. Prospective investors shall be advised that these cautionary remarks expressly qualify all forward-looking statements attributable to the Corporation or persons acting on our behalf.

### 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".

Cardiol Therapeutics Inc. is a clinical-stage life sciences company focused on developing anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease. The Corporation's lead small molecule drug candidate, CardiolRx<sup>TM</sup> (cannabidiol) oral solution, is pharmaceutically manufactured and in clinical development for use in the treatment of heart disease. It is recognized that cannabidiol modulates 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 U.S. 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 completed Phase II MAVERIC-Pilot study (NCT05494788) and the ongoing Phase III MAVERIC trial (NCT06708299). The completed 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 2025 Fiscal Period**

(i) In February 2025, the Corporation announced publication of research in the *Journal of the American College of Cardiology: Basic to Translational Science* ("*JACBTS*"), titled "Cannabidiol Prevents Heart Failure Dysfunction and Remodeling Through Preservation of Mitochondrial Function and Calcium Handling," that Supports Development of its Proprietary Subcutaneous Drug Candidate, CRD-38, for the Treatment of Heart Failure. This research was conducted by scientists from TecSalud who, together with researchers from the DeBakey Heart and Vascular Center in Houston, TX, are collaborating with Cardiol on the development of the Corporation's proprietary subcutaneous formulation of cannabidiol, CRD-38, to treat heart failure with preserved ejection fraction. These newly published data demonstrate that pharmaceutically manufactured cannabidiol, administered subcutaneously, provides cardioprotection in a preclinical model of heart failure by improving cardiac function and reducing cardiac hypertrophy, remodeling, inflammation, and cell death, and provides additional important rationale for the development of CRD-38 as a new approach to the treatment of heart failure.

The JACBTS publication comprises results from multiple models of heart failure:

- an in vivo model of angiotensin II-induced heart failure
  - Subcutaneous administration resulted in attenuation of cardiac fibrosis, hypertrophy, and inflammation, and also improved ejection fraction and cardiac output.
- an ex vivo analysis of heart failure ventricular myocytes from the in vivo model
  - Cannabidiol preserved mitochondrial function and redox balance resulting in both cell shortening and calcium handling.
- an in vitro investigation in hypertrophic cardiac myoblast cells
  - Cannabidiol provided a cardioprotective effect that may be dependent on peroxisome proliferatoractivated receptor gamma activation, thereby decreasing mitochondrial calcium uniporter hyperactivity and preventing mitochondrial dysfunction.
- (ii) In April 2025, the Corporation announced the enrollment of the first patient in its Phase III MAVERIC trial ("MAVERIC") evaluating CardiolRx™ for the prevention of recurrent pericarditis.
- (iii) In May 2025, the Corporation announced the election of Dr. Timothy Garnett to the Corporation's Board of Directors at its 2025 Annual General Meeting of shareholders.

Dr. Garnett is a distinguished pharmaceutical industry executive with over 30 years' experience, including two decades at Eli Lilly and Company, where he served as Chief Medical Officer from 2008 until his retirement in 2021. During his tenure at Eli Lilly, he led the successful development of therapeutics in women's health, endocrinology, and neuroscience, resulting in multiple global commercial launches. Dr. Garnett has played a key role in the successful development of numerous drugs across both early- and late-stage clinical development. He has broad experience leading clinical development, portfolio management, medical affairs, regulatory strategy, and safety functional areas, and has a strategic understanding of the evolving metabolic therapy landscape.

# Subsequent to June 30, 2025

(i) In August 2025, the Corporation announced topline results from the Phase II ARCHER trial of CardiolRx™ in Acute Myocarditis. See "ARCHER Program – Phase II Trial – Acute Myocarditis (ARCHER)".

### MAVERIC PROGRAM

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, usually viral, 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 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 U.S.\$20,000 and U.S.\$30,000 in the U.S.².

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 Program is led by an independent Advisory Committee and key trial investigators, consisting of international thought leaders in cardiovascular disease, including:

- MAVERIC Program 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;
- MAVERIC Program Co-Chair: Massimo Imazio, MD, FESC Departments of Medicine (DMED), University of Udine and Cardiotoracic Department, University Hospital Santa Maria della Misericordia, Udine, Italy;
- MAVERIC-Pilot Phase II Study Principal 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:
- MAVERIC Phase III Trial Principal Investigator: Paul Cremer, MD Departments of Medicine and Radiology, Northwestern University, and Multimodality Cardiac Imaging and Clinical Trials Unit, Bluhm Cardiovascular Institute;
- Antonio Abbate, MD, PhD Ruth C. Heede Professor of Cardiology, School of Medicine, and Department of Medicine, Division of Cardiovascular Medicine - Heart and Vascular Center, University of Virginia; and
- **Stephen Nicholls, MBBS, PhD** Program Director, Victorian Heart Hospital, Director, Monash Victorian Heart Institute, and Professor of Cardiology, Monash University, Melbourne.

# Recurrent Pericarditis – Phase II MAvERIC-Pilot Study (MAvERIC-Pilot)

The completed MAvERIC-Pilot open label study 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 change in NRS pain score after 26 weeks of treatment, and changes in high

sensitivity CRP. Importantly, the study assessed freedom from pericarditis recurrence.

In June 2024, the Corporation reported positive topline 8-week clinical data from its MAVERIC-Pilot study and in November 2024, the Corporation reported comprehensive MAVERIC-Pilot study results concurrent with the American Heart Association Scientific Sessions 2024. The data were included in an oral presentation as part of the Laennec Clinician-Educator Award & Lecture at the American Heart Association Scientific Sessions 2024. Dr. S. Allen Luis, Co-Director of the Pericardial Diseases Clinic and Associate Professor of Medicine in the Department of Cardiovascular Medicine at the Mayo Clinic, presented on behalf of the MAVERIC-Pilot investigators.

The MAVERIC-Pilot study enrolled 27 participants (average age 53 years; 67% female) with symptomatic recurrent pericarditis at eight clinical sites across the United States. Baseline characteristics reflected a patient cohort with high disease burden. Average disease duration and the number of pericarditis episodes per year prior to trial entry were 2.7 years and 5.8 events per year, respectively. The number of previous episodes of pericarditis were as follows: 9 patients (33%) with 2 previous episodes; 9 (33%) with 3; 4 (15%) with 4; and 5 (19%) with >4. Baseline pericarditis pain score averaged 5.8 out of 10 and the CRP level averaged 2.0 mg/dL. In addition to pericarditis chest pain, other manifestations of pericarditis-confirmed diagnosis were pericardial effusion in 21 patients (78%), pericardial rub in 4 (15%), and ST-segment elevation or PR depression in 5 (19%). Stable doses of baseline medications for recurrent pericarditis, in any combination, included colchicine (85% of patients), non-steroidal anti-inflammatory drugs (78%), and corticosteroids (41%). The 26-week study consisted of an 8-week treatment period ("TP") followed by an 18-week extension period ("EP"). In the first 10 days of the TP, CardiolRx™ was added to baseline medications for recurrent pericarditis and up titrated to 10 mg/kg twice daily, or the maximum tolerated dose. Throughout the TP, patients continued receiving this concomitant therapy but were weaned off baseline medications during the EP to assess pericarditis recurrence while on CardiolRx™ monotherapy.

# Key results:

- Primary endpoint of patient-reported pericardial pain on the 11-point NRS from 0-10 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 week 8. 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'.
- Median time to resolution or near resolution of pain (defined as a score of <= 2) was rapid and was observed just 5
  days following initiation of CardiolRx™ treatment.</li>
- At week 8, 93% (25/27) of patients reported a pain score reduction.
- Reduction in pain was maintained throughout the duration of the trial with a mean reduction of 4.3, from 5.8 at baseline to 1.5 at week 26.
- CRP levels for the entire group of patients were reduced from 2.0 mg/dL at baseline to 0.74 and 0.55 at weeks 8 and 26 respectively, with a median time to CRP normalization of 21 days. 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.
- CRP normalized (<=0.5 mg/dL) at week 8 in 80% (8/10) of the patients with a baseline CRP of >=1 mg/dL, with a substantial mean reduction of 5.4 mg/dL being observed (5.7mg/dL to 0.3 mg/dL).
- Freedom from recurrence was maintained in 71% (17/24) of patients during the EP when CardiolRx™ was continued, and patients were weaned off baseline medications. For those patients experiencing a recurrence the median time to an episode was 7.7 weeks during the EP.
- Number of pericarditis episodes per year was markedly reduced from 5.8 prior to study to 0.9 during the study.
- CardiolRx<sup>™</sup> was well tolerated with eighty-nine percent of patients (24/27) progressing to the EP and overall study drug compliance reported at 95%.

In summary, marked, rapid, and durable reductions in both pericarditis pain and inflammation were observed in MAvERIC-Pilot and importantly these reductions were maintained throughout the 6-month study in a recurrent pericarditis population who presented with significant disease burden. In addition, CardiolRx™ substantially reduced the number of pericarditis episodes per year.

On the basis of the MAvERIC-Pilot findings, Cardiol commenced patient enrollment in a Phase III clinical trial designed to definitively demonstrate the impact of CardiolRx™ on pericarditis recurrence in a patient population at high risk for recurrence. See "Phase III Trial – Recurrent Pericarditis (MAVERIC)".

# Phase III Trial – Recurrent Pericarditis (MAVERIC)

MAVERIC is a randomized, double-blind, placebo-controlled Phase III trial and is expected to enroll 110 patients at approximately 20 clinical sites across the United States, Canada & Europe. 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 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 75% and onset is rapid following cessation of IL-1 blocker therapy.

The primary efficacy endpoint is the number of study subjects (percentage) free from a new episode of recurrent pericarditis at 24 weeks. The secondary endpoint is the median time to new recurrent episode and exploratory endpoints will assess the change in NRS and CRP.

CardiolRx<sup>™</sup> 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<sup>™</sup> has led to marked reductions in pericarditis pain. This evidence provides the rationale for undertaking MAVERIC.

The Corporation has budgeted costs to complete this study to be approximately \$11 million. The first patient was enrolled in April 2025, with completion of enrolment anticipated to be during H1 2026. If Cardiol determines that the Phase III study meets its objectives, the details of next steps will be determined in conjunction with its external clinical advisors and regulatory agencies. The Corporation may involve a pharmaceutical industry commercial partner to fund commercialization of CardiolRx™ for the treatment of recurrent pericarditis. Based on a successful end-of-Phase II meeting with the U.S. FDA and subject to MAVERIC outcomes, Cardiol believes the results from MAVERIC will support a New Drug Application.

# ARCHER PROGRAM

# 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 inhospital mortality, with average hospital charge per stay estimated at U.S.\$110,000 in the U.S. $^3$ .

Data from multiple sources, including the 'Global Burden of Disease Study', reports that the number of cases of myocarditis per year 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>.

ARCHER was 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 were evaluated after 12 weeks of double-blind therapy, consist of the following cardiac magnetic resonance imaging ("CMR") measures: left ventricular function (global longitudinal strain) and myocardial edema/fibrosis (extracellular 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, Director of the Center for Heart Failure Research at the University of Pittsburgh Medical Center;
- **Co-Chair: Leslie T. Cooper, Jr., MD** General cardiologist and the Elizabeth C. Lane, Ph.D. and M. Nadine Zimmerman, Ph.D. Professor of Internal Medicine, Mayo Clinic, Jacksonville, FL;
- **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 August 2025, the Corporation announced topline results from the ARCHER trial, which enrolled 109 patients at leading cardiovascular research centers in the United States, France, Brazil, and Israel.

In the two primary endpoints - extracellular volume ("ECV") and global longitudinal strain ("GLS") - CardiolRx $^{\text{TM}}$  showed a notable improvement in ECV (p = 0.0538) compared to placebo following 12 weeks of double-blind therapy. No significant difference was observed in GLS in a population that had preserved left ventricular ("LV") function at baseline. The reduction in ECV was associated with improvements over placebo in multiple pre-specified CMR endpoints, including a significant reduction in LV mass.

The ARCHER trial results provide compelling clinical proof of concept for CardiolRx $^{\text{TM}}$  and strongly support advancing the clinical development of CardiolRx $^{\text{TM}}$  and CRD-38 in cardiomyopathies, heart failure, and myocarditis. Consistent with findings from Cardiol's Phase II MAvERIC trial in recurrent pericarditis, CardiolRx $^{\text{TM}}$  was shown to be safe and well tolerated. The ARCHER results have been submitted for presentation at an upcoming scientific meeting and will also be submitted for publication.

The Corporation intends to discuss the full ARCHER results with key opinion leaders in myocarditis and heart failure, regulatory agencies, and representatives from the pharmaceutical industry to determine next steps. Once this determination has been made, the Corporation will provide an update regarding the timeline for completing potential

additional clinical development programs based on the ARCHER data, as well as associated costs—all of which will depend on a variety of factors. The Corporation also may involve a pharmaceutical industry partner to support additional clinical development and commercialization of CardiolRx™ and CRD-38 for the treatment of myocarditis, and other inflammatory cardiac conditions including heart failure.

# 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 (U.S.).

# 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

Within the next 12 – 18 months, the Corporation expects to achieve the following corporate milestones:

- Present and publish the results of the ARCHER trial;
- Complete the Phase III MAVERIC study evaluating CardiolRx™ in pericarditis patients at high risk for recurrence, with anticipated completion of enrolment during H1 2026;
- Advance the development of CRD-38.

The Corporation expects that the June 30, 2025, cash and cash equivalents of \$18,195,052 will be sufficient to fund operations and capital requirements associated with achieving these corporate milestones into Q3, 2026.

# **Use of Offering Proceeds**

As disclosed in the Corporation's prospectus dated October 9, 2024 (the "October 2024 Offering"), the Corporation intends to use the net proceeds of the October 2024 Offering to support the clinical development of CardiolRx™ for the treatment of recurrent pericarditis and for general and administrative expenses, working capital, and other expenses. The Corporation may reallocate the net offering proceeds that it obtained 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, and investment-grade securities. As of June 30, 2025, \$1.1M of the October 2024 Offering proceeds have been used for the clinical development of CardiolRx™ for the treatment of recurrent pericarditis.

# **Summary of Quarterly Results**

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

	Total	otal Profit or (Loss)		Total	
Three Months Ended	Revenue (\$)	Total (\$)	Per Share <sup>(9)</sup> (\$)	Assets (\$)	
June 30, 2025 <sup>(1)</sup>	nil	(8,354,371)	(0.10)	19,937,699	
March 31, 2025 <sup>(2)</sup>	nil	(8,287,653)	(0.10)	25,454,895	
December 31, 2024 <sup>(3)</sup>	nil	(8,178,310)	(0.10)	31,863,751	
September 30, 2024 <sup>(4)</sup>	nil	(12,728,484)	(0.18)	17,519,645	
June 30, 2024 <sup>(5)</sup>	nil	(6,590,873)	(0.10)	26,312,660	
March 31, 2024 <sup>(6)</sup>	nil	(9,179,632)	(0.14)	31,126,280	
December 31, 2023 <sup>(7)</sup>	nil	(7,637,017)	(0.12)	36,700,508	
September 30, 2023 <sup>(8)</sup>	nil	(5,930,185)	(0.11)	43,053,024	

### Notes:

- 1. Net loss of \$8,354,371 included general and administration of \$4,944,477, research and development of \$2,731,681, and loss on foreign exchange of \$858,880. These are partially offset by interest income of \$180,667.
- 2. Net loss of \$8,287,653 included general and administration of \$4,671,651, research and development of \$3,757,412, and loss on foreign exchange of \$106,859. These are partially offset by interest income of \$248,269.
- 3. Net loss of \$8,178,310 included general and administration of \$5,760,555, and research and development of \$4,228,869. These are partially offset by interest income of \$306,775, and gain on foreign exchange of \$1,500,692.

- 4. 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.
- 5. 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.
- 6. 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.
- 7. 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.
- 8. 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.
- 9. Basic and fully diluted.

# **Discussion of Operations**

# Six months ended June 30, 2025, compared to the six months ended June 30, 2024

For the six months ended June 30, 2025, the Corporation's net loss was \$16,642,024, compared to a net loss of \$15,770,505 for the six months ended June 30, 2024. The increase in net loss of \$871,519 is a result of the following:

- General and administration expenses decreased to \$9,616,128 for the six months ended June 30, 2025, compared
  to \$10,114,254 for the six months ended June 30, 2024. The decrease was primarily due to a decrease in
  corporate communications, marketing, and investor relations, partially offset by an increase in non-cash sharebased compensation.
- Research and development increased to \$6,489,093 for the six months ended June 30, 2025, compared to \$6,032,573 for the six months ended June 30, 2024. During the six months ended June 30, 2025, the Corporation incurred research and development costs related to basic science, pre-clinical studies, and clinical studies, specifically relating to the ARCHER and MAVERIC programs, in the amount of \$1,525,323 and \$1,878,409, respectively. This compares to \$2,775,974 and \$1,206,452, respectively, relating to the ARCHER and MAVERIC programs for the six months ended June 30, 2024.
- During the six months ended June 30, 2025, there was no gain or loss on the change in derivative liability, compared to the loss on the change in derivative liability for the six months ended June 30, 2024, of \$1,117,556.
- A loss on foreign exchange is included in the net loss for the six months ended June 30, 2025, of \$965,739, compared to a gain on foreign exchange during the six months ended June 30, 2024, of \$780,952. This is mainly the result of the revaluation of funds held in USD.

# Three months ended June 30, 2025, compared to the three months ended June 30, 2024

For the three months ended June 30, 2025, the Corporation's net loss was \$8,354,371, compared to a net loss of \$6,590,873 for the three months ended June 30, 2024. The increase in net loss of \$1,763,498 is a result of the following:

Research and development slightly increased to \$2,731,681 for the three months ended June 30, 2025, compared to \$2,709,644 for the three months ended June 30, 2024. During the three months ended June 30, 2025, the Corporation incurred research and development costs related to basic science, pre-clinical studies, and clinical studies, specifically relating to the ARCHER and MAVERIC programs, in the amount of \$592,413 and \$924,114,

respectively. This compares to \$1,389,279 and \$499,955, respectively, relating to ARCHER and MAvERIC-Pilot for the three months ended June 30, 2024.

- General and administration expense decreased slightly to \$4,944,477 for the three months ended June 30, 2025, compared to \$5,031,702 for the three months ended June 30, 2024. The decrease was a result of reductions in corporation communications, marketing, and investor relations, partially offset by an increase in non-cash share-based compensation.
- Included in the net loss for the three months ended June 30, 2025 is a loss on foreign exchange during of \$858,880, compared to a gain on foreign exchange during the three months ended June 30, 2024, of \$152,017. This is mainly the result of the revaluation of funds held in USD.
- During the three months ended June 30, 2025, there was no gain or loss on the change in derivative liability, compared to the gain on the change in derivative liability for the three months ended June 30, 2024, of \$691,047.

# **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 June 30, 2025, totaled \$11,807,875 (December 31, 2024 – \$24,728,483).

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 June 30, 2025, Cardiol had \$18,195,052 in cash and cash equivalents (December 31, 2024 – \$30,580,029).

At June 30, 2025, accounts payable and accrued liabilities were \$7,987,270 (December 31, 2024 – \$6,976,736). The Corporation's cash and cash equivalents balances as at June 30, 2025, and December 31, 2024, 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 June 30, 2025, December 31, 2024, 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 2025 Fiscal Period

Cash and cash equivalents used in operating activities were \$11,704,341 for the six months ended June 30, 2025. Operating activities were affected by a net loss of \$16,642,024 and the net change in non-cash working capital balances of \$519,531, and partially offset by other non-cash adjustments of \$4,418,152. Non-cash adjustments mainly consisted of \$3,687,156 for share-based compensation. Non-cash working capital was mainly the result of an increase in accounts payable and accrued liabilities of \$1,010,534, partially offset by an increase in prepaid expenses of \$572,737.

Cash and cash equivalents used in investing activities were \$18,378 for the six months ended June 30, 2025 as a result of the purchase of property and equipment.

Cash and cash equivalents provided by financing activities were \$6,572 for the six months ended June 30, 2025, as a result of exercise of stock options, partially offset by the payment of lease liability during the period.

# **Use of Working Capital**

As of June 30, 2025, Cardiol's cash and cash equivalents were \$18,195,052 and working capital was \$11,751,359. Based on current projections, Cardiol believes that this amount is sufficient to fund operations and capital requirements, associated with achieving corporate milestones into Q3 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.

	Total	Up to 1 year	1 – 3 years	4 – 5 years	After 5 years
Contractual Obligations	(\$)	(\$)	(\$)	(\$)	(\$)
Amounts payable and other liabilities	7,987,270	7,987,270	Nil	Nil	Nil
Office lease <sup>(1)</sup>	357,406	107,222	214,444	35,740	Nil
Consulting agreements	317,629	200,199	117,430	Nil	Nil
Contract research	1,372,917	1,303,002	69,915	-	Nil
Total	10,035,222	9,597,693	401,789	35,740	Nil

### Note:

<sup>(1)</sup> The Corporation has leased premises from third parties.

# **Related Party Transactions**

a) 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 was as follows:

	Three months ended June 30, 2025 (\$)	Three months ended June 30, 2024 (\$)	Six months ended June 30, 2025 (\$)	Six months ended June 30, 2024 (\$)
Salaries and benefits	\$ 570,714	\$ 540,335	\$ 1,875,727	\$ 1,804,739
Share-based payments	469,829	154,291	938,789	275,731
	\$ 1,040,543	\$ 694,626	\$ 2,814,516	\$ 2,080,470

As at June 30, 2025, \$nil (December 31, 2024 - \$nil) was owed to key Management personnel.

# 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 share-based awards, including performance share units;
- The estimate of the percentage of completion of certain research and development agreements; and
- The valuation of income tax accounts.

# 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; and
- 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.

# **Future Accounting Policies**

In April 2024, the IASB issued IFRS 18, focusing on presentation and disclosure in financial statements. Key changes would impact the structure of the consolidated statement of loss and comprehensive loss and amendments to disclosure requirements for certain profit or loss performance measures. IFRS 18 will replace IAS 1, effective reporting period beginning on January 1, 2027. This will also impact comparative information at the point of adoption.

An assessment of the applicability of the new standard will be performed on the consolidated financial statements to

which the pronouncement applies.

# **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 83,729,448 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**

	Exercise	Options	Options
Expiry date	price (\$)	outstanding	exercisable
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
December 8, 2026	3.59	325,000	325,000
January 11, 2027	2.18	220,000	220,000
March 1, 2027	2.56	200,000	200,000
March 9, 2027	1.55	1,200,000	50,000
May 12, 2027	1.46	70,000	70,000
September 13, 2027	1.61	207,500	138,334
July 7, 2029	2.07	30,000	10,000
August 19, 2029	1.50	30,000	-
May 25, 2030	1.49	120,000	-
May 25, 2030	2.12	100,000	-
May 29, 2030	1.59	60,000	-
Total		1,802,500	1,253,334

# Performance Share Units

The Corporation has 2,447,277 outstanding performance share units ("PSUs") subject to vesting conditions specific to each grant. Of the outstanding PSUs, 1,724,000 have fully vested as of the date of this MD&A.

# **Restricted Share Units**

The Corporation has 4,811,566 outstanding restricted share units ("RSUs") subject to vesting conditions specific to each grant. Of the outstanding RSUs, 3,013,236 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 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.

# **Impairment**

The Corporation assesses all information available, including on a forward-looking basis the expected credit losses associated with any financial assets carried at amortized cost. The impairment methodology applied depends on whether there has been a significant increase in credit risk. To assess whether there is a significant increase in credit risk, the Corporation compares the risk of a default occurring on the asset as at the reporting date with the risk of default as at the date of initial recognition based on all information available, and reasonable and supportive forward-looking information.

### **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 fair value of all financial instruments approximates their carrying amounts due to the relatively short period to maturity.

# **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 2025 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 \$778,000 (December 31, 2024 – \$1,985,000).

# **Commitments and Contingency**

(i) The Corporation has leased premises from third parties. The minimum committed lease payments as at June 30, 2025, which include the lease liability payments, are as follows:

Fiscal year	
2025	53,611
2026	107,222
2027	107,222
2028	89,351
Total	\$ 357,406

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

Fiscal year	
2025	\$ 200,199
2026	83,231
2027	34,199
Total	\$ 317,629

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

Fiscal year	
2025	\$ 1,280,272
2026	44,306
2027	23,085
2028	25,254
Total	\$ 1,372,917

# **Breakdown of Expensed Research and Development**

	Three months ended June 30, 2025	Three months ended June 30, 2024	Six months ended June 30, 2025	Six months ended June 30, 2024
Contract research	\$1,839,535	\$2,145,786	\$4,134,236	\$4,584,324
Wages	379,900	391,755	1,200,146	1,039,593
Supplies	(165)	913	6,297	3,612
Regulatory	200,355	144,961	527,730	325,471
Share-based compensation	312,056	26,229	620,684	79,573
	\$2,731,681	\$2,709,644	\$6,489,093	\$6,032,573

# **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 Accounting Standards. The CEO and CFO have concluded that the DCP and ICFR were adequately designed and operating effectively to provide such assurance as at June 30, 2025.

### **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 June 30, 2025, 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, 2024 (available on SEDAR+ at sepdarplus.ca and EDGAR at www.sec.gov).

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