CARDIOL THERAPEUTICS INC.
MANAGEMENT'S DISCUSSION AND ANALYSIS
YEAR ENDED DECEMBER 31, 2024

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 year ended December 31, 2024 (the "2024 Fiscal Period"). This discussion should be read in conjunction with the consolidated financial statements for the years ended December 31, 2024 and 2023 ("Financial Statements"), together with the respective notes thereto. The Financial Statements and the financial information contained in this MD&A are prepared in accordance with International Financial Reporting Standards and International Accounting Standards 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 March 31, 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 March 31, 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 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 re-alignment, and potentially significant reductions in workforce or other resources, including at FDA and other US 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™ (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 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 completed Phase II MAvERIC-Pilot study (NCT05494788) and the ongoing Phase III MAVERIC trial (NCT06708299). The ongoing 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 US 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[1].

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 granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis (a rare disease) 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”). See "Phase II Trial – Acute Myocarditis (ARCHER)".

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, as well as normalization of inflammation – as measured by C-reactive protein (“CRP”) – in 80% of patients with elevated CRP at baseline. See "Phase II Open Label Pilot Study - Recurrent Pericarditis (MAvERIC-Pilot)".

(vii) In September 2024, the Corporation announced that it had achieved its target patient enrollment of 100 patients for the ARCHER trial. See "Phase II Trial – Acute Myocarditis (ARCHER)".

(viii) 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.

(ix) In October 2024, the Corporation announced plans to expand the MAVERIC clinical development program and advance CardiolRx™ into a Phase III clinical trial (“MAVERIC”) to evaluate the impact of CardiolRx™ in a recurrent pericarditis patient population at high risk for recurrence. See “Phase III Trial – Recurrent Pericarditis (MAVERIC)”.

(x) In November 2024, the Corporation announced MAVERIC-Pilot results at the American Heart Association Scientific Sessions 2024. The study demonstrated rapid and sustained reductions in both pericarditis pain and inflammation, with a substantial decrease in pericarditis episodes per year. See "Phase II Open Label Pilot Study - Recurrent Pericarditis (MAvERIC-Pilot)".

Subsequent to December 31, 2024

(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 Company'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 pre-clinical 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 proliferator-activated receptor gamma activation, thereby decreasing mitochondrial calcium uniporter hyperactivity and preventing mitochondrial dysfunction.

MAVERIC PROGRAM

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, 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 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[2].

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[2].

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.[2].

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 assessed the change in objective measures of disease, and during an extension period, assessed 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 with symptomatic recurrent pericarditis, 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.

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:

- **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;
- **Study Principle 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 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.
- 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™ 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 is currently in the process of initiating patient enrollment in a Phase III clinical trial designed to definitively demonstrate the impact of CardiolRx™ on pericarditis recurrence in a high-risk patient population. 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 & 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 seventy-five percent and onset is rapid following cessation of IL-1 blocker therapy.

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

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.

The Corporation has budgeted costs to complete this study to be approximately $12 million. First patient is expected to be enrolled during H1 2025, with anticipated completion of enrolment 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 commercial partner from the pharmaceutical industry to fund commercialization of CardiolRx™ for the treatment of recurrent pericarditis.

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 chemo-therapeutic agents and immune checkpoint inhibitors[3].

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.[3].

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[3].

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 enrolled patients at major cardiac centers in North America, Europe, Latin America and Israel. In September 2024, the Corporation announced that the ARCHER trial had achieved its target patient enrollment of 100 patients. 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.

The Corporation expects to report topline data from ARCHER during H1 2025. Cardiol has budgeted costs to complete this study to be approximately $1 million. If Cardiol determines that the Phase II study meets its objectives, next steps in the clinical development program will be assessed in consultation with 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:

- Complete Phase II ARCHER trial in acute myocarditis and report topline data during H1, 2025;
- Complete the Phase III MAVERIC study evaluating CardiolRx™ in pericarditis patients at high risk for recurrence with anticipated completion of enrolment to be during H1 2026;
- Advance the development of CRD-38.

The Corporation expects that the December 31, 2024, cash and cash equivalents of $30,580,029 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 December 31, 2024, no proceeds of the October 2024 Offering have been used.

Selected Annual Financial Information

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Revenue	$-	$-	$-
Net loss	$(36,677,299)	$(28,128,292)	$(30,930,647)
Net loss per share (basic and fully diluted)	$(0.51)	$(0.44)	$(0.49)
	As at December 31, 2024	**As at December 31, 2023**	**As at December 31, 2022**
Total assets	$31,863,751	$36,700,508	$62,028,518
Total long-term financial liabilities	$125,523	$158,532	$22,424

Summary of Quarterly Results

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

Three Months Ended	Total Revenue ($)	Profit or (Loss) Total ($)	Profit or (Loss) Per Share[9] ($)	Total Assets ($)
December 31, 2024[1]	nil	(8,178,310)	(0.10)	31,863,751
September 30, 2024[2]	nil	(12,728,484)	(0.18)	17,519,645
June 30, 2024[3]	nil	(6,590,873)	(0.10)	26,312,660
March 31, 2024[4]	nil	(9,179,632)	(0.14)	31,126,280
December 31, 2023[5]	nil	(7,637,017)	(0.12)	36,700,508
September 30, 2023[6]	nil	(5,930,185)	(0.11)	43,053,024
June 30, 2023[7]	nil	(7,471,754)	(0.12)	47,169,272
March 31, 2023[8]	nil	(7,089,336)	(0.11)	52,685,268

Notes:

1. 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.

2. Net loss of $12,728,484 included general and administration of $10,389,712, and 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. Basic and fully diluted.

Discussion of Operations

Year ended December 31, 2024, compared to the year ended December 31, 2023

For the year ended December 31, 2024, the Corporation's net loss was $36,677,299, compared to a net loss of $28,128,292 for the year ended December 31, 2023. The increase in net loss of $8,549,007 is a result of the following:

- Research and development decreased to $14,012,130 for the year ended December 31, 2024, compared to $14,224,287 for the year ended December 31, 2023. During the year ended December 31, 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 $5,310,037 and $3,041,331, respectively. This compares to $5,641,811 and $2,837,228, respectively, relating to ARCHER and MAvERIC-Pilot for the year ended December 31, 2023.

- General and administration expenses increased to $26,264,521 for the year ended December 31, 2024, compared to $15,561,217 for the year ended December 31, 2023. The increase was primarily due to an increase in non-cash share-based compensation.

- The net loss for the year ended December 31, 2024, is partially offset by a gain on the change in derivative liability, based on the revaluation as at December 31, 2024, of $238,176, compared to the gain on the change in derivative liability for the year ended December 31, 2023, of $181,725.

- The net loss is partially offset by a gain on foreign exchange during the year ended December 31, 2024, of $2,139,611, compared to a loss on foreign exchange during the year ended December 31, 2023, of $712,717. This is mainly the result of the revaluation of funds held in USD.

- The net loss is partially offset by interest income during the year ended December 31, 2024, of $1,193,342, compared to interest income during the year ended December 31, 2023, of $2,038,465. The decrease is the result of a decrease in cash balance.

Three months ended December 31, 2024, compared to the three months ended December 31, 2023

For the three months ended December 31, 2024, the Corporation's net loss was $8,178,310, compared to a net loss of $7,637,017 for the three months ended December 31, 2023. The increase in net loss of $541,293 is a result of the following:

- Research and development increased to $4,228,869 for the three months ended December 31, 2024, compared to $4,040,455 for the three months ended December 31, 2023. During the three months ended December 31, 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 $1,227,276 and $1,174,502, respectively. This compares to $1,937,174 and $1,271,350, respectively, relating to ARCHER and MAvERIC-Pilot for the three months ended December 31, 2023.

- General and administration expense increased to $5,760,555 for the three months ended December 31, 2024, compared to $3,988,373 for the three months ended December 31, 2023. The increase was a result of an increase in non-cash share-based compensation.

- The net loss for the three months ended December 31, 2024, is partially offset by the gain on the change in derivative liability, based on the revaluation as at December 31, 2024, of $3,647, compared to the gain on the change in derivative liability for the three months ended December 31, 2023, of $571,656.

- The net loss is partially offset by a gain on foreign exchange during the three months ended December 31, 2024 of $1,500,692. compared to a loss on foreign exchange during the three months ended December 31, 2023, of $628,148. 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 December 31, 2024 of $306,775, compared to interest income during the three months ended December 31, 2023, of $448,303. 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 December 31, 2024, totaled $24,728,483 (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 December 31, 2024, Cardiol had $30,580,029 in cash and cash equivalents (December 31, 2023 – $34,931,778).

At December 31, 2024, accounts payable and accrued liabilities were $6,976,736 (December 31, 2023 – $8,041,485). The Corporation’s cash and cash equivalents balances as at December 31, 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 December 31, 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.

<u>For the 2024 Fiscal Period</u>

Cash and cash equivalents used in operating activities were $25,060,867 for the year ended December 31, 2024. Operating activities were affected by a net loss of $36,677,299 and the net change in non-cash working capital balances of $(931,565), and partially offset by other non-cash adjustments of $12,547,997. Non-cash adjustments

mainly consisted of $14,277,406 for share-based compensation, and $(1,890,071) 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 $1,064,749.

Cash and cash equivalents used in investing activities were $21,290 for the year ended December 31, 2024 as a result of the purchase of property and equipment.

Cash and cash equivalents provided by financing activities were $18,840,337 for the year ended December 31, 2024, as a result of a public offering of common shares in October 2024, and exercise of stock options.

Use of Working Capital

As of December 31, 2024, Cardiol's working capital was $24,658,414. 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.

Contractual Obligations	Total ($)	Up to 1 year ($)	1 – 3 years ($)	4 – 5 years ($)	After 5 years ($)
Amounts payable and other liabilities	6,976,736	6,976,736	Nil	Nil	Nil
Office lease (1)	411,017	107,222	214,444	89,351	Nil
Consulting agreements	166,844	166,844	Nil	Nil	Nil
Contract research	2,122,652	2,018,692	73,864	30,096	Nil
Total	**9,677,249**	**9,269,494**	**288,308**	**119,447**	**Nil**

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

Related Party Transactions

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

   i. Included in research and development expense is $1,233,301 for the year ended December 31, 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:

	Year ended December 31, 2024	Year ended December 31, 2023
Salaries and benefits	$ 2,949,120	$ 2,779,707
Share-based payments	2,966,651	985,174
	$ 5,915,771	**$ 3,764,881**

As at December 31, 2024, $nil (December 31, 2023 - $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 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 income tax accounts; and
- Initial valuation and estimated useful lives of intangible assets.

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

(i) IFRS 18 - Presentation and disclosure in financial statements

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 82,608,992 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

Expiry date	Exercise price ($)	Options outstanding	Options 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
September 10, 2026	1.00(1)	25,000	25,000
December 8, 2026	3.59	325,000	325,000
January 11, 2027	2.18	220,000	220,000
March 1, 2027	2.56	350,000	350,000
May 12, 2027	1.46	70,000	46,667
September 12, 2027	1.61	207,500	138,334
July 7, 2029	2.07	30,000	-
March 9, 2027	1.13(1)	1,200,000	-
Total		**2,667,500**	**1,345,001**

(1) Exercise price denoted in USD.

Restricted Share Units

The Corporation has 4,852,299 outstanding restricted share units ("RSUs") subject to vesting conditions specific to each grant. Of the outstanding RSUs, 2,221,465 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 Corporation's derivative liabilities were measured at fair value Level 3. The fair value of all other 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 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 $1,985,000 (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 December 31, 2024, which include the lease liability payments, are as follows:

Fiscal year		
2025		107,222
2026		107,222
2027		107,222
2028		89,351
Total	**$**	**411,017**

(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	$	166,844
Total	**$**	**166,844**

(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	$	2,018,692
2026		52,039
2027		21,825
2028		30,096
Total	**$**	**2,122,652**

Breakdown of Expensed Research and Development

	Year ended December 31, 2024	**Year ended December 31, 2023**
Contract research	$10,209,985	$11,066,232
Wages	1,741,939	1,689,123
Supplies	3,980	534,552
Regulatory	695,282	584,530
Share-based compensation	1,360,944	349,850
	$14,012,130	$14,224,287

Breakdown of Intangible Assets

	As at December 31, 2024	**As at December 31, 2023**
Exclusive global license agreement	$ 767,228	$ 767,228
Accumulated amortization	(620,203)	(556,870)
Write-off	(147,025)	-
Carrying value	**$ -**	**$ 210,358**

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 December 31, 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 and year ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, the Corporation's ICFR.

Risk Factors

The Corporation's prospects depend on the success of our subcutaneous product candidate which is in early stages of development, and the success of our Phase II trial in acute myocarditis and Phase III trial in recurrent pericarditis. We do not expect to generate revenue for several years, if at all, from the acute myocarditis, recurrent pericarditis, and subcutaneous product candidates.

Given the early stage of development of our subcutaneous product candidate, and the uncertainty inherent in clinical trials, we can make no assurance that our research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, we, alone or with others, must successfully develop, gain regulatory approval, and market our product candidates, if approved. We currently have no products that have been approved by the FDA, Health Canada, or any similar regulatory authority. To obtain regulatory approvals for our product candidates being developed and to achieve commercial success, if approved, clinical trials must demonstrate that the product candidates are safe for human use and that they demonstrate efficacy, as determined by the appropriate regulatory agency.

Many product candidates never reach the stage of clinical testing and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Product candidates may fail for a number of reasons, including, but not limited to, being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the standard of treatment at the time of testing. Positive results of early pre-clinical research may not be indicative of the results that will be obtained in later stages of pre-clinical or clinical research. Interim results of a clinical trial do not necessarily predict final results. Similarly, positive results from early-stage clinical trials may not be indicative of favorable outcomes in later-stage clinical trials. We can make no assurance that any future studies, if undertaken, will yield favorable results. The early stage of our subcutaneous product development makes it particularly uncertain whether any of these product development efforts will prove to be successful and meet applicable regulatory requirements, and whether any of our product candidates will receive the requisite regulatory approvals, be capable of being manufactured at a reasonable cost, or be successfully marketed, if approved. If we are successful in developing our current and future product candidates into approved products, we will still experience many potential obstacles such as the need to develop or obtain manufacturing, marketing, and distribution capabilities. If we are unable to successfully commercialize any of our product candidates, our financial condition and results of operations may be materially and adversely affected.

The continued development of the Corporation will require additional financing. If we fail to raise such capital, it could result in the delay or indefinite postponement of our current business strategy, or we could cease to carry on business.

There is no guarantee that the Corporation will be able to execute on its strategy. The continued development of the Corporation will require additional financing. The failure to raise needed capital could result in the delay or indefinite postponement of current business strategy or the Corporation ceasing to carry on business. There can be no assurance that additional capital or other types of financing will be available if needed or that, if available, the terms of such financing will be favorable to the Corporation. If additional funds are raised through issuances of equity or convertible debt securities, existing shareholders could suffer significant dilution, and any new equity securities issued could have rights, preferences, and privileges superior to those of holders of common shares. In addition, from time to time, the Corporation may enter into transactions to acquire assets or the shares of other companies. These transactions may be financed wholly or partially with debt, which may temporarily increase the Corporation's debt levels above industry standards. Any debt financing secured in the future could involve restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for the Corporation to obtain additional capital and to pursue business opportunities, including potential acquisitions. Debt financings may contain provisions, which, if breached, may entitle lenders to accelerate repayment of loans and there is no assurance that the Corporation would be able to repay such loans in such an event or prevent the enforcement of security granted pursuant to such debt financing. The Corporation may require additional financing to fund its operations to the point where it is generating positive cash flows. Negative cash flow may restrict the Corporation's ability to pursue its business objectives.

In the event of bankruptcy, liquidation, or reorganization of Cardiol, holders of its debt and its trade creditors will generally be entitled to payment of their claims from the assets of Cardiol before any assets are made available for distribution to Cardiol or its shareholders. The common shares are effectively subordinated to the debt and other

obligations of Cardiol.

We intend to expend our limited resources to pursue our current product candidates, and may fail to capitalize on other product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we are focusing on research programs relating to our current product candidates, which concentrates the risk of product failure in the event that our current product candidates prove to be unsafe or ineffective or inadequate for clinical development or commercialization. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on proprietary research and development programs relating to our current product candidates may not yield any commercially viable products.

We have a history of operating losses and may never achieve or maintain profitability in the future.

It is possible that we will never have sufficient product sales revenue to achieve profitability. We expect to continue to incur losses for at least the next several years as we or our collaborators and licensees pursue clinical trials and research and development efforts. To become profitable, we, either alone or with our collaborators and licensees, must successfully market our pharmaceutical cannabidiol and develop, manufacture, and market our current product candidates, as well as continue to identify, develop, manufacture, and market new product candidates. It is possible that we will never have significant product sales revenue or receive royalties on our licensed product candidates. If funding is insufficient at any time in the future, we may not be able to develop or commercialize our products, take advantage of business opportunities, or respond to competitive pressures.

We currently do not earn any revenues from our drug candidates and are therefore considered to be in the development stage. The continuation of our research and development activities and the commercialization of the targeted therapeutic products are dependent upon our ability to successfully finance and complete our research and development programs through a combination of equity financing and payments from strategic partners. We have no current sources of significant payments from strategic partners.

We rely on Management and need additional key personnel to grow our business, and the loss of key employees or inability to hire key personnel could harm our business.

The loss of David Elsley, our President and CEO, or other key members of our staff, could harm us. We also depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial, medical, clinical, and regulatory personnel, particularly as we expand our activities and seek regulatory approvals for clinical trials. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, key opinion leaders, and academic partners in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who will recruit patients into our clinical trials on our behalf in the ordinary course of our business. Notwithstanding these arrangements, we face significant competition for these types of personnel from other companies, research and academic institutions, government entities, and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth. The loss of the services of any of our executive officers or other key personnel could potentially harm our business operating results, or financial condition.

Clinical trials for our product candidates are expensive, time consuming, uncertain, and susceptible to change, delay, or termination.

Clinical trials are expensive, time consuming, and difficult to design and implement. Even if the results of our clinical trials are favorable, the clinical trials for a number of our product candidates are expected to continue for several years and may take significantly longer to complete. In addition, we, the FDA, Health Canada or other regulatory authorities, including state and local authorities may suspend, delay, or terminate our clinical trials at any time, require us to conduct additional clinical trials, require a particular clinical trial to continue for a longer duration than originally planned, or require a change to our development plans such that we conduct clinical trials for a product candidate in a different order, e.g., in a step-wise fashion rather than running two trials of the same product candidate in parallel. Any of the foregoing could have a material adverse effect on our business, results of operations, and financial condition.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct pre-clinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete, and has uncertain outcomes. The outcome of pre-clinical studies and early clinical trials may not predict the success of later clinical trials and interim results of a clinical trial do not necessarily predict final results.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. We do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk we face is the possibility that none of our product candidates under development will successfully gain market approval from the FDA, Health Canada, or other regulatory authorities, resulting in us being unable to derive any commercial revenue from them after investing significant amounts of capital in multiple stages of pre-clinical and clinical testing.

If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, if approved, and our business may be substantially harmed.

We cannot predict whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before us, which would impair our ability to successfully commercialize our product candidates, if approved, and may harm our financial condition, results of operations, and prospects. The commencement and completion of clinical trials for our product candidates may be delayed for a number of reasons, including delays related, but not limited, to:

- failure by regulatory authorities to grant permission to proceed or placing the clinical trial on hold;
- difficulties obtaining institutional review board ("IRB") or ethics committee approval to conduct a clinical trial at a prospective site;
- import/export and research restrictions for cannabinoid-based pharmaceuticals delaying or preventing clinical trials in various geographical jurisdictions;
- patients failing to enroll or remain in our trials at the rate we expect;
- suspension or termination of clinical trials by regulators for many reasons, including concerns about patient safety or failure of our contract manufacturers to comply with cGMP requirements;
- delays or failure to obtain clinical supply from contract manufacturers of our product candidates necessary to conduct clinical trials;
- product candidates demonstrating a lack of safety or efficacy during clinical trials;
- patients choosing an alternative treatment for the indications for which we are developing any of our product candidates or participating in competing clinical trials and/or scheduling conflicts with participating clinicians;
- patients failing to complete clinical trials due to dissatisfaction with the treatment, adverse events or other reasons;
- reports of clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- clinical investigators not performing our clinical trials on their anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial protocol, and regulatory requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- failure of our Contract Research Organizations ("CROs") to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical trial sites by regulatory authorities or IRBs, or ethics committees finding regulatory violations that require us to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more IRBs or ethics committees rejecting, suspending, or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- failure to reach agreement on acceptable terms with prospective clinical trial sites.

In addition, a clinical trial may be suspended or terminated by us, the FDA, IRBs, ethics committees, data safety monitoring boards, or other foreign regulatory authorities overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- inspection of the clinical trial operations or clinical trial sites by the FDA, the European Medicines Agency, or other foreign regulatory authorities that reveal deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;
- unforeseen safety issues, including any safety issues that could be identified in our ongoing pre-clinical studies;
- adverse effects or lack of effectiveness; and
- changes in government regulations or administrative actions.

Our product development costs will increase if we experience delays in testing or approval or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur, and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to regulatory authorities, IRBs, or ethics committees for re-examination, which may impact the cost, timing, or successful completion of that trial. Delays or increased product development costs may have a material adverse effect on our business, financial condition, and prospects.

Negative results from clinical trials or studies of others and adverse safety events involving the targets of our product candidates may have an adverse impact on our future commercialization efforts.

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors, or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to our product candidates, or the therapeutic areas in which our product candidates compete, could adversely affect the price of our securities and our ability to finance future development of our product candidates, and our business and financial results could be materially and adversely affected.

Our activities are subject to comprehensive regulation, including under healthcare laws and compliance requirements.

In the United States, our activities are potentially subject to additional regulation by various federal, state, and local authorities in addition to the FDA, including, among others, the Centers for Medicare and Medicaid Services, other divisions of Health and Human Services, or HHS, (for example, the Office of Inspector General), the Department of Justice, and individual United States Attorney offices within the Department of Justice, and state and local governments.

In Canada, our activities are potentially subject to additional regulation by various federal and provincial authorities in addition to Health Canada, including among others, publicly mandated organizations given a provincial sales license under the *Cannabis Act*.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

We may not achieve our projected development goals in the time frames and cost estimates we announce and expect.

We set goals for, and make public statements regarding, the expected timing and costs of the accomplishment of objectives material to our success, the commencement and completion of clinical trials and the expected costs to develop our product candidates. The actual timing and costs of these events can vary dramatically due to factors within

and beyond our control, such as delays or failures in our clinical trials, issues related to the manufacturing of drug supply, uncertainties inherent in the regulatory approval process, market conditions, and interest by partners in our product candidates among other things. We may not make regulatory submissions or receive regulatory approvals as planned; our clinical trials may not be completed; or we may not secure partnerships for any of our product candidates. Any failure to achieve one or more of these milestones as planned would have a material adverse effect on our business, financial condition, and results of operations.

Unpredictable and volatile market price for common shares.

The market price for common shares may be volatile and subject to wide fluctuations in response to numerous factors, many of which are beyond our control, including the following:

- actual or anticipated fluctuations in our quarterly results of operations;
- recommendations by securities research analysts;
- changes in the economic performance or market valuations of companies in the industry in which we operate;
- addition or departure of our executive officers and other key personnel;
- sales or perceived sales of additional common shares;
- significant acquisitions or business combinations, strategic partnerships, joint ventures, or capital commitments by or involving us or our competitors;
- operating and share price performance of other companies that investors deem comparable to us;
- fluctuations to the costs of vital production materials and services;
- changes in global financial markets and global economies and general market conditions, such as interest rates and pharmaceutical product price volatility;
- operating and share price performance of other companies that investors deem comparable to the Corporation or from a lack of market comparable companies; and
- news reports relating to trends, concerns, technological or competitive developments, regulatory changes, and other related issues in our industry or target markets.

Financial markets have recently experienced significant price and volume fluctuations that have particularly affected the market prices of equity securities of companies and that have often been unrelated to the operating performance, underlying asset values, or prospects of such companies. Accordingly, the market price of the common shares may decline even if our operating results, underlying asset values or prospects have not changed. Additionally, these factors, as well as other related factors, may cause decreases in asset values that are deemed to be other than temporary, which might result in impairment losses. There can be no assurance that continuing fluctuations in price and volume will not occur. If such increased levels of volatility and market turmoil continue, our operations could be adversely affected, and the trading price of the common shares might be materially adversely affected.

Securities or industry analysts may publish inaccurate or unfavorable research reports, stock price, and trading volume could decline.

The trading market for our common shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common shares or publish inaccurate or unfavorable research about our business, our share price would likely decline. If one or more of these analysts cease coverage of our Corporation or fail to publish reports on us regularly, demand for our common shares could decrease, which might cause our share price and trading volume to decline.

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.

Our success, competitive position, and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes, and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights, and to operate without infringing the proprietary rights of third parties.

To date, we have exclusive rights to certain Canadian, the United States, and other foreign intellectual property. We anticipate filing additional patent applications in Canada, the United States, and in other countries, as appropriate. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Our success also depends upon the skills, knowledge, and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade-secret protection and confidentiality agreements. To this end, it is our policy generally to require our employees, consultants, advisors, and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries, and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how, or other proprietary information is disclosed, the value of our trade secrets, know-how, and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Owning a patent does not *per se* prevent competition. To stop third-party infringement, a patent owner and/or licensee must take steps to enforce the patent through court proceedings. This can be a very lengthy and costly process and the outcome may be uncertain.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The Canadian Intellectual Property Office ("CIPO") and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Periodic maintenance fees on any issued patent are due to be paid to CIPO and various foreign national or international patent agencies in several stages over the lifetime of the patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents.

If we fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

While a patent may be granted by a national patent office, there is no guarantee that the granted patent is valid. Options exist to challenge the validity of the patent which, depending upon the jurisdiction, may include re-examination, opposition proceedings before the patent office, and/or invalidation proceedings before the relevant court. Patent validity may also be the subject of a counterclaim to an allegation of patent infringement.

Pending patent applications may be challenged by third parties in protest or similar proceedings. Third parties can typically submit prior art material to patentability for review by the patent examiner. Regarding Patent Cooperation Treaty applications, a positive opinion regarding patentability issued by the International Searching Authority does not guarantee allowance of a national application derived from the Patent Cooperation Treaty application. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and the patent's scope can be modified after issuance. It is also possible that the scope of claims granted may vary from jurisdiction to jurisdiction.

The grant of a patent does not have any bearing on whether the invention described in the patent application would infringe the rights of earlier filed patents. It is possible to both obtain patent protection for an invention and yet still infringe the rights of an earlier granted patent.

We may become subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Our commercial success depends upon our ability to develop, manufacture, market, and sell our product candidates, and to use our related proprietary technologies without violating the intellectual property rights of others. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before CIPO, United States Patent and Trademark Office ("USPTO"), and other applicable patents offices in foreign jurisdictions. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing the applicable product candidate. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Therefore, we have filed applications and/or obtained patents only in key markets, such as the United States, Canada, and certain countries internationally. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and their products may compete with ours.

We rely and will continue to rely on third parties to conduct and monitor many of our pre-clinical studies and our clinical trials, and their failure to perform as required could cause substantial harm to our business.

We rely and will continue to rely, on third parties to conduct a significant portion of our pre-clinical and clinical development activities. Pre-clinical activities include *in vivo* studies providing access to specific disease models, pharmacology and toxicology studies, and assay development. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management, contract manufacturing, and quality assurance. If there is any dispute or disruption in our relationship with third parties, or if they are unable to provide quality services in a timely manner and at a feasible cost, our active development programs will face delays. Further, if any of these third parties fails to perform as we expect or if their work fails to meet regulatory requirements, our testing could be delayed, cancelled, or rendered ineffective.

Our product candidates contain compounds that may be classified as "controlled substances" in jurisdictions outside of Canada and are classified as cannabis in Canada. Outside of Canada they may be subject to controlled substance laws and regulations; within Canada they will be subject to the *Cannabis Act* and the Cannabis Regulations. In all jurisdictions, failure to receive necessary approvals may delay the launch of our products and failure to comply with these laws and regulations may adversely affect the results of our business operations.

Our product candidates contain substances related to the cannabis plant and are subject to the *Cannabis Act* and the Cannabis Regulations in Canada. As a pharmaceutical product, cannabidiol will be subject to both the *Food and Drugs Act* and regulations issued thereunder and the *Cannabis Act* and the Cannabis Regulations. This will include the need for an establishment license, import and export permits, and extensive record keeping.

In addition, since our product candidates contain a cannabinoid, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for our product candidates. These pressures could also limit or restrict the introduction and marketing of our product candidates. Adverse publicity from cannabis misuse or adverse events associated with cannabis or other cannabinoid products may adversely affect the commercial success or market penetration achievable for our product candidates. The nature of our business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed. Furthermore, if our product candidates are classified as "controlled substances", they may be subject to import/export and research restrictions that could delay or prevent the development of Cardiol's product candidates in various geographical jurisdictions.

Our ability to successfully produce our product candidates is dependent on extensive ongoing regulatory compliance and reporting requirements by the FDA, Health Canada, and other foreign regulatory authorities.

Failure to comply with such requirements could have a material adverse impact on our business, financial condition and operating results. There is no assurance that regulatory approval will be granted or continued for our product candidates. Should regulatory approval not be granted or continued, our business, financial condition, and operating results would be materially adversely affected. Even if we receive regulatory approval for our product candidates, this approval may carry conditions that limit the market for the products or put the products at a competitive disadvantage relative to alternative therapies. For instance, regulatory approval may limit the indicated uses for which we can market a product (if approved) or the patient population that may utilize the product, or the product may be required to carry a warning on its packaging. Once a product candidate is approved, we remain subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing.

If our operations are found to be in violation of any of the federal and state laws or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our product candidates (if approved) are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

In both domestic and foreign markets, the development, formulation, manufacturing, packaging, labelling, handling, distribution, import, export, licensing, sale, and storage of pharmaceuticals are affected by a body of laws, governmental regulations, administrative determinations, including those by the Canadian Food Inspection Agency and the FDA, court decisions, and similar constraints. Such laws, regulations and other constraints can exist at the federal, provincial or local levels in Canada and at all levels of government in foreign jurisdictions. We and our partners may be required to incur significant costs to comply with such laws and regulations in the future, and such laws and regulations may have an adverse effect on the business. The failure of us or our partners to comply with current or future regulatory requirements could lead to the imposition of significant penalties or claims and may have a material adverse effect on our business. In addition, the adoption of new laws, regulations or other constraints or changes in the interpretations of such requirements might result in significant compliance costs or lead us and our partners to discontinue product development and could have an adverse effect on our business.

Our ability to research, develop, and commercialize product candidates, if approved, is dependent on our ability to obtain and maintain licenses relating to possession and supply of controlled substances.

Our current manufacturing facilities are located in Canada. In Canada, various licenses are required to produce pharmaceutical cannabinoids. Our continued ability to research, develop, and commercialize our product candidates is dependent on our ability to obtain, and subsequently maintain, licenses relating to possession and supply of controlled substances. Loss of such licenses or inability to obtain such licenses could have an adverse effect on our business.

Controlled substance legislation differs between countries and legislation in certain countries may restrict or limit ability to sell products.

Most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including cannabis. Countries may interpret/implement their treaty obligations in a way that creates a legal obstacle to our obtaining marketing approval for our product candidates in those countries even though our cannabinoids are pharmaceutically manufactured and not botanically derived. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit our product candidates to be marketed, if approved, or achieving such amendments to the laws and regulations may take a prolonged period of time.

Changes in laws and regulations may make compliance challenging, costly, and time consuming for us.

Our operations are subject to a variety of laws, regulations, and guidelines relating to pharmacology, cannabinoids, and drug delivery, as well as laws and regulations relating to health and safety, the conduct of operations, and the protection

of the environment. While, to our knowledge, we are currently in material compliance with all such laws, changes to such laws, regulations and guidelines due to matters beyond our control may cause adverse effects to our operations and financial condition. These changes may require us to incur substantial costs associated with legal and compliance fees and ultimately require us to alter our business plan.

In addition, if the governments of Canada or the U.S. were to enact or amend laws relating to our industry, it may decrease the size of, or eliminate entirely, the market for our product candidates, if approved, may introduce significant new competition into the market and may otherwise potentially materially and adversely affect our business, results of operations, and financial condition.

Tax and accounting requirements may change in ways that are unforeseen to the Corporation and the Corporation may face difficulty or be unable to implement and/or comply with any such changes.

The Corporation is subject to numerous tax and accounting requirements, and changes in existing accounting or taxation rules or practices, or varying interpretations of current rules or practices, could have a significant adverse effect on the Corporation's financial results, the manner in which it conducts its business, or the marketability of any of its products (if approved). In the future, the geographic scope of the Corporation's business may expand, and such expansion will require the Corporation to comply with the tax laws and regulations of multiple jurisdictions. Requirements as to taxation vary substantially among jurisdictions. Complying with the tax laws of these jurisdictions can be time consuming and expensive and could potentially subject the Corporation to penalties and fees in the future if the Corporation were to inadvertently fail to comply. In the event the Corporation was to inadvertently fail to comply with applicable tax laws, this could have a material adverse effect on the business, results of operations, and financial condition of the Corporation.

Management may not be able to successfully implement adequate internal controls over financial reporting ("ICFR").

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. However, the Corporation does not expect that its Disclosure, Controls, and Procedures or ICFR will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be 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, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Due to the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected in a timely manner or at all. If the Corporation cannot provide reliable financial reports or prevent fraud, its reputation and operating results could be materially adversely affected, which could cause investors to lose confidence in the Corporation's reported financial information, which in turn could result in a reduction in the value of the common shares.

Medical research on cannabidiol remains limited.

Research regarding the medical benefits, viability, safety, efficacy, and dosing of cannabidiol remains limited. There have been relatively few well-designed clinical trials conducted on the benefits of cannabidiol, and the Corporation is not aware of any randomized placebo-controlled studies of cannabidiol in heart diseases such as recurrent pericarditis, acute myocarditis and heart failure. The statements made in this MD&A concerning the potential medical benefits of cannabidiol are based on the published peer-reviewed articles and reports from pre-clinical research studies, as well as the results from the Corporation's MAvERIC-Pilot Phase II study of CardiolRx™ in patients with recurrent pericarditis. As a result, the statements made in this MD&A are subject to the clinical and experimental parameters, qualifications, and limitations in the studies that have been completed.

Although the Corporation believes that the articles, reports, and results referenced in this MD&A reasonably support the medical benefits, viability, safety, efficacy, and dosing of cannabidiol as set out in this MD&A, future research and clinical trials in pursuit of our development efforts may prove such statements to be incorrect, or could raise concerns regarding and perceptions relating to, cannabidiol. Given these risks, uncertainties and assumptions, undue reliance should not be placed on such articles, reports, and results. Future research studies may draw opposing conclusions to those stated in this MD&A or reach negative conclusions regarding the viability, safety, efficacy, dosing, social acceptance or other facts and perceptions related to cannabidiol, which could have a material adverse effect on the future demand for the Corporation's product candidates, if approved, and therefore materially impact the business, financial condition, and operating results of the Corporation.

Product candidates, if approved, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue from new products.

Even if product development is successful and regulatory approval is obtained, our ability to generate significant revenue depends on the acceptance of our products by physicians and patients. We cannot assure that our product candidates will achieve the expected market acceptance and revenue if and when they obtain the requisite regulatory approvals. The market acceptance of any product depends on a number of factors, including the indication statement and warnings approved by regulatory authorities on the product label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payers such as government health care systems and insurance companies, the price of the product, the nature of any post-approval risk management plans mandated by regulatory authorities, competition, and marketing and distribution support. Any factors preventing or limiting the market acceptance of our products could have a material adverse effect on our business, results of operations, and financial condition.

We currently have no commercialized products to date.

Even if we obtain regulatory approval for a product candidate, our future success will still depend on our ability to successfully commercialize our products, which depends on a number of factors beyond our control, including the willingness of physicians to prescribe our products to patients, payers' willingness and ability to pay for the product, the level of pricing achieved, patients' response to our products, the ability of our marketing partners to generate sales, and our ability to manufacture products on a cost-effective and efficient basis. If we are not successful in the commercialization of our products, our business, results of operations, and financial condition may be harmed.

We rely on contract manufacturers over whom we have limited control. If we are subject to quality, cost, or delivery issues with the pre-clinical and clinical grade materials supplied by contract manufacturers, our business operations could suffer significant harm.

We currently have no manufacturing experience and rely on Dalton and other contract manufacturing organizations ("CMOs") to manufacture our product candidates for pre-clinical studies and clinical trials. We rely on CMOs for manufacturing, filling, packaging, storing, and shipping of product candidates in compliance with current good manufacturing practice, or cGMP, regulations applicable to our product candidates. The FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with cGMP regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packaging of a drug product. If our CMOs increase their prices or fail to meet our quality standards, or those of regulatory agencies such as the FDA, and cannot be replaced by other acceptable CMOs, our ability to obtain regulatory approval for and commercialize our product candidates may be materially adversely affected.

Business disruptions affecting our third-party suppliers, manufacturers, and CROs could harm our future revenues and financial condition and increase our costs and expenses.

We rely on third parties to supply the materials for and manufacture our APIs for our pre-clinical and clinical trials. There are only a limited number of suppliers and manufacturers of our APIs and our ability to obtain these materials could be disrupted if the operations of these manufacturers are affected by earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, regulatory enforcement activity, medical epidemics, and other natural or man-made disasters or business interruptions. We also rely on CROs, clinical data management organizations, and consultants to design, conduct, supervise, and monitor pre-clinical studies of our product candidates and will do the same for our planned clinical trials. If their facilities are unable to operate because of an accident or incident, even for a short period of time, some or all of our research and development programs may be harmed or delayed, and our operations and financial condition could suffer.

Our existing collaboration agreements and any such agreements entered into in the future may not be successful, which would have adverse consequences.

We are a party to, and may seek additional, collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our current and potential product candidates. We may enter into new arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for each product candidate, both in Canada and internationally. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document, and implement. We may not be

successful in our efforts to establish, implement, and maintain collaborations or other alternative arrangements if we choose to enter into such arrangements. In addition, the terms of any collaboration or other arrangements that we may establish may not be favorable to us.

Any existing or future collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding development, intellectual property, regulatory, or commercialization matters, can lead to delays in the development process or commercialization of the applicable product candidate, if approved, and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Product candidate shipment delays would have an adverse effect on the business.

The shipment, import, and export of our product candidates may require import and export licenses. In the United States, the FDA, United States Customs and Border Protection, and in other countries, similar regulatory authorities, regulate the import and export of pharmaceutical products that contain controlled substances. Specifically, the import and export process may require the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country. Once we are in the production phase, we may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of our product candidates may be held up in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipments resulting in a partial or total loss of revenue from one or more shipments of our other product candidates. A partial or total loss of revenue from one or more shipments of our product candidates could have a material adverse effect on our business, results of operations and financial condition.

Our ability to generate product revenues will be diminished if our product candidates (if approved) sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our product candidates, if approved, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, Health Canada or any similar regulatory authority, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our product candidates (if approved). If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our product candidates, once approved, market acceptance of such product candidates could be reduced.

We do not have a history of selling, marketing, or distributing products.

We may not be able to market, sell, and distribute our product candidates, if approved, successfully. Our future success may depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the product candidates under development, and such collaborator's ability to successfully market and sell any such product candidates, if approved. Although we intend to pursue collaborative arrangements regarding the sale and marketing of our product candidates, if approved, there can be no assurance that we will be able to establish or maintain our own sales operations or effect collaborative arrangements, or that if we are able to do so, our collaborators will have effective sales forces. There can also be no assurance that we will be able to establish or maintain effective relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we will in the future depend on third parties for marketing and distribution, any revenues

we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product candidates, if approved, internationally.

We may face intense competition from other companies which may be larger and better financed.

Competition from pharmaceutical companies, biotechnology companies, and universities is intense and is expected to increase. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition, and results of operations of the Corporation. The Corporation's future success depends in part on its ability to maintain a competitive position, including the ability to further progress its product candidates through the necessary pre-clinical and clinical trials towards regulatory approval for sale and commercialization. Other companies may succeed in commercializing products earlier than the Corporation is able to commercialize its product candidates, if approved, or they may succeed in developing products that are more effective. While the Corporation will seek to expand its capabilities in order to remain competitive, there can be no assurance that developments by others will not render its product candidates, if approved, non-competitive or that the Corporation or its licensors will be able to keep pace with technological developments. Competitors have developed or could develop technologies that could be the basis for competitive products. Some of those products may have an entirely different approach or means of accomplishing the desired therapeutic effect than the Corporation's product candidates and may be more effective or less costly than the Corporation's product candidates, if approved. In addition, other forms of medical treatment may offer competition to the Corporation's product candidates, if approved. The success of the Corporation's competitors and their products relative to the Corporation's capabilities and competitiveness could have a material adverse effect on the future of pre-clinical and clinical trials of the Corporation's product candidates, including its ability to obtain the necessary regulatory approvals for the conduct of such trials.

Research and development, and evolving technology and products, may render our product candidates (if approved) obsolete, if we are unable to continue to improve our product offerings in the future.

Rapidly changing markets, technology, emerging industry standards, and frequent introduction of new products characterize the Corporation’s business. The introduction of new products embodying new technologies, including new manufacturing processes, and the emergence of new industry standards may render the Corporation’s product candidates, if approved, obsolete, less competitive, or less marketable. The process of developing the Corporation’s product candidates is complex and requires significant continuing costs, development efforts, and third-party commitments. The Corporation’s failure to develop new technologies and product candidates and the obsolescence of existing technologies could adversely affect the business, financial condition, and operating results of the Corporation. The Corporation may be unable to anticipate changes in its potential customer requirements that could make the Corporation’s existing technology obsolete. The Corporation’s success will depend, in part, on its ability to continue to enhance its existing technologies, develop new technology that addresses the increasing sophistication and varied needs of the market, and respond to technological advances and emerging industry standards and practices on a timely and cost-effective basis. The development of the Corporation’s proprietary technology entails significant technical and business risks. The Corporation may not be successful in using its new technologies or exploiting its niche markets effectively or adapting its businesses to evolving customer or medical requirements or preferences or emerging industry standards.

Negative public or consumer perception around cannabinoids may negatively affect the development and commercialization of our product candidates.

The Corporation believes the cannabinoid industry is highly dependent upon consumer perception regarding the safety, efficacy, and quality of the cannabinoid produced. Consumer perception of the Corporation’s pharmaceutical cannabinoid product candidates can be significantly influenced by scientific research or findings, regulatory investigations, litigation, media attention, and other publicity regarding the consumption of cannabinoids. There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention, or other research findings or publicity will be favorable to the cannabinoid market or any particular product, or consistent with earlier publicity. Future research reports, findings, regulatory proceedings, litigation, media attention, or other publicity that are perceived as less favorable than, or that question, earlier research reports, findings, or publicity could have a material adverse effect on the demand for the Corporation’s pharmaceutical cannabinoids, if approved, and the business, results of operations, financial condition, and cash flows of the Corporation. The Corporation’s dependence upon consumer perceptions means that adverse scientific research reports, findings, regulatory proceedings, litigation, media attention, or other publicity, whether or not accurate or with merit, could have a material adverse effect on the Corporation, the demand for the Corporation’s pharmaceutical cannabinoids, if approved, and the business, results of operations, financial condition, and cash flows of the Corporation. Further, adverse publicity reports or other media

attention regarding the safety, efficacy, and quality of cannabinoids in general, or the Corporation's pharmaceutical cannabinoids, if approved, specifically, or associating the consumption of cannabinoids with illness or other negative effects or events, could have such a material adverse effect. Such adverse publicity reports or other media attention could arise even if the adverse effects associated with such products resulted from consumers' failure to consume such products legally, appropriately, or as directed.

We may face risks from product liability claims if our product candidates are approved.

If we become a manufacturer and distributor of products designed to be ingested by humans, the Corporation faces an inherent risk of exposure to product liability claims, regulatory action, and litigation if its product candidates (once approved) are alleged to have caused significant loss or injury. In addition, the manufacture and sale of products involve the risk of injury to consumers due to tampering by unauthorized third parties or product contamination. Previously unknown adverse reactions resulting from human consumption of our product candidates alone or in combination with other medications or substances could occur. The Corporation may be subject to various product liability claims, including, among others, that the products produced by the Corporation caused injury or illness, include inadequate instructions for use or include inadequate warnings concerning possible adverse events or interactions with other substances. A product liability claim or regulatory action against the Corporation could result in increased costs, could adversely affect the Corporation's reputation with its clients and consumers generally, and could have a material adverse effect on the business, financial condition, and operating results of the Corporation. There can be no assurances that the Corporation will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive and may not be available in the future on acceptable terms, or at all. The inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of product candidates (if approved).

The Corporation's product candidates, if approved, may be subject to product recalls.

Manufacturers and distributors of products are sometimes subject to the recall or return of their products for a variety of reasons, including product defects, such as contamination, unintended harmful adverse events or interactions with other substances, packaging safety and inadequate or inaccurate labeling disclosure. If any of the product candidates (if approved) that the Corporation produces or intends to produce are recalled due to an alleged product defect or for any other reason, the Corporation could be required to incur the unexpected expense of the recall and any legal proceedings that might arise in connection with the recall. The Corporation may lose a significant amount of sales and may not be able to replace those sales at an acceptable margin or at all. In addition, a product recall may require significant Management attention. Although the Corporation has detailed procedures in place for testing finished products (if our product candidates are approved), there can be no assurance that any quality, potency, or contamination problems will be detected in time to avoid unforeseen product recalls, regulatory action, or lawsuits. Additionally, if one of the Corporation's product candidates, if approved, were subject to recall, the image of that product and the Corporation could be harmed. A recall for any of the foregoing reasons could lead to decreased demand for products produced by the Corporation and could have a material adverse effect on the results of operations and financial condition of the Corporation. Additionally, product recalls may lead to increased scrutiny of the operations of the Corporation by Health Canada or other regulatory agencies, requiring further Management attention and potential legal fees and other expenses.

The Corporation may seek to expand its business and operations into jurisdictions outside of Canada and the United States, and there are risks associated with doing so.

The Corporation may in the future expand its operations and business into jurisdictions outside of Canada and the United States. There can be no assurance that any market for the Corporation's product candidates (if approved) will develop in any such foreign jurisdiction. The Corporation may face new or unexpected risks or significantly increase its exposure to one or more existing risk factors, including economic instability, changes in laws and regulations, and the effects of competition. These factors may limit the Corporation's capability to successfully expand its operations and may have a material adverse effect on the Corporation's business, financial condition, and results of operations.

The Corporation may become subject to liability arising from any fraudulent or illegal activity by its employees, contractors, and consultants.

The Corporation is exposed to the risk that its employees, independent contractors, and consultants may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to the Corporation that violates: (i) government regulations;

(ii) manufacturing standards; (iii) federal and provincial healthcare fraud and abuse laws and regulations; or (iv) laws that require the true, complete, and accurate reporting of financial information or data. It is not always possible for the Corporation to identify and deter misconduct by its employees and other third parties, and the precautions taken by the Corporation to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting the Corporation from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against the Corporation, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of the Corporation's operations, any of which could have a material adverse effect on the Corporation's business, financial condition and results of operations.

The Corporation's business is dependent on key inputs, and the inability to secure such inputs may negatively affect our business.

The Corporation's business is dependent on a number of key inputs and their related costs including raw materials and supplies related to its growing operations, as well as electricity, water, and other local utilities. Any significant interruption or negative change in the availability or economics of the supply chain, for key inputs could materially impact the business, financial condition, and operating results of the Corporation. Any inability to secure required supplies and services or to do so on appropriate terms could have a materially adverse impact on the business, financial condition, and operating results of the Corporation.

The Corporation's development plans may be impacted by global supply chain challenges including extended delivery times, increases in pricing and constraints on the availability of materials and components required by the Corporation and the development and manufacturing firms it has engaged. Prices of numerous materials and components have increased and they may continue to increase due to increased demand and supply constraints.

Our insurance coverage may be insufficient to protect us from our operating risk.

The Corporation has insurance to protect its assets, operations, and employees. While the Corporation believes its insurance coverage addresses all material risks to which it is exposed and is adequate and customary in its current state of operations, such insurance is subject to coverage limits and exclusions and may not be available for all risks and hazards to which the Corporation is exposed. In addition, no assurance can be given that such insurance will be adequate to cover the Corporation's liabilities or will be generally available in the future or, if available, that premiums will be commercially justifiable. If the Corporation were to incur substantial liability and such damages were not covered by insurance or were in excess of policy limits, or if the Corporation were to incur such liability at a time when it is not able to obtain liability insurance, its business, results of operations, and financial condition could be materially adversely affected.

We may be unable to manage our growth effectively.

The Corporation may be subject to growth-related risks, including capacity constraints and pressure on its internal systems and controls. The ability of the Corporation to manage growth effectively will require it to continue to implement and improve its operational and financial systems and to expand, train, and manage its employee base. The inability of the Corporation to deal with this growth may have a material adverse effect on the Corporation's business, financial condition, results of operations, and prospects.

Some of our Directors and/or officers may have conflicts of interest from other business activities.

The Corporation may be subject to various potential conflicts of interest because of the fact that some of its officers and Directors may be engaged in a range of business activities. In addition, the Corporation's executive officers and Directors may devote time to their outside business interests, so long as such activities do not materially or adversely interfere with their duties to the Corporation. In some cases, the Corporation's executive officers and Directors may have fiduciary obligations associated with these business interests that interfere with their ability to devote time to the Corporation's business and affairs and that could adversely affect the Corporation's operations. These business interests could require significant time and attention from the Corporation's executive officers and Directors. In addition, the Corporation's executive officers and Directors control a percentage of common shares and may have the ability to control matters affecting the Corporation.

The Corporation may also become involved in other transactions which conflict with the interests of its Directors and the officers who may from time-to-time deal with persons, firms, institutions, or companies with which the Corporation may

be dealing, or which may be seeking investments similar to those desired by it. The interests of these persons could conflict with those of the Corporation. In addition, from time to time, these persons may be competing with the Corporation for available investment opportunities. Conflicts of interest, if any, will be subject to the procedures and remedies provided under applicable laws. In particular, in the event that such a conflict of interest arises at a meeting of the Corporation's Directors, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. In accordance with applicable laws, the Directors of the Corporation are required to act honestly, in good faith, and in the best interests of the Corporation.

Certain publicity may cause damage to our reputation.

Damage to the Corporation's reputation could be the result of the actual or perceived occurrence of any number of events, and could include any negative publicity, whether true or not. The increased usage of social media and other web-based tools used to generate, publish, and discuss user generated content and to connect with other users has made it increasingly easier for individuals and groups to communicate and share opinions and views in respect to the Corporation and its activities, whether true or not. Although the Corporation believes that it operates in a manner that is respectful to all stakeholders and that it takes care in protecting its image and reputation, the Corporation ultimately does not have direct control over how it is perceived by others. Reputation loss may result in decreased investor confidence, increased challenges in developing and maintaining community relations, and an impediment to the Corporation's overall ability to advance its product candidates, thereby having a material adverse impact on financial performance, financial condition, cash flows, and growth prospects.

Third parties may perceive reputational risk for doing business with us as a company involved in the development and marketing of cannabinoid-based treatments.

The parties with which the Corporation does business may perceive that they are exposed to reputational risk as a result of the Corporation's cannabinoid-related activities. This may impact the Corporation's ability to retain current partners, such as its banking relationship, or source future partners as required for growth or future expansion in Canada or internationally. Failure to establish or maintain business relationships could have a material adverse effect on the Corporation.

Our relationships with healthcare providers, patients and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, customers, and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products for which we obtain marketing approval. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid, or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

We and our third-party providers may face security threats to information systems.

The Corporation has entered into agreements with third parties for hardware, software, telecommunications, and other information technology ("IT") services in connection with its operations. The Corporation's operations depend, in part, on how well it and its suppliers protect networks, equipment, IT systems, and software against damage from a number of threats, including, but not limited to, cable cuts, damage to physical plants, natural disasters, terrorism, fire, power loss, hacking, computer viruses, vandalism, and theft. The Corporation's operations also depend on the timely

maintenance, upgrade, and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. Any of these and other events could result in information system failures, delays and/or an increase in capital expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact the Corporation's reputation and results of operations.

The Corporation has not experienced any material losses to date relating to cyber-attacks or other information security breaches, but there can be no assurance that the Corporation will not incur such losses in the future. The Corporation's risk and exposure to these matters cannot be fully mitigated because of, among other things, the evolving nature of these threats. As a result, cybersecurity and the continued development and enhancement of controls, processes, and practices designed to protect systems, computers, software, data, and networks from attack, damage, or unauthorized access is a priority. As cyber threats continue to evolve, the Corporation may be required to expend additional resources to continue to modify or enhance protective measures or to investigate and remediate any security vulnerabilities.

We do not currently, and have no plans to, pay dividends on our common shares.

Our current policy is to retain earnings to finance the development and enhancement of our product candidates and to otherwise reinvest in the Corporation. Therefore, we do not anticipate paying cash dividends on the common shares in the foreseeable future. Our dividend policy will be reviewed from time to time by our Board of Directors in the context of our earnings, financial condition, and other relevant factors. Until the time that we do determine to pay dividends, which we might never do, our shareholders will not be able to receive a return on their common shares unless they sell them.

Future sales of common shares by existing shareholders.

Holders of stock options, performance share units, restricted share units, deferred share units and other share-based awards to purchase common shares may have an immediate income inclusion for tax purposes when they exercise these awards (that is, tax is not deferred until they sell the underlying common shares). As a result, these holders may need to sell common shares purchased on the exercise of these awards in the same year that they exercise. This might result in a greater number of common shares being sold in the public market, and fewer long-term holds of common shares by Management and our employees.

The Corporation may be subject to securities litigation which is expensive and could divert Management's attention.

The market price of the common shares may be volatile, and in the past companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our Management's attention from other business concerns, which could seriously harm our business.

Our common shares are subject to market price volatility.

The market price of common shares may be adversely affected by a variety of factors relating to the Corporation's business, including fluctuations in the Corporation's operating and financial results, the results of any public announcements made by the Corporation and its failure to meet analysts' expectations. In addition, from time to time, the stock market experiences significant price and volume volatility that may affect the market price of common shares for reasons unrelated to the Corporation's performance. Additionally, the value of common shares is subject to market value fluctuations based upon factors that influence the Corporation's operations, such as legislative or regulatory developments, competition, technological change, global capital market activity and changes in interest and currency rates. There can be no assurance that the market price of common shares will not experience significant fluctuations in the future, including fluctuations that are unrelated to the Corporation's performance.

The market value of common shares may also be affected by the Corporation's financial results and political, economic, financial, and other factors that can affect the capital markets generally, the stock exchanges on which common shares are traded, and the market segments of which the Corporation is a part.

Failure to comply with the U.S. Foreign Corrupt Practices Act ("FCPA"), the Canadian Corruption of Foreign Public Officials Act ("CFPOA"), and other global anti-corruption and anti-bribery laws could subject the Corporation to penalties and other adverse consequences.

The FCPA and the CFPOA, as well as any other applicable domestic or foreign anti-corruption or anti-bribery laws to which the Corporation is or may become subject, generally prohibit corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity and requires companies to maintain accurate books and records and internal controls, including at foreign-controlled subsidiaries.

Compliance with these anti-corruption laws and anti-bribery laws may be expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, these laws present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and physicians and other hospital employees are considered to be foreign officials. Certain payments by other companies to hospitals in connection with clinical trials and other work have been deemed to be improper payments to governmental officials and have led to FCPA enforcement actions.

The Corporation's internal control policies and procedures may not protect it from reckless or negligent acts committed by the Corporation's employees, distributors, licensees, or agents. The Corporation can make no assurance that they will not engage in prohibited conduct, and the Corporation may be held liable for their acts under applicable anti-corruption and anti-bribery laws. Noncompliance with these laws could subject the Corporation to investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, whistleblower complaints, reputational harm, adverse media coverage, and other collateral consequences. Any investigations, actions or sanctions or other previously mentioned harm could have a material adverse effect on the Corporation's business, operating results, and financial condition.

The Corporation may be classified as a "passive foreign investment company" for U.S. federal income tax purposes, which would subject U.S. investors that hold the Corporation's common shares to potentially significant adverse U.S. federal income tax consequences.

If the Corporation is classified as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes in any taxable year, U.S. investors holding the Corporation's common shares generally will be subject, in that taxable year and all subsequent taxable years (whether or not the Corporation continued to be a PFIC), to certain adverse U.S. federal income tax consequences. The Corporation will be classified as a PFIC in respect of any taxable year in which, after taking into account its income and gross assets (including the income and assets of 25% or more owned subsidiaries), either (i) 75% or more of its gross income consists of certain types of "passive income" or (ii) 50% or more of the average quarterly value of its assets is attributable to "passive assets" (assets that produce or are held for the production of passive income). Based upon the current and expected composition of the Corporation's income and assets, the Corporation believes that it was a PFIC for the taxable year ended December 31, 2024 and expects that it may be a PFIC for the current taxable year. Because the Corporation's PFIC status must be determined annually with respect to each taxable year and will depend on the composition and character of the Corporation's assets and income, including the Corporation's use of proceeds from offerings, and the value of the Corporation's assets (which may be determined, in part, by reference to the market value of common shares, which may be volatile) over the course of such taxable year, the Corporation may be a PFIC in any taxable year. Because there are uncertainties in the application of the relevant rules and PFIC status is a factual determination made annually after the close of each taxable year, there can be no assurance that the Corporation will not be a PFIC for any future taxable year. In addition, it is possible that the U.S. Internal Revenue Service may challenge the Corporation's classification of certain income and assets as non-passive, which may result in the Corporation being or becoming a PFIC in the current or subsequent years.

If the Corporation is a PFIC for any year during a U.S. Holder's (as defined below) holding period, then such U.S. Holder generally will be required to treat any gain realized upon a disposition of common shares, or any "excess distribution" received on its common shares, as ordinary income ratable allocated over its holding period, and to pay an interest charge on the underpayment of tax attributable to such gain or distribution, unless the U.S. Holder makes a timely and effective "qualified electing fund" election ("QEF Election") or a "mark-to-market" election with respect to its common shares. A U.S. Holder who makes a QEF Election generally must report on a current basis its share of the Corporation's net capital gain and ordinary earnings for any year in which the Corporation is a PFIC, whether or not the Corporation distributes any amounts to its shareholders. However, U.S. Holders should be aware that there can be no assurance that the Corporation will satisfy the record keeping requirements that apply to a QEF, or that the Corporation will supply U.S. Holders with information that such U.S. Holders require to report under the QEF Election rules, in the event that the Corporation is a PFIC and a U.S. Holder wishes to make a QEF Election. Thus, U.S. Holders may not be

able to make a QEF Election with respect to their common shares. A U.S. Holder who makes a mark-to-market election generally must include as ordinary income each year the excess of the fair market value of the common shares over the taxpayer's basis therein. Each U.S. Holder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership, and disposition of common shares.

As used in this discussion, the term "U.S. Holder" means a beneficial owner of common shares that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes.

It may be difficult for United States investors to obtain and enforce judgments against the Corporation because of the Corporation's Canadian incorporation and presence.

The Corporation is a corporation existing under the laws of Ontario, Canada. Many of the Corporation's Directors and officers are residents of Canada, and all or a substantial portion of their assets, and a substantial portion of the Corporation's assets, are located outside the United States. Consequently, it may be difficult for holders of the Corporation's securities who reside in the United States to effect service of process within the United States upon those Directors, officers, and experts who are not residents of the United States. It may also be difficult for holders of the Corporation's securities who reside in the United States to realize in the United States upon judgments of courts of the United States predicated upon the Corporation's civil liability and the civil liability of the Corporation's Directors, officers and experts under United States federal securities laws. Investors should not assume that Canadian courts would (i) enforce judgments of United States courts obtained in actions against the Corporation or such Directors or officers predicated upon the civil liability provisions of the United States federal securities laws or the securities or "blue sky" laws of any state or jurisdiction of the United States or (ii) would enforce, in original actions, liabilities against the Corporation or such Directors, officers or experts predicated upon the United States federal securities laws or any securities or "blue sky" laws of any state or jurisdiction of the United States. In addition, the protections afforded by Canadian securities laws may not be available to investors in the United States.

As a foreign private issuer, the Corporation is subject to different U.S. securities laws and rules than a U.S. domestic issuer, which may limit the information publicly available to U.S. investors.

The Corporation is a "foreign private issuer", under applicable U.S. federal securities laws, and is, therefore, not subject to the same requirements that are imposed upon U.S. domestic issuers by the Securities and Exchange Commission ("SEC"). Under the U.S. Securities Exchange Act, the Corporation is subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. As a result, the Corporation does not file the same reports that a U.S. domestic issuer would file with the SEC, although the Corporation is required to file with or furnish to the SEC the continuous disclosure documents that it is required to file in Canada under Canadian securities laws. In addition, the Corporation's officers, Directors, and principal shareholders are exempt from the reporting and short-swing profit recovery provisions of Section 16 of the U.S. Exchange Act. Therefore, the Corporation's shareholders may not know on as timely a basis as with U.S. domestic issuers when the Corporation's officers, Directors and principal shareholders purchase or sell common shares, as the reporting periods under the corresponding Canadian insider reporting requirements are longer. As a foreign private issuer, the Corporation is exempt from the rules and regulations under the U.S. Exchange Act related to the furnishing and content of proxy statements. The Corporation is also exempt from Regulation FD, which prohibits issuers from making selective disclosures of material non-public information. While the Corporation complies with the corresponding requirements relating to proxy statements and disclosure of material non-public information under Canadian securities laws, these requirements differ from those under the U.S. Exchange Act and Regulation FD and shareholders should not expect to receive the same information at the same time as such information is provided by U.S. domestic companies. In addition, the Corporation may not be required under the U.S. Exchange Act to file annual and quarterly reports with the SEC as promptly as U.S. domestic companies whose securities are registered under the U.S. Exchange Act. In addition, as a foreign private issuer, the Corporation has the option to follow certain Canadian corporate governance practices, except to the extent that such laws would be contrary to U.S. securities laws, and provided that the Corporation disclose the requirements it is not following and describe the Canadian practices it follows instead. The Corporation has elected to follow home country practices in Canada with regard to certain corporate governance matters. As a result, the Corporation's shareholders may not have the same protections afforded to shareholders of U.S. domestic companies that are subject to all corporate governance requirements.

The Corporation may lose its foreign private issuer status in the future, which could result in significant additional costs and expenses to the Corporation.

In order to maintain its status as a foreign private issuer, a majority of the Corporation's common shares must be either directly or indirectly owned by non-residents of the U.S. unless the Corporation also satisfies one of the additional requirements necessary to preserve this status. The Corporation may in the future lose its foreign private issuer status if a majority of its common shares are held in the U.S. and if the Corporation fails to meet the additional requirements necessary to avoid loss of its foreign private issuer status. The regulatory and compliance costs under U.S. federal securities laws as a U.S. domestic issuer may be significantly more than the costs incurred as a Canadian foreign private issuer. If the Corporation is not a foreign private issuer, it would not be eligible to use the MJDS or other foreign issuer forms and would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer, and would be required to file financial statements prepared in accordance with United States generally accepted accounting principles. In addition, the Corporation may lose the ability to rely upon exemptions from Nasdaq corporate governance requirements that are available to foreign private issuers.

The Corporation relies upon certain accommodations available to it as an "emerging growth company."

The Corporation is an "emerging growth company" as defined in section 3(a) of the U.S. Exchange Act (as amended by the JOBS Act, enacted on April 5, 2012), and the Corporation will continue to qualify as an emerging growth company until the earliest to occur of: (a) the last day of the fiscal year during which the Corporation has total annual gross revenues of US$1,235,000,000 (as such amount is indexed for inflation every five years by the SEC) or more; (b) the last day of the fiscal year of the Corporation following the fifth anniversary of the date of the first sale of common equity securities of the Corporation pursuant to an effective registration statement under the U.S. Securities Act; (c) the date on which the Corporation has, during the previous three-year period, issued more than US$1,000,000,000 in non-convertible debt; and (d) the date on which the Corporation is deemed to be a "large accelerated filer", as defined in Rule 12b-2 under the U.S. Exchange Act. The Corporation will qualify as a large accelerated filer (and would cease to be an emerging growth company) at such time when on the last business day of its second fiscal quarter of such year the aggregate worldwide market value of its common equity held by non-affiliates will be US$700,000,000 or more. For so long as the Corporation remains an emerging growth company, it is permitted to and intends to rely upon exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. The Corporation cannot predict whether investors will find the common shares less attractive because the Corporation relies upon certain of these exemptions. If some investors find the common shares less attractive as a result, there may be a less active trading market for the common shares and the Common Share price may be more volatile. On the other hand, if the Corporation no longer qualifies as an emerging growth company, the Corporation would be required to divert additional management time and attention from the Corporation's development and other business activities and incur increased legal and financial costs to comply with the additional associated reporting requirements, which could negatively impact the Corporation's business, financial condition, and results of operations.

Our operations could be adversely affected by events outside of our control, such as natural disasters, wars or health epidemics.

We may be impacted by business interruptions resulting from pandemics and public health emergencies, including those related to geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods, and fires. An outbreak of infectious disease, a pandemic or a similar public health threat or a fear of any of the foregoing, could adversely impact us by causing operating, manufacturing supply chain, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures). It is unknown whether and how we may be affected if such an epidemic persists for an extended period of time. We may incur expenses or delays relating to such events outside of our control, which could have a material adverse impact on our business, operating results, and financial condition.

Failure to meet regulatory or ethical expectations on environmental impact, including climate change.

Environmental issues will become more material in the marketplace as the wider healthcare system embraces net-zero climate targets. The environmental targets and performance of our business will come under increased scrutiny by investors, governments, and non-governmental organizations. Environmental considerations are starting to become

embedded in the public procurement of goods and services, including medicinal products and devices. Specific intermediates used to manufacture medicines, or those used in excipients or propellants, are coming under increased regulation and some may be subject to time-limited exemptions or potential phase-out. The physical impacts of climate change could impact the resilience of our business operations and supply chain.

Our operations could be adversely affected by macroeconomic risks

In recent years, economies and markets have faced the phenomenon of inflation, the control of which is the focus of regulatory institutions around the world. In 2024, the inflation rate decreased and the benchmark interest rate has also declined. However, uncertain inflation and the recently announced tariffs on imports into the United States represent a significant risk to macroeconomic stability; it results in rising energy and commodity costs, and global equity and capital markets may experience significant volatility and weakness. These factors could have a material adverse effect on our business, operating results, and financial condition.

Delays in the timing of regulatory authority decision-making, actions, and securing meetings as a result of workforce re-alignment, and potentially significant reductions in workforce or other resources at FDA and other US federal agencies

Delays in the timing of regulatory authority decision-making, actions, and securing meetings, which may result from workforce re-alignment, potentially significant reductions in workforce, or other resource constraints, can pose significant risks to the Corporation's operations. Such delays may impact the timely approval of permits, licenses, or other regulatory requirements, potentially affecting the Corporation's ability to execute its business plans, meet regulatory deadlines, and respond to market opportunities. These delays could result in operational disruptions, increased costs, and the postponement or cancellation of key projects, thereby affecting overall business performance and shareholder value.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years, including as a result of government shutdowns and the furlough of FDA employees. There is added uncertainty with the new US presidential administration which has begun terminating federal employees, including at the FDA. The impact of mass layoffs at FDA and any other governmental offices with which we interact is unclear at this time. However, it is expected that with a potential reduction in staff of up to 50%, the FDA in the future may be unable to meet its application review goals or to continue to be available for timely interactions with the pharmaceutical industry. It is currently unclear how the pharmaceutical industry as a whole will be affected by these actions or other legislative or judicial actions, but they could have a material adverse effect on our business, operating results, and financial condition. In addition, government funding of other government agencies on which our operations may rely, including the USPTO and those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Issuances of our equity securities in the future may result in dilution to current shareholders.

Our articles of incorporation and by-laws allow us to issue an unlimited number of common shares for such consideration and on such terms and conditions as established by the Corporation's Board of Directors, in many cases, without shareholder approval. The Corporation may issue additional common shares in future offerings (including through the sale of securities convertible into or exchangeable for common shares) and on the exercise of stock options or other securities exercisable for common shares. The Corporation cannot predict the size of future issuances of common shares or the effect that future issuances and sales of common shares will have on the market price of common shares. Issuances of a substantial number of additional common shares, or the perception that such issuances could occur, may adversely affect prevailing market prices for common shares. With any additional issuance of common shares, investors will suffer dilution to their voting power and may experience dilution in its earnings per share.

The Corporation may use the proceeds from prior equity offerings for purposes other than those previously set out.

Management will have discretion in the actual use of the proceeds raised in prior equity offerings and may elect to allocate proceeds differently from the purposes previously disclosed if it believes that it would be in the best interests of the Corporation to do so. The failure by Management to apply these funds effectively could have a material adverse effect on the Corporation's business.

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials.

We rely and intend to rely in the future on third-party clinical investigators, CROs, and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of the time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs.

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