

# CARDIOL THERAPEUTICS INC. MANAGEMENT'S DISCUSSION AND ANALYSIS THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021

#### MANAGEMENT'S DISCUSSION AND ANALYSIS

#### Introduction

The following management's discussion and analysis ("MD&A") of the financial condition and results of the operations of Cardiol Therapeutics Inc. (the "Corporation" or "Cardiol") constitutes Management's review of the factors that affected the Corporation's financial and operating performance for the three and nine months ended September 30, 2021 (the "2021 Fiscal Period"). This MD&A was written to comply with the requirements of National Instrument 51-102 – Continuous Disclosure Obligations. This discussion should be read in conjunction with the financial statements for the years ended December 31, 2020 and 2019 and the unaudited condensed interim financial statements for the three and nine months ended September 30, 2021 ("Financial Statements"), together with the respective notes thereto. Results are reported in Canadian dollars, unless otherwise noted. The Financial Statements and the financial information contained in this MD&A are prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board and interpretations of the IFRS Interpretations Committee. In the opinion of Management, all adjustments (which consist only of normal recurring adjustments) considered necessary for a fair presentation have been included.

This MD&A is dated November 11, 2021. All dollar amounts in this MD&A are reported in Canadian dollars, unless otherwise stated. Unless otherwise noted or the context indicates otherwise, the terms "we", "us", "our", "Cardiol" or the "Corporation" refer to Cardiol Therapeutics Inc.

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

### **Forward-Looking Information**

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

- our anticipated cash needs, and the need for additional financing;
- the ability for our subcutaneous product candidates to deliver cannabinoids and other anti-inflammatory drugs to inflamed tissue in the heart;
- our development of proprietary cannabidiol formulations for near-term commercialization;
- our ability to develop new formulations;
- the successful development and commercialization of our current product candidates and the addition of future products;
- our intention to build a pharmaceutical brand and cannabidiol products focused on addressing heart disease, with a particular focus on heart failure;
- the expected medical benefits, viability, safety, efficacy, and dosing of cannabidiol;
- patents, including, but not limited to, our ability to have patents issued covering our drugs, drug candidates and processes, as well as successfully defending oppositions and legal challenges;
- our competitive position and the regulatory environment in which we operate;
- our financial position; our business strategy; our growth strategies; our operations; our financial results; our dividends policy; our plans and objectives; and
- expectations of future results, performance, achievements, prospects, opportunities, or the market in which we operate.

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

- the inherent uncertainty of product development;
- our requirement for additional financing;
- our negative cash flow from operations;
- our history of losses;
- dependence on success of our early-stage product candidates which may not generate revenue;
- reliance on Management, loss of members of Management or other key personnel, or an inability to attract new Management team members;
- our ability to successfully design, commence, and complete clinical trials, including the high cost, uncertainty, and delay of clinical trials, and additional costs associated with any failed clinical trials;
- potential negative results from clinical trials and their adverse impacts on our future commercialization efforts;
- our ability to establish and maintain commercialization organizations in the U.S., Mexico, and elsewhere;
- our ability to receive and maintain regulatory exclusivities, including Orphan Drug Designations, for our drugs and drug candidates;
- · delays in achievement of projected development goals;
- · management of additional regulatory burdens;
- volatility in the market price for our securities;
- failure to protect and maintain and the consequential loss of intellectual property rights;
- third-party claims relating to misappropriation by our employees of their intellectual property;
- reliance on third parties to conduct and monitor our pre-clinical studies and clinical trials;
- our product candidates being subject to controlled substance laws which may vary from jurisdiction to jurisdiction;
- changes in laws, regulations, and guidelines relating to our business, including tax and accounting requirements;
- our reliance on current early-stage research regarding the medical benefits, viability, safety, efficacy, and dosing of cannabinoids:
- claims for personal injury or death arising from the use of products and product candidates produced by us;
- uncertainty relating to market acceptance of our product candidates;
- our lack of experience in commercializing any products;
- the level of pricing and reimbursement for our products and product candidates, if approved;
- our dependence on Dalton Chemical Laboratories, Inc. operating as Dalton Pharma Services ("Dalton") and other contract manufacturers;
- unsuccessful collaborations with third parties;
- business disruptions affecting third-party suppliers and manufacturers;
- lack of control in future prices of our product candidates;
- our lack of experience in selling, marketing, or distributing our products;
- competition in our industry;
- our inability to develop new technologies and products and the obsolescence of existing technologies and products;
- unfavorable publicity or consumer perception towards cannabidiol;
- product liability claims and product recalls;
- · expansion of our business to other jurisdictions;
- fraudulent activities of employees, contractors, and consultants;
- our reliance on key inputs and their related costs;
- difficulty associated with forecasting demand for products;
- operating risk and insurance coverage;
- our inability to manage growth;
- conflicts of interest among our officers and Directors;

- managing damage to our reputation and third-party reputational risks;
- relationships with customers and third-party payors and consequential exposure to applicable anti-kickback, fraud, and abuse, and other healthcare laws:
- exposure to information systems security threats;
- no dividends for the foreseeable future;
- future sales of common shares and warrants by existing shareholders causing the market price for the common shares and warrants to fall;
- the issuance of common shares in the future causing dilution; and
- the impact of the recent novel coronavirus ("COVID-19") pandemic on operations, including clinical trials.

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

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

#### Overview

On December 20, 2018, the Corporation completed its initial public offering (the "IPO") on the Toronto Stock Exchange (the "TSX"). As a result, the common shares commenced trading on the TSX under the symbol "CRDL". On May 30, 2019, the common shares also began trading on the OTCQX Best Market ("OTCQX") under the symbol "CRTPF". On May 12, 2021, warrants arising from a "bought deal" short form prospectus offering that closed on the same date, commenced trading on the TSX. These warrants trade under the symbol "CRDL.WT.A". On August 10, 2021, the Corporation's common shares commenced trading on the Nasdaq Capital Market ("Nasdaq") under the symbol "CRDL". Concurrent with the listing on the Nasdaq, the common shares ceased to be quoted on the OTCQX.

The Corporation is a clinical-stage life sciences company focused on the research and clinical development of anti-inflammatory therapies for the treatment of cardiovascular disease ("CVD"). In September 2020, the Corporation received clearance from the U.S. Food and Drug Administration (the "FDA") for its Investigational New Drug ("IND") application to commence a Phase II/III, double-blind, placebo-controlled clinical trial investigating the efficacy and safety of its lead product, CardiolRx, in hospitalized COVID-19 patients with a prior history of, or risk factors for, CVD ("LANCER"). CardiolRx is an oral cannabidiol formulation that is pharmaceutically manufactured under cGMP.

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

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

In August 2021, the Corporation received clearance from the FDA for its IND application for a Phase II international trial of CardiolRx in acute myocarditis, a condition caused by inflammation in heart tissue, which remains a leading cause of sudden cardiac death in people less than 35 years of age. Cardiol is also developing a subcutaneous formulation of CardiolRx for the treatment of inflammation in the heart that is associated with the development and progression of heart failure. Heart failure is a leading cause of death and hospitalization in North America, with associated annual healthcare costs in the U.S. alone exceeding \$30 billion.

#### **Operations Highlights**

#### **During the 2021 Fiscal Period**

- (i) During the 2021 Fiscal Period, the Corporation has granted 1,961,666 stock options to certain consultants, officers, and employees with a weighted average exercise price of \$4.38 and expiries ranging from two to five years, as more fully described in the Financial Statements.
- (ii) In February 2021, the Corporation received proceeds of \$7,968,220 on the exercise of 2,451,760 warrants with an exercise price of \$3.25, and \$503,068 on the exercise of 201,227 warrants with an exercise price of \$2.50. In addition, there was a total of 916,666 stock option exercises, resulting in proceeds of \$2,604,648.
- (iii) In March 2021, The Corporation announced that it submitted an application to list the Corporation's common shares on The Nasdaq Capital Market (the "Nasdaq").
- (iv) In March 2021, the Corporation announced that Dr. Andrew Hamer joined the Corporation as Chief Medical Officer (CMO). Dr. Hamer leads the research and development of the Corporation's clinical-stage products and also guides the development of additional novel therapeutics in the Corporation's pipeline.
- Dr. Andrew Hamer brings 30 years of experience in the global life sciences industry, medical affairs, and cardiology practice to the Corporation. Most recently he served as Executive Director, Global Development-Cardiometabolic at California-based Amgen Inc., where he led the Global Development group for Repatha<sup>®</sup>, the LDL cholesterol lowering PCSK9 inhibitor evolocumab, which generated revenues of almost USD \$900 million in 2020. As development lead, Dr. Hamer headed the Repatha<sup>®</sup> global evidence generation team collaborating with safety, regulatory, health economics, observational research, scientific communications, publications, medical affairs, and clinical operations teams to design and execute several multi-center clinical trials in support of FDA and international regulatory filings. Prior to his five-year tenure with Amgen, Dr. Hamer served for two years as VP Medical Affairs at Capricor Therapeutics Inc., where he was responsible for the development of novel therapeutics for heart disease and for the supervision of the clinical operations of the company, including clinical trial design and execution.

Prior to joining the life sciences industry, Dr. Hamer practiced cardiology and internal medicine in New Zealand for 19 years. His distinguished career in cardiology culminated as Chief Cardiologist at Nelson Hospital, Nelson Marlborough District Health Board, Nelson, while concurrently leading cardiac services nationally in New Zealand. Dr. Hamer graduated with a medical degree (MB, ChB) from the University of Otago, New Zealand, an internationally recognized medical school which recently ranked among the top twenty universities in the world in several medical subject categories. His clinical research training took place at various centers in New Zealand and London, UK, followed by a cardiology fellowship at Deaconess Hospital, Harvard Medical School, Boston.

- Dr. Hamer has co-authored many high-quality peer-reviewed scientific publications reflecting his considerable experience as a clinical trialist, having served as a principal or co-investigator for 40 multi-centre clinical trials in therapies for acute coronary syndrome, heart failure, hypertension, cholesterol disorders, atrial fibrillation, and diabetes.
- (v) In May 2021, the Corporation completed a short form base shelf prospectus offering of units of the Corporation for aggregate gross proceeds of \$22,003,200. Under the offering, the Corporation sold a total of 6,112,000 units at a price of \$3.60. Each unit is comprised of one common share of the Corporation and one-half purchase warrant of the Corporation. Each full warrant entitles the holder thereof to acquire one common share at a price of \$4.60 for a period of 36 months from issuance. The warrants are listed for trading on the TSX under the symbol "CRDL.WT.A". Concurrent with the closing, the underwriter purchased an additional 433,400 warrants for gross proceeds \$8,668, pursuant to the over-allotment option.

- (vi) In June 2021, the Corporation adopted an Omnibus Equity Incentive Plan which permits the grant or issuance of stock options, Restricted Share Units, Performance Share Units, and Deferred Share Units, as well as other share-based awards to participants.
- (vii) In July 2021, the Corporation announced that its Board of Directors appointed Dr. Guillermo Torre-Amione as the new Chairman. Dr. Torre-Amione has been an independent director of Cardiol since August 2018 and has took over from Dr. Eldon Smith, the founding Chairman of Cardiol and who has now retired from the Board.
- (viii) On August 10, 2021, the Corporation's common shares commenced trading on the Nasdaq under the symbol "CRDL". Concurrent with the listing on the Nasdaq, the common shares ceased to be quoted on the OTCQX.
- (ix) In August 2021, the Corporation announced that the FDA provided clearance to proceed with the Corporation's IND application to commence a Phase II, multi-center, double-blind, randomized, placebo-controlled trial designed to study the safety and tolerability of CardiolRx, as well as its impact on myocardial recovery in patients presenting with acute myocarditis.
- (x) In September 2021, the Corporation announced the appointment of Michael J. Willner, Esq. to its Board of Directors.

Michael J. Willner has practiced as both an Attorney and a Certified Public Accountant. He graduated from Emory University Law School as a member of the Emory Law Review. Subsequently, he practiced real estate and corporate law with New York City-based Milbank, Tweed, Hadley & McCloy, one of the nation's most prominent international law firms. Prior to his legal career, Mr. Willner was employed by the former Arthur Andersen & Company, a national accounting firm, where he practiced in Arthur Andersen's tax department.

Mr. Willner has been a very active and successful opportunistic investor for over forty years and is the founder of Willner Capital, Inc., an investment company specializing in public and private equities, as well as debt instruments. Willner Capital primarily uses fundamental analysis as an evaluation method and event-driven strategies. Over the past ten years, Willner Capital has made significant investments in both the biotechnology and pharmaceutical cannabinoid industries, focusing primarily on clinical-stage companies that seek to address significant unmet medical needs. Mr. Willner has been quoted in the New York Times business section and has served as a moderator and participant on numerous panel discussions and advisory boards regarding his investments in the pharmaceutical side of the cannabinoid industry.

(xi) In September 2021, the Corporation announced the acceleration of the expiry date of all outstanding common share purchase warrants of the Corporation that were issued on June 4, 2020, to October 12, 2021, from the original expiry date of June 4, 2022.

#### Subsequent to September 30, 2021

- (i) In October 2021, the Corporation announced that it is expanding its LANCER trial to include several hospital centers in Brazil, Mexico, and Canada.
- (ii) In October 2021, the Corporation announced that it is received approval from Health Canada to proceed with the Corporation's Phase II, multi-center, double-blind, randomized, placebo-controlled trial designed to study the safety and tolerability of CardiolRx as well as its impact on myocardial recovery in patients presenting with acute myocarditis.
- (iii) In November 2021, the Corporation completed a short form base shelf prospectus offering of units of the Corporation for aggregate gross proceeds of USD\$50,194,500. Under the offering, the Corporation sold a total of 16,350,000 units at a price of USD\$3.07. Each unit is comprised of one common share of the Corporation and one-half purchase warrant of the Corporation. Each full warrant entitles the holder thereof to acquire one common share at a price of USD\$3.75 for a period of 36 months from issuance.
- (iv) Subsequent to September 30, 2021, the Corporation granted 600,000 performance share units to certain consultants. Each performance share unit allows the holder to acquire one common share. Vesting of the performance share units is based on specific performance metrics that must be achieved prior to the expiry date of October 14, 2022.

#### **Clinical Highlights**

#### Phase II/III study - COVID-19 (LANCER)

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

On December 15, 2020, Cardiol announced the appointment of contract research organization (the "CRO") Worldwide Clinical Trials ("Worldwide"), as the Corporation initiates its Phase II/III trial in high-risk patients hospitalized with COVID-19 at clinical centers throughout the United States. Worldwide has been the CRO for several international COVID-19 clinical programs and has extensive experience in conducting clinical research focused on cardiovascular disease. With a global footprint, Worldwide provides drug development expertise from early phase to late-stage clinical development, post-approval, and real-world evidence studies; delivering high quality clinical programs designed to support regulatory approvals in multiple jurisdictions. Employing more than 1,900 professionals, Worldwide provides drug development support services in over 60 countries with offices in North and South America, Europe, and Asia.

Cardiol's Phase II/III trial has been designed to assess the efficacy, safety, and tolerability of CardiolRx in preventing cardiovascular complications in patients hospitalized within the previous 48 hours, with a confirmed diagnosis of COVID-19, and who have pre-existing CVD and/or significant risk factors for CVD. The composite primary efficacy endpoint will be the difference between the active and placebo groups in the percentage of patients who develop, during the first twenty-eight days following randomization and first dose of study medication, a composite endpoint consisting of one or more of several common outcomes in this patient population, including all-cause mortality, requirement for ICU admission and/or ventilatory support, as well as cardiovascular complications, including the development of heart failure, acute myocardial infarction, myocarditis, stroke, or new sustained or symptomatic arrhythmia.

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

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

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

#### Dennis M. McNamara, MD (Chair)

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

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

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

### Arvind Bhimaraj, MD

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

# Barry Trachtenberg, MD

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

#### Wai Hong Wilson Tang, MD

Dr. Wai Hong Wilson Tang is the Advanced Heart Failure and Transplant Cardiology specialist at the Cleveland Clinic in Cleveland, Ohio. Dr. Tang is also the Director of the Cleveland Clinic's Center for Clinical Genomics; Research Director, and staff cardiologist in the Section of Heart Failure and Cardiac Transplantation Medicine in the Sydell and Arnold Miller Family Heart & Vascular Institute at the Cleveland Clinic. He attended and graduated from Harvard Medical School in 1996, having over 23 years of diverse experience, especially in Advanced Heart Failure and Transplant Cardiology. Dr. Tang is affiliated with many hospitals including the Cleveland Clinic and cooperates with other doctors and physicians in medical groups including The Cleveland Clinic Foundation.

# Peter Liu, MD

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

#### Carsten Tschöpe, MD

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

#### Matthias Friedrich, MD

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

#### Guilherme Oliveira, MD, MBA

Dr. Guilherme Oliveira is a Professor of Medicine and Chairman of Cardiovascular Sciences at the University of South Florida Health Morsani College of Medicine. He is also the Executive Director of the Tampa General Hospital Heart and Vascular Institute, located in Tampa, Florida. Dr. Oliveira received his Doctor of Medicine from Universidade Federal do Rio De Janeiro, Rio De Janeiro, Brazil and completed the Internal Medicine Residency Program at the Mayo Graduate School, Rochester, Minnesota. He served a Fellowship at the Baylor College of Medicine, Houston, Texas, and earned an MBA at the Massachusetts Institute of Technology, Cambridge, Massachusetts. Dr. Oliveira's areas of expertise include advanced heart failure; left ventricular assist devices; onco-cardiology; heart transplantation; and mechanical circulatory support. For his outstanding work, Dr. Oliveira was granted admission into the Fellowship of the American College of Cardiology.

On January 21, 2021, the Corporation announced the formation of the Data Safety Monitoring Committee (the "DSMC") and the Clinical Endpoint Committee (the "CEC"). The DSMC comprises independent experts who will assess the patient safety data, and, if needed, critical efficacy endpoints of the trial. In order to do so, the DSMC may review unblinded study information (on a patient level or treatment group level) during the conduct of the trial. After each data review, the DSMC will advise the study Steering Committee with recommendations for protocol modifications, if concerns over safety have developed, or that the study should continue according to the protocol if no concerns are identified. The DSMC will also perform an interim analysis after 200 patients have completed the study, to be certain that the investigational drug is not exposing trial patients to undo risk. Study management will also perform a blinded analysis at this time to determine if the expected number of endpoints have occurred or if the sample size for the study needs to be adjusted so that enough patients will be enrolled to achieve statistical significance.

The DSMC currently consists of three members:

- Chair: Dr. Jean Lucien Rouleau Professor and Former Dean, University of Montreal and Cardiologist, Montreal
  Heart Institute. Dr. Rouleau has an international reputation in cardiovascular research, particularly in basic
  mechanisms and improving the clinical care of patients with heart failure. His publication list includes more than
  475 articles and seven book chapters;
- Statistician: Dr. George Wells Professor, School of Epidemiology, Public Health and Preventive Medicine,
  University of Ottawa and Director, Cardiovascular Research Methods Centre, University of Ottawa Heart Institute.
  Dr. Wells has worked extensively with governments and non-government research organizations, as well as
  private pharmaceutical and biotechnology companies. He has been an Investigator in over 240 research projects
  with research funding exceeding \$120 million. Dr. Wells is the author or co-author of over 400 published articles;
  and

• Dr. John Teerlink – Professor of Medicine, University of California, San Francisco and Director of Heart Failure and the Echocardiographic Laboratory at the San Francisco Veterans Affairs Center. Dr. Teerlink is actively involved in many acute and chronic heart failure clinical trials, serving on endpoint, data safety monitoring and steering committees for numerous international cardiovascular studies. He currently serves on the Acute Heart Failure Committee of the European Society of Cardiology Heart Failure Association and has served on the National Committee on Heart Failure and Transplantation of the American Heart Association. Dr. Teerlink was profiled in *The Lancet* as an internationally recognized leader in heart failure.

The CEC comprises clinical experts in cardiology and Intensive Care and has been established to ensure accurate and consistent assessment of the trial endpoints and/or serious adverse events. In order to ensure an unbiased endpoint assessment, members of the CEC are blinded to treatment assignment. The goal of the CEC is to standardize endpoints and optimize data quality.

The CEC currently consists of three members:

- Chair: Dr. Brent Mitchell Professor of Cardiac Sciences and Former Director of the Libin Cardiovascular Institute, University of Calgary. Dr. Mitchell completed a Fellowship in Clinical Cardiology at Dalhousie University in Halifax, and a Fellowship in clinical electrophysiology at Stanford University Medical Centre, California. Dr. Mitchell's clinical practice and research interests are in the area of cardiac electrophysiology, particularly in the diagnosis and management of tachyarrhythmias. Dr. Mitchell has published several sentinel papers in the diagnosis and management of serious cardiac arrhythmias;
- Dr. Maria Rosa Costanzo Professor, Rush Medical College and Cardiologist, Advocate Health, Naperville, IL.
   Dr. Costanzo is Board Certified in Advanced Heart Failure and Cardiac Transplantation. Dr. Costanzo is currently the Medical Director of the Midwest Heart Specialists Advocate Medical Group Heart Failure and Pulmonary Arterial Hypertension Programs, and Medical Director of the Edward Hospital Center for Advanced Heart Failure.
   Dr. Costanzo has published nearly 200 peer-reviewed manuscripts and is the author of numerous review papers, monographs, and book chapters; and
- Dr. Courtney Bennett Cardiologist and Intensive Care Physician, Director of Quality Improvement in the Cardiac Intensive Care Unit, Mayo Clinic, Rochester, MN. Dr. Bennett is a board-certified cardiologist and is board-eligible in critical care medicine. Her clinical interests include cardiac critical care and contrast echocardiography. Dr. Bennett is Mayo Quality Academy gold-certified and serves as the Director of Quality Improvement in the Cardiac Intensive Care Unit.

On April 28, 2021, Cardiol announced first patient enrolled in the Phase II/III study. Top-line data from the study is expected during H1, 2022. Cardiol has budgeted additional costs of approximately USD \$6.6 million for study execution and \$1.3 million for potential post study analysis.

Subject to study outcomes, Management's discussions with the FDA indicated that the design and scope of the Phase II/III trial may be used as a registration study in conjunction with any further studies, where required, in support of a New Drug Application. Cardiol may also involve a commercial partner from the pharmaceutical industry, with research, development and commercialization costs potentially being shared with its commercial partner.

#### Phase I study

On April 12, 2021, the Corporation announced topline results from a Phase I single and multiple ascending dose clinical trial of CardiolRx.

The Phase I trial was a randomized, placebo-controlled, double-blind study designed to evaluate the safety, tolerability, and pharmacokinetic (PK) profile of CardiolRx at various dose levels. The study randomized 52 subjects (age range 25 to 60 years) to one of two groups. In Group A, there were three sub-groups, each involving 12 subjects (nine active and three placebo), with each subject receiving a single dose of 5 mg/kg or 15 mg/kg of CardiolRx, in either the fed or fasted state. In Group B, there were two sub-groups, each involving eight subjects (six active and two placebo) with each subject receiving 5 mg/kg or 15 mg/kg twice daily for six days. Serial blood samples were taken to measure the level of cannabidiol and its two main metabolites.

Topline results demonstrated that CardiolRx was safe and generally well tolerated at all dose levels, with no serious adverse events reported in the study. Fifty-one of the 52 enrolled subjects completed all requirements of the protocol. Each subject had repeated standard measures of safety including physical examination (with vital signs), electrocardiogram (ECG) to monitor cardiac time intervals (particularly, the QTc interval, which is an important measure of the risk for abnormal heart rhythms), as well as a number of biochemical and coagulation laboratory tests. Despite the relatively high doses of CardiolRx administered during the study, there were no ECG or abnormal laboratory findings after six days of dosing; specifically, no elevation of liver enzymes or QTc changes were detected. The recorded adverse events were all mild or moderate in severity and were primarily related to the gastro-intestinal tract.

The results of the study formed an integral part of the Corporation's IND application with the FDA for an international Phase II clinical trial in acute myocarditis.

#### Phase II study - Acute myocarditis

In August 2021, Cardiol received clearance from the FDA for its IND application for a Phase II clinical trial of CardiolRx in acute myocarditis. Cardiol's acute myocarditis program has been designed by an independent Steering Committee comprised of thought leaders in cardiology from North America and Europe. The study is expected to commence in Q1 2022, with patient recruitment estimated to take 12 to 18 months. Cardiol has predicted costs of this study, including the IND application, to be approximately \$600,000 for 2021; however, the total costs of the study cannot be determined at this stage as they will depend on a variety of factors.

If Cardiol determines that the Phase II study meets its objectives, it currently expects to undertake the next steps of its clinical development program, which would consist of a larger clinical study, the details of which will be determined in conjunction with discussions with the regulatory authorities. The Corporation expects the completion of this currently planned clinical development program, if undertaken, to take at least until 2025 and may involve a commercial partner from the pharmaceutical industry, with research, development, and commercialization costs potentially being shared with its commercial partner. Cardiol relies on CROs, clinical data management organizations, and consultants to assist with the design, conduct, supervision, and monitoring of pre-clinical and clinical studies. The total costs of the clinical development program cannot be determined at this stage as they will depend on a variety of factors.

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

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

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

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

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

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

#### Outlook

The Corporation expects that the September 30, 2021 working capital of \$28,368,711 will be sufficient to fund operations and capital requirements for more than 12 months (see "Operational Highlights - Subsequent to September 30, 2021").

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

- 1. Complete enrollment of 422 patients in International Phase II/III COVID-19 trial investigating the cardioprotective properties of CardiolRx;
- 2. Commence an international Phase II acute myocarditis trial;
- 3. Complete pre-clinical development of a subcutaneous cannabidiol formulation of CardiolRx for treatment of chronic heart failure, a leading cause of death and hospitalization in North America;

# **Use of Offering Proceeds**

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

A comparison between the projected use of proceeds for the two-year period subsequent to closing the offering, as disclosed in the Corporation's prospectus dated May 26, 2020, and spending from June 4, 2020 (offering closing date) to September 30, 2021 is as follows:

Use of Proceeds	Amount	Spent	Remaining
Clinical Trials (Phase I and Phase II/III)	6,400,000	4,081,822	2,318,178
Pre-clinical studies	900,000	900,000	-
Product Development	1,100,000	163,823	936,177
Marketing & Business Development	900,000	94,897	805,103

A comparison between the projected use of proceeds for the two-year period subsequent to closing the offering, as disclosed in the Corporation's prospectus dated April 30, 2021, and spending from May 12, 2021 (offering closing date) to September 30, 2021 is as follows:

Use of Proceeds	Amount	Spent	Remaining
Phase II/III Clinical Trials in Acute Myocarditis	6,500,000	161,583	6,338,417
Pre-clinical studies	1,500,000	239,172	1,260,828
Research and Development of Subcutaneous Formulation	4,000,000	-	4,000,000

#### **Summary of Quarterly Results**

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

	Total		Profit or (Loss)	Total
	Revenue		Per Share <sup>(9)</sup>	Assets
Three Months Ended	(\$)	Total (\$)	(\$)	(\$)
September 30, 2021 <sup>(1)</sup>	nil	(9,909,991)	(0.23)	31,731,649
June 30, 2021 <sup>(2)</sup>	78,760	(6,560,943)	(0.16)	36,749,684
March 31, 2021 <sup>(3)</sup>	nil	(8,909,848)	(0.26)	21,097,832
December 31, 2020 <sup>(4)</sup>	nil	(9,666,527)	(0.15)	15,893,181
September 30, 2020 <sup>(5)</sup>	nil	(4,401,243)	(0.13)	24,455,341
June 30, 2020 <sup>(6)</sup>	nil	(3,624,518)	(0.13)	27,421,000
March 31, 2020 <sup>(7)</sup>	nil	(2,948,647)	(0.11)	13,351,298
December 31, 2019 <sup>(8)</sup>	nil	(3,058,709)	(0.12)	15,502,865

#### Note:

- 1. Net loss of \$9,909,991 included general and administration of \$7,571,515 and research and development of \$2,592,094.
- 2. Net loss of \$6,560,943 included general and administration of \$4,430,388 and research and development of \$2,071,681.
- 3. Net loss of \$8,909,848 included general and administration of \$6,301,398 and research and development of \$2,678,812.
- 4. Net loss of \$9,666,527 included research and development of \$7,240,594 and general and administration of \$2,377,762.
- 5. Net loss of \$4,401,243 included general and administration \$2,494,297 and research and development of \$1,916,486.
- 6. Net loss of \$3,624,518 included general and administration of \$2,750,456 and research and development of \$833,536.
- 7. Net loss of \$2,948,647 included general and administration of \$2,465,095 and research and development of \$611.875.
- 8. Net loss of \$3,058,709 included general and administration of \$2,250,038 and research and development of \$1.041.188.
- 9. Basic and fully diluted.

# **Discussion of Operations**

# Three months ended September 30, 2021, compared to the three months ended September 30, 2020

For the three months ended September 30, 2021, the Corporation's net loss was \$9,909,991, compared to a net loss of \$4,401,243 for the three months ended September 30, 2020. The increase in net loss of \$5,508,748 is a result of the following:

- General and administration expense increased to \$7,571,515 for the three months ended September 30, 2021, compared to \$2,494,297 for the three months ended September 30, 2020. During the three months ended September 30, 2021, the Corporation's operations increased significantly due to clinical trials in progress, as well as additional pre-clinical research. As a result of the increased activity, the Corporation incurred additional costs due to hiring additional employees as well as other related administrative expenses. Furthermore, due to the recent listing on the Nasdaq and financing initiatives, the Corporation has incurred additional costs associated with corporate communications and investor relations.
- Research and development increased to \$2,592,094 for the three months ended September 30, 2021, compared to \$1,916,486 for the three months ended September 30, 2020. During the three months ended September 30, 2021, the Corporation incurred increased research and development costs related to basic science, pre-clinical studies, and clinical studies, specifically relating to the Phase II/III COVID-19 trial.

#### Nine months ended September 30, 2021, compared to the nine months ended September 30, 2020

For the nine months ended September 30, 2021, the Corporation's net loss was \$25,380,782, compared to a net loss of \$10,974,408 for the nine months ended September 30, 2020. The increase in net loss of \$14,406,374 is a result of the following:

- General and administration expenses increased to \$18,303,301 for the nine months ended September 30, 2021, compared to \$7,709,848 for the nine months ended September 30, 2020. During the nine months ended September 30, 2020, the Corporation's operations increased significantly due to clinical trials in progress, as well as additional pre-clinical research. As a result of the increased activity, the Corporation incurred additional costs due to hiring additional employees as well as other related administrative expenses. Furthermore, due to the recent listing on the Nasdaq and financing initiatives, the Corporation has incurred additional costs associated with corporate communications and investor relations.
- Research and development increased to \$7,342,587 for the nine months ended September 30, 2021, compared to \$3,361,897 for the nine months ended September 30, 2020. During the nine months ended September 30, 2021, the Corporation incurred increased research and development costs related to basic science, pre-clinical studies, and clinical studies, specifically relating to the Phase II/III COVID-19 trial.

#### **Capital Management**

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

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

The Corporation considers its capital to be total equity, comprising share capital, warrants, and contributed surplus, less accumulated deficit which at September 30, 2021, totaled \$29,085,478 (December 31, 2020 – \$13,270,353).

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

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

#### **Off-Balance Sheet Arrangements**

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

## **Liquidity and Financial Position**

At September 30, 2021, Cardiol had \$28,652,391 in cash and cash equivalents (December 31, 2020 – \$14,025,187). As of November 11, 2021, the Corporation's current cash balance is \$85,652,125.

At September 30, 2021, accounts payable and accrued liabilities were \$2,518,540 (December 31, 2020 – \$2,466,262). The Corporation's cash and cash equivalents balances as at September 30, 2021 and December 31, 2020 are sufficient to pay these liabilities.

The Corporation currently has minimal operating revenues and therefore must utilize its funds from financing transactions to maintain its capacity to meet ongoing operating activities.

As of September 30, 2021, December 31, 2020, and to the date of this MD&A, the cash resources of Cardiol are held with one Canadian chartered bank. The Corporation has no variable interest rate debt and its credit and interest rate risk is minimal. Accounts payable and accrued liabilities are short-term and non-interest bearing.

#### For the 2021 Fiscal Period

Cash and cash equivalents used in operating activities were \$19,543,366 for the nine months ended September 30, 2021. Operating activities were affected by a net loss of \$25,380,782 and the net change in non-cash working capital balances of \$1,310,901 offset partially by non-cash adjustments of \$7,148,317. Non-cash adjustments mainly consisted of \$3,909,056 for share-based compensation and \$3,048,365 for expenses settled through the grant of common shares. Non-cash working capital was the result of an increase in prepaid expenses of \$1,215,697, a decrease in inventory of \$17,968, an increase in accounts payable and accrued liabilities of \$52,278, an increase in accounts receivable of \$65,799, and an increase in other receivables of \$99,651.

Cash and cash equivalents used in investing activities were \$12,916 for the nine months ended September 30, 2021.

Cash and cash equivalents provided by financing activities were \$34,183,486 for the nine months ended September 30, 2021, mainly as a result of the proceeds from warrants and stock options exercised, as well as the issuance of units, net of share issuance cost on the closing of the offering on May 12, 2021.

#### **Use of Working Capital**

As of September 30, 2021, Cardiol's working capital was \$28,368,711. Based on current projections, Cardiol believes that this amount is sufficient to meet its planned development activities for more than 12 months as described in the "Outlook" section above.

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

Contractual Obligations	Total (\$)	Up to 1 year (\$)	1 – 3 years (\$)	4 – 5 years (\$)	After 5 years (\$)
Amounts payable and other liabilities	2,518,540	2,518,540	Nil	Nil	Nil
Office lease (1)	283,618	104,914	178,704	Nil	Nil
Consulting agreements	464,444	397,422	67,022	Nil	Nil
Contract research	1,390,981	1,390,981	Nil	Nil	Nil
Total	4,657,583	4,411,857	245,726	Nil	Nil

#### Note:

<sup>(1)</sup> 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 \$291,844 and \$1,072,580 for the three and nine months ended September 30, 2021 (three and nine months ended September 30, 2020 \$589,370 and \$1,009,490) paid to a company, Dalton Chemical Laboratories, Inc. operating as Dalton, that is related to a director (Peter Pekos). Mr. Pekos is also the President and CEO of Dalton. As at September 30, 2021, \$781,799 (December 31, 2020 \$505,195) was owed to this company and this amount was included in accounts payable and accrued liabilities and \$33,927 (December 31, 2020 \$1,470) was paid to this company and was included in prepaid expenses. Cardiol entered into an exclusive master services agreement with Dalton for the exclusive supply of pharmaceutical cannabidiol, and Cardiol has subcontracted the manufacturing of its drug product candidates to Dalton.
- b) Key management personnel are those persons having authority and responsibility for planning, directing, and controlling the activities of the Corporation directly or indirectly, including any Directors (executive and non-executive) of the Corporation. Remuneration of Directors and key management personnel of the Corporation, except as noted in (a) above, was as follows:

	Three months ended Three months ended		Nine months ended	Nine months ended	
	September 30, 2021	<b>September 30, 2020</b>	<b>September 30, 2021</b>	<b>September 30, 2020</b>	
	(\$)	(\$)	(\$)	(\$)	
Salaries and benefits	559,845	339,369	1,995,733	1,141,957	
Share-based payments	358,126	135,559	811,774	504,760	
	917,971	474,928	2,807,507	1,646,717	

As at September 30, 2021, nil (December 31, 2020 - \$190,940) was owed to key management personnel and this amount was included in accounts payable and accrued liabilities.

#### Critical Accounting Judgments, Estimates, and Assumptions

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

#### **Critical accounting estimates**

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

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

# **Critical accounting judgments**

- Management applied judgment in determining the functional currency of the Corporation as Canadian dollars;
- Management applied judgment in determining the Corporation's ability to continue as a going concern. The
  Corporation has incurred significant losses since inception. Management determined that a material going concern
  uncertainty does not exist due to the sufficient working capital to support their planned expenditure levels. Future
  financing may come from product sales, licensing arrangements, research and commercial development
  partnerships, government grants, and/or corporate finance arrangements;
- Management's assessment that no impairment exists for intangible assets, based on the facts and circumstances that existed during the period; and
- Management's assessment of the impact the novel coronavirus (COVID-19) pandemic will have on operations (see "Risk Factors COVID-19 pandemic" below).

#### **Share Capital**

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

As of the date of this MD&A, the outstanding capital of the Corporation includes 60,954,499 issued and outstanding common shares, of which 75,000 common shares are subject to vesting of 1/3 on each of March 29, 2022, September 29, 2022, and March 29, 2023; 100,000 common shares are subject to vesting of 1/4 on each of November 17, 2021, February 17, 2022, May 17, 2022, and August 17, 2022; 1,020,000 Meros Special Warrants convertible automatically into common shares (upon the Corporation achieving the Meros Milestone) for no additional consideration pursuant to the Meros License Agreement; 400,000 common shares issuable to Dalton if Dalton meets certain performance objectives, and stock options, warrants and performance share units as shown below:

# **Stock Options**

Stock Options	Exercise	Options	Options
Expiry date	price (\$)	outstanding	exercisable
June 22, 2022	2.58	83,334	83,334
February 8, 2023	4.56	416,666	416,666
February 18, 2023	4.80	560,000	405,000
February 23, 2023	4.46	130,000	80,000
October 15, 2024	3.23	76,666	56,666
December 2, 2024	4.08	60,000	20,000
December 5, 2024	3.69	60,000	45,000
February 23, 2025	3.54	86,300	86,300
August 16, 2025	5.00	200,000	200,000
August 19, 2025	2.12	100,000	33,333
August 30, 2025	5.00	580,000	580,000
October 7, 2025	2.90	35,000	11,667
December 2, 2025	2.59	130,000	-
January 2, 2026	4.30	150,000	150,000
January 24, 2026	5.34	60,000	40,000
March 29, 2026	4.51	400,000	-
April 1, 2026	5.77	140,000	93,333
April 4, 2026	5.42	60,000	40,000
May 12, 2026	3.00	75,000	-
June 5, 2026	3.26	60,000	-
August 16, 2026	3.26	60,000	-
August 24, 2026	3.81	140,000	-
September 13, 2026	4.88	55,000	
Total		3,717,966	2,341,299

#### Warrants

Expiry date	Exercise price (\$)	Warrants outstanding
August 31, 2022	4.00	824,000
May 12, 2024	4.60	3,453,178
November 5, 2024	3.75 <sup>(1)</sup>	8,175,000
Total		12,452,178

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

#### Performance Share Units and Other Share-Awards

The Corporation granted 700,000 share awards to certain consultants in August 2021. These are subject to time-based vesting of a 1/4 on each of September 17, 2021, October 17, 2021, November 17, 2021, and December 17, 2021. As of the date of this MD&A, 350,000 common shares have been issued and are included in share capital, with the unvested 350,000 common shares still to be issued on vesting.

The Corporation granted 600,000 performance share units ("PSU") to certain consultants in October 2021. Each PSU entitles the holder to one common share. The PSUs contain vesting conditions that are performance-based and are set to expire on October 14, 2022.

#### **Financial Instruments**

#### Recognition

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

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

#### **Classification and Measurement**

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

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

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

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

- amortized cost;
- FVTPL, if the Corporation has made an irrevocable election at the time of recognition, or when required (for items such as instruments held for trading or derivatives); or,

FVTOCI, when the change in fair value is attributable to changes in the Corporation's credit risk.

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

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

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

#### **Fair Value**

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

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

The Corporation has no financial instruments measured at fair value.

#### **Financial Instrument Risks**

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

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

There were no changes to credit risk, liquidity risk, or market risk for the 2021 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 trade 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 \$330,000 (December 31, 2020 - \$219,000).

#### **Commitments and Contingency**

(i) The Corporation has leased premises from third parties. The minimum committed lease payments as at September 30, 2021, which include the lease liability payments, are as follows:

Fiscal year	
2021	25,940
2022	105,780
2023	107,222
2024	44,676
Total	\$ 283,618

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

Total	\$ 464,444
2022	67,022
2021	397,422
Fiscal year	

(iii) Pursuant to the terms of agreements with various other contract research organizations, the Corporation is committed for contract research services for 2021 at a cost of approximately \$1,390,981.

#### **Breakdown of Expensed Research and Development**

	Three months ended September 30, 2021 (\$)	Three months ended September 30, 2020 (\$)	Nine months ended September 30, 2021 (\$)	Nine months ended September 30, 2020 (\$)
Contract research	2,056,429	1,526,779	5,913,188	2,440,257
Wages	133,745	105,833	594,365	289,142
Supplies	56,660	157,217	104,913	349,036
Regulatory	166,168	111,010	309,601	224,716
Share-based compensation	179,092	15,647	420,520	58,746
	2,592,094	1,916,486	7,342,587	3,361,897

#### **Breakdown of Intangible Assets**

	As at September 30, 2021 (\$)	As at December 31, 2020 (\$)
Exclusive global license agreement	767,228	767,228
Accumulated amortization	(366,871)	(303,538)
Carrying value	400,357	463,690

# **Internal Controls Over Financial Reporting**

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

The CEO and CFO have concluded that the design of DCP and ICFR were adequate and to provide such assurance as at September 30, 2021.

#### **Limitations of Controls and Procedures**

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

#### **Risk Factors**

An investment in the securities of the Corporation is highly speculative and involves numerous and significant risks. Such investment should be undertaken only by investors whose financial resources are sufficient to enable them to assume these risks. Prospective investors should carefully consider the risk factors that have affected, and which in the future are reasonably expected to affect, the Corporation and its financial position. Please refer to the section entitled "Risk Factors" in the Corporation's MD&A for the financial year ended December 31, 2020 (available on SEDAR at www.sedar.com and EDGAR at www.sec.gov). As the Corporation became subject to certain reporting requirements under U.S. securities laws on August 4, 2021, the following additional risk factors are also relevant to

prospective investors:

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, 2020 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, and to pay an interest charge on a portion of 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. Most 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 "blue sky" laws of any state or jurisdiction of 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 of 1934, as amended (the "US 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 eligible to use the multi-jurisdictional disclosure system adopted by the securities regulatory authorities in Canada and the United States (the "MJDS"). 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\$1,070,000,000 (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.

# The impacts of COVID-19 on the Corporation's business are uncertain.

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. In response to the outbreak, governmental authorities in Canada and internationally have introduced various recommendations and measures to try to limit the pandemic, including travel restrictions, border closures, non-essential business closures, quarantines, self-isolations, shelters-in-place, and social distancing. The COVID-19 outbreak and the response of governmental authorities to try to limit it are having a significant impact on the private sector and individuals, including unprecedented business, employment, and economic disruptions.

Although the Corporation has taken steps to mitigate the impact of COVID-19, the continued presence and spread of COVID-19 nationally and globally could have a material adverse impact on the Corporation's business, operations, financial results and position and prospects, including through employee attrition, disruptions to the Corporation's

activities, as well as a deterioration of general economic conditions including a possible national or global recession. Due to the speed with which the COVID-19 situation is developing and the uncertainty of its magnitude, outcome, and duration, it is not possible to estimate its impact on the Corporation's business, operations, financial results and position or prospects at this time.

The Corporation continues to monitor the situation and work with its stakeholders (including customers, employees, and suppliers) in order to assess further possible implications to its business, supply chain and customers, and, where practicable, mitigate adverse consequences and responsibly address this global pandemic.