

# CARDIOL THERAPEUTICS INC. MANAGEMENT'S DISCUSSION AND ANALYSIS YEAR ENDED DECEMBER 31, 2019

#### 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 year ended December 31, 2019 (the "2019 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, 2019 and 2018 ("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 March 26, 2020. 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 launch, marketing, and sale of a pharmaceutically-produced pure cannabidiol oil as a *Cannabis Act* product line in 2020;
- the ability of our nanotherapeutics to deliver cannabinoids and other anti-inflammatory drugs to inflamed tissue in the heart:
- our intention to initiate clinical development during the first half of 2020;
- 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 expectation of a significant increase in the market and interest for pure pharmaceutical cannabidiol products that are THC free (<5 ppm);
- the expected growth in the size of the market for cannabidiol in Canada, the United States ("U.S."), and internationally:
- 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 expectation of a near-term revenue opportunity from the sale of pure cannabidiol products;
- 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 the sale of our pharmaceutically-produced pure cannabidiol oil as a Cannabis Act product line and 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;
- unpredictable and volatile market price for our Class A common shares and the common share purchase warrants of the Corporation (the "Warrants");
- 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 by existing shareholders causing the market price for the common shares to fall; and
- the issuance of common shares in the future causing dilution.

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" and the Warrants commenced trading under the symbol "CRDL.WT". On May 30, 2019, the Corporation also began trading on the OTCQX Best Market under the symbol "CRTPF".

The Corporation is focused on producing pharmaceutical cannabidiol (CBD) products and developing innovative therapies for heart disease, including acute myocarditis and other causes of heart failure. The Corporation's lead product, CardiolRx™, is formulated to be the most consistent cannabidiol formulation on the market. CardiolRx is pharmaceutically produced, manufactured under cGMP, and is THC free (<5 ppm). The Corporation also plans to commercialize CardiolRx in the billion-dollar market for medicinal cannabinoids in Canada and is pursuing distribution opportunities in Europe and Latin America.

In heart failure, Cardiol is planning an international clinical study of CardiolRx in acute myocarditis, a condition caused by inflammation in heart tissue, which remains the most common cause of sudden cardiac death in people less than 35 years of age. The Corporation is also developing proprietary nanotechnology to uniquely deliver pharmaceutical cannabidiol and other anti-inflammatory drugs directly to sites of inflammation in the heart that are associated with heart failure. Heart failure is the leading cause of death

and hospitalization in North America with associated annual healthcare costs in the U.S. alone exceeding \$30 billion.

The Corporation has research programs focused on developing nanotherapeutics to treat heart failure underway at international centers of excellence, including the University of Alberta, the Houston Methodist DeBakey Heart & Vascular Center, and TecSalud del Tecnológico de Monterrey ("TecSalud"). Cardiol has also established an exclusive manufacturing arrangement with Dalton Pharma Services, a Health Canada approved, U.S. Food and Drug Administration ("FDA") registered and inspected, Current Good Manufacturing Practice ("cGMP") manufacturer of pharmaceuticals, including cannabinoids, for supplying finished pharmaceutically-manufactured cannabidiol products to support the Corporation's research and commercial development programs.

Cardiol has an exclusive supply agreement with Noramco, Inc. ("Noramco") to support Dalton's manufacturing program with large scale supply of pure pharmaceutical cannabidiol. Subsequent to December 31, 2019, the Noramco Exclusive Supply Agreement was assigned to Purisys, LLC ("Purisys"), an affiliate of Noramco headquartered in Athens, Georgia. This assignment had no impact on Cardiol's rights under the Noramco Agreement.

Based on Cardiol making certain minimum purchases, Noramco shall not sell pharmaceutical cannabidiol to any third party for use in the production of products in Canada and Mexico (the "Territory"), or to any third party for delivery of products of any kind into the Territory. Notwithstanding this restriction, Noramco shall have the right to sell pharmaceutical cannabidiol to third parties outside Canada for use in products that are approved as prescription medicines by the Therapeutic Products Directorate of Health Canada for delivery into Canada.

Effective upon entering into a supply agreement with Shoppers Drug Mart on March 17, 2020, (see "Operations Highlights - Subsequent to December 31, 2019" below), the Noramco Agreement was amended such that Cardiol's exclusive rights for products sold to retail pharmacies in the Territory, such as Shoppers Drug Mart, were no longer conditional upon Cardiol meeting any minimum purchase requirements.

In November 2019, Purisys announced the U.S. Drug Enforcement Agency ("DEA") has removed their cannabinoid ingredients from Schedule I of the Controlled Substances Act ("CSA"). The cannabinoids produced by Purisys are distinguished by their ultra-low THC concentration, purity, world-scale capacity, exacting quality control, ease of formulation compared to hemp-derived isolates, and strong regulatory support.

Cardiol brings together a wealth of research and development experience, advanced manufacturing capabilities, and a Management team, Board of Directors, and Scientific Advisory Board comprising business and thought leaders with extensive industry experience and expertise in commercializing proprietary drugs.

#### **Operations Highlights**

#### **During the 2019 Fiscal Period**

- (i) In January 2019, the remaining outstanding convertible debenture, with a face value of \$400,000, was converted into 2,700,000 common shares.
- (ii) In January 2019, the Corporation granted 150,000 stock options to a certain officer of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$4.30 and expires on January 2, 2026. The options vested on grant.
- (iii) In January 2019, the Corporation granted 285,000 stock options to certain employees and consultants of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$5.34. 125,000 stock options expire July 24, 2020 and vest 25% every three months

from the grant date. 100,000 stock options expire January 24, 2024 and vest 25% every three months from the grant date. 60,000 stock options expire January 24, 2026 and vest 1/3 each on the first, second, and third anniversaries of the grant date.

- (iv) In January 2019, an additional 374,544 common shares at \$4.62 per share for gross proceeds of \$1,730,393 were granted under the Over-Allotment Option. As a result, an additional 22,472 compensation warrants were issued.
- (v) In March 2019, the Corporation announced the appointment of Thomas (Tom) Moffatt, BBA, as Chief Commercial Officer.

Mr. Moffatt was most recently the Chief Operating Officer and Vice-President, Operations at Rx Drug Mart Inc., where he was responsible for the growth, marketing, and development of all operations for more than 45 stores, including marketing, personnel, and strategic activities. Established in 2015, Rx Drug Mart is a pharmacy retail organization that brings the priority back to the pharmacy, the patient, and the community.

Mr. Moffatt gained extensive experience during a tenure of more than 20 years at Shoppers Drug Mart, where he honed his analytical skills, specifically in the areas of finance, marketing, communications and development, P&L, merchandising, and corporate strategy. He rose through the ranks from Director Operations Ontario West, to National Vice-President Operations and Strategy. Shoppers Drug Mart is Canada's leading drug store retailer, with more than 1,300 locations across Canada.

Following his wide-ranging career at Shoppers Drug Mart, Mr. Moffatt joined World Vintners Inc. where he was Senior Vice-President Retail and Corporate Development, Corporate Secretary, and President Retail. Mr. Moffatt oversaw the company's purchase and merger of two wine-producing and retail entities prior to their sale in 2008. He also developed and launched new wine brands specifically for big-box retailers and Independent Wine Dealers.

From 2010 to 2015, Mr. Moffatt was Senior Director of Mergers and Acquisitions/Pharmacy Operations at Loblaw Companies Ltd. and participated in the successful acquisition of Shoppers Drug Mart. Mr. Moffatt also established the current set of operational standards for the 503-store pharmacy group.

- (vi) In March 2019, the Corporation cancelled 40,000 stock options exercisable at \$5.00 and originally to expire August 30, 2025.
- (vi) In April 2019, the Corporation granted 140,000 stock options to certain officers and consultants of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$5.77 and expires on April 1, 2026. The options vest 1/3 each on the first, second, and third anniversaries of the grant date.
- (vi) In April 2019, the Corporation granted 60,000 stock options to a certain officer of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$5.42 and expires on April 4, 2026. The options vest 1/3 each on the first, second, and third anniversaries of the grant date.
- (vii) In June 2019, the Corporation announced it is planning a clinical trial in acute myocarditis utilizing its CardiolRx cannabidiol formulation. See "Clinical Highlights" below.
- (viii) In October 2019, the Corporation completed the manufacturing scale-up for commercialization of its CardiolRx 100 CBD formulation.
- (ix) In October 2019, the Corporation granted 160,000 stock options to certain employees of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$3.23 and expires on October 15, 2024. The options vest 1/3 each on the first, second and third anniversaries of the grant date.

- (x) In October 2019, the Corporation granted 90,000 stock options to certain consultants of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$3.28 and expires on October 29, 2021. The options vest 25% every three months from the grant date.
- (xi) In November 2019, the Corporation granted 50,000 stock options to a consultant of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$3.34 and expires on November 24, 2021. The options vest 50% immediately and 50% six months from the grant date.
- (xii) In December 2019, the Corporation announced the appointment of Mr. Colin Stott to its Board of Directors. Mr. Stott is the former Scientific Affairs Director, International and R&D Operations Director for GW Pharmaceuticals plc ("GW Pharma"), a world leader in the development of cannabinoid therapeutics and the company which created Epidiolex®, the first FDA-approved cannabidiol therapy for use as an orphan drug in rare forms of pediatric epilepsy.

Currently Chief Operating Officer of Alinova Biosciences Ltd, Mr. Stott is a veteran of the pharmaceutical and biotech industries, having almost 30 years' experience in pre-clinical and clinical development, with specific expertise in the development of cannabinoid-based medicines, and 19 years' experience in the field. As R&D Operations Director at GW Pharma for over 16 years, Colin was a key player in the development of their discovery and development pipeline, and was closely involved in the Marketing Authorization Application submission and approval of Sativex® and the New Drug Application submission of Epidiolex®, which was approved by the U.S. Food and Drug Administration in June 2018. More recently, as Scientific Affairs Director, International, he was part of the Medical Affairs team responsible for the preparation of the international launch of Epidiolex®.

Mr. Terry Lynch stepped down from the Board of Directors to accommodate Mr. Stott's appointment.

- (xiii) In December 2019, the Corporation granted 60,000 stock options to a director of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$4.08 and expires on December 2, 2024. The options vest 1/3 each on the first, second, and third anniversaries of the grant date.
- (xiv) In December 2019, the Corporation announced it appointed Michael J. Willner, Esq. as a Business Advisor to the Corporation.

Mr. Willner has been an active investor for over forty years and is the founder of Willner Capital, Inc., an investment company specializing in both public and private equities. Over the past several years, Willner Capital has made significant investments in both the biotechnology and medicinal cannabinoid industries, focusing primarily on clinical-stage companies that seek to address significant unmet medical needs. Mr. Willner has served on numerous panels and advisory boards and as a judge in the medicinal cannabinoid industry start-up competitions and conferences. He has been quoted in the New York Times regarding his investments and is considered an expert in the medicinal/pharmaceutical cannabinoids industry.

Mr. Willner currently serves on the advisory boards of CannaVC, a cannabis-focused venture capital fund for the Israeli market, managed by the Everest Group, which plans to invest in companies that have developed an innovative solution/service/product for the cannabinoid sector, and CURE Pharmaceutical®, a vertically integrated drug delivery and development company that partners with biotech and pharmaceutical companies worldwide.

(xv) In December 2019, the Corporation granted 60,000 stock options to a consultant of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$3.69 and expires on December 5, 2024. The options vest 25% every six months from the grant date.

(xvi) In December 2019, the Corporation's exclusive manufacturing partner, Dalton, received a three-year renewal and license amendment of its *Cannabis Act* Processing License from Health Canada. The renewal and amendment will permit scaled commercial production of Cardiol's high concentration pharmaceutical cannabidiol formulations and their sale to other license holders.

#### Subsequent to December 31, 2019

- (i) In February 2020, the Corporation granted 109,300 stock options to certain employees and consultants of the Corporation. Each stock option allows the holder to acquire one common share of the Corporation at an exercise price of \$3.54 and expires on February 23, 2025. The options vest 50% on grant and 50% twelve months from the grant date.
- (ii) In March 2020, the Corporation announced that it signed a supplier agreement to become a medical cannabidiol supplier to Shoppers Drug Mart ("Shoppers"), Canada's largest pharmacy retailer. Under the terms of the agreement, the Corporation will supply Cardiol's pharmaceutical cannabidiol products to Shoppers for sale in all provinces and territories in Canada through Shoppers' online store, Medical Cannabis by Shoppers™. Manufactured under cGMP and THC free (<5 ppm), Cardiol's products are designed to be the most consistent pharmaceutical cannabidiol formulations available and will be sold initially in three dosage formats: 100mg/mL, 50mg/mL, and 25mg/mL. Shoppers also has the right to purchase all future products available from Cardiol's product line, subject to any and all regulations.

#### **Clinical Highlights**

#### Phase 1 study

Cardiol received a No Objection Letter from Health Canada to conduct a Phase 1 study of the Corporation's pharmaceutically produced high concentration, pure cannabidiol formulation. The Corporation plans to initiate the study in Q2, 2020. This timeline could be affected by the current COVID-19 pandemic (see "Risk Factors - COVID-19 pandemic" below).

The Phase 1 study is designed to measure the pharmacokinetics (blood levels of drug) following single and multiple doses of the Corporation's extra strength 100mg/mL concentration pharmaceutical cannabidiol formulation in up to up to 55 healthy subjects, both in the fasting and fed states. The study will also measure standard safety parameters at escalating doses to help select the optimal dosing levels for the Corporation's planned international Phase 2 study in acute myocarditis, an inflammatory form of heart failure that represents a leading cause of sudden cardiac death in children and young adults.

#### Phase 2 study - Acute myocarditis

Cardiol is planning a Phase 2 clinical program in acute myocarditis utilizing its pharmaceutically produced, pure cannabidiol formulation. Cardiol's acute myocarditis program is being designed by an independent Steering Committee comprising thought leaders in cardiology from North America and Europe.

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. 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 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 Heart Failure/Transplantation Program 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 anti-fibrotic 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.

#### 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 centres in Germany at the Charité University 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.

#### 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.

#### 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.

#### 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.

#### 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.

#### Outlook

The Corporation expects that the current working capital of \$13,680,135 will be sufficient to fund operations and capital requirements through March 31, 2021.

During 2020, the Corporation expects the following catalysts for growth:

- 1. The announcement of distribution agreements for the sale of the Corporation's CardiolRx pharmaceutical CBD formulation in Canada (See "Operations Highlights Subsequent to December 31, 2019" above);
- 2. The commercial launch of CardiolRx pharmaceutical CBD, which is expected to set a new industry standard for product purity and consistency;
- 3. The initiation of a Phase 2 clinical trial program expected to begin in H2 2020, designed to demonstrate impact of the Corporation's proprietary pharmaceutical cannabidiol formulation on inflammatory heart disease (acute myocarditis). This timeline could be affected by the current COVID-19 pandemic (see "Risk Factors COVID-19 pandemic" below);
- 4. The development of global expansion plans to support the commercialization of CardiolRx pharmaceutical CBD in Europe and Latin America.

#### Use of IPO Proceeds

The Corporation may reallocate the net IPO 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 IPO 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 IPO, as disclosed in the Corporation's prospectus dated December 14, 2018 and spending from January 1, 2019 to December 31, 2019 is as follows:

Use of Proceeds	Amount	Spent	Remaining
Cardiol CTX product series and acute myocarditis:			
Basic science, preclinical studies, and a Phase 1 clinical program <sup>(1)</sup>	1,700,000	1,166,946	533,054
Phase 2 clinical trial program (1)	2,500,000	93,889	2,406,111
Glioblastoma Multiforme:			
Fund the development of immunotherapy in combination with cannabinoids for its target indication of Glioblastoma Multiforme	1,100,000	ı	1,100,000
Market introduction, distribution, and marketing of a pharmaceutically manufactured commercial cannabidiol oil product:			
Direct-to-consumer sales expenditure, including website development and marketing to third-party partners and logistics (2)	1,500,000	246,728	1,253,272
Prescription sales expenditure, including physician information, creative developments, and producing material samples (2)	2,000,000	139,714	1,860,286
Other:			
Exclusivity payment to Noramco (USD \$3.0 million) (3)	3,900,000	3,900,000	-
100,000 expected to be made on the initiation of a Phase 2 program, to Meros (1)	100,000	1	100,000

- 1. Spending includes basic science, pre-clinical studies, and preparations for the initiation of a clinical trial program in inflammatory heart disease.
- 2. Expenses are expected to increase in 2020 as the Corporation commercializes its first pharmaceutical CBD product.
- 3. Exclusivity payment, made in December 2018, is included in working capital (in prepaid inventory) less approximately \$200,000 included in research and development expenses at December 31, 2019.

#### **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 (\$)	(\$)	(\$)
December 31, 2019 <sup>(1)</sup>	nil	(3,058,709)	(0.12)	15,502,865
September 30, 2019 <sup>(2)</sup>	nil	(3,491,816)	(0.13)	18,303,737
June 30, 2019 <sup>(3)</sup>	nil	(3,642,636)	(0.14)	20,535,419
March 31, 2019 <sup>(4)</sup>	nil	(3,490,862)	(0.14)	22,914,147
December 31, 2018 <sup>(5)</sup>	nil	(9,073,590)	(0.58)	24,684,773
September 30, 2018 <sup>(6)</sup>	nil	(4,910,232)	(0.32)	13,094,086
June 30, 2018 <sup>(7)</sup>	nil	(1,358,280)	(0.09)	12,143,959
March 31, 2018 <sup>(8)</sup>	nil	(551,633)	(0.04)	2,854,705

#### Note:

- (1) Net loss of \$3,058,709 included administration of \$885,240, research and development of \$1,031,020, share-based compensation of \$588,746, salaries and benefits of \$447,933 and investor relations and promotions of \$267,916, which was partially offset by other income of \$219,000.
- (2) Net loss of \$3,491,816 included research and development of \$1,237,727, administration of \$815,102, share-based compensation of \$551,977, investor relations and promotions of \$459,473, and salaries and benefits of \$459,037.
- (3) Net loss of \$3,642,636 included share-based compensation of \$867,906, administration of \$813,674, research and development of \$748,481, investor relations and promotions of \$688,290, and salaries and benefits of \$541,488.
- (4) Net loss of \$3,490,862 included share-based compensation of \$1,257,658, investor relations and promotions of \$665,738, administration of \$598,856, research and development of \$512,745 and salaries and benefits of \$385,434.
- (5) Net loss of \$9,073,590 included change in derivative liability of \$5,635,573, share-based compensation of \$895,960, administration of \$731,852, salaries and benefits of \$577,675, listing expense of \$397,528, investor relations and promotions of \$355,291, research and development of \$281,098 and accretion and interest on convertible debentures of \$268,900.
- (6) Net loss of \$4,910,232 included change in derivative liability of \$2,246,688, share-based compensation of \$757,285, administration of \$716,192, research and development of \$447,023, salaries and benefits of \$410,912, accretion and interest on convertible debentures of \$267,727, and investor relations and promotions of \$81,187.
- (7) Net loss of \$1,358,280 included research and development of \$548,262, administration of \$322,502, salaries and benefits of \$315,342, accretion and interest on convertible debentures of \$108,041 and investor relations and promotions of \$41,038.
- (8) Net loss of \$551,633 included research and development of \$256,223, administration of \$164,957, salaries and benefits of \$60,778, investor relations and promotions of \$30,326 and accretion and interest on convertible debentures of \$18,705.
- (9) Basic and fully diluted.

#### **Discussion of Operations**

#### Year ended December 31, 2019, compared to the year ended December 31, 2018

For the year ended December 31, 2019, the Corporation's net loss was \$13,684,023, compared to a net loss of \$15,893,735 for the year ended December 31, 2018. The decrease in net loss of \$2,209,712 is a result of the following:

- Research and development increased to \$3,530,183 for the year ended December 31, 2019, compared to \$1,532,606 for the year ended December 31, 2018. During the year ended December 31, 2019, the Corporation incurred higher costs associated with the scale-up of manufacturing of CardiolRx. As well, the Corporation incurred increased research and development costs related to basic science, preclinical and clinical studies.
- Share-based compensation increased to \$3,266,287 for the year ended December 31, 2019, compared to \$1,653,245 for the year ended December 31, 2018. The increase in this non-cash expense is the result of the vesting of certain stock options granted during the year ended December 31, 2018 and additional grants in the year ended December 31, 2019, versus certain stock options granted during the year ended December 31, 2018.
- Administration expense increased to \$3,112,872 for the year ended December 31, 2019, compared to \$1,935,503 for the year ended December 31, 2018. During the year ended December 31, 2019, the Corporation's operations increased significantly following the completion of the Corporation's IPO, resulting in increased costs related to insurance, office and computer expenses, director fees, professional fees and travel. This increase was partially offset by non-recurring costs related to preparing for the IPO, which were incurred in the year ended December 31, 2018.

- Investor relations and promotions increased to \$2,081,417 for the year ended December 31, 2019, compared to \$507,841 for the year ended December 31, 2018. During the year ended December 31, 2019, the Corporation incurred higher costs on investor relations and promotion as a result of being a newly listed public company, as well as costs related to the Corporation's upcoming launch of CardiolRx.
- Salaries and benefits increased to \$1,833,892 for the year ended December 31, 2019, compared
  to \$1,364,707 for the year ended December 31, 2018. The increase is the result of the Corporation
  hiring additional employees at increased salary levels in the current period due to the increased
  level of operations.
- Accretion on convertible debentures decreased to \$621 for the year ended December 31, 2019, compared to \$663,373 for the year ended December 31, 2018. The decrease is the result of the debentures being converted on the IPO and in January 2019.
- Change in derivative liability was \$7,882,261 for the year ended December 31, 2018. This expense
  is the result of the derivative liability being settled on the IPO.
- Listing expense was \$397,528 for the year ended December 31, 2018. This expense related to the portion of IPO costs incurred considered to be attributable to the stock listing on the TSX.
- Other income was \$298,795 for the year ended December 31, 2019 versus \$nil in the year ended December 31, 2018. This income is the result of refundable investment tax credits ("ITCs") of \$79,795 for 2017 scientific research and experimental development ("SRED") expenses being received in 2019 and \$219,000 of ITCs for 2018 SRED expenses being recorded as receivable in 2019.

#### Three months ended December 31, 2019, compared to the three months ended December 31, 2018

For the three months ended December 31, 2019, the Corporation's net loss was \$3,058,709, compared to a net loss of \$9,073,590 for the three months ended December 31, 2018. The decrease in net loss of \$6,354,693 is a result of the following:

- Research and development increased to \$1,031,230 for the three months ended December 31, 2019, compared to \$281,098 for the three months ended December 31, 2018. During the three months ended December 31, 2019, the Corporation incurred increased research and development costs related to basic science, preclinical studies and clinical studies.
- Administration expense increased to \$885,240 for the three months ended December 31, 2019, compared to \$731,852 for the three months ended December 31, 2018. During the three months ended December 31, 2019, the Corporation's operations increased significantly following the completion of the Corporation's IPO, resulting in increased costs related to insurance, office and computer expenses, director fees, professional fees, and travel. This increase was partially offset by non-recurring professional fees associated with completing the IPO, which were incurred in the three months ended December 31, 2018.
- Share-based compensation decreased to \$588,746 for the three months ended December 31, 2019, compared to \$895,960 for the three months ended December 31, 2018. The decrease in this non-cash expense is the result of the vesting of certain stock options granted during the year ended December 31, 2018 and additional grants in the year ended December 31, 2019. This compares to certain stock options granted during the year ended December 31, 2018.

- Listing expense was \$397,528 for the three months ended December 31, 2018. This expense related to the portion of IPO costs incurred considered to be attributable to the stock listing on the TSX.
- Accretion on convertible debentures decreased to \$nil for the three months ended December 31, 2019, compared to \$268,900 for the three months ended December 31, 2018. The decrease is the result of the debentures being converted on the IPO and in January 2019.
- Change in derivative liability decreased to \$nil for the three months ended December 31, 2019, compared to \$5,635,573 for the three months ended December 31, 2018. The decrease is the result of the derivative liability being settled on the IPO.
- Other income was \$219,000 for the three months ended December 31, 2019 versus \$nil in the three months ended December 31, 2018. This income is the result of ITCs for 2018 SRED expenses being recorded as receivable in 2019.

#### **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, contributed surplus, and the equity portion of convertible debentures less accumulated deficit which at December 31, 2019, totalled \$14,672,037 (December 31, 2018 – \$22,274,159).

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 December 31, 2019, Cardiol had \$6,956,203 in cash and cash equivalents (December 31, 2018 – \$16,731,500).

At December 31, 2019, accounts payable and accrued liabilities were \$640,076 (December 31, 2018 – \$2,141,398). The Corporation's cash and cash equivalents balances as at December 31, 2019 and December 31, 2018 are sufficient to pay these liabilities.

As at December 31, 2019, the Corporation had convertible debentures payable with an aggregate principal amount of \$nil (December 31, 2018 - \$400,000). The \$400,000 was converted into 2,700,000 common shares in January 2019.

The Corporation currently has no operating revenues and therefore must utilize its funds from financing transactions to maintain its capacity to meet ongoing operating activities.

As of December 31, 2019, December 31, 2018, 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 2019 Fiscal Period

Cash and cash equivalents used in operating activities were \$11,380,080 for the year ended December 31, 2019. Operating activities were affected by a net loss of \$13,684,023 and the net change in non-cash working capital balances of \$(1,620,659) offset partially by non-cash adjustments of \$3,924,602. Non-cash adjustments mainly consisted of \$3,266,287 for share-based compensation and \$496,500 for research and development expenses to be settled through warrant exercise. Non-cash working capital was the result of a decrease in accounts payable and accrued liabilities of \$1,501,322, an increase in inventory of \$1,118,748, and an increase in other receivables of 489,513. This was partially offset by a decrease in prepaid inventory of \$1,261,326.

Cash and cash equivalents used in investing activities were \$424,305 for the year ended December 31, 2019. This pertained to the purchase of property and equipment.

Cash and cash equivalents provided by financing activities were \$2,029,088 for the year ended December 31, 2019, which represents net proceeds from the over-allotment portion of the IPO and the exercise of warrants, partially offset by the payment of lease liability.

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

As of December 31, 2019, Cardiol's working capital was \$13,680,135. 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	640,076	640,076	Nil	Nil	Nil
other liabilities					
Office lease (1)	471,918	110,479	209,541	151,898	Nil
Consulting agreements	560,131	560,131	Nil	Nil	Nil
Contract research	72,250	72,250	Nil	Nil	Nil
Total	1,744,375	1,382,936	209,541	151,898	Nil

#### Note:

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

#### **Related-Party Transactions**

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

#### For the 2019 Fiscal Period

- (i) Included in research and development expense is \$1,171,900 for the year ended December 31, 2019 (year ended December 31, 2018 \$206,255) 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 December 31, 2019, \$76,784 (December 31, 2018 \$9,852) was owed to this company and this amount was included in accounts payable and accrued liabilities and \$65,973 and \$35,040 (December 31, 2018 \$nil) was paid to this company and was included in prepaid expenses and inventory, respectively. 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.
- (ii) Included in administration is \$230,000 for the year ended December 31, 2019 (year ended December 31, 2018 \$125,000) for corporate advisory services, paid to a company (Fission Creative Solutions Inc., formerly known as Punchcast Inc.) related to a former director (Terry Lynch). Fission Creative Solutions Inc. is controlled by a son of Terry Lynch. The Corporation has entered into an agreement with Fission Creative Solutions Inc. for corporate advisory services as at December 31, 2019. As at December 31, 2019, \$20,000 (December 31, 2018 \$11,300) is included in prepaid expenses.
- (iii) Included in administration is \$nil (year ended December 31, 2018 \$130,238) for Chief Financial Officer, accounting, and other administrative services, paid to a company (lan S. Hulbert Professional Corporation) controlled by the former Chief Financial Officer of the Corporation. As at December 31, 2019, \$nil (December 31, 2018 \$9,900) was owed to this company and this amount was included in accounts payable and accrued liabilities. The Corporation has no ongoing contractual commitment with Ian S. Hulbert Professional Corporation.
- (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:

	Year ended	Year ended
	December 31, 2019	December 31, 2018
	(\$)	(\$)
Salaries and benefits	1,204,209	1,157,702
Share-based payments	1,506,339	1,363,157
	2,710,548	2,520,859

As at December 31, 2019, \$2,005 (December 31, 2018 - \$134,138) 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 valuation of the liability component of convertible debt is estimated using the prevailing market interest rate for similar non-convertible instruments at the date of issue. This amount is recorded as liability on an amortized cost basis using the effective interest method until extinguished upon conversion or at the instrument's maturity date.
- The estimate of the percentage of completion of certain research and development agreements.
- The valuation of the income tax non-current asset would increase if there was virtual certainty that the tax benefit of net operating losses could be applied to future periods' taxable income.
- 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 9 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 not yet generated revenue and 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 into 2021;
- Management's assessment that no indicators of impairment exist for intangible assets, based on the facts and circumstances that existed during the period;
- Management's assessment of the impact the novel coronavirus (COVID-19) pandemic will have on operations (see "Risk Factors - COVID-19 pandemic" below); and
- Management applied judgment in determining the allocation of IPO costs between share issuance costs and listing expense.

#### Change in accounting policies

IFRS 16 - Leases ("IFRS 16") was issued on January 13, 2016 and replaces IAS 17 – Leases, as well as some lease related interpretations. With certain exceptions for leases under twelve months in length or for assets of low value, IFRS 16 states that upon lease commencement a lessee recognizes a right-of-use asset and a lease liability. The right-of-use asset is initially measured at the amount of the liability plus any initial direct costs. After lease commencement, the lessee shall measure the right-of-use asset at cost less accumulated depreciation and accumulated impairment. A lessee shall either apply IFRS 16 with full retrospective effect or alternatively not restate comparative information but recognize the cumulative effect of initially applying IFRS 16 as an adjustment to opening equity at the date of initial application. IFRS 16 requires that lessors classify each lease as an operating lease or a finance lease. A lease is classified as a finance lease if it transfers substantially all the risks and rewards incidental to ownership of an underlying asset. Otherwise it is an operating lease. At January 1, 2019, the Corporation adopted these amendments and there was no impact on transition on the Corporation's Financial Statements as the Corporation elected

to apply IFRS 16 to short-term leases less than twelve months in length. See note 7 of the Financial Statements for the current period impact of IFRS 16.

#### **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 25,877,686 issued and outstanding common shares, 1,020,000 Meros Special Warrants convertible automatically into common shares (upon the Corporation achieving the Meros Milestone) for no additional consideration pursuant to the Meros License Agreement, 400,000 common shares issuable to Dalton if Dalton meets certain performance objectives, and stock options and warrants as shown below:

#### Stock Options

Expiry date	Exercise price (\$)	Options outstanding	Options exercisable
July 24, 2020	5.34	50,000	50,000
March 9, 2021	3.04	50,000	12,500
October 29, 2021	3.28	90,000	22,500
November 24, 2021	3.34	50,000	25,000
January 24, 2024	5.34	100,000	100,000
October 15, 2024	3.23	160,000	-
December 2, 2024	4.08	60,000	-
December 5, 2024	3.69	60,000	-
February 23,2025	3.54	109,300	54,650
August 16, 2025	5.00	200,000	200,000
August 30, 2025	5.00	580,000	206,670
January 2, 2026	4.30	150,000	150,000
January 24, 2026	5.34	60,000	20,000
April 1, 2026	5.77	140,000	-
April 4, 2026	5.42	60,000	-
Total		1,919,300	841,320

#### <u>Warrants</u>

Expiry date	Exercise price (\$)	Warrants outstanding
December 20, 2020	6.50	3,374,544
August 31, 2022	4.00	824,000
Total		4,198,544

#### **Financial Instruments**

#### Recognition

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

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

#### **Classification and Measurement**

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

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

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

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

- amortized cost:
- FVTPL, if the Corporation has made an irrevocable election at the time of recognition, or when required (for items such as instruments held for trading or derivatives); or,
- FVTOCI, when the change in fair value is attributable to changes in the Corporation's credit risk.

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

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

The Corporation's financial 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);
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The Corporation's financial instruments measured at fair value, which consisted of the derivative liability allocated to share capital on the IPO, was considered level one in the fair value hierarchy and was measured at the IPO price.

#### **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 2019 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 interest 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. 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 \$152,000 (December 31, 2018 - \$285,000).

#### **Commitments and Contingency**

(i) The Corporation has leased premises from third parties. The minimum committed lease payments as at December 31, 2019, which include the lease liability payments, are as follows:

Fiscal year	
2020	\$ 110,479
2021	103,761
2022	105,780
2023	107,222
2024	44,676
Total	\$ 471,918

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

Fiscal year	
2020	\$560,131

(iii) Pursuant to the terms of agreements with various other contract research organizations, the Corporation is committed for contract research services for 2020 at a cost of approximately \$72,250.

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

	Year ended December 31, 2019 (\$)	Year ended December 31, 2018 (\$)
Contract research	2,031,194	1,007,332
Wages	230,654	276,984
Supplies	506,322	206,255
Regulatory	762,013	42,035
	3,530,183	1,532,606

#### **Breakdown of Operating Expenses**

	Year ended December 31, 2019 (\$)	Year ended December 31, 2018 (\$)
Administration	3,112,872	1,935,503
Depreciation of property and equipment	66,128	7,048
Amortization of intangible assets	84,444	84,444
Accretion and interest on convertible debentures	621	663,373
Investor relations and promotions	2,081,417	507,841
Salaries and benefits	1,833,892	1,364,707
Transfer agent and regulatory	152,546	10,817
Share-based compensation	3,266,287	1,653,245
•	10.598.207	6.226.978

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

	As at December 31, 2019 (\$)	As at December 31, 2018 (\$)
Exclusive global license agreement	767,228	767,228
Accumulated amortization	(219,094)	(134,650)
Carrying value	548,134	632,578

#### **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 December 31, 2019.

#### **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**

The Corporation's prospects depend on the success of our acute myocarditis and nanotherapeutic product candidates which are at early stages of development, and from sales of our pharmaceutical cannabidiol products. We do not expect to generate revenue for several years, if at all, from the acute myocarditis and nanotherapeutic product candidates.

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

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

We currently have no products for commercial sale (See "Operations Highlights – Subsequent to December 31, 2019" above). Our only current potential source of revenue is the sale of our pharmaceutical cannabidiol, and initial revenues from the sale of pharmaceutical cannabidiol are not expected until Q2 2020. As a result, we are not currently generating revenue from our products, and may never generate significant revenue from the sale or licensing of our products, or otherwise.

#### The Continued Development of the Corporation will Require Additional Financing

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

loans in such an event or prevent the enforcement of security granted pursuant to such debt financing. The Corporation may require additional financing to fund its operations to the point where it is generating positive cash flows. Negative cash flow may restrict the Corporation's ability to pursue its business objectives.

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

#### **Negative Cash Flow from Operations**

During the 2019 Fiscal Period, the Corporation had negative cash flow from operating activities. Although the Corporation anticipates it will have positive cash flow from operating activities in future periods, to the extent that the Corporation has negative cash flow in any future period, current working capital may be used to fund such negative cash flow from operating activities, if any.

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

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

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

Cardiol's net loss for the year ended December 31, 2019 was \$13,684,023 and for the year ended December 31, 2018 was \$15,893,735. We have not generated any revenue to date and it is possible that we will never have sufficient product sales revenue (if any) to achieve profitability. We expect to continue to incur losses for at least the next several years as we or our collaborators and licensees pursue clinical trials and research and development efforts. To become profitable, we, either alone or with our collaborators and licensees, must successfully market our pharmaceutical cannabidiol and develop, manufacture and market our current product candidates, as well as continue to identify, develop, manufacture and market new product candidates. It is possible that we will never have significant product sales revenue or receive royalties on our licensed product candidates. If funding is insufficient at any time in the future, we may not be able to develop or commercialize our products, take advantage of business opportunities, or respond to competitive pressures.

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

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

The loss of David Elsley, our President and CEO, or other key members of our staff, could harm us. We also depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial, medical, clinical, and regulatory personnel, particularly as we expand our activities and seek regulatory approvals for clinical trials. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, key

opinion leaders, and academic partners in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who will recruit patients into our clinical trials on our behalf in the ordinary course of our business. Notwithstanding these arrangements, we face significant competition for these types of personnel from other companies, research and academic institutions, government entities, and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth. The loss of the services of any of our executive officers or other key personnel could potentially harm our business, operating results or financial condition.

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

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

# Our Activities are Subject to Comprehensive Regulation, including under Healthcare Laws and Compliance Requirements

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

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

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

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

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

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

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

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

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

- resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more IRB or ethics committees rejecting, suspending, or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- failure to reach agreement on acceptable terms with prospective clinical trial sites.

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

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

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

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

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

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

We set goals for, and make public statements regarding, the expected timing of the accomplishment of objectives material to our success, the commencement and completion of clinical trials and the expected costs to develop our product candidates. The actual timing and costs of these events can vary dramatically due to factors within and beyond our control, such as delays or failures in our clinical trials, issues related to the manufacturing of drug supply, uncertainties inherent in the regulatory approval process, market conditions, and interest by partners in our product candidates among other things. We may not make regulatory submissions or receive regulatory approvals as planned; our clinical trials may not be completed; or we may not secure partnerships for any of our product candidates. Any failure to achieve one or more of these milestones as planned would have a material adverse effect on our business, financial condition, and results of operations.

#### Unpredictable and volatile market price for common shares and Warrants

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pending patent applications may be challenged by third parties in protest or similar proceedings. Third parties can typically submit prior art material to patentability for review by the patent examiner. Regarding

Patent Cooperation Treaty applications, a positive opinion regarding patentability issued by the International Searching Authority does not guarantee allowance of a national application derived from the Patent Cooperation Treaty application. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and the patent's scope can be modified after issuance. It is also possible that the scope of claims granted may vary from jurisdiction to jurisdiction.

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

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

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

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

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

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

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

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

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

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

# Our ability to research, develop, and commercialize products is dependent on our ability to obtain and maintain licenses relating to possession and supply of controlled substances

Our research and manufacturing facilities are located in Canada. In Canada, various licenses are required to produce pharmaceutical cannabinoids. Our continued ability to research, develop, and commercialize our product candidates is dependent on our ability to obtain, and subsequently maintain, licenses relating to possession and supply of controlled substances.

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

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

#### Changes in laws and regulations

The Corporation endeavours to comply with all relevant laws, regulations, and guidelines. To the Corporation's knowledge, it is in compliance with all such laws, regulations, and guidelines as described elsewhere in this MD&A.

On April 13, 2017, the federal government of Canada introduced the *Cannabis Act*. On June 20, 2018, the Senate approved the *Cannabis Act* and the Act received Royal Assent on June 21, 2018. The *Cannabis Act* came into effect on October 17, 2018. The Cannabis Act creates a strict legal framework for controlling the production, distribution, sale and possession of recreational cannabis in Canada. The Cannabis Act lifts the ban on the recreational use of cannabis in Canada dating back to 1923. The impact of any such new legislative system on the medical cannabis industry and the Corporation's business plan and operations is uncertain.

As of October 17, 2019, The Cannabis Act grants authorization to LPs who have been approved by Health Canada, to produce and sell "edibles containing cannabis" and "cannabis concentrates" no earlier than December 17, 2019. In June 2019, amended Cannabis Regulations were published outlining changes to the Cannabis Act that came into force October 17, 2019. The new rules stipulate the addition of three new product classes: edibles, extracts and topicals.

On June 19th, 2019, Health Canada opened a consultation on potential market for cannabis health products (CHP) that would not require practitioner oversight. The contemplated regulatory pathway would allow for specific health claims that would need to be supported by scientific evidence. Provinces and territories would continue to have the flexibility to authorize CHP sellers operating at any physical location. This could allow for CHPs for human and veterinary uses to be sold at pharmacies, veterinary clinics, pet stores, or livestock medicine outlets under strict conditions that respect federal requirements. Strictly controlled online sales would also remain possible. This consultation closed on September 3rd, 2019.

On February 27th, 2020 the government of Canada announced a call for nomination of a new Science Advisory Committee for Health Products Containing Cannabis which will provide independent scientific and clinical advice to support the Department's consideration of appropriate safety, efficacy, and quality standards for health products containing cannabis, including the conditions under which these products would be suitable to be used without practitioner oversight. Nominations for the Science Advisory Committee must be made by April 9th, 2020. First meeting for the committee is expected in the summer of 2020.

The Cannabis Act provides provincial, territorial and municipal governments with the authority to prescribe regulations regarding retail and distribution of recreational cannabis. As such, the distribution model for recreational cannabis is prescribed by provincial and territorial regulations and differs in each jurisdiction. Some provinces have government-run retailers, while others have government-licensed retailers, and some have a combination of the two.

After a restricted lottery-based retail rollout, the government of Ontario announced on December 12, 2019 changes to the cannabis licensing regulations under the Cannabis License Act, 2018. Premier Doug Ford announced several changes to the licensing rules governing private cannabis retail stores in Ontario. The government of Ontario anticipates that, initially, approximately 20 retail store authorizations will be issued per month in Ontario, starting in April 2020. Additionally, on February 10, 2020 the government of Ontario initiated public consultations on providing consumers with more choice and convenience on cannabis, including consumption venues.

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

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

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

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. However, the Corporation does not expect that its Disclosure, Controls, and Procedures

or ICFR will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Due to the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected in a timely manner or at all. If the Corporation cannot provide reliable financial reports or prevent fraud, its reputation and operating results could be materially adversely affected, which could cause investors to lose confidence in the Corporation's reported financial information, which in turn could result in a reduction in the value of the common shares.

#### Medical research of cannabinoids remains in early stages

Research in Canada, the U.S., and internationally regarding the medical benefits, viability, safety, efficacy, and dosing of cannabinoids remains in early stages. There have been relatively few clinical trials conducted on the benefits of cannabinoids. The statements made in this MD&A concerning the potential medical benefits of cannabinoids are based on published articles and reports with details of research studies and clinical trials. As a result, the statements made in this MD&A are subject to the experimental parameters, qualifications, and limitations in the studies that have been completed.

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

# Pharmaceutical cannabinoid and other product candidates, if approved, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue from new products

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

#### We have not commercialized any products to date

We have yet to bring a product to market. Even if we obtain regulatory approval for a product, our future success will still depend on our ability to successfully commercialize our products, which depends on a number of factors beyond our control, including the willingness of physicians to prescribe our products to patients, payers' willingness and ability to pay for the drug, the level of pricing achieved, patients' response to our products, the ability of our marketing partners to generate sales, and our ability to manufacture

products on a cost-effective and efficient basis. If we are not successful in the commercialization of our products, our business, results of operations, and financial condition may be harmed.

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

We currently have no manufacturing experience and rely on Dalton and other contract manufacturing organizations ("CMOs") to manufacture our product candidates for preclinical studies and clinical trials and on Purisys to supply Dalton with cannabidiol with less than 5 ppm THC. We rely on CMOs for manufacturing, filling, packaging, storing, and shipping of drug products in compliance with current good manufacturing practice, or cGMP, regulations applicable to our products. The FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with cGMP regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. If our CMOs increase their prices or fail to meet our quality standards, or those of regulatory agencies such as the FDA, and cannot be replaced by other acceptable CMOs, our ability to obtain regulatory approval for and commercialize our product candidates may be materially adversely affected.

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

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

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

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

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

Disagreements between parties to a collaboration arrangement regarding development, intellectual property, regulatory or commercialization matters, can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, termination of the collaboration

arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

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

#### Product shipment delays would have adverse effect on the business

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

# Our ability to generate product revenues will be diminished if our pharmaceutical cannabinoid drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement

Our ability to commercialize our pharmaceutical cannabinoid, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

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

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

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

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

#### Competition

The Corporation expects to face intense competition from other companies in the sale of cannabidiol, some of which can be expected to have more financial resources and manufacturing and marketing experience than the Corporation. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition and results of operations of the Corporation.

The sale of cannabinoid products is regulated under the Cannabis Act and various provincial regimes in Canada. With the opening of the cannabinoids market under the Cannabis Act, the Corporation expects to face additional competition from new entrants. If the number of users of medical cannabis in Canada increases, the demand for products will increase and the Corporation expects that competition will become more intense, as current and future competitors begin to offer an increasing number of diversified products. To remain competitive, the Corporation will require a continued high level of investment in research and development, marketing, sales, and client support. The Corporation may not have sufficient resources to maintain research and development, marketing, sales, and client support efforts on a competitive basis which could materially and adversely affect the business, financial condition, and operating results of the Corporation.

#### Research and development and product obsolescence

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

#### We may be subject to unfavourable publicity or consumer perception

The Corporation believes the cannabinoid industry is highly dependent upon consumer perception regarding the safety, efficacy, and quality of the cannabinoid produced. Consumer perception of the Corporation's pharmaceutical cannabinoid products can be significantly influenced by scientific research or findings, regulatory investigations, litigation, media attention, and other publicity regarding the consumption of cannabinoids. There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention, or other research findings or publicity will be favourable to the cannabinoid market or any particular product, or consistent with earlier publicity. Future research reports, findings, regulatory proceedings, litigation, media attention, or other publicity that are perceived as less favourable than, or that question, earlier research reports, findings, or publicity could have a material adverse effect on the demand for the Corporation's pharmaceutical cannabinoids and the business, results of operations, financial condition, and cash flows of the Corporation. The Corporation's dependence upon consumer perceptions means that adverse scientific research reports, findings, regulatory proceedings, litigation, media attention, or other publicity, whether or not accurate or with merit, could have a material adverse effect on the Corporation, the demand for the Corporation's pharmaceutical cannabinoids, and the business, results of operations, financial condition, and cash flows of the Corporation, Further, adverse publicity reports or other media attention regarding the safety, efficacy, and quality of cannabinoid in general, or the Corporation's pharmaceutical cannabinoids specifically, or associating the consumption of cannabinoid with illness or other negative effects or events, could have such a material adverse effect. Such adverse publicity reports or other media attention could arise even if the adverse effects associated with such products resulted from consumers' failure to consume such products legally, appropriately, or as directed.

#### Product liability once the Corporation begins the production phase

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

#### Manufacturers and distributors can be subject to product recalls

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

# The presence or absence of one or more large new orders in a specific quarter, ability to process orders, or order cancellation could cause results of operations to fluctuate on a quarterly basis

Once we are in the production phase, we will supply products to our commercial partners in response to their purchase order schedules. The size of each purchase order may fluctuate. As a result, the presence or absence in a specific quarter of one or more new large orders or delays in our ability to process large orders or the cancellation of previous orders may cause our results of operations to fluctuate on a quarterly basis. These fluctuations may be significant from one quarter to the next. Any demands that require us to quickly increase production may create difficulties for us. In addition, our lack of commercial history and the characteristic of our orders in any quarterly period make it very difficult to accurately predict or forecast our future operating results.

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

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

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

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

#### Corporation's business is dependent on key inputs

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

#### Operating risk and insurance coverage

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

#### Management of growth

The Corporation may be subject to growth-related risks, including capacity constraints and pressure on its internal systems and controls. The ability of the Corporation to manage growth effectively will require it to

continue to implement and improve its operational and financial systems and to expand, train, and manage its employee base. The inability of the Corporation to deal with this growth may have a material adverse effect on the Corporation's business, financial condition, results of operations, and prospects.

#### Conflicts of interest

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

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

#### In certain circumstances, the Corporation's reputation could be damaged

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

#### Third party reputational risk

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

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

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

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

Also, the <u>Corruption of Foreign Public Officials Act</u> (Canada) and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-Canadian officials for the purpose of obtaining or retaining business. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, licensees, or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties, or prosecution and have a negative impact on our business, results of operations, and reputation.

#### **Information systems security threats**

The Corporation has entered into agreements with third parties for hardware, software, telecommunications, and other information technology ("IT") services in connection with its operations. The Corporation's operations depend, in part, on how well it and its suppliers protect networks, equipment, IT systems, and software against damage from a number of threats, including, but not limited to, cable cuts, damage to physical plants, natural disasters, terrorism, fire, power loss, hacking, computer viruses, vandalism, and theft. The Corporation's operations also depend on the timely maintenance, upgrade, and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. Any of these and other events could result in information system failures, delays and/or increase in capital expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact the Corporation's reputation and results of operations.

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

#### No dividends

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

#### Future sales of common shares by existing shareholders

Sales of a substantial number of common shares in the public market could occur at any time before or after the expiration of the lock-up agreements. These sales, or the market perception that the holders of a large number of common shares intend to sell common shares, could reduce the market price of our common shares. Holders of options to purchase common shares will have an immediate income inclusion for tax purposes when they exercise their options (that is, tax is not deferred until they sell the underlying common shares). As a result, these holders may need to sell common shares purchased on the exercise of options in the same year that they exercise their options. This might result in a greater number of common shares being sold in the public market, and fewer long-term holds of common shares by Management and our employees.

### Cardiol may be subject to securities litigation which is expensive and could divert Management's attention

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

#### Dilution and future sales of common shares

We may issue additional common shares in the future, which may dilute a Shareholder's holding in the Corporation. Our articles will permit the issuance of an unlimited number of common shares, and Shareholders will have no pre-emptive rights in connection with such further issuances. The Directors of the Corporation have the discretion to determine if an issuance of common shares is warranted, the price at which such issuance is effected, and the other terms of issue of common shares. Also, we may issue additional common shares upon the exercise of options to acquire common shares under the Option Plan, which will result in further dilution to the Shareholders. Potential future acquisitions may also divert Management's attention and result in further dilution to the Shareholders.

#### **COVID-19** pandemic

The recent novel coronavirus (COVID-19) pandemic has impacted and could further impact our operations and the operations of our third-party suppliers, manufacturers, and CROs as a result of quarantines, facility closures, travel and logistics restrictions and other limitations in connection with the outbreak. While we expect this to be temporary, there is uncertainty around its duration and its broader impact.