CARDIOL THERAPEUTICS INC.
MANAGEMENT'S DISCUSSION AND ANALYSIS
YEAR ENDED DECEMBER 31, 2020

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, 2020 (the "2020 Fiscal Period"). This MD&A was written to comply with the requirements of National Instrument 51102 – Continuous Disclosure Obligations. This discussion should be read in conjunction with the financial statements for the years ended December 31, 2020 and 2019 ("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 31, 2021. All dollar amounts in this MD&A are reported in Canadian dollars, unless otherwise stated. Unless otherwise noted or the context indicates otherwise the terms "we", "us", "our", "Cardiol" or the "Corporation" refer to Cardiol Therapeutics Inc.

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

Forward-Looking Information

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

- our anticipated cash needs, and the need for additional financing;
- our marketing and sale of a pharmaceutically produced pure cannabidiol ("CBD") oil as a *Cannabis Act* product line;
- the ability for our subcutaneous product candidates to deliver cannabinoids and other anti-inflammatory drugs to inflamed tissue in the heart;
- our development of proprietary cannabidiol formulations for near-term commercialization;
- our ability to develop new formulations;
- the successful development and commercialization of our current product candidates and the addition of future products;
- our expectation of a significant increase in the market and interest for pure pharmaceutical cannabidiol products that are tetrahydrocannabidiol ("THC") free (<10 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;
- management of additional regulatory burdens;
- volatility in the market price for our common shares;
- 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;
- the issuance of common shares in the future causing dilution; and
- the impact of the recent novel coronavirus ("COVID-19") pandemic on operations, including clinical trials.

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

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

Overview

On December 20, 2018, the Corporation completed its initial public offering (the "IPO") on the Toronto Stock Exchange (the "TSX"). As a result, the common shares commenced trading on the TSX under the symbol "CRDL". On May 30, 2019, the Corporation also began trading on the OTCQX Best Market under the symbol "CRTPF".

The Corporation is a clinical-stage biotechnology company focused on the research and clinical development of anti-inflammatory therapies for the treatment of cardiovascular disease ("CVD"). The Corporation recently received approval from the U.S. Food and Drug Administration (the “FDA”) for its Investigational New Drug ("IND") application to commence a Phase II/III, double-blind, placebo-controlled clinical trial investigating the efficacy and safety of its lead product, CardiolRx, in hospitalized COVID-19 patients with a prior history of, or risk factors for, CVD. CardiolRx is an ultra-pure, high concentration cannabidiol oral formulation that is pharmaceutically produced, manufactured under cGMP, and is THC free (<10 ppm).

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

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

Cardiol is also planning to file an IND for a Phase II international trial 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 and is developing a subcutaneous formulation of CardiolRx for the treatment of inflammation in the heart that is associated with the development and progression of heart failure. Heart failure is the leading cause of death and hospitalization in North America, with associated annual healthcare costs in the U.S. alone exceeding $30 billion.

In parallel with the clinical programs in inflammatory heart disease, Cardiol is also developing a commercial opportunity in the Canadian medical cannabinoid market through an exclusive supply agreement with *Medical Cannabis by Shoppers*™. Cardiol's Cortalex™ brand is the first THC-free (<10 ppm) extra-strength cannabidiol formulation developed for patients who wish to avoid THC or for whom THC exposure is not recommended. Cortalex is manufactured in a Health Canada approved, FDA registered, cGMP facility that meets the quality standards set by the pharmaceutical industry. This quality standard ensures that Cortalex meets the highest standards for product purity, consistency, and reproducibility.

Operations Highlights

During the 2020 Fiscal Period

(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 Inc.* ("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 (<10 ppm), Cardiol's products are designed to be the most consistent pharmaceutical cannabidiol formulations available. Shoppers also has the right to purchase all future products available from Cardiol's product line, subject to any and all regulations.

(iii) In April 2020, the Corporation announced that data submitted by its international research collaborators were accepted for presentation at the American College of Cardiology's ("ACC") 69th Annual Scientific Session & Expo together with the World Congress of Cardiology, held virtually from March 28 - 30.

The effects of Cardiol's pharmaceutically produced cannabidiol formulation were assessed in a model of non-ischemic heart failure. Heart failure was induced by four weeks of infusion of angiotensin II, a substance that produces hypertension, cardiac enlargement, and subsequent heart failure. Two dosages of Cardiol's cannabidiol formulation (or placebo) were administered by subcutaneous injection every three days for four weeks. In addition, the effects of cannabidiol on angiotensin-induced hypertrophy (cell enlargement) and expression of B-type Natriuretic Peptide ("BNP") in a cardiac cell line ("H9c2") were assessed. BNP is a substance released from stretched heart cells which is a widely used clinical indicator of the severity of heart failure.

The study found that Cardiol's cannabidiol formulation significantly reduced hypertrophy and produced a dose-dependent reduction of key inflammation markers, decreases in fibrosis, and lower BNP expression. These findings confirm the anti-inflammatory and anti-fibrotic activity of Cardiol's cannabidiol formulation in a model of heart failure. Moreover, the data show that cannabidiol reduced the amount of BNP released, thereby confirming the role of Cardiol's cannabidiol formulation as a cardioprotective therapy.

(iv) In April 2020, the Corporation announced that data describing Cardiol's nanotechnology approach to drug delivery were submitted by the Corporation's international research collaborators and accepted for presentation at the ACC's 69th Annual Scientific Session & Expo together with the World Congress of Cardiology, held virtually from March 28 - 30.

Results from this study, conducted at the Houston Methodist DeBakey Heart & Vascular Center, showed that there was a greater than 100-fold increase in uptake of Cardiol's nanoparticles in heart failure hearts compared with control hearts in a pre-clinical model of non-ischemic heart failure. The nanoparticles localized within the diseased hearts, predominantly in areas of fibrosis. Fibrosis is an important component of the pathology of heart failure and is primarily responsible for the stiffening and reduced function of the heart muscle. Moreover, the nanoparticles accumulated within the cytoplasm of the cultured fibroblasts. This evidence of Cardiol's nanoparticles preferentially accumulating intracellularly in fibroblasts shows potential for the successful delivery of anti-fibrotic drugs, such as cannabidiol, to the diseased region of the heart.

Cardiol's proprietary nanotechnology is designed to enable the distribution of water insoluble drugs within the blood (aqueous) circulation, improve pharmacokinetics, and facilitate drug accumulation in the failing heart. Cardiol's nanoparticles are based on a patented family of biocompatible and biodegradable amphiphilic block co-polymers made from polyethylene glycol ("PEG") and polycaprolactone ("PCL"). Both PEG and PCL have a long history of safe use in humans.

(v) In May 2020, the Corporation announced the filing of a new patent application covering the use of cannabidiol to improve the outcome of patients with COVID-19. This new patent application includes the administration of CBD to reduce the severity of disease in COVID-19 patients with pre-existing cardiovascular conditions, and to prevent the progression of such conditions.

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

There is a growing body of experimental evidence that CBD reduces cardiac and vascular inflammation, oxidative stress, and cardiac dysfunction. Pre-clinical research in a model involving cardiac injury demonstrated that Cardiol's pharmaceutically produced (cGMP) cannabidiol has a cardioprotective effect, resulting in a reduction of fibrosis, cardiac hypertrophy (enlargement of the heart), and the cardiac remodeling marker BNP (See (iii) above).

(vi) In June 2020, the Corporation announced the completion of its short form prospectus offering (the "Offering") by issuing 6,900,000 common share units at $2.50 per unit for gross proceeds of $17,250,000. Each unit consisted of one common share and one-half of one common share purchase warrant. Each whole warrant is exercisable into one common share at the price of $3.25 per share for a period of two years from closing, subject to accelerated expiry if, at any time, the volume weighted average trading price of the common shares is equal to or greater than $4.50 for any ten consecutive trading day period.

(vii) In June 2020, the Corporation announced that it appointed Steven Grasso as Business Advisor to the Corporation. Steven Grasso began his career on the floor of the New York Stock Exchange in 1993. He joined Stuart Frankel & Co. as an institutional sales trader in 1999. As Director of Institutional Sales for Stuart Frankel & Co., Steven has worked closely with some of the largest mutual funds, pension funds, insurance companies, and hedge funds in the world directly from the floor of the Stock Exchange. Over his 27-year career, Steven has actively participated in various Stock Exchange committees ranging from allocating new listings to designated market makers to developing standardized tests that the floor community uses for continuing education. Steven closely follows the Washington D.C./Markets connection, using his extensive Capitol Hill and SEC relationships to better inform his clients on policy changes and regulation.

Steven is perhaps best known for being a CNBC market analyst and is a regular on CNBC's popular "Fast Money" show, which airs daily during the business week and has an average daily viewership that currently exceeds 250,000. Mr. Grasso also speaks at many traders' conferences across the country on a regular basis, as well as business round tables with many influential leaders of industry where he addresses a broad range of market related issues, including the effects of regulation and the political process on equities.

As Business Advisor, Mr. Grasso will assist with raising Cardiol's profile within the U.S. investment community. Steven has the ability to provide important introductions to investors, analysts, investment banks, and other key investment industry participants. He also has an extensive network of connections with senior management of many of the largest pharmaceutical and biotechnology companies in the world, which will be of assistance to the Corporation in achieving its commercial and business development objectives.

(viii) In October 2020, the Corporation announced the commercial introduction of Cortalex, a THC-free (<10 ppm) extra-strength (100 mg/mL concentration) oral cannabidiol formulation. Cortalex is now available across Canada exclusively at *Medical Cannabis by Shoppers*™ online portal, a subsidiary of *Shoppers Drug Mart Inc.*, and is the first pharmaceutically produced CBD specifically formulated for the large number of patients who should not be exposed to THC.

Subsequent to December 31, 2020

(i) Subsequent to December 31, 2020, the Corporation granted 1,146,666 stock options to certain consultants of the Corporation. Each option allows the holder to acquire one common share of the Corporation at an exercise price ranging from $3.16 to $4.80 and expires between January 31, 2023 and February 22, 2023. 696,666 of the options vest immediately, while the remainder vest 25% per quarter from the grant date.

(ii) Subsequent to December 31, 2020, the Company received proceeds of $7,968,220 on the exercise of 2,451,760 warrants with an exercise price of $3.25, and $503,068 on the exercise of 201,227 warrants with an exercise price of $2.50. In addition, there were a total of 916,666 stock option exercises, resulting in cumulative proceeds of $2,604,648.

(iii) In March 2021, The Corporation announced that it submitted an application to list the Corporation's common shares on The Nasdaq Capital Market (the "Nasdaq").

(iv) Subsequent to December 31, 2020, the Corporation announced that that Dr. Andrew Hamer has joined the Company as Chief Medical Officer (CMO). Dr. Hamer will lead the research and development of the Company's clinical-stage products and will also guide the development of additional novel therapeutics in the Company's pipeline. Retiring CMO and co-founder of Cardiol, Dr. Eldon Smith, will continue to serve as Chair of the Board of Directors and as an advisor to the Company.

Dr. Andrew Hamer brings 30 years of experience in the global life sciences industry, medical affairs, and cardiology practice to the Company. Most recently he served as Executive Director, Global Development-Cardiometabolic at California-based Amgen Inc., where he led the Global Development group for Repatha®, the LDL cholesterol lowering PCSK9 inhibitor evolocumab, which generated revenues of almost USD $900 million in 2020. As development lead, Dr. Hamer headed the Repatha® global evidence generation team collaborating with safety, regulatory, health economics, observational research, scientific communications, publications, medical affairs, and clinical operations teams to design and execute several multi-center clinical trials in support of FDA and international regulatory filings. Prior to his five-year tenure with Amgen, Dr. Hamer served for two years as VP Medical Affairs at Capricor Therapeutics Inc., where he was responsible for the development of novel therapeutics for heart disease and for the supervision of the clinical operations of the company, including clinical trial design and execution.

Prior to joining the life sciences industry, Dr. Hamer practiced cardiology and internal medicine in New Zealand for 19 years. His distinguished career in cardiology culminated as Chief Cardiologist at Nelson Hospital, Nelson Marlborough District Health Board, Nelson, while concurrently leading cardiac services nationally in New Zealand. Dr. Hamer graduated with a medical degree (MB, ChB) from the University of Otago, New Zealand, an internationally recognized medical school which recently ranked among the top twenty universities in the world in several medical subject categories. His clinical research training took place at various centres in New Zealand and London, UK, followed by a cardiology fellowship at Deaconess Hospital, Harvard Medical School, Boston. Dr. Hamer has co-authored many high-quality peer-reviewed scientific publications reflecting his considerable experience as a clinical trialist, having served as a principal or co-investigator for 40 multi-centre clinical trials in therapies for acute coronary syndrome, heart failure, hypertension, cholesterol disorders, atrial fibrillation, and diabetes.

Clinical Highlights

Phase II/III study – COVID-19

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

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

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

Patients with COVID-19 primarily present with respiratory symptoms which can progress to bilateral pneumonia and serious pulmonary complications. It is now recognized that the impact of COVID-19 is not limited to the pulmonary system. Individuals with pre-existing CVD or who have risk factors for CVD (such as diabetes, hypertension, obesity, abnormal serum lipids, or age greater than 64) are at significantly greater risk of developing serious disease from COVID-19 and experience greater morbidity. Moreover, such COVID-19 patients are at significant risk of developing cardiovascular complications (such as acute myocardial infarction, cardiac arrhythmias, myocarditis, stroke, and heart failure) during the course of their illness, and which are frequently fatal, with an estimated 30 – 40% of patients who die from COVID-19 doing so from cardiovascular complications. A strategy to prevent or limit the number or severity of these cardiovascular complications is likely to considerably improve outcomes from this disease.

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

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

<u>Dennis M. McNamara, MD (Chair)</u>

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

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

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

Arvind Bhimaraj, MD

Dr. Arvind Bhimaraj is a specialist in Heart Failure and Transplantation Cardiology and is Assistant Professor of Cardiology, Institute for Academic Medicine, at Houston Methodist and at Weill Cornell Medical College, NYC. He has been Co-Director of the Heart Failure Research Laboratory at Houston Methodist since 2016. His area of focus is 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.

Barry Trachtenberg, MD

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

Wai Hong Wilson Tang, MD

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

Peter Liu, MD

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

Carsten Tschöpe, MD

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

Matthias Friedrich, MD

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

Guilherme Oliveira, MD, MBA

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

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

The DSMC currently consists of three members:

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

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

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

The CEC currently consists of three members:

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

The Phase II/III study is anticipated to commence during Q2, 2021 and is expected to be completed during H2, 2021. Cardiol has budgeted costs of approximately USD $6.4 million for study execution and $1.4 million for potential post study analysis.

Subject to study outcomes, Management's discussions with the FDA indicated that the design and scope of the Phase II/III trial may be used as a registration study in support of a New Drug Application in 2022. Cardiol may involve a commercial partner from the pharmaceutical industry, with research, development and commercialization costs potentially being shared with its commercial partner.

Phase I study

On December 22, 2020, the Corporation announced the completion of the Phase I study described below. The results of the study are expected in Q2, 2021 and will form an integral part of the Corporation's planned IND application with the FDA for an international Phase II clinical trial in acute myocarditis.

Cardiol's Phase I double-blind, placebo-controlled, randomized study was designed to assess safety, tolerability, and pharmacokinetics of single, followed by multiple day ascending doses of CardiolRx administered orally to 52 healthy adult subjects, both in the fasting and fed states. The therapy was shown to be generally well tolerated with no serious adverse events reported in the study and 51 subjects completed all requirements of the study protocol. By measuring standard safety parameters and the pharmacokinetics of CardiolRx, including the degree of drug absorption and resulting blood levels at escalating doses, the Phase I study will provide important information to optimize dosing levels.

Phase II study – Acute myocarditis

Cardiol is planning a Phase II clinical program in acute myocarditis utilizing its pharmaceutically produced, pure cannabidiol formulation. Cardiol's acute myocarditis program has been designed by an independent Steering Committee comprised of thought leaders in cardiology from North America and Europe. The IND filing for the Phase II trial is planned for Q3, 2021. It is anticipated that the IND application will be granted during the second half of 2021, with the study commencing soon thereafter. It is estimated that patient recruitment will take 12 to 18 months following the initiation of the clinical trial centers. Cardiol has predicted costs of this study, including the IND application, to be approximately $600,000 for 2021; however, the total costs of the study cannot be determined at this stage as they will depend on a variety of factors.

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

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

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

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

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

Members of Cardiol’s Acute Myocarditis Steering Committee are included above under “Phase II/III study – COVID-19.”

Outlook

The Corporation expects that the December 31, 2020 working capital of $12,431,760 will be sufficient to fund operations and capital requirements for more than 12 months. Additionally, subsequent to December 31, 2020, the Corporation raised an additional approximately $11 million through the exercise of warrants and stock options - (see Operational Highlights - Subsequent to December 31, 2020).

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

1. Complete enrollment of 422 patients in International Phase II/III COVID-19 trial examining the cardioprotective properties of CardiolRx;
2. Submit IND application to the FDA and commence an international Phase II acute myocarditis trial led by highly distinguished Steering Committee;
3. Expand market awareness of Cortalex, the Corporation's commercial cannabidiol product, amongst physicians, as well as consumers in the almost $600 million Canadian cannabinoid medical market;
4. Complete development of a subcutaneous cannabidiol formulation of CardiolRx for treatment of chronic heart failure, a leading cause of death and hospitalization in North America;
5. Up-list to Nasdaq with the goal of significantly increasing U.S. investor awareness.

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, 2020 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 [1]	1,700,000	1,700,000	-
Phase 2 clinical trial program [1]	2,500,000	106,977	2,393,023
Glioblastoma Multiforme:			
Fund the development of immunotherapy in combination with cannabinoids for its target indication of Glioblastoma Multiforme	1,100,000	-	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	1,500,000	338,743	1,161,257
Prescription sales expenditure, including physician information, creative developments, and producing material samples	2,000,000	329,136	1,670,864
Other:			
Exclusivity payment to Noramco (USD $3.0 million) [2]	3,900,000	3,900,000	-
100,000 expected to be made on the initiation of a Phase 2 program, to Meros	100,000	-	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. Exclusivity payment made in December 2018.

Use of Offering Proceeds

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

A comparison between the projected use of proceeds for the two-year period subsequent to closing the Offering, as disclosed in the Corporation's prospectus dated May 26, 2020 and spending from June 4, 2020 (Offering closing date) to December 31, 2020 is as follows:

Use of Proceeds	Amount	Spent	Remaining
Clinical Trials (Phase I and Phase II/III)	6,400,000	1,172,184	5,227,816
Pre-clinical studies	900,000	180,550	719,450
Product Development	1,100,000	44,896	1,055,104
Marketing & Business Development	900,000	-	900,000

Selected Annual Financial Information

Year Ended December 31	2020	2019	2018
Net loss	$(20,640,935)	$(13,684,023)	$(15,893,735)
Net loss per share (basic and fully diluted)	$(0.69)	$(0.53)	$(1.03)
As at December 31	**2020**	**2019**	**2018**
Total assets	$15,893,181	$15,502,865	$24,684,773
Total long-term financial liabilities	$104,651	$140,279	$269,216

Summary of Quarterly Results

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

Three Months Ended	Total Revenue ($)	Profit or (Loss) Total ($)	Profit or (Loss) Per Share[9] ($)	Total Assets ($)
December 31, 2020[1]	nil	(9,666,527)	(0.15)	15,893,181
September 30, 2020[2]	nil	(4,401,243)	(0.13)	24,455,341
June 30, 2020[3]	nil	(3,624,518)	(0.13)	27,421,000
March 31, 2020[4]	nil	(2,948,647)	(0.11)	13,351,298
December 31, 2019[5]	nil	(3,058,709)	(0.12)	15,502,865
September 30, 2019[6]	nil	(3,491,816)	(0.13)	18,303,737
June 30, 2019[7]	nil	(3,642,636)	(0.14)	20,535,419
March 31, 2019[8]	nil	(3,490,862)	(0.14)	22,914,147

Note:

1. Net loss of $9,666,527 included research and development of $7,212,105, administration of $1,044,280, investor relations and promotions of $514,859, salaries and benefits of $445,326, and share-based compensation of $325,901.

2. Net loss of $4,401,243 included research and development of $1,900,839, administration of $849,330, share-based compensation of $620,277, investor relations and promotions of $463,418, and salaries and benefits of $480,459.

3. Net loss of $3,624,518 included share-based compensation of $1,070,188, research and development of $818,059, administration of $714,185, salaries and benefits of $648,861, and investor relations and promotions of $216,865.

4. Net loss of $2,948,647 included share-based compensation of $748,693, administration of $679,545, research and development of $584,253, salaries and benefits of $511,531, and investor relations and promotions of $447,372.

5. 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.

6. 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.

7. 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.

8. 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.

9. Basic and fully diluted.

Discussion of Operations

Year ended December 31, 2020, compared to the year ended December 31, 2019

For the year ended December 31, 2020, the Corporation's net loss was $20,640,935, compared to a net loss of $13,684,023 for the year ended December 31, 2019. The increase in net loss of $6,956,912 is a result of the following:

- Implementation of a supply chain and digital platform to support the distribution, marketing, and sale of Cortalex during 2021. The Corporation also conducted soft launch activities to test the consumer experience and responsiveness to product attributes and pricing. During the next 12 months, the Corporation expects to expand market awareness of Cortalex amongst physicians, as well as consumers in the Canadian medical cannabinoid market.

- Research and development increased to $10,515,256 for the year ended December 31, 2020, compared to $3,530,183 for the year ended December 31, 2019. During the year ended December 31, 2020, the Corporation incurred increased research and development costs related to basic science, pre-clinical studies, and clinical studies. In addition, prepaid inventory was received during Q4 2020 that is to be used for research and development purposes and as a result $5,436,424 of inventory was expensed. Given it is the Corporation's intention to use this inventory exclusively for future clinical programs and other research and development, under IFRS the inventory is required to be expensed immediately. Although expensed for accounting purposes, the majority of this inventory is still being held by the Corporation and will be utilized in future periods.

- Share-based compensation decreased to $2,765,059 for the year ended December 31, 2020, compared to $3,266,287 for the year ended December 31, 2019. The decrease in this non-cash expense is the result of the timing of the vesting of certain stock options in the prior period versus during the year ended December 31, 2020.

- Salaries and benefits increased to $2,086,177 for year ended December 31, 2020, compared to $1,833,892 for the year ended December 31, 2019. The increased is mainly the result of additional employees hired during fiscal 2020 due to the increased level of operations.

- Investor relations and promotions decreased to $1,642,514 for the year ended December 31, 2020, compared to $2,081,417 for the year ended December 31, 2019. 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, partially offset in the year ended December 31, 2020 by costs related to the Corporation's launch of Cortalex.

- Other income was $7,398 for the year ended December 31, 2020 versus $298,795 in the year ended December 31, 2019. This decrease is the result of refundable investment tax credits for 2017 and 2018 SRED expenses being recorded as receivable in 2019 that did not occur in 2020.

Three months ended December 31, 2020, compared to the three months ended December 31, 2019

For the three months ended December 31, 2020, the Corporation's net loss was $9,666,527, compared to a net loss of $3,058,709 for the three months ended December 31, 2019. The increase in net loss of $6,607,818 is a result of the following:

- Implementation of a supply chain and digital platform to support the distribution, marketing, and sale of Cortalex during 2021. The company also conducted soft launch activities to test the consumer experience and responsiveness to product attributes and pricing. During the next 12 months, the Corporation expects to expand market awareness of Cortalex amongst physicians, as well as consumers in the Canadian medical cannabinoid market.

- Research and development increased to $7,212,105 for the three months ended December 31, 2020, compared to $1,031,230 for the three months ended December 31, 2019. During the three months ended December 31, 2020, the Corporation incurred increased research and development costs related to basic science, pre-clinical studies, and clinical studies. In addition, prepaid inventory was received during Q4 2020 that is to be used for research and development purposes and as a result $5,436,424 of inventory was expensed. Given it is the Corporation's intention to use this inventory exclusively for future clinical programs and other research and development, under IFRS the inventory is required to be expensed immediately. Although expensed for accounting purposes, the majority of this inventory is still being held by the Corporation and will be utilized in future periods.

- Administration expense increased to $1,044,280 for the three months ended December 31, 2020, compared to $885,240 for the three months ended December 31, 2019. During the three months ended December 31, 2020, the Corporation's operations increased significantly due to clinical trials in progress, as well as the launch of Cortalex, resulting in increased costs.

- Share-based compensation decreased to $325,901 for the three months ended December 31, 2020, compared to $588,746 for the three months ended December 31, 2019. The decrease in this non-cash expense is the result of the timing of the vesting of certain stock options in the prior period versus during the year ended December 31, 2020.

- Investor relations and promotions increased to $514,859 for the three months ended December 31, 2020, compared to $267,916 for the three months ended December 31, 2019. During the three months ended December 31, 2020, the Corporation incurred higher costs on investor relations and promotion as a result of costs related to the Corporation's launch of Cortalex.

- Other income was $nil for the three months ended December 31, 2020 versus $219,000 in the three months ended December 31, 2019. This income is the result of refundable investment tax credits for 2018 SRED expenses being recorded as receivable in 2019 that did not occur in 2020.

Capital Management

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

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

The Corporation considers its capital to be total equity, comprising share capital, warrants, and contributed surplus, less accumulated deficit which at December 31, 2020, totaled $13,270,353 (December 31, 2019 – $14,672,037).

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, 2020, Cardiol had $14,025,187 in cash and cash equivalents (December 31, 2019 – $6,956,203).

At December 31, 2020, accounts payable and accrued liabilities were $2,466,262 (December 31, 2019 – $640,076). The Corporation's cash and cash equivalents balances as at December 31, 2020 and December 31, 2019 are sufficient to pay these liabilities.

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

As of December 31, 2020, December 31, 2019, 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 2020 Fiscal Period

Cash and cash equivalents used in operating activities were $9,185,430 for the year ended December 31, 2020. Operating activities were affected by a net loss of $20,640,935 and the net change in non-cash working capital balances of $8,315,917 offset partially by non-cash adjustments of $3,139,588. Non-cash adjustments mainly consisted of $2,765,059 for share-based compensation and $78,992 for research and development expenses to be settled through warrant exercise. Non-cash working capital was the result of a decrease in prepaid inventory of $4,745,148, an increase in accounts payable and accrued liabilities of $1,826,186, a decrease in inventory of $1,100,780, and a decrease in other receivables of $702,072.

Cash and cash equivalents used in investing activities were $40,602 for the year ended December 31, 2020. This pertained to the purchase of property and equipment.

Cash and cash equivalents provided by financing activities were $16,295,016 for the year ended December 31, 2020, mainly as a result of the issuance of units, net of share issuance costs and proceeds from warrants exercised.

Use of Working Capital

As of December 31, 2020, Cardiol's working capital was $12,431,760. Based on current projections, Cardiol believes that this amount is sufficient to meet its planned development activities for more than 12 months as described in the "Outlook" section above.

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

Contractual Obligations	Total ($)	Up to 1 year ($)	1 – 3 years ($)	4 – 5 years ($)	After 5 years ($)
Amounts payable and other liabilities	2,466,262	2,466,262	Nil	Nil	Nil
Office lease (1)	361,439	103,761	213,002	44,676	Nil
Consulting agreements	830,763	830,763	Nil	Nil	Nil
Contract research	1,271,434	1,271,434	Nil	Nil	Nil
Total	**4,929,898**	**4,672,220**	**213,002**	**44,676**	**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 2020 Fiscal Period

i. Included in research and development expense is $1,149,098 for the year ended December 31, 2020 (year ended December 31, 2019 - $1,171,900) 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, 2020, $505,195 (December 31, 2019 - $76,784) was owed to this company and this amount was included in accounts payable and accrued liabilities and $1,470 and $nil (December 31, 2019 - $65,973 and $35,040) 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 $nil for the year ended December 31, 2020 (year ended December 31, 2019 - $230,000) 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. As at December 31, 2020, $nil (December 31, 2019 - $20,000) is included in prepaid expenses.

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 December 31, 2020 ($)	Year ended December 31, 2019 ($)
Salaries and benefits	1,499,613	1,145,571
Share-based payments	617,999	1,506,339
	2,117,612	**2,651,910**

As at December 31, 2020, $190,940 (December 31, 2019 - $2,005) was owed to key management personnel and this amount was included in accounts payable and accrued liabilities.

Critical Accounting Judgments, Estimates, and Assumptions

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

Critical accounting estimates

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

- The inputs used in the Black-Scholes valuation model that were based on unobservable assumptions when the Corporation was private at the time of issuance of the equity instruments (share price and volatility) in accounting for share-based payment transactions. Share-based payments are valued on the date of grant;
- The estimate of the percentage of completion of certain research and development agreements;
- The valuation of the income tax noncurrent asset would increase if there was virtual certainty that the tax benefit of net operating losses could be applied to future periods' taxable income; and
- Intangible assets are comprised of the exclusive global license. Intangible assets are initially stated at cost, less accumulated amortization and accumulated impairment losses. Intangible assets with finite useful lives are amortized over their estimated useful lives. The exclusive global license's useful life is 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 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 through 2021. Management will need to raise additional financing to support their planned level of expenditure through the end of 2022. Such financing may come from product sales, licensing arrangements, research and commercial development partnerships, government grants, and/or corporate finance arrangements;
- Management's assessment that no impairment exists for intangible assets, based on the facts and circumstances that existed during the period; and
- Management's assessment of the impact the novel coronavirus (COVID-19) pandemic will have on operations (see "Risk Factors - COVID-19 pandemic" below).

Share Capital

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

As of the date of this MD&A, the outstanding capital of the Corporation includes 36,590,594 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
June 22, 2022	2.58	83,334	83,334
February 8, 2023	4.56	416,666	416,666
February 18, 2023	4.80	560,000	250,000
February 23, 2023	4.46	130,000	30,000
October 15, 2024	3.23	110,000	36,667
December 2, 2024	4.08	60,000	20,000
December 5, 2024	3.69	60,000	30,000
February 23, 2025	3.54	86,300	86,300
August 16, 2025	5.00	200,000	200,000
August 19, 2025	2.12	100,000	-
August 30, 2025	5.00	580,000	423,330
October 7, 2025	2.90	35,000	-
December 2, 2025	2.59	210,000	-
January 2, 2026	4.30	150,000	150,000
January 24, 2026	5.34	60,000	40,000
March 29, 2026	4.51	400,000	-
April 1, 2026	5.77	140,000	46,667
April 4, 2026	5.42	60,000	20,000
Total		**3,441,300**	**1,832,964**

Warrants

Expiry date	Exercise price ($)	Warrants outstanding
June 4, 2022	3.25	1,090,048
June 4, 2022[(1)]	2.50	55,182
August 31, 2022	4.00	824,000
Total		**1,969,230**

(1) Exercisable into one common share and one-half of one common share purchase warrant. Each additional whole warrant is exercisable into one common share at the price of $3.25 per share until June 4, 2022.

Financial Instruments

Recognition

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

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

Classification and Measurement

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

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

- those to be measured subsequently at amortized cost.

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

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

- amortized cost;

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

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

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

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

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

Fair Value

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

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

The Corporation has no financial instruments measured at fair value.

Financial Instrument Risks

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

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

There were no changes to credit risk, liquidity risk, or market risk for the 2020 Fiscal Period.

Credit risk

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation. The Corporation's financial instruments that are exposed to concentrations of credit risk relate primarily to cash and cash equivalents and accounts receivable.

The Corporation mitigates its risk by maintaining its funds with large reputable financial institutions, from which Management believes the risk of loss to be minimal. Interest receivable relates to guaranteed investment certificates and cash balances held with large reputable financial institutions as well as trade receivables. The Corporation's Management considers that all the above financial assets are of good credit quality.

Liquidity risk

Liquidity risk is the risk that the Corporation encounters difficulty in meeting its obligations associated with financial liabilities. Liquidity risk includes the risk that, as a result of operational liquidity requirements, the Corporation will not have sufficient funds to settle a transaction on the due date; will be forced to sell financial assets at a value which is less than what they are worth; or may be unable to settle or recover a financial asset. Liquidity risk arises from accounts payable and accrued liabilities and commitments. The Corporation limits its exposure to this risk by closely monitoring its cash flow.

Market risk

Market risk is the risk of loss that may arise from changes in market factors, such as interest rates and foreign exchange rates.

(a) Interest rate risk

The Corporation currently does not have any short-term or long-term debt that is variable interest bearing and, as such, the Corporation's current exposure to interest rate risk is minimal.

(b) Foreign currency risk

Foreign exchange risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in the foreign exchange rates. The Corporation enters into foreign currency purchase transactions and has assets that are denominated in foreign currencies and thus is exposed to the financial risk of earnings fluctuations arising from changes in foreign exchange rates and the degree of volatility of these rates. The Corporation does not currently use derivative instruments to reduce its exposure to foreign currency risk.

The Corporation holds balances in U.S. dollars which could give rise to exposure to foreign exchange risk. Sensitivity to a plus or minus 10% change in the foreign exchange rate of the U.S. dollar against the Canadian dollar would affect the reported loss and comprehensive loss by approximately $219,000 (December 31, 2019 - $152,000).

Commitments and Contingency

(i) The Corporation has leased premises from third parties. The minimum committed lease payments as at December 31, 2020, which include the lease liability payments, are as follows:

Fiscal year		
2021		103,761
2022		105,780
2023		107,222
2024		44,676
Total	**$**	**361,439**

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

Fiscal year		
2021	$	830,763

(iii) Pursuant to the terms of agreements with various other contract research organizations, the Corporation is committed for contract research services for 2021 at a cost of approximately $1,271,434.

Breakdown of Expensed Research and Development

	Year ended December 31, 2020 ($)	Year ended December 31, 2019 ($)
Contract research	3,815,700	2,031,194
Wages	424,681	230,654
Supplies	6,021,365	506,322
Regulatory	253,510	762,013
	10,515,256	**3,530,183**

Breakdown of Operating Expenses

	Year ended December 31, 2020 ($)	Year ended December 31, 2019 ($)
Administration	3,287,340	3,112,872
Depreciation of property and equipment	145,095	66,128
Amortization of intangible assets	84,444	84,444
Accretion and interest on convertible debentures	-	621
Investor relations and promotions	1,642,514	2,081,417
Salaries and benefits	2,086,177	1,833,892
Transfer agent and regulatory	164,576	152,546
Share-based compensation	2,765,059	3,266,287
	10,175,205	**10,598,207**

Breakdown of Intangible Assets

	As at December 31, 2020 ($)	As at December 31, 2019 ($)
Exclusive global license agreement	767,228	767,228
Accumulated amortization	(303,538)	(219,094)
Carrying value	**463,690**	**548,134**

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, 2020.

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 subcutaneous product candidates which are at early stages of development, the success of our Phase II/III trial in high-risk patients hospitalized with COVID-19, 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 subcutaneous product candidates.

Given the early stage of development of our acute myocarditis and subcutaneous product candidates, and the uncertainty inherent in clinical trials, we can make no assurance that our research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, we, alone or with others, must successfully develop, gain regulatory approval, and market our 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.

Many product candidates never reach the stage of clinical testing and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Product candidates may fail for a number of reasons, including, but not limited to, being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the standard of treatment at the time of testing. Positive results of early pre-clinical research may not be indicative of the results that will be obtained in later stages of pre-clinical or clinical research. 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 subcutaneous product development makes it particularly uncertain whether any of these product development efforts will prove to be successful and meet applicable regulatory requirements, and whether any of our product candidates will receive the requisite regulatory approvals, be capable of being manufactured at a reasonable cost, or be successfully marketed. If 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.

Our only current source of revenue is the sale of our pharmaceutical cannabidiol. As a result, we are only generating revenue from one product, and may never generate significant revenue from the sale or licensing of other products, or otherwise. Moreover, sales of our pharmaceutical cannabidiol are not expected to generate sufficient revenue during 2021 to fully fund our operations.

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 2020 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, 2020 was $20,640,935 and for the year ended December 31, 2019 was $13,684,023. We have recently started generating revenue and it is possible that we will never have sufficient product sales revenue to achieve profitability. We expect to continue to incur losses for at least the next several years as we or our collaborators and licensees pursue clinical trials and research and development efforts. To become profitable, we, either alone or with our collaborators and licensees, must successfully market our pharmaceutical cannabidiol and develop, manufacture, and market our current product candidates, as well as continue to identify, develop, manufacture, and market new product candidates. It is possible that we will never have significant product sales revenue or receive royalties on our licensed product candidates. If funding is insufficient at any time in the future, we may not be able to develop or commercialize our products, take advantage of business opportunities, or respond to competitive pressures.

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

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

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

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

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

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

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

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

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

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

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

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

If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, 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, and regulatory requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- failure of our CROs to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical trial sites by regulatory authorities or Institutional Review Boards ("**IRBs**"), or ethics committees finding regulatory violations that require us to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more IRBs or ethics committees rejecting, suspending, or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- failure to reach agreement on acceptable terms with prospective clinical trial sites.

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

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols;

- inspection of the clinical trial operations or clinical trial sites by the FDA, the 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 pre-clinical 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, IRBs, or ethics committees for re-examination, which may impact the cost, timing, or successful completion of that trial. Delays or increased product development costs may have a material adverse effect on our business, financial condition, and prospects.

Negative results from clinical trials or studies of others and adverse safety events involving the targets of our 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 and cost estimates we announce and expect

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

Unpredictable and volatile market price for common shares

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

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

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

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

The trading market for our common shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common shares or publish inaccurate or unfavorable research about our business, our share price would likely decline. If one or more of these analysts cease coverage of our Corporation or fail to publish reports on us regularly, demand for our 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, United States, and other foreign intellectual property. We anticipate filing additional patent applications in Canada, the United States, and in other countries, as appropriate. However, we cannot predict:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our product candidates contain substances related to the cannabis plant and are subject to the *Cannabis Act* and the Cannabis Regulations in Canada. As a pharmaceutical product, cannabidiol will be subject to both the *Food and Drugs Act* and regulations issued under the *Cannabis Act* and Cannabis 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 a cannabinoid, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for our product candidates. These pressures could also limit or restrict the introduction and marketing of our product candidates. Adverse publicity from cannabis misuse or adverse 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, including those relating to the production, distribution, sale, and possession of cannabis in Canada. 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 licensed producers 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. On November 18, 2020, Health Canada released the names of the initial members of the Science Advisory Committee. The committee has a one-year term with an option of renewal based on the Department's needs.

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.

On December 12, 2020, Health Canada opened up a consultation period on possible amendments to the regulations made under the *Cannabis Act*. Interested parties had until January 11, 2021 to provide comments on Health Canada's cannabis research involving human participants and cannabis testing, and to provide feedback on additional regulatory issues. The key issues Health Canada has identified for discussion are cannabis research involving human participants, cannabis testing, public possession limits, product labelling requirements, micro-class and nursery licensing regime, and measures to support the industry during COVID-19.

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 United States, 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 only commercialized one product to date

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 pre-clinical and clinical grade materials supplied by contract manufacturers, our business operations could suffer significant harm

We currently have no manufacturing experience and rely on Dalton and other contract manufacturing organizations ("CMOs") to manufacture our product candidates for pre-clinical studies and clinical trials. We rely on CMOs for manufacturing, filling, packaging, storing, and shipping of 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 pre-clinical and clinical trials. There are only a limited number of suppliers and manufacturers of our APIs and our ability to obtain these materials could be disrupted if the operations of these manufacturers are affected by earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man-made disasters or business interruptions. We also rely on CROs, clinical data management organizations, and consultants to design, conduct, supervise, and monitor pre-clinical studies of our product candidates and will do the same for our planned clinical trials. If their facilities are unable to operate because of an accident or incident, even for a short period of time, some or all of our research and development programs may be harmed or delayed, and our operations and financial condition could suffer.

Our existing collaboration agreements and any 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 may require import and export licenses. In the United States, the FDA, United States Customs and Border Protection, and in other countries, similar regulatory authorities regulate the import and export of pharmaceutical products that contain controlled substances. Specifically, the import and export process 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

As a manufacturer and distributor of products designed to be ingested by humans, the Corporation faces an inherent risk of exposure to product liability claims, regulatory action, and litigation if its 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 produces or intends to produce are recalled due to an alleged product defect or for any other reason, the Corporation could be required to incur the unexpected expense of the recall and any legal proceedings that might arise in connection with the recall. The Corporation may lose a significant amount of sales and may not be able to replace those sales at an acceptable margin or at all. In addition, a product recall may require significant Management attention. Although the Corporation has detailed procedures in place for testing finished products, 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

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 large new 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 *Corruption of Foreign Public Officials Act* (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, cybersecurity and the continued development and enhancement of controls, processes, and practices designed to protect systems, computers, software, data, and networks from attack, damage, or unauthorized access is a priority. As cyber threats continue to evolve, the Corporation may be required to expend additional resources to continue to modify or enhance protective measures or to investigate and remediate any security vulnerabilities.

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

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.

COVID-19 pandemic

The recent novel coronavirus (COVID-19) pandemic has impacted and could further impact our expected timelines, 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.

Common shares are subject to market price volatility

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

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

Potential Dilution

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

Forward-Looking Information May Prove to be Inaccurate

Investors should not place undue reliance on forward-looking information. By its nature, forward-looking information involves numerous assumptions, known and unknown risks and uncertainties, of both general and specific nature, that could cause actual results to differ materially from those suggested by the forward-looking information or contribute to the possibility that predictions, forecasts or projections will prove to be materially inaccurate. Additional information on the risks, assumptions and uncertainties can be found under the heading "*Forward-Looking Information*".

The Corporation May Use the Proceeds of the Offering for Purposes Other Than Those Previously Set Out

The Corporation currently intends on allocating the net proceeds received from any Offerings as described under the heading "*Use of Proceeds*". However, the Corporation's Management will have discretion in the actual application of the proceeds and may elect to allocate proceeds differently from that described under the heading "*Use of Proceeds*" if it believes that it would be in the best interests of the Corporation to do so if circumstances change. The failure by Management to apply these funds effectively could have a material adverse effect on the Corporation's business.

Negative Operating Cash Flow

The Corporation is currently incurring expenditures related to its operating activities that have generated negative operating cash flows. Operating cash flows may decline in certain circumstances, many of which are beyond the Corporation's control. There is no assurance that sufficient revenues will be generated in the near future and the Corporation may continue to incur negative operating cash flow.

Nasdaq Listing Application

The Corporation made application to list its common shares on The Nasdaq Capital Market® (the "Nasdaq") on March 1, 2021. The listing of the Corporation's common shares on the Nasdaq is subject to the approval of the Nasdaq and the satisfaction of all applicable listing criteria and requirements. No assurance can be given that such application will be approved or that such listing will be completed. If the Nasdaq listing occurs, the Corporation's common shares would no longer be listed on the OTCQX exchange. The Corporation plans to maintain its current listing on the TSX.

The listing of the Corporation's common shares on Nasdaq is subject to the Corporation's satisfaction of a number of conditions, including registration of Corporation's common shares with the U.S. Securities and Exchange Commission (the "SEC") and a determination by the Nasdaq Listing Qualifications Staff that the Corporation satisfies all applicable criteria for initial listing.

Investors are cautioned that although the Corporation has submitted an application to list its common shares on Nasdaq, the successful completion of the Nasdaq listing process is subject to the Corporation's receipt of certain regulatory approvals from Nasdaq and the SEC, and satisfaction of all applicable qualitative and quantitative criteria for initial listing on Nasdaq. There can be no assurance that a U.S. listing will be obtained. Furthermore, the Corporation believes that, if its common shares are accepted for listing on Nasdaq and are registered with the SEC, its ongoing financial reporting, listing, compliance, and insurance costs will increase as a result.