CARDIOL THERAPEUTICS INC.

Annual Information Form

For the year ended December 31, 2025

March 31, 2026

TABLE OF CONTENTS

GLOSSARY OF TERMS

"**ANDA**" means abbreviated new drug application.

"**APIs**" means active pharmaceutical ingredients.

"**ARCHER**" means the Corporation's Phase II multi-national, double-blind, placebo-controlled clinical study evaluating the tolerance, safety and efficacy of its lead product candidate, CardiolRx, in acute myocarditis.

"**Audit Committee**" means the Corporation's Audit Committee.

"**BDO**" means the independent registered public accounting firm of the Corporation, BDO Canada LLP, Chartered Professional Accountants, of 360 Oakville Place Drive, Suite 500, Oakville, ON L6H 6K8.

"**BNP**" means B-type Natriuretic Peptide.

"**Board of Directors**" or "**Board**" means the board of directors of the Corporation and "**Director**" means each director of the Corporation.

"**Cannabis**" has the meaning set out in Canada's *Cannabis Act* (S.C. 2018, c. 16).

"**Cannabis Act**" means *Cannabis Act* (Canada), as amended from time to time.

"**Cannabis Regulations**" means regulations issued pursuant to the Cannabis Act.

"**Cardiol**" or the "**Corporation**" means Cardiol Therapeutics Inc. and its subsidiaries.

"**Cardiol USA**" means the wholly owned subsidiary of the Corporation, Cardiol Therapeutics USA Inc.

"**CARO**" means the Instituto Tecnológico y de Estudios Superiores de Monterrey's Clinical Academic Research Organization, S.A. de C.V.

"**CEO**" means Chief Executive Officer.

"**CFO**" means Chief Financial Officer.

"**CG&C Committee**" means the Corporate Governance and Compensation Committee.

"**cGMP**" means the FDA's current Good Manufacturing Practice regulations.

"**CHMP**" means the Committee for Medicinal Products for Human Use.

"**CIPO**" means the Canadian Intellectual Property Office.

"**CMOs**" means contract manufacturing organizations.

"CMR" means cardiac magnetic resonance imaging

"**Common Shares**" or "**Shares**" means the Class A Common Shares in the capital of the Corporation.

"**COVID-19**" means a disease caused by the severe acute respiratory syndrome coronavirus .

"**CRO**" means contract research organizations.

"CRP" means C-reactive protein.

"**CSA**" means the U.S. Controlled Substances Act.

"**CTA**" means clinical trial application.

"**Dalton**" means Dalton Chemical Laboratories, Inc., operating as Dalton Pharma Services.

"**Dalton Services Agreement**" has the meaning set out under the heading "Commercial Relationships – Dalton".

"**DEA**" means the Drug Enforcement Agency.

"DIN" means the Drug Identification Number.

"**DSUs**" means deferred share units.

"**EMA**" means European Medicines Agency.

"**EndoMT**" means endothelial-to-mesenchymal cell transition.

"**E.U.**" means European Union.

"**FCPA**" means the U.S. Foreign Corrupt Practices Act of 1977.

"**FDA"** means the U.S. Food and Drug Administration.

"**FDCA**" means the U.S. Federal Food, Drug, and Cosmetic Act.

"**GCP**" means Good Clinical Practices.

"GLP" means Good Laboratory Practice.

"**Health Canada**" means the department of the government of Canada with responsibility for national public health.

"**HF**" means heart failure.

"**HFpEF**" means heart failure with preserved ejection fraction.

"**ICFR**" means internal controls over financial reporting.

"**IFRS**" means International Financial Reporting Standards.

"IL-1ß" means interleukin-1ß.

"IL-6" means interleukin-6.

"**IND**" means an FDA investigational new drug.

"**IRB**" means Institutional Review Boards.

"**IT**" means information technology.

"**Legacy Equity Compensation Plan**" means the stock option plan the Board of Directors has adopted whereby options and shares may be granted to the Corporation's Directors, officers, employees, and consultants. This plan was replaced by the Omnibus Equity Incentive Plan.

"**MAA**" means marketing authorization application.

"**Management**" means the management of the Corporation.

"**Market Price**" means the 5-day VWAP.

"MAvERIC-Pilot" means the Corporation's Phase II Open Label Pilot study evaluating the tolerance, safety, and efficacy of its lead product candidate, CardiolRx, in recurrent pericarditis.

"MAVERIC" means the Corporation's Phase III study evaluating the impact of CardiolRx in recurrent pericarditis patients.

"MJDS" means Multijurisdictional Disclosure System.

"MMT" means mesothelial to mesenchymal transition.

"**Nasdaq**" means the Nasdaq Stock Market LLC.

"**NDA**" means a New Drug Application under the FDA.

"**NDS**" means New Drug Submission.

"**NI 52-110**" means National Instrument 52-110 – Audit Committees.

"**NOC**" means Notice of Compliance.

"**NON**" means Notice of Noncompliance.

"**Noramco**" means Noramco, Inc.

"Omnibus Equity Incentive Plan" means the equity compensation plan the Board of Directors has adopted whereby options, shares, and other share awards may be granted to the Corporation's Directors, officers, employees, and consultants.

"**Option**" means an option under the Legacy Equity Compensation Plan or Omnibus Equity Incentive Plan.

"**Orphan Drug"** means a drug or biological product to prevent, diagnose, or treat a rare disease or condition affecting fewer than 200,000 citizens in the U.S. or 5 per 10,000 citizens in the E.U. An Orphan Drug benefits from 7 years' market exclusivity in the U.S and 10 years' market exclusivity in the E.U.

"**Orphan Drug Designation**" means the FDA's designation and approval of an Orphan Drug under the standards and procedures as set out in the Orphan Drug Act (21 CFR Part 316).

"PFIC" means passive foreign investment company.

"PDD" means pharmaceutical Drugs Directorate.

"**pharmacokinetics**" or "**PK**" means the fate of a drug once administered, for e.g., concentration and duration retained in circulation.

"**ppm**" means parts-per-million.

"**PSUs**" means performance share units.

"**Purisys**" means Purisys, LLC.

"**Purisys Exclusive Supply Agreement**" has the meaning set out under the heading "Commercial Relationships – Purisys".

"**Regulations**" has the meaning ascribed thereto under "Regulatory Framework in Canada for Cannabis".

"**RSUs**" means restricted share units.

“**Share-Based Awards**” means shares, performance share units, restricted share units, and deferred share units.

“**Shareholder**” means a shareholder of the Corporation.

“**SEC**” means the U.S. Securities and Exchange Commission.

“**TecSalud**” means TecSalud del Tecnológico de Monterrey, Mexico.

“**TSX**” means the Toronto Stock Exchange.

“**U.S.**” means the United States of America.

"**U.S. Exchange Act**” means the U.S. Securities Exchange Act of 1934, as amended.

“USPTO” means United States Patent and Trademark Office

MEANINGS OF CERTAIN REFERENCES

In this annual information form (“Annual Information Form” or “AIF”), references to the “Corporation”, “Cardiol”, “we”, “us” or “its” are references to Cardiol Therapeutics Inc. References to “management” in this AIF mean the persons acting in the capacities of Cardiol’s President and Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, and Chief Medical Officer. Any statements in this AIF made by or on behalf of management are made in such persons’ capacities as officers of Cardiol and not in their personal capacities.

FORWARD-LOOKING INFORMATION

The AIF includes certain "forward looking information" within the meaning of applicable Canadian securities legislation (collectively, "Forward-Looking Information").

Forward-looking information can be identified by words or phrases such as: "may", "might", "could", "will", "expect", "anticipate", "estimate", "intend", "plan", "indicate", "seek", "believe", "predict", or "likely", or the negative of these terms, or other similar expressions or references to future periods. All information other than historical facts, included in this AIF that address activities, events or developments that the Corporation expects or anticipates will or may occur in the future, including such things as future business strategy, competitive strengths, goals, expansion and growth of the Corporation's business, operations, plans and other such matters is intended to identify forward-looking information. Statements containing forward-looking information are not historical facts.

The Corporation has based the forward-looking information on its current expectations and projections about future events and financial trends that it believes might affect its financial condition, results of operations, business strategy, and financial needs. The forward-looking information includes, among other things, statements relating to:

- our anticipated cash needs, and the need for additional financing;
- our development of our product candidates for use in testing, research, pre-clinical studies, clinical studies, and commercialization;
- our ability to develop new routes of administration of our product candidates, including parenteral, for use in testing, research, pre-clinical studies, clinical studies, and commercialization;
- our ability to develop new formulations of our product candidates for use in testing, research, pre-clinical studies, clinical studies, and commercialization;
- the successful development and commercialization of our current product candidates and the addition of future products and product candidates;
- the ability of our product delivery technologies to deliver our product candidates to inflamed and/or fibrotic tissue;
- our intention to build a pharmaceutical brand and our products focused on addressing inflammation and fibrosis in heart disease, including, but not limited to, acute myocarditis, recurrent pericarditis, and heart failure;
- the expected medical benefits, viability, safety, efficacy, effectiveness, and dosing of our product candidates;
- our patents and intellectual property, including, but not limited to, our (a) ability to procure, defend, and/or enforce our intellectual property relating to our products, product formulations, routes of administration, product candidates, and associated uses, methods, and/or processes, and (b) freedom to operate;
- our competitive position and the regulatory environment in which we operate;
- the molecular targets and mechanism of action of our product candidates;
- our financial position; our business strategy; our growth strategies; our operations; our financial results; our dividend policy; our plans and objectives; and

- expectations of future results, performance, milestones, achievements, prospects, opportunities, or the market in which we operate.

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

- the inherent uncertainty of product development including testing, research, pre-clinical studies, and clinical trials;
- our requirement for additional financing;
- our negative cash flow from operations;
- our history of losses;
- dependence on the success of our product candidates which may not generate revenue, if approved;
- reliance on management, loss of members of management or other key personnel, or an inability to attract new management team members;
- our ability to successfully design, initiate, execute, and complete clinical trials, including the high cost, uncertainty, and delay of clinical trials and additional costs associated with any failed clinical trials;
- the uncertainty our investigational products will have a therapeutic benefit in the clinical indications we are pursuing;
- potential equivocal or negative results from clinical trials and their adverse impacts on our future commercialization efforts;
- our ability to receive and maintain regulatory exclusivities in multiple jurisdictions, including Orphan Drug/Medicine Designations/Approvals, for our product candidates;
- delays in achievement of projected development goals;
- management of additional regulatory burdens;
- volatility in the market price for the Common Shares;
- failure to protect and maintain and the consequential loss of intellectual property rights;
- third-party claims relating to misappropriation by the Corporation of their intellectual property;
- reliance on third parties to conduct and monitor our pre-clinical studies and clinical trials;
- our product candidates being subject to controlled substance laws which may vary from jurisdiction to jurisdiction;
- changes in laws, regulations, and guidelines relating to our business, including tax and accounting requirements;
- our reliance on research regarding the medical benefits, viability, safety, efficacy, and dosing of our product candidates;
- claims for personal injury or death arising from the use of our future products and product candidates;
- uncertainty relating to market acceptance of our product candidates, if approved;
- our lack of experience in commercializing any products, including selling, marketing, or distributing

pharmaceutical products;

- securing third-party payor reimbursement for our product candidates, if approved;
- the level of pricing and reimbursement for our product candidates, if approved;
- our dependence on contract manufacturers;
- unsuccessful collaborations with third parties;
- business disruptions affecting third-party suppliers and manufacturers;
- delays in the timing of regulatory authority decision-making, actions, and meetings as a result of workforce re-alignment, and potentially significant reductions in workforce or other resources, including at FDA and other U.S. federal agencies;
- lack of control in future production and selling prices of our product candidates, if approved;
- competition in our industry;
- our inability to develop new technologies and products and the obsolescence of existing technologies and products;
- unfavorable publicity or consumer perception towards any products for which we receive marketing authorization;
- product liability claims and product recalls;
- inability to expand our business to other jurisdictions;
- fraudulent activities of employees, contractors, and consultants;
- our reliance on key inputs and their related costs;
- difficulty associated with forecasting demand for products;
- operating risk and insurance coverage;
- our inability to manage growth;
- conflicts of interest among our officers and directors;
- managing damage to our reputation and third-party reputational risks;
- relationships with customers and third-party payors and consequential exposure to applicable anti-kickback, fraud, and abuse and other healthcare laws;
- exposure to information systems security threats;
- no dividends for the foreseeable future;
- future sales of Common Shares by existing shareholders causing the market price for the Common Shares to fluctuate;
- the issuance of Common Shares in the future causing dilution;
- events outside of our control could adversely affect our operations;
- our ability to remediate any material weakness in our internal control over financial reporting;
- global geo-political events, and the responses of governments having a significant effect on the world economy; and
- failure to meet regulatory or ethical expectations on environmental impact, including climate change.

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

Although the Corporation has attempted to identify important factors that could cause actual actions, events, or

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

DATE OF INFORMATION

The information in this AIF is presented as of December 31, 2025, unless otherwise indicated.

PRESENTATION OF FINANCIAL INFORMATION

Unless otherwise indicated, all references to "$" or "dollars" are to Canadian dollars, which is Cardiol's functional currency. The fiscal year end of all entities within the corporate structure of Cardiol is December 31. Cardiol's financial statements are prepared in accordance with International Financial Reporting Standards ("IFRS"). References to H1 refer to the six-month period ending June 30 of the relevant fiscal year, and references to H2 refer to the six-month period ending December 31 of the relevant fiscal year.

THIRD-PARTY INFORMATION

Unless otherwise indicated, information contained in this AIF concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunities and market share, is based on information from independent industry organizations, other third-party sources (including industry publications, surveys, and forecasts), and management studies and estimates.

Unless otherwise indicated, our estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and include assumptions made by us which we believe to be reasonable based on our knowledge of our industry and markets. Although Cardiol believes these sources to be generally reliable, market and industry data are subject to interpretation and cannot be verified with complete certainty due to limits on the availability and reliability of raw data, the voluntary nature of the data gathering process, and other limitations and uncertainties inherent in any statistical survey. Our internal research and assumptions have not been verified by any independent source, and we have not independently verified any third-party information. While we believe the market position, market opportunity, and market share information included in this AIF are generally reliable, such information is inherently imprecise. In addition, projections, assumptions, and estimates of our future performance and the future performance of the industry and markets in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described under the heading "Forward-Looking Statements" and "Risk Factors".

CORPORATE STRUCTURE

The Corporation was incorporated under the *Business Corporations Act* (Ontario) on January 19, 2017. The Corporation has one wholly owned subsidiary, Cardiol Therapeutics USA Inc., incorporated under the laws of Delaware on March 30, 2022.

The head and registered office of the Corporation is located at Suite 602 – 2265 Upper Middle Road East, Oakville, Ontario L6H 0G5, Canada.

On August 14, 2018, the Board of Directors of the Corporation approved an amendment and restatement of By-law No. 1 of the Corporation to: (i) amend the by-law to change the number of shares required to be represented at a meeting from a majority of such shares to twenty-five percent (25%) of such shares (the "By-Law Quorum Amendment"); and (ii) adopt by-laws requiring advance notice of director nominees from Shareholders (the "Advance Notice By-Law Amendment" and, together with the By-Law Quorum Amendment, the "By-Law Amendment"). The purpose of the By-law Quorum Amendment is to ensure that if the Corporation's shares become widely held, a quorum for meetings of Shareholders will be more easily obtained. The purpose of the Advance

Notice By-Law Amendment is to ensure that an orderly nomination process is observed, that Shareholders are well-informed about the identity, intentions, and credentials of director nominees, and that Shareholders vote in an informed manner after having been afforded reasonable time for appropriate deliberation. The By-Law Amendment was confirmed by an ordinary resolution of Shareholders of the Corporation on August 28, 2018. The Articles of the Corporation were amended on February 13, 2017, to provide that its authorized capital consists of an unlimited number of Common Shares and make certain amendments of a "housekeeping" nature. The Articles of the Corporation were amended on August 29, 2018, to remove certain share transfer restrictions.

See "Capital Structure".

BUSINESS OF CARDIOL

Corporation's Overview

Cardiol Therapeutics Inc. is a clinical-stage life sciences company advancing late-stage, anti-inflammatory and anti-fibrotic therapies for heart disease. The Corporation's lead small molecule drug candidate, CardiolRx™, modulates inflammasome pathway activation, an intracellular process known to play an important role in the development and progression of inflammation and fibrosis associated with pericarditis, myocarditis, and heart failure.

The MAVERIC Program is evaluating CardiolRx™ for the treatment of recurrent pericarditis, an inflammatory disease of the pericardium associated with symptoms including debilitating chest pain, shortness of breath, and fatigue, which can lead to physical limitations, reduced quality of life, emergency department visits, and hospitalizations. The program comprises the completed Phase II MAvERIC-Pilot study (NCT05494788) and the ongoing pivotal Phase III MAVERIC trial (NCT06708299). The U.S. FDA has granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis, including recurrent pericarditis.

The ARCHER Program has studied CardiolRx™, in acute myocarditis—an important cause of acute and fulminant heart failure in young adults and a leading cause of sudden cardiac death in individuals under 35 years of age. The program comprises the completed Phase II ARCHER study (NCT05180240), which evaluated the safety, tolerability, and efficacy of CardiolRx™ in this patient population.

The Corporation is also developing CRD-38, a novel subcutaneously administered drug formulation intended for the treatment of inflammatory heart disease, including heart failure—a leading cause of death and hospitalization in the developed world, with associated healthcare costs in the United States exceeding US$30 billion per year[1].

Corporate History

Cardiol was founded by current President and CEO David Elsley, Dr. Eldon Smith, and Dr. Anthony Bolton. For over 25 years they have had an active interest in the role that inflammation plays in the development and progression of heart disease. Prior to the formation of Cardiol, the founders pursued scientific and clinical research in this area and were successful in securing funding to support the development of a novel therapeutic from concept through to completion of Phase III multi-center and multi-national clinical trials. Based on an extensive review of the scientific literature conducted in 2014, the founders identified cannabidiol as a molecule of interest to investigate in heart disease due to its anti-inflammatory, anti-fibrotic, and cardioprotective properties.

Cardiol was incorporated on January 19, 2017, and on December 20, 2018, the Corporation completed its initial public offering on the Toronto Stock Exchange. As a result, the Common Shares commenced trading on the TSX under the symbol "CRDL". On August 10, 2021, the Corporation's Common Shares commenced trading on the Nasdaq Capital Market under the symbol "CRDL".

Following is a description of Cardiol's development over its last three completed financial years.

Year Ended December 31, 2023

In January 2023, the Corporation announced that the first patient was enrolled in MAvERIC-Pilot. See "Recurrent Pericarditis – Phase II MAvERIC-Pilot Study (MAvERIC-Phase II)".

In March 2023, the Corporation announced study results from one of its international collaborating research centers demonstrating that its pharmaceutically manufactured cannabidiol significantly prevents cardiac dysfunction and the development of fibrosis and cardiomyocyte hypertrophy in a pre-clinical model of heart failure and reduces expression of key inflammatory and fibrotic markers.

The studies were presented by researchers from TecSalud at the American College of Cardiology's 72nd Annual Scientific Session together with World Congress of Cardiology ("ACC.23/WCC"). TecSalud is one of the Corporation's international collaborating research centers working towards the common goal of developing therapies to advance the treatment of heart diseases.

In August 2023, the Corporation announced that it received notice from the Nasdaq stating the Corporation has regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.

In September 2023, the Corporation announced that all collaborating research centers had been initiated and were eligible to enroll patients in ARCHER (See below – "Phase II study – Acute myocarditis (ARCHER)").

In October 2023, the Corporation announced positive study results from one of its international collaborating research centers demonstrating that subcutaneously administered cannabidiol, the active pharmaceutical ingredient in Cardiol's novel CRD-38 subcutaneous formulation, slowed increases in body weight and heart weight, and prevented increases in key cardiac inflammatory and remodeling markers in a model of HFpEF.

The poster entitled "Cannabidiol As A Potential Treatment For Heart Failure With Preserved Ejection Fraction" was presented on October 7th within the "ePoster Viewing Session III" of HFSA2023. This work was performed using a model of HFpEF that is induced using a combination of high-fat diet and hypertension that leads to an increase in heart weight to tibia length ratio, and an increase in markers for inflammation and cardiac remodeling. Cannabidiol administered subcutaneous was associated with significantly lower BNP (a cardiac stress marker raised in heart failure patients), IL-10 (a promotor of fibrosis in HFpEF), and visceral adipose tissue to subcutaneous adipose tissue ratio.

In October 2023, the Corporation announced that it received a notice from the Nasdaq, stating that the Corporation was not in compliance with the minimum bid price requirement of US$1.00 per share under the Nasdaq Listing Rule 5550(a)(2) based upon the closing bid price of the Common Shares for the 30 consecutive business days prior to the date of the notice. In January 2024, the Corporation announced that it received notice from the Nasdaq stating the Corporation regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.

In November 2023, the Corporation announced that it has exceeded 50% of the patient enrollment target for MAvERIC-Pilot. See "Recurrent Pericarditis – Phase II MAvERIC-Pilot Study (MAvERIC-Phase II)".

In November 2023, the Corporation announced that study results demonstrated an experimental model of pericarditis induces MMT and that this process is inhibited by cannabidiol treatment, the active pharmaceutical ingredient in CardiolRx™. An abstract summarizing these results was submitted by the Corporation's international research collaborators from the University of Virginia and Houston Methodist DeBakey Heart & Vascular Center to the 2023 Annual Meeting of the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases ("MPD2023") held on November 15 and 16, 2023, in Belgrade, Serbia.

The poster entitled "Cannabidiol Inhibits the Mesothelial to Mesenchymal Transition in Experimental Pericarditis" was presented for general viewing within the poster sessions of the MPD2023 Scientific Programme. The results presented are a continuation of a research collaboration between Cardiol and the University of Virginia, which previously reported at the American Heart Association Scientific Sessions 2022 that cannabidiol reduces pericardial effusion and thickness in the same experimental model of pericarditis.

In December 2023, the Corporation announced that Massachusetts General Hospital was initiated and eligible to enroll patients in MAvERIC-Pilot. See "Recurrent Pericarditis - Phase II MAvERIC-Pilot Study (MAvERIC-Phase II)".

Year Ended December 31, 2024

In January 2024, the Corporation announced it had exceeded 50% patient enrollment for ARCHER. See "Phase II Trial – Acute Myocarditis (ARCHER)".

In January 2024, the Corporation announced that it received notice on January 23, 2024, from The Nasdaq Stock Market LLC stating the Corporation had regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.

In February 2024, the Corporation announced that the FDA granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis (a rare disease), which includes recurrent pericarditis.

In February 2024, the Corporation announced completion of patient enrollment in MAvERIC-Pilot. See "Recurrent Pericarditis – Phase II MAvERIC-Pilot Study (MAvERIC-Phase II)".

In May 2024, the Corporation announced its Phase II ARCHER trial was the subject of an oral presentation at the World Congress on Acute Heart Failure 2024 in Lisbon, Portugal, at the annual congress of the Heart Failure Association of the European Society of Cardiology (“ESC”).

The trial design, rationale, and blinded baseline data on the first 50 patients randomized into ARCHER were presented by Univ.-Prof. Dr. med. Carsten Tschöpe from the Berlin Institute of Health – Charité, on behalf of the ARCHER Study Group, an independent steering committee comprising distinguished thought leaders in heart failure and myocarditis from international centers of excellence who contributed to the design and execution of ARCHER. Concurrent with the presentation the journal ESC Heart Failure, which is dedicated to advancing knowledge about heart failure worldwide, accepted the manuscript describing the rationale and design of the ARCHER trial and it was published in June 2024.

In June 2024, the Corporation reported positive topline 8-week clinical data from its Phase II open-label MAvERIC-Pilot study investigating the impact of CardiolRx™ administered to patients with symptomatic recurrent pericarditis. The data showed a marked reduction in the primary efficacy endpoint of patient-reported pericarditis pain at the end of the 8-week treatment period, as well as normalization of inflammation—as measured by CRP—in 80% of patients with elevated CRP at baseline. See "Recurrent Pericarditis - Phase II MAvERIC-Pilot Study (MAvERIC-Phase II)".

In September 2024, the Corporation announced that it had achieved its target patient enrollment of 100 patients for the ARCHER trial.

In October 2024, the Corporation successfully closed a public offering of 9,703,125 Common Shares, at a price of US$1.60 per common share, for gross proceeds of US$15,525,000.

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

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

Year Ended December 31, 2025

In February 2025, the Corporation announced publication of research in the *Journal of the American College of Cardiology: Basic to Translational Science* (“*JACBTS*”), titled “Cannabidiol Prevents Heart Failure Dysfunction and Remodeling Through Preservation of Mitochondrial Function and Calcium Handling,” that supports development of its proprietary subcutaneous drug candidate, CRD-38, for the treatment of heart failure. This research was conducted by scientists from TecSalud, who, together with researchers from the DeBakey Heart and Vascular

Center in Houston, TX, are collaborating with Cardiol on the development of the Corporation's proprietary subcutaneous formulation of cannabidiol, CRD-38, to treat heart failure with preserved ejection fraction. These newly published data demonstrate that pharmaceutically manufactured cannabidiol, administered subcutaneously, provides cardioprotection in a pre-clinical model of heart failure by improving cardiac function and reducing cardiac hypertrophy, remodeling, inflammation, and cell death, and provides additional important rationale for the development of CRD-38 as a new approach to the treatment of heart failure.

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

- an in vivo model of angiotensin II-induced heart failure
    - Subcutaneous administration resulted in attenuation of cardiac fibrosis, hypertrophy, and inflammation, and also improved ejection fraction and cardiac output.
- an ex vivo analysis of heart failure ventricular myocytes from the in vivo model
    - Cannabidiol preserved mitochondrial function and redox balance resulting in both cell shortening and calcium handling.
- an in vitro investigation in hypertrophic cardiac myoblast cells
    - Cannabidiol provided a cardioprotective effect that may be dependent on peroxisome proliferator-activated receptor gamma activation, thereby decreasing mitochondrial calcium uniporter hyperactivity and preventing mitochondrial dysfunction.

In April 2025, the Corporation announced the enrollment of the first patient in its pivotal Phase III MAVERIC trial evaluating CardiolRx™ for the prevention of recurrent pericarditis. See "Phase III Trial – Recurrent Pericarditis (MAVERIC)".

In May 2025, the Corporation announced the election of Dr. Timothy Garnett to the Corporation's Board of Directors at its 2025 Annual General Meeting of shareholders.

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

In October 2025, the Corporation announced the completion of a US$11.4 million financing.

In November 2025, the Corporation announced that it has received a Notice of Allowance for the Corporation's U.S. patent application entitled "Cannabidiol Compositions for Use in Treating Heart Conditions" from the United States Patent and Trademark Office. Once issued, the new patent will establish broad intellectual property protection for the use of CardiolRx™ and CRD-38 in the treatment or prevention of an extensive range of cardiac conditions, including heart failure, myocarditis, acute pericarditis, inflammatory cardiomyopathy, cardiac toxicity from anti-cancer therapies, and atherosclerosis, to October 2040.

In December 2025, the Corporation announced new and comprehensive data from ARCHER that was presented at the European Society of Cardiology Scientific Meeting on Myocardial and Pericardial Disease. The data showed meaningful improvements in cardiac MRI measures of myocardial recovery in patients with acute myocarditis. See "Phase II Trial – Acute Myocarditis (ARCHER)".

Subsequent to Year Ended December 31, 2025

In January 2026, the Corporation announced that it has surpassed 50% of the target patient enrollment in MAVERIC.

In January 2026, the Corporation announced the closing of its bought deal financing and full exercise of over-allotment option for gross proceeds of $14.85 million.

In February 2026, the Corporation announced the publication of results from its Phase II ARCHER study in *ESC Heart Failure*, a journal of the European Society of Cardiology.

MAVERIC PROGRAM IN RECURRENT PERICARDITIS

Pericarditis refers to inflammation of the pericardium (the membrane or sac that surrounds the heart), frequently resulting from a viral infection. Recurrent pericarditis is the reappearance of symptoms after a symptom-free period of at least four to six weeks following the initial acute episode of pericarditis. Patients may have multiple recurrences. Symptoms include debilitating chest pain, shortness of breath, and fatigue, resulting in physical limitations, reduced quality of life, emergency department visits, and hospitalizations. Causes of pericarditis can include infection, usually viral, systemic disorders such as autoimmune and inflammatory diseases, cancer, and post-cardiac injury syndromes. Pericarditis (and its recurrences) are symptomatic events, the diagnosis of which is based on meeting two of four criteria: chest pain; pericardial friction rub; electrocardiogram changes; and new or worsening pericardial swelling. Elevation of inflammatory markers such as C-reactive protein ("CRP"), and evidence of pericardial inflammation by an imaging technique (computed tomography scan or cardiac magnetic resonance) may help the diagnosis and the monitoring of disease activity. Although generally self-limited and not life threatening, pericarditis is diagnosed in 0.2% of all cardiovascular in-hospital admissions and is responsible for 5% of emergency room admissions for chest pain in North America and Western Europe[2].

Recurrent pericarditis appears in 15% to 30% of patients following the acute index episode and usually within 18 months. Furthermore, up to 50% of patients with a recurrent episode of pericarditis experience more recurrences. Standard first-line medical therapy consists of non-steroidal anti-inflammatory drugs with or without colchicine. Corticosteroids such as prednisone are second-line therapy in patients with continued recurrence and inadequate response to conventional therapy. The only FDA-approved therapy for recurrent pericarditis, launched in 2021, is a costly subcutaneously injected interleukin-1 blocker with immunosuppressive effects. It is generally used as a third-line intervention in patients with persistent underlying disease, multiple recurrences, and an inadequate response to conventional therapy[2].

On an annual basis, the number of patients in the U.S. having experienced at least one recurrence is estimated at 38,000. Approximately 60% of patients with multiple recurrences (>1) still suffer for longer than two years, and one-third are still impacted at five years. Hospitalization due to recurrent pericarditis is often associated with a 6 – 8-day length of stay and cost per stay is estimated to range between U.S.$20,000 and U.S.$30,000 in the U.S.[2].

Recurrent pericarditis is a rare disease in the U.S., and in February 2024, the FDA granted Orphan Drug Designation to CardiolRx™ for the treatment of pericarditis, which includes recurrent pericarditis.

The MAVERIC Program is led by an independent Steering Committee (“SC”), consisting of international thought leaders in cardiovascular disease, including:

- **MAVERIC Program Chair: Allan Klein, MD, CM** – Director, Center for the Diagnosis and Treatment of Pericardial Diseases, and Professor of Medicine, Heart, Vascular and Thoracic Institute, Cleveland Clinic;
- **MAVERIC Program Co-Chair: Massimo Imazio, MD, FESC** – Departments of Medicine (DMED), University of Udine and Cardiotoracic Department, University Hospital Santa Maria della Misericordia, Udine, Italy;
- **SC Member and MAvERIC-Pilot Phase II Study Principal Investigator: Allen Luis, MBBS, PhD** – Co-Director of the Pericardial Diseases Clinic, Associate Professor of Medicine, Department of Cardiovascular Medicine, at Mayo Clinic Rochester Minnesota;
- **SC Member and MAVERIC Phase III Trial Principal Investigator: Paul Cremer, MD** – Departments of Medicine and Radiology, Northwestern University, and Multimodality Cardiac Imaging and Clinical Trials Unit, Bluhm Cardiovascular Institute;
- **SC Member: Antonio Abbate, MD, PhD** – Ruth C. Heede Professor of Cardiology, School of Medicine, and Department of Medicine, Division of Cardiovascular Medicine - Heart and Vascular Center, University of Virginia;
- **SC Member: Stephen Nicholls, MBBS, PhD** – Program Director, Victorian Heart Hospital, Director, Monash

Victorian Heart Institute, and Professor of Cardiology, Monash University, Melbourne;

- **SC Member: Tom Kai Ming Wang, MBChB** – Cardiologist, Section of Cardiovascular Imaging of the Tomsich Family Department of Cardiovascular Medicine, Sydell and Arnold Miller Heart, Vascular and Thoracic Institute, Cleveland Clinic; and
- **SC Member: Mohamed M Al-Kazaz** – Cardiologist, Assistant Professor of Medicine at the Feinberg School of Medicine, Northwestern University, and Section chief of general cardiology, at Bluhm Cardiovascular Institute, Northwestern.

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

The completed MAvERIC-Phase II open label study enrolled 27 patients at eight prominent clinical centers in the U.S. specializing in pericardial disease care. The primary efficacy endpoint of the study is the change, from baseline to eight weeks, in patient-reported pericarditis pain using an 11-point numeric rating scale ("NRS"). The NRS is a validated clinical tool used across multiple conditions with acute and chronic pain, including previous studies of recurrent pericarditis. Secondary endpoints include the change in NRS pain score after 26 weeks of treatment, and changes in high sensitivity CRP. Importantly, the study assessed freedom from pericarditis recurrence.

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

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

Key results:

- Primary endpoint of patient-reported pericardial pain on the 11-point NRS from 0-10 showed a mean reduction of 3.7, from 5.8 at baseline (range of 4 to 10) to 2.1 (range of 0 to 6) at week 8. NRS is a validated instrument used to assess patient-reported pericarditis pain. Zero represents ‘no pain at all’, whereas the upper limit of 10 represents ‘the worst pain ever possible’.
- Median time to resolution or near resolution of pain (defined as a score of <= 2) was rapid and was observed just 5 days following initiation of CardiolRx™ treatment.
- At week 8, 93% (25/27) of patients reported a pain score reduction.
- Reduction in pain was maintained throughout the duration of the trial with a mean reduction of 4.3, from 5.8 at baseline to 1.5 at week 26.
- CRP levels for the entire group of patients were reduced from 2.0 mg/dL at baseline to 0.74 and 0.55 at weeks 8 and 26 respectively, with a median time to CRP normalization of 21 days. CRP is a commonly used clinical marker of inflammation, and in combination with the NRS score, is used by clinicians to assess clinical

response and determine a recurrence.

- CRP normalized (<=0.5 mg/dL) at week 8 in 80% (8/10) of the patients with a baseline CRP of >=1 mg/dL, with a substantial mean reduction of 5.4 mg/dL being observed (5.7mg/dL to 0.3 mg/dL).
- Freedom from recurrence was maintained in 71% (17/24) of patients during the EP when CardiolRx™ was continued, and patients were weaned off baseline medications. For those patients experiencing a recurrence the median time to an episode was 7.7 weeks during the EP.
- Number of pericarditis episodes per year was markedly reduced from 5.8 prior to study to 0.9 during the study.
- CardiolRx™ was well tolerated with eighty-nine percent of patients (24/27) progressing to the EP and overall study drug compliance reported at 95%.

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

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

Phase III Trial – Recurrent Pericarditis (MAVERIC)

Cardiol’s Phase III MAVERIC trial is designed to definitively assess the impact of CardiolRx™ on pericarditis recurrence. The randomized, double-blind, placebo-controlled study is expected to enroll approximately 110 patients at 25 clinical sites in the United States, Canada, and Europe. Completion of enrollment is anticipated in Q2 2026.

MAVERIC is recruiting patients at high risk of recurrence following cessation of IL-1 blocker therapy, a setting associated with increased IL-1–driven disease recurrence. If CardiolRx™ significantly reduces recurrence rates, the study will provide evidence that the drug favorably modulates the pro-inflammatory cytokine profile and may modify the disease.

The primary efficacy endpoint of the MAVERIC trial is the number of patients (percentage) free from a new episode of pericarditis recurrence at 24 weeks. Additional clinical endpoints include median time to new episode of pericarditis recurrence, percentage of days with no or minimal pain, and change in patient-reported pericarditis chest pain score and the inflammatory marker CRP.

IL-1 is a key pro-inflammatory cytokine in the pathophysiology of recurrent pericarditis. It is generated downstream following activation of the NLRP3 inflammasome and amplifies the autoinflammatory response characteristic of the disease. CardiolRx™ has been shown experimentally to inhibit the assembly and activation of the NLRP3 inflammasome and the subsequent generation of IL-1. Results from the MAvERIC-Phase II study demonstrated that treatment with CardiolRx™ led to marked reductions in pericarditis pain and recurrence episodes. These findings provide the rationale for undertaking the MAVERIC Phase III trial.

The Corporation has budgeted costs to complete this study to be approximately $8 million. If the MAVERIC trial meets its objectives, the details of next steps will be determined in consultation with regulatory agencies and the Corporation's external clinical advisors. Based on a successful end-of-Phase II meeting with the U.S. FDA and subject to MAVERIC outcomes, Cardiol believes the results from MAVERIC will support a New Drug Application. The Corporation may involve a pharmaceutical industry commercial partner to fund commercialization of CardiolRx™ for the treatment of recurrent pericarditis.

ARCHER PROGRAM IN ACUTE MYOCARDITIS

Myocarditis is an acute inflammatory condition of the heart muscle (myocardium) characterized by chest pain, impaired cardiac function, atrial and ventricular arrhythmias, and conduction disturbances. Although the symptoms are often mild, myocarditis remains an important cause of acute and fulminant heart failure and is a leading cause of sudden cardiac death in people under 35 years of age. Although viral infection is the most

common cause of myocarditis, the condition can also result from administration of therapies used to treat several common cancers, including chemo-therapeutic agents and immune checkpoint inhibitors[3].

In a proportion of patients, the inflammation in the heart persists and causes decreased heart function with symptoms and signs of heart failure, and as such pharmacological treatment is based on conventional therapy for heart failure. This includes diuretics, ACE inhibitors, angiotensin receptors blockers, beta blockers, and aldosterone inhibitors. For those with a fulminant presentation, intensive care is often required, with the use of inotropic medications (to increase the force of the heart muscle contraction). Severe cases frequently require ventricular assist devices or extracorporeal oxygenation and may necessitate heart transplantation. There are no FDA-approved therapies for acute myocarditis. Patients hospitalized with acute myocarditis experience an average 7-day length of stay and a 4 – 6% risk of in-hospital mortality, with average hospital charge per stay estimated at U.S.$110,000 in the U.S.[3].

Data from multiple sources, including the 'Global Burden of Disease Study', reports that the number of cases of myocarditis per year range from approximately 10 to 22/100,000 persons (estimated U.S. patient population of 33,000 to 73,000), qualifying the condition as a rare disease in the U.S. and in European Union. Cardiol believes that there is a significant opportunity to develop a therapy for acute myocarditis that may be eligible for designation as an orphan drug under the FDA's Orphan Drug Designation and the European Medicines Agency Orphan Medicine programs[3].

The Corporation's Phase II ARCHER trial (ARCHER) was designed in collaboration with an independent steering committee comprising distinguished thought leaders in heart failure and myocarditis from international centers of excellence. The primary endpoints of the trial, which were evaluated after 12 weeks of double-blind therapy, consist of the following CMR measures: myocardial edema/fibrosis (extra-cellular volume) and left ventricular ("LV") function (global longitudinal strain). Additional CMR measures of interest include change in LV mass.

The ARCHER Steering Committee comprised distinguished thought leaders in heart failure and myocarditis from international centers of excellence who contributed to the design and execution of the ARCHER trial.

- **Chair: Dennis M. McNamara, MD** – Professor of Medicine at the University of Pittsburgh, Director of the Center for Heart Failure Research at the University of Pittsburgh Medical Center;
- **Co-Chair: Leslie T. Cooper, Jr., MD** – General cardiologist and the Elizabeth C. Lane, Ph.D. and M. Nadine Zimmerman, Ph.D. Professor of Internal Medicine, Mayo Clinic, Jacksonville, FL;
- **Arvind Bhimaraj, MD** – Specialist in Heart Failure and Transplantation Cardiology and Associate Professor of Cardiology, DeBakey Heart & Vascular Center and J.C. Walter Jr. Transplant Center, Houston Methodist Hospital;
- **Wai Hong Wilson Tang, MD** – Advanced Heart Failure and Transplant Cardiology specialist at the Cleveland Clinic in Cleveland, Ohio. Dr. Tang is also the Director of the Cleveland Clinic's Center for Clinical Genomics; Research Director, and staff cardiologist in the Section of Heart Failure and Cardiac Transplantation Medicine in the Sydell and Arnold Miller Family Heart & Vascular Institute at the Cleveland Clinic;
- **Peter Liu, MD** – Chief Scientific Officer and Vice President, Research, of the University of Ottawa Heart Institute, and Professor of Medicine and Physiology at the University of Toronto and University of Ottawa;
- **Carsten Tschöpe, MD** – Clinical Professor in Cardiology, Head of the Cardiomyopathy Unit, Department of Cardiology, Angiology and Intensive Care, Campus Virchow, German Heart Center (DHZC) at Charité, Berlin;
- **Matthias Friedrich, MD** – Full Professor within the Departments of Medicine and Diagnostic Radiology at McGill University in Montreal, and Chief, Cardiovascular Imaging at the McGill University Health Centre;
- **Yaron Arbel, MD** – Cardiologist and Director of the CardioVascular Research Center (CVRC) at the Tel Aviv "Sourasky" Medical Center;
- **Edimar Bocchi, MD** – Serves as the Head of Heart Failure Clinics and Heart Failure Team at Heart Institute (Incor) of Hospital das Clinicas of São Paulo University Medical School, Associate Professor of São University Medical School, São Paulo, Brazil; and
- **Mathieu Kerneis, MD, PhD** – Interventional cardiologist at Pitié Salpêtrière Hospital (Sorbonne

University), and ACTION Study Group Investigator.

In August 2025, the Corporation announced topline results from the ARCHER trial, which completed with 109 enrolled patients at leading cardiovascular research centers in the United States, France, Brazil, and Israel.

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

The ARCHER trial results provide compelling clinical proof of concept for CardiolRx™ and support advancing the clinical development of CardiolRx™ and CRD-38 in cardiomyopathies, heart failure, and myocarditis. Consistent with findings from Cardiol’s Phase II MAvERIC trial in recurrent pericarditis, CardiolRx™ was shown to be safe and well tolerated. The ARCHER results were presented in an oral session at the Annual Meeting of the European Society of Cardiology (ESC) Working Group on Myocardial & Pericardial Disease (M&PD) in Trieste, Italy, on November 29, 2025, and subsequently published online ahead-of-print on January 16, 2026, in the journal *ESC Heart Failure*.

The Corporation is reviewing the full ARCHER results with key opinion leaders in myocarditis and heart failure, regulatory agencies, and representatives from the pharmaceutical industry to determine next steps. Following these discussions, the Corporation will provide an update regarding the timeline for completing potential additional clinical development programs based on the ARCHER data, as well as associated costs—all of which will depend on a variety of factors. The Corporation also may involve a pharmaceutical industry partner to support additional clinical development and commercialization of CardiolRx™ and CRD-38 for the treatment of myocarditis, and other inflammatory cardiac conditions including heart failure.

CRD-38 PROGRAM FOR TREATMENT OF HEART DISEASE

Cardiol is developing CRD-38, a novel subcutaneously administered cannabidiol formulation intended for the treatment of heart failure and other inflammatory cardiac conditions. Pre-clinical studies have demonstrated cardioprotective effects, including improvements in cardiac function and reductions in cardiac hypertrophy, fibrosis, and inflammation. The Corporation is currently advancing Investigational New Drug ("IND")-enabling studies to support a future IND application with the U.S. FDA to initiate first-in-human Phase I clinical studies. The Corporation has budgeted costs to complete IND-enabling studies to be approximately $2 million. These studies are underway and are currently anticipated to be completed in H2 2026.

If Cardiol determines that the IND-enabling studies meet its objectives, next steps related to the clinical development of CRD-38 will be assessed in consultation with external clinical advisors and regulatory agencies. The total cost and timeline to complete this clinical development program cannot be determined at this stage as this will depend on a variety of factors. The Corporation may involve a commercial partner from the pharmaceutical industry to fund the clinical development and commercialization of CRD-38.

Cardiol’s Approach to the Treatment of Heart Disease

Cardiol is investigating the potential of its lead small molecule drug candidate CardiolRx™, a pharmaceutically manufactured oral cannabidiol solution currently in clinical trials for the treatment of recurrent pericarditis and acute myocarditis. In addition, Cardiol is developing CRD-38, a subcutaneous cannabidiol formulation currently in IND enabling studies. It is recognized that cannabidiol inhibits activation of the inflammasome pathway, an intracellular process known to play an important role in the development and progression of inflammation and fibrosis associated with myocarditis, pericarditis, and heart failure.

Published peer-reviewed research has reported that there is a basis for clinically investigating the efficacy of cannabidiol in cardiovascular disease. Cannabidiol has been shown in pre-clinical models to improve endothelial function by reducing inflammatory activation of the endothelial lining of blood vessels thus improving endothelial vasorelaxation and blood flow. Cannabidiol has also been shown to attenuate a number of other measures of potential importance in the treatment of cardiovascular disease, including cardiac dysfunction, oxidative stress,

fibrosis, and inflammatory and cell death signaling pathways, in models of diabetes, a common co-morbidity in cardiovascular disease and heart failure patients.

The rationale for investigating cannabidiol to treat patients with cardiovascular disease is based on pre-clinical investigations by Cardiol and others in models of cardiovascular disease which have demonstrated that cannabidiol has anti-fibrotic and anti-inflammatory activity, as well as anti-ischemic, and anti-arrhythmic action. 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 BNP, which is typically elevated in patients with heart failure.

In addition, Cardiol is developing CRD-38 injection for subcutaneous administration, currently in IND enabling studies.

Research Programs

Cardiol has assembled an international network of experts in the synthesis, formulation, pharmacology and testing of drugs. Cardiol has several research programs underway or completed with the following organizations:

- Virginia Commonwealth University and University of Virginia
- The Houston Methodist DeBakey Heart & Vascular Center
- TecSalud del Tecnológico de Monterrey

Due to the early stage of these research programs, the total costs and timing of these programs beyond the costs previously funded cannot be determined at this stage as they will depend on a variety of factors. Cardiol relies on researchers and clinicians, CROs, clinical data management organizations, and consultants to assist with the design, conduct, supervision, and monitoring of these research programs.

Virginia Commonwealth University and University of Virginia

Cardiol has been working with collaborators at Virginia Commonwealth University (VCU) and the University of Virginia (UVA) to add to the data generated to date in support of cannabidiol in pre-clinical in vivo and *in vitro* models of cardiovascular diseases. A pre-clinical model of pericarditis has been developed at VCU that induces pericarditis, characterized as an acute inflammatory response in the pericardium, in an NLRP3 inflammasome-dependent manner. The model was previously used to show the efficacy of, among other drugs, rilonacept, which is an emerging novel treatment for pericarditis following a successful Phase III trial.

A study was performed using Cardiol's cannabidiol formulation in VCU's model of pericarditis, results were positive, and data were presented at American Heart Association Annual Scientific Sessions 2022. These data demonstrating Cardiol's formulations' ability to mitigate pericarditis led to further collaboration and, in 2023, the design of experiments, between UVA and Houston Methodist. This work investigated whether mesenchymal transition is also implicated in the progression of disease in UVA's model of pericarditis, and tested Cardiol's cannabidiol ability to inhibit the disease progression. Results were positive, and data from this work were presented at the 2023 Annual Meeting of the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases. Results from this study support provided rationale for Cardiol's MAvERIC-Pilot and MAVERIC Phase III trials.

Houston Methodist DeBakey Heart & Vascular Center

The Houston Methodist DeBakey Heart & Vascular Center is recognized internationally as a center of excellence for the treatment of heart failure.

Cardiol entered into a research contract with the Houston Methodist DeBakey Heart & Vascular Center that generated the first data investigating the method of action of cannabidiol in a model of EndoMT (endothelial to mesenchymal transition). EndoMT is a process in which endothelial cells undergo a series of events that lead to a change in phenotype towards mesenchymal cell types; for example, myofibroblasts and smooth muscle cells. The EndoMT process is normal during development, but there is increasing evidence of its involvement in adult cardiovascular diseases such as atherosclerosis and pulmonary hypertension. EndoMT has also been suggested

to cause fibrosis, leading to heart failure. The *in vitro* model of EndoMT developed at Houston uses endothelial cells in which transition is induced using L-NAME and angiotensin II. Results presented show that Cardiol's cannabidiol can inhibit the transition from endothelial to mesenchymal cell types.

Research into the interaction between cannabidiol and the EndoMT process was pursued, and further experimentation demonstrated that cannabidiol can not only inhibit the transition from endothelial to mesenchymal cell types but can also promote the reversal of the EndoMT process. These data that suggest cannabidiol may protect cardiac function via EndoMT inhibition and reversal, were presented at Heart Failure Society of America's Annual Scientific Meeting 2022. In 2023 and 2024, work progressed the investigation of potential targets of cannabidiol in EndoMT and investigation of the effect of cannabidiol on EndoMT *in vivo*, in order to further elucidate how cannabidiol has its effects. This long-term investigation will complete in 2026. Preliminary data have been presented at the Technology and Heart Failure Therapeutics Conference 2026.

TecSalud

Cardiol established a research and development collaboration (See "Commercial Relationships") with CARO and TecSalud, both of the Instituto Tecnológico y de Estudios Superiores de Monterrey, Mexico, to collaborate on the research and development of proprietary therapeutics for the treatment of heart failure. This research collaboration combines the significant research capability of TecSalud extensive experience in pre-clinical cardiovascular research with Cardiol's scientific, clinical, and business expertise. By combining these intellectual resources, Cardiol expects to accelerate the necessary research towards the mutual goal of developing a breakthrough heart failure treatment.

TecSalud is committed to delivering outstanding patient care with four state-of-the-art academic medical centers that combine innovative research, clinical services, and education. TecSalud has collaborative relationships with the Houston Methodist DeBakey Heart & Vascular Center and has established a formal agreement with the Massachusetts Institute of Technology to promote research and development in Mexico.

The primary objective of this collaboration is to develop the experimental evidence necessary to support advancing potential breakthrough medicines for heart failure into clinical development. Research has focused on investigating the therapeutic potential of cannabidiol formulations that target inflammation in a model of hypertension-induced heart failure. Initial research was completed in 2021 showing encouraging results. In 2023, following positive experimental results showing the impact of Cardiol's cannabidiol formulation, data were accepted for presentation at The American College of Cardiology's 72nd Annual Scientific Session Together with the World Congress of Cardiology. Throughout 2024, data from this model was expanded upon by our collaborators at TecSalud resulting in a publication in the *Journal of the American College of Cardiology: Basic to Translation Science* in February 2025.

In 2023, a new model of heart failure of preserved ejection fraction (HFpEF) was developed and is currently being used to test Cardiol's cannabidiol used in CardiolRx. Preliminary data were positive and presented at the Heart Failure Society of America Annual Scientific Meeting 2023. This model will in addition be used to investigate CRD-38 in the prevention and treatment HFpEF, recently reporting positive preliminary results.

Commercialization Relationships

Dalton

Cardiol entered into an exclusive master services agreement (the "Dalton Services Agreement") dated April 17, 2018, and effective as of June 12, 2017, for pharmaceutical cannabidiol and has subcontracted the manufacturing of its drug product candidates to Dalton. Dalton has the manufacturing capability for Cardiol's clinical trial materials, scalable to support all stages of the drug development process (Phase I, II, III, and commercial). As consideration under the Dalton Services Agreement, Cardiol issued 400,000 Common Shares to Dalton. Cardiol also agreed to issue to Dalton an additional 400,000 Common Shares if Dalton meets certain performance objectives. The Dalton Services Agreement may be terminated by Cardiol upon provision of thirty days' notice of termination.

The services provided by Dalton under the Dalton Services Agreement are undertaken on a project and product basis. With respect to each project or product, Cardiol and Dalton agree in writing upon objectives, scope, price,

and fees payable, specifications, deliverables, milestones, and timelines in a work order.

Purisys

Cardiol entered into an exclusive supply agreement (the "Purisys Exclusive Supply Agreement") with Noramco (Purisys) dated September 28, 2018, as amended on December 7, 2018, December 11, 2018, July 2, 2019, September 11, 2019, and November 12, 2019, pursuant to which Purisys will be the exclusive supplier of pharmaceutical cannabidiol for Cardiol, provided Purisys is able to meet Cardiol's supply requirements.

In 2020, the agreement was assigned to Purisys, an affiliate of Noramco headquartered in Athens, Georgia. This assignment had no impact on Cardiol's rights under the original agreement.

Effective upon entering into a supply agreement with Shoppers Drug Mart Inc. ("Shoppers") on March 16, 2020. Purisys shall not sell pharmaceutical cannabidiol to any third party for use in the production of products sold to retail pharmacies in Canada and Mexico, such as Shoppers. Notwithstanding this restriction, Purisys shall have the right to sell pharmaceutical cannabidiol to third parties outside Canada for use in products that are approved as prescription medicines by the Therapeutic Products Directorate of Health Canada for delivery into Canada.

The initial term of the Purisys Exclusive Supply Agreement expires on December 31, 2038, and thereafter automatically renews for successive periods of two calendar years each, unless written notice of termination is given by either party at least 18 months before the expiration of the initial term or completion of the then-current renewal term.

TecSalud (CARO)

Cardiol entered into development agreements with CARO dated August 28, 2018, and December 15, 2023, for research and development of proprietary drug formulations for the treatment of heart failure. CARO is a Mexican corporation dedicated to providing clinical and scientific experimentation and consulting, as well as performing its own development activities or through third-party providers. TecSalud is a third party through which CARO will provide its consulting and development activities for Cardiol.

Competitive Conditions

Cardiol's competitors include multinational pharmaceutical companies and specialized biotechnology companies, universities, and other research institutions that have commercialized products or are conducting research related to developing products that target inflammation, the NLRP3 inflammasome, its pathways and the inflammatory mediators it produces, for the treatment of pericarditis, acute myocarditis and heart failure.

More established companies may have a competitive advantage over Cardiol due to their greater size, capital resources, cash flows, and institutional experience. Compared to Cardiol, many competitors may have significantly greater financial, technical, and human resources at their disposal. Due to these factors, competitors may have an advantage in marketing their approved products and may obtain regulatory approval of their product candidates before Cardiol, which may limit Cardiol's ability to develop or commercialize its product candidates. Competitors may also develop drugs that demonstrate a better safety profile, are more effective, are more widely used, are more cost-effective, more efficient in manufacturing, and may also be more successful in promoting and marketing their products.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in resources being concentrated among a smaller number of Cardiol's competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties also compete with Cardiol in recruiting and retaining qualified scientists, management, and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, Cardiol's programs.

Recurrent Pericarditis

Rilonacept (Arcalyst™; Kiniksa Pharmaceuticals) is an interleukin-1 blocker and is the only FDA-approved therapy

for treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older. Rilonacept is not approved in Europe. Rilonacept is a once-weekly injectable immunosuppressant biologic that binds to (i.e., traps) circulating cytokines IL-1β and IL-1α, effectively blocking the engagement of IL-1β to pro-inflammatory cell surface receptors, inhibiting the downstream activation of the inflammatory cascade. Rilonacept is primarily used as a third-line intervention and/or in patients with multiple recurrences.

First-line treatment for recurrent pericarditis comprises a combination of aspirin or NSAID + colchicine + exercise restriction. Low-dose corticosteroids are considered for second-line treatment when there are contraindications to the other drugs or when there is an incomplete response to aspirin or NSAIDs + colchicine; unfortunately, use of these drugs favour chronicity, more recurrences, and side effects. NSAIDs, colchicine and corticosteroids are all used off-label for the treatment of recurrent pericarditis, but are included in European treatment guidelines.

Anakinra (KINERET), marketed by Swedish Orphan Biovitrum AB, is used off-label for the treatment of recurrent pericarditis.

Acute Myocarditis

There are no FDA- or EMA-approved medical therapies indicated for the treatment for myocarditis. Heart failure drugs are used off-label to provide supportive care (i.e., diuretics, ACE inhibitors, angiotensin receptors blockers, beta blockers, and aldosterone inhibitors). Colchicine is being investigated by academia in the Phase III ARGO trial to assess its effects versus placebo on the extent of late gadolinium enhancement (LGE) evaluated on CMR.

Heart Failure with Preserved Ejection Fraction (HFpEF)

Management of HFpEF focuses on: 1) risk stratification and management of comorbidities, including hypertension, DM, obesity, AF, CAD, CKD, and obstructive sleep apnea; 2) nonpharmacological management, including the role of exercise and weight loss and the use of wireless, implantable pulmonary artery monitors; and 3) symptom management and disease-modifying therapy with loop diuretic agents, SGLT2is, mineralocorticoid antagonists (MRAs), angiotensin receptor-neprilysin inhibitors (ARNIs), and angiotensin receptor blockers (ARBs). Whereas the role of inflammation in heart failure is well recognized, there are no specifically targeted anti- inflammatory or immunomodulatory therapies currently approved for clinical practice.

Employees

As of December 31, 2025, Cardiol had 18 employees and 5 management consultants providing management services to Cardiol.

Intellectual Property Rights

Cardiol strives to obtain and protect intellectual property that is important to its business. Such intellectual property includes, or may in future include, granted patents, patent applications, regulatory dossiers, manufacturing and process know-how, proprietary unpatented information including trade secrets, contractual arrangements, and trademarks. Patents and patent applications owned by Cardiol cover compositions/formulations methods of use, related technology, and other applicable inventions.

Cardiol's intellectual property portfolio has been built from in-house technology and product research and development, as well as strategic relationships with partners, including Dalton Pharma Services, the Houston Methodist DeBakey Heart and Vascular Centre, Virginia Commonwealth University, University of Virginia, and TecSalud Instituto Tecnológico y de Estudios Superiores de Monterrey.

The Corporation has been granted and/or has patent applications pending in major pharmaceutical markets, including Canada, U.S., Japan, and countries of Europe. Cardiol also relies on proprietary unpatented information, including trade secrets. Furthermore, Cardiol has registered and applied for trademarks in many of the same jurisdictions.

The Corporation's patent portfolio includes granted and pending applications in the following families:

- Stable Medicinal Cannabidiol Compositions
- Parenteral or Oral Cannabidiol Compositions for Treating Heart Conditions
- Stable Oral Cannabidiol Compositions
- Stable Injectable Cannabinoid Formulations
- Cannabidiol For Use In Treating Or Preventing Recurrent Pericarditis
- Beta-Caryophyllene For Use In Treating Or Preventing Pericarditis

Scientific Advisory Board

The Corporation's has established a Scientific Advisory Board comprised of distinguished thought leaders in cardiovascular medicine. These individuals will lend their expertise in cardiovascular research and provide invaluable guidance to the Corporation's research and clinical programs. The Scientific Advisory Board members include:

Paul M. Ridker, MD, MPH

Dr. Paul Ridker is Director of the Center for Cardiovascular Disease Prevention at Brigham and Women's Hospital in Boston, where he leads a major translational research program focused mainly on inflammation in atherosclerotic cardiovascular disease. He is the Eugene Braunwald Professor of Medicine at Harvard Medical School and Professor of Epidemiology at the Harvard T.H. Chan School of Public Health.

Dr. Ridker received his medical degree from Harvard School of Medicine and completed an internal medicine residency and a cardiology fellowship at Brigham and Women's Hospital. Dr. Ridker is board certified in internal medicine. His clinical interests include coronary artery disease and the prevention of atherosclerotic events in high risk populations. Internationally recognized for defining the role of inflammation in atherothrombosis, Dr. Ridker's primary research has focused on inflammatory mediators of heart disease, biomarkers such as high sensitivity C reactive protein, and the molecular and genetic epidemiology. He has served as Principal Investigator or Study Chair for multiple large, international randomized trials demonstrating that targeting vascular inflammation can reduce major adverse cardiovascular events, thereby directly informing the development of novel anti inflammatory strategies for the prevention and treatment of coronary disease.

Dr. Ridker is the author of over 900 original reports plus 150 reviews and book chapters, and six textbooks related to cardiovascular medicine. He has a long tenure of serving on the Board of External Experts for the National Heart Lung and Blood Institute (NHLBI), as well as on multiple US FDA review panels and has delivered many invited lectures worldwide.

His contributions to cardiovascular prevention and inflammation biology have been recognized with numerous honors, exemplified by his inclusion in TIME magazine's list of 100 most influential people of 2004, ranking among the ten most cited cardiovascular researchers worldwide between 2000 and 2010, the American Heart Association Distinguished Scientist Award (2013), the Braunwald Lecture of the American College of Cardiology (2019), the Gotto Prize for Atherosclerosis Research from the International Atherosclerosis Society (2021), and election to the National Academy of Medicine (USA).

Bruce McManus, PhD, MD

Dr. McManus is Professor Emeritus, Department of Pathology and Laboratory Medicine at the University of British Columbia and an internationally recognized leader in inflammatory heart disease with a particular focus on viral myocarditis and heart failure. His academic and leadership roles have spanned CEO of the Centre of Excellence for Prevention of Organ Failure (PROOF Centre), Director of the UBC Centre for Heart Lung Innovation, the inaugural Director of the Providence Heart and Lung Institute at St. Paul's Hospital, Co-Director of the community-wide Institute for Heart and Lung Health, and inaugural Scientific Director of the Institute of Circulatory and Respiratory Health at the Canadian Institutes of Health Research.

Dr. McManus's investigative work relates to mechanisms, consequences, and detection of myocardial injury and

aberrant repair in inflammatory diseases of the heart and blood vessels, informing contemporary approaches to the diagnosis and management of acute viral myocarditis and its progression to heart failure. His life's scholarship includes more than 450 peer-reviewed publications, over 60 invited chapters, and several books, and he has trained a generation of clinicians and scientists who are advancing novel therapies for inflammatory cardiomyopathies.

Dr. McManus holds BA and MD degrees from the University of Saskatchewan, an MSc from Pennsylvania State University, and a PhD from the University of Toledo. He completed post-doctoral fellowships in Environmental Physiology at the University of California, Santa Barbara and Cardiovascular & Pulmonary Pathology at the National Heart, Lung, and Blood Institute in Bethesda, as well as residency training in Internal Medicine and Pathology at the Peter Bent Brigham Hospital, Harvard University. Prior to his appointment at the University of British Columbia, Dr. McManus served on the faculty of the University of Nebraska Medical Center for eleven years.

Dr. McManus has been widely honored for his scientific and mentoring contributions, including the prestigious Max Planck Research Award, the Distinguished Achievement Award by the Society for Cardiovascular Pathology, the Howard Morgan Award from the International Academy of Cardiovascular Sciences, and the Lifetime Achievement Award from Canadian Blood Services. He is a Fellow of the Royal Society of Canada and has been appointed to both the Order of Canada and the Order of British Columbia.

Joseph A. Hill, MD, PhD

Dr. Hill is Professor of Internal Medicine and Molecular Biology at UT Southwestern Medical Center in Dallas, TX, and Director of the Harry S. Moss Heart Center. He served as Chief of Cardiology at UT Southwestern for 21 years prior to stepping down in 2023.

Dr. Hill holds the James T. Willerson, MD, Distinguished Chair in Cardiovascular Diseases, and the Frank M. Ryburn Jr. Chair in Heart Research. His research focuses on molecular mechanisms of structural, functional, metabolic, and electrophysiological remodeling in cardiac hypertrophy and heart failure, with direct relevance to developing novel therapies for inflammatory and fibrotic heart disease.

After graduating from Duke University with MD and PhD degrees in 1987, Dr. Hill completed a five-year postdoctoral fellowship in molecular neurobiology at the Institut Pasteur in Paris, studying central and peripheral nicotinic receptors. Subsequently, he completed an internal medicine internship and residency, as well as a clinical cardiology fellowship, at the Brigham and Women's Hospital, Harvard Medical School.

After serving on the faculty at the University of Iowa for five years, Dr. Hill joined UT Southwestern in 2002 as Chief of Cardiology, where he has built a translational research program aimed at elucidating pathways that drive adverse cardiac remodeling and heart failure progression. His work has helped identify molecular targets with potential to modulate inflammation, fibrosis, and cardiomyocyte survival, supporting the development of next-generation cardioprotective therapies.

In addition to publishing nearly 280 scholarly articles, Dr. Hill has co-edited a major textbook and has contributed chapters to 14 books. He has served on many NIH panels and committees and delivered numerous invited lectures worldwide. His contributions have been recognized with multiple honors, including the 2018 Research Achievement Award from the International Society for Heart Research, the 2019 Louis and Artur Lucian Award from McGill University, the 2023 Medal of Merit from the International Academy of Cardiovascular Sciences, the 2025 Gill Heart and Vascular Institute Award for Outstanding Contributions to Cardiovascular Research, and the 2025 Bohuslav Ostadal Award for Excellence in Cardiovascular Sciences from the International Academy of Cardiovascular Sciences.

Dr. Hill has served on the editorial boards and as a reviewer for leading journals, including the *Journal of the American Medical Association, Circulation, Circulation Research, American Journal of Cardiology, and Proceedings of the National Academy of Sciences of the USA.* For the past 10 years, he has served as the Editor-in-Chief of the esteemed American Heart Association journal Circulation.

REGULATORY OVERVIEW

Drugs are evaluated for safety, efficacy, and manufacturing quality as a condition of market access, and promotional messages must adhere to approved product labelling. Drug prices also are regulated in most countries with national health insurance systems. Regulation of market access and promotion derives from uncertainty about the real-life value of drugs. Real-life product characteristics can only be determined from accumulated experience over large numbers of patients in carefully designed epidemiological trials or observational studies.

Government Regulation and Product Approval

As a biopharmaceutical company that intends to test, register, and commercialize products in Canada, U.S. and other jurisdictions, we are subject to extensive regulation by various regulatory authorities. The primary regulatory agency in the U.S. is the FDA, in Canada it is Health Canada, and in the E.U. it is the EMA. Together with these three, there are other federal, state, and local regulatory agencies. In the U.S., the FDCA, and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, and advertising and promotion of our products. Although the discussion below focuses on regulation in the U.S., we anticipate seeking approval for, and marketing of, our products in other countries will be very similar.

Generally, our activities outside the U.S. will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Approval in the U.S., Canada, or the E.U. does not assure approval by other regulatory agencies, although often test results from one country may be used in applications for regulatory approval in another country. Additionally, some significant aspects of regulation in the E.U. are addressed in a centralized way through the EMA, but country-specific regulation remains essential in many respects. The April 2015 publication titled “Medicinal Products in the E.U., the legal framework for medicines for human use”[4] from the European Parliamentary Research Service gives a general overview of several aspects of E.U. legislation on human medicines.[1] A major difference in Europe, when compared to Canada and the United States, is with the approval process. In the E.U., there are different procedures that can be used to gain marketing authorization. The first procedure is referred to as the centralized procedure and requires that a single application be submitted to the EMA and, if approved, allows marketing in all countries of the E.U. The centralized procedure is mandatory for certain types of medicines and optional for others. The second procedure is the decentralized procedure which requires one member state to act as the reference member state conducting the review of the application which is simultaneously filed to the reference member state and to selected other member states. The third procedure is a state-by-state application.

The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources and may not be successful. See “Risk Factors” in this Annual Report.

The Corporation has a business relationship with Purisys, which is a U.S.-based company. Purisys is a manufacturer of controlled drug substance APIs and is registered with the DEA for the manufacturing of controlled drug substances.

New Drug Submissions (NDS) – Health Canada

To obtain approval to market a drug in Canada, a sponsor usually requests a pre-submission meeting with the review division of Health Canada responsible for the therapeutic field. If the meeting is granted, the sponsor must submit a Pre-Submission Information package to Health Canada to meet with the review division. This process occurs prior to submitting the NDS application. The purpose of the pre-submission meeting is to review the evidence (non-clinical and clinical research, quality information, indication) that will be submitted in the NDS application.

During the drug development process, the sponsor prepares study reports. Once the sponsor releases the last study required for the submission, the sponsor completes the NDS application and submits it to Health Canada. Prior to submitting the NDS and if applicable based on the intended use of the product in the identified patient population, the sponsor may submit in advance a request for priority review status.

After submitting the NDS application, the file undergoes a screening process prior to being accepted for review. The PDD has 45 calendar days from receipt to complete the screening review process. If granted a priority review, the screening period is reduced to 25 calendar days.

After a comprehensive review of an NDS application, Health Canada will issue a NOC if the product is approved or a NON if further questions remain. If a NOC is issued, a DIN is also issued that is required to be printed on each label of the product, as well as the final version of the Product Monograph that has been agreed to between Health Canada and the sponsor.

The average target time for reaching a first decision on an NDS is 300 calendar days unless the submission has received a priority review in which case the time is 180 calendar days.

Fees are levied for a review of an NDS application.

U.S. Government Regulation

The FDA is the main regulatory body that controls pharmaceuticals in the United States, and its regulatory authority is based in the FDCA. Pharmaceutical products are also subject to other federal, state, and local statutes. A failure to comply explicitly with any requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an Institutional Review Board ("IRB") of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, or criminal prosecution. As presented on the section of the FDA's website titled "Drug Review Process: Ensuring Drugs are Safe and Effective"[5], the steps required before a new drug may be marketed in the United States generally include:

- completion of nonclinical studies, animal studies, and formulation studies in compliance with the FDA's GLP regulations;
- submission to the FDA of an IND application to support human clinical testing in the United States;
- approval by an IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with federal regulations and with GCP, and regulations to establish the safety and efficacy of the investigational product candidate for each target indication;
- submission of an NDA to the FDA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational product candidate is produced to assess compliance with cGMP regulations, and to assure that the facilities, methods, and controls are adequate; and
- FDA review and approval of the NDA.

Clinical Trials

An IND is a request for authorization from the FDA to administer an investigational product candidate to humans. This authorization is required before interstate shipping and administration of any new drug product to humans in the U.S. that is not the subject of an approved NDA. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease under study, under the supervision of qualified investigators following GCPs, an international standard meant to protect the rights and health of patients with the disease under study and to define the roles of clinical trial sponsors, administrators, and monitors. Clinical trials are conducted under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. Each protocol involving testing on patients in the U.S. and subsequent protocol amendments must be submitted to the FDA as part of the IND application. Cardiol has submitted three IND applications on CardiolRx, and has received three "Study May Proceed" letters from the FDA.

As set out in the October 6, 2021, publication "ICH E8(R1) Guideline – General Considerations for Clinical Trials"[6],

published by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, the three phases of clinical investigation are as follows:

- Phase I. Phase I includes the initial introduction of an investigational product candidate into humans. Phase I clinical trials may be conducted in patients with the target disease or condition, or in healthy volunteers. These studies are designed to evaluate the safety, metabolism, PK, and pharmacologic actions of the investigational product candidate in humans, adverse events associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational product's PK and pharmacological effects may be obtained to inform the design of Phase II clinical trials. The total number of participants included in Phase I clinical trials varies but is generally in the range of 20 to 80.
- Phase II. Phase II includes the controlled clinical trials conducted to evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse events and safety risks associated with the product candidate. Phase II clinical trials are typically well-controlled, closely monitored, conducted in a limited subject population, and usually involve no more than several hundred participants.
- Phase III. Phase III clinical trials are controlled clinical trials conducted in an expanded subject population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product has been obtained, are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product candidate, and to provide an adequate basis for drug approval. Phase III clinical trials usually involve several hundred to several thousand participants. In many cases, the FDA requires two adequate and well-controlled Phase III clinical trials to demonstrate the efficacy of the drug.

The decision to terminate development of an investigational product may be made by either a health authority body, such as the FDA or IRB/ethics committees, or by a company for various reasons. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor or the clinical monitoring board. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of products on public registries and the disclosure of certain information pertaining to the trials, as well as clinical trial results after completion.

New Drug Applications (NDA) – FDA

In order to obtain approval to market a drug in the U.S., a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the product candidate for the proposed indication. The application includes all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product candidate to the satisfaction of the FDA. In most cases, the NDA must be accompanied by a substantial user fee; there may be some instances in which the user fee is waived, e.g., NDAs for products with an Orphan Drug Designation. The FDA will initially review the NDA for completeness before it accepts it for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. After the NDA is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review products are reviewed within ten to twelve months. The FDA can extend this review by three months to consider certain late submitted information or information intended to clarify data already provided in the submission. The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel products that present difficult

questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information (though not specifically required for Phase I trials) on a public website maintained by the U.S. National Institutes of Health ("NIH"). Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the design and progress of our development programs.

Advertising and Promotion

As set out in the FDA`s website discussion[7] on the "The Prescription Drug Marketing Act of 1987", the FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling (package insert) approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses—that is, uses not approved by the FDA and, therefore, not described in the drug's labeling—because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses.

Post-Approval Regulations

As set out in the FDA`s website discussion[8] on "Post Marketing Requirements and Commitments", after regulatory approval of a drug is obtained, a company is required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, the FDA may require post-marketing testing, including Phase IV clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, as a holder of an approved NDA, a company would be required to report adverse drug reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long-term stability of the drug or biological product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and substantive record keeping requirements. In addition, changes to the manufacturing

process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Controlled Substances

Potential sources of API for our cannabinoid products are in the U.S., Canada, and certain E.U. countries. In the U.S., pharmaceutically produced cannabidiol is not on any of the five schedules of controlled substances as established by the CSA and the U.S. DEA. Whether a pharmaceutically produced cannabinoid product is controlled in the U.S. depends on whether the product contains any quantity of tetrahydrocannabinol or any other controlled substance. If the product contains more than 0.3% tetrahydrocannabinol on a dry weight basis it is controlled in schedule I of the CSA, unless it is specifically excepted or listed in another schedule. The DEA has indicated our pharmaceutically produced cannabidiol is not controlled under the CSA as it is free of tetrahydrocannabinol with none detected at the detection limit of ten parts per million.

We may choose to conduct clinical trials for any of our drug candidates outside the U.S. subject to regulatory approval. We may decide to develop, manufacture, or commercialize our product candidates in additional countries, which may consider pharmaceutically produced cannabidiol a controlled substance. As a result, we may be subject to controlled substance laws and regulations from the various other regulatory agencies in other countries where we develop, manufacture, or commercialize our cannabinoid products in the future.

Marketing Exclusivity

As discussed in the May 19, 2015, issue[9] of the "FDA/CDER SBIA Chronicles" published by the FDA, upon NDA approval of a new chemical entity, which for this purpose is defined as a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot approve any ANDA seeking approval of a generic version of that drug. Certain changes to the scope of an approval for a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes the change. A Section 505(b)(2) NDA may be eligible for three-year marketing exclusivity, assuming the NDA includes reports of new clinical studies (other than bioequivalence studies) essential to the approval of the NDA.

An ANDA may be submitted one year before marketing exclusivity expires if a Paragraph IV certification is filed. In this case, the 30-months' stay, if applicable, runs from the end of the five-year marketing exclusivity period. If there is no listed patent in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Additionally, six months of marketing exclusivity in the United States is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. This six-month pediatric exclusivity period is not a stand-alone exclusivity period, but rather is added to any existing patent or non-patent exclusivity period for which the drug product is eligible.

Patent Term Extension

As set out in the FDA`s website discussion[10] "Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program", the term of a patent that covers an FDA-approved drug may be eligible for patent-term extension, which provides patent-term restoration as compensation for the patent term lost during the FDA regulatory review process. The U.S. Federal Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent-term extension of up to five years beyond the expiration of the patent. The length of the patent-term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent

applicable to an approved drug may be extended. Similar provisions are available in Canada, Europe, and other foreign jurisdictions to extend the term of a patent that covers an approved drug.

European and Other International Government Regulation

In addition to regulations in the U.S. and Canada, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Some countries outside of the U.S. have a similar process that requires the submission of a CTA much like the IND prior to the commencement of human clinical trials. In the E.U., for example, a CTA must be submitted under the centralized Clinical Trial Regulation where simultaneous regulatory review and ethics committee (EC) review is done, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with the clinical trial regulator, country's requirements, clinical trial development may proceed.

To obtain regulatory approval to commercialize a new drug under E.U. regulatory systems, we must submit an MAA. The MAA is similar to the NDA, with the exception of, among other things, country-specific document requirements.

For other countries outside of the E.U., such as countries in Latin America, or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP, applicable regulatory requirements of each jurisdiction, and the medical ethics principles that have their origin in the Declaration of Helsinki.

Compliance

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention, or refusal to permit the import or export of products, injunctions, fines, civil penalties, or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect.

Other Special Regulatory Procedures

Fast Track Designation

According to the discussion[11] on the FDA's website on "Fast Track", under the Fast Track program, the sponsor of an IND may request the FDA to designate the drug candidate as a Fast Track drug if it is intended to treat a serious condition and fulfill an unmet medical need. The FDA must determine if the drug candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. Once the FDA designates a drug as a Fast Track candidate, it is required to facilitate the development and expedite the review of that drug by providing more frequent communication with and guidance to the sponsor.

In addition to other benefits such as the ability to use surrogate endpoints and have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's review period for filing and reviewing an application does not begin until the last section of the NDA has been submitted. Additionally, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

According to discussion[12] on the FDA's website on "Breakthrough Therapy", the FDA may provide the Breakthrough Therapy designation to drugs to expedite the development and review of a candidate that is planned for use to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug

may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A Breakthrough Therapy designation includes all of the Fast Track program features, as well as more intensive FDA guidance on an efficient drug development program. The FDA also has an organizational commitment to involve senior management in such guidance.

Orphan Drug Designation

As set out in the FDA website discussion[13] on "Designating an Orphan Product: Drugs and Biological Products", the FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S., or, if the disease or condition affects more than 200,000 individuals in the U.S., if there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the U.S. As set out in the EMA's website discussion[14] on "Orphan Designation", in the E.U., the EMA's Committee for Orphan Medicinal Products grants orphan medicine designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the E.U. community. Additionally, the orphan medicine designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the E.U. would be sufficient to justify the necessary investment in developing the drug.

In the U.S., Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research, and user fee waivers under certain circumstances. In addition, if a product receives the first FDA approval for the indication for which it has Orphan Drug Designation, the Orphan Drug is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for the same drug for the same indication for a period of seven years, in limited circumstances, such as a showing of clinical superiority over the product with orphan drug exclusivity. Orphan Drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. In the E.U., orphan medicine designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug approval. This period may be reduced to six years if the orphan medicine designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan Drug Designation and orphan medicine designation must be requested before submission of an application for marketing approval. Orphan Drug Designation and orphan medicine designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan Drug Designation was granted on February 14, 2024, in the U.S. to the Corporation for CardiolRx for the treatment of pericarditis.

Priority Review (United States) and Accelerated Assessment (European Union)

Based on results of the Phase III clinical trial(s) submitted in an NDA, upon the request of an applicant, a priority review designation may be granted to a product by the FDA, which sets the target date for FDA action on the application at six months from the FDA's decision on priority review application, or eight months from the NDA filing. According to the FDA website discussion[15] on "Priority Review", this status is given where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. If criteria are not met for priority review, the standard FDA review period is ten months from the FDA's decision on priority review application, or 12 months from the NDA filing. The priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

According to the EMA website discussion[16] on "Accelerated Assessment", under the Centralised Procedure in the E.U., the maximum timeframe for the evaluation of a MAA is 210 days (excluding "clock stops," when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP.

Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, which takes into consideration: the seriousness of the disease (e.g., heavy-disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the

opinion of the CHMP is given within 150 days.

Accelerated Approval

As set out in the FDA website discussion[17] on "Accelerated Approval Program", under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. This approval mechanism is provided for under 21CRF314 Subpart H and Subpart E. In this case, clinical trials are conducted in which a surrogate endpoint is used as the primary outcome for approval. A surrogate endpoint is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. This surrogate endpoint substitutes for a direct measurement of how a patient feels, functions, or survives and is considered reasonably likely to predict clinical benefit. Such surrogate endpoints may be measured more easily or more rapidly than clinical endpoints. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. When the Phase IV commitment is successfully completed, the biomarker is deemed to be a surrogate endpoint. Failure to conduct required post-approval studies or confirm a clinical benefit during post-marketing studies could lead the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Regulatory Framework in Canada for Cannabis

The production, processing, and sale of the Corporation's CardiolRx and CRD-38 products are subject to regulation under Canada's regulatory framework for cannabis.

Cannabis Act and Cannabis Regulations

The *Cannabis Act* came into force on October 17, 2018 and has been amended from time to time. Health Canada proposed a risk-based approach to regulation, balancing the protection of health and safety of Canadians while enabling a competitive legal industry made up of large and small enterprises in all regions of Canada producing quality-controlled cannabis. On July 11, 2018, Health Canada released the regulations of cannabis in Canada Gazette, Part II, Volume 152, Number 14 – SOR/2018 144.

The impact of any further regulatory changes on the Corporation's business is unknown. See "Risk Factors – Changes in laws and regulations may make compliance challenging, costly and time consuming for us."

Licenses, Permits and Authorizations

The Regulations establish different types of authorizations based on the activity being undertaken and, in some cases, the scale of the activity. Rules and requirements for different categories of authorized activities are intended to be proportional to the public health and safety risks posed by each category of activity. The types of authorizations include: (i) cultivation; (ii) processing; (iii) sale to the public for medical purposes and non-medical purposes in provinces and territories that have not enacted a retail framework; (iv) analytical testing; (v) import/export; and (vi) research.

Security Clearances

Select personnel (including individuals occupying a "key position", such as directors, officers, large shareholders, and individuals identified by the Minister of Health) associated with certain licenses issued under the *Cannabis Act* are obliged to hold a valid security clearance issued by the Minister of Health. The Regulations enable the Minister of Health to refuse to grant security clearances to individuals with associations to organized crime or with past convictions for, or an association with, drug trafficking, corruption, or violent offences.

Reporting and Disclosure

Under the *Cannabis Act*, the Minister of Health is authorized to establish and maintain a national cannabis tracking system. The purpose of this system is to track cannabis throughout the supply chain to help prevent diversion of cannabis into, and out of, the legal market. The Regulations provide the Minister of Health with the authority to make a ministerial order that would require certain persons named in such order to report specific information about their authorized activities with cannabis, in the form and manner specified by the Minister.

Formulated Cannabis

The Regulations permit the sale to the public by licensed entities of dried cannabis, fresh cannabis, cannabis plants, cannabis seeds, edibles containing cannabis, topical cannabis and cannabis concentrates (extracts). The Regulations acknowledge that a range of product forms should be enabled to help the legal industry displace the illegal market.

A solution containing 100% pharmaceutically manufactured cannabidiol and no tetrahydrocannabinol is classified as "Cannabis" under the *Cannabis Act*. Specifically, Schedule 1 of the Cannabis Act defines "Cannabis" to include "any substance that is identical to any phytocannabinoid produced by, or found in, such a plant (cannabis), regardless of how the substance was obtained." Cannabidiol, pharmaceutically manufactured, is identical to cannabidiol found in the cannabis plant. However, our formulated products are not Cannabis Products since they are defined as drugs.

Packaging and Labeling

The Regulations set out requirements pertaining to the packaging and labelling of cannabis products. Such requirements promote informed consumer choice and allow for the safe handling and transportation of cannabis. The Regulations require all cannabis products to be packaged in a manner that is tamper-evident and child-resistant. While minor allowances for branding are permitted, Health Canada has mandated strict limits on the use of colours, graphics, and other special characteristics of packaging, and products are required to be labelled with specific information about the product, contain mandatory health warnings similar to tobacco products, and be marked with a clearly recognizable standardized cannabis symbol. All packaging is required to contain a standardized cannabis symbol for those products containing greater than 10 ppm of tetrahydrocannabinol.

Drugs Containing Cannabis

Health Canada is following a scientific, evidenced-based approach for the oversight of health products with cannabis that are approved with health claims, including prescription and non-prescription drugs, natural health products, veterinary drugs and veterinary health products, and medical devices. Health products can only be sold if they have been approved by Health Canada following a scientific review.

Provincial and Territorial Regulatory Regimes

While the *Cannabis Act* provides for the regulation of the commercial production of cannabis for recreational purposes and related matters by the federal government, the *Cannabis Act* states that the provinces and territories of Canada have authority to regulate other aspects of recreational cannabis (similar to what is currently the case for liquor and tobacco products), such as sale and distribution, minimum age requirements, pricing and promotion, places where cannabis can be consumed, and a range of other matters.

The government of each Canadian province and territory has in place regulatory regimes for the distribution and sale of cannabis for consumer purposes within those jurisdictions.

Corporate Social Responsibility and Environmental Social and Governance ("ESG")

As a rapidly growing, clinical-stage biotech company, we are not yet in a position to implement a broad-based ESG policy and program. However, our corporate goals are inspired by our potential to impact the care of patients who suffer with cardiovascular disease and are informed by our corporate values of acting with integrity, collaboration, innovation and embracing diversity. In 2025, our corporate goals focused on certain clinical, manufacturing, and

business operations and support our desire to obtain an approval for innovative treatments for heart diseases. Each year we work hard to achieve our goals and objectives while maintaining a respectful, collaborative, and caring work environment.
While we do not formally report on our ESG policies and compliance, we publicly disclose elements of our ESG activities. Our governance policies like our board mandates, code of ethics and conduct, and our public filings are all on our website at www.cardiolrx.com.

RISK FACTORS

Following is a list of risks that the Corporation faces in its normal course of business. These are factors which, individually or in the aggregate, we think could cause our actual results to differ significantly from anticipated or historical results. The risks and uncertainties set out below are not exhaustive and are not the only ones the Corporation is facing. If any of the following risks actually occur, the Corporation's business may be harmed, and the Corporation's financial condition and results of operations may suffer significantly. Investors should carefully consider the risk factors set out below and consider all other information contained herein and in the Corporation's other public filings before making an investment decision. The risks set out below are not an exhaustive list and should not be taken as a complete summary or description of all the risks associated with the Corporation's business and the biotechnology business generally. Additionally, investors should not interpret the disclosure of a risk to imply that the risk has not already materialized.

Risks Related to our Business and Industry

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

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

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

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

There is no guarantee that the Corporation will be able to execute on its strategy. The continued development of the Corporation will require additional financing. The failure to raise needed capital could result in the delay or

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

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

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

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

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

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

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

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

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

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

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

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

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct pre-clinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete, and has uncertain outcomes. The outcome of pre-clinical studies and early clinical trials may not predict the success of later clinical trials and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. We do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk we face is the possibility that none of our product candidates under development will successfully gain market approval from the FDA, Health Canada, or other regulatory authorities, resulting in us being unable to derive any commercial revenue from them after investing significant amounts of capital in multiple stages of pre-clinical and clinical testing.

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

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

- failure by regulatory authorities to grant permission to proceed or placing the clinical trial on hold;
- difficulties obtaining institutional review board ("IRB") or ethics committee approval to conduct a clinical trial at a prospective site;
- import/export and research restrictions for cannabinoid-based pharmaceuticals delaying or preventing clinical trials in various geographical jurisdictions;
- patients failing to enroll or remain in our trials at the rate we expect;

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

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

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

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

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

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

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

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

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

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

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

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

Unpredictable and volatile market price for Common Shares.

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

- actual or anticipated fluctuations in our quarterly results of operations;
- recommendations by securities research analysts;
- changes in the economic performance or market valuations of companies in the industry in which we operate;
- addition or departure of our executive officers and other key personnel;
- sales or perceived sales of additional Common Shares;
- significant acquisitions or business combinations, strategic partnerships, joint ventures, or capital commitments by or involving us or our competitors;
- operating and share price performance of other companies that investors deem comparable to us;
- fluctuations to the costs of vital production materials and services;
- changes in global financial markets and global economies and general market conditions, such as interest rates and pharmaceutical product price volatility;

- operating and share price performance of other companies that investors deem comparable to the Corporation or from a lack of market comparable companies; and
- news reports relating to trends, concerns, technological or competitive developments, regulatory changes, and other related issues in our industry or target markets.

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

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

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

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

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

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

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

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

Owning a patent does not *per se* prevent competition. To stop third-party infringement, a patent owner and/or

licensee must take steps to enforce the patent through court proceedings. This can be a very lengthy and costly process and the outcome may be uncertain.

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

The CIPO, USPTO, 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, USPTO, 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, USPTO, and other applicable patents offices in foreign jurisdictions. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing the applicable product candidate. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

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

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

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

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

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

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

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

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

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

obligations, including regulatory oversight of promotion and marketing.

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

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

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

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

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

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

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

Our operations are subject to a variety of laws, regulations, and guidelines relating to pharmacology, cannabinoids, and drug delivery, as well as laws and regulations relating to health and safety, the conduct of operations, and the protection of the environment. While, to our knowledge, we are currently in material compliance with all such laws, changes to such laws, regulations and guidelines due to matters beyond our control may cause adverse effects to our operations and financial condition. These changes may require us to incur substantial costs associated with legal and compliance fees and ultimately require us to alter our business plan.

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

business, results of operations, and financial condition.

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

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

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

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

Medical research on cannabidiol in heart diseases remains limited.

Research regarding the medical benefits, viability, safety, efficacy, and dosing of cannabidiol in heart disease remains limited. The statements made in this AIF concerning the potential medical benefits of cannabidiol in heart diseases are based on the published peer-reviewed articles and reports from pre-clinical research studies, as well as the results from the Corporation's MAvERIC-Pilot Phase II studies of CardiolRx™ in patients with recurrent pericarditis and from the Corporation's Phase II ARCHER trial in patients with acute myocarditis, respectively. As a result, the statements made in this AIF are subject to the clinical and experimental parameters, qualifications, and limitations in the studies that have been completed.

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

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

Even if product development is successful and regulatory approval is obtained, our ability to generate significant

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

We currently have no commercialized products to date.

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

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

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

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

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

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

We are a party to, and may seek additional, collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our current and potential product candidates. We may enter into new arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for each product candidate, both in Canada and internationally. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document,

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

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

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

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

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

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

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

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

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

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs.

In addition, there has been increased political, legislative and regulatory focus on reducing the cost of drugs to patients, including through limiting prices that may be charged, imposing mandatory rebates and including direct government price negotiations. These and other future initiatives may reduce pricing flexibility or adversely affect the commercial prospects of the Corporation.

Even if our product candidates are approved by the FDA, Health Canada or any similar regulatory authority, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our product candidates (if approved). Furthermore, the price limitations imposed by governments may adversely affect the commercial prospects of the Corporation’s product candidates. If government and other healthcare payers do not

provide adequate coverage and reimbursement levels for our product candidates, once approved, market acceptance and revenues of such product candidates could be reduced.

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

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

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

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

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

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

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

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

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

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

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

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

lead to decreased demand for products produced by the Corporation and could have a material adverse effect on the results of operations and financial condition of the Corporation. Additionally, product recalls may lead to increased scrutiny of the operations of the Corporation by Health Canada or other regulatory agencies, requiring further Management attention and potential legal fees and other expenses.

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

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

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

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

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

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

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

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

The Corporation has insurance to protect its assets, operations, and employees. While the Corporation believes its insurance coverage addresses all material risks to which it is exposed and is adequate and customary in its current state of operations, such insurance is subject to coverage limits and exclusions and may not be available for all risks and hazards to which the Corporation is exposed. In addition, no assurance can be given that such insurance will be adequate to cover the Corporation's liabilities or will be generally available in the future or, if available, that premiums will be commercially justifiable. If the Corporation were to incur substantial liability and

such damages were not covered by insurance or were in excess of policy limits, or if the Corporation were to incur such liability at a time when it is not able to obtain liability insurance, its business, results of operations, and financial condition could be materially adversely affected.

We may be unable to manage our growth effectively.

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

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

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

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

Certain publicity may cause damage to our reputation.

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

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

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

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

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

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

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

The Corporation has entered into agreements with third parties for hardware, software, telecommunications, and other information technology ("IT") services in connection with its operations. The Corporation's operations depend, in part, on how well it and its suppliers protect networks, equipment, IT systems, and software against damage from a number of threats, including, but not limited to, cable cuts, damage to physical plants, natural disasters, terrorism, fire, power loss, hacking, computer viruses, vandalism, and theft. The Corporation's operations also depend on the timely maintenance, upgrade, and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. Any of these and other events could result in information system failures, delays and/or an increase in capital expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact the Corporation's reputation and results of operations.
The Corporation has not experienced any material losses to date relating to cyber-attacks or other information security breaches, but there can be no assurance that the Corporation will not incur such losses in the future. The Corporation's risk and exposure to these matters cannot be fully mitigated because of, among other things, the evolving nature of these threats. As a result, cybersecurity and the continued development and enhancement of controls, processes, and practices designed to protect systems, computers, software, data, and networks from attack, damage, or unauthorized access is a priority. As cyber threats continue to evolve, the Corporation may be required to expend additional resources to continue to modify or enhance protective measures or to investigate and remediate any security vulnerabilities.

We do not currently, and have no plans to, pay dividends on our Common Shares.

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

Future sales of Common Shares by existing shareholders.

Holders of stock options, performance share units, restricted share units, deferred share units and other share-

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

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

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

Our Common Shares are subject to market price volatility.

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

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

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

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

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

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

financial condition.

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

If the Corporation is classified as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes in any taxable year, U.S. investors holding the Corporation's Common Shares generally will be subject, in that taxable year and all subsequent taxable years (whether or not the Corporation continued to be a PFIC), to certain adverse U.S. federal income tax consequences. The Corporation will be classified as a PFIC in respect of any taxable year in which, after taking into account its income and gross assets (including the income and assets of 25% or more owned subsidiaries), either (i) 75% or more of its gross income consists of certain types of "passive income" or (ii) 50% or more of the average quarterly value of its assets is attributable to "passive assets" (assets that produce or are held for the production of passive income). Based upon the current and expected composition of the Corporation's income and assets, the Corporation believes that it was a PFIC for the taxable year ended December 31, 2025 and expects that it may be a PFIC for the current taxable year. Because the Corporation's PFIC status must be determined annually with respect to each taxable year and will depend on the composition and character of the Corporation's assets and income, including the Corporation's use of proceeds from offerings, and the value of the Corporation's assets (which may be determined, in part, by reference to the market value of Common Shares, which may be volatile) over the course of such taxable year, the Corporation may be a PFIC in any taxable year. Because there are uncertainties in the application of the relevant rules and PFIC status is a factual determination made annually after the close of each taxable year, there can be no assurance that the Corporation will not be a PFIC for any future taxable year. In addition, it is possible that the U.S. Internal Revenue Service may challenge the Corporation's classification of certain income and assets as non-passive, which may result in the Corporation being or becoming a PFIC in the current or subsequent years.

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

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

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

The Corporation is a corporation existing under the laws of Ontario, Canada. Many of the Corporation's Directors and officers are residents of Canada, and all or a substantial portion of their assets, and a substantial portion of

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

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

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

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

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

United States generally accepted accounting principles. In addition, the Corporation may lose the ability to rely upon exemptions from Nasdaq corporate governance requirements that are available to foreign private issuers.

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

The Corporation is an "emerging growth company" as defined in section 3(a) of the U.S. Exchange Act (as amended by the JOBS Act, enacted on April 5, 2012), and the Corporation will continue to qualify as an emerging growth company until the earliest to occur of: (a) the last day of the fiscal year during which the Corporation has total annual gross revenues of U.S.$1,235,000,000 (as such amount is indexed for inflation every five years by the SEC) or more; (b) the last day of the fiscal year of the Corporation following the fifth anniversary of the date of the first sale of common equity securities of the Corporation pursuant to an effective registration statement under the U.S. Securities Act; (c) the date on which the Corporation has, during the previous three-year period, issued more than U.S.$1,000,000,000 in non-convertible debt; and (d) the date on which the Corporation is deemed to be a "large accelerated filer", as defined in Rule 12b-2 under the U.S. Exchange Act. The Corporation will qualify as a large accelerated filer (and would cease to be an emerging growth company) at such time when on the last business day of its second fiscal quarter of such year the aggregate worldwide market value of its common equity held by non-affiliates will be U.S.$700,000,000 or more. For so long as the Corporation remains an emerging growth company, it is permitted to and intends to rely upon exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. The Corporation cannot predict whether investors will find the Common Shares less attractive because the Corporation relies upon certain of these exemptions. If some investors find the Common Shares less attractive as a result, there may be a less active trading market for the Common Shares and the Common Share price may be more volatile. November 5, 2026, will mark the fifth anniversary of the date of the first sale of common equity securities of the Corporation pursuant to an effective registration statement under the U.S. Securities Act and, as a result, the Corporation will cease to qualify as an emerging growth company at the end of the fiscal year ending December 31, 2026. The Corporation expects to be required to divert additional management time and attention from the Corporation's development and other business activities and incur increased legal and financial costs to comply with the additional associated reporting requirements, following its loss of emerging growth company status presuming no other reporting accommodations are available to it, which could negatively impact the Corporation's business, financial condition, and results of operations.

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

We may be impacted by business interruptions resulting from pandemics and public health emergencies, including those related to geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods, and fires. An outbreak of infectious disease, a pandemic or a similar public health threat or a fear of any of the foregoing, could adversely impact us by causing operating, manufacturing supply chain, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures).

It is unknown whether and how we may be affected by existing or possible events outside of our control for an extended period of time. We may incur expenses or delays relating to such events outside of our control, which could have a material adverse impact on our business, operating results, and financial condition.

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

Environmental issues will become more material in the marketplace as the wider healthcare system embraces net-zero climate targets. The environmental targets and performance of our business will come under increased scrutiny by investors, governments, and non-governmental organizations. Environmental considerations are starting to become embedded in the public procurement of goods and services, including medicinal products and devices. Specific intermediates used to manufacture medicines, or those used in excipients or propellants, are coming under increased regulation and some may be subject to time-limited exemptions or potential phase-out. The physical impacts of climate change could impact the resilience of our business operations and supply chain.

Our operations could be adversely affected by macroeconomic risks.

In recent years, economies and markets have faced the phenomenon of inflation, the control of which is the focus of regulatory institutions around the world. In 2025, the inflation rate decreased and the benchmark interest rate has also declined. However, uncertain inflation and the uncertainty surrounding tariffs on imports into the United States represent a significant risk to macroeconomic stability; it results in rising energy and commodity costs, and global equity and capital markets may experience significant volatility and weakness.

In 2025, the U.S. government issued executive orders imposing new tariffs on imports from certain countries, including Canada. Such announcements and potential retaliatory tariffs have created uncertainty, which has permeated the economic and investment outlook, impacting current global economic conditions. Beyond its impact on the global economy, tariffs may have negative impacts to the Corporation and its suppliers, partners and future patients.

In light of these developments, the Corporation is closely monitoring the impacts of macroeconomic developments and the potential consequences to its operations and financial position. The extent to which the Corporation and its suppliers, partners and future patients are impacted by macroeconomic developments largely depends on the nature and duration of uncertain and unpredictable events, the duration and possible escalation of tariffs, the evolution of retaliatory measures, fiscal and monetary responses, and reactions to ongoing changes by the global financial markets. These factors could have a material adverse effect on our business, operating results, and financial condition.

Disruptions at the FDA and other government agencies caused by reductions in force, funding shortages, government shutdowns, or internal policy changes could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner, which could negatively impact our business.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, sufficient staffing, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA’s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Ongoing changes in government policies and practices, may adversely impact our development and commercialization efforts. Decisions about the development of product candidates are often based on interactions with FDA and regulatory guidance provided by the agency following such interactions. If the FDA does not agree with our decisions resulting from such interactions and guidance or there are subsequent policy changes, review and approval of our product candidates may be delayed or not occur at all.

Artificial Intelligence

Artificial intelligence (“AI”) and advanced data-driven tools are increasingly used in the pharmaceutical industry and healthcare to support functions such as data analysis, forecasting, supply chain optimization, regulatory processes and commercial operations. While these technologies offer efficiency, they also carry risks, including reliance on flawed or biased data or algorithms, which may lead to incorrect decisions, operational disruptions, compliance issues and reputational harm. AI systems can be difficult to validate and audit especially in regulated environments which may raise compliance risks.

In addition, regulatory frameworks globally are rapidly evolving and differ across various jurisdictions. New

legislation or regulatory guidance may increase costs, limit the utility of AI systems, or expose the Corporation to certain liabilities. The Corporation's third-party suppliers may also use AI systems, and any failure, misuse or breach of these systems could compromise sensitive data, disrupt operations or enable sophisticated cyber-attacks and fraud. If any of these risks from AI systems were to materialize, they could significantly impact the Corporation's business, financial condition, operations and cash flows.

General Risk Factors

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

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

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

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

DIVIDENDS

We have not declared dividends on our Common Shares in the past. We currently intend to reinvest all future earnings in order to finance the development and growth of our business. As a result, we do not intend to pay dividends on our Common Shares in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors and will depend on the financial condition, business environment, operating results, capital requirements, any contractual restrictions on the payment of dividends, and any other factors that the Board of Directors deems relevant.

CAPITAL STRUCTURE

Common Shares

As of the date hereof, our authorized share capital consists of an unlimited number of Common Shares, of which 111,872,084 are issued and outstanding; 400,000 Common Shares issuable to Dalton if Dalton meets certain performance objectives, and stock options and other share-based awards as shown below.

Under our articles, each Common Share entitles the holder to receive notice of and attend all meetings of the shareholders. Each Common Share carries the right to one vote. The holders of Common Shares are entitled to receive any dividends declared by the Corporation in respect of the Common Shares at such time and in such amount as may be determined by the Board of Directors, in its discretion. In the event of the liquidation, dissolution, or winding-up of the Corporation, whether voluntary or involuntary, holders of Common Shares are also entitled to participate, rateably, in the distribution of the assets of the Corporation, subject to the rights of the holders of any other class of shares ranking in priority to the Common Shares. No Common Shares have been issued subject to call or assessment. The Common Shares must be issued as fully paid and non-assessable, and are not subject to further capital calls by the Corporation.

Warrants

The following table sets out the current number of warrants outstanding and details the expiry date and the exercise price:

Expiry date	Exercise price ($)	Warrants outstanding
October 17, 2027	1.35[(1)]	4,977,500
October 20, 2027	1.35[(1)]	735,000
January 23, 2028	1.75	5,711,539
Total		**11,424,039**

(1) Exercise price denoted in USD.

Stock Options and other Share-Based Awards

The Board of Directors has adopted a Legacy Equity Compensation Plan, and subsequently an Omnibus Equity Incentive Plan under which options to purchase Common Shares and other Share-Based Awards (as defined below) may be granted to the Corporation's Directors, officers, employees, and consultants. See below "Summary of Legacy Equity Compensation Plan" and "Summary of Omnibus Equity Incentive Plan".

The following table sets out the current number of options outstanding and details the expiry date, the grant date, the exercise price, and options exercisable:

Expiry date	Grant Date	Exercise price ($)	Options outstanding	Options exercisable
April 1, 2026	April 2, 2019	5.77	60,000	60,000
December 8, 2026	December 9, 2021	3.59	325,000	325,000
January 11, 2027	January 12, 2022	2.18	220,000	220,000
March 1, 2027	March 1, 2024	2.56	200,000	200,000
March 9, 2027	March 10, 2025	1.13[(1)]	200,000	200,000
May 12, 2027	May 13, 2022	1.46	70,000	70,000
September 13, 2027	September 13, 2022	1.61	207,500	207,500
July 21, 2028	July 22, 2025	1.67	50,000	25,000
July 7, 2029	December 11, 2024	2.07	30,000	10,000
August 19, 2029	May 26, 2025	1.50	30,000	10,000
May 25, 2030	May 26, 2025	1.09[(1)]	120,000	90,000
May 25, 2030	May 26, 2025	2.12	100,000	75,000
May 29, 2030	May 30, 2025	1.16[(1)]	60,000	-
December 2, 2030	December 3, 2025	1.40	2,620,000	-
December 2, 2030	December 3, 2025	1.00[(1)]	490,000	-
Total			**4,782,500**	**1,492,500**

(1) Exercise price denoted in USD.

The Corporation has 4,763,443 outstanding RSUs subject to vesting conditions specific to each grant. Of the outstanding RSUs, 2,762,184 have fully vested as of the date of this Annual Report.

The Corporation has 3,478,300 outstanding PSUs subject to vesting conditions specific to each grant. Of the outstanding PSUs, 1,279,671 have fully vested as of the date of this Annual Report.

Omnibus Equity Incentive Plan

The Omnibus Equity Incentive Plan is administered by the Board, and the Board has the authority to interpret the Omnibus Equity Incentive Plan, including in respect of any award granted thereunder. The Omnibus Equity Incentive Plan permits the Board to approve awards of Options, RSUs, PSUs, DSUs or other Share-Based Awards to eligible participants.

Common Shares Subject to the Omnibus Equity Incentive Plan

The Omnibus Equity Incentive Plan is a rolling plan which, subject to the adjustment provisions provided for therein (including a subdivision or consolidation of Common Shares), provides that the aggregate maximum number of Common Shares that may be issued upon the exercise or settlement of awards granted under the Omnibus Equity Incentive Plan shall not exceed 15% of the Corporation's issued and outstanding Common Shares from time to time (including Common Shares reserved for issuance in respect of 60,000 Options outstanding under the Equity Compensation Plan and in respect of any other Security Based Compensation Arrangement). The Omnibus Equity Incentive Plan is considered an "evergreen" plan, since the Common Shares covered by awards which have been exercised, settled, or terminated shall be available for subsequent grants under the Omnibus Equity Incentive Plan and the number of awards available to grant increases as the number of issued and outstanding Common Shares increases.

Outstanding Securities Awarded:

As March 31, 2026, the total number of Common Shares issuable upon exercise of any awards granted under the Omnibus Equity Incentive Plan is 13,024,243 Shares (representing approximately 11.6% of the Common Shares outstanding). This assumes that each outstanding stock option, PSU and RSU is redeemed for Common Shares.

Remaining Securities Available for Grant:

As of March 31, 2026, the number of Common Shares available for issuance pursuant to future awards granted under the Omnibus Equity Incentive Plan is 3,756,569 Shares (representing approximately 3.4% of the Common Shares outstanding).

Insider Participation Limit

The Omnibus Equity Incentive Plan provides that the aggregate number of Common Shares (a) issuable to insiders at any time (under all of the Corporation's security-based compensation arrangements) cannot exceed 10% of the Corporation's issued and outstanding Common Shares and (b) issued to insiders within any one-year period (under all of the Corporation's security-based compensation arrangements) cannot exceed 10% of the Corporation's issued and outstanding Common Shares.

Administration of the Omnibus Equity Incentive Plan

The Plan Administrator (as defined in the Omnibus Equity Incentive Plan) is determined by the Board, and is initially the Board. The Omnibus Equity Incentive Plan may in the future be administered by a committee of the Board. That committee may in turn sub delegate certain functions to an officer or director. The Plan Administrator determines which Directors, officers, consultants, and employees are eligible to receive awards under the Omnibus Equity Incentive Plan, the time or times at which awards may be granted, the conditions under which awards may be granted or forfeited to the Corporation, the number of Common Shares to be covered by any award, the exercise price of any award, whether restrictions or limitations are to be imposed on the Common Shares issuable pursuant to grants of any award, and the nature of any such restrictions or limitations, any acceleration of exercisability or vesting, or waiver of termination regarding any award, based on such factors as the Plan Administrator may determine.

Eligibility

All Directors, employees, and consultants of the Corporation, its subsidiary and future subsidiaries, if any, are eligible to participate in the Omnibus Equity Incentive Plan (referred to as "Participants"). The extent to which any

such individual is entitled to receive a grant of an award pursuant to the Omnibus Equity Incentive Plan will be determined in the sole and absolute discretion of the Plan Administrator.

Types of Awards

Awards of Options, RSUs, PSUs, DSUs, and other share-based awards may be made under the Omnibus Equity Incentive Plan, as further summarized below. All of the awards described below are subject to the conditions, limitations, restrictions, exercise price, vesting, settlement, and forfeiture provisions determined by the Plan Administrator, in its sole discretion, subject to such limitations provided in the Omnibus Equity Incentive Plan and will generally be evidenced by an award agreement. In addition, subject to the limitations provided in the Omnibus Equity Incentive Plan and in accordance with applicable law, the Plan Administrator may accelerate or defer the vesting or payment of awards, cancel, or modify outstanding awards, and waive any condition imposed with respect to awards or Common Shares issued pursuant to awards.

Options

An Option entitles a holder thereof to purchase a prescribed number of treasury Common Shares at an exercise price set at the time of the grant. The Plan Administrator will establish the exercise price at the time each Option is granted, which exercise price must in all cases be not less than the five-day volume weighted average closing price (the "5-day VWAP") of the Common Shares on the TSX for the five trading days immediately preceding the date of grant (for the purposes of this section, the "Market Price"). Subject to any accelerated termination as set forth in the Omnibus Equity Incentive Plan, each Option expires on its respective expiry date. The Plan Administrator will have the authority to determine the vesting terms applicable to grants of Options. Once an Option becomes vested, it shall remain vested and shall be exercisable until expiration or termination of the Option, unless otherwise specified by the Plan Administrator, or as otherwise set forth in any written employment agreement, award agreement or other written agreement between the Corporation and the Participant. The Plan Administrator has the right to accelerate the date upon which any Option becomes exercisable. The Plan Administrator may provide at the time of granting an Option that the exercise of that Option is subject to restrictions, in addition to those specified in the Omnibus Equity Incentive Plan, such as vesting conditions relating to the attainment of specified performance goals.

Unless otherwise specified by the Plan Administrator at the time of granting an Option and set forth in the particular award agreement, an exercise notice must be accompanied by payment of the exercise price. A Participant may, with the consent of the Corporation, in lieu of exercising an Option pursuant to an exercise notice, elect to surrender such Option to the Corporation (a "Cashless Exercise") in consideration for an amount from the Corporation equal to (i) the Market Price of the Common Shares issuable on the exercise of such Option (or portion thereof) as of the date such Option (or portion thereof) is exercised, less (ii) the aggregate exercise price of the Option (or portion thereof) surrendered relating to such Common Shares (the "In-the-Money Amount") by written notice to the Corporation indicating the number of Options such participant wishes to exercise using the Cashless Exercise, and such other information that the Corporation may require. Subject to the provisions of the Omnibus Equity Incentive Plan, the Corporation will satisfy payment of the In-the-Money Amount by delivering to the participant such number of Common Shares having a fair market value equal to the In-the-Money Amount.

Restricted Share Units

An RSU is a unit equivalent in value to a Share credited by means of a bookkeeping entry in the books of the Corporation which entitles the holder to receive one Share (or the value thereof) for each RSU after a specified vesting period. The Plan Administrator may, from time to time, be subject to the provisions of the Omnibus Equity Incentive Plan and such other terms and conditions as the Plan Administrator may prescribe, grant RSUs to any participant in respect of a payment for services rendered by the applicable participant in a taxation year.

The number of RSUs (including fractional RSUs) granted at any particular time under the Omnibus Equity Incentive Plan will be calculated by dividing (a) the amount of the payment that is to be paid in RSUs, as determined by the Plan Administrator, by (b) the greater of (i) the Market Price of a Share on the date of grant and (ii) such amount as determined by the Plan Administrator in its sole discretion. The Plan Administrator shall have the authority to determine any vesting terms applicable to the grant of RSUs.

Upon settlement, holders will redeem each vested RSU for one Share in respect of each vested RSU (or, at the election of the holder and subject to the approval of the Plan Administrator, a cash payment or a combination of Common Shares and cash). Any such cash payments made by the Corporation shall be calculated by multiplying the number of RSUs to be redeemed for cash by the Market Price per Share as at the settlement date.

Performance Share Units

A PSU is a unit equivalent in value to a Share credited by means of a bookkeeping entry in the books of the Corporation which entitles the holder to receive one Share (or the value thereof) for each PSU after specific performance-based vesting criteria determined by the Plan Administrator, in its sole discretion, have been satisfied. The performance goals to be achieved during any performance period, the length of any performance period, the amount of any PSUs granted, the effect of termination of a participant's service and the amount of any payment or transfer to be made pursuant to any PSU will be determined by the Plan Administrator and by the other terms and conditions of any PSU, all as set forth in the applicable award agreement. The Plan Administrator may, from time to time, subject to the provisions of the Omnibus Equity Incentive Plan and such other terms and conditions as the Plan Administrator may prescribe, grant PSUs to any participant in respect of a bonus or similar payment in respect of services rendered by the applicable participant in a taxation year (the "PSU Service Year").

The Plan Administrator shall have the authority to determine any vesting terms applicable to the grant of PSUs. Upon settlement, holders will redeem each vested PSU for the following at the election of such holder but subject to the approval of the Plan Administrator: (a) one Share in respect of each vested PSU, (b) a cash payment, or (c) a combination of Common Shares and cash. Any such cash payments made by the Corporation to a participant shall be calculated by multiplying the number of PSUs to be redeemed for cash by the Market Price per Share as at the settlement date. Subject to the provisions of the Omnibus Equity Incentive Plan and except as otherwise provided in an award agreement, no settlement date for any PSU shall occur, and no Share shall be issued, or cash payment shall be made in respect of any PSU any later than the final business day of the third calendar year following the applicable PSU Service Year.

Deferred Share Units

A DSU is a unit equivalent in value to a Share credited by means of a bookkeeping entry in the books of the Corporation which entitles the holder to receive one Share (or, at the election of the holder and subject to the approval of the Plan Administrator, the cash value thereof) for each DSU on a future date. The Board may fix from time to time a portion of the total compensation (including annual retainer) paid by the Corporation to a director in a calendar year for service on the Board that are to be payable in the form of DSUs. In addition, a Participant may, with the Corporation's consent, be given, subject to the provisions of the Omnibus Equity Incentive Plan, the right to elect to receive a portion of the compensation owing to them in the form of DSUs.

Share-based Awards

The Plan Administrator may grant other types of equity-based or equity-related awards (including the grant or offer for sale of unrestricted Common Shares) in such amounts and subject to such terms and conditions, including, but not limited to, being subject to performance criteria, or in satisfaction of such obligations, as the Plan Administrator shall determine. Such awards may involve the issuance of actual Common Shares to Participants, or payment in cash or otherwise of amounts based on the value of Common Shares.

Dividend Equivalents

Except as otherwise determined by the Plan Administrator or as set forth in the particular award agreement, RSUs, PSUs, and DSUs shall be credited, in accordance with the terms of the Omnibus Equity Incentive Plan, with dividend equivalents in the form of additional RSUs, PSUs, and DSUs, as applicable, as of each dividend payment date in respect of which normal cash dividends are paid on Common Shares.

Blackout Periods

In the event an award expires, at a time when a scheduled blackout is in place or an undisclosed material change

or material fact in the affairs of the Corporation exists, the expiry of such award will be the date that is ten business days after which such scheduled blackout terminates or there is no longer such undisclosed material change or material fact.

Term

While the Omnibus Equity Incentive Plan does not stipulate a specific term for awards granted thereunder, as discussed below, awards may not expire beyond ten years from its date of grant, except where Shareholder approval is received or where an expiry date would have fallen within a blackout period of the Corporation. All awards must vest and settle in accordance with the provisions of the Omnibus Equity Incentive Plan and any applicable award agreement, which award agreement may include an expiry date for a specific award.

Financial Assistance

The Omnibus Equity Compensation Plan does not provide for the Corporation to give financial assistance to facilitate the purchases under the plan.

Termination of Employment or Services

The following describes the impact of certain events upon the participants under the Omnibus Equity Plan Incentive Plan, including termination for cause, resignation, termination without cause, disability, death or retirement, subject, in each case, to the terms of a Participant's applicable employment agreement, award agreement or other written agreement:

- Termination for Cause / Resignation: Any Option or other award held by the Participant that has not been exercised, surrendered, or settled as of the Termination Date (as defined in the Omnibus Equity Incentive Plan) shall be immediately forfeited and cancelled as of the Termination Date.
- Termination without Cause: Any unvested Option or other award which would otherwise vest or become exercisable in accordance with its terms based solely on the Participant remaining in the service of the Corporation on or prior to the date that is 90 days after the Termination Date shall immediately vest. Any vested Options may be exercised by the Participant within the time period contemplated by the Omnibus Equity Incentive Plan.
- Death or Disability: Any award that is held by the Participant that has not vested as of the date of the death or disability (as defined under the Omnibus Equity Incentive Plan) of such Participant shall vest on such date. Any vested Options may be exercised by the Participant, or Participant's beneficiary or legal representative (as applicable), within the time period contemplated by the Omnibus Equity Incentive Plan.
- Retirement: Any (i) outstanding award that vests or becomes exercisable based solely on the Participant remaining in the service of the Corporation or its subsidiary will become 100% vested, and (ii) outstanding award that vests based on the achievement of Performance Goals (as defined in the Omnibus Equity Incentive Plan) that has not previously become vested shall continue to be eligible to vest based upon the actual achievement of such Performance Goals. Any vested Options may be exercised by the Participant within the time period contemplated by the Omnibus Equity Incentive Plan.

Change in Control

Under the Omnibus Equity Incentive Plan, except as may be set forth in an employment agreement, award agreement or other written agreement between the Corporation or a subsidiary of the Corporation and a participant:

(a) If within 12 months following the completion of a transaction resulting in a Change in Control (as defined in the Omnibus Equity Inventive Plan), a Participant's employment, consultancy or directorship is terminated by the Corporation or a subsidiary of the Corporation without Cause (as defined in the Omnibus Equity Incentive Plan), without any action by the Plan Administrator:

(i) any unvested awards held by the participant at Termination Date shall immediately vest; and

(ii) any vested awards may be exercised, surrendered to the Corporation, or settled by the participant at any time during the period that terminates on the earlier of: (A) the expiry date of such award; and (B) the date that is 90 days after the Termination Date. Any award that has not been exercised,

surrendered, or settled at the end of such period being immediately forfeited and cancelled.

(b) Unless otherwise determined by the Plan Administrator, if, as a result of a Change in Control, the Common Shares will cease trading on the TSX, the Corporation may terminate all of the awards, other than an Option held by a participant that is a resident of Canada for the purposes of the *Income Tax Act* (Canada), granted under the Omnibus Equity Incentive Plan at the time of and subject to the completion of the Change in Control transaction by paying to each holder at or within a reasonable period of time following completion of such Change in Control transaction an amount for each Award equal to the fair market value of the award held by such participant as determined by the Plan Administrator, acting reasonably.

Non-Transferability of Awards

Except as permitted by the Plan Administrator and to the extent that certain rights may pass to a beneficiary or legal representative upon death of a participant, by will or as required by law, no assignment or transfer of awards, whether voluntary, involuntary, by operation of law or otherwise, vests any interest or right in such awards whatsoever in any assignee or transferee and immediately upon any assignment or transfer, or any attempt to make the same, such awards will terminate and be of no further force or effect. To the extent that certain rights to exercise any portion of an outstanding award pass to a beneficiary or legal representative upon the death of a participant, the period in which such award can be exercised by such beneficiary or legal representative shall not exceed one year from the Participant's death.

Amendments to the Omnibus Equity Incentive Plan

The Plan Administrator may also from time to time, without notice and without approval of the holders of voting Common Shares, amend, modify, change, suspend or terminate the Omnibus Equity Incentive Plan or any awards granted pursuant thereto as it, in its discretion, determines appropriate, provided that (a) no such amendment, modification, change, suspension or termination of the Omnibus Equity Incentive Plan or any award granted pursuant thereto may materially impair any rights of a participant or materially increase any obligations of a participant under the Omnibus Equity Incentive Plan without the consent of such participant, unless the Plan Administrator determines such adjustment is required or desirable in order to comply with any applicable securities laws or stock exchange requirements, and (b) any amendment that would cause an award held by a U.S. taxpayer to be subject to the income inclusion under Section 409A of the United States Internal Revenue Code of 1986, as amended, shall be null and void *ab initio*.

Notwithstanding the above, and subject to the rules of the TSX, the approval of Shareholders will be required to effect any of the following amendments to the Omnibus Equity Incentive Plan:

(a) increasing the number of Common Shares reserved for issuance under the Omnibus Equity Incentive Plan, except pursuant to the provisions in the Omnibus Equity Incentive Plan which permit the Plan Administrator to make equitable adjustments in the event of transactions affecting the Corporation or its capital;
(b) increasing or removing the 10% limits on Common Shares issuable or issued to insiders;
(c) reducing the exercise price of an option award (for this purpose, a cancellation or termination of an award of a participant prior to its expiry date for the purpose of reissuing an award to the same participant with a lower exercise price shall be treated as an amendment to reduce the exercise price of an award) except pursuant to the provisions in the Omnibus Equity Incentive Plan which permit the Plan Administrator to make equitable adjustments in the event of transactions affecting the Corporation or its capital;
(d) extending the term of an Option award beyond the original expiry date (except where an expiry date would have fallen within a blackout period applicable to the participant or within ten business days following the expiry of such a blackout period);
(e) permitting an Option award to be exercisable beyond ten years from its date of grant (except where an expiry date would have fallen within a blackout period);
(g) permitting awards to be transferred to a person;
(h) changing the eligible Participants; and
(i) deleting or otherwise limiting the amendments which require approval of the Shareholders.

Except for the items listed above, amendments to the Omnibus Equity Incentive Plan will not require Shareholder approval. Such amendments include (but are not limited to): (a) amending the general vesting provisions of an award, (b) amending the provisions for early termination of awards in connection with a termination of employment or service, (c) adding covenants of the Corporation for the protection of the Participants, (d) amendments that are desirable as a result of changes in law in any jurisdiction where a Participant resides, and (e) curing or correcting any ambiguity or defect or inconsistent provision or clerical omission or mistake or manifest error.

EQUITY COMPENSATION PLAN

The Corporation's Equity Compensation Plan dated June 1, 2020, is a "rolling" stock option plan that allows the Corporation to grant Share-Based Awards as well. “Award” means, individually or collectively, a grant under this Equity Compensation Plan of either options or share-based awards, in each case subject to the terms of the Equity Compensation Plan. A description of the Equity Compensation Plan in accordance with the disclosure requirements of the TSX is set out below. Due to adoption of the Omnibus Equity Incentive Plan, no further Options or share-based awards will be granted under the Equity Incentive Plan.

Eligible Participants: Directors, Employees, and Service Providers (as those terms are defined in the Equity Compensation) are eligible to be granted options and share-based awards under the Equity Compensation Plan and are Participants.

Plan Maximum: The number of Common Shares which may be issued pursuant to options granted under the Equity Compensation Plan may not exceed 10% of the issued Common Shares from time to time. Common Shares covered by an option that have been exercised, terminated, or expired shall again be available for an option grant. The maximum number of Share-Based Awards granted or issued in any fiscal year shall not exceed 3% of the issued and outstanding Common Shares of the corporation on the first day of such fiscal year.

Outstanding Securities Awarded: As of March 31, 2026, the total number of Common Shares issuable upon exercise of options granted under the Equity Compensation Plan is 60,000 Common Shares (representing approximately 0.05% of the Common Shares outstanding).

Remaining Securities Available for Grant: Due to adoption of the Omnibus Equity Incentive Plan, no further Options or share-based awards will be granted under the Equity Compensation Plan.

Limitations on Grants: The aggregate number of Common Shares issuable to insiders of the Corporation within any one-year period under the Equity Compensation Plan, or when combined with all of the Corporation’s other security-based compensation arrangements, shall not exceed 13% of the Corporation’s total issued and outstanding Common Shares. The number of Common Shares which may be issuable pursuant to exercise of Options shall not exceed 10% of issued Common Shares from time to time. The maximum number of Share-Based Awards granted or issued in any fiscal year shall not exceed 3% of the issued Common Shares, on the first day of such fiscal year. The aggregate number of Common Shares reserved for issuance to insiders of the Corporation at any time under the Equity Compensation Plan, or when combined with all of the Corporation’s other security-based compensation arrangements, shall not exceed 10% of the Corporation’s total issued and outstanding Common Shares.

Exercise Price: The exercise price of the Common Shares covered by each Option is determined by the Board. While the Common Shares are listed on the TSX, the exercise price shall not be less than the “Market Price” of the Common Shares at the time the option is granted. “Market Price” is defined in the Equity Compensation Plan as the closing price of the Common Shares on the TSX, or another stock exchange where the majority of the trading volume and value of the Common Shares occurs, on the day immediately preceding the relevant date.

Vesting: The Equity Compensation Plan provides that an option may be exercised (in each case to the nearest full share) during the term of the Option as follows: (a) one-third on the first anniversary of the date of the Option certificate relating to the options; (b) one-third on the second anniversary of the date of the option certificate; and the remaining one-third shall vest on the third anniversary of the date of the option certificate.

Term of Options: Subject to the termination and change of control provisions noted below, the term of any option granted under the Equity Compensation Plan is determined by the Board and may not exceed ten years from the

date of grant. Should the expiry date for an option fall within a blackout period or within nine business days following the expiration of a blackout period, such expiry date shall be automatically extended without any further act or formality to that date which is the tenth business day after the end of the blackout period, such tenth business day to be considered the expiry date for such option for all purposes under the Equity Compensation Plan. A "blackout period" is a period during which designated persons cannot trade Common Shares of the Corporation pursuant to any policy of the Corporation respecting restrictions on trading.

Termination: If the Participant is a director, Employee, or Service Provider of the Corporation and ceases to be such, other than by reason of death, then the expiry date of the Option is 90 days following the termination date, provided that, the Board has the discretion to waive the 90-day termination requirement, to permit the Participant to exercise any options for the full term of the Options, unless the Participant is terminated as a result of certain specified circumstances (including termination for cause for Employees and Service Providers) in which case the expiry date will be the date the Participant is terminated.

In the event of the death of a Participant, the Participant's Option may be exercised only within one year next succeeding such death and then only (i) by the person or persons to whom the Participant's rights under the Option shall pass by the Participant's will or the laws of descent and distribution, and (ii) to the extent that the Participant was entitled to exercise the Option at the date of death.

Change of Control: In the event of an actual or potential change of control, the Board has the right to deal with any Awards in the manner it deems equitable and appropriate in the circumstances, including the right to: (i) determine that any Awards will remain in full force and effect in accordance with their terms after the change of control; (ii) cause any Awards to be converted or exchanged for options to acquire shares of another entity involved in the change of control, having the same value and terms and conditions as the Awards; (iii) accelerate the vesting of any unvested Awards; (iv) provide Participants with the right to surrender any Awards for an amount per underlying Share equal to the positive difference, if any, between the fair market value of the Share on the date of surrender and the Award exercise price of such Awards; and (v) accelerate the date by which any Awards must be exercised.

Assignability: The benefits, rights, and Awards accruing to any Participant in accordance with the terms and conditions of the Equity Compensation Plan are not transferable or assignable. During the lifetime of a Participant any benefits, rights, and Awards may only be exercised by the Participant.

Amendment Provisions: The Equity Compensation Plan provides that the Board may from time to time amend the Equity Compensation Plan and the terms and conditions of any Award granted thereunder, provided that any such amendment, modification, or change to the provisions of the Equity Compensation Plan shall: (a) not adversely alter or impair any Award previously granted except as permitted by the adjustment provisions in the Equity Compensation Plan; (b) be subject to any regulatory approvals, where required, including the approval of the TSX, where necessary; (c) be subject to Shareholder approval in accordance with the rules of the TSX in circumstances where the amendment, modification, or change to the Equity Compensation Plan would (i) reduce the exercise price of an option held by an insider of the Corporation; (ii) extend the term of an Award held by an insider of the Corporation beyond the original term of the Award (other than pursuant to the blackout-period provisions); (iii) amend to remove or to exceed the insider participation limits in the Equity Compensation; (iv) increase the fixed maximum percentage of issued and outstanding Common Shares which may be issued pursuant to the Equity Compensation Plan or change from a fixed maximum percentage of issued and outstanding Common Shares to a fixed maximum number of Common Shares; or (v) amend the amendment provisions and (d) not be subject to Shareholder approval in circumstances where the amendment, modification, or change to the Equity Compensation Plan or Award would (i) be of a "housekeeping nature"; (ii) be necessary for Awards to qualify for favourable treatment under applicable tax laws; (iii) alter, extend, or accelerate any vesting terms or condition in the Equity Compensation Plan or any option; (iv) introduce, amend or modify any mechanics for exercising any Award (including relating to a cashless exercise feature or an automatic exercise feature); (v) change the term of an Award or change any termination provision in the Equity Compensation Plan or any Award (for example, relating to termination of employment, resignation, retirement, or death), provided that such change does not entail an extension beyond the original term of such option (other than such period being extended by virtue of the blackout provisions); (vi) introduce a share appreciation right feature payable in cash or Common Shares, provided that such feature provides for a full deduction of the number of underlying Common Shares from the Equity Compensation Plan maximum as applicable; (vii) change the application of the adjustment or change of control provisions; (viii) add a form of financial assistance or amend a financial assistance provision which is adopted; or

(ix) change the eligible participants under the Equity Compensation Plan.

Financial Assistance: The Equity Compensation Plan does not provide for the Corporation to give financial assistance to facilitate the purchase of Common Shares under the Equity Compensation Plan.

Taxes and Source Deductions: The Equity Compensation Plan provides that the Corporation or any subsidiary may take such reasonable steps for the deduction and withholding of any taxes and other required source deductions that the Corporation or the subsidiary, as the case may be, is required by any law or regulation of any governmental authority whatsoever to withhold, deduct, or remit in connection with the Equity Compensation Plan, any exercise or surrender of any option, or a portion thereof, by a Participant or any issuance of Common Shares to a Participant.

In addition, the delivery of any Common Shares to be issued to a Participant on the exercise or termination of options by the Participant, may be made conditional upon the Participant (or other person) reimbursing or compensating the Corporation or making arrangements satisfactory to the Corporation for the payment to it in a timely manner of all taxes required to be remitted for the account of the Participant.

During the 2021 fiscal year, the Corporation adopted the Omnibus Equity Incentive Plan which replaced the Equity Compensation Plan. No further grants will be made under the Equity Compensation Plan.

MARKET FOR SECURITIES

Common Shares

The Common Shares currently trade under the symbol “CRDL” on the TSX and the Nasdaq. The Common Shares commenced trading on the TSX on December 20, 2018 and commenced trading on the Nasdaq on August 10, 2021. The following table sets out the price range and trading volume of the Common Shares, as reported by the TSX, for each month traded in Cardiol’s financial year ended December 31, 2025, and the current fiscal year to date:

Common Shares

Month	Price Range		Total Volume
	High ($)	Low ($)	
January 2025	2.12	1.69	1,114,340
February 2025	2.12	1.51	1,172,096
March 2025	1.75	1.27	1,856,022
April 2025	1.63	1.09	2,143,442
May 2025	1.80	1.44	1,424,968
June 2025	2.04	1.64	1,360,812
July 2025	2.17	1.56	2,675,750
August 2025	2.05	1.31	4,754,442
September 2025	1.65	1.43	2,747,822
October 2025	1.93	1.41	3,702,110
November 2025	1.63	1.35	1,686,709
December 2025	1.55	1.24	2,324,396
January 2026	1.57	1.28	1,554,201
February 2026	1.49	1.28	1,405,384
March 1-30, 2026	1.77	1.23	3,266,960

ESCROWED SECURITIES AND SECURITIES SUBJECT TO CONTRACTUAL RESTRICTIONS ON TRANSFER

As at December 31, 2025, no outstanding Common Shares or other securities of Cardiol were held in escrow or subject to contractual restrictions on transfer, other than as described under “Capital Structure – Stock Options and other Share-Based Awards.

DIRECTORS AND MANAGEMENT

The following table sets out, for each of our directors and executive officers, the person’s name, province or state, and country of residence, position with us, principal occupation and, if a director, the date on which the person became a director. Our directors are expected to hold office until our next annual general meeting of Shareholders. Our directors are elected annually and, unless re-elected, retire from office at the end of the next annual general meeting of Shareholders. As a group, the Directors and executive officers beneficially own, or control or direct, directly or indirectly, a total of 3,414,864 Common Shares, representing 3.05% of the Common Shares outstanding.

Directors and Executive Officers

Name and Province or State and Country of Residence	Position with the Corporation	Since	Principal Occupation
David Elsley Ontario, Canada	Director, President and Chief Executive Officer	January 19, 2017	President and Chief Executive Officer of Cardiol since January 19, 2017.
Chris Waddick Ontario, Canada	Director, Chief Financial Officer and Corporate Secretary	Chief Financial Officer and Corporate Secretary since August 16, 2018 and Director since May 19, 2022	Chief Financial Officer and Corporate Secretary of Cardiol since August 16, 2018. Executive Vice President and CFO of Active Energy Inc., a private energy company, since January 2018 and President of NRJ Consulting Inc., a consulting company since November 2009.
Bernard Lim Ontario, Canada	Chief Operating Officer	December 3, 2020	Chief Operating Officer of Cardiol since December 3, 2020. Chair of the Board of AndersDx (UK), a technology company since 2009. Chair of the Board for Acuity Insights Inc., a technology company focused on professional screening for academic institutions since 2015. Chair of the Board of Front Line Medical, a vascular trauma medical device company since 2020.
Dr. Andrew Hamer New York, USA	Chief Medical Officer and Head of Research and Development	March 29, 2021	Chief Medical Officer of Cardiol since March 29, 2021. Served as Executive Director, Global Development-Cardiometabolic at California-based Amgen Inc.
Peter Pekos[(2)(5)] Ontario, Canada	Director	December 15, 2017	Founder of Dalton Pharma Services

Dr. Guillermo Torre-Amione[2][5] Monterrey, Mexico	Chair and Director	Director since August 20, 2018, and Chair since July 7, 2021	President of TecSalud. Previously, Chief of Heart Failure Division and Medical Director of Cardiac Transplantation, Houston Methodist DeBakey Heart & Vascular Center.
Colin Stott[1][5] Southport, United Kingdom	Director	December 3, 2019	Chief Operating Officer of Alterola Biotech Inc. Previously Chief Operating Officer of Protagenic Therapeutics Inc. and Alinova Biosciences Ltd. Previously Scientific Affairs Director, International and R&D Operations Director for GW Pharmaceuticals plc.
Jennifer Chao[2][4][5] New York, USA	Director	March 15, 2022	Founder/Advisory Analyst, CoreStrategies Management, LLC. Biopharma securities expert witness for biopharma litigation matters. Board Director for biopharma companies. Previously Managing Director and Senior Lead Biotechnology Securities Analyst at Deutsche Bank and RBC Capital Markets, and VP, Senior Lead Analyst, Leerink Swann & Co.
Teri Loxam[1][3][5] Pennsylvania, USA	Director	May 19, 2022	Chief Financial Officer of Compass Pathways plc. Director and Audit Chair of Vaxcyte Inc. Previously Chief Financial Officer of Gameto. Previously Chief Operating Officer and Chief Financial Officer of Kira Pharmaceuticals. Previously Chief Financial Officer of SQZ Biotech.
Timothy Garnett[1][5] Illinois, USA	Director	May 28, 2025	Chairman of the Board of Ophirex, Inc. Board Member of DAP Health and MapLight Therapeutics. Previously Chief Medical Officer of Eli Lilly and Company.

Notes:

(1) Member of the Audit Committee
(2) Member of the Corporate Governance and Compensation Committee
(3) Chair of the Audit Committee
(4) Chair of the CG&C Committee
(5) Independent

Biographies of Directors and Executive Officers

The following are brief profiles of our executive officers and directors, including a description of each individual's

principal occupation within the past five years.

David Elsley, MBA – President, Chief Executive Officer, and Director

Mr. David Elsley is a business leader with a proven track record of developing, financing, and managing all aspects of corporate development in life sciences organizations.

In 1990, Mr. Elsley founded Vasogen Inc., a biotechnology company focused on the research and commercial development of novel therapeutics for the treatment of heart failure and other inflammatory conditions. Mr. Elsley assembled a team of management, directors, and scientific advisors comprising industry professionals and thought leaders from North America and Europe.

Mr. Elsley managed and directed Vasogen's growth from start-up to an organization employing over 250 people with operations and R&D programs in Canada, the United States, and Europe. Mr. Elsley established the research and development infrastructure, partnerships, manufacturing capability, and corporate quality systems necessary to advance two anti-inflammatory therapies from concept to completion of international multi center pivotal phase III clinical trials involving 2,500 patients. Vasogen went public on the TSX and the Nasdaq, raising over $200 million to support corporate development and reached a market capitalization of over US$1 billion.

Mr. Elsley holds a Master of Business Administration from the Ivey School of Business, University of Western Ontario.

Andrew Hamer, MB, ChB – Chief Medical Officer and Head of Research and Development

Dr. Andrew Hamer brings 30 years of experience in the global life sciences industry, medical affairs, and cardiology practice to the Corporation. Most recently he served as Executive Director, Global Development-Cardiometabolic at California-based Amgen Inc., where he led the Global Development group for Repatha®, the LDL cholesterol lowering PCSK9 inhibitor evolocumab, which generated revenues of almost US$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.

Chris Waddick, MBA, CPA, CA – Chief Financial Officer, Corporate Secretary, and Director

Mr. Chris Waddick has over thirty years of experience in financial and executive roles in the biotechnology and energy industries, with substantial knowledge of public company management and corporate governance, and in designing, building, and managing financial processes, procedures, and infrastructure.

Mr. Waddick has served as Chief Financial Officer and Corporate Secretary of Cardiol since August 16, 2018. He serves as Executive Vice President and Chief Financial Officer for a private Ontario energy company where he was retained by the shareholders to refinance the company and establish a new strategic direction, as well as the appropriate financial infrastructure.

Mr. Waddick spent more than twelve years at Vasogen Inc., a biotechnology company focused on the research and commercial development of novel therapeutics for the treatment of heart failure and other inflammatory conditions. While serving as Chief Financial Officer and Chief Operating Officer, the company grew from start up to an organization employing over 250 employees that established the necessary systems and infrastructure to advance an anti-inflammatory therapy through to the completion of an international multi-center pivotal trial involving 2,500 patients. Vasogen went public on the TSX and the NASDAQ, raising over $200 million to support corporate development and reached a market capitalization of over US$ 1 billion. Prior to Vasogen, he held progressively senior financial positions at Magna International Inc. and Union Gas Limited. Mr. Waddick is a CPA and earned a business degree from Wilfrid Laurier University and a Master of Business Administration from York University.

Bernard Lim, BSc, PgDip, CEng (UK) – Chief Operating Officer

Mr. Bernard Lim is a senior executive with a proven track record of over thirty years in the life sciences industry spanning biotechnology, diagnostics, medical devices, and high-technology companies in North America and Europe. He was founder and CEO of a highly successful drug delivery company that he led from R&D through to commercialization and its eventual acquisition by Eli Lily. As Chair of the Board of Acuity Insights, he guided the company's spinout from the university and its subsequent rapid growth to become market leader in the US and Canada. As Chair of the Board of AndersDx, a private UK-based technology company, he led its growth to a profitable enterprise. He is also currently Chair of the Board of Front Line Medical Technologies, a vascular trauma company. Previously, Bernard was board director of Aventamed (Ireland), Senior Vice President, Operations for Vasogen, as well as head of UK operations for a technology multinational where he scaled its operations exponentially and delivered multifold improvements in quality and financial performance. He was also CEO of a glaucoma, Alzheimer's and an *in-vitro* diagnostics company and prior to that was head of R&D for a leading neonatology and pediatrics company.

Guillermo Torre-Amione, MD, PhD – Chair and Director

Board certified in Cardiovascular Disease and Advanced Heart Failure/Transplant Cardiology, Dr. Guillermo Torre-Amione is former chief of the Heart Failure Division and former medical director of Cardiac Transplantation at the Houston Methodist DeBakey Heart & Vascular Center.

He is a senior member at The Methodist Hospital Research Institute, full professor of medicine at the Weill Cornell Medical College of Cornell University, New York, and, more recently, became President of TecSalud, an academic medical center and medical school of the Instituto Tecnológico y de Estudios Superiores de Monterrey ("ITESM") in Mexico.

Dr. Torre-Amione spearheads the Gene and Judy Campbell Laboratory for Cardiac Transplant Research, where his primary areas of research include heart failure, cardiac transplant, and the role of the immune response in modulating the progression of heart failure. Dr. Torre-Amione initiated a series of clinical studies that led to an FDA-approved Phase II clinical trial of neurostimulation in heart failure, a novel approach to the treatment of patients with advanced heart failure.

After receiving his medical degree from the ITESM in Monterrey, Mexico, Dr. Torre-Amione moved to Chicago, where he conducted graduate studies in immunology that led to a doctorate degree in immunology from the University of Chicago. He completed his internship, residency, and cardiology fellowship at Baylor College of Medicine, Houston where he received his first academic appointment as a clinical instructor in 1995. [CF1.1]Dr. Torre-Amione has published more than 170 manuscripts in peer-reviewed journals and currently divides his time between his clinical and academic activities in Houston at The Methodist Hospital and in Monterrey, Mexico, at ITESM.

Peter Pekos, BSc, MSc – Director

Mr. Pekos is a veteran of the pharmaceutical services industry. In 1986, he was a founder of Dalton Pharma Services (Dalton).

Over three decades, he directed Dalton's growth based on strong client relationships. Dalton provides pharma and biotech clients with an array of integrated services in a world-class 42,000 square foot facility, with more than 100

employees, in the heart of one of North America's largest biomedical clusters. This includes premium contract chemistry research, a full range of analytical support, medicinal chemistry, formulation, cGMP manufacture of solid dosage forms, and cGMP aseptic fill-in vials and syringes.

Mr. Pekos is the former CEO of Dalton, where he guided the evolution of the company to best serve the changing needs of its clients throughout the major global economies, including the world's largest pharmaceutical companies. In 1983, he obtained a Chemistry/Biochemistry Double Specialist Degree with a Minor in Biology from the University of Toronto. In 1986, he completed a Master's Degree in synthetic chemistry at York University, and with his Professor, Doug Butler, founded Dalton with a very modest amount of capital. The company used incubator facilities at York University, and initially manufactured and sold specialty chemical compounds. Mr. Pekos also founded Ashbury Biologicals. Inc., a phyto-pharmaceutical company, Jupiter Consumer Products, a company that targeted the development of adult-focused confections, and several other technology-based companies focused on advanced materials and pharmaceutical development tools. Mr. Pekos was founding Chairman of ventureLAB a Regional Innovation Center located at IBM's York Region campus. VentureLAB guides government program delivery to support the innovation ecosystem for biotechnology and related industries in southern Ontario.

Colin G. Stott, BSc (Hons) – Director

Mr. Colin Stott is a veteran of the pharmaceutical and biotech industries, having almost 35 years' experience in pre-clinical and clinical development, with specific expertise in the development of cannabinoid-based medicines, and 19 years' experience in the field. Currently Chief Operating Officer of Alterola Biotech Inc., Mr. Stott is the former Scientific Affairs Director, International and R&D Operations Director for GW Pharmaceuticals plc ("GW Pharma"), a world leader in the development of cannabinoid therapeutics. As R&D Operations Director at GW Pharma for over 16 years, he was a key player in the development of their discovery and development pipeline, and was closely involved in the Marketing Authorization Application submission and approval of Sativex® and the New Drug Application submission of Epidiolex®, which was approved by the U.S. Food and Drug Administration as an orphan drug for the treatment of rare forms of paediatric epilepsy in June 2018, and the European Medicines Agency in September 2019 (as Epidyolex®). More recently, as Scientific Affairs Director, International, he was part of the Medical Affairs team responsible for the preparation of the international launch of Epidiolex®. Mr. Stott holds a BSc (Hons) in Medicinal & Pharmaceutical Chemistry and a Diploma in Industrial Studies from Loughborough University of Technology, U.K., as well as a Post Graduate Diploma in Clinical Research from the Welsh School of Pharmacy, Cardiff University, U.K. He has published over 20 research papers and is a named inventor on 17 international patent applications.

Jennifer Chao – Director

Ms. Jennifer Chao has over 25 years of experience in the biotech and life sciences industries focused primarily on securities analysis, drug development, expert witness litigation, and corporate strategy.

Ms. Chao is Founder/Advisory Analyst, CoreStrategies Management, LLC, providing transformational corporate and financial strategies to biotech/life science companies for maximizing core valuation. Ms. Chao also serves as a biopharma securities expert witness for high-level biopharma litigation matters working with large economic consulting firms and law firms on cases involving material and fair disclosure, securities valuation, insider trading, and corporate governance.

Prior, Ms. Chao has served on the Board of Directors of Endo International plc ("Endo") (member, Audit Committee and Compliance Committee), Edesa Biotech (Chair, Nominating and Corporate Governance Committee and member, Audit Committee), and Chair, BioSpecifics Technologies Corp. (BioSpecifics) through its acquisition by Endo for approximately US $660 million in December 2020 (Chair, BioSpecifics' Compensation Committee, member of the Audit Committee, Strategy Committee, Intellectual Property Committee, and Nominating and Corporate Governance Committee from 2015 to 2020).

Additionally, from 2004 to 2008, Ms. Chao served as Managing Director and Senior Lead Biotechnology Securities Analyst at Deutsche Bank, responsible for U.S. large- and small- to mid-cap biotechnology companies with global client coverage with a focus on differentiated fundamentals securities analysis and high visibility coverage of game changing technologies, paradigm shifting treatment algorithms, industry trends and portfolio risk/reward management. Ms. Chao has also served as Managing Director and Senior Lead Biotechnology Analyst at RBC Capital Markets and VP, Senior Biotechnology Analyst at Leerink Swann & Co. Ms. Chao is a recipient of the

BioMedical Research Career Award and served as a research fellow at Massachusetts General Hospital/Harvard Medical School, and received her B.A. in Politics and Greek Classics from New York University.

Teri Loxam – Director

Teri Loxam has over 25 years of experience in the pharmaceutical, life sciences, and TMT industries with diverse roles spanning strategy, investor relations, finance, and communications. Ms. Loxam is the Chief Financial Officer of Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. Ms. Loxam previously served as Chief Financial Officer of Gameto, a biotechnology company using cell engineering to develop therapeutics for diseases of the female reproductive system. In this role, Ms. Loxam oversaw the financial function, as well as playing a key role in overall company strategy. Prior to joining Gameto, Ms. Loxam was Chief Operating Officer and Chief Financial Officer at Kira Pharmaceuticals, a clinical-stage biotech company developing transformative therapies for people with complement-mediated diseases. Prior to joining Kira, Ms. Loxam served as Chief Financial Officer at SQZ Biotech where she led the company's financial operations, investor relations and communications/public relations functions. While at SQZ, she was instrumental in helping the company raise over $200M in private and public funding, including taking the company public through an IPO on the NYSE in October 2020. Prior to joining SQZ, Ms. Loxam held various positions at Merck, IMAX Corporation, and Bristol-Myers Squibb across strategy, investor relations, treasury, and communications. She started her career as a marine biologist and worked at Sea World of San Diego before making a transition into business. Ms. Loxam is a member of the board of directors and audit chair of Vaxcyte, Inc. (Nasdaq: PCVX). She holds an MBA from the University of California, Irvine, and a Bachelor of Science degree in Biology from the University of Victoria, B.C., Canada.

Timothy Garnett, MD – Director

Dr. Garnett is a distinguished veteran of the pharmaceutical industry. Dr. Garnett spent over 20 years at Eli Lilly and Company in roles of increasing responsibility including serving as Chief Medical Officer from 2008 until 2021.

At Eli Lilly he led the successful development of therapeutics in women's health care, endocrinology, and neuroscience resulting in multiple product launches globally. Dr. Garnett has extensive experience leading clinical development and in portfolio management, medical, regulatory, and safety functions, and he has a strategic understanding of the landscape for metabolic therapeutics. He is currently Board Chair of Ophirex, a public benefit corporation focused on developing an affordable, accessible, oral antivenom treatment and is a Board member of MapLight Therapeutics, Inc., a clinical stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating brain disorders.

In addition, Dr. Garnett is also a member of the Advisory Panel of Cambridge Innovation Capital and an equity partner at Recode Health Ventures LLC. He holds a Bachelor of Medicine and a Bachelor of Surgery (MBBS) from St. George's, University of London, and is a Fellow of both the Faculty of Pharmaceutical Medicine (FFPM), and the Royal College of Obstetricians and Gynaecologists (FRCOG).

Corporate Cease-Trade Orders

None of our Directors or executive officers has, within the ten years prior to the date of this Annual Report, been a director, chief executive officer, or chief financial officer of any company (including Cardiol) that, while such person was acting in that capacity (or after such person ceased to act in that capacity but resulting from an event that occurred while that person was acting in such capacity) was the subject of a cease-trade order, an order similar to a cease-trade order, or an order that denied the company access to any exemption under securities legislation, in each case for a period of more than 30 consecutive days.

Corporate Bankruptcies

Other than as provided below, none of our Directors or executive officers has, within the ten years prior to the date of this Annual Report, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager, or trustee appointed to hold its assets, been a director or executive officer of any company, that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted

any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager, or trustee appointed to hold its assets.

Ms. Chao was a director of Endo International plc in August 2022, when it voluntarily filed a petition for Chapter 11 bankruptcy protection in the US Bankruptcy Court for the Southern District of New York. In connection with the Chapter 11 filing, Endo entered into a Restructuring Support Agreement with senior secured debtholders. In March 2024, the US Bankruptcy Court for the Southern District of New York approved a proposed plan of reorganization that included the sale of substantially all of the assets of Endo International plc to a newly formed entity, Endo, Inc. In April 2024, Endo, Inc. completed the acquisition of substantially all of the assets of Endo International plc.

Penalties or Sanctions

No Director or executive officer of the Corporation or Shareholder holding sufficient securities of the Corporation to affect materially the control of the Corporation has:

- been subject to any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
- been subject to any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor making an investment decision.

Conflicts of Interest

To the best of our knowledge, there are no known existing or potential conflicts of interest among us and our Directors, officers, or other members of Management as a result of their outside business interests except that certain of our Directors and officers serve as directors and officers of other companies, and therefore it is possible that a conflict may arise between their duties to us and their duties as a director or officer of such other companies.

AUDIT COMMITTEE INFORMATION

Charter of the Audit Committee

The full text of the current Terms of Reference for the Audit Committee is attached as Schedule A to this AIF.

Composition of the Audit Committee

The Corporation's Audit Committee consists of three Directors, all of whom are independent pursuant to Nasdaq's independence standards. They are also all financially literate, including within the meaning of NI 52-110. The members of the Audit Committee are Teri Loxam (Chair), Timothy Garnett, and Colin Stott.

Relevant Education and Experience

See the respective biographies of each member of the Audit Committee in "Directors and Management – Biographies of Directors and Executive Officers" for a description of the experience that is relevant to the performance of their responsibilities as Audit Committee members.

Reliance on Certain Exemptions

At no time since the commencement of Cardiol's most recently completed financial year has the Corporation relied on any of the exemptions provided in NI 52-110.

Audit Committee Oversight

At no time since the commencement of the Corporation's most recently completed financial year have any recommendations by the Audit Committee respecting the appointment and/or compensation of the Corporation's external auditors not been adopted by the Board of Directors of Cardiol.

Pre-Approval Policies and Procedures

The policy and procedures relating to the pre-approval of non-audit services provided to the Corporation are described in the Terms of Reference for the Audit Committee attached as Schedule A to this AIF.

External Auditor Service Fees

The aggregate fees billed by Cardiol's external auditors in each of the last two fiscal years for audit fees are as follows:

Fee Category	Year Ended December 31, 2025	Year Ended December 31, 2024
Audit Fees[1]	$403,570	$468,286
Audit-Related Fees[2]	$nil	$nil
Tax Fees[3]	$nil	$nil
All Other Fees[4]	$nil	$nil
Total	**$403,570**	**$468,286**

Notes:

(1) "Audit fees" means the aggregate fees billed for professional services rendered by our principal accounting firm for the audit of the Corporation's annual financial statements and the review of its comparative interim financial statements.
(2) "Audit-related fees" means the aggregate fees billed for professional services rendered by the Corporation's principal accounting firm for the assurance and related services, which mainly included the audit and review of financial statements and are not reported under "Audit fees" above.
(3) "Tax fees" means the aggregate fees billed for professional services rendered by the Corporation's principal accounting firm for tax compliance, tax advice and tax planning.
(4) "Other fees" means the aggregate fees incurred in each of the fiscal years listed for the professional tax services rendered by the Corporation's principal accounting firm other than services reported under "Audit fees," "Audit-related fees" and "Tax fees."

The policy of the Corporation's Audit Committee is to pre-approve all non-audit services provided by BDO Canada LLP, its independent registered public accounting firm, including audit services, audit-related services, tax services, and other services as described above. Pursuant to this policy, the Audit Committee pre-approved all of the services provided to us by BDO Canada LLP during the year ended December 31, 2025.

PROMOTERS

Mr. David Elsley may be considered to be a promoter of the Corporation within the meaning of applicable securities legislation. As of the date hereof: Mr. Elsley owns 1,344,500 Common Shares, representing 1.20% of the outstanding Common Shares of the Corporation.

During 2025, for services as President, Chief Executive Officer and Director of the Corporation, Mr. Elsley received an annual salary of $525,000 (paid in cash and securities) and 350,000 stock options, exercisable at $1.40 for 5 years from grant.

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

Cardiol was not involved in any legal proceedings during the year ended December 31, 2025 that had, or could have, a material adverse effect on Cardiol. Moreover, to the knowledge of Cardiol's management, Cardiol is not currently involved in any outstanding, threatened or pending litigation that could have a material adverse effect on Cardiol.

To the knowledge of Cardiol, during the financial year ended December 31, 2025, there were no: (i) penalties or sanctions imposed against Cardiol by a court relating to securities legislation or by a securities regulatory authority;

(ii) any other penalties or sanctions imposed by a court or regulatory body against Cardiol that would likely be considered important to a reasonable investor in making an investment decision; or (iii) settlement agreements Cardiol entered into before a court relating to securities legislation or with a securities regulatory authority.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

There have been no related-party transactions in the two most recently completed financial years of Cardiol that required disclosure under any applicable Canadian securities laws other than disclosed in note 16 to the Corporation's 2025 audited financial statements, and note 17 to the Corporation's 2024, and 2023 audited financial statements, copies of which are available on SEDAR+ at www.sedarplus.com.

TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar for the Common Shares in Canada and the United States is Odyssey Trust Company, and the register of transfers of the Common Shares is located in Toronto, Ontario.

MATERIAL CONTRACTS

The following are material contracts of Cardiol required to be filed on SEDAR+ pursuant to NI 51-102:

1. the Dalton Services Agreement (See "Business of Cardiol - Commercialization Relationships – Dalton"),
2. the Purisys Exclusive Supply Agreement (See "Business of Cardiol - Commercialization Relationships – Purisys"),

Copies of the material contracts set out above are available under our profile on SEDAR+ at www.sedarplus.com.

INTERESTS OF EXPERTS

BDO is independent with respect to the Corporation within the meaning of the Rules of Professional Conduct of the Chartered Professional Accountants of Ontario.

ADDITIONAL INFORMATION

Additional information relating to Cardiol may be found on SEDAR+ at www.sedarplus.com. Additional financial information is provided in Cardiol's audited financial statements and management's discussion and analysis for Cardiol's most recently completed financial year, copies of which have been filed on SEDAR+ and are available at www.sedarplus.com.

SCHEDULE A

CARDIOL THERAPEUTICS INC.
(THE "CORPORATION")

AUDIT COMMITTEE CHARTER

1. POLICY STATEMENT

It is the policy of the Corporation to establish and maintain an Audit Committee (the "Committee") to assist the directors (individually a "Director" and collectively the "Board") of the Corporation in carrying out the Board's oversight responsibility for the accounting, internal controls, financial reporting, audits of financial statements, and risk management processes of the Corporation.

The Committee shall be provided with resources commensurate with the duties and responsibilities assigned to it by the Board including appropriate administrative support. Without limiting the generality of the foregoing, the Corporation shall provide for appropriate funding, as determined by the Committee in its capacity as a committee of the Board, for payment of: (a) compensation to any registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Corporation; (b) compensation to any advisors engaged by the Committee under Section 4(c)(iii) of this charter; and (c) ordinary administrative expenses of the Committee that are necessary or appropriate in carrying out its duties.

If determined appropriate by the Committee, it shall have the discretion to institute investigations of improprieties, or suspected improprieties, within the scope of its responsibilities, including the standing authority to retain special counsel or other experts. The Committee shall have unrestricted access to the Corporation's External Auditors, is authorized to seek any information that it requires from any employee and all employees are directed to co-operate with any request made by the Committee.

2. COMPOSITION OF COMMITTEE

(a) The Committee shall be established by a resolution of the Board. The Committee shall consist of a minimum of three Directors. The Board shall appoint the members of the Committee and may seek the advice and assistance of the Corporate Governance Committee in identifying qualified candidates. The Board shall appoint one member of the Committee to be the chair of the Committee (the "Chair").

(b) All of the members of the Committee shall be Directors who are independent within the meaning of National Instrument 52-110 – Audit Committees ("NI 52-110"), and the rules of any stock exchange or market on which the Corporation's shares are listed or posted for trading (collectively, "Applicable Governance Rules"). In this charter, the term "independent" includes the meanings given to similar terms by Applicable Governance Rules, including the terms "non-executive", "outside" and "unrelated" to the extent such terms are applicable under Applicable Governance Rules. No member of the Committee shall have participated in the preparation of the financial statements of the Corporation or any current subsidiary of the Corporation at any time during the past three years. In addition, in order to be considered to be independent, a member of the Committee may not, other than in his or her capacity as a member of the Committee, the Board or any other Board committee: (i) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the Corporation or any subsidiary thereof, provided that, unless the rules of any stock exchange or market on which the Corporation's shares are listed or posted for trading provide otherwise, compensatory fees do not include the receipt of fixed amounts of compensation under a retirement plan (including deferred compensation) for prior service with the Corporation (provided that such compensation is not contingent in any way on continued service); or (ii) be an affiliated person of the Corporation or any subsidiary thereof.

(c) All members of the Committee must be able to read and understand fundamental financial

statements (including a balance sheet, income statement and cash flow statement) and read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and level of complexity of the issues that can reasonably be expected to be raised by the Corporation's financial statements.

(d) The Committee must have at least one member who has past employment in finance or accounting, requisite professional certification in accounting, or any other comparable experience or background which results in that individual's financial sophistication, including being or having been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities.

(e) A Director appointed by the Board to the Committee shall be a member of the Committee until replaced by the Board or until his or her resignation.

3. MEETINGS OF THE COMMITTEE

(a) The Committee shall convene a minimum of four times each year at such times and places as may be determined by the Chair of the Committee and whenever a meeting is requested by the Board, a member of the Committee, the auditors or senior management of the Corporation. Scheduled meetings of the Committee shall correspond with the review of the quarterly and year-end financial statements and management discussion and analysis.

(b) Notice of each meeting of the Committee shall be given to each member of the Committee.

(c) Notice of a meeting of the Committee shall:

(i) be in writing, which includes electronic communication facilities;

(ii) state the nature of the business to be transacted at the meeting in reasonable detail;

(iii) to the extent practicable, be accompanied by a copy of any documentation to be considered at the meeting; and

(iv) be given at least two business days prior to the time stipulated for the meeting or such shorter period as the members of the Committee may permit.

(d) A quorum for the transaction of business at a meeting of the Committee shall consist of a majority of the members of the Committee. However, it shall be the practice of the Committee to require review, and, if necessary, approval of important matters by all members of the Committee.

(e) A member or members of the Committee may participate in a meeting of the Committee by means of such telephonic, electronic, or other communication facilities as permits all persons participating in the meeting to communicate with each other. A member participating in such a meeting by any such means is deemed to be present at the meeting.

(f) In the absence of the Chair of the Committee, the members of the Committee shall choose one of the members present to chair the meeting. In addition, the members of the Committee shall choose one of the persons present to be the secretary of the meeting.

(g) The Committee may invite such persons to attend meetings of the Committee as the Committee considers appropriate, except to the extent exclusion of certain persons is required pursuant to this charter or by applicable laws.

(h) The Committee may invite the External Auditors to be present at any meeting of the

Committee and to comment on any financial statements, or on any of the financial aspects, of the Corporation.

(i) The Committee (A) shall meet with the External Auditors separately from individuals other than the Committee, and (B) may meet separately with management of the Corporation.

(j) Minutes shall be kept of all meetings of the Committee and shall be signed by the chair and the secretary of the meeting. The Chair of the Committee shall circulate the minutes of the meetings of the Committee to all members of the Board.

4. DUTIES AND RESPONSIBILITIES OF THE COMMITTEE

(a) The Committee, in its capacity as a committee of the Board, is directly responsible for selecting the public accounting firm to be nominated for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Corporation (the "External Auditor") as well as the compensation of the External Auditor. The Committee shall also be directly responsible for the oversight of the work of the External Auditor (including resolution of disagreements between management and the auditor regarding financial reporting) and each such External Auditor must report directly to the Committee.

(b) The other primary duties and responsibilities of the Committee are to:

(i) identify and monitor the management of the principal risks that could impact the financial reporting of the Corporation;

(ii) monitor the integrity of the Corporation's financial reporting process and system of internal controls regarding financial reporting and accounting compliance;

(iii) monitor the independence, objectivity, and performance of the External Auditors, including, without limitation: (A) ensuring the Committee's receipt from the External Auditors at least annually of a formal written statement delineating all relationships between the External Auditors and the Corporation; (B) actively engaging in dialogue with the External Auditors with respect to any disclosed relationships or services that may impact the objectivity and independence of the External Auditor; and (C) taking, or recommending that the Board take, appropriate action to oversee the independence of the External Auditors;

(iv) evaluate the performance of the External Auditors at least annually; deal directly with the External Auditors to approve external audit plans, other services (if any), and fees;

(v) directly oversee the external audit process and results (in addition to items described in Section 4(e) below);

(vi) provide an avenue of communication between the External Auditors, management, and the Board;

(vii) review annually with management of the Corporation the anti-fraud, anti-bribery, anti-corruption, and risk assessment programs of the Corporation;

(viii) carry out a review designed to ensure that an effective "whistle blowing" procedure exists to permit stakeholders to express any concerns regarding accounting or financial matters to an appropriately independent individual; and

(c) The Committee shall have the authority to:

(i) inspect any and all of the books and records of the Corporation and its subsidiaries;

(ii) discuss with the management of the Corporation and its subsidiaries, any affected

party and the External Auditors, such accounts, records, and other matters as any member of the Committee considers appropriate;

(iii) engage independent counsel and other advisors as it determines necessary to carry out its duties; and

(iv) set and pay the compensation for any advisors engaged by the Committee.

Relationship with the Board

(d) The Committee shall, at the earliest opportunity after each meeting, report to the Board the results of its activities and any reviews undertaken and make recommendations to the Board as considered appropriate.

Relationship with External Auditors

(e) The Committee shall:

(i) review the audit plan with the External Auditors and with management;

(ii) review with the External Auditors the critical accounting policies and practices used by the Corporation, all alternative treatments of financial information within IFRS that the External Auditors have discussed with management, the ramifications of the use of such alternative disclosures and treatments, and the treatment preferred by the External Auditors;

(iii) discuss with management and the External Auditors any proposed changes in major accounting policies or principles, the presentation and impact of material risks and uncertainties and key estimates and judgments of management that may be material to financial reporting;

(iv) review with management and with the External Auditors material financial reporting issues arising during the most recent financial period and the resolution or proposed resolution of such issues;

(v) review any problems experienced or concerns expressed by the External Auditors in performing any audit, including any restrictions imposed by management or any material accounting issues on which there was a disagreement with management;

(vi) review with the External Auditors any accounting adjustments that were noted or proposed by the independent auditor but that were “passed” (as immaterial or otherwise), any communications between the audit team and the External Auditor’s national office respecting auditing or accounting issues presented by the engagement, any “management” or “internal control” letter or schedule of unadjusted differences issued, or proposed to be issued, by the External Auditors to the Corporation, or any other material written communication provided by the External Auditors to the Corporation’s management;

(vii) review with senior management the process of identifying, monitoring, and reporting the principal risks affecting financial reporting;

(viii) review and discuss with management and the External Auditors any off-balance sheet transactions or structures and their effect on the Corporation’s financial results and operations, as well as the disclosure regarding such transactions and structures in the Corporation’s public filings;

(ix) review the audited annual financial statements (including management discussion and analysis) and related documents in conjunction with the report of the External

Auditors and obtain an explanation from management of all material variances between comparative reporting periods;

(x) consider and review with management the internal control memorandum or management letter containing the recommendations of the External Auditors and management's response, if any, including an evaluation of the adequacy and effectiveness of the internal financial controls and procedures for financial reporting of the Corporation and subsequent follow-up to any identified weaknesses;

(xi) review with financial management and the External Auditors the quarterly unaudited financial statements and management discussion and analysis before release to the public;

(xii) periodically meet separately with management and the External Auditors;

(xiii) oversee the financial affairs of the Corporation and its subsidiaries and, if deemed appropriate, make recommendations to the Board, External Auditors, or management;

(xiv) discuss with management and the External Auditors any correspondence with regulatory or governmental agencies that raise material issues regarding the Corporation's financial statements or accounting policies;

(xv) consider the recommendations of management in respect of the appointment and terms of engagement of the External Auditor;

(xvi) pre-approve all audit and non-audit services to be provided to the Corporation or its subsidiaries by its External Auditors, or the External Auditors of subsidiaries of the Corporation, subject to the overriding principle that the External Auditors not be permitted to be retained by the Corporation to perform internal audit outsourcing services or financial information systems services; provided that notwithstanding the above, the foregoing pre-approval of non-audit services may be delegated to a member of the Committee, with any decisions of the member with the delegated authority reporting to the Committee at the next scheduled meeting;

(xvii) approve the engagement letter for non-audit services to be provided by the External Auditors or affiliates of External Auditors, together with estimated fees, and consider the potential impact of such services on the independence of the External Auditors;

(xviii) when there is to be a change of External Auditors, review all issues and provide documentation related to the change, including the information to be included in the notice of change of auditors and documentation required pursuant to the then current legislation, rules, policies and instruments of applicable regulatory authorities and the planned steps for an orderly transition period; and

(xix) review all reportable events, including disagreements, unresolved issues and consultations, as defined by applicable laws, on a routine basis, whether or not there is to be a change of the External Auditors.

(f) In connection with the public disclosure of financial information and other public disclosure, the Committee shall:

(i) review the Corporation's financial statements, management discussion and analysis, and annual and interim profit or loss press releases before the Corporation publicly discloses this information;

(ii) review with management its evaluation of the Corporation's procedures and

controls designed to assure that information required to be disclosed in the Corporation's periodic public reports is recorded, processed, summarized, and reported in such reports within the time periods specified by applicable securities laws for the filing of such reports ("Disclosure Controls") and consider whether any changes are appropriate in light of management's evaluation of the effectiveness of such Disclosure Controls;

(iii) establish a policy, which may include delegation to an appropriate member or members of management, for release of earnings press releases, as well as for the release of financial information and earnings guidance provided to analysts and rating agencies;

(iv) satisfy itself that adequate procedures are in place for the review of the Corporation's public information extracted from the Corporation's financial statements, other than the public information reviewed in accordance with Section 4(f)(i), and periodically assess the adequacy of those procedures;

(v) to the extent deemed appropriate, review and supervise the preparation by management of:

(A) the annual information forms, management information circulars, and annual and interim financial statements of the Corporation and any other information of the Corporation filed by the Corporation with applicable securities regulators;

(B) press releases of the Corporation containing financial information, earnings guidance, forward-looking statements, information about operations, or any other material information;

(C) correspondence broadly disseminated to shareholders of the Corporation; and

(D) other relevant written and oral communications or presentations;

(vi) before release, review and if appropriate, recommend for approval by the Board, all public disclosure documents containing audited or unaudited financial information, including any prospectuses, annual reports, annual information forms, management discussion and analysis, and press releases, focusing particularly on:

(A) any changes in accounting policies and practices;

(B) any important areas where judgment must be exercised;

(C) significant adjustments resulting from the audit;

(D) the going concern assumption, if any;

(E) compliance with accounting standards; and

(F) compliance with stock exchange and legal requirements.

(g) The Committee shall enquire into and determine the appropriate resolution of any conflict of interest in respect of audit or financial matters which are directed to the Committee by any member of the Board, a shareholder of the Corporation, the External Auditors, or senior management.

(h) The Committee shall periodically review with management the need for an internal audit function.

(i) The Committee shall review the accounting and reporting of costs, liabilities, and

contingencies of the Corporation.

(j) The Committee shall periodically discuss with management the Corporation's major financial risk exposures, and the steps management has taken to monitor and control such exposures.

(k) The Committee shall establish, monitor, and review policies and procedures for internal accounting, financial control, and management information.

(l) The Committee shall periodically discuss with management the Corporation's process for performing its quarterly certifications pursuant to Multilateral Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings and the U.S. Sarbanes-Oxley Act.

(m) The Committee shall review with the Chief Executive Officer and Chief Financial Officer of the Corporation any report on significant deficiencies in the design or operation of the internal controls that could adversely affect the Corporation's ability to record, process, summarize, or report financial data, any material weaknesses in internal controls identified to the auditors, and any fraud, whether or not material, that involves management or other employees who have a significant role in the Corporation's internal controls.

(n) The Committee shall establish and maintain procedures for:

(i) the receipt, retention, and treatment of complaints received by the Corporation regarding accounting, internal accounting controls, or auditing matters;

(ii) the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or auditing matters; and

(iii) reviewing arrangements by which staff of the Corporation may, in confidence, raise concerns about possible improprieties in matters of financial reporting and ensuring that arrangements are in place for proportionate and independent investigation and follow-up action.

(o) At each meeting of the Committee, the Committee shall review any complaints or concerns of employees of the Corporation regarding accounting, internal accounting controls, or auditing matters relating to the Corporation and violations of any applicable law, rule, or regulation and shall follow the procedures established under the Corporation's Whistleblower Policy regarding such concerns and complaints.

(p) The Committee shall review all related-party transactions and discuss the business rationale for these transactions and determine whether appropriate disclosures have been made. For this purpose, the term "related-party transactions" includes any "material transaction" required to be disclosed under Item 13 of Form 51-102F2 under National Instrument 51-102 – Continuous Disclosure Obligations.

(q) The Committee shall review the Corporation's compliance and ethics programs, including consideration of legal and regulatory requirements, and shall review with management its periodic evaluation of the effectiveness of such programs.

(r) The Committee shall review and approve the Corporation's hiring policies regarding partners, employees, and former partners and employees of the present and former External Auditors.

(s) The Committee shall receive any reports from legal counsel of evidence of a material violation of securities laws or breaches of fiduciary duty by the Corporation.

(t) The Committee shall review with the Corporation's legal counsel, on no less than an annual

basis, any legal matter that could have a material impact on the Corporation's financial statements and any enquiries received from regulators or government agencies.

(u) The Committee shall assess, on an annual basis, the adequacy of this charter and the performance of the Committee.

SCHEDULE B

References

1. Bragazzi NL, Zhong W, Shu J, et al. Burden of heart failure and underlying causes in 195 countries and territories from 1990 to 2017. Eur J Prev Cardiol. 2021;28(15):1682-1690. doi:10.1093/eurjpc/zwaa147

   Tsao CW et al.; American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2023 Update: A Report From the American Heart Association. Circulation. 2023 Jan 25.

2. Adler Y, Charron P. The 2015 ESC Guidelines on the diagnosis and management of pericardial diseases. Eur Heart J. 2015;36(42):2873-2874. doi:10.1093/eurheartj/ehv479

   Chiabrando JG, Bonaventura A, Vecchié A, et al. Management of Acute and Recurrent Pericarditis: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020;75(1):76-92. doi:10.1016/j.jacc.2019.11.021

   Lin D, Laliberté F, Majeski C, et al. Disease and economic burden associated with recurrent pericarditis in a privately insured United States population. Adv Ther. 2021;38(10):5127.

   Luis SA, LeWinter MM, Magestro M, et al. Estimating the US pericarditis prevalence using national health encounter surveillance databases. Curr Med Res Opin. 2022;38(8):1385-1389. doi:10.1080/03007995.2022.2070381

   Klein A, Cremer P, Kontzias A, et al. US Database Study of Clinical Burden and Unmet Need in Recurrent Pericarditis. J Am Heart Assoc. 2021;10(15):e018950. doi:10.1161/JAHA.120.018950

   Imazio M, Brucato A, Adler Y. A randomized trial of colchicine for acute pericarditis. N Engl J Med. 2014;370(8):781. doi:10.1056/NEJMc1315351

   Tingle LE, Molina D, Calvert CW. Acute pericarditis. Am Fam Physician. 2007;76(10):1509-1514.

   Kytö V, Sipilä J, Rautava P. Clinical profile and influences on outcomes in patients hospitalized for acute pericarditis. Circulation. 2014;130(18):1601-1606. doi:10.1161/CIRCULATIONAHA.114.010376

   Mody P, Bikdeli B, Wang Y, Imazio M, Krumholz HM. Trends in acute pericarditis hospitalizations and outcomes among the elderly in the USA, 1999-2012. Eur Heart J Qual Care Clin Outcomes. 2018;4(2):98-105. doi:10.1093/ehjqcco/qcx040

3. Ammirati E, Cipriani M, Moro C, et al. Clinical Presentation and Outcome in a Contemporary Cohort of Patients With Acute Myocarditis: Multicenter Lombardy Registry. Circulation. 2018;138(11):1088-1099. doi:10.1161/CIRCULATIONAHA.118.035319

   Ammirati E, Moslehi JJ. Diagnosis and Treatment of Acute Myocarditis: A Review. JAMA. 2023;329(13):1098-1113. doi:10.1001/jama.2023.3371

   Basso C. Myocarditis. N Engl J Med. 2022; 387(16):1488-1500. doi:10.1056/NEJMra2114478

   Bemtgen X, Kaier K, Rilinger J, et al. Myocarditis mortality with and without COVID-19: insights from a national registry. Clin Res Cardiol. 2024;113(2):216-222. doi:10.1007/s00392-022-02141-9

   Khorolsky, C, Shi, J, Chkhikvadze, T. TRENDS IN HOSPITALIZATION COSTS, LENGTH OF STAY AND COMPLICATIONS AMONG PATIENTS WITH ACUTE MYOCARDITIS: A 10-YEAR UNITED STATES PERSPECTIVE. J Am Coll Cardiol. 2019 Mar, 73 (9_Supplement_1) 935.

   Lynge TH, Nielsen TS, Gregers Winkel B, Tfelt-Hansen J, Banner J. Sudden cardiac death caused by myocarditis in persons aged 1-49 years: a nationwide study of 14?294 deaths in Denmark. Forensic Sci Res. 2019;4(3):247-256. Published 2019 Aug 19. doi:10.1080/20961790.2019.1595352

   Tschöpe C, Ammirati E, Bozkurt B, et al. Myocarditis and inflammatory cardiomyopathy: current evidence and future directions. Nat Rev Cardiol. 2021;18(3):169-193. doi:10.1038/s41569-020-00435-x

   Wang X, Bu X, Wei L, Liu J, Yang D, Mann DL, Ma A and Hayashi T (2021) Global, Regional, and National Burden of Myocarditis From 1990 to 2017: A Systematic Analysis Based on the Global Burden of Disease Study 2017. Front. Cardiovasc. Med. 8:692990. doi: 10.3389/fcvm.2021.692990

Klein AL, Imazio M, Cremer P, et al. Phase 3 Trial of Interleukin-1 Trap Rilonacept in Recurrent Pericarditis [RHAPSODY]. N Engl J Med. 2021;384(1):31-41.

Imazio M, Klein AL, Brucato A, et al. Sustained Pericarditis Recurrence Risk Reduction With Long-Term Rilonacept. J Am Heart Assoc. 2024;13(6).

Brucato A, Imazio M, Gattorno M, et al. Effect of Anakinra on Recurrent Pericarditis Among Patients With Colchicine Resistance and Corticosteroid Dependence: The AIRTRIP Randomized Clinical Trial. JAMA. 2016;316(18):1906-1912.

Imazio et al. Multi-Year Recurrent Pericarditis Disease Duration in Italian Patients: Clinical Outcomes After Cessation of Long-term IL-1 Blocker Pathway Inhibition Provide Insights for Chronic Management. Poster presented at ESC2024.

Cremer P, Wang T, Klein AL et al. Outcomes of Rilonacept Cessation in Patients with Chronic Recurrent Pericarditis. Poster presented at ACC2024.

4. htttps://www.europarl.europa.eu/RegData/etudes/IDAN/2015/554174/EPRS_IDA(2015)554174_EN.pdf
5. https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm
6. ICH_E8-R1_Guideline_Step4_2021_1006.pdf
7. https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/prescription-drug-marketing-act-1987
8. https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments
9. SBIA Chronicles. Patents and Exclusivity. May 19, 2015. https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM447307. pdf
10. ttps://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program
11. https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm
12. https://www.fda.gov/ForPatients/Approvals/Fast/ucm405397.htm
13. https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products
14. https://www.ema.europa.eu/en/human-regulatory-overview/orphan-designation-overview
15. https://www.fda.gov/forpatients/approvals/fast/default.htm
16. https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/accelerated-assessment
17. https://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm