

Corporate Presentation

## Heal the heart with innovative science

We are a clinical-stage life sciences company focused on the research and clinical development of anti-inflammatory and anti-fibrotic therapies for the treatment of heart disease

Cardiolrx.com
June 2024

TSX: CRDL NASDAQ: CRDL



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CardiolRx™ is a registered trademark of Cardiol Therapeutics Inc.



# Developing Novel Therapeutic Approaches for Patients with Underserved Heart Diseases



#### Phase II Programs in Rare Diseases

CardiolRx™, lead small molecule oral drug candidate, granted FDA orphan drug designation (ODD) for treatment of pericarditis and ODD eligible for treatment of acute myocarditis.



#### **Broad Exclusivity Protection**

Comprehensive intellectual property portfolio. Focused on rare diseases eligible for FDA and EMA orphan drug and medicine designations with 7–10-year marketing exclusivity.



#### **Actionable Drug Target**

Modulation of inflammasome activation reduces the release of mediators responsible for the inflammation and fibrosis contributing to myopericardial disease and heart failure.



#### Leadership

Experienced Management team, Board of Directors, and Scientific Advisory Board, with extensive expertise in developing therapeutics for inflammatory heart disease.



#### **Innovative Research**

Advancing the development of CRD-38, a novel proprietary subcutaneously administered pharmaceutical intended for use in heart failure.

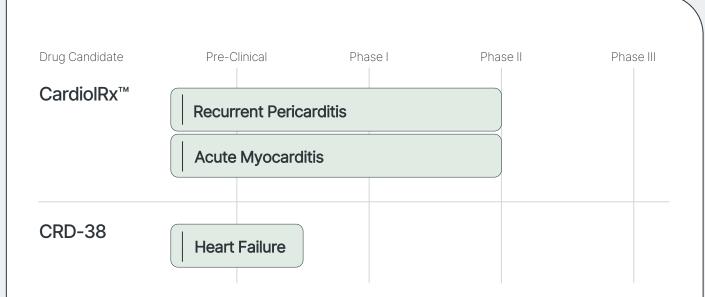


#### **Strong Financial Position**

Debt-free and well-capitalized to achieve corporate milestones into 2026.

### Product Pipeline

Developing small molecule drug candidates that attenuate multiple inflammatory signaling pathways, including inhibiting activation of the NLRP3 inflammasome, known to play an important role in the inflammation and fibrosis associated with pericarditis, myocarditis, and heart failure.



- FDA Orphan Drug Designation (ODD) granted to CardiolRx™ for the treatment of pericarditis.
- CardiolRx™ eligible for FDA ODD in acute myocarditis and EMA orphan medicine designations for recurrent pericarditis and acute myocarditis.

#### Key Global Research and **Clinical Collaborators**

Working together with world-class researchers and clinicians at international centers of excellence and leveraging their expertise in drug development, experimental execution, inflammation and fibrosis, the treatment of cardiovascular diseases, and clinical trial protocol design. The collaborations provide optimal advice and knowledge platform in pursuit of Cardiol's purpose: heal the heart with innovative science.

























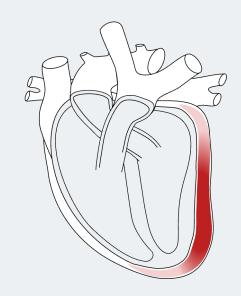
#### **MAVERIC-Pilot Study**

Phase II study to evaluate the tolerability, safety, and efficacy of CardiolRx<sup>™</sup> in patients with recurrent pericarditis.



#### **Recurrent Pericarditis**

- Pericarditis refers to inflammation of the pericardium (the membrane, or sac, surrounding the heart) that leads to fluid accumulation (effusion) and pericardial thickening.
- Recurrent pericarditis is the reappearance of symptoms after a symptom-free period of at least 4 6 weeks following an index acute episode.
- Symptoms include debilitating chest pain, shortness of breath, and depression.
- Quality of life and physical activity adversely affected with severe cases requiring emergency department visits or hospitalizations.
- CardiolRx<sup>™</sup> granted FDA Orphan Drug Designation for the treatment of pericarditis, which includes recurrent pericarditis – eligible as an orphan drug with EMA.



4.7 - 6.2 years

The average duration of recurrent pericarditis in patients who are difficult to treat.

18,000

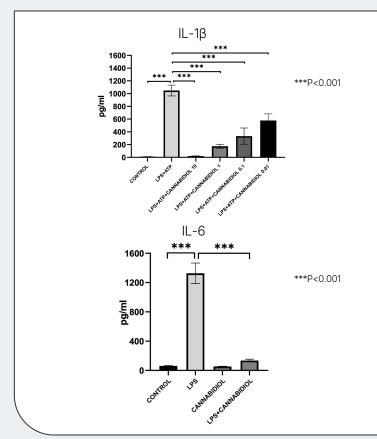
Pericarditis hospitalizations per year in the United States (based on 5.4/100,000).

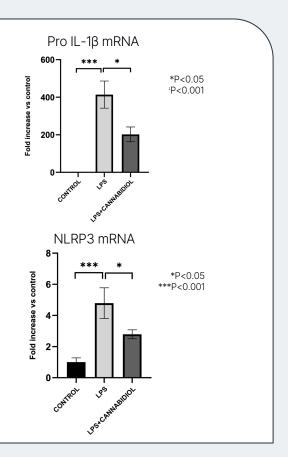
38,000

Number of recurrent pericarditis patients in the United States annually.

# Significant Reduction of Multiple in vitro Parameters Demonstrated Pre-clinically

IL-1 $\beta$  & IL-6 Secretion Inhibited; Transcription Levels of pro-IL-1 $\beta$  & NLRP3 Reduced.

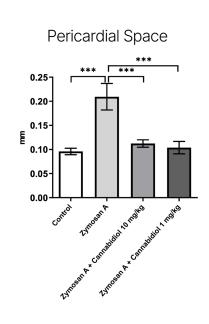




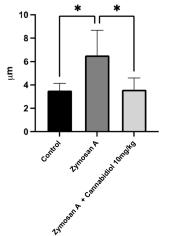


Martinez-Naya N et al. Circ Res 2022; 131:e169-e190.

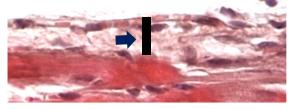
#### Significant Reduction in **Pericardial** Effusion & **Pericardial Thickness** Demonstrated in vivo **Pre-clinically**



#### Pericardial Thickness



#### Zymosan A



Zymosan A + Cannabidiol 10 mg/kg



Pericardial thickness of heart sections stained with hematoxylin and eosin.



#### Advisors and Key Investigators for the MAvERIC-Pilot Study



Allan Klein, MD, CM Study Chair Director, Center for the Diagnosis and Treatment of Pericardial Diseases, and Professor of Medicine, Heart, Vascular and Thoracic Institute, Cleveland Clinic.



Departments of Medicine and Radiology, Northwestern University, and Multimodality Cardiac Imaging and Clinical Trials Unit, Bluhm Cardiovascular Institute.



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.



Allen Luis, MBBS, PhD

Co-Director of the Pericardial Diseases Clinic, Associate Professor of Medicine, Department of Cardiovascular Medicine, at Mayo Clinic Rochester Minnesota.



Stefano Toldo, PhD
Associate Professor of Medicine, Department of Medicine, Cardiovascular Medicine at University of Virginia.



**Stephen Nicholls,** MBBS, PhD Program Director, Victorian Heart Hospital, Director, Monash Victorian Heart Institute, and Professor of Cardiology, Monash University, Melbourne.

Paul Cremer, MD

#### CardiolRx<sup>™</sup> for Recurrent Pericarditis

Phase II MAvERIC-Pilot Study

Multi-center, open-label pilot study to assess the safety and tolerability of CardiolRx™ during the resolution of a pericarditis recurrence, evaluate improvement in objective measures of disease, and assess the feasibility of weaning concomitant background therapy while taking CardiolRx™.

25

**Patients** 

Open-label design

5 - 10

**Clinical Sites** 

**United States** 

#### Primary Efficacy Endpoint

• Change, from baseline to 8 weeks, in patientreported pericarditis pain using an 11-point numeric rating scale (NRS\*).

#### Additional Endpoints during Extension Period

- The NRS score after 26 weeks of treatment.
- Changes in the inflammatory marker C-reactive protein (CRP).

\*The NRS is a validated clinical tool used across multiple conditions with acute and chronic pain, including previous studies of recurrent pericarditis

ClinicalTrials.gov identifier: NCT05494788

## Recurrent Pericarditis: Market Opportunity

Unmet Medical Need: An oral drug targeting the inflammatory process for patients intolerant to treatment, colchicine resistant, or corticosteroid dependent.

#### **Current Pharmacotherapy**

- First-line conventional treatment: NSAIDs or aspirin with or without colchicine<sup>(1)</sup>.
- Second-line therapy for patients with continued recurrence and inadequate response: corticosteroids (despite safety issues and difficulty tapering or discontinuation<sup>(1)</sup>).
- One FDA-approved therapy: >\$150,000/year (rilonacept) primarily used for ≥3 recurrences.

#### Cases/year (United States) & Impact

- 160,000 (based on 40/100,000<sup>(2)</sup>) annual prevalence; includes 38,000 with a recurrence.
- \$20 \$30k average hospitalization costs and 6 8-day length of stay<sup>(3)</sup>.
- $30\%^{(3)}$  experience a recurrence  $\leq$  18 months; up to 50% with a recurrent episode experience more recurrences<sup>(4)</sup>.

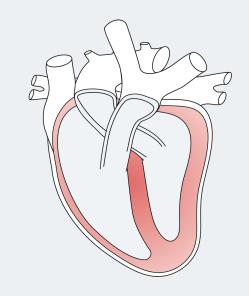
#### **ARCHER Trial**

Phase II study of CardiolRx™ in patients with acute myocarditis.



#### **Acute Myocarditis**

- Inflammatory condition of the heart muscle (myocardium) often resulting from viral infection.
- Characterized by chest pain, impaired heart function, arrythmias, and conduction disturbances.
- An important cause of acute and fulminant heart failure in young adults and a leading cause of sudden cardiac death in people <35 years of age.</li>
- CardiolRx<sup>™</sup> eligible as an orphan drug with FDA and EMA.



37 years

Average age of patient hospitalized with acute myocarditis in the United Kingdom.

4 - 6%

In-hospital mortality as a percentage of acute myocarditis admissions.

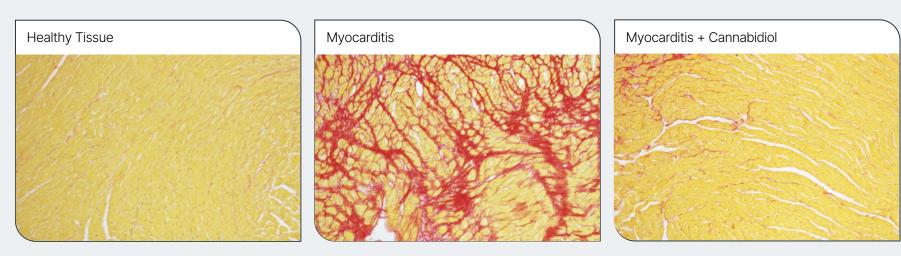
32,400

Number of deaths worldwide due to myocarditis in 2019.

#### Cannabidiol Attenuates Myocarditis-induced Fibrosis

Effect of Cannabidiol on Heart Fibrosis

#### Sections of Heart Tissue – Fibrosis



Representative images of Sirius red-stained LV myocardium sections. Magnification: 100x.

NASDAQ: CRDL | TSX: CRDL June 2024

#### Steering Committee for the ARCHER Trial



Dennis M. McNamara, MD

Chair

Professor of Medicine at the University of Pittsburgh. He is also the Director of the Heart Failure/Transplantation Program at the University of Pittsburgh Medical Center.



**Arvind Bhimaraj,** MD

Specialist in Heart Failure and Transplantation Cardiology and Associate Professor of Cardiology, Institute for Academic Medicine at Houston Methodist and at Weill Cornell Medical College, NYC.



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.



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.



Leslie T. Cooper, Jr., MD

Co-Chair

General cardiologist and the Chair of the Mayo Clinic Enterprise Department of Cardiovascular Medicine, as well as chair of the Department of Cardiovascular Medicine at the Mayo Clinic in Florida.



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



Carsten Tschöpe, MD

Professor of Medicine and Cardiology and Vice Director of the Department of Internal Medicine and Cardiology, University Medicine Berlin.



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.



Mathieu Kerneis, MD, PhD

Interventional cardiologist at Pitié Salpêtrière Hospital (Sorbonne University).

#### **CardiolRx**<sup>™</sup> for Acute Myocarditis

Phase II ARCHER Trial

Multi-national, double-blind, randomized, placebocontrolled trial designed to study the safety and tolerability of CardiolRx™, as well as its impact on myocardial recovery in patients presenting with acute myocarditis.

100

Randomized patients

50 to CardiolRx™, 50 to placebo

25 - 35

**Clinical Sites** 

North America, Europe, Latin America, and Israel

#### **Primary Efficacy Endpoints\***

- Extracellular volume (ECV).
- Global longitudinal strain (GLS).

#### Secondary Efficacy Endpoint\*

· Left ventricular ejection fraction.

\*Measured by cardiac magnetic resonance imaging at 12 weeks post randomization

ClinicalTrials.gov identifier: NCT05180240

# Acute Myocarditis: Market Opportunity

Unmet Medical Need: A well-tolerated therapeutic targeting the myocardial inflammatory process.

#### **Current Pharmacotherapy**

- No FDA-approved therapies for acute myocarditis.
- Management: guideline directed therapy for heart failure and arrythmia (e.g., β-blockers, ACE-I, ARBs, inotropes, diuretics).
- Goal: decrease cardiac workload, reduce congestion and improve hemodynamics.
- Corticosteroids to treat inflammation: not uniformly prescribed due to patient tolerance, side effects, optimal dosing.

#### Cases/year (United States) & Impact

- 46,000 (based on 14.4/100,000<sup>(1)</sup>).
- $\sim$ 10% hospitalized<sup>(2)(3)</sup>: >\$110K average hospital charges and 7-day average length of stay.
- Complications: heart failure, cardiogenic shock, unstable heart rhythm, cardiac arrest, and/or organ failure.
- Severe cases: ventricular assist device, extracorporeal oxygenation, or heart transplant.
- Up to 30% develop a chronic inflammatory dilated cardiomyopathy $^{(4)(5)}$ .

#### **Heart Failure**

CRD-38 is a novel proprietary subcutaneously administered drug formulation of cannabidiol intended for use in heart failure.



#### **Heart Failure**

- A complex clinical syndrome with signs and symptoms that result from any structural or functional impairment of ventricular filling or ejection of blood in the heart.
- Patients experience shortness of breath, rapid heart rate, and edema, resulting in reduced exercise capacity, limitations undertaking simple daily activities, and frequent hospitalizations.
- Risk factors: hypertension (high blood pressure), obesity, diabetes, smoking, and atherosclerotic cardiovascular disease.
- Developing CRD-38 as a potential therapeutic strategy in heart failure care\*.

#### \$108 billion

Estimated economic cost of heart failure globally in 2012.

#### 3.3 million

Annual number of physician visits with a primary diagnosis of heart failure in the United States.

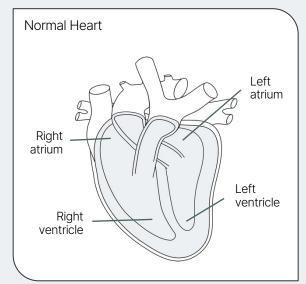
#### 53%

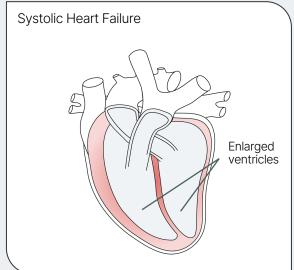
The 5-year overall mortality rate for patients with heart failure.

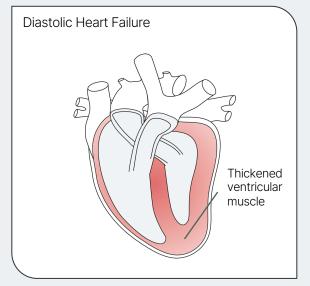
\*The Company is pursuing IND-enabling activities to support the clinical evaluation of CRD-38.

#### Types of Heart Failure

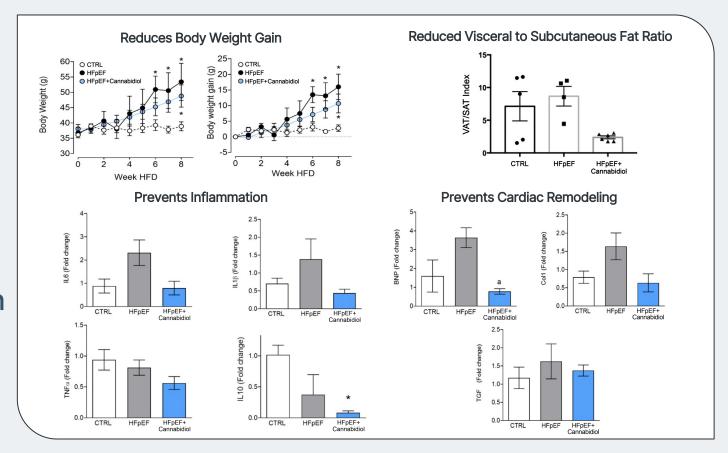
- Systolic heart failure, also referred to as heart failure with reduced ejection fraction (HFrEF), occurs when the heart loses its ability to contract normally and is unable to pump with sufficient force to push enough blood into circulation.
- Diastolic heart failure, also referred to as heart failure with preserved ejection fraction (HFpEF), occurs when the heart loses its ability to relax normally (because the myocardium has become fibrotic and stiff) and cannot properly fill with blood during the resting period between each beat.







#### Subcutaneous **CRD-38 Administered** Cannabidiol as a Potential **Treatment For Heart Failure** With Preserved **Ejection Fraction**



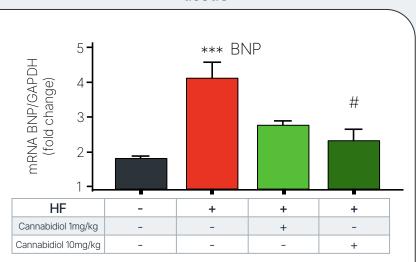




#### Cardioprotective Properties of Subcutaneous Cannabidiol Formulation

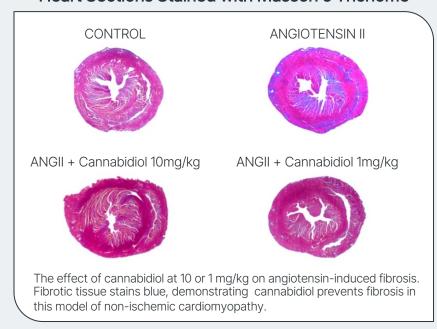
#### Demonstrated in a Non-ischemic Model of Heart Failure

#### Measurements of BNP mRNA expression in heart tissue



Groups of animals with angiotensin II-induced heart failure treated with cannabidiol at 1 or 10 mg/kg show attenuated BNP increase. Raised BNP levels reflect cardiac stretch indicative of heart failure.

#### Heart Sections Stained with Masson's Trichome



Lozano O et al., JACC 75, no. 11 (March 2020): 705.

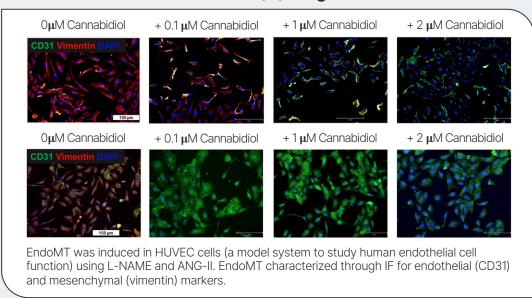
### Cannabidiol Inhibits and also Promotes Reversal of Mechanisms leading to Cardiac Fibrosis in a Dose Dependent Manner

Protects cardiac function and exhibits an anti-fibrotic effect, possibly mediated by endothelial-to-mesenchymal transition ("EndoMT")

**Top Panel:** Cannabidiol was added during 4 days of EndoMT induction; the transition process was inhibited in a dose dependent manner as exhibited by a reduced expression of vimentin through IF.

**Bottom Panel:** Cannabidiol added to EndoMT transitioned calls (after Day 4 of EndoMT) and IF performed on Day 8; Cannabidiol was shown to reduce vimentin expression k suggesting reversal of EndoMT *in vitro* 

#### Immunoflourescence (IF) images of HUVEC cells



Krishnamoorthi MK et al. J Card Fail. 2023;29(4):567

#### Heart Failure: Market Opportunity

Unmet Medical Need: A therapeutic targeting the inflammation and fibrosis associated with the syndrome.

#### **Current Pharmacotherapy**

- Treatment goals: improve symptoms, patient clinical status, functional capacity, and quality of life; prevent hospitalizations; reduce mortality.
  - HFrEF (systolic): guideline directed therapy includes four core medication classes RAS inhibitors, MRAs, β-blockers, and SGLT2 inhibitors; diuretics as needed.
  - HFpEF (diastolic): SGLT2 inhibitors and diuretics as needed; treat underlying hypertension and/or CAD with RAS inhibitors, MRAs, β-blockers.

#### Cases/year (United States) & Impact

- 6 million people >20 years of age are living with heart failure; number projected to increase to 8 million by 2030.
- Total cost estimated at >\$30 billion; by 2030, projected to increase to \$69.8 billion.
- Annual healthcare utilization: 1.9 million physician visits, 414,000 emergency department visits, and up to 1.2 million hospitalizations.

#### **Major Milestones**

- Phase II Recurrent
  Pericarditis Study
- Topline results Q2 2024.
- Initiate Phase III program\*.

- Phase II Acute
  Myocarditis Study
- Complete 100% enrollment.
- Report top-line data.

- 3 Subcutaneous Administered CRD-38
- Complete IND-enabling studies.
- Initiate Phase I clinical program.

#### **Management Team**



**David Elsley,** MBA

President and Chief Executive Officer

Founder and former President and CEO of Vasogen Inc. More than 30 years' experience developing, financing, and managing corporate development of life sciences companies.



Chris Waddick, CPA, CMA, MBA

Chief Financial Officer

Thirty years of experience in financial and executive roles in the biotechnology and energy industries, former Chief Financial Officer and Chief Operating Officer of Vasogen Inc.



Andrea B. Parker, MSc, PhD

Senior Director of Clinical Operations

Clinical Epidemiologist with more than 30 years' experience in clinical trials design, management, and execution in industry and academic settings. Former Chief Scientific Officer at Peter Munk Cardiac Centre, University Health Network.



Anne Tomalin, BA, BSc, RAC

Director of Regulatory and Quality

Founder of CanReg Inc. and TPIreg, regulatory firms previously sold to Optum Insight and Innomar Strategies, respectively. An expert in regulatory affairs in Canada, the United States, and Europe.



Andrew Hamer, MBChB

Chief Medical Officer and Head of Research & Development

Thirty years of global life sciences industry, medical affairs, and cardiology practice experience. Served as Executive Director, Global Development Cardiometabolic at Amgen Inc. Principal or co-investigator for 40 multi-centre clinical trials.



Bernard Lim, MIET, CEng (UK)

**Chief Operating Officer** 

Thirty years in the life sciences industry spanning biotechnology, diagnostics, medical devices, and high-technology. 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 Lilv.



John A. Geddes, MBA

Vice President, Business Development

Over 25 years experience in the healthcare industry, comprising roles within pharmaceutical, biotechnology, clinical diagnostics, and life science research technology companies. Former Corporate Senior Director, Business Development at Luminex Corporation, a DiaSorin Company.

#### **Board of Directors**



Guillermo Torre-Amione, MD, PhD

Chairman

Professor of Cardiology at the Methodist Hospital Research Institute, Professor of Medicine at the Weill Cornell Medical College of Cornell University, and President of TecSalud. Former Chief of the Heart Failure Division and former medical director of Cardiac Transplantation at the Houston Methodist DeBakey Heart & Vascular Center.



Jennifer Chao, BA

Managing Partner of CoreStrategies Management

Over twenty-five years of experience in the biotech and life sciences industries focused primarily on finance and corporate strategy. Founded CoreStrategies Management in 2008 to provide transformational corporate and financial strategies to biotech/life science companies for maximizing core valuation.



Colin G. Stott, BSc (Hons)

Chief Operating Officer of Alterola Biotech Inc.

Thirty years' experience in pre-clinical and clinical development, with specific expertise in the development of cannabinoid-based medicines. Former Scientific Affairs Director, International and R&D Operations Director for GW Pharmaceuticals plc, a world leader in the development of cannabinoid therapeutics.



Teri Loxam, MBA

Chief Financial Officer of Compass Pathways

Over twenty-five years of experience in the pharmaceutical, life sciences, and TMT industries with diverse roles spanning strategy, investor relations, finance, and communications. Former Chief Financial Officer of Gameto, and Chief Operating Officer and Chief Financial Officer at Kira Pharmaceuticals



David Elsley, MBA

President and Chief Executive Officer

Founder and former President and CEO of Vasogen Inc. More than 30 years' experience developing, financing, and managing corporate development of life sciences companies.



Peter Pekos, BSc, MSc

Founder of Dalton Pharma Services

Broad experience in the research, development, and commercialization of pharmaceuticals, products, and services.



Chris Waddick, CPA, CMA, MBA

Chief Financial Officer

Thirty years of experience in financial and executive roles in the biotechnology and energy industries, former Chief Financial Officer and Chief Operating Officer of Vasogen Inc.



Michael J. Willner, Esq.

Founder of Willner Capital, Inc.

Active and successful investor for +40 years, with a focus on the life sciences and pharmaceutical cannabinoid sectors. As both former Attorney and a Certified Public Accountant, he practiced real estate and corporate law at a prominent NYC based international law firm following his initial tenure as a tax accountant with an international accounting firm.

#### Scientific Advisory Board



Dr. Paul M. Ridker, MD, MPH

Senior Advisor

Director of the Center for Cardiovascular Disease Prevention, a translational research unit at Brigham and Women's Hospital (BWH), he is also the Eugene Braunwald Professor of Medicine at Harvard School of Medicine (HMS). Dr. Ridker's clinical interests include coronary artery disease and the underlying causes and prevention of atherosclerotic disease. He has authored of over 900 peer-reviewed publications and reviews. 64 book chapters, and six textbooks related to cardiovascular medicine. Notably, Dr. Ridker has been the Principal Investigator or Study Chairman of several large international trials that have demonstrated the role of inflammation in the genesis and management of coronary artery disease. He was awarded the Gotto Prize for Atherosclerosis Research from the International Atherosclerosis Society in 2021 and is an elected Member of the National Academy of Medicine (USA).



Dr. Bruce McManus, PhD, MD

Senior Advisor

Professor Emeritus, Department of Pathology and Laboratory Medicine, the University of British Columbia. He has served as CEO. Centre of Excellence for Prevention of Organ Failure (PROOF Centre), Director, UBC Centre for Heart Lung Innovation, and Scientific Director, Institute of Circulatory and Respiratory Health, CIHR. Dr. McManus' investigative passion relates to mechanisms, consequences, detection and prevention of injury and aberrant repair in inflammatory diseases of the heart and blood vessels. His life's scholarship is reflected in more than 400 original peer-reviewed publications, over 60 chapters, and several books. Dr. McManus received the prestigious Max Planck Research Award in 1991, was elected a Fellow of the Royal Society of Canada in 2002, was appointed a Member of the Order of Canada in 2018, and to the Order of British Columbia the following year.



Dr. Joseph A. Hill, MD, PhD

Senior Advisor

Professor of Internal Medicine and Molecular Biology, Chief of Cardiology at UT Southwestern Medical Center, Dallas, TX, and Director of the Harry S. Moss Heart Center. Dr. Hill holds both the James T. Willerson, M.D., Distinguished Chair in Cardiovascular Diseases, and the Frank M. Ryburn Jr. Chair in Heart Research. His research examines molecular mechanisms of structural, functional, metabolic, and electrophysiological remodeling in cardiac hypertrophy and heart failure. Dr. Hill was elected to the Association of American Professors and given the 2018 Research Achievement Award from the International Society for Heart Research. For the past seven years, Dr. Hill has been the Editor-in-Chief of the prestigious American Heart Association journal Circulation.

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#### Phase II Programs in Rare Diseases

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#### **Broad Exclusivity Protection**

Comprehensive intellectual property portfolio. Focused on rare diseases eligible for FDA and EMA orphan drug and medicine designations with 7–10-year marketing exclusivity.



#### **Actionable Drug Target**

Modulation of inflammasome activation reduces the release of mediators responsible for the inflammation and fibrosis contributing to myopericardial disease and heart failure.



#### Leadership

Experienced Management team, Board of Directors, and Scientific Advisory Board, with extensive expertise in developing therapeutics for inflammatory heart disease.



#### Innovative Research

Advancing the development of CRD-38, a novel proprietary subcutaneously administered pharmaceutical intended for use in heart failure.



#### Strong Financial Position

Debt-free and well-capitalized to achieve corporate milestones into 2026.

### Cardiol Therapeutics