CORPORATE PRESENTATION

# \*\*CardiolTherapeutics

NASDAQ: CRDL | TSX: CRDL

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#### FORWARD-LOOKING INFORMATION

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CardiolRx™ is a registered trademark of Cardiol Therapeutics Inc.



## Focused on Advancing Therapies that Target Inflammation in the Heart



#### LATE-STAGE PIPELINE IN UNDERSERVED HEART DISEASE MARKETS

Inflammatory heart diseases including recurrent pericarditis, acute myocarditis, and heart failure.



#### LARGE MARKET OPPORTUNITIES

Lead drug candidate CardiolRx<sup>™</sup> for recurrent pericarditis targets a \$600M/year market, expected to exceed \$1B by 2028. CRD-38 in development for the multi-billion-dollar heart failure market.



#### **DISEASE-MODIFYING POTENTIAL**

Targeting inflammasome activation pathways to address the underlying inflammation central to heart disease without immune suppression.



#### STRONG PHASE II CLINICAL DATA

MAVERIC results demonstrate rapid and durable reductions in pericarditis pain; ARCHER data show significant improvements in cardiac structure associated with increased risk of mortality and hospitalization.



#### **NEAR-TERM CATALYSTS**

Presentation and publication of new ARCHER data in myocarditis; report data from pivotal Phase III MAVERIC trial in recurrent pericarditis; advance CRD-38 into clinical development for heart failure; progress strategic partnering discussions.

## Late-stage Clinical Pipeline in Pericarditis and Myocarditis, with IND-Enabling Program in Heart Failure

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

	PRODUCT	INDICATION	STATUS	PRE-CLINICAL PHASE I PHASE III PHASE III	
	<b>CardiolRx™</b> Oral*	Recurrent Pericarditis	MAVERIC Phase III initiated		MECH (Ca
		Acute Myocarditis	ARCHER Phase II topline data reported		Mod path the re
	CRD-38 Subcutaneous*	Heart Failure	IND-enabling		These the deve
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#### MECHANISM OF ACTION

(CardiolRx<sup>™</sup> & CRD-38)

Modulate inflammasome pathway activation and the release of inflammatory cytokines (IL-1 & IL-6).

These cytokines contribute to the development and progression of pericarditis, myocarditis, and heart failure.

\*Chemically synthesized pharmaceutical formulation of cannabidiol.



# MAVERIC Program

Late-stage Clinical Development of CardiolRx™ for the Treatment of Recurrent Pericarditis

## Recurrent Pericarditis

Strikes healthy adults in the prime of their lives

- Pericarditis refers to inflammation of the membrane that surrounds the heart (the pericardium).
- Symptoms include severe chest pain, shortness of breath, fatigue, and reduced quality of life.
- Recurrent pericarditis is a repeat episode of pericardial inflammation after a 4 – 6-week symptom-free period.

38,000

Recurrent pericarditis patients in the U.S.

18,000

Pericarditis hospitalizations per year in the U.S.

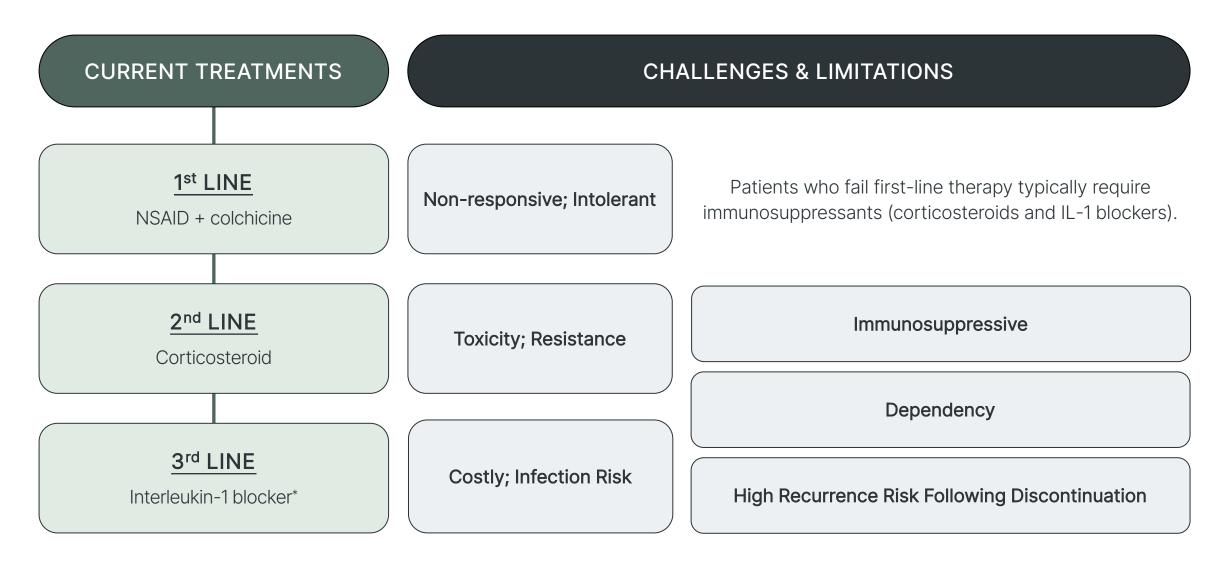
4.7 - 6.2 years

Duration of recurrent pericarditis in difficult to treat patients

\$286,000/year

One FDA-approved therapy primarily used for multiple recurrences

### Recurrent Pericarditis Treatment Challenges



\*Only FDA-approved therapy for recurrent pericarditis. List price \$286,000/year, primarily used for multiple recurrences.

## MAvERIC-Pilot Phase II Study

Results presented at the American Heart Association Scientific Sessions 2024

## 27 Patients Enrolled at 8 U.S Sites

















#### PRIMARY ENDPOINT

Change in pericarditis pain score (NRS\*) at 8 weeks

#### SECONDARY ENDPOINTS

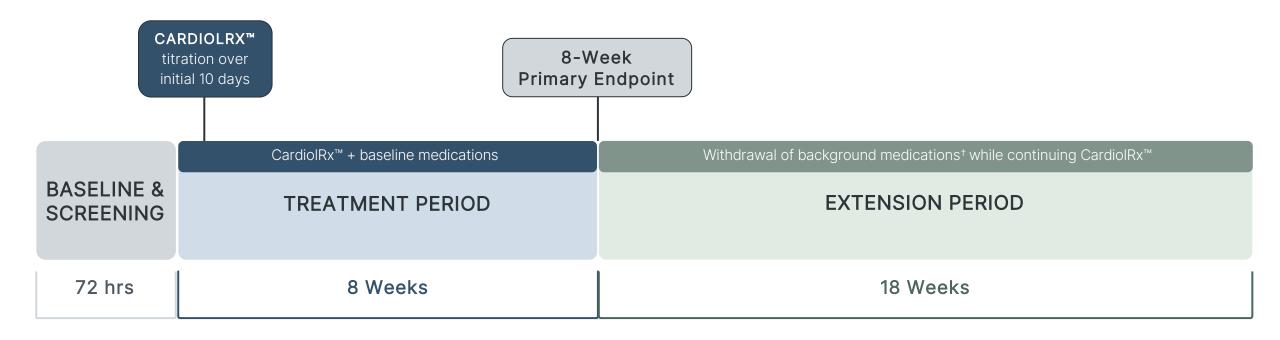
- Pain score at 26 weeks
- Freedom from pericarditis recurrence
- Change in C-reactive protein (CRP) and CRP normalization

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



#### MAvERIC-Pilot Phase II Study Design

27 patients enrolled (met ESC criteria) → 24 progressed to Extension Period on CardiolRx™.



## STUDY PARTICIPANTS

- Male /female ≥18 yrs
- ≥2 previous episodes of recurrent pericarditis
- ≥4 NRS pain score in the last 7 days

- Elevated CRP or MRI evidence of pericardial inflammation
- Receiving NSAIDs, colchicine, and/or corticosteroids
- Not receiving immunosuppressant therapy

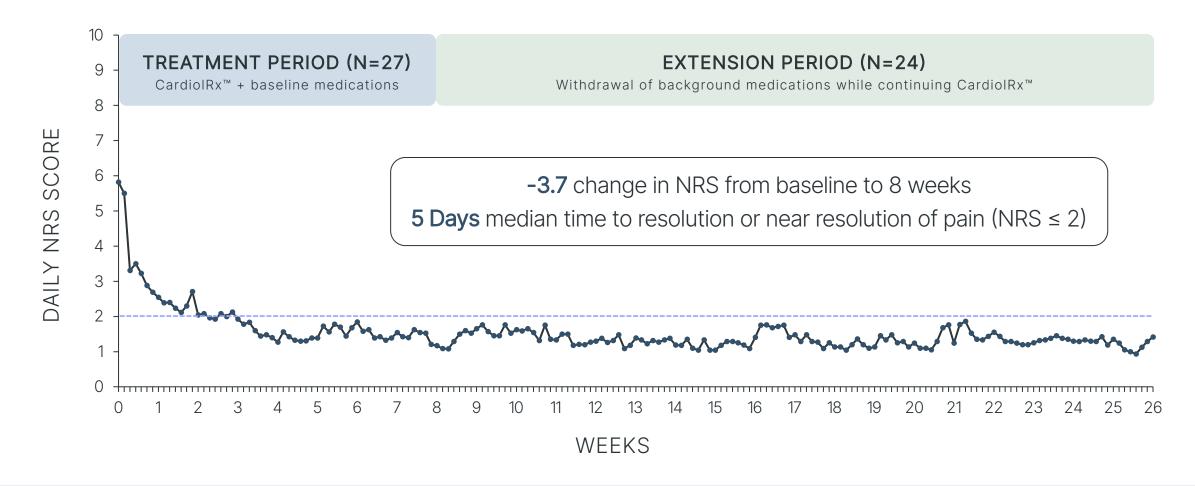
<sup>\*10-</sup>day dose titration: Days 1 - 3: 5 mg/kg b.i.d.; Days 3 - 5: 7.5 mg/kg b.i.d; Day 10 - end of study: 10 mg/kg b.i.d. If the next higher dose was not tolerated, it was reduced to the previous tolerated dose.

†Within the first 10 weeks of Extension Period, background therapies for pericarditis were weaned and patients continued on CardiolRx™.



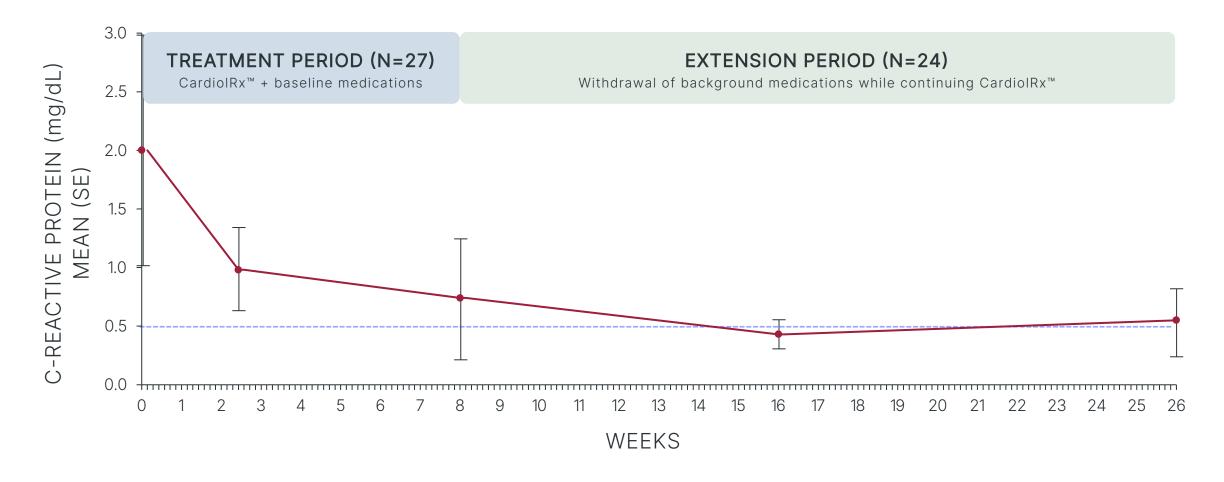
## CardiolRx™ Resulted in a Marked, Rapid, and Durable Reduction in Pericarditis Pain

#### CHANGE IN NRS PAIN SCORE OVER 26 WEEKS

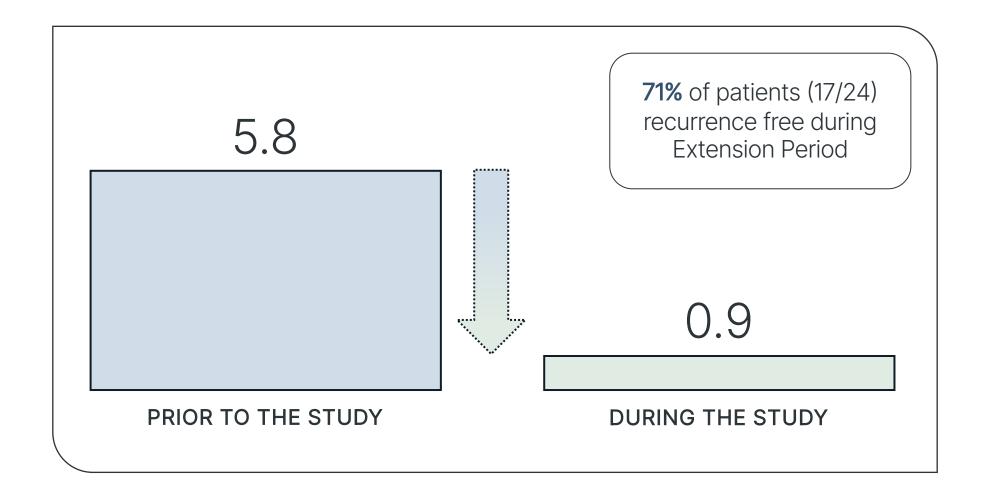


## CardiolRx™ Resulted in a Clinically Meaningful and Rapid Reduction in Inflammation (CRP)

#### CHANGE IN CRP LEVEL OVER 26 WEEKS



#### CardiolRx™ Substantially Reduced Pericarditis Events Per Year



#### MAVERIC Phase III Trial

Multi-national, double-blind, randomized, placebo-controlled

Trial designed to demonstrate the impact of CardiolRx™ on pericarditis recurrence in a high-risk patient population.

## 110 Patients at $\sim$ 20 Clinical Sites

United States, Canada, and Europe

Enrollment initiated and ongoing.

























#### PRIMARY EFFICACY ENDPOINT

 Number of patients (percentage) free from a new episode of recurrent pericarditis at 24 weeks

#### SECONDARY ENDPOINT

Median time to new recurrence episode

#### KEY ELIGIBILITY CRITERIA

- Male or female
- ≥18 years
- Stable disease
- NRS\* score ≤2
- Receiving IL-1 blocker for ≥12 months and scheduled for discontinuation

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



### MAVERIC Program and Phase III Leadership



ALLAN KLEIN, MD, CM
MAVERIC PROGRAM CHAIR
Director, Center for the Diagnosis and Treatment of
Pericardial Diseases, and Professor of Medicine, Heart,

Vascular and Thoracic Institute, Cleveland Clinic.



MASSIMO IMAZIO, MD, FESC
MAVERIC PROGRAM CO-CHAIR
Department of Medicine (DMED), University of Udine and
Cardiothoracic Department, University Hospital Santa Maria
della Misericordia, Udine, Italy.



PAUL CREMER, MD

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



ALLEN LUIS, MBBS, PhD

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

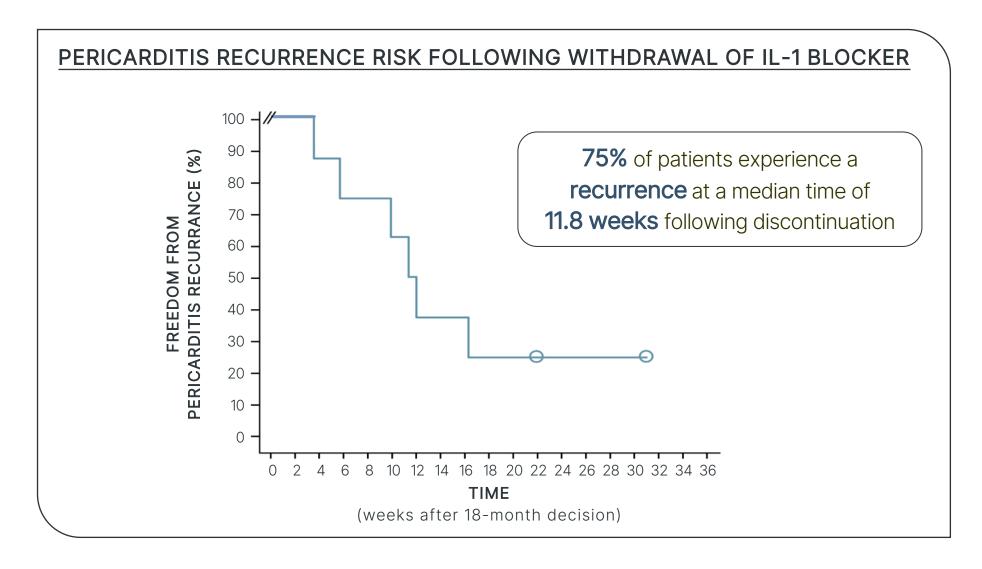


ANTONIO ABBATE, MD, PhD
STEERING COMMITTEE MEMBER
Ruth C. Heede Professor of Cardiology, School of Medicine, and Department of Medicine, Division of Cardiovascular Medicine – Heart and Vascular Center, University of Virginia.



STEPHEN NICHOLLS, MBBS, PhD
STEERING COMMITTEE MEMBER
Program Director, Victorian Heart Hospital, Director, Monash
Victorian Heart Institute, and Professor of Cardiology,
Monash University, Melbourne.

### MAVERIC Phase III Recruiting Patients at High Risk for Recurrence

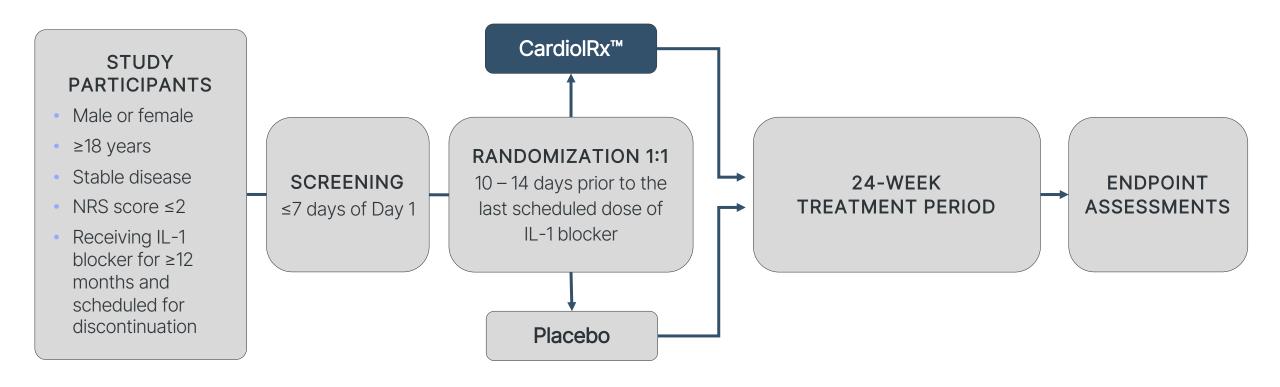


Imazio M, Klein AL, Brucato A, et al. Sustained Pericarditis Recurrence Risk Reduction With Long-Term Rilonacept. J Am Heart Assoc. 2024;13(6):e032516. doi:10.1161/JAHA.123.032516. Placebo arm shown.



#### MAVERIC Phase III Trial Design

Multi-national, double-blind, randomized, placebo-controlled trial to assess the impact of CardiolRx™ on pericarditis recurrence in a high-risk patient population



#### Market Opportunity in Recurrent Pericarditis

CardiolRx<sup>™</sup> offers an accessible and non-immune-suppressing profile with disease-modifying therapeutic potential by targeting inflammasome activation underlying inflammation



## LARGE ORPHAN DISEASE POPULATION

Pericarditis affects ~160,000 patients in the U.S.; ~38,000 patients suffer from recurrent pericarditis.



## HIGH UNMET NEED

FDA Orphan Drug Designation granted to CardiolRx™ for treatment of pericarditis, including recurrent pericarditis.



## GROWING MARKET

Revenue >\$600M (U.S.) for immunosuppressant therapies in recurrent pericarditis; analysts' forecast to grow to >\$1B by 2028.



## DIFFERENTIATED VALUE

Product profile provides access to a potentially larger patient pool than is currently addressed by 2<sup>nd</sup> and 3<sup>rd</sup>-line therapies.

# ARCHER Program

Late-stage Clinical Development of CardiolRx™ for the Treatment of Acute Myocarditis

## Acute Myocarditis

A leading cause of sudden cardiac death in people under 35 years of age

- Inflammatory condition of the heart muscle (the myocardium)
   resulting in chest pain, impaired heart function, and arrythmias.
- Complications include heart failure, unstable heart rhythm, cardiac arrest, and organ failure.
- Severe cases may necessitate heart transplantation.
- No FDA- or EMA-approved therapies for acute myocarditis.

46,000

Patients in the U.S.

32,400

Deaths worldwide due to myocarditis in 2019

4 - 6%

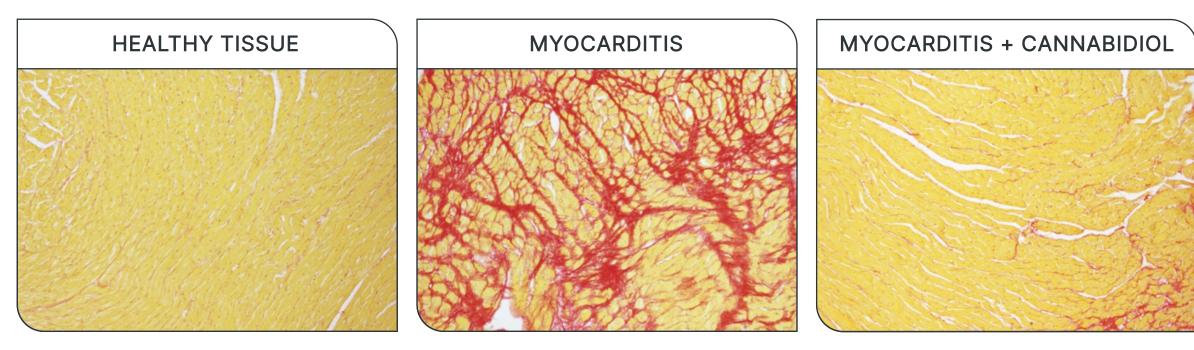
In-hospital mortality

37 years

Median age of diagnosis

#### Cannabidiol Attenuates Myocarditis-induced Fibrosis

#### SECTIONS OF HEART TISSUE



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

Lee W-S et al. (2016). Mol. Med. 22, 136-146

## 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 Elizabeth C. Lane, Ph.D. and M. Nadine Zimmerman, Ph.D. Professor of Internal Medicine, Mayo Clinic, Jacksonville, FL.



WAI HONG WILSON TANG, MD

Advanced Heart Failure & Transplant Cardiology specialist at the Cleveland Clinic. 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.



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).

#### **ARCHER Phase II Trial**

Multinational, double-blind, randomized, placebo-controlled

Trial designed to study the impact of CardiolRx<sup>™</sup> on myocardial recovery in patients with acute myocarditis.

## 109 Patients at 34 Clinical Sites

United States, Canada, France, Brazil, and Israel

- Topline data announced on August 6, 2025 (CLICK HERE).
- The ARCHER results will be presented at an upcoming scientific meeting and submitted for publication.

#### PRIMARY EFFICACY ENDPOINTS\*

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

#### KEY ELIGIBILITY CRITERIA

- Male or female ≥18 years
- Diagnosed with acute myocarditis including:
  - Clinical criteria (symptoms of chest pain, arrhythmia or shortness of breath, or history of viral-like illness) PLUS
  - CMR diagnosis (Lake Louise Criteria) OR
  - Endomyocardial biopsy: cellular inflammation and/or immunohistochemistry consistent with inflammation.

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

### **ARCHER Trial Topline Results and Key Takeaways**

Supports advancing the clinical development of CardiolRx™ in myocarditis and CRD-38 in heart failure

Improvements in multiple CMR Endpoints

Significant reduction in LV Mass

Notable decrease in FCV

2<sup>nd</sup> proof-of-concept clinical trial result for **Cardiol's** pipeline 1st trial to show structural and remodeling improvement in myocarditis patients

Reaffirms excellent safety and tolerability of CardiolRx™

Supports an additional U.S. FDA Orphan Drug Designation Application for acute myocarditis

Blockbusters drugs
(Mounjaro®; Entresto®;
Jardiance®) that
reduce LV mass shown
to reduce mortality and
HF hospitalization

ECV= extracellular volume; LV mass = left ventricular (LV) mass; CMR = cardiac magnetic resonance imaging; HF= heart failure, a condition marked by increased cardiac workload resulting from the inflammation and fibrosis associated with risk factors such as hypertension, obesity, and diabetes.



# CRD-38 Program

Subcutaneous Drug in Development for Heart Failure

## Heart Failure

A leading cause of death and hospitalization affecting more than 64 million people globally

- Chronic, progressive syndrome; heart muscle is unable to pump enough blood to meet the body's needs.
- Patients experience shortness of breath, rapid heart rate, and edema, resulting in reduced exercise capacity and hospitalizations.
- No drugs approved targeting inflammatory/fibrotic mechanisms.

## \$30 billion

Associated healthcare costs in the U.S.

## 8 million

Patients in the U.S. by 2030

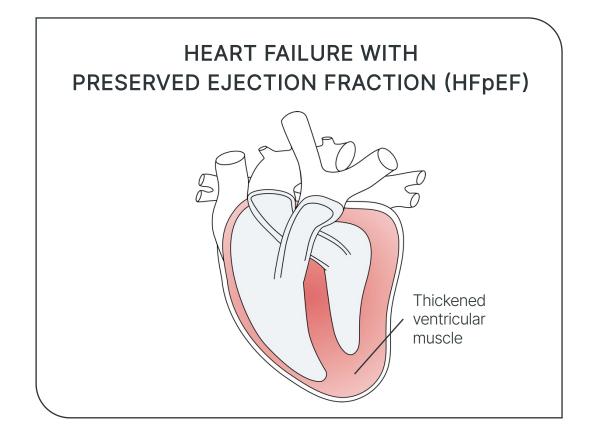
## 1.2 million

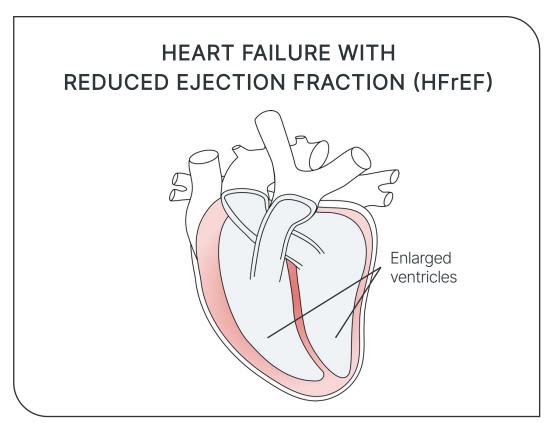
Hospitalizations annually in the U.S.

53%

5-year overall mortality rate

#### Types of Heart Failure



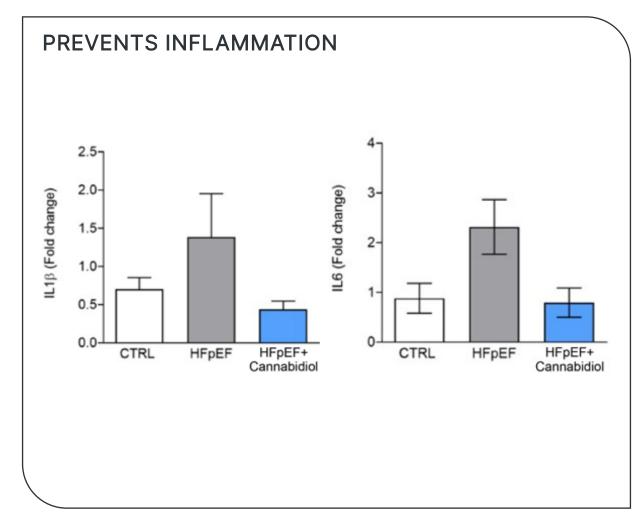


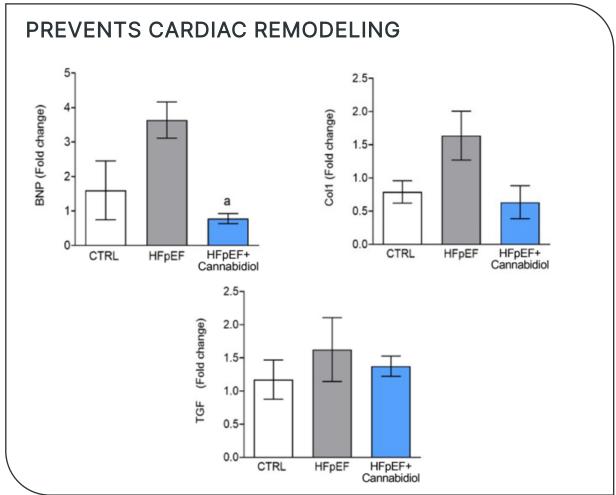
HFpEF accounts for ~50% of heart failure cases worldwide. It drives high hospitalization and mortality rates and has morbidity and costs comparable to HFrEF, making it one of the greatest unmet needs in cardiovascular medicine.

# CRD-38: Potential Treatment For Heart Failure With Preserved Ejection Fraction (HFpEF)







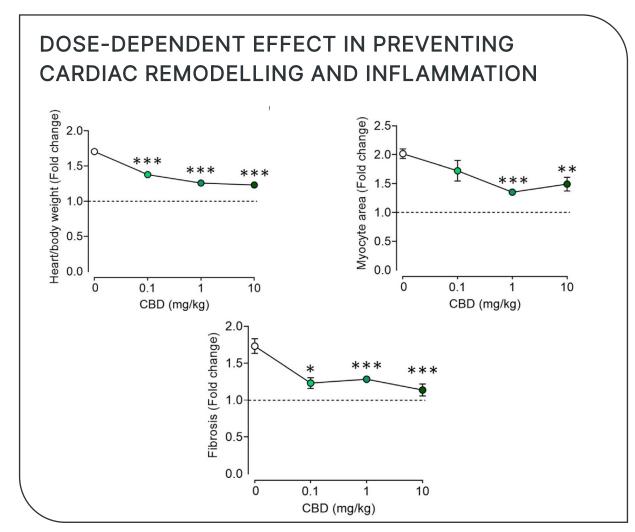


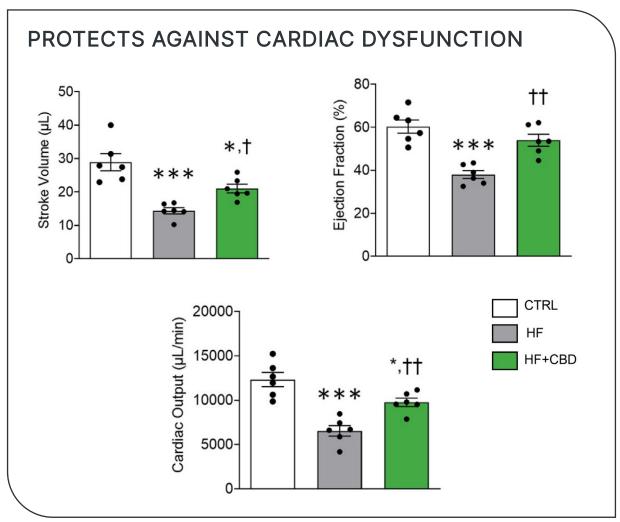
Lozano O et al. Heart Failure Society of America Annual Scientific Meeting 2023: ePoster Viewing Session III. October 7, 2023.



# CRD-38: Potential Treatment to Prevent Heart Failure Dysfunction & Remodeling

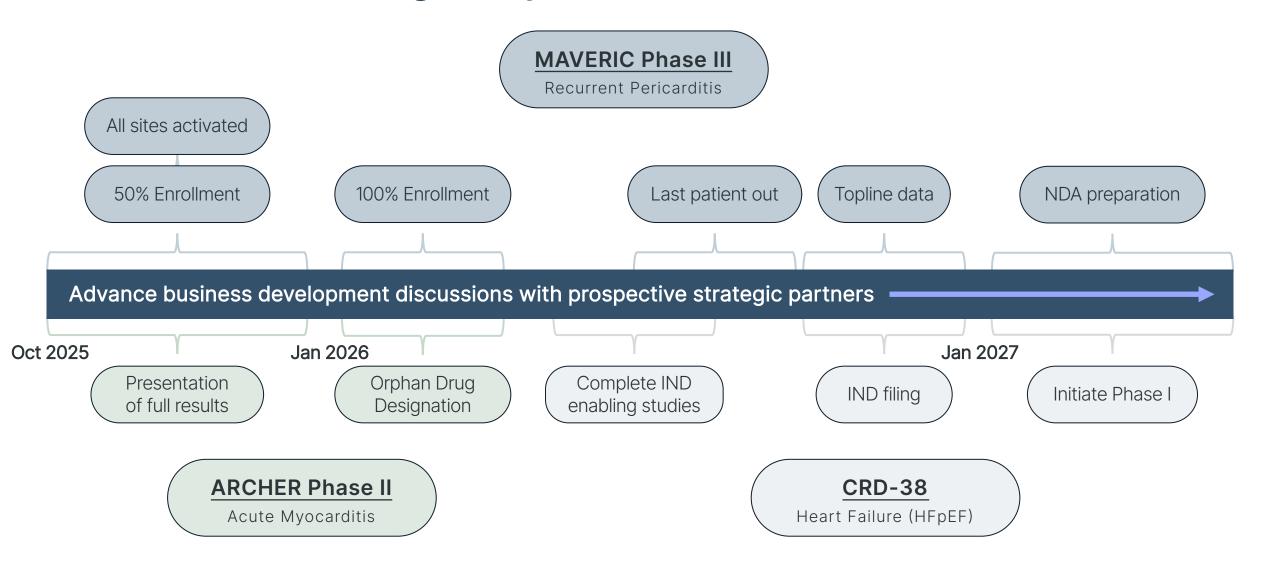






García-Rivas, G, Lozano, O, Bernal-Ramírez, J. et al. J Am Coll Cardiol Basic Trans Science. Published online February 20, 2025

### **Near-term Value Driving Catalysts**



#### 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 R&D

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 Lily.



JOHN A. GEDDES, MBA
VICE PRESIDENT, CORPORATE 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.



TIMOTHY J. GARNETT, MD
CHAIR OF OPHIREX AND DIRECTOR OF MAPLIGHT THERAPEUTICS

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 commercial launches globally.

#### Scientific Advisory Board



DR. PAUL M. RIDKER, MD, MPH

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

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

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.

# CardiolTherapeutics

Developing life-changing medicines for people living with heart disease



**GROWING MARKETS** 

CARDIOLRX.COM

IN HEART DISEASE

**ACTIVATION** 

NASDAQ: CRDL | TSX: CRDL

**CENTERS OF** 

**EXCELLENCE**