

## Cardiol Therapeutics Inc. \*5a,5b,6b,7,11

**Rating: Coming Soon**  
**Target Price: Coming Soon**

Current price: 4,63 CAD  
03/26/2021 / TSX / 21:22 h  
Currency: CAD

**Key Data:**

ISIN: CA14161Y2006  
WKN: A2PA9E  
TSX: CRDL  
OTCQX: CRTPF  
NASDAQ: ongoing application  
FSE: CT9  
Number of shares<sup>3</sup>: 42.9 M  
Marketcap<sup>3</sup>: 198,63M  
<sup>3</sup> in m / in m USD / fully diluted  
Free float: 76%

Primary listing: Canada TSX  
Secondary listing: Frankfurt

Accounting Standard:  
IFRS

FY End: 31/12/

**Analysts:**

Julien Desrosiers  
desrosiers@gbc-ag.de

Felix Haugg  
Haugg@gbc-ag.de

\* Catalogue of possible  
conflicts of interest on  
page 7

Date (time) completion:  
03/29/2021 (12:45 h)

Date (time) first  
distribution:  
03/29/2021 (14:00 h)

**Company Profile**

Sector: Biotechnology

Focus: cannabidiol therapies for inflammatory heart disease

Headquartered in Oakville (Ontario - Canada)

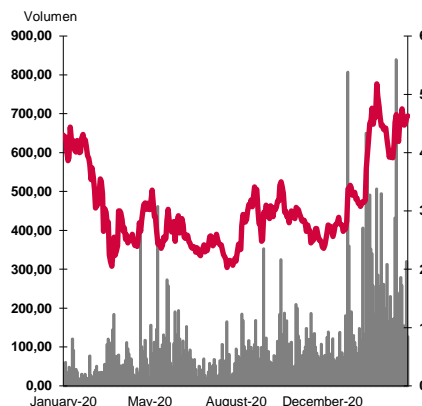
Management: David Elsley (President & CEO, Director), Dr. Eldon R. Smith (CMO, Director), Chris Waddick (CFO), Thomas Moffatt (CCO), Bernard Lim (COO)

Cardiol Therapeutics is a clinical-stage biotechnology company focused on developing innovative cannabidiol therapies for inflammatory heart disease.

The company portfolio is composed of three therapies in development and one commercial authorization product, Cortalex™, commercialized in late 2020, which is now available across Canada exclusively at *Medical Cannabis by Shoppers* online portal, part of the largest retail pharmacy chain in Canada. Cortalex's unique proposition addresses the growing market for high concentration CBD formulations that do not contain THC. Cortalex, which is essentially THC free (<10ppm), is formulated for pediatric and elderly patients, as well as any person who does not wish to be exposed to potential intoxication from THC.

Cardiol has recently filed an application for uplisting on the NASDAQ Capital Market and has recently received proceeds of over \$10M from the exercise of warrants and stock options.

The company has 42.9M shares fully diluted, with 18% insider and employee ownership, and sufficient cash resources to support their research and clinical development programs.

**\*\* Last research by GBC:**

Date: publication/target price in CAD rating

\*\* The research studies indicated above may be viewed at [www.gbc-ag.de](http://www.gbc-ag.de), or requested at GBC AG, Halderstr. 27, D86150 Augsburg

**Financial calendar**

TBA April 2021, Q1 2021 financial results

TBA June 2021, General assembly

## GBC Research Watchlist: Cardiol Therapeutics Inc.

“The right moment to participate in this exciting growth story”

### Cortalex – The purest form of CBD, no THC. It matters.

For many patient segments, CBD medication can be linked to the possibility of becoming intoxicated by THC. For children, young adults under 25, workers that cannot be intoxicated at work, or the elderly, having access to a CBD formulation that does not contain intoxicating amounts of THC is of the upmost importance. These consumers represent an important part of the medical CBD market. Specifically, the elderly population (over 65 years old) is the fastest growing segment of the almost \$600 million medicinal cannabinoid market in Canada.

One of the main issues in the medicinal cannabinoid market is purity. When clients are looking for a high concentration of CBD, they often sacrifice product purity as the level of THC and other impurities rises significantly. This issue can prove to be a real challenge for those patients mentioned above.

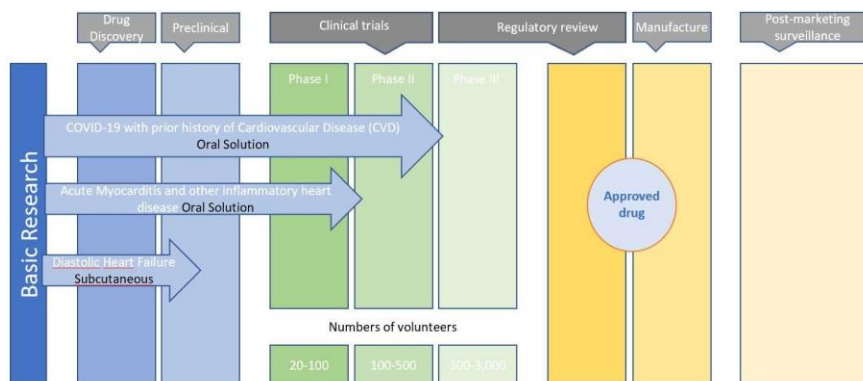
Cortalex™, the company's commercial oral CBD formulation product, is pharmaceutically produced and formulated to be consistent from batch to batch with proven purity and stability. Containing less than 10 parts per million THC, it is considered THC free. Their exclusive manufacturing partner, Dalton Pharma Services, is cGMP compliant and meets the highest standards set by the pharmaceutical industry. CBD has been shown to be effective in treating seizures associated with the pediatric epilepsies Dravet and Lennox-Gastaut Syndromes, and tuberous sclerosis complex<sup>1</sup>. There are also claimed benefits of CBD in the treatment of medical conditions including: anxiety, sleep disorders, depression, and chronic pain<sup>2</sup>.

To the best of our knowledge, of the high concentration oral CBD formulations currently available in the Canadian medical market, Cortalex is by far the purest, containing virtually undetectable levels of THC (<10ppm).



Source: Cardiol Therapeutics

### CARDIOLRx™, 1 formulation, 3 massive potential vectors of revenues.



Source: GBC AG

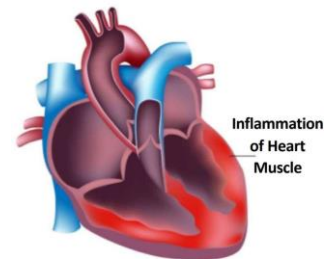
<sup>1</sup> Lattanzi S, Brigo F, Trinka E, et al. Efficacy and Safety of Cannabidiol in Epilepsy: A Systematic Review and Meta-Analysis. *Drugs*. 2018;78(17):1791-1804. (

<sup>2</sup> "Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids": <https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-medication/cannabis/information-medical-practitioners/information-health-care-professionals-cannabis-cannabinoids-eng.pdf>.

### CardiolRx™ – targeting inflammatory heart disease

The company is following a strategy similar to GW Pharmaceuticals (GW), the developer of the FDA approved high concentration CBD formulation for rare forms of pediatric epilepsy. This strategy led to the recently announced acquisition of GW pharma by Jazz Pharmaceuticals for over USD \$7 billion. This acquisition serves as a powerful validation of Cardiol Therapeutics' business model, as it demonstrates the magnitude of shareholder value that can be created by developing pure cannabidiol medicines for important disease targets. In the case of Cardiol, these disease targets include acute myocarditis and heart failure, poorly served inflammatory heart diseases that represent much larger markets than the pediatric epilepsies.

### Myocarditis

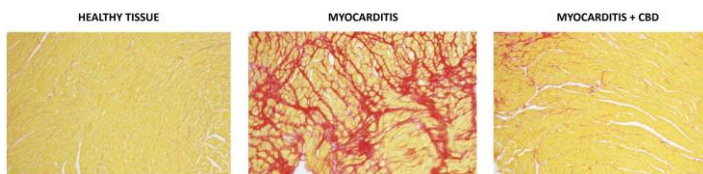


Source: Cardiol Therapeutics

### Acute Myocarditis – Phase I completed and Phase II in the Approval Process

Cardiol Therapeutics recently successfully completed a Phase I study of CardiolRx. The randomized controlled study was completed without any serious adverse events reported. The complete report of the 52 healthy adult subjects should be published during early Q2 2021. The Phase I study is intended to test the safety, tolerability, and pharmacokinetics (PK) of single and multiple ascending doses of CardiolRx™.

The company has announced its intention to file an IND application with the U.S. FDA for an international Phase II clinical trial. Acute myocarditis is recognized as an orphan disease making Cardiol's CBD formulation eligible for orphan drug designation – the same designation GW pharma was granted by the FDA which enabled the fast-track development of their CBD formulation in rare pediatric epilepsies. In the U.S. and other major international markets, any disease that affects fewer than 200,000 people nationwide qualifies for orphan drug status. An orphan drug allows for accelerated marketing approvals and the company developing the drug can benefit from numerous incentives, such as a prolonged period of marketing exclusivity.



Source: Cardiol Therapeutics

Cardiol's planned Phase II program in Acute Myocarditis is an international study designed to recruit 100 patients at major cardiovascular research centers in Canada, the U.S., and Europe. The study will assess the cardioprotective effects of its high concentration CBD formulation, CardiolRx, versus placebo, on key measures of myocardial (heart muscle) recovery including: i) Left ventricular ejection fraction, ii) Extracellular volume and iii) Global longitudinal strain.

### High risk COVID-19 patients with history of cardiovascular disease – Cardiol could help

Following an IND application approved by the U.S. FDA, the company is preparing a Phase II/III clinical trial to assess the safety and effectiveness of their CardiolRx formulation on 422 COVID-19 hospitalized patients at clinical centers throughout the U.S. Each patient will have a history of, or risk factors for, cardiovascular disease. Due to the severity of the COVID-19 situation worldwide, this trial could result in an accelerated approval. The company has engaged the services of *Worldwide Clinical Trials* to act as Contract Research Organization ("CRO"). The company's independent Steering Committee and Data Safety Monitoring Committee comprise world renowned specialists in heart failure, acute myocarditis, and other inflammatory heart diseases.

Specifically, the trial will assess the cardioprotective effects of CardiolRx on reducing a composite of the following significant adverse outcomes: i) all-cause mortality, ii) requirement for ICU admission and/or ventilatory support, and iii) cardiovascular complications, including the development of heart failure, acute myocardial infarction, myocarditis, stroke, or new sustained or symptomatic arrhythmia. The study will compare the cardioprotective effects of CardiolRx versus placebo after 28 days of treatment.

### **CardiolRx, well positioned during and beyond the current pandemic**

As all eyes remain on the current COVID-19 pandemic, it is important to note that as a result of a global increase in diabetes, high blood pressure and obesity, heart failure was an epidemic before COVID-19 and will remain an epidemic during and after COVID-19. Regardless of how the COVID-19 pandemic plays out, there remains a desperate need for new forms of treatment for heart failure and to the extent that COVID-19 becomes endemic, there will be a need for cardioprotective treatments for high-risk patients for many years to come.

### **Diastolic heart failure – Incredible Future Potential**

Cardiol's research has demonstrated that a new formulation of CardiolRx that will be delivered like insulin significantly reduced inflammation in a model of heart failure. This treatment is still in the pre-clinical development stage but holds tremendous promise for the future. Heart failure affects over 26 million people in the developed world and remains a leading cause of death and hospitalization, with associated annual healthcare costs in the U.S. alone exceeding \$30 billion.

### **Well-funded – Cash on account for the studies**

The company had cash on hand as of September 30, 2020 of \$16.5M CDN and recently raised proceeds of over CAD \$10M from warrant and option exercises.

### **Leadership – An experienced team that is up to the task at hand**

Cardiol Therapeutics is led by David Elsley. He has already been through the Phase III approval process for an inflammatory heart treatment, as CEO of a public company prior to founding Cardiol Therapeutics. He has surrounded himself with a team of experts with decades of experience in developing new therapeutics for cardiovascular disease. Cardiol's COVID-19 and acute myocarditis Steering Committee comprise thought leaders in heart disease from around the globe, including representation from prestigious institutions such as the Heart Failure/Transplantation Program at the University of Pittsburgh Medical Center, the Mayo Clinic, McGill University, Ottawa Heart Institute, the Charité University Hospital in Berlin, and many more.

### **Entering NASDAQ – Application for up-listing recently filed**

The company has filed its application to be uplisted on the NASDAQ. With a market cap of approx. \$200M CDN, the company currently trades on the TSX: CRDL, OTCQX: CRTPF and FSE: CT9. GBC Initial Coverage Research Report coming soon.

### **Accomplished milestones**

- Proprietary formulation that produces ultra-pure, high concentration, pharmaceutical cannabidiol (CBD) without the psychotropic effects of THC (2H2019)
- U.S. FDA approval to commence a Phase II/III COVID-19 trial investigating the cardioprotective properties of CardiolRx (2H2020)
- Distribution with *Medical Cannabis by Shoppers* to retail Cortalex on an exclusive basis across Canada (2H2020)

### **Next milestones**

- Sales from the commercial availability of Cortalex across Canada through *Medical Cannabis by Shoppers*. (Ongoing)
- Announce data from recently completed Health Canada approved Phase 1 study (1H2021)
- Commencement of Phase II international trial of CardiolRx in acute myocarditis (2H2021)
- Initiation of Cardiol's Phase II/III trial of CardiolRx for COVID-19 patients with a prior history of, or risk factors for, cardiovascular disease. (1H2021)

### **GBC initial research coverage is coming soon**

We are currently working on the Initial Coverage of Cardiol, which is coming soon. Based on this, we will start ongoing coverage on Cardiol Therapeutics as we believe now is the ideal time to own the shares to participate in this exciting growth story. The company has already referred to a number of important upcoming milestones that could trigger additional increases in the share price.

## ANNEX

### I.

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BUY	The expected return, based on the derived target price, incl. dividend payments within the rel 10%.
HOLD	The expected return, based on the derived target price, incl. dividend payments within the rel 10% and < + 10%.
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The analysts responsible for this analysis are:

**Julien Desrosiers, Financial Analyst**

**Felix Haugg, Analyst**

Other person involved:

**Manuel Hölzle, Dipl. Kaufmann, Chief Financial Analyst**

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GBC AG  
Halderstraße 27  
D 86150 Augsburg  
Tel.: 0821/24 11 33-0  
Fax.: 0821/24 11 33-30  
Internet: <http://www.gbc-ag.de>

E-Mail: [compliance@gbc-ag.de](mailto:compliance@gbc-ag.de)





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GBC AG  
Halderstraße 27  
86150 Augsburg  
Internet: <http://www.gbc-ag.de>  
Fax: ++49 (0)821/241133-30  
Tel.: ++49 (0)821/241133-0  
Email: [office@gbc-ag.de](mailto:office@gbc-ag.de)