With an effective anti-inflammatory and anti-fibrotic agent, Cardiol Therapeutics is focused on our hearts

written by InvestorNews | July 31, 2023

Two very serious heart conditions are pericarditis and myocarditis. Both involve heart infection and can occur after having a flu, Covid-19, or other infection typically occurring in otherwise healthy young adults or in immune suppressed individuals (such as those undergoing cancer chemotherapy). ‘Pericarditis’ is an infection in the sack around the heart and ‘myocarditis’ is an infection in the heart’s muscle tissue.

Thomas Smeenk provides an update on Hemostemix’s ACP-01 stem cell treatment for heart disease

written by InvestorNews | July 31, 2023

Peter Clausi interviews Hemostemix Inc.’s (TSXV: HEM | OTCQB: HMTXF) Co-Founder, President and CEO Thomas Smeenk about an update on their stem cell therapeutics to treat heart diseases and critical limb ischemia. Providing an update on the production timeline for ACP-01, Thomas discusses how Hemostemix

has strengthened its scientific advisory board.

Thomas talks about the appointment of Dr. Nadia Giannetti and Dr. Renzo Cecere, two of the world's top cardiovascular physicians and stem cell scientists, as Co-Lead Medical Consultants, Cardiovascular Medicine and Clinical Trials. He explains how the recent addition to its scientific advisory board is a significant validation of ACP-01 to be "a first-to-patient approved therapeutic to treat heart disease and critical limb ischemia amongst other diseases of ischemia."

To access the full InvestorIntel interview, click here

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About Hemostemix Inc.

Hemostemix is an autologous stem cell therapy company, founded in 2003. A winner of the World Economic Forum Technology Pioneer Award, the Company has developed, patented, and is scaling a patient's blood-based stem cell therapeutics platform that includes angiogenic cell precursors, neuronal cell precursor and cardiomyocyte cell precursors. Seven studies including 260 ACP-01 recipients define its safety and efficacy profile as a treatment for heart diseases such as Dilated and Ischemic Cardiomyopathy, Angina, and diseases of Ischemia such as Critical Limb Ischemia. The Company owns 91 patents across five patent families. For more information, please visit **www.hemostemix.com.**

To learn more about Hemostemix Inc., click here.

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Cardiol Therapeutics is concerned with affairs of the heart

written by InvestorNews | July 31, 2023

One thing I really enjoy about writing for InvestorIntel is all the random learning I get from reading MD&As of the various companies I write about. Some of it is very informative, some of it is fascinating and some of it is just plain entertaining. Today's company falls into the first two categories, at least for me, as it sent me down a bit of a rabbit hole on cardiovascular disease (CVD). Coming from a long family history of unfortunate events related to the heart and its functions, I'm always keen to understand more about the prevention and cure of various heart maladies.

You may or may not be curious about which specific diseases we are dealing with today, but I'm going to tell you anyway – acute myocarditis and recurrent pericarditis, two underserved diseases affecting the heart. Acute myocarditis is an inflammatory condition of the heart muscle (myocardium) characterized by chest pain, impaired cardiac function, atrial and ventricular arrhythmias, and conduction disturbances. While recurrent pericarditis refers to inflammation of the pericardium (the membrane or sac that surrounds the heart) that follows an initial episode (frequently resulting from a viral infection). Perhaps that's too much information but it's important to understand if you have any interest in today's company.

That company is Cardiol Therapeutics Inc. (NASDAQ: CRDL | TSX:

CRDL), 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 diseases. The Company's lead product candidate, CardiolRx™, is a pharmaceutically manufactured oral cannabidiol formulation that is being clinically developed for use in heart diseases. Cardiol has received Investigational New Drug Application authorization from the United States Food and Drug Administration to conduct clinical studies to evaluate the efficacy and safety of CardiolRx™ in the two aforementioned diseases affecting the heart: (i) a Phase II multi-national, randomized, double-blind, placebo-controlled trial (the "ARCHER" trial) in acute myocarditis, an important cause of acute and fulminant heart failure in young adults and a leading cause of sudden cardiac death in people less than 35 years of age; and (ii) a Phase II multi-center open-label pilot study in recurrent pericarditis (inflammation of the pericardium), which is associated with symptoms including debilitating chest pain, shortness of breath, and fatigue, and results in physical limitations, reduced quality of life, emergency department visits, and hospitalizations.

Now that we've covered a small encyclopedia worth of medical terminology, let's get down to the business catalysts behind Cardiol. In early October the Company announced data that was presented at The Annual Scientific Meeting of the Heart Failure Society of America (is it just me or does this seem like an awful name for a society?). The study results demonstrate the active pharmaceutical ingredient in CardiolRx™ inhibits and also promotes the reversal of mechanisms known to play a role in the occurrence and development of fibrotic CVD. Cardiol is currently advancing its Phase II ARCHER trial, designed to assess CardiolRx™ in acute myocarditis. The Company has received regulatory clearance in multiple jurisdictions and is expected

to enroll 100 patients at major cardiac centers in North America, Europe, Latin America, and Israel. The primary endpoints of the trial will be evaluated after 12 weeks of double-blind therapy. Concurrent with the ARCHER trial, the Company is also undertaking a Phase II pilot study in recurrent pericarditis. Cardiol's study is expected to enroll 25 patients at major clinical centers specializing in pericarditis in the U.S.

But now, possibly the most interesting thing about Cardiol, is the fact that it is trading at or even below its current cash value. The Company ended Q2/22 with working capital of C$62 million and currently has a market cap of just over C$50 million. With a quarterly burn rate of roughly C$6.5 million, that suggests the cash value alone in Cardiol is somewhere in the neighborhood of C$54 million give or take, which is C$0.06/share or 8% higher than yesterday's close. Regardless of what the back of the envelope math says, the Company itself has stated that its cash runway now extends into 2026. That is plenty of time to see the ARCHER trial through to completion as well as the pilot study in recurrent pericarditis.

It appears Cardiol has plenty of available resources to make something happen over the coming weeks and months.

Hemostemix adds depth and strength to its scientific

bench on the road to commercialization

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Since we last covered Hemostemix where they released the promising results of their retrospective study of heart disease and the phase II clinical trial results of ACP-01 as a treatment for critical limb ischemia, their team has been making serious moves.

You may recall that Hemostemix Inc. (TSXV: HEM | OTCQB: HMTXF) is developing new treatments to treat ischemic (restricted blood flow) diseases by collecting a patient's own cells from their blood and manufacturing a personalized regenerative therapy that can be administered to a patient within 7 days. The efficient, scalable, and cost-effective platform has the potential to generate therapies for a broad range of ischemic diseases.

In a quartet of recent press releases, Hemostemix announced the addition of four new distinguished members to its Scientific Advisory Board – Dr. Terry Hébert, Ph.D., Dr. Nadia Giannetti, MD, Dr. Johannes Grillari, and Dr. Renzo Cecere, MD, FRCSC. They are all internationally recognized experts in their respective fields with a wealth of experience in cardiovascular care, clinical research, and drug development.

Through his research, Dr. Hébert strives to improve our understanding of G protein-coupled receptor (GPCR) and G protein signaling architectures to enhance drug discovery for heart disease and other serious diseases. Dr. Hébert's expertise will be a valuable asset to the Hemostemix team as they continue to work to develop innovative treatments for patients with cardiovascular disease.

Dr. Giannetti is a highly respected researcher and physician who has worked with more than 1000 patients with heart failure. She is a clinical researcher interested in improving care and outcomes for patients with heart failure and dilated cardiomyopathy. She is also the co-principal investigator of a large initiative looking at the role of stem cells in personalized therapy for cardiomyopathy, making her an excellent addition to Hemostemix's Scientific Advisory Board.

Dr. Grillari is a renowned expert on cellular aging and tissue regeneration, with over 20 years of research experience in the field. His appointment will bring a wealth of knowledge and expertise to the Hemostemix team and will help to further their understanding of the molecular and physiological changes that occur during cell aging. His contributions will be invaluable in helping their team to achieve their goal of improving heart disease patient outcomes.

Dr. Cecere is an expert in the field of stem cell research and has been investigating novel methods to strengthen the stem-cell-induced regeneration of infarcted heart tissue for over a decade. In fact, Dr. Cecere's recent publication—systematic review and meta-analysis—demonstrates that stem cells, along with bioactive scaffolds, provide enhanced tissue regeneration in animal models of myocardial infarction (MI) compared to stem cells injected alone. His study gives more backing to the theory that ACP-01 bioactive scaffolds improve stem cell-induced repair after a patient suffers a MI.

The new Scientific Advisory Board members' experience should greatly assist in advancing to their phase II clinical trial, a step towards the goal of bringing ACP-01 to market and potentially improving the lives of heart failure patients around the world.

Hemostemix is also poised to gain more value from its NCP-01, which are autologous neuronal cell precursors. These precursors have the potential to treat the central and peripheral nervous systems. Hemostemix has announced Mr. Thomas Abraham has been appointed as President of PreCerv Inc., a wholly owned subsidiary of Hemostemix. PreCerv has obtained a global field of use license to NCP-01 and its autologous stem cell technologies from Hemostemix. This license will allow PreCerv to fund its studies to unlock NCP's value for the shareholders of Hemostemix. Mr. Abraham is a highly accomplished business professional with more than 25 years of experience in financing, business development, governance, and risk management. He will be responsible for financing and leading the team that studies, develops, and commercializes NCP-01 and ACP-01 in the neuronal field, and bringing them to market for the benefit of patients suffering from neurological diseases.

Success for a public company often owes a lot to the team and talent it assembles, especially in the field of biotech and therapeutics. With these additions, Hemostemix has taken a big step toward advancing its suite of products in development.

The EYES have it, Early Stage Detection of Diabetes and Cardiovascular Disease

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Using Artificial Intelligence (AI) to better image and analyze the retina of the eye to detect early stage disease is a

potential game changer in the prevention of blindness and cardiovascular diseases such as stroke, heart attack, and diabetic related disease.

Today's company is pioneering its work in this field with USA clinical trials commencing soon and a global commercialization rollout already underway. The company is Diagnos Inc. (TSXV: ADK | OTCQB: DGNOF) ("DIAGNOS").

DIAGNOS has developed an Artificial Intelligence (AI) tele-ophthalmology platform, which uses Computer Assisted Retina Analysis (CARA) to examine a patient's retina (back of the eye) for the early detection of diseases, such as diabetes, and conditions such as cardiovascular disease, hypertension and stroke. CARA's image enhancement algorithms provide sharper, clearer and, thus, easier-to-analyze retinal images.

CARA has been cleared for commercialization by the following regulators: Health Canada, the FDA (USA), CE (Europe), COFEPRIS (Mexico) and Saudi FDA (Saudi Arabia). DIAGNOS already operates in 16 countries, with 131 screening sites, has 222,034 patients under their care, and has performed more than 400,000 retinographies around the world. DIAGNOS' CARA achieves great precision in diabetic retinopathy pre-diagnoses, reaching a sensitivity of 98.4%, specificity of 97.6% and a certainty of 97.9%.

DIAGNOS uses an AI technology know as CARA to better analyze the retina of the eye, a key way to detect early cardiovascular disease

Source: DIAGNOS website

DIAGNOS achieves two firsts and an eight at the GAMMA (*G*laucoma

gr*A*ding from *M*ulti-*M*odality im*A*ges) contest

At the recent GAMMA competition, DIAGNOS achieved some stunning results including two firsts and an eighth place out of a total of 566 teams. Now that's super impressive!

The October 28, 2021 announcement stated: "DIAGNOS was the only one, of the top 8 teams, that competed with a marketed, commercialized system. DIAGNOS used the same platform that it currently uses for diabetic retinopathy screening, which is marketed worldwide, while the others were principally from academic institutions."

Key results included:

- Localization of macula fovea in fundus images. **(DIAGNOS placed 1st overall)**
- Segmentation of optic disc and cup in fundus images. **(DIAGNOS placed 1st overall)**
- Grading glaucoma using multi-modality data. **(DIAGNOS placed 8th overall)**

USA clinical trial for the early detection and prevention of stroke using CARA-STROKE

On November 23 DIAGNOS announced: "DIAGNOS will start a clinical trial study in the USA commencing December 6th, 2021 for early detection and prevention of stroke using CARA-STROKE." The trial aims to confirm early Proof-of-Concept results that showed a strong potential in the early detection of stroke through the inspection and micro circulation analysis of the retina.

The upcoming USA clinic trial at the CommonSpirit Health Research Institute, Chattanooga Center for Neurologic Research LLC, is intended to further prove the effectiveness of DIAGNOS's CARA technology.

Note: CommonSpirit Health is a non-profit national Catholic healthcare system that operates 137 hospitals and more than 1,000 care sites across 21 states of the USA.

Some facts about cardiovascular disease including stroke

- Stroke causes 1 out of every 20 deaths.
- The management of stroke represents a cost of around US$34 billion per year in the United States.
- According to the WHO, 15 million people suffer a stroke worldwide each year. Of these, 5 million die and another 5 million are permanently disabled.
- Europe averages approximately 650,000 stroke related deaths each year.
- Worldwide Research Institutes says that the worldwide market size for stroke management will hit over $66 billion by 2023.

Source: DIAGNOS announcement

Clearly, the above facts speak volumes as to the need to diagnose cardiovascular disease early. And that is exactly what DIAGNOS does.

Not just an idea, commercialization has begun

As previously discussed in some detail here, DIAGNOS commercialization is gaining momentum. Some examples include:

- July 22, 2021 – DIAGNOS announced the official opening of the AI Assisted screening clinic at Magrabi Hospital in Saudi Arabia. Magrabi Hospitals and Centers has **thirty-four branches in the Middle East.**
- July 28, 2021 – DIAGNOS announced a pilot in Spain with three franchisees from Opticalia Group.
- August 16, 2021 – DIAGNOS announced signing a Memorandum of Understanding (MoU) for a distribution agreement with

Essilor International. **Essilor International is the world's leading ophthalmic optics company.**

- September 2, 2021 – DIAGNOS announced a three-year contract renewal with Optina Diagnostics providing a Telemedicine Platform to support their early detection of Alzheimer's Disease.
- September 14, 2021 – DIAGNOS announced a 3-year contract with Cielo Vista Eye Clinic in Mexico.
- September 16, 2021 – DIAGNOS announced a multi-year contract with Juarez Health & Medical Tourism Cluster in Mexico, who focuses on medical tourism and **serves between 10-12,000 patients a day.**

Closing remarks

DIAGNOS's CARA technology is clearly a winner. It has already won numerous global contracts and the recent GAMMA competition. Any potentially positive results from the upcoming CommonSpirit Health Research Institute clinical trial would just be icing on the cake.

With 15 million people suffering a stroke worldwide each year the time has come for better early diagnosis to allow earlier treatment and prevention, potentially reducing this terrible statistic.

Diagnos Inc. trades on a market cap of just C$30 million which seems very small when compared to the massive market for cardiovascular disease diagnosis. One to follow closely in the years ahead.

Expanding globally in the AI image based diagnosis sector, Diagnos is actively commercializing their CARA technology

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CARA's Artificial Intelligence image enhancement algorithms make standard retinal images sharper, clearer and easier to read. CARA is accessible securely over the internet, and is compatible with all recognized image formats and brands of fundus cameras, and is EMR compatible. Targeting the early detection of these diseases by using AI to better examine and diagnose patients as early as possible is the focus for Diagnos Inc. (TSXV: ADK | OTCQB: DGNOF) ('Diagnos').

Diagnos uses an Artificial Intelligence (AI) tool known as CARA (Computer Assisted Retina Analysis) to examine patient's retinas in the eye for the early detection of diseases such as diabetics, hypertension and other cardiovascular disease. CARA is a tele-ophthalmology platform that integrates with existing equipment (hardware and software). CARA's AI image enhancement algorithms make standard retinal images sharper, clearer and easier to read.

Key winning features of CARA:

- CARA is accessible securely over the internet and is compatible with all recognized image formats and brands of fundus cameras.
- CARA is a cost-effective tool for screening large numbers

of patients in real-time.
- CARA complies with local regulations, is FDA cleared for commercialization in the United States of America, is Health Canada licensed for commercialization in Canada, licensed by the Saudi FDA, COFEPRIS in Mexico and is CE marking compliant in Europe.

Diagnos' AI software enhances the ability to detect early-stage cardiovascular disease by viewing the retina of the eye

Source: www.diagnos.ca/

Diagnos has already had their CARA platform in production since mid-February 2020 and will be following with further applications and enhancements for the technology. Diagnos already operates in 16 countries, 131 screening sites, and has 222,034 patients under their care. The Company is fully funded until about mid 2022 and should continue to grow revenues as their CARA platform commercializes further.

Diagnos operates in 16 countries and has 222,034 patients under care

Source: www.diagnos.ca/

The latest news just the past month shows how quickly Diagnos is commercializing. For example:

- 24 February, 2021 – Exclusive Strategic Partnership Agreement with Labtician Ophthalmics, a leader in Canadian and International eyecare markets. Labtician Ophthalmics has customers across Canada and will introduce and commercialize Diagnos' AI platform to monitor ocular

health and improve patient care in diabetic patients.

- 2 February, 2021 – Further deployment of Diagnos' AI based CARA Technology in Saudi Arabia. Dr. Salman Abdullah Al-Mutairi, Executive Director of Enayah Charitable Association stated:

"For almost three years, Enayah has been using DIAGNOS' AI based CARA platform successfully to screen thousands of diabetic patients for diabetic retinopathy with an early detection test. By using DIAGNOS' telemedicine solution we have been able to identify patients needing care early so their vision can be saved. As part of our "Combating Blindness" program, we are extremely pleased to extend this service and add it to other tests in our fleet of vans of Mobile Smart Eye Clinics."

Closing remarks

Diagnos Inc. is in the early days of commercializing their CARA technology having only begun in mid-February 2020, approximately a year ago. This is good news for investors as the company is trading on a market cap of just C$39 million.

I see (no pun intended) exciting times ahead for this company in a potentially huge market.

- Diagnos' Andre Larente on the benefits of using AI for the early detection of critical health issues (video)