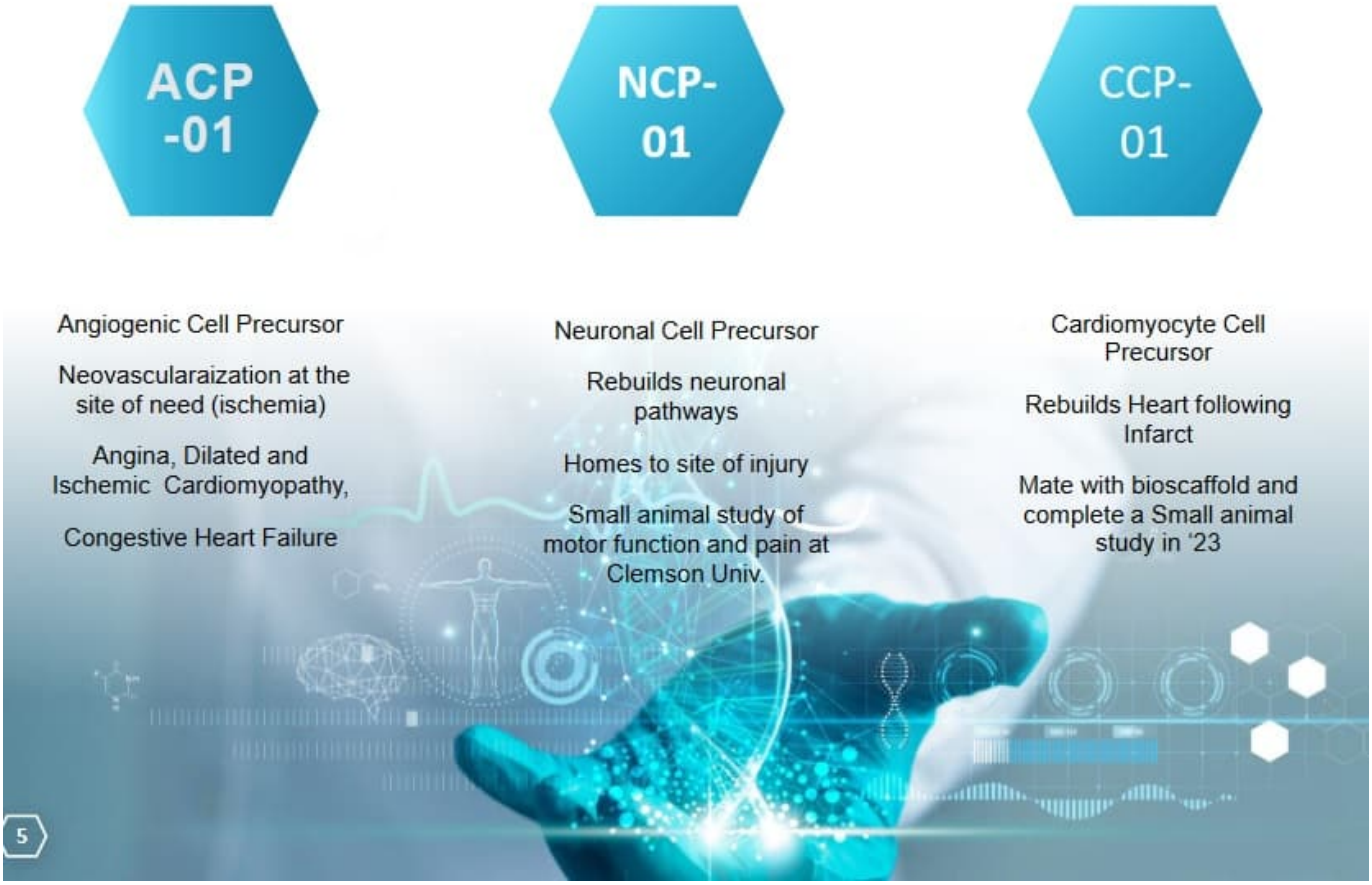
Hemostemix Plans to Revolutionize Stem Cell Therapy with Scalable Production and New Sales Goals

written by InvestorNews | February 13, 2023

Hemostemix Inc. (TSXV: HEM | OTCQB: HMTXF | FSE: 2VF0) has developed an effective “stem cell therapy” for the treatment of ischemic (lack of blood flow) disease and several other diseases including cardiomyopathy (heart tissue disease) and neuropathy (nerve cell disease). Hemostemix’s initial goal is to treat heart attack (ischemic heart disease) and various ischemic conditions such as ischemic limb disease.

Hemostemix’s Product Platform (targets to repair) – ACP-01 (blood vessel cells), NCP-01 (nerve cells), CCP-01 (heart cells)



Source: Hemostemix company presentation

Hemostemix's leading product is called ACP-01. It refers to Hemostemix's first stem cell treatment called angiogenic cell precursor ("ACP") one ("01"). The ACP technology uses a patient's own stem cells to treat that patient's disease by extracting the stem cells, growing the number of cells within 7 days, then using them to treat the patient with their own harvested stem cells. According to Hemostemix: "*ACP-01 has been used as a treatment of 500 subjects, studied in including clinical trials, and are demonstrated to be completely safe and effective as a treatment of Angina, Dilated and Ischemic Cardiomyopathy, Peripheral Arterial Disease and Critical Limb Ischemia*."

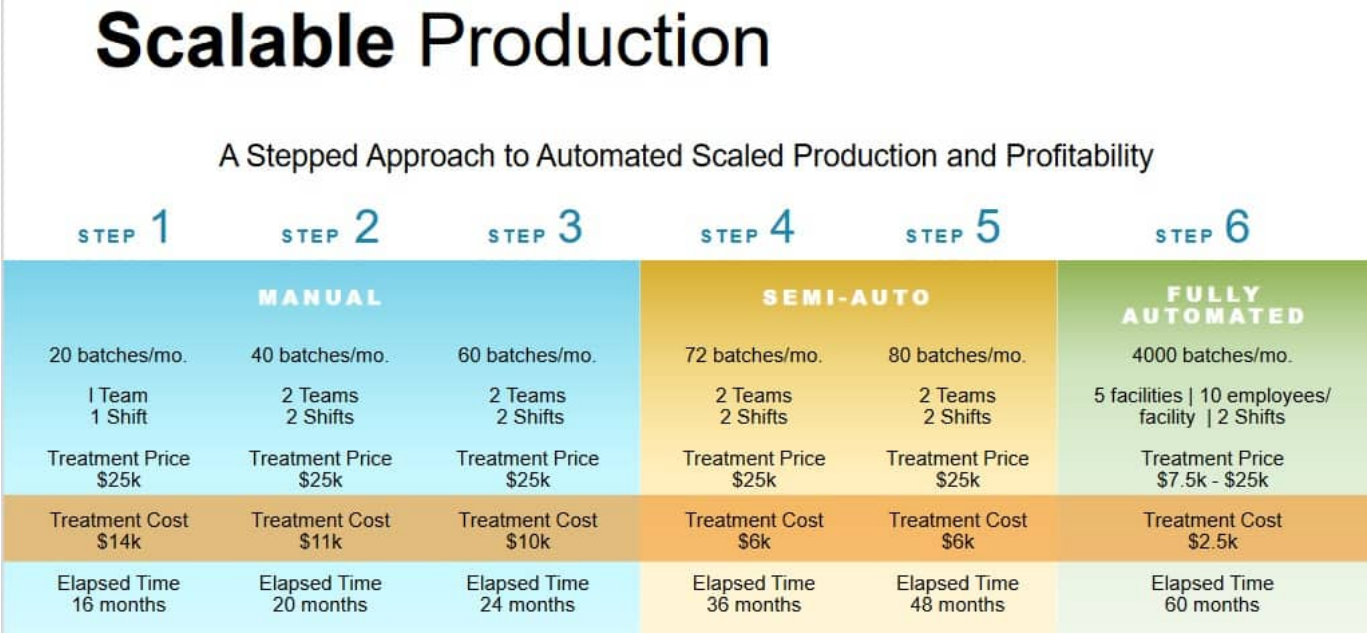
Hemostemix plans to increase production of their ACP stem cell therapy for ischaemic disease

In some recent news announced in January this year, Hemostemix has ramped up their team in order to increase the production of ACP-01. Hemostemix President and CEO, Thomas Smeenk, stated: "*Adding four employees to our team enables Hemostemix to produce up to 20 ACP treatments per month for clinical trials and compassionate treatments approved by regulators……We expect up to 174 revenue production slots for the first full year of production. To fill them and balance our production schedule, we are working on a forward sales plan.*"

A "sales plan" suggests that the commercialization of ACP is potentially in the near term.

In a recent InvestorIntel CEO video, Thomas Smeenk revealed more about Hemostemix's master plan. He said Hemostemix's goal is to scale up production of ACP to "4,000 or more batches per month" and "the numbers are very significant, at $25,000 per treatment…$30,000 per treatment…..the numbers get very large very fast".

Hemostemix's scalable production plans over a 60-month period



Hemostemix's sales target is to reach $360 million of risk-adjusted sales in 2027 (see below or page 14). Quite impressive given Hemostemix's current market cap is C$16 million.

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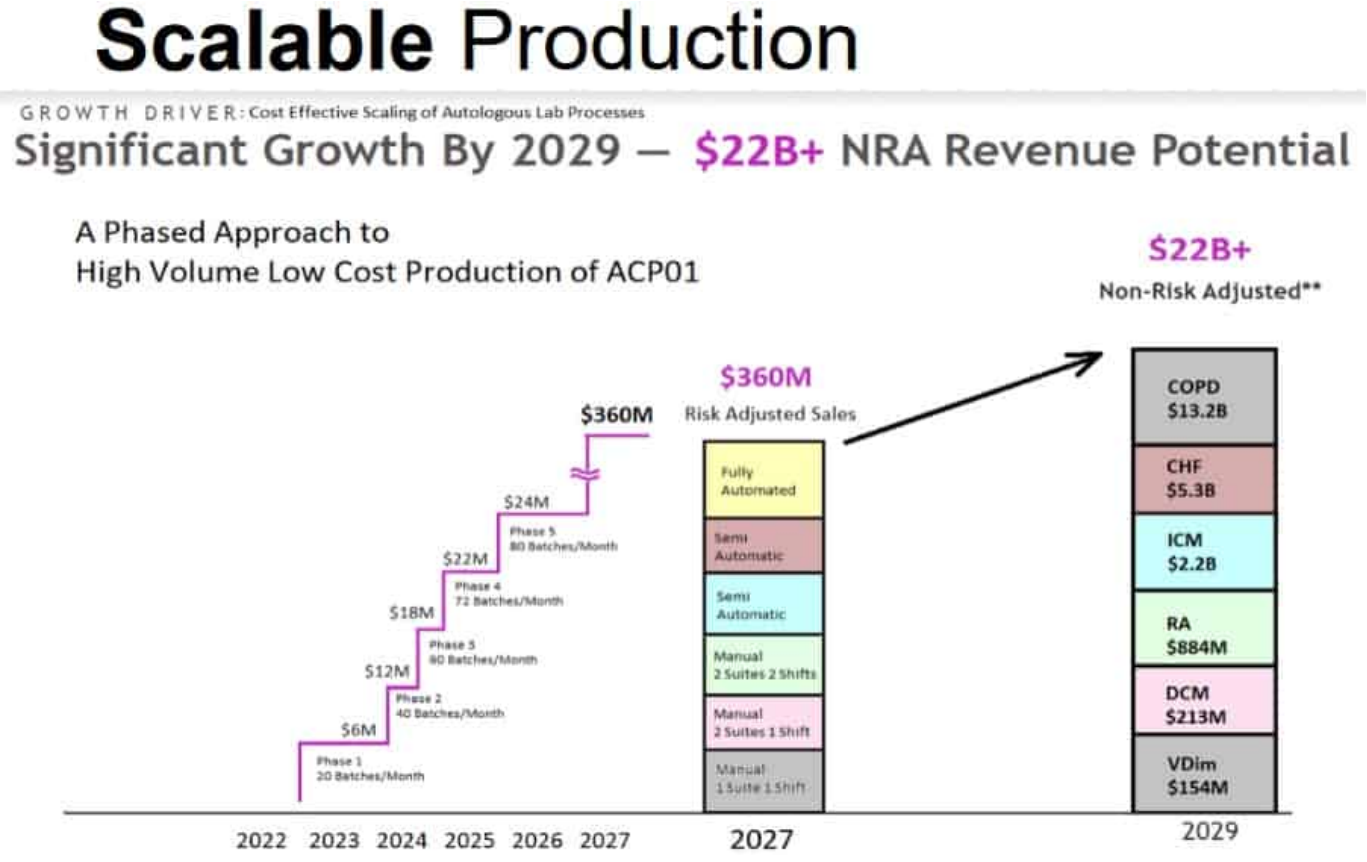

Source: Hemostemix company presentation

Is Hemostemix's stem cell therapy effective?

Hemostemix's ACP treatments have been successful to date. For example, in a 2019 Phase II CLI Trial with 12 randomized double-blind subjects, the results included: *"Healing of ulcers and resolution of ischemic rest pain occurred in 10 of the 12 patients (83%). There were no clinically significant safety issues. Outcomes were maintained for up to 4.5 years……"*

You can see more results including pictures in a past InvestorIntel article here.

Closing remarks

Some risks apply and there is still work ahead for Hemostemix to implement its plan of action. At this stage, the Company has received US FDA Clinical Trial approval and further regulatory approvals may be necessary, as well as further funding to achieve the Company's goals.

The best companies develop effective products that both help society and fill a strong need. Tesla (NASDAQ: TSLA) is doing this with electric vehicles (EVs) and sustainable energy. Hemostemix is working towards becoming a leading biotech health company using stem cells to significantly help some of society's most common and severe diseases. They have already won the World Economic Forum Technology Pioneer Award, have proven their treatment efficacy in clinical trials, and have a highly qualified management team and reputable advisors.

2023 could potentially be a breakout year for Hemostemix Inc.

Hemostemix adds depth and strength to its scientific bench on the road to commercialization

written by InvestorNews | February 13, 2023
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.

Built on arguably one of the greatest medical breakthroughs of our time, Hemostemix has ‘your fountain of youth’…

written by InvestorNews | February 13, 2023

Stem cell therapy is potentially one of the greatest medical breakthroughs of our time. It is truly amazing that we can use our own bodies’ stem cells to heal certain diseases. The technology is evolving, but today’s company is making great steps forward to bringing stem cell therapy to patients.

Hemostemix Inc. (TSXV: HEM | OTCQB: HMTXF | FSE: 2VFO) is a company that is developing ‘stem cell therapy’ for the treatment of ischemic (lack of blood flow) disease and several other diseases. Some examples include using the patient’s own stem cells to heal ischemic heart disease (causing angina and heart attack), limb ischemia, vascular dementia, ischemic kidney disease, possibly diabetes, and even in some cases chronic pain. Hemostemix’s stem cell therapy platform uses the patient’s own blood to harvest the stem cells and uses them in a treatment that helps to restore circulation (blood flow) in damaged tissues.

How does it work?

Hemostemix explains how their stem cell therapy works by stating:

“Hemostemix’s technology uses a patient’s own cells to treat that patient’s disease. The cornerstone of this autologous technology is a novel cell population within the blood called

the **synergetic cell population** (SCP). The synergetic cell population, which can be collected from a simple blood draw, consists of progenitor and other supporting cells that are being developed for the treatment of ischemic diseases. Hemostemix's proprietary technology includes methods for collecting the synergetic cell population and manufacturing (isolation, enrichment and differentiation) a personalized regenerative therapy that can be administered to a patient within 7 days of the initial cell collection."

About Hemostemix and their lead therapy ACP

Hemostemix was founded in 2003 and is a winner of the World Economic Forum Technology Pioneer Award. Hemostemix's pioneering stem cell treatment is called angiogenic cell precursor (ACP), or ACP-01 for the first one.

Hemostemix has published numerous peer reviewed clinical trials regarding the safety and efficacy of ACP-01 for the treatment of limb ischemia, peripheral arterial disease (PAD), angina, and ischemic cardiomyopathy, involving treatment of over 300 patients.

Case studies show that Hemostemix's stem cell therapy (named ACP) is effective

Below are just 3 of many case study results:

For example:

1. The results of the 106 subjects suffering from ischemic cardiomyopathy "[experienced] improved cardiac function (Left Ventricle Ejection Fraction), improved exercise capacity, and improved quality of life…"
2. The results of 41 subjects treated by direct injection of ACP into the heart to treat ischemic and dilated

cardiomyopathy: “Overall ejection fraction improved significantly… At a mean of 180 days after injection, NYHA functional class improved significantly…subjects …improving nearly 126 meters in walking capacity in six minutes.”

3. The 83% of subjects treated compassionately for critical limb ischemia who “… had clinically significant improvement of adequate circulation at the distal limb for…complete healing.”

Latest news

In the latest news, Hemostemix announced on February 14 that they have trademarked the term “Your Fountain of Youth” for a period of 10 years.

In other news Hemostemix recently announced a partnership with My Next Health. My Next Health Inc. (MNH) is the world’s leading patient focused, AI-functional-medicine-based genomic medical analysis company.

Finally, an exciting piece of news from January 2022, when Hemostemix announced that they plan to combine ACP-01 with Dr. James Shapiro’s Islet Cells to treat Type 1 Diabetes. The news states: “Following technology transfer, the team will create a new product by combining the two formulations, beginning with human islets. Thereafter, the team will complete preclinical studies to demonstrate the product’s characteristics in vivo, with a plan to move forward with first-in-human testing.”

Note: The global diabetes care drugs market reached US$69.7 billion in 2019. The global market for diabetes care products including drugs and devices is expected to exceed US$111.2 billion by 2027.

Closing remarks

Hemostemix is at an interesting stage of development where they have spent many years proving their science and technology works, with several favorable clinical trial results. The next stage is the most exciting for investors, when the Company gets to commercialize the technology. Of course, once this starts to gain success the stock price would typically be much higher. Hemostemix states: "91 Patents. More to follow as we scale Manufacturing and R&D."

The market for stem cell therapy to treat various diseases is potentially huge. Just think of how many people suffer from ischemic and degenerative diseases. There may also be a market to treat diabetes if the latest Dr. Shapiro pre-clinical studies go well. If we can safely grow back healthy cells in our body to repair damaged tissue, then the potential rewards are enormous. Hemostemix gets this, as we can see from their recent trademark name – "Your Fountain of Youth".

Hemostemix trades on a market cap of C$8 million. Patience is required but there is huge potential for reward if Hemostemix takes off.

Revolutionizing the way we treat lack of blood flow diseases by using stem cell

therapy

written by InvestorNews | February 13, 2023

Every year modern medicine makes new breakthroughs that continue to amaze. Today's company has a breakthrough 'stem cell therapy,' designed to regenerate diseased and damaged tissue, focused on patient's with "ischemic" disease (a lack of blood flow) such as limb ischemia or ischemic heart disease (often leading to a heart attack). The company is a winner of the World Economic Forum Technology Pioneer Award.

Ischemic diseases are a huge global problem. For example, ischemic heart disease (also called coronary disease) affects **around 126 million individuals**, which is **approximately 1.72% of the world's population, annually.** Nine million deaths per annum are caused by ischemic heart disease globally. Limb ischemia, often caused by diabetes, smoking, or age, is another huge area in need of innovative and better treatment.

Today's company is stem cell therapy developer, Hemostemix Inc. (TSXV: HEM | OTCQB: HMTXF). Hemostemix's stem cell therapy platform uses the patient's own blood to harvest the stem cells and uses them in a treatment that helps to restore circulation (blood flow) in damaged tissues.

Hemostemix's leading product, ACP-01, has been used to treat over 500 patients, and it is the subject of a randomized, placebo-controlled, double blind trial of its safety and efficacy in patients with advanced critical limb ischemia (CLI) who have exhausted all other options to save their limb from amputation.

Hemostemix state on their website:

"Hemostemix's proprietary platform technology is based on more

than 10 years of clinical data demonstrating the ability of our autologous cell product to regenerate diseased and damaged tissue. Our efficient, scalable and cost-effective platform has **the potential to generate therapies for a broad range of ischemic diseases**. ACP-01, our lead clinical stage candidate, is an autologous cell therapy for the treatment of critical limb ischemia. ACP-01 is currently in a Phase 2 clinical trial in Canada and the United States."

Note: Autologous refers to using the patient's 'own' stem cells.

ACP-01 testing

Twelve patients with critical limb ischemia (CLI) and no interventional options were enrolled (10 male, 2 female, mean age 76 years) in an abstract trial test.

Hemostemix quote the results stating:

"Prior to treatment with ACP–01 or placebo, 3 patients had ischemic rest pain, 8 patients had ulceration, and one patient had gangrene. Post treatment, one patient with unremitting rest pain and toe gangrene required a below knee amputation, and one patient with gangrene of the first to third toes required a forefoot amputation. **Healing of ulcers and resolution of ischemic rest pain occurred in the other 10 (83%) patients.** There were no clinically significant safety issues. Outcomes have been maintained for up to 4.5 years (3.5 years for 2 patients, 3 years for 1 and 1 patient died after ulcer healing secondary to congestive heart failure at 6 months)."

Hemostemix latest development for their leading product ACP-01

Hemostemix is currently working on the source document verification for their Phase II clinical trials for their lead product 'ACP-01' for the treatment of critical limb ischemia

(CLI), peripheral artery disease (PAD), angina, ischemic cardiomyopathy, dilated cardiomyopathy and other conditions of ischemia. The document verification completion is expected to be completed by the end of 2021.

Note: Clinical trials follow a typical series from early, small-scale, Phase 1 studies to late-stage, large scale, Phase 3 studies, followed hopefully by FDA approval.

Closing remarks

Hemostemix is revolutionizing the way we treat ischemic disease by using stem cells developed from a patient's own blood. Abstract trials on ACP-01 led to an 83% success rate and the Company is now working towards Phase II trials.

Hemostemix is working towards revolutionizing the way we treat lack of blood flow, ischemic, diseases by using its stem cell therapy and has a market cap of C$11 million,

Further learning

- Hemostemix Announces the Second Stem Cell Recipient Interview: One Week to No Chest Pain
- Hemostemix Announces the First of a Series of 2021 Video Interviews with ACP-01 Recipients: What the Successful Compassionate Treatment of Ischemic Cardiomyopathy Looks Like After 13 Years