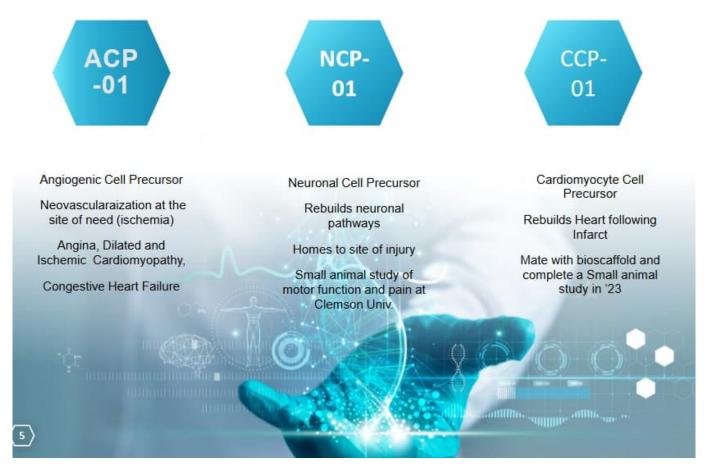
Hemostemix Plans to Revolutionize Stem Cell Therapy with Scalable Production and New Sales Goals

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)

The Hemostemix Platform



Source: <u>Hemostemix company presentation</u>

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 <u>announced</u> 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, <u>stated</u>: "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 <u>InvestorIntel CEO video</u>, 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

Scalable Production

A Stepped Approach to Automated Scaled Production and Profitability

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
MANUAL			SEMI-AUTO		FULLY AUTOMATED
20 batches/mo.	40 batches/mo.	60 batches/mo.	72 batches/mo.	80 batches/mo.	4000 batches/mo.
l Team	2 Teams	2 Teams	2 Teams	2 Teams	5 facilities 10 employees/
1 Shift	2 Shifts	2 Shifts	2 Shifts	2 Shifts	facility 2 Shifts
Treatment Price					
\$25k	\$25k	\$25k	\$25k	\$25k	\$7.5k - \$25k
Treatment Cost					
\$14k	\$11k	\$10k	\$6k	\$6k	\$2.5k
Elapsed Time					
16 months	20 months	24 months	36 months	48 months	60 months

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

Hemostemix's sales target is to reach \$360 million of risk-adjusted sales in 2027

Scalable Production

2022 2023 2024 2025 2026 2027

GROWTH DRIVER: Cost Effective Scaling of Autologous Lab Processes Significant Growth By 2029 - \$22B+ NRA Revenue Potential A Phased Approach to \$22B+ High Volume Low Cost Production of ACP01 Non-Risk Adjusted** \$360M COPD \$360M Risk Adjusted Sales \$13.2B CHF Fully Automated \$5.3B ICM \$2.28 Automatic \$884M Manual 2 Suites 2 Shifts DCM \$213M 2 Suites 1 Shift **VDim** 13utte 15hift \$154M

2027

2029

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 <u>included</u>: "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 <u>US FDA Clinical Trial approval</u> 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.

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

written by InvestorNews | February 13, 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 <u>appointment</u> 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

Don't miss other InvestorIntel interviews. Subscribe to the InvestorIntel YouTube channel by clicking here.

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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If you have any questions surrounding the content of this interview, please contact us at +1 416 792 8228 and/or email us direct at info@investorintel.com.

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

written by InvestorNews | February 13, 2023 Since we last <u>covered Hemostemix</u> 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, <u>Dr. Hébert</u> 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.

<u>Dr. Grillari</u> 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 stemcell-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.

Hemostemix CEO on ACP's Response to Ischemia in the Circulatory System

written by InvestorNews | February 13, 2023 In a recent InvestorIntel interview, Peter Clausi speaks with Thomas Smeenk, Co-Founder, President and CEO of Hemostemix Inc. (TSXV: HEM | OTC: HMTXD), about Hemostemix's technology that uses patients own blood to treat ischemia in the circulatory system of the body.

In this InvestorIntel interview, which may also be viewed on YouTube (click here to subscribe to the InvestorIntel Channel), Thomas said, "We take blood from patient's arm. We fractionate out their stem cell from that blood." He continued, "Then we culture them and change them from a raw stem cell into an angiogenic cell precursor that is programed to address ischemia in the circulatory system of the body. It is common in diabetics, in individuals who suffer from heart disease such as

angina or ischemic cardiomyopathy, in wound care."

Thomas stated that Hemostemix has treated more than 500 patients using the technology which is now in clinical trials. He added, "The second one we patented is NCP (Neural Cellular Precursor). This is a cell that can be used to treat stroke, diseases that have nerve damage."

To watch the full interview, click here

About Hemostemix Inc.

Hemostemix is a publicly traded autologous stem cell therapy company, founded in 2003. A winner of the World Economic Forum Technology Pioneer Award, the Company developed and is commercializing its lead product ACP-01 for the treatment of CLI, PAD, Angina, Ischemic Cardiomyopathy, Dilated Cardiomyopathy and other conditions of ischemia. ACP-01 has been used to treat over 300 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 who have exhausted all other options to save their limb from amputation.

On <u>October 21, 2019</u>, the Company announced the results from its Phase II CLI trial abstract presentation entitled "Autologous Stem Cell Treatment for CLI Patients with No Revascularization Options: An Update of the Hemostemix ACP-01 Trial With 4.5 Year Follow-up" which noted healing of ulcers and resolution of ischemic rest pain occurred in 83% of patients, with outcomes maintained for up to 4.5 years.

The Company owns 91 patents across five patent families titled: Regulating Stem Cells, In Vitro Techniques for use with Stem Cells, Production from Blood of Cells of Neural Lineage, and Automated Cell Therapy.

To know more about Hemostemix Inc., click here

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Co-founder Thomas Smeenk on the benefits of Hemostemix autologous stem cell therapy

written by InvestorNews | February 13, 2023 In a recent InvestorIntel interview, Peter Clausi speaks with Thomas Smeenk, Co-Founder, President and CEO of Hemostemix Inc. (TSXV: HEM | OTC: HMTXD), about using Hemostemix's patented autologous stem cell therapy platform to treat Ischemia and Angina with significant success in more than 500 patients.

In this InvestorIntel interview, which may also be viewed on YouTube (click here to subscribe to the InvestorIntel Channel), Thomas went on to give an introduction about the origin of the company and talked about the strong management team and well known board members. "I have come across some good technologies and put together a team that have succeeded," Thomas commented.

Thomas also provided an update on Hemostemix's ACP-01 Phase 2 Clinical Trials. ACP-01 uses a patient's own cells to restore blood flow to ischemic limbs and has the potential to treat a range of ischemic diseases.

To watch the full interview, click here

About Hemostemix Inc.

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Hemostemix steps into the new year with capital and its critical clinical study data in hand

written by InvestorNews | February 13, 2023 With a new management team spearheading Hemostemix Inc. (TSXV: HEM | OTC: HMTXF), the Company started 2021 with its Critical clinical study data in hand. Raising over \$4 million in 2020 and then in December adding an additional \$4 million to the coffers (\$2.75 million at a 50% premium), Hemostemix completed a 1-for-20 share consolidation as it charges into the New Year.

Receiving a copy of its entire clinical trial database relating to the clinical trial for Critical Limb Ischaemia (CLI) using its ACP-01 therapy (Angiogenic Cell Precursors) in November 2020 was a key event for Hemostemix's management team and it garnered real interest from the market.

Hemostemix - Platform for Stem Cell Therapies

Based in Calgary and founded in 2006, Hemostemix is a clinical-stage biotechnology company specializing in blood-derived stem cell therapeutics with its lead product (ACP-01) in Stage 2 clinical trials for the treatment of CLI.

CLI is a disease caused by the narrowing of arteries in the limbs, particularly the legs, hands, and feet, causing chronic pain and soreness. Untreated CLI can sometimes require the amputation of the specific limb.

Stem cell treatments have been used for over 30 years to treat people with cancer conditions such as leukemia and lymphoma.

There are two main types of stem cell transplants: allogeneic and autologous. In an allogeneic stem cell transplant procedure, the patient receives stem cells from a donor. In an autologous stem cell transplant procedure, the patient provides themselves the stem cells for the procedure from various sources, including bone marrow or blood.

Hemostemix's autologous stem cell therapy platform uses the patient's own blood to harvest the stem cells and the treatment helps to restore circulation in the damaged tissues.

Hemostemix has a strong intellectual property (IP) portfolio of 91 patents and has treated more than 500 patients with clinical results showing an improvement in 83% of the patients receiving its ACP-01 stem cell therapy.

Advantages with Hemostemix's process include the use of blood, which is safer and less invasive than extracting bone marrow, and since you are using the patient's own blood, there is no immune rejection.

The clinical trials have shown that ACP-01 is safe and effective in the treatment of CLI. Now that Hemostemix has received the entire clinical trial database, it has entered into a contract with a new Clinical Research Organization (CRO) to complete the midpoint statistical analyses of the efficacy of ACP-01 and expects to publish the results this quarter.

Hemostemix — **Not** a 1-Trick **Pony** Company

ACP-01 has the potential to treat other conditions such as Angina, Ischemic & Dilated Cardiomyopathy, and Peripheral Artery Disease (PAD). Currently, Hemostemix is preparing for Phase 2 trials for the treatment of Angina and is seeking joint-venture partners to fund the other Phase 2 trials.

Hemostemix has also developed NCP-01 (Neural Cellular Precursor) from blood with the potential, through building new neuronal lineage cells in a patient, to treat Alzheimer's disease, Amyotrophic Lateral Sclerosis (ALS), Parkinson's disease, spinal cord injuries, and stroke-related issues. NCP-01 is currently in the R&D phase and is pre-clinical.

Market Size

According to the American Heart Association, Cardiovascular disease (CVD) accounted for approximately 1 of every 3 deaths in the United States in 2019.

Factors that increase the risk of CLI include diabetes, high cholesterol levels, high blood pressure, obesity, or smoking, all risk factors also associated with CVD.

Unfortunately, most of these factors are increasing at an alarming rate — a study by the Centers for Disease Control and Prevention (CDC) in the United States, showed the prevalence of diagnosed diabetes has more than doubled from 3.3% in 1995 to 7.40% in 2015, affecting 23.4 million Americans.

According to a market research report released in 2019, the value of just the global CLI treatment market is projected to reach US\$5.39 billion by 2025, up from US\$3.13 billion in 2018, at an annual growth rate of 8%.

Competitive Landscape and Market Cap Comparisons

Even with Hemostemix's recent market surge, its market cap is only C\$32.5 million. Similar-sized biotech companies focusing on CLI trade much higher.

Cynata Therapeutics Limited (ASX: CYP) is an Australian biotechnology company with a Phase 2 clinical-stage trial for its stem cell therapy for CLI using bone marrow and has a market

cap of C\$93.6 million.

Pluristem Therapeutics Inc. (NASDAQ: PSTI) is a Phase 3 biotherapeutics company, based in Israel, that also has an allogeneic cell therapy for the treatment of CLI using the placenta and has a market cap of C\$231.9 million.

In November 2020, Bristol-Myers Squibb Company (NYSE: BMY) bought MyoKardia, Inc. for US\$13.1 billion. MyoKardia was a clinical-stage biopharmaceutical company that developed therapies for the treatment of cardiovascular diseases and its lead product was a Phase III clinical trial drug used in the treatment of hypertrophic cardiomyopathy (HCM).

As a company shifts from Phase 2 to Phase 3 clinical trials, the market cap often has a step-function shift higher, making it an ideal time to look at Hemostemix.



SOURCE: