Thomas Smeenk of Hemostemix talks about market reaction to successful litigation settlement

written by InvestorNews | May 13, 2022 In this InvestorIntel interview with host Stephen Lautens, <u>Hemostemix Inc.</u>'s (TSXV: HEM | OTCQB: HMTXF) Co-Founder, President and CEO Thomas Smeenk talks about Hemostemix achieving a major <u>milestone</u> this week by announcing it had successfully settled all litigation regarding its ownership of its intellectual property and the market's immediate positive reaction.

In the interview, which can also be viewed in full on the InvestorIntel YouTube channel (click here), Thomas Smeenk talks about Hemostemix's portfolio of autologous stem cell therapies that uses patient's own blood to save limbs from amputation, treat heart diseases and other conditions of ischemia. With 91 patents issued worldwide, Thomas says that with the successful return of all of its intellectual property and clinical trial data, Hemostemix is now cleared to continue to move forward with its promising therapies.

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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 has published seven peer reviewed articles about the safety and efficacy of its lead product ACP-01 as a 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, placebocontrolled, 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 October 21, 2019, 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 learn more about Hemostemix Inc., <u>click here</u>.

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Any projections given are principally intended for use as objectives and are not intended, and should not be taken, as assurances that the projected results will be obtained by the Company. The assumptions used may not prove to be accurate and a potential decline in the Company's financial condition or results of operations may negatively impact the value of its securities. Prospective investors are urged to review the Company's profile on <u>Sedar.com</u> and to carry out independent investigations in order to determine their interest in investing in the Company.

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 <u>info@investorintel.com</u>.

Built on arguably one of the greatest medical breakthroughs

of our time, Hemostemix has 'your fountain of youth'…

written by InvestorNews | May 13, 2022

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:

- The results of the 106 subjects suffering from ischemic cardiomyopathy "[experienced] <u>improved cardiac function</u> <u>(Left Ventricle Ejection Fraction</u>), 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 <u>83% of subjects</u> 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 <u>announced</u> on February 14 that they have trademarked the term "Your Fountain of Youth" for a period of 10 years.

In other news Hemostemix recently <u>announced</u> 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 <u>announced</u> 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 <u>US\$69.7</u> billion in 2019. The global market for diabetes care products including drugs and devices is expected to exceed <u>US\$111.2</u> <u>billion</u> 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 <u>states</u>: "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 <u>C\$8 million</u>. 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 | May 13, 2022 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, <u>Hemostemix Inc.</u> (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, smallscale, 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 $\frac{C$11 \text{ million}}{C}$,

Further learning

- <u>Hemostemix Announces the Second Stem Cell Recipient</u> <u>Interview: One Week to No Chest Pain</u>
- 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

Fully funded with strong IP Portfolio, Hemostemix marches forward towards FDA Phase II Clinical Trial Completion

written by InvestorNews | May 13, 2022 <u>Hemostemix Inc</u>. (TSXV: HEM | OTC: HMTXF) continues to move forward with its FDA Phase II clinical trial program of its blood-derived, stem cell therapeutics product (ACP-01) at sites in the United States and Canada.

ACP-01 is being tested as a treatment for medical conditions such as Critical Limb Ischemia (CLI). CLI is a blockage in the arteries, which reduces blood flow and oxygen in the limbs, and can cause conditions such as severe pain in the feet or toes, wounds that won't heal, and if left untreated, could result in the amputation of the affected limb.

Although ACP-01 has been used to treat over 500 patients, currently it is part of a Phase II clinical trial of its safety and efficacy in patients with advanced CLI who have exhausted all other options to save their limb from amputation.

Recently, Hemostemix <u>announced an update</u> on the ACP-01 clinical trial as the company believes that all follow-up visits of the enrolled trial subjects should be completed by March 31, 2021.

In the clinical trial, 65 subjects were enrolled and randomly 2/3 of the participants received ACP-01 with the other participants receiving a placebo. Once the last follow-up appointment is completed and trial data has been analyzed, the company will provide an update. We expect this information in late April or early May.

The earlier clinical trials have shown that ACP-01 is safe and effective in the treatment of CLI. The data collected will include treatment success or failure, pain, quality of life, and any adverse effects.

Signs "BREAD" Contract with Canadian Department of Foreign Affairs

In January, Hemostemix also <u>announced</u> it signed the Building Relationships Entrepreneurs & Dealmakers (BREAD) contract with the Department of Foreign Affairs, Trade and Development.

The BREAD agreement is a Canadian government initiative to assist high-potential, biotech-focused Canadian Small and Medium Enterprises and is designed to accelerate the growth of Canadian biotechnology companies.

The Trade Commissioner Service (TCS) department, within the Department of Foreign Affairs, helps Canadian companies grow into international markets by assessing market potential, finding qualified partners, and resolving problems.

Hemostemix is working with the TCS to source qualified partners to license ACP-01 in foreign markets including the United States, Japan, and South Korea,

Hemostemix – a Platform for Stem Cell Therapies

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

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

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

The company is also investigating the use of ACP-01 to treat patients hospitalized with COVID-19 that exhibit low oxygen levels and significant inflammation.

Hemostemix has also developed NCP-01 (Neural Cellular Precursor) from blood with the potential to treat neurological conditions such as Alzheimer's, Amyotrophic Lateral Sclerosis ("ALS"), Parkinson's, spinal cord injuries, and stroke-related issues. NCP-01 is currently in the R&D phase and is pre-clinical.

Fully Funded for the Year

In December 2020, Hemostemix <u>raised \$2.75 million</u> at \$0.30 per unit that comprised of a share and a warrant priced at \$1.00 for a period of 12 months. Proceeds from the offering are expected to be used to pay for various corporate expenses and to fund the clinical trial costs.

In addition to the cash on hand, Hemostemix has a strong intellectual property (IP) portfolio of 91 patents.

To generate some cash flow, Hemostemix plans to ramp up the revenue side of the business by reinstating its compassionate care revenue stream in the United States.

Final Thoughts

Stem cell treatments have been used for over 30 years to treat people with cancer conditions such as leukemia and lymphoma and earlier trials of Hemotemix's ACP-01 have shown positive effects in the treatment of CLI.

Factors that increase the risk of CLI include diabetes, high cholesterol levels, high blood pressure, obesity, or smoking. Unfortunately, most of these factors are increasing at an alarming rate. Treatment for these conditions has a billiondollar market potential.

Currently, Hemostemix has a market cap of only C\$25 million with similar-sized biotech companies focusing on CLI trading much higher. As a company shifts from FDA Phase II to Phase III clinical trials, we expect the share price and market cap to shift higher to reflect the potential of ACP-01.

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

written by InvestorNews | May 13, 2022 In a recent InvestorIntel interview, Peter Clausi speaks with Thomas Smeenk, Co-Founder, President and CEO of <u>Hemostemix Inc.</u> (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, <u>click here</u>

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 October 21, 2019, 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 | May 13, 2022

In a recent InvestorIntel interview, Peter Clausi speaks with Thomas Smeenk, Co-Founder, President and CEO of <u>Hemostemix Inc.</u> (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, <u>click here</u>

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Hemostemix steps into the new year with capital and its

critical clinical study data in hand

written by InvestorNews | May 13, 2022

With a new management team spearheading <u>Hemostemix Inc.</u> (TSXV: HEM | OTC: HMTXF), the Company started 2021 with its <u>critical</u> <u>clinical study data</u> 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 1for-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 <u>November 2020</u> 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 clinicalstage 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 <u>91 patents</u> 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 bio-

therapeutics 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.

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SOURCE: