Dr. McNorgan Discusses Hemostemix's Stem Cell Technology and Potential with Elon Musk's Neuralink

written by InvestorNews | June 1, 2023 In this InvestorIntel interview, Tracy Weslosky talks with Hemostemix Inc.'s (TSXV: HEM | OTCQB: HMTXF) Advisory Board Member Dr. Chris McNorgan, Ph.D. about why Hemostemix's NCP-01 (Neural Cellular Precursors) technology would be of interest to a company like Neuralink.

With Elon Musk's brain implant company Neuralink recently receiving FDA approval for human trials, Dr. McNorgan explains how NCP-01 can potentially assist in all phases of the implantation process, including mitigating complications and ensuring proper functionality of the brain implants.

Neurons do not naturally regenerate, causing lifelong problems when damaged. With the potential to regenerate neuronal cells, Dr. McNorgan discusses how Hemostemix's NCP-01 technology can also help restore brain functionality in patients suffering from progressive dementia.

<u>Dr. McNorgan</u> directs the Computational Cognitive Neuroscience (CCN) laboratory at the University of Buffalo. His research focuses on computational cognitive neuroscience, developing computer models to simulate how the brain functions, and is directly relatable to neural electrode-based implantation.

Dr. McNorgan estimates the current market for assistive technologies related to brain signal interception and decoding

is estimated to be around \$36.5 billion, but the potential market is much larger once the technology is perfected.

The applications of Hemostemix's technology extend beyond assistive technologies, including addressing conditions like blindness, hearing loss, and dementia.

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 precursors, and cardiomyocyte cell precursors. The Company develops cell therapy products from the patient's own blood, which is a non-invasive source of therapeutic cells. Its lead product is ACP-01, an autologous cell therapy, which is in FDA Phase II clinical trial for the treatment of vascular diseases, such as cardiovascular disease, peripheral arterial disease, angina pectoris, and ischemia. Its second product is NCP-01, used to help rebuild neuronal pathways in the brain after injury or disease.

To learn more about Hemostemix Inc., click here

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Thomas Smeenk Discusses the Intersection of Hemostemix's NCP Treatment and Elon Musk's Neuralink

written by InvestorNews | June 1, 2023 With Dr. McNorgan's appointment, it brings another expert onto the team that includes Dr. Henderson, a neurosurgeon, and Dr. Inna Sorel, the mother of the invention of NCP itself, to help drive the legitimacy of licensing the NCP-01 platform. Thomas discusses the potential for licensing and partnerships to take NCP-01 to the neural electrode-based implantation market, an industry that is being led by players such as Elon Musk's

Neuralink.

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

written by InvestorNews | June 1, 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 <u>ACP technology</u> 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. <u>According to Hemostemix</u>: "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.

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

written by InvestorNews | June 1, 2023 | Hemostemix Inc. (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 billion-dollar 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.