HEMOSTEMIX

Healthcare, Diabetic Leg Ulcers, Cardiomyopathy

A Safe Scalable Tested Delivery Platform of Autologous Stem Cell Therapeutics

Hemostemix is a phase III clinical-stage biotechnology company focused on developing and commercializing a proprietary stem cell therapy to treat diseases caused by restricted blood flow (ischemia).

The patient's blood is the source of an enhanced synergetic cell therapeutic that restores blood flow to ischemic tissues and organs. The process is safe, simple, scalable, patented (87) and cost effective. The therapeutic, angiogenic cells precursors ("ACP"), are cultured in the patient's serum, minimally manipulated, maintaining the body's natural signaling processes. ACP home to and engraft into the site of ischemia to regenerate it. By maintaining the synergetic signaling capacities of one's DNA, ACP recruits other stem cells circulating in the blood to the site of ischemia to aid in its regeneration (European Journal of Heart Failure).

Six published studies of ACP-01, including a retrospective study of 53 consecutively treated ischemic cardiomyopathy patients, 345 study subjects in total, demonstrate ACP-01 is safe and preliminarily efficacious in the treatment of peripheral arterial disease, critical limb ischemia, angina, ischemic and dilated cardiomyopathy. ACP has also been used compassionately to treat vascular dementia successfully

The five year survival rate of a no-option CLI amputees is < 30%. In its CLI Phase II clinical trial of 68 subjects randomized 2:1 to receive ACP, 93.5% of ACP-01 treated limbs were saved from amputation. An interim data point of the phase II trial published by the University of British Columbia and University of Toronto noted "…healing of ulcers and resolution of ischemic rest pain occurred in 83% of subjects (10 of 12), and that outcomes were maintained for up to 4.5 years." It is estimated there are 236 Million who suffer from peripheral arterial disease (PAD), the preceding condition of CLI. Approximately 10% of PAD patients progress to CLI (23,600,000), and approximately 40% of CLI patients face limb amputation.

ACP-01 as a treatment of heart disease (ischemic cardiomyopathy), demonstrated statistically significant improvements in 245 patients who participated in one of three phase 1 studies (171 subjects), or who were consecutively treated compassionately for ischemic cardiomyopathy and studied retrospectively. In the retrospective study, absolute left ventricle ejection fraction improved 7.69% on average at 12 months after treatment ($p<0.003$). The global market for these two indications is $9 Billion.

The company will generate revenue from compassionate treatments of CLI and cardiovascular disease, while completing clinical trials, following the reestablishment of production in Montreal. Hemostemix is working on a program to sell 500 regulatory approved exempt compassionate treatments at $35,000 each ($17.5M), to generate revenue, and fund the scaling of production to meet demand less dilutively. The Company is scaling production to 4,000 batches per month by the end of 2027, to optimize margins. Management forecast it is able to reduce its costs of goods sold to a level that is less than the disposable costs of competiting manufacturing technologies.

Management and Directors have more than $8.3 Million invested, and they invite you to join them at a favorable valuation. To discuss your interest in Hemostemix, you may reach Thomas Smeenk, CEO, at +1-905-580-4170, and TSmeenk@Hemostemix.com.