Hemostemix Provides a Clinical Trial Update and Announces the Release and Filing of 2020 Year-end Audited Financial Statements and Management Discussion and Analysis

written by Raj Shah | May 1, 2021

April 30, 2021 (Source) - Hemostemix Inc. (TSXV: HEM) (OTC: HMTXF) [](FSE: 2VF0) ("Hemostemix" or the "Company") is pleased to announce that, with the last patient follow up completed in April, the Company is now focusing its efforts on completing the key areas of the trial including, but not limited to, data entry, source document verification, data base query management and validation as more fully described below, biostatistical analyses and final reporting documentation. This process is expected to take approximately three months.

The Company has contracted a clinical data management services company to provide Hemostemix with clinical trial data base management services, including data base management plan adherence, data base edit checks, data base query management, data base integration and validation, data base reconciliations by events, data base analysis readiness reporting, data base hard lock, and data base closeout and delivery. Hemostemix is continuing with the data entry and source document verifications. As announced on April 23, the 65th (final) subject has completed their last follow-up visit and the Company has contracted two additional clinical research associates to assist with the completion of the source document verification process.

Hemostemix filed on SEDAR its audited annual financial statements for the period ending December 31, 2020, with a comparison to the year earlier period, including the notes related thereto and also including the management discussion and analysis (MD&A).

ABOUT HEMOSTEMIX

Hemostemix is a publicly traded autologous stem cell therapy company. 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 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 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 entitled "Autologous Stem Cell Treatment for CLI Patients with No Revascularization Options: An Update of the Hemostemix ACP-01 Trial With 4.5 Year Followup" 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. For more information, please visit <u>www.hemostemix.com</u>.

Contact: Thomas Smeenk, President, CEO & Co-Founder

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Forward-Looking Information: This news release contains "forward-looking information" within the meaning of applicable Canadian securities legislation. All statements, other than statements of historical fact, included herein are forwardlooking information. In particular, this news release contains forward-looking information in relation to: the Offerings including the size of the Offerings, the potential lead order for the Debenture Offering, potential insider participation in the Offerings, the use of proceeds of the Offerings, the closing of the Offerings, the potential exemptions used for the Offerings, any potential finder's fee paid on the Offerings, the potential accelerated expiry date of the Warrants and the Debenture Warrants, and the approval required for the Offerings, including Exchange acceptance of the Offerings \Box ; and the commercialization of ACP-01.
There can be no assurance that such forward-looking information will prove to be accurate. Actual results and future events could differ materially from those anticipated in such forward-looking information. This forward-looking information reflects Hemostemix's current beliefs and is based on information currently available to Hemostemix and on assumptions Hemostemix believes are reasonable. These assumptions include, but are not limited to: the underlying value of Hemostemix and its Common Shares; market acceptance of the Offerings; Exchange acceptance of the Offerings; the successful resolution of the litigation that Hemostemix is pursuing or defending (the "Litigation"); the results of ACP-01 research, trials, studies and analyses, including the midpoint analysis, being equivalent to or better

than previous research, trials or studies as well as management's *[]expectations* of anticipated results; Hemostemix's general and administrative costs remaining constant; the receipt of all required regulatory *Dapprovals* for research, trials or studies; the level of activity, market acceptance and market trends in the healthcare sector; the \square economy generally; consumer \square interest in Hemostemix's services and products; competition and *[]Hemostemix's* competitive advantages; and Hemostemix obtaining satisfactory financing to ∏fund Hemostemix's operations including any research, trials or studies, and the Litigation. Forward-looking information is subject to known and unknown risks, uncertainties and other factors that may cause the actual results, level of activity, performance or achievements of Hemostemix to be materially different from those expressed or implied by such forwardlooking information. Such risks and other factors may include, but are not limited to: the ability of Hemostemix to complete its current CLI clinical trial, complete a satisfactory analyses and the results of such analyses and future clinical □trials; □litigation and potential litigation that Hemostemix may face; general business, economic, competitive, political and social uncertainties; general capital market conditions and market prices for securities; delay or failure to receive board or regulatory approvals; the actual results of future operations including the actual results of future research, trials or studies; competition; changes in legislation \square affecting Hemostemix; the timing and availability of external financing on acceptable terms; long-term capital requirements and future developments in Hemostemix's markets and the markets in which it expects to compete; ☐ lack of qualified, skilled labour or loss of key individuals; and risks *[]*related to the COVID-19 pandemic including various recommendations, orders and measures of governmental authorities to \Box try to limit the pandemic, including travel restrictions, border closures, non-essential

business closures, □service disruptions, quarantines, selfisolations, shelters-in-place and social distancing, disruptions to markets, disruptions to economic activity and [financings, disruptions to supply chains and sales channels, and a deterioration of general economic conditions including a □possible national or global recession or depression; the potential impact that the COVID-19 pandemic may have on Hemostemix which may include a decreased demand for the services that Hemostemix *□offers*; and a deterioration of financial markets that could limit Hemostemix's ability to obtain external financing. A description of additional risk factors that may cause actual results to differ materially from forward-looking information can be found in Hemostemix's disclosure documents on the SEDAR website at www.sedar.com. Although Hemostemix has attempted to identify important factors that could cause actual results to differ materially from those contained in forwardlooking information, there may be other factors that cause results not to be as anticipated, estimated or intended. Readers are cautioned that the foregoing list of factors is not exhaustive. Readers are further cautioned not to place undue reliance on forward-looking information as there can be no assurance that the plans, intentions or expectations upon which they are placed will occur. Forward-looking information contained in this news release is expressly qualified by this cautionary statement. The forward-looking information contained in this news release represents the expectations of Hemostemix as of the date of this news release and, accordingly, it is subject to change after such date. However, Hemostemix expressly disclaims any intention or obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as expressly required by applicable securities law.

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