## Hemostemix Inc.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF THE RESULTS OF OPERATIONS AND FINANCIAL CONDITION

For the three month period ended March 31, 2018 and 2017 as at May 28, 2018

# **BASIS OF PRESENTATION**

The following Management's Discussion and Analysis ("MD&A") covers the operations, financial position and operating results of Hemostemix Inc. (the "Company", "HEMOSTEMIX", "we", "us" or "our") for the three month periods ended March 31, 2018 and 2017. It is intended to help readers better understand the operations and key financial results, as they are, in our opinion, at the date of this report and should be read in conjunction with the unaudited interim condensed consolidated financial statements of the Company for the three month periods ended March 31, 2018 and March 31, 2017 and the accompanying notes which have been prepared under International Financial Reporting Standards ("IFRS"). The interim condensed consolidated financial statements have been reviewed by the Audit Committee of the Company and have been approved by its Board of Directors on May 28, 2018. Additional information relating to the Company is available on SEDAR at <a href="www.sedar.com">www.sedar.com</a> as well as the Company's website at <a href="www.hemostemix.com">www.hemostemix.com</a>.

## CAUTIONARY STATEMENT REGARDING FORWARD LOOKING INFORMATION

This MD&A contains certain forward-looking information and forward-looking statements, as defined in applicable securities laws (collectively referred to herein as "forward-looking statements"). These statements relate to future events or the Company's future performance. All statements other than statements of historical fact are forward-looking statements. Often, but not always, forward-looking statements can be identified by the use of words such as "plans", "expects", "is expected", "budget", "scheduled", "estimates", "continues", "forecasts", "projects", "predicts", "intends", "anticipates" or "believes", or variations of, or the negatives of, such words and phrases, or state that certain actions, events or results "may", "could", "would", "should", "might" or "will" be taken, occur or be achieved. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially from those anticipated in such forward-looking statements. The forward-looking statements in this MD&A speak only as of the date of this MD&A or as of the date specified in such statement. Specifically, this MD&A includes, but is not limited to, forward-looking statements regarding: the Company's goal of creating shareholder value; its ability to meet its operating costs for the fiscal year ended December 31, 2018; the plans, costs, and timing for future research and development of the Company's stem cell technologies, including the costs and potential impact of complying with existing and proposed laws and regulations and clinical trials; management's outlook regarding future trends; sensitivity analysis on financial instruments that may vary from amounts disclosed; prices and price volatility of the Company's products; and general business and economic conditions.

By their nature forward-looking statements are subject to known and unknown risks, uncertainties, and other factors which may cause actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such factors include, among other things, the Company's stage of development, long-term capital requirements and future ability to fund operations, future developments in the Company's markets and the markets in

which it expects to compete, risks associated with its strategic alliances and the impact of entering new markets on the Company's operations. Each factor should be considered carefully, and readers are cautioned not to place undue reliance on such forward-looking statements. See "Risks and Uncertainties."

These statements are essentially forward-looking and are subject to risks and uncertainties, as described in the "Risks and Uncertainties" section, below. Actual results, levels of activity, performance or achievements could differ materially from those projected, discussed or contemplated herein and are dependent upon on several factors, including the successful and timely completion of research and development initiatives, the uncertainties related to the market acceptance, and the commercialization of our products thereafter.

The Company disclaims any intention or obligation to update or revise these forward-looking statements, resulting from additional or new information, future events or otherwise, except as may be required by law.

## THE COMPANY

Hemostemix Inc. is a biotechnology company whose principal business is to develop, manufacture and commercialize blood-derived cell therapies for medical conditions not adequately addressed by current treatments.

The consolidated financial statements of the Company comprise the accounts of Hemostemix Inc., (formerly Theravitae Inc.) Hemostemix Ltd, and Kwalata Trading Limited, the Company's wholly-owned subsidiaries. Hemostemix Inc. was originally incorporated on May 6, 2006 under the provisions of the Canada Business Corporations Act. Hemostemix Ltd. was incorporated on June 20, 2011 in Israel and Kwalata Trading Limited ("Kwalata") was incorporated on November 1, 2007 in Cyprus. Effective October 1, 2017 Hemostemix Ltd. ceased operations (See 'Discontinued Operations'). During 2014, the Company completed a reverse takeover transaction to form a new entity under the Business Corporations Act (Alberta) called "Hemostemix Inc." On November 27, 2014, shares of the Company began trading on the TSX Venture Exchange under the symbol "HEM". The Company's head office is located at Suite 1049, 150 – 9<sup>th</sup> Avenue SW, Calgary, Alberta T2P 3H9.

## **BUSINESS OVERVIEW**

We are a clinical stage biotechnology company with a patented technology whose principal business is to develop, manufacture and commercialize blood-derived cell therapies to treat various diseases not adequately addressed by current therapies. Hemostemix has five families of patents related to its products and manufacturing processes. The intellectual property of the Company broadly covers synergetic cell populations and angiogenic cell precursors (ACPs, including the lead cell product ACP-01), myocardial cell precursors (MCPs), and neural cell precursors (NCPs).

# CORPORATE, PRODUCT AND CLINICAL TRIAL UPDATES

The following items highlight the Company's activities during the three month period ended March 31, 2018 and any subsequent development up until the date hereof.

## **Corporate Update**

# Management

Effective May 1, 2018 the transition of the Chief Financial Officer ("CFO") role, as previously announced, was complete with the appointment of Kristin Gulka, CPA, CA. The previous CFO, Mr. Berman, will continue to provide services on an as needed basis for the Company on a consultancy basis.

# **Product Update**

# Angogenic Cellular Precursor (ACP-01)

Our main product, called ACP-01, is created from a process we discovered and developed whereby a patient's own blood is drawn, and stem cells from the blood draw are raised and expanded, then reinjected into the patient's diseased tissue. 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. This results in an enhanced stem cell therapy treatment that restores circulation to tissues damaged by disease. Our process for harvesting stem cells is less invasive than some other stem cell therapies on the market as the stem cells are taken from a patient's blood which is a simple process as compared to taking stem cells from fatty tissue or bone marrow. 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.

# Intellectual Property

Our proprietary 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, which has the potential to generate therapies for a broad range of ischemic diseases such as critical limb ischemia, peripheral artery disease, congestive heart failure and other vascular diseases. Hemostemix develops its cell therapy products from a patient's own blood which is a relatively low risk, cost effective and non-invasive source of therapeutic cells. Hemostemix is conducting a Phase II clinical trial for its lead product ACP-01 for treating critical limb ischemia ("CLI").

The Company continues to monitor its patent portfolio with the goal of protecting and expanding its Intellectual Property. The Company has over 50 patents and patent applications in more than 25 jurisdictions.

# **Clinical Trial Updates**

# Phase II Clinical Trial for Patients with Critical Limb Ischemia

Critical limb ischemia ("CLI") is a severe blockage in the arteries of the lower extremities, which markedly reduces blood-flow. It is a serious form of peripheral arterial disease ("PAD"). PAD is caused by atherosclerosis, the hardening and narrowing of the arteries over time due to the buildup of fatty deposits called plaque. CLI is a chronic condition that results in severe pain in the feet or toes due to nerve and tissue damage. Complications of poor circulation can include sores and wounds that won't heal in the legs and feet. Left untreated, the complications of CLI may result in the amputation of the affected limb.

Most patients with CLI are treated surgically and depending on the severity, the surgery can be minimally invasive (angioplasty or stents) to very invasive (bypass surgery, grafts or amputation). Our therapy provides an alternative to surgery, which we believe is safer and more cost effective as no lengthy hospital stay or recovery time is needed. The prevalence of CLI is increasing, as CLI predominately affects the growing population aged 50 and older. According to The Sage Group LLC, in the United States alone, approximately 20 million people are affected by PAD, and it is estimated that approximately 7-8 million people in the United States and Europe suffer from CLI. The Sage Group LLC, estimates that in the United States, medical costs attributable to CLI amount to US\$25 billion annually.

The clinical trial is a randomized, placebo-controlled, double blind Phase II clinical trial to confirm the safety and efficacy of ACP-01. Under the current USA Food and Drug Administration ("FDA") and Health Canada approved protocol approximately 95 patients will be followed for a minimum period of six months and a maximum of twelve months. The first clinical trial site started in 2014 in Canada. A second Canadian site was added in 2015 as well as three sites in South Africa.

In June 2016, the Company's Phase II clinical trials of ACP-01 used in the treatment of CLI was suspended. At the same time the agreement with a contract research organization managing these clinical trials was terminated. After the reorganization of Hemostemix in early 2017, the new management team actively reviewed and evaluated proposals from various other contract research organizations with the goal of being prepared to restart the clinical trial in an effective and efficient manner.

On September 8, 2017 the Company entered an agreement with Topstone Research Inc. ("Topstone") to provide clinical research monitoring services, project management, regulatory document management, and related services to advance the Company's international, multicenter, Phase II clinical trial for patients with CLI. Topstone, is a Toronto, Ontario based global full-service contract research organization ("CRO") service provider.

With the engagement of Topstone, the Company began actively identifying and selecting qualified clinical trial sites in both Canada and the USA in October 2017. To date over 25 facilities and institutions have been identified as having good potential to be sites for the clinical trial. The site onboarding process is rigorous with the Company reviewing equipment, facilities, principal investigators, the estimated number of potential patients as well as putting in place agreements, budgets, procedures and protocols. From the clinical trial site perspective there are internal approvals of the Company's clinical trial protocol, agreement, overall budget and general procedures and equipment requirements.

In the third quarter of 2017, amendments to the approved clinical trial protocol were submitted to the FDA and Health Canada, which addressed the change in manufacturing sites (see "Manufacturing Agreement")

and updated various protocol procedures. In December 2017 the Company announced that it received a No Objection Letter from Health Canada the change in manufacturing site and protocol updates. The Company further announced on April 19, 2018 that the FDA raised no objections to the Company's Investigational New Drug ("IND") application.

In April 2018 Hemostemix entered into an agreement and received all approvals from the Vancouver Coastal Health Research Institute ("VCHRI") located in Vancouver, BC to be a clinical trial site for the Company's Phase II clinical trial for CLI. VCHRI is a world leader in translational health research for new therapies, led by the principal investigator, Dr. York N. Hsiang, MB ChB MHSc FRCSC and has over 1,500 personnel engaged in research. It is the research body of Vancouver Coastal Health and a health partner of the University of British Columbia. VCHRI includes three of BC's largest academic and teaching health sciences centers — Vancouver General Hospital, UBC Hospital and GF Strong Rehabilitation Centre — as well as other hospitals and public health agencies across Vancouver Coastal Health. In May 2018 the Company treated its first patient at VCHRI under its continuing Phase II Clinical Trial for CLI.

Currently there are approximately 20 sites are in various stages of the onboarding process. As of the date herein, clinical trial agreements have been executed with four clinical trial sites which are now open to patient enrollment. Additionally, there are twelve clinical trial sites in the final stages of the start-up process and another four sites which were recently identified and are in the early start-up stages.

It is anticipated that the trials will be conducted at approximately 20 sites located throughout Canada and the United States. When the trials were suspended in 2016, there were a total of thirteen patients enrolled in the trials at two sites in Canada. Management believes that these two sites will be able to participate in the reactivated trial and that the data obtained from majority of the thirteen patients previously treated will also be able to be used in the reactivated trial.

## Commercialization of ACP-01

To achieve commercial production of its lead product, ACP-01 for CLI, Hemostemix is required to obtain regulatory approval in each respective country it intends to market ACP-01. Management believes it may be possible to achieve regulatory approval in a few jurisdictions on the strength of positive Phase II data, but in most jurisdictions, clinical data from a Phase III clinical trial will be required to obtain such approval. While focusing on developing ACP-01 through the clinical trial process in the United States and Canada, Hemostemix hopes to achieve commercialization alone or with partners in countries having a suitable regulatory framework.

# Manufacturing Agreement

As part of the overall review of Hemostemix, management reviewed the manufacturing laboratory operations. The Company had a leased manufacturing laboratory facility in Israel. After a review of the facility, operations, logistics and cost it was decided that a manufacturing laboratory closer to the clinical trial sites in North America made sound business sense. In the first half of 2017 various options were reviewed including having the Company continuing to run a dedicated site as well as outsourcing options. In Q4 2017, management decided not to renew the lease on the Israeli manufacturing laboratory and to wind down the Israel operations and move manufacturing to North America. It was also decided that a contract manufacturer would be retained to provide the laboratory manufacturing services.

On February 22, 2018 it was announced that Hemostemix signed a Manufacturing Agreement with Aspire Health Science, LLC ("Aspire") which owns a FDA cGMP ("Certified Good Manufacturing Practices") facility located in Orlando, Florida. It is anticipated that having the product manufactured in Florida will result in improved cost efficiencies and better logistics for the North American clinical trial sites.

The Manufacturing Agreement has an initial one-year term with provisions to renew for additional sixmonth extensions. Basic charges and pricing is fixed throughout the initial one-year term. In addition to ordinary contract manufacturing provisions, the Manufacturing Agreement will also provide Hemostemix with access to Aspire's laboratory and personnel for research and development ("R&D") purposes. Hemostemix will have dedicated work space in Aspire's Orlando lab facility throughout the term of the Manufacturing Agreement and the freedom to conduct R&D work there at its discretion so long as it does not interfere with Aspire's production schedules. Any and all improvements to the Company's pre-existing technology or otherwise related to ACP-01 made pursuant to the Manufacturing Agreement are to remain or become (upon discovery) the property of Hemostemix.

# License Agreement

On February 23, 2018 the Company announced it finalized the terms of a license agreement (the "License Agreement") with Aspire Health Science, LLC ("Aspire") for ACP-01. Under the terms of the License Agreement, Aspire has the exclusive rights to use, sell and import ACP-01 in The Bahamas, Costa Rica, the Dominican Republic, Mexico, Panama and the State of Florida for the treatment of certain approved medical indications, namely Coronary Artery Disease ("CAD"), Peripheral Artery Disease ("PAD"), CLI, Congestive Heart Failure ("CHF") and such other indications as may be designated by Hemostemix from time to time. Aspire also has related rights to manufacture ACP-01 at its Orlando, Florida facilities for such purposes.

Hemostemix receives a percentage of sales on net sales from all revenue generated from ACP-01 in the assigned territories. The License Agreement has an initial three (3) year term, with options for Hemostemix to renew for additional two (2) year extensions. The agreement calls for the development of a business plan including minimum revenue targets. The failure to achieve the minimum revenue targets gives Hemostemix a consequential right to terminate the license(s) granted for an assigned territory or territories.

Hemostemix will continue to maintain control of all aspects of the product(s) subject to the License Agreement (including in particular ACP-01), manufacturing protocols, intellectual property rights, all improvements in the related technology, as well as the use of the technology and products in terms of specific applications. Management expects that the License Agreement will allow Hemostemix to begin generating revenue from its technology while it continues with the Phase II CLI trial in Canada and the United States.

As a first step towards commercialization under the License Agreement, Aspire is in late stages of negotiating terms with The Partners Stem Cell Centre ("PSCC") operating within The Medical Pavilion Bahamas ("TMPB"), based in Nassau, Bahamas, to complete a Phase I Open Trial, Non-Randomized, Single Center Study at their Nassau facility. TMPB, founded in 1990, is a private medical facility with more than 50 full-time medical staff and international directors, including world-renowned specialists in multiple disciplines and collaborative centres, including The Bahamas Heart Centre, The Cancer Centre Bahamas, The Institute for Advanced Medical Procedures and the PSCC. A clinical trial for ACP-01 at the PSCC has been approved by the local Ministry of Health and will consist of twenty (20) heart patients

and twenty (20) CLI patients for treatment under the same clinical trial protocol applicable to the Hemostemix Phase II clinical trial. In accordance with the License Agreement, Hemostemix will also receive all the pertinent data collected during this trial. The data collected from the heart patients in particular will be of significant value to Hemostemix as it builds the necessary safety and efficacy data for ACP-01 that will allow the Company to expand into future clinical trials in Canada and the United States.

## **FINANCINGS**

#### **Debt Conversion**

On January 25, 2017, The Company converted \$1,184,000 in debt through the issuance of 6,725,000 shares of the Company. The debt conversions included (a) \$644,000 in promissory notes converted at \$0.16 per share resulting in the issuance of 4,025,000 shares, (b) \$500,000 of demand loans at \$0.20 per share resulting in the issuance of a further 2,500,000 shares, and (c) \$40,000 owed pursuant to a Right of First Refusal Waiver Agreement resulting in a further issuance of 200,000 shares.

## Capital Raise

The Company completed a capital raising program consisting of (i) a Brokered Private Placement (supplemented by the Non-Brokered Private Placement); (ii) a Rights Offering (iii) a \$4,400,000 secured credit transaction, and (iv) a series of shares for debt transactions (collectively, the "Financings").

On August 25, 2017, the Company raised gross proceeds of \$5,144,140 from a brokered private placement of subscription receipts ("Subscription Receipts") at a price of \$0.05 per Subscription Receipt. The Company closed on the Brokered Private Placement together with a related Non-Brokered Private Placement of Subscription Receipts pursuant to which it raised additional gross proceeds of \$163,445 and the Rights Offering which the Company raised gross proceeds of \$1,063,751, for aggregate gross proceeds from the three sources of \$6,371,336. The Company issued an aggregate of 127,426,715 Subscription Receipts, consisting of 102,882,800 pursuant to the Brokered Private Placement, 3,268,900 pursuant to the Non-Brokered Private Placement and 21,275,015 pursuant to the Rights Offering.

On September 15, 2017, all of the Subscription Receipts were converted into 127,426,715 units ("Units") consisting of 127,426,715 common shares in the capital of Hemostemix and 63,713,357 transferable warrants (each whole warrant, a "Warrant"). Each Warrant will entitle the holder thereof to purchase one Common Share (a "Warrant Share") at price of \$0.20 for a period of 2 years from the Release Date, with an accelerated exercise provision attached to each Warrant commencing on the day following (i) the conversion of the applicable Subscription Receipts into Units and (ii) the expiry of any applicable hold period on the underlying common share, stating that if, for ten consecutive trading days, the closing price of the listed shares of the Company exceeds \$1.00, then the Company may elect to accelerate the expiry date by providing the Warrant holders, 30 days' notice by way of a press release of the accelerated expiry date.

The Company also issued 88,000,000 Units at a price of \$0.05 per Unit pursuant to the conversion of \$4,400,000 of senior secured debt. Each Unit consisted of one common share and one half of one Warrant. The Company also completing a series of shares for debt transactions with certain of the Company's creditors by issuing a total of 6,664,886 common shares to such creditors in full satisfaction of a total of \$366,991 in trade debts and other debts payable.

In connection with the Brokered Private Placement and the Rights Offering, the Company issued a total of 7,879,961 Agent Warrants. Each Agent Warrant entitles the Agent to acquire one Unit at an exercise price of \$0.05 per Unit expiring 3 years from the date of issuance. Each Unit consists of one common share and one-half of one warrant ("Agent's Unit Warrant"). Each whole Agent's Unit Warrant is exercisable until September 15, 2019 at an exercise price of \$0.20 per common shares and is subject to an accelerated exercise provision attached to each commencing on the day following the expiry of any applicable hold period on the underlying common share, stating that if, for ten consecutive trading days, the closing price of the listed shares of the Company exceeds \$1.00, then the Company may elect to accelerate the expiry date by providing the Agent's Unit Warrant holders, 30 days written notice together with the issue of a press release of the accelerated expiry date. On September 15, 2017, the Company granted stock options pursuant to a management agreement. 20,767,230 stock options were granted at an exercise price of \$0.05 per share and exercisable for a period of five years from the date of grant. These stock options were granted pursuant to the Company's existing incentive stock option plan and as such be subject to the general terms of the Option Plan and all applicable policies of the TSX Venture Exchange, including without limitation those that provide for maximum issuances to single participants under the Option Plan in any 12-month period.

# **OUTLOOK**

With the successful conclusion of the capital raise program in 2017 (see "Financings") and the organizational restructuring being substantially complete, the Company is focused on execution of the Phase II clinical trials for CLI.

As the Phase II clinical trial for CLI progresses, management believes that an interim analysis will reinforce the safety record of the therapy, as shown in previous Phase I trials, and provide a clear view of the effectiveness of the therapy. Based on our current planning, the interim analysis should be available in the first half of 2019.

In addition to ACP-01 utility as a therapy for CLI, management believes that ACP-01 can be a safe and effective therapy for certain heart related damage. Over 400 heart patients have received the therapy in previous open trials and in compassionate care situations with promising curative effects for patients. Management is in the early stages of compiling data and reviewing information with the goal of applying for a FDA-approved clinical trial for one or more specific heart conditions. If this review reveals promising efficacy, then the Company would like to make a submission for a clinical trial to the FDA before the end of the 3<sup>rd</sup> quarter of 2018.

In addition to the Licensing Agreement the Company announced earlier this year, the Company intends to seek other commercialization partners for its leading therapy and development partners for accelerating clinical development of novel therapies for significant and unmet medical needs.

Management has developed plans to continue research and development, including improvements in the manufacturing process for ACP-01 and development of novel therapies. It is important to continue to research and develop therapeutic products to diversify the clinical pipeline and increase the potential value of the Company. The Company has other proprietary cell products and it will continue to advance these through its pipeline with research, development and non-human testing towards first use in humans. The Company's intellectual property broadly covers synergetic cell populations, myocardial cell precursors ("MCPs"), and neural cell precursors "(NCPs"). Management has also developed specific plans to

continue research and development for improvements in efficiency and cost of the manufacturing process for ACP-01.

The Company was pleased to announce on May 23, 2018 that it hat it has been granted a new patent in the European Union (the "EU") for its patent entitled "Regulating Stem Cells". This patent has previously been granted in Canada and the United States, however, having this patent awarded in the EU is significant as it provides validation in multiple countries. In addition, the EU patent is important as the European stem cell market is one of the most rapidly growing markets in the world. According to a Mordor Intelligence report entitled "Europe Stem Cell Market Growth, Trends and Forecasts (2016-2021)", the market is currently valued at US\$4.2 billion and is expected to grow at a compound annual growth rate of 15.7% over a forecast period.

## CONSOLIDATION AND PRESENTATION

# **Discontinued Operations**

On October 1, 2017 the Company ceased its operations in Israel and outsourced its clinical trial activities to a third-party manufacturer located in North America. The operating results of its activities in Israel have been presented as discontinued operations.

## **Functional and Presentation Currency**

The consolidated financial statements are presented in Canadian dollars, which is the Company's functional and presentation currency. Each subsidiary determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. The functional currency of the subsidiaries is Canadian dollars. Transactions denominated in foreign currency (other than the functional currency) are recorded on initial recognition at the exchange rate at the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at the end of each reporting period into the functional currency at the exchange rate at that date. Exchange differences, other than those capitalized to qualifying assets or recorded in equity in hedging transactions, are recognized in profit or loss. Non-monetary assets and liabilities measured at cost in a foreign currency are translated at the exchange rate at the date of the transaction. Non-monetary assets and liabilities denominated in foreign currency and measured at fair value are translated into the functional currency using the exchange rate prevailing at the date when the fair value was determined.

## SELECTED FINANCIAL INFORMATION FOR THE PERIOD

The following table provides selected consolidated financial information for the Company as at and for the three months ended March 31, 2018 and March 31, 2017.

	As at or for the three-	As at or for the three-
	month period ended	month period ended
	March 31, 2018	March 31, 2017
	Total \$	Total \$
Current assets	5,008,110	300,675
Total assets	5,008,111	392,513
Total liabilities	866,811	3,219,498
Total expenses from continuing operations	1,080,597	358,660
Net loss from continuing operations	(1,080,597)	(358,660)
Loss from discontinued operations, net of		
tax	(3,196)	(190,099)
Net loss and comprehensive loss	(1,083,793)	(548,759)
Basic and diluted loss per share:		
From continuing operations	(0.00)	(0.01)
From discontinued operations	(0.00)	(0.00)

**Current and Total Assets** increased period over period as a result of completion of the financing and conversion of the Subscription Receipts on September 15, 2017 resulting in higher cash and cash equivalents and short-term investments.

**Total Liabilities** decreased during the period over period as result of converting demand notes and the convertible debenture outstanding at March 31, 2017 into shares during 2017. Furthermore, various legal matters that were accrued for at March 31, 2017 were settled prior to the end of 2017.

**Net loss from continuing operations** increased compared to the prior year as a result of increased activity relating to the renewal of the Phase II CLI clinical trial. In order to support the Phase II clinical trial additional costs relating to research and development consulting fees, management fees and legal fees have been incurred. In addition, non-cash expenses such as stock compensation increased which were partially offset by a foreign exchange gain.

Loss from discontinued operations, net of tax decreased during three months ended March 31, 2018 as compared to March 31, 2017 as a result of the decision to discontinue operations on October 1, 2017 and not renew the lease in Israel as well as lay off the remaining staff.

## RESULTS OF OPERATIONS

Comparison of Expenses from Continuing Operations	Three months ended Mar 31, 2018	Three months ended Mar 31, 2017	Dollar Increase (decrease)	Percentage Increase (decrease)
Research and development expense	258,862	7,162	251,700	3514%
Consultant and management fees	396,273	166,672	229,601	138%
Stock compensation expense	387,396	-	387,396	100%
Lease and office maintenance	43,786	19,595	24,191	123%
Professional fees	107,836	56,005	51,831	93%
Travel expenses	7,872	-	7,872	100%
Accretion expense	-	100,920	(100,920)	-100%
Foreign exchange loss (gain)	(106,980)	(7,582)	(99,398)	1311%
Interest (income) expense, net	(14,448)	15,888	(30,336)	191%
Net loss from continuing operations	1,080,597	358,660	721,937	201%

Expenses from continuing operations relate to the North American activities of the Company, excluding Israel operations.

2017 figures have been restated to classify Israel expenses as discontinued operations.

# **Analysis of expenses from Continuing Operations**

Research and development expense is the cost for the Contract Research Organization ("CRO") which provides services to conduct the clinical trials and for the third party manufacturing laboratory which produces ACP-01 that is used in the clinical trials. Costs for the three months ended March 31, 2018 were \$258,862 compared to \$7,162 for the three months ended March 31, 2017, an increase of \$251,700 or 3514%. During the first quarter of 2017 there was a temporary postponement of our clinical trial while the Company evaluated various alternatives for continuing the clinical trial. In contrast, during the first quarter of 2018 the Company was actively working with our CRO to recruit and onboard clinical trial sites and ensure that all the appropriate processes and procedures were in place between the Company and its contract manufacturer.

Consultant and management fees for the three months ended March 31, 2018 were \$396,273 compared to \$166,672 for the three months ended March 31, 2017 representing an increase of 229,601 or 138%. The increase is due to a slight increase in the number of personnel working on Hemostemix projects as clinical trial activities began. In addition, the management fee is based on 15% of expenses, so as other expenses increase so too does the management fee (see "Management Agreement").

**Stock compensation expense** for the three months ended March 31, 2018 was \$387,396 compared to \$Nil compared to the same period in 2017, representing an increase of 387,396 or 100%. This increase resulted from the issuance of 20,767,230 stock options during 2017 which were granted with respect to an existing management agreement. The estimated fair value of the granted options using the Black-Scholes option pricing model will be expensed over the vesting period of three years for which \$387,396 has recorded as an expense during the three months ended March 31, 2018.

Lease and office maintenance expense for the three months ended March 31, 2018 was \$43,786 compared to \$19,595 for the three months ended March 31, 2017, representing a decrease of \$24,191 or 123%. Lease and office maintenance includes office administration costs including rent, courier and utilities as well as investor relations and communications costs. Costs increased as a result of increased insurance coverage to cover the clinical trial and increased courier costs related to the trial shipment of patient blood between site locations and the manufacturing site. In addition, the Company leased office space in Calgary where as in 2017 staff used home offices.

**Professional fees** for the three months ended March 31, 2018 were \$107,836 compared to \$56,005 compared to the same period last year, representing an increase of \$51,831 or 93%. Included in the first quarter of 2018 were legal fees related to the Company's licensing agreement and manufacturing agreement, these legal costs were one-time costs relating to these agreements resulting in a increase during this fiscal period. There were also additional legal fees related to the review of various clinical trial applications for different site locations, these costs are expected to continue, at a reduced rate, until all clinical trial sites have been fully signed on.

**Travel expenses** for the three months ended March 31, 2018 were \$7,872 compared to \$Nil for the three months ended March 31, 2017, an increase of \$7,842 or 100%. This increase resulted from additional travel related to the clinical trials and investor relations activities.

Accretion expense for the three months ended March 31, 2018 was \$nil compared to \$100,920 for same period in 2017, representing a decrease of \$100,920 or 100%. The accretion expense in 2017 represents amortization of the discount on convertible promissory notes payable and on the convertible debenture which were issued on September 2, 2016. The promissory notes were converted into common shares on January 25, 2017 and interest was fully accreted up to the full discount at that date, representing an amount of \$65,492. The remaining amount of \$35,428 represents accretion on the convertible debenture for the 3 months ended March 31, 2017. As the convertible debenture was converted into common shares in September 2017 there was no accretion expense in the first quarter of 2018.

**Foreign exchange loss (gain)** for the three months ended March 31, 2018 was a gain of \$106,980 compared to a gain of \$7,582 for the three months ended March 31, 2017, a decrease of \$99,398 or 1311%. The gain in the first quarter of 2018 relates to an unrealized foreign exchange gain from the large cash balance denominated in US currency at December 31, 2017 and the weakening of the Canadian Dollar between December 31, 2017 and March 31, 2018. In the first quarter of 2017 there were minimal US currency holdings and therefore the unrealized foreign exchange was much smaller.

**Interest (income) expense, net** for the three months ended March 31, 2018 was income of \$14,448 compared to an expense of \$15,888 for comparative three month period in 2017, representing a decrease in expense of \$30,336. The Company earned interest on short term investments held from January 1, 2018 to March 31, 2018, whereas, in the same period last year the Company recorded interest expense related to the \$750,000 demand loan issued in January 2017.

## RESULTS OF DISCONTINUED OPERATIONS

The following table summarizes the Israel activities classified as discontinued operations for the three month periods ended March 31, 2018 and 2017:

Comparison of Expenses	Three months	Three months	Dollar	Percentage	
from Discontinued Operations	ended	ended	Increase	Increase	
	Mar 31, 2018	Mar 31, 2017	(decrease)	(decrease)	
Research and development salaries and benefits	-	117,976	(117,976)	-100%	
Lease and office maintenance	1,215	42,850	(41,635)	-97%	
Professional fees	1,981	15,534	(13,553)	-87%	
Travel expenses	-	-	-	0%	
Depreciation	-	10,000	(10,000)	-100%	
Foreign exchange loss (gain)	-	(1,183)	1,183	100%	
Interest expense, net	-	1,183	(1,183)	-100%	
Loss from discontinued operations	(3,196)	(186,360)	183,164	-98%	
Income tax expense	-	3,739	(3,739)	-100%	
Net loss from discontinued operations	(3,196)	(190,099)	186,903	-98%	

Expenses from discontinued operations relate to the Israel operations of the Company. 2017 figures have been restated to classify Israel expenses as discontinued operations.

**Research and development salaries and benefits** for the three months ended March 31, 2018 was \$Nil compared to \$117,976 for the three months ended March 31, 2017 a decrease of \$117,976 or 100%. There was no staff on payroll during the first quarter of 2018 as compared to the first quarter of 2017 where there was still staff on payroll.

**Lease and office maintenance** for the three months ended March 31, 2018 was \$1,215 compared to \$42,850 for the three months ended March 31, 2017 representing a decrease of \$41,635 or 97%. Lease and office maintenance include rent for leased space for the labs in Israel, costs for supplies and materials, equipment rental, courier and utilities, communications and office administration. This cost decreased mainly as a result of the decision to not renew the lease space at the beginning of Q4 2017; where in the first quarter of 2017 the Israel office still had some operations.

**Professional fees** for the three months ended March 31, 2018 were \$1,981 compared to \$15,534 for the three months ended March 31, 2017, representing a decrease of \$13,553 or 87%. Due to lower activity levels and the ultimate decision to discontinue operations, fewer hours were required from our accounting professionals.

**Depreciation** for the three months ended March 31, 2018 was \$Nil compared to \$10,000 for the three months ended March 31, 2017, representing a decrease of \$10,000 or 100%. As the assets of the Israeli operation were disposed of in the fourth quarter of 2017 there was no depreciation in the first quarter of 2018, whereas depreciation was recorded during the first quarter of 2017.

**Foreign exchange loss (gain)** for the three months ended March 31, 2018 was \$Nil compared to a gain of \$1,183 for the three months ended March 31, 2017, a decrease of \$1,183 or 100%. The reduction in

foreign exchange is as a result of decreased activity during the year that was denominated in a foreign currency.

**Interest expense, net** for the three months ended March 31, 2018 was \$Nil compared to an expense of \$1,183 for the three months ended March 31, 2017, a decrease of 100%. Interest charges were incurred in the three months ended March 31, 2017 as the Company made payment arrangements with various vendors.

**Income tax expense** was \$Nil for the three months ended March 31, 2018 compared to \$3,739 for the three months ended March 31, 2017 a decrease of \$3,739 or 100%. Due to the temporary postponement of the clinical trials followed by the decision to close the Israeli laboratory no revenues were earned on research and development thus reducing the amount of tax payable.

## **QUARTERLY FINANCIAL INFORMATION**

The following table sets out the quarterly results for the most recently completed 8 quarters:

	2018 (unaudited)	2017 (unaudited)			2016 (unaudited)			
	Mar 31	Dec 31	Sep 30	Jun 30	Mar 31	Dec 31	Sep 30	Jun 30
Net Loss (\$)	(1,083,793)	(921,210)	(1,955,141)	(509,801)	(548,759)	(858,165)	(1,602,949)	(636,762)
Weighted Average # of Shares	296,874,720	296,874,720	111,605,053	74,208,397	73,758,953	67,858,119	67,525,119	67,154,786
Loss per Share (\$)	(0.004)	(0.003)	(0.018)	(0.007)	(0.007)	(0.013)	(0.024)	(0.009)

## LIQUIDITY AND CAPITAL RESOURCES

Hemostemix is a development stage company that to date, has had no net earnings, minimal revenue and negative operating cash flows, which are expected to continue in the foreseeable future. As a development stage company, we require significant additional investment for research and development, manufacturing, clinical testing and regulatory submissions prior to commercialization. Since inception, we have financed our cash requirements primarily through issuances of equity and debt securities. Our ability to continue as a going concern is dependent upon obtaining additional investment capital and grant monies.

Based on the foregoing, we will continue to pursue various funding opportunities, however, no assurances can be made that we will be successful in raising additional investment capital, to continue as a going concern. If we are not able to raise capital we will have to reduce our cash requirements by eliminating or deferring spending on research, development and corporate activities.

For the three months ended March 31, 2018, there was a net cash inflow from operating activities of \$978,754 compared to a net cash outflow of \$619,484 for the three months ended March 31, 2017, an increase of \$1,598,237.

Expressed in tabular form, the increase from the net cash generated for operations is as follows:

Increase in net loss from continuing operations for the year	(721,937)
Increase in stock compensation expense	387,396
Decrease in accretion expense	(100,920)
Movement of short term investments to cash and cash equivalents	1,254,659
Change in other receivables and prepaid expenses	38,575
Change in HST receivable	(15,216)
Change in accounts payable and accrued liabilities	573,972
Change in income taxes payable	4,805
Cashflow from discontinued operations	176,903
Increase in the net cash used for operations	1,598,237

As at March 31, 2018 the Company had working capital of \$4,141,299 compared to working capital of \$4,837,696 at December 31, 2017, resulting in a decrease in working capital of \$696,397. This lower working capital is a result of:

- 1) An increase in cash and cash equivalents of \$978,754;
- 2) A decrease in short term investments of \$1,254,659;
- 3) An increase in HST receivable of \$10,416;
- 4) A decrease in other receivables and prepaid expenses of 28,889;
- 5) An increase in accounts payable and accrued expenses of \$402,019;

The main reason for the decrease in working capital is the increase in clinical trial activity which increased operating expenses and related accounts payable.

# **Outstanding Share Data**

As at March 31, 2018, the number of issued and outstanding shares was 296,874,720 (December 31, 2017 – 296,874,720). Subsequent to March 31, 2018, a total of 793,434 Agent's Warrants were exercised in 2018 resulting in the issuance of 793,434 common shares and 396,717 share purchase warrants. As at May 28, 2018 the number of shares issued and outstanding was 297,668,154.

As at March 31, 2018, the Company had 21,437,230 share purchase options outstanding (December 31, 2017 – 21,437,230). Subsequent to March 31, 2018, 6,300,000 options were granted to certain directors, officers, employees and consultants of the Company. As at May 28, 2018, the number of outstanding share purchase options was 27,407,230.

As at March 31, 2018, the Company had 116,831,010 share purchase warrants outstanding (December 31, 2017 – 116,831,010). As at May 28, 2018 the number of outstanding warrants was 116,495,293.

See "Subsequent Events".

#### SIGNIFICANT ACCOUNTING POLICIES

Refer to Note 2 in the audited annual consolidated financial statements for a detailed description of our significant accounting policies. We have consistently applied the same accounting policies for all periods presented in these interim consolidated financial statements as those used in our audited consolidated financial statements for the year ended December 31, 2017, except for the adoption of new standards effective as of January 1, 2018.

## CHANGES IN ACCOUNTING POLICIES AND DISCLSOURE

Changes in Accounting Policies and Disclosure

IFRS 15 – Revenue from Contracts with Customers is effective for annual periods beginning on or after January 1, 2018 and provides new requirements for recognizing revenue. IFRS 15's core principle is for a company to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which the Company expects to be entitled in exchange for those goods or services. IFRS 15 sets out enhanced disclosures about revenue, provides guidance for transactions that were not previously addressed comprehensively and improves guidance for multiple-element arrangements. As the Company is not currently earning revenue there is no impact on its financial reporting.

IFRS 9 – Financial Instruments was issued by the IASB to establish principles for the financial reporting of financial assets and liabilities, including requirements to present certain information relating to the amounts, timing, and uncertainty of the entity's future cash flows. We have applied IFRS 9 retrospectively, with the initial application date of January 1, 2018. There were no changes to the measurement of our financial assets and liabilities or adjustments to comparative information as a result of the adoption of IFRS 9.

#### Financial Instruments

# Classification and measurement

# Financial Assets

At initial recognition, the Company measures a financial asset at its fair value plus transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at fair value through profit or loss are expensed in profit or loss.

Subsequent measurement of financial assets depends on the Company's business model for managing the asset and the cash flow characteristics of the asset. There are three measurement categories into which the Company classifies its financial assets:

Amortized cost: Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortized cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on de-recognition is recognized directly in profit or loss and presented together with foreign exchange gains and losses. Impairment losses are presented as separate line item in profit or loss.

Fair value through other comprehensive income: Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets' cash flows represent solely payments of principal and interest, are measured at fair value through other comprehensive income. Movements in the carrying amount are taken through other comprehensive income, except for the recognition of impairment gains or losses, interest revenue and foreign exchange gains and losses which are recognized in profit or loss. When the financial asset is derecognized, the cumulative gain or loss previously recognized in other comprehensive income is reclassified from equity to profit or loss and recognized in other gains and losses. Interest income from these financial assets is included in finance income using the effective interest rate method. Foreign exchange gains and losses are presented in other gains or losses and impairment expenses are presented as separate line item in profit or loss.

Fair value through profit or loss: Assets that do not meet the criteria for amortized cost or fair value through other comprehensive income are measured at fair value through profit or less. A gain or loss on a financial asset that is subsequently measured at fair value through profit or loss is recognized in profit or loss and presented net within other gains or losses in the period in which it arises.

Our financial assets include cash and cash equivalents, short term investments, and other receivables. The classification and measurement of these financial assets are at amortized cost, as these assets are held within our business model with the objective to hold the financial assets in order to collect contractual cash flows that meet the 'solely payments of principal and interest' (SPPI) criterion.

## Financial liabilities

Financial liabilities are initially measured at fair value and are subsequently measured at amortized cost. The accounting for our financial liabilities remained the same as it was under IAS 39.

# **Impairment**

Under IFRS 9, accounting for impairment losses for financial assets uses a forward-looking expected credit loss (ECL) approach.

IFRS 9 requires that we record a loss allowance for ECLs on all financial assets not held at FVPL. ECLs are based on the difference between the contractual cash flows due in

accordance with the contract and all the cash flows that the Company expects to receive. The shortfall is then discounted at an approximation to the asset's original effective interest rate.

There were no adjustments in impairment allowances of our financial assets as a result of the adoption of the ECL requirements of IFRS 9.

#### STANDARDS ISSUED BUT NOT YET ADOPTED

The following are not expected to be adopted prior to their effective dates and are being evaluated to determine their impact on the Company.

#### IFRS 16 - Leases

IFRS 16 - Leases sets out a new model for lease accounting, replacing IAS 17. IFRS 16 will be effective for accounting periods beginning on or after January 1, 2019. Early adoption will be permitted, provided the Company adopts IFRS 15.

#### **COMMITMENTS**

#### **Clinical Trial Costs**

The Company is committed to payments totaling approximately \$2.9 million for activities related to our Phase II clinical trial such as manufacturing and contract research. These payments are expected to be made over the next 24 months; however, the timing and dollar amount can vary by month depending on amount of clinical trial activity taking place. Additionally, the Company has the right to cancel these future commitments by providing the agreed upon notice in the contract, generally 60 days.

## **Management Agreement**

Effective December 16, 2016, the Company entered into a Management Contractor Agreement to oversee and manage a reorganization of the Company including the appointment of a new board of directors and management team. The agreement has a term of two years and the management contractor ("Management Contractor") will be compensated based on 15% of total operating expenses over the term of the agreement and options to acquire 7% of the Company's outstanding shares.

## RELATED PARTY BALANCES AND TRANSACTIONS

Related party transactions are conducted on the terms and conditions agreed to by the related parties. It is the Company's policy to conduct all transactions and settle all balances with related parties on market terms and conditions.

During the three months ended March 31, 2018 the Company incurred \$123,800 of research and development expense from a company related to Hemostemix by virtue of common management (March 31, 2017 - \$Nil). At March 31, 2018 the Company had \$123,800 in accounts payable and accrued liabilities owing to this company (December 31, 2017 - \$Nil).

The following includes all compensation to key management personnel:

The Company incurred \$348,855 in consulting fees to the CFO of the Company and to the Management Contractor, who is providing a Chief Executive Officer, accountant and technical consultant among other services, during the three months ended March 31, 2018 (March 31, 2017 - \$126,671). The Management Contractor was also reimbursed \$6,581 in travel and other expenses during the three months ended March 31, 2018 (March 31, 2017 - \$Nil). As at March 31, 2018, the Company had \$293,852 in accounts payable and accrued liabilities owing to the Management Contractor and CFO (December 31, 2017 - \$116,382).

On January 25, 2017, the Company secured a credit facility providing and initial \$750,000 in funding from the Management Contractor. In early 2017, the Management Contractor assigned the demand loan agreement and sold the related indebtedness of the Company to a company related to the Management Contractor. The Company received an additional \$500,000 bringing total advances to \$1,250,000. On September 15, 2017, as part of the secured credit transaction, this debt was converted into common shares of the Company.

In 2016, the Company received proceeds of \$1,000,000 from the issuance of a convertible debenture. The debenture was acquired by the company that became the Management Contractor on December 22, 2016. In early 2017, the debenture was sold to a company related to the Management Contractor. On September 15, 2017, as part of a series of the secured credit transaction, this debenture was converted into common shares of the Company.

#### FINANCIAL INSTRUMENTS

Our financial instruments consist of cash and cash equivalents, short term investments, other receivables and accounts payable and accrued liabilities. As at March 31, 2018, there are no significant differences between the carrying values of these amounts and their estimated market values.

# Credit risk

Credit risk is the risk of financial loss if counterparty to a financial instrument fails to meet its contractual obligations. We are exposed to credit risk on our cash and cash equivalents and short term investments in the event of non-performance by counterparties, but we do not anticipate such non-performance. Our maximum exposure to credit risk at the end of the period is the carrying value of our cash and cash equivalents and short term investments.

We mitigate our exposure to credit risk by maintaining our primary operating and investment bank accounts with Schedule I banks in Canada.

## Interest rate risk

Interest rate risk is the risk that future cash flows of a financial instrument will fluctuate because of changes in market interest rates. We are exposed to interest rate risk through our cash and cash equivalents and our short-term investments. We mitigate this risk by investment of excess cash resources in investment grade vehicles while matching maturities with our operational requirements.

Fluctuations in market rates of interest do not have a significant impact on our results of operations due to the short term to maturity of the investments held.

#### Currency risk

Currency risk is the risk that future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. In the normal course of our operations, we are exposed to currency risk from the purchase of goods and services in the United States. In addition, we are exposed to currency risk to the extent cash is held in foreign currencies. The impact of a \$0.01 increase in the value of the U.S. dollar against the Canadian dollar would have increased our net loss in 2018 by approximately \$2,299.

We mitigate our foreign exchange risk by maintaining sufficient foreign currencies, through the purchase of foreign currencies to settle our foreign accounts payable and future commitments.

Balances in foreign currencies at March 31, 2018 are as follows:

	US Dollars
	\$
Cash and cash equivalents	2,971,173
Accounts payable and accrued expenses	(184,115)
	2,787,058

## Liquidity risk

Liquidity risk is the risk that we will encounter difficulty in meeting obligations associated with financial liabilities. We manage liquidity risk through the management of our capital structure. Accounts payable are all due within the current operating period.

# SUBSEQUENT EVENTS

## **Expiry of Share Options**

On April 17, 2018, 330,000 share purchase options, with an exercise price of \$0.10 expired

## **Exercise of Agent Unit Warrants**

On April 20, 2018, the Company received \$9,954 from the exercise of 199,079 Agent's Warrants issued pursuant to the 2017 Private Placement offering. The agent's warrants were exercised into 199,079 common shares and 99,539 Agent's Unit Warrant.

On April 23, 2018 the Company received \$26,643 from the exercise of 532,855 Agent's Warrants issued pursuant to the rights offering. The agent's warrants were exercised into 532,855 common shares and 266,427 Agent's Unit Warrant.

On May 4, 2018 the Company received \$3,075 from the exercise of 61,500 Agent's Warrants issued pursuant to the rights offering. The agent's warrants were exercised into 61,500 common shares and 30,750 Agent's Unit Warrant.

# **Granting of Options**

On April 27, 2018, the Company granted 6,300,000 options to directors, officers, employees and consultants at an exercise price of \$0.10 per common share. These options expire five years from the date of grant and generally have up to one-third vesting on each of the first, second and third anniversaries from the date of grant.

# DISCLOSURE CONTROLS, PROCEDURES AND INTERNAL CONTROLS OVER FINANCIAL REPORTING

Management has established and continues to complement a system of disclosure controls and procedures and internal controls over financial reporting. This system is designed to provide reasonable assurance that material information relating to the issuer and its subsidiaries are available and reported to senior management and permits timely decisions regarding public disclosure. As of March 31, 2018, the Company's Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based on this evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that the Company's disclosure controls and procedures, as defined in Multilateral Instrument 52-109 — Certification of Disclosure in Issuer's Annual and Interim Filings are effective, except as noted below, to ensure that the information required to be disclosed in reports that are filed or submitted under Canadian Securities legislation are recorded, processed, summarized and reported within the time period specified in those rules.

The Company's disclosure controls and procedures are indicative of many small and growing companies. Consequently, management has identified certain weaknesses that currently exist in the disclosure controls and procedures including, but not limited to, the segregation of duties and expertise in specific areas of public disclosure. The existence of these weaknesses is partially compensated for by senior management monitoring these issues, and in the case of complex or extraordinary transactions, consulting with external experts to advise management in their analysis and conclusions.

Throughout the year management continued to address, as required, steps to improve disclosure controls and procedures and internal controls over financial reporting. However, no specific changes to disclosure controls and procedures were made during the period. The Company recognizes this is an ongoing and dynamic process and continues to focus on internal controls related to financial reporting and disclosure controls and procedures and is committed to further improvements in the future.

#### RISKS AND UNCERTAINTIES

## Possible Failure to Realize Anticipated Benefits of the Arrangement

Hemostemix completed a "going public" transaction by way of a reverse take-over in November 2014, to create a stronger and better positioned entity to strengthen their position in the clinical stage biotechnology industry and to create the opportunity to realize certain benefits including, among other things, the commercialization of the stem cell industry, increased liquidity, greater access to capital markets and increased ability to pursue and the development and acquisition opportunities. Achieving the benefits of this transaction depends, in part, on successfully consolidating the operations of Hemostemix in an efficient manner. There can be no assurance that, after giving effect to the transaction, Hemostemix will be able to realize the anticipated growth opportunities and synergies required to achieve the anticipated benefits.

## **Biotech Public Market Risks**

Prospects for companies in the biotechnology industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in biotechnology companies should be regarded as speculative. Biotechnology research and development involves a significant degree of risk. An investor should carefully consider the risks and uncertainties described below. The risks and uncertainties described below are not an exhaustive list. Additional risks and uncertainties not presently known to Hemostemix or that Hemostemix believes to be immaterial may also adversely affect Hemostemix's business. If any one or more of the following risks occur, Hemostemix business, financial condition and results of operations could be seriously harmed. Further, if Hemostemix fails to meet the expectations of the public market in any given period, the market price of Hemostemix shares could decline.

# **Early Stage Development and Scientific Uncertainty**

Hemostemix's products are at an early stage of development. Significant additional investment in research and development, product validation, manufacturing, production scale-up, manufacturing, clinical testing, and regulatory submissions of such product candidates is required prior to commercialization. There can be no assurance that any such products will actually be developed. The development and regulatory processes may require access to raw materials and inputs which may not be available to Hemostemix in sufficient amounts or in a timely fashion to allow Hemostemix to complete the development or receive regulatory approval of any product or process. A commitment of substantial time and resources is required to conduct research and clinical trials if Hemostemix is to complete the development of any product. It is not known whether any of these product or process candidates will meet applicable health regulatory standards and obtain required regulatory approvals, or whether such products can be produced in commercial quantities at reasonable costs and be successfully marketed, or if Hemostemix 's investment in any such products will be recovered through sales or royalties.

# Additional Financing Requirements and Access to Capital

Hemostemix will require substantial additional funds for further research and development, planned clinical testing, regulatory approvals, establishment of manufacturing capabilities and, if necessary, the marketing and sale of its products. Hemostemix may attempt to raise additional funds for these purposes through public or private equity or debt financing, collaborations with other biopharmaceutical companies and/or from other sources. There can be no assurance that additional funding or partnership

will be available on terms acceptable to Hemostemix and which would foster successful commercialization of Hemostemix products.

# **Government Regulations**

Biotechnology and pharmaceutical companies operate in a high-risk regulatory environment. The manufacture and sale of human diagnostic and therapeutic products is governed by numerous statutes and regulations in the United States, Canada and other countries where Hemostemix intends to market its products. The subject matter of such legislation includes approval of manufacturing facilities, controlled research and testing procedures, review and approval of manufacturing, preclinical and clinical data prior to marketing approval, as well as regulation of marketing activities, notably advertising and labelling.

The process of completing clinical testing and obtaining required approvals is likely to take several years and require the expenditure of substantial resources. Furthermore, there can be no assurance that the regulators will not require modification to any submissions which may result in delays or failure to obtain regulatory approvals. Any delay or failure to obtain regulatory approvals could adversely affect the ability of Hemostemix to utilize its technology, thereby adversely affecting operations. Further, there can be no assurance that Hemostemix's diagnostic product candidates will achieve levels of sensitivity and specificity sufficient for regulatory approval or market acceptance, or that its therapeutic product candidates prove to be safe and effective in clinical trials or receive the requisite regulatory approval. There is no assurance that Hemostemix will be able to timely and profitably produce its products while complying with all the applicable regulatory requirements. Foreign markets, other than the United States and Canada, generally impose similar restrictions.

#### **Hazardous Materials and Environmental Matters**

Certain of Hemostemix's research and development processes may involve the controlled use of hazardous materials. Hemostemix is subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although management of Hemostemix believes that its procedures for handling and disposing of such materials comply with the standards prescribed, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, Hemostemix could be held liable for damages and such liability could exceed the resources of Hemostemix. Hemostemix is not specifically insured with respect to this liability. Although management of Hemostemix believes that it currently complies in all material respects with applicable environmental laws and regulations, Hemostemix may be required to incur significant costs to comply with environmental laws and regulations in the future. Furthermore, there can be no assurance that the operations, business or assets of Hemostemix will not be materially adversely affected by current or future environmental laws or regulations.

# **Patents and Proprietary Technology**

Hemostemix's success will depend in part on its ability to obtain, maintain, and enforce patent rights, maintain trade secret protection and operate without infringing the proprietary rights of third parties. There can be no assurance that pending patent applications will be allowed, that Hemostemix will develop additional proprietary products that are patentable, that issued patents will provide Hemostemix with any competitive advantage or will not be challenged by any third parties, or that patents of others will not have an adverse effect on the ability of Hemostemix to do business.

Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of the Hemostemix products, or design around the products patented by Hemostemix. In addition, Hemostemix may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under such patents or proprietary rights will be available on terms acceptable to Hemostemix. If Hemostemix does not obtain such licenses it could encounter delays in introducing one or more of its products to the market, while it attempts to design around such patents, or could find that the development, manufacturing or sale of products requiring such licenses could be foreclosed. In addition, Hemostemix could incur substantial costs in defending itself in suits brought against it on such patents or in suits where it attempts to enforce its own patents against other parties.

Until such time, if ever, that patent applications are filed, the ability of Hemostemix to maintain the confidentiality of its technology may be crucial to its ultimate possible commercial success. While Hemostemix has adopted procedures designed to protect the confidentiality of its technology, no assurance can be given that such arrangements will be effective, that third parties will not gain access to Hemostemix trade secrets or disclose the technology, or that Hemostemix can meaningfully protect its rights to its trade secrets.

# **Dependence on Collaborative Partners, Licensors and Others**

Hemostemix activities will require it to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of its products. Hemostemix intends to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that Hemostemix will be able to establish such additional collaborations on favorable terms, if at all, or that its current or future collaborations will be successful. Failure to attract commercial partners for its products may result in Hemostemix incurring substantial clinical testing, manufacturing and commercialization costs prior to realizing any revenue from product sales or result in delays or program discontinuance if funds are not available in sufficient quantities.

If any collaborative partner fails to develop, manufacture, or commercialize successfully any product to which it has rights, or any partner's product to which Hemostemix will have rights, Hemostemix's business may be adversely affected. Failure of a collaborative partner to continue to participate in any particular program could delay or halt the development or commercialization of products generated from such program. In addition, there can be no assurance that the collaborative partners will not pursue other technologies or develop alternative products either alone or in collaboration with others, including Hemostemix's competitors, as a means for developing treatments for the diseases targeted by Hemostemix programs.

Furthermore, Hemostemix will hold licenses for certain technologies and there can be no assurance that these licenses will not be terminated, or that they will be renewed on conditions acceptable to Hemostemix. Hemostemix intends to negotiate additional licenses in respect of technologies developed by other companies and academic institutions. Terms of license agreements to be negotiated may include, inter alia, a requirement to make milestone payments, which may be substantial. Hemostemix will also be obligated to make royalty payments on the sales, if any, of products resulting from licensed technology and, in some instances, may be responsible for the costs of filing and prosecuting patent applications. Should any of Hemostemix licensees breach their regulatory, clinical, operational or legal

requirements this may impact Hemostemix reputation and/or ability to conduct its business or make progress as anticipated.

# **Rapid Technological Change**

The biotechnology and pharmaceutical industries are characterized by rapid and substantial technological change. There can be no assurance that developments by others will not render Hemostemix proposed products or technologies noncompetitive, or that Hemostemix will keep pace with technological developments. Competitors have developed or are developing technologies that could be the basis for competitive products. Some of these products have an entirely different approach or means of accomplishing the desired diagnostic or therapeutic effect as compared with products to be developed by Hemostemix and could be more effective and less costly than the products to be developed by Hemostemix. In addition, alternative forms of medical treatment may be competitive with Hemostemix products.

# Competition

Technological competition from pharmaceutical companies, biopharmaceutical companies and universities are intense and is expected to increase. Potential competitors of Hemostemix have or may develop product development capabilities or financial, scientific, marketing and human resources exceeding those of Hemostemix. Competitors may develop products before Hemostemix develops its own products, obtain regulatory approval for such products more rapidly than Hemostemix, or develop products which are more effective than those which Hemostemix intends to develop. Research and development by others may render Hemostemix's proposed technology or products obsolete or non-competitive or produce treatments or cures superior to any therapy developed or to be developed by Hemostemix, or otherwise preferred to any therapy developed by Hemostemix.

#### **Status of Healthcare Reimbursement**

Hemostemix 's ability to successfully market certain diagnostic or therapeutic products may depend in part on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement. Furthermore, challenges to the price of medical products and services are becoming more frequent. There can be no assurance that adequate third-party coverage will be available to establish price levels, which would allow Hemostemix to realize an acceptable return on its investment in product development.

## **Potential Product Liability**

Pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Product liability insurance is costly, and availability is limited and may not be available on terms which would be acceptable to Hemostemix, if at all. An inability to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of Hemostemix's products. A product liability claim brought against Hemostemix, or withdrawal of a product from the market, could have a material adverse effect upon Hemostemix and its financial condition.

# Manufacturing

Hemostemix product manufacturing is currently done at a single facility without secondary backup. Hemostemix's ability to conduct its clinical trial depends on its uninterrupted ability to manufacture product and ship product in and out of its third party facility location.

# **Reliance on Key Personnel**

Hemostemix is dependent on certain members of its management and scientific staff as well as consultants and contractors, the loss of services of one or more of whom could adversely affect Hemostemix. In addition, Hemostemix's ability to manage growth effectively will require it to continue to implement and improve its management systems and to recruit and train new employees. There can be no assurance that Hemostemix will be able to successfully attract and retain skilled and experienced personnel.

## **Lack of Product Revenues and History of Losses**

To date, Hemostemix has not recorded any revenues from the sale of biopharmaceutical products. Hemostemix expects to incur additional losses during the periods of research and development, clinical testing, and application for regulatory approval of its product candidates. Hemostemix expects to incur losses unless and until such time as payments from corporate collaborations, product sales and/or royalty or license payments generate sufficient revenues to fund its continuing operations.

# Volatility of Share Price, Absence of Dividends and Fluctuation of Operating Results

Market prices for the securities of biotechnology companies, including Hemostemix, have historically been highly volatile. Factors such as fluctuation of Hemostemix operating results, announcements of technological innovations, patents or new commercial products by Hemostemix or competitors, results of clinical testing, regulatory actions, or public concern over the safety of biopharmaceutical products and other factors could have a significant effect on the share price or trading volumes for the common shares. Hemostemix's shares, may be subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future. Hemostemix has not paid dividends to date and does not expect to pay dividends in the foreseeable future.

## **Conflict of Interest**

Certain of the directors and senior officers of Hemostemix may, from time to time, be employed by or affiliated with organizations which have entered into agreements with Hemostemix. As disputes may arise between these organizations and Hemostemix, or certain of these organizations may undertake or have undertaken research with competitors of Hemostemix, there exists the possibility for such persons to be in a position of conflict. Any decision or recommendation made by these persons involving Hemostemix will be made in accordance with his or her duties and obligations to deal fairly and in good faith with Hemostemix and such other organizations. In addition, as applicable, such directors and officers will refrain from voting on any matter in which they have a conflict of interest.

#### No Kev Man Insurance

The Company does not currently have key man insurance in place in respect of any of its senior officers or personnel.

## ADDITIONAL DISCLOSURE FOR VENTURE ISSUERS WITHOUT SIGNIFICANT REVENUE

The Company's main focus is to develop autologous, blood-derived cell therapies primarily for the treatment of severe medical conditions not adequately addressed by current treatments. The Company is currently conducting a Phase 2 clinical trial in patients with critical limb ischemia.

To achieve commercialization of its products, the Company must obtain regulatory approval in each respective jurisdiction it intends to market its products. Management of Hemostemix believes it may be possible to achieve this in certain jurisdictions on the basis of positive Phase 2 clinical trial data, but in most jurisdictions additional clinical data from larger clinical trials will be required to obtain such approval.

Hemostemix does not currently distribute any commercial products or provide any commercial services in any markets. Future revenues should come through royalty payments from partnering, licensing arrangements or through direct commercialization of its products.