

# Hemostemix Inc.

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

For the three and six months ended June 30, 2019 and 2018 as at August 28, 2019

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### 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 and six months ended June 30, 2019 and 2018. 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 and six months ended June 30, 2019 and 2018 and the accompanying notes which have been prepared under International Financial Reporting Standards ("IFRS"). The unaudited 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 August 28, 2019. Additional information relating to the Company is available on SEDAR at [www.sedar.com](http://www.sedar.com) as well as the Company's website at [www.hemostemix.com](http://www.hemostemix.com).

### 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:

- belief that the Company will be successful in raising additional capital to continue as a going concern
- belief that its products and research and development efforts are targeting diseases and conditions with significant unmet medical treatment needs;
- the Company's goal of creating shareholder value;
- its ability to meet its operating costs for the fiscal year ended December 31, 2019;
- the Company's belief that ACP-01 has advantages over current treatments for critical limb ischemia;
- the Company's belief that the ACP-01 technology process can be commercialized more effectively than other technologies;
- 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;

- belief that the Company's prior ACP-01 trial data will be sufficient to support regulatory submissions and approvals for additional indications, such as congestive heart failure;
- management's outlook regarding future trends;
- expectations regarding the completion of its current clinical trial for CLI, including the patient enrollment numbers anticipated number of trial sites and timing of interim analysis;
- expectations regarding the performance of critical suppliers and service providers, including its CRO;
- expectations for additional commercialization partners;
- plans and objectives of management for future operations;
- general business and economic conditions and outlook.

Various assumptions or factors are typically applied in drawing conclusions or making the forecasts or projections set out in forward-looking information. Those assumptions and factors are based on information currently available to the Company, including information obtained from third-party industry analysts and other third-party sources. In some instances, material assumptions and factors are presented or discussed elsewhere in this MD&A in connection with the statements or disclosure containing the forward-looking information. You are cautioned that the following list of material factors and assumptions is not exhaustive.

The factors and assumptions include, but are not limited to, assumptions that there be no:

- unforeseen changes in the legislative and operating framework for the business of the Company;
- unstable competitive environment; and
- significant events occurring outside the ordinary course of business such as a natural disaster or other calamity.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors including the risks set out in the section entitled "Risks and Uncertainties" below, which may cause the Company's or its industry's actual results, levels of activity, performance and achievements to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to the following risks:

- the successful and timely completion of research and development initiatives;
- the effects of government regulation on the Company's business;
- the development of superior technology by the Company's competitors;
- the failure of consumers and the medical community to accept the Company's technology as safe and effective;
- risks associated with the performance of commercial partners and critical suppliers and service providers;
- risks associated with the Company's ability to obtain and protect rights to its intellectual property;
- risks associated with the Company's ability to raise additional capital;
- other factors beyond the Company's control.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity or performance. Furthermore, any forward-looking statement speaks only as of the date on which such statement is made, and except as required by applicable law, the Company undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is

made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for management to predict all of such factors and to assess in advance the impact of such factors on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement.

## **THE COMPANY**

Hemostemix 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. Hemostemix, an entity under the Business Corporations Act (Alberta) was formed in November 2014. On November 27, 2014, shares of the Company began trading on the TSX Venture Exchange under the symbol "HEM". The Company's common shares are also traded on the OTCQB Venture Market, a US trading platform, under the symbol "HMTXF". The Company's head office is located at 2150, 300 – 5 Ave SW, Calgary, AB T2P 3C4.

The consolidated financial statements of the Company comprise the accounts of Hemostemix, Hemostemix Ltd, and Kwalata Trading Limited, the Company's wholly-owned subsidiaries. Kwalata Trading Limited ("Kwalata"), incorporated under the laws of Cyprus, was established to own intellectual property ("IP"). On October 1, 2018 management sold the IP from Kwalata to Hemostemix and began the planning process to wind up Kwalata (see "Discontinued Operations"). Hemostemix Ltd., another wholly owned subsidiary, was incorporated under the laws of Israel to conduct manufacturing and perform research and development. Effective October 1, 2017, Hemostemix Ltd. ceased operations (see "Discontinued Operations").

## **BUSINESS OVERVIEW**

We are a clinical stage biotechnology company with 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 UPDATE**

The following items highlight the Company's activities during the three and six month periods ended June 30, 2019 and any subsequent development up until the date hereof.

### **Corporate Update**

#### **Management & Scientific Leadership**

In April 2019, Dr. Alan J. Jacobs, M.S.EE, M.D, Ph.D was appointed the Company's President and Chief Medical Officer. Dr. Jacobs takes over the role of President from Kyle Makofka who remains as the Company's Chief Executive Officer. In the first quarter, Dr. Ravi Jain resigned from the position of Chief Scientific Officer of the Company. Dr. Jacobs is responsible for the overall management and coordination of the scientific and research operations of the Company surrounding the angiogenic cell precursor (ACP-01) and neuronal cell precursor (NCP) products, oversight of the Company's current Phase II clinical trial for critical limb ischemia ("CLI"), preparation of the Phase III trial for CLI, investigational new drug ("IND")

submissions for additional clinical indications, as well as identifying new therapeutic opportunities for the Company.

The Company entered into a new management contractor agreement with Kingsman Scientific Management Inc. (“KSM” or the “Management Contractor”), dated April 18, 2019 with an effective date of January 1, 2019. KSM is majority owned by Kyle Makofka, the current CEO of the Company. Pursuant to this agreement, KSM will oversee and manage all aspects of the operations and management of Hemostemix, including the Company’s current clinical trial, as well as assist in identifying additional appointments to the Company’s Board of Directors and management team.

The KSM agreement has a term of one year with an option for an additional one-year renewal period. KSM will be compensated based on a fixed fee for key management personnel costs, support services, accounting and office rental and cost plus 15% for clinical trial operations as well as be entitled to bonuses should it achieve costs savings for the current Phase II clinical trial for critical limb ischemia. In addition, KSM will be granted stock options to acquire common shares in the capital of the Company to be granted in an amount equivalent to up to five percent (5%) of the Company’s total issued and outstanding common shares.

On June 25, 2019, Hemostemix announced the resignation of Ms. Kristin Gulka from the role of Chief Financial Officer. On July 11, 2019, the Company announced that Mr. Angus Jenkins, the Company’s chairman of the board, agreed to act as the Company’s interim Chief Financial Officer and Corporate Secretary until a permanent CFO replacement can be found.

### **Financing**

#### **Cancellation of Non-Brokered Private Placement (“Other Debenture Offering”)**

On July 11, 2019, the Company announced that due to market conditions, it will not be proceeding with its previously announced non-brokered private placement of up to a maximum of \$6,000,000 principal amount of secured convertible debentures.

#### **Cancellation of Second Tranche of Non-Brokered Private Placement of Convertible Debentures**

On July 11, 2019, the Company announced that it will not be having a second closing of its non-brokered private placement of up to a maximum of \$1,000,000 principal amount of secured convertible debentures. As announced on May 16, 2019, total gross proceeds of \$525,000 were raised pursuant to this offering.

#### **Announcement of Loan Agreement**

Hemostemix Inc. entered into a loan agreement dated July 31, 2019 (the “Loan”) with J.M. Wood Investments Ltd. (“JMWI”) for a secured loan in an aggregate principal amount of up to \$2 million.

Under the terms of the loan, JMWI will advance a minimum amount of \$500,000 to the Company upon execution of the loan agreement. Thereafter, the Company may request additional monthly advances, subject to the JMWI’s review and approval of the Company’s monthly budget expenditures, up to a maximum of \$2 million. The Loan bears interest at a rate of 12 per cent per annum and is secured by a general security agreement in favour of JMWI in respect of all of the personal property of the Company. The Loan is repayable on a maturity date which is 12 months from the date of the first advance and the Company is entitled to prepay any amount outstanding under the Loan without penalty. After Sept. 30, 2019, JMWI may provide the Company with at least 60 days of written notice requiring repayment of the outstanding principal amount of the loan plus any accrued and unpaid interest. The proceeds of the

Loan will be used to finance the company's current Phase II clinical trial for critical limb ischemia, the Company's other clinical trial applications and for general working capital.

The Company is at arm's length with JMWI and JMWI is not a related party of the Company within the meaning of Multilateral Instrument 61-101. As of August 28, 2019, a total of \$925,746.90 has been advanced to Hemostemix under this Loan.

## **Product & Clinical Trial Update**

### *Angiogenic Cellular Precursor (ACP-01)*

Hemostemix lead product, ACP-01, is an angiogenic stem cell product derived from peripheral blood that is in clinical development for the treatment of vascular diseases. ACP-01 has been shown to form microtubules and to secrete angiogenic growth factors and cytokines in culture. A significant advantage of ACP-01 over other mesenchymal stem cell products is its derivation from a standard blood collection compared to the invasive surgical harvesting procedures required for stem cells collected from bone marrow or adipose tissue.

ACP-01 has been previously studied in 4 phase 2a clinical studies: 2 clinical studies in patients with myocardial ischemia and 2 clinical studies in patients critical limb ischemia. The clinical studies of ACP-01 in patients with myocardial ischemia reported improvement in New York Heart Association and Canadian Cardiovascular Society Scores and increased ejection fraction (Chaithiraphan et al., 2009). In patients with critical limb ischemia (CLI), the previous clinical studies of ACP-01 reported improvement in tissue perfusion, healing of ischemic ulcers, and reduction of major amputation (Szabó et al, 2013).

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.

We believe that further research will show ACP-01 to have applications in the treatment of additional diseases, such as cardiovascular disease, idiopathic pulmonary hypertension, peripheral artery disease, burns, and erectile dysfunction.

### *Clinical Trial Update for ACP-01*

ACP-01 is currently in a Phase 2 randomized, placebo-controlled clinical trial in CLI patients who have no surgical or endovascular option for revascularization. This study is being conducted in the US and Canada where approximately 95 patients will be enrolled, treated with either ACP-01 or a placebo and followed for twelve months.

During the second quarter of 2019, the Company had a substantial increase in enrollment rate ending the quarter with 40 patients enrolled and treated with either ACP-01 or a placebo. The Company continued its work to select and initiate additional clinical trial sites and had a total of 14 clinical trial sites activated. Management feels that the growing enrollment and number of clinical trial sites are a strong indicator of positive momentum for Hemostemix as a company, and for our CLI clinical trial. The company plans in the coming quarters to continue to recruit and activate additional clinical trial sites in

Canada and the US. As at August 28, 2019 a total of 43 patients have been enrolled and been treated in the trials.

The Company is anticipating a planned Data Safety Monitoring Board (“DSMB”) meeting in the third quarter of 2019 and that interim analysis data will be available in the fourth quarter of 2019. Management believes that the DSMB meeting and the interim analysis will provide a clear view of the safety and effectiveness of ACP-01 that is consistent with the results reported in the previous clinical studies.

The Company also anticipates submitting a Phase 2 clinical protocol to regulatory agencies for ACP-01 in a second clinical indication in the fourth quarter of 2019.

#### Research and Development Update for ACP-01

During the second quarter, we worked on furthering our research and development (“R&D”) initiatives for ACP-01, including process improvements, scale up for Phase 3 and commercialization, and cost reduction.

We believe based on R&D work performed to date that the production of ACP-01 is a readily scalable process. The current procedure to produce autologous ACP-01 encompasses 7 days, from blood collection, culture, harvest, delivery and administration to the patient. Our research data suggest that the process can be reduced to 3-5 days. Research data also suggests that the process of autologous ACP-01 production is amenable to point of care automation.

Research activities are also underway to support an allogeneic ACP-01 product derived from healthy young donors, meaning cells from one donor may be used in many different recipients. Although an autologous product is beneficial in that there is no potential for tissue rejection, cryopreserved allogeneic ACP-01 could address the acute patient population too ill for blood collection and in urgent need for ACP-01 treatment. Such an allogeneic product would allow the Company to create an “off the shelf” product, increasing the number of patients that could be treated with the Company’s therapy and expanding the commercialization potential of its technology platform.

#### Regulatory Update for ACP-01

In the first quarter of 2019, we submitted an application to the US Food and Drug Administration (“FDA”) for Orphan Drug Designation for ACP-01 for the treatment of patients with critical limb ischemia. The Orphan Drug Act provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. Our application sought Orphan Drug Designation for the treatment of end-stage CLI patients. The FDA responded to the Company’s application stating that based on the information and data they reviewed, ACP-01 had the potential to treat all patients suffering from CLI, not just those with end-stage CLI. Based on the potential for to treat such a large patient population, ACP-01 did not qualify for Orphan Drug Status.

#### Neural Cellular Precursor (NCP-01)

Last year we initiated an R&D program for generation of NCP-01 (Neural Cellular Precursors) from peripheral blood. The Company’s R&D will focus on showing that NCP-01 is a product candidate that has the potential to treat such indications as amyotrophic lateral sclerosis (“ALS”), spinal cord injuries, Parkinson’s disease and Alzheimer’s disease through building new neuronal lineage cells in a patient. The NCP-01 product is in the early stages of the development process, however the Company believes this is an important market with significant unmet medical treatment needs.

### Bone Cellular Precursor (BCP-01)

We have performed preliminary R&D work for BCP-01 (Bone Cellular Precursors) from peripheral blood. In 2019, we did limited work on BCP-01, as we focused our efforts on the current clinical trial for our lead product ACP-01 and initiating R&D on NCP-01. Future R&D on BCP-01 will focus on showing that BCP-01 is a product candidate that has the potential to treat indications such as bone fractures, skeletal breaks and surgical procedures.

### Manufacturing Agreement

On July 31, 2019 the Manufacturing Agreement (“MA”) with Aspire Health Science, LLC (“Aspire”) expired. As of August 28, 2019 the Company is negotiating with Aspire to extend the MA to December 31, 2019 under the same terms as the original agreement. Aspire owns an FDA cGMP (“Certified Good Manufacturing Practices”) facility located in Orlando, Florida. Basic charges and pricing are fixed throughout the term. In addition to ordinary contract manufacturing provisions, the MA 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 MA 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 MA are to remain or become (upon discovery) the property of Hemostemix.

## **OUTLOOK**

We are focused on execution of the Phase 2 clinical trial for CLI, which includes the recruitment and enrollment of patients and initiation of additional clinical trial sites in Canada and the US. As the Phase 2 clinical trial for CLI progresses, management believes that an interim analysis will reinforce the safety and effectiveness of ACP-01 as shown in the previous trials. Based on our current planning, it is anticipated the interim analysis will be conducted in the second half of 2019.

In addition to the treatment of CLI, management believes that ACP-01 can be a safe and effective therapy for other indications and anticipates submitting a Phase II clinical protocol to regulatory agencies for ACP-01 in a second clinical indication in the fourth quarter of 2019.

Management has developed plans to continue research and development, including building on the improvements in the autologous manufacturing process for ACP-01 and expanding the platform to include an allogeneic manufacturing process. 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 angiogenic cell precursors, myocardial cell precursors, neural cell precursors, and bone cell precursors. Management has also developed specific plans to continue research and development to improve efficiency and reduce costs of the manufacturing process for ACP-01.

Our ability to accomplish all our future strategic plans is dependent upon obtaining additional financing or executing other strategic options and there is no assurance that we will achieve these objectives.

Management will continue to pursue various options to raise additional funding, some which could be dilutive to existing shareholders. Alternatives for raising further capital could include the issuance of additional equity, debt, convertible debentures, government or partnership funding. We intend to seek commercialization partners for our therapy and development partners for accelerating clinical development of novel therapies for significant and unmet medical needs.

## **CONSOLIDATION AND PRESENTATION**

### **Discontinued Operations**

On October 1, 2018, management sold the IP from Kwalata to Hemostemix and began the planning process to wind up Kwalata. For the three and six months ended June 30, 2019, Kwalata had no assets, liabilities or net income.

On October 1, 2017 the Company ceased its operations in Israel and outsourced its clinical trial activities to a contract 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 YEAR

The following table provides selected consolidated financial information for the Company as at and for the three and six months ended June 30, 2019 and 2018.

| (unaudited)                                   | Three months ended June 30, |             | Six months ended June 30, |             |
|---|-----------------------------|-------------|---------------------------|-------------|
|   | 2019                        | 2018        | 2019                      | 2018        |
|   | \$                          | \$          | \$                        | \$          |
| Total assets                                  | 102,314                     | 3,945,527   | 102,314                   | 3,945,527   |
| Total liabilities                             | 1,832,537                   | 843,813     | 1,832,537                 | 843,813     |
| Total expenses from continuing operations     | (1,326,424)                 | (435,754)   | (2,896,268)               | (882,516)   |
| Net loss from continuing operations           | (1,326,424)                 | (1,659,334) | (2,896,268)               | (2,739,931) |
| Loss from discontinued operations, net of tax | -                           | -           | -                         | (3,196)     |
| Net loss and comprehensive loss               | (1,326,424)                 | (1,659,334) | (2,896,268)               | (2,743,127) |
| Basic and diluted loss per share:             |                             |             |                           |             |
| From continuing operations                    | (0.01)                      | (0.01)      | (0.01)                    | (0.01)      |
| From discontinued operations                  | -                           | -           | -                         | -           |
| Weighted average number of shares outstanding | 300,898,610                 | 297,482,782 | 300,898,610               | 297,183,751 |

**Total Assets** decreased period over period as a result of using cash to fund our CLI phase II clinical trial, ongoing research and development and general and administrative expenses.

**Total Liabilities** increased period over period as a result of increased clinical trial activity resulting in increased costs and liabilities.

**Net loss from continuing operations** decreased to \$1,326,424 in the three months ended June 30, 2019, as compared to \$1,659,334 in the corresponding period of the prior year as a result of lower stock-based compensation and professional fees offset by an increase in finance expense. For the six months ended June 30, 2019, net loss increased to \$2,896,268 compared to \$2,739,931 in the same period of the prior year as a result of increased activity relating to the costs of the Phase II CLI clinical trial. In order to support the Phase II clinical trial additional costs relating to research and development fees have been incurred. These costs include manufacturing the treatment for our trial, continued research and development in the lab, patient treatment flow through costs from clinical sites and fees related to services provided by our Contract Research Organization.

## RESULTS OF OPERATIONS

### Comparison of Expenses from Consulting Operations

|                                     | Three months ended June 30, |            | Increase<br>(Decrease)<br>\$ | Increase<br>(Decrease)<br>% |
|-------------------------------------|-----------------------------|------------|------------------------------|-----------------------------|
|                                     | 2019<br>\$                  | 2018<br>\$ |                              |                             |
| Research and development            | 566,013                     | 526,225    | 39,788                       | 8%                          |
| Consultant and management fees      | 363,688                     | 411,698    | (48,010)                     | -12%                        |
| Stock-based compensation (note 7)   | 197,311                     | 578,576    | (381,265)                    | -66%                        |
| Lease and office maintenance        | 53,897                      | 52,612     | 1,285                        | 2%                          |
| Professional fees                   | 78,839                      | 130,370    | (51,531)                     | -40%                        |
| Travel                              | 46,831                      | 33,353     | 13,478                       | 40%                         |
| Foreign exchange loss (gain)        | 898                         | (64,584)   | 65,482                       | -101%                       |
| Finance expense                     | 18,257                      | (8,916)    | 27,173                       | -305%                       |
| Depreciation and amortization       | 690                         | -          | 690                          | 100%                        |
| Net loss from continuing operations | 1,326,424                   | 1,659,334  | (332,910)                    | -20%                        |

|                                     | Six months ended June 30, |            | Increase<br>(Decrease)<br>\$ | Increase<br>(Decrease)<br>% |
|-------------------------------------|---------------------------|------------|------------------------------|-----------------------------|
|                                     | 2019<br>\$                | 2018<br>\$ |                              |                             |
| Research and development            | 1,196,626                 | 785,087    | 411,539                      | 52%                         |
| Consultant and management fees      | 700,001                   | 807,971    | (107,970)                    | -13%                        |
| Stock-based compensation (note 7)   | 631,803                   | 965,972    | (334,169)                    | -35%                        |
| Lease and office maintenance        | 117,265                   | 96,398     | 20,867                       | 22%                         |
| Professional fees                   | 125,486                   | 238,206    | (112,720)                    | -47%                        |
| Travel                              | 74,438                    | 41,225     | 33,213                       | 81%                         |
| Foreign exchange loss (gain)        | 31,745                    | (171,564)  | 203,309                      | -119%                       |
| Finance expense                     | 18,214                    | (23,364)   | 41,578                       | -178%                       |
| Depreciation and amortization       | 690                       | -          | 690                          | 100%                        |
| Net loss from continuing operations | 2,896,268                 | 2,739,931  | 156,337                      | 6%                          |

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

### Analysis of expenses from Continuing Operations

#### Research and development ("R&D")

R&D expense is the cost for the third party manufacturing laboratory which produces ACP-01 that is used in the clinical trials and provides continued research and development work in their laboratory. It also includes the costs paid to clinical trial sites to reimburse them for the costs associated with the treatment and follow-up for patients in our study, as well as the fees paid the Contract Research Organization ("CRO") which provides services to conduct the clinical trials. R&D costs for the three and six months ended June 30, 2019 were \$566,013 and \$1,196,626 compared to \$526,225 and \$785,087 for the three and six months ended June 30, 2018 representing an increase of \$39,788 and \$411,539 respectively. The majority of the increase is related to the number of patients treated, as there were 7 patients treated in the first quarter of 2019 and 7 patients treated in the second quarter of 2019 as compared to zero patients treated in the three months ended June 2018 and 1 patient treated in the six

months ended June 2018. Furthermore, the Company paid for six months of contract manufacturing in the first half of 2019 as compared to five months in the same period last year.

#### **Consultant and management fees (“C&M”)**

C&M fees decreased by 12% to \$363,688 in the three months ended June 30, 2019, as compared to \$411,698 in the corresponding period of the prior year. For the six months ended June 30, 2019, C&M fees decreased 13% to \$700,001 compared to \$807,971 in the same period of the prior year. The decrease is due to lower advisory consulting services and the new management agreement with KSM which has an overall lower fee in relation to management fees.

#### **Stock-based compensation expense (“SBC”)**

SBC decreased by 66% and 35% for the three and six months ended June 30, 2019 compared to the corresponding periods of 2018. The decrease is mainly due to a lower annual grant value in 2019 as compared to 2018 and the impact of the change in vesting terms for certain stock options issued in 2018. Stock options are granted to certain officers, directors, employees and consultants, with the number, term and vesting period of the options granted being determined at the discretion of the Company’s board of directors to a maximum of 10% of the outstanding Common Shares. The estimated fair value of granted options, using the Black-Scholes option pricing model, is expensed over the relevant vesting periods for which \$197,311 was recorded as an expense during the three months ended June 30, 2019.

As at June 30, 2019, the Company had 29,967,230 stock options outstanding representing 9.9% of Common Shares outstanding (June 30, 2018 – 27,407,230 representing 9.2% of Common Shares outstanding).

**Lease and office maintenance expense** for the three months ended June 30, 2019 was \$53,897 compared to \$52,612 for the three months ended June 30, 2018, representing an increase of \$1,285 or 2%. For the six months ended June 30, 2019, lease and office maintenance expense increased 22% to \$117,265 compared to \$96,398 in the same period of the prior year. Lease and office maintenance include office administration costs including rent, courier and utilities as well as investor relations and communications costs. The increase in costs relates to an increase in investor relations and communications, computer software and rent expense. During the first half of 2018 the Company rented individual offices in a shared office space whereas in late 2018 the Management Contractor provides office space for the Company and \$30,000 of rental expense was included in lease and office maintenance expense.

#### **Professional fees**

|                                   | Three months ended June 30, |                   |             | Six months ended June 30, |                   |             |
|-----------------------------------|-----------------------------|-------------------|-------------|---------------------------|-------------------|-------------|
|                                   | 2019                        | 2018              | % change    | 2019                      | 2018              | % change    |
| Patent costs                      | \$ 57,388                   | \$ 51,540         | 11%         | \$ 91,088                 | \$ 92,783         | -2%         |
| Accounting & audit fees           | (210)                       | 11,798            | -102%       | 6,767                     | 31,133            | -78%        |
| Legal - clinical trial agreements | 5,750                       | 8,375             | -31%        | 10,750                    | 23,410            | -54%        |
| Legal - compliance                | 10,843                      | 25,470            | -57%        | 11,812                    | 33,801            | -65%        |
| Legal - financing                 | -                           | 25,121            | -100%       | -                         | 25,313            | -100%       |
| Legal - other                     | 5,068                       | 8,066             | -37%        | 5,069                     | 31,766            | -86%        |
| <b>Total</b>                      | <b>\$ 78,839</b>            | <b>\$ 130,370</b> | <b>-40%</b> | <b>\$ 125,486</b>         | <b>\$ 238,206</b> | <b>-47%</b> |

Professional fees decreased by 40% to \$78,839 in the three months ended June 30, 2019, as compared to \$130,370 in the corresponding period of the prior year as a result of fewer clinical trial sites onboarded lowering legal costs related to the review of clinical trial agreements and patent applications.

Professional fees decreased 47% to \$125,486 for the six months ended June 30, 2019, as compared to \$238,206 in the corresponding period of the prior year, primarily as a result of lower legal costs and accounting fees which were incurred relating to one-time occurrences such as the wind down of our foreign subsidiaries and licensing and manufacturing agreements, whereas no such events took place in the same period of 2019.

**Travel expenses** for the three and six months ended June 30, 2019 were \$46,831 and \$74,438 respectively, an increase of \$27,607 or 37%. This increase resulted from additional travel related to the clinical trials, investor relations activities and visits to our contract manufacturer.

**Depreciation expense** for the three and six months ended June 30, 2019, totaled \$690 compared to \$nil in the corresponding periods of the prior year as a result of additional computer equipment acquired in the second quarter 2019.

**Finance expense** includes interest on bank deposits and accretion representing the change in the time value of the convertible debentures issued in May 2019. In the second quarter of 2019, the Company recorded finance expense of \$18,257 compared to finance income of \$8,916 in the same period of 2018. For the six months of 2019, the Company recorded finance expense of \$18,254 compared to finance income of \$23,364 in the comparable period of 2018.

**Foreign exchange loss (gain)** for the three months ended June 30, 2019 was a loss of \$898 compared to a gain of \$64,584 for the three months ended June 30, 2018, a change in the amount of \$65,481 or 101%. The gain in the three and six months ended June 30, 2018 related to an unrealized foreign exchange gain due to substantial US currency holdings and the weakening of the Canadian dollar against the US dollar. The loss in the current quarter, relates to an unrealized foreign exchange loss due to lower US currency holdings and the strengthening of the Canadian dollar against the US dollar.

#### QUARTERLY FINANCIAL INFORMATION

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

|                                    | June 30,<br>2019 | Mar 31,<br>2019 | Dec 31,<br>2018 | Sept 30,<br>2018 | June 30,<br>2018 | Mar 31,<br>2018 | Dec 31,<br>2017 | Sept 30,<br>2017 |
|------------------------------------|------------------|-----------------|-----------------|------------------|------------------|-----------------|-----------------|------------------|
| Net Loss (\$)                      | (1,326,424)      | (1,569,844)     | (1,738,998)     | (1,705,560)      | (1,659,334)      | (1,083,793)     | (921,210)       | (1,955,141)      |
| Weighted<br>Average #<br>of Shares | 300,898,610      | 300,898,610     | 300,801,231     | 299,025,877      | 297,482,782      | 296,874,720     | 296,874,720     | 111,605,053      |
| Loss per<br>Share (\$)             | (0.01)           | (0.01)          | (0.01)          | (0.01)           | (0.01)           | (0.004)         | (0.003)         | (0.018)          |

#### LIQUIDITY AND CAPITAL RESOURCES

Hemostemix is a development stage company that to date, has had minimal revenue, no net earnings 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 six months ended June 30, 2019, there was a net cash outflow from operating activities of \$1,940,536 compared to a net cash outflow of \$136,807 for the six months ended June 30, 2018, an increase in outflow of \$1,803,729.

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

|   |                |
|---|----------------|
| Increase in net loss from continuing operations for the period  | \$ (156,337)   |
| Increase in stock compensation expense                          | (334,169)      |
| Increase in finance expense                                     | 18,214         |
| Increase in interest expense                                    | (8,926)        |
| Increase in depreciation and amortization                       | 690            |
| Movement of short term investments to cash and cash equivalents | (1,254,659)    |
| Change in other receivables and prepaid expenses                | 34,367         |
| Change in HST/GST receivable                                    | 102,681        |
| Change in accounts payable and accrued liabilities              | (208,786)      |
| Change in income taxes payable                                  | -              |
| Cash flow from discontinued operations                          | 3,196          |
| <hr/>   |                |
| Increase in the net cash used for operations                    | \$ (1,803,729) |

As at June 30, 2019 the Company had a working capital deficit of \$1,735,672 compared to positive working capital of \$487,799 at December 31, 2018, resulting in a decrease in working capital of \$2,223,471. This lower working capital is a result of:

- 1) A decrease in cash and cash equivalents of \$1,421,674;
- 2) A decrease in HST/GST receivable of \$66,103;
- 3) A decrease in other receivables and prepaid expenses of \$77,613;
- 4) An increase in accounts payable and accrued expenses of \$170,235;
- 5) An increase in convertible debentures of \$487,846;

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 June 30, 2019, the number of issued and outstanding common shares was 300,898,610 (December 31, 2018 – 300,898,610). As at August 28, 2019 the number of common shares issued and outstanding remained at 300,898,610.

As at June 30, 2019, the Company had 29,967,230 share purchase options outstanding (December 31, 2018 – 29,417,230). As at August 28, 2019, the number of outstanding share purchase options remained at 29,967,230.

As at June 30, 2019, the Company had 114,818,564 share purchase warrants outstanding (December 31, 2018 – 114,818,564). As at August 28, 2019 the number of outstanding warrants remained at 114,818,564.

## **SIGNIFICANT ACCOUNTING POLICIES**

Refer to Note 2 in the 2018 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, 2018, except for the adoption of new standards beginning on, after or as of January 1, 2019.

### Changes in Accounting Policy

#### **IFRS 16 – Leases**

IFRS 16 - Leases sets out a new model for lease accounting, replacing IAS 17. IFRS 16 is effective for accounting periods beginning on or after January 1, 2019. IFRS 16 specifies how a reporter will recognize, measure, present and disclose leases. The standard provides a single lessee accounting model, requiring lessees to recognize assets and liabilities for all leases unless the lease term is 12 months or less or the underlying asset has a low value. The Company adopted the new standard on its effective date and there no impact on its financial reporting as the Company is currently not party to any financial leases.

## **COMMITMENTS & CONTINGENCIES**

### **Commitments**

#### **New Management Contract**

The Company entered into a new management contractor agreement with Kingsman Scientific Management Inc. (“KSM”), effective January 1, 2019. KSM is majority owned by Kyle Makofka, the current CEO of the Company. Pursuant to this agreement, KSM will oversee and manage all aspects of the operations and management of Hemostemix, including the Company’s current clinical trial, as well as assist in identifying additional appointments to the Company’s Board of Directors and management team.

The agreement has a term of one year with an option for an additional one-year renewal period. KSM will be compensated based on a fixed fee for key management personnel costs, support services, accounting and office rental and cost plus 15% for clinical trial operations as well as be entitled to bonuses should it achieve costs savings for the current Phase II clinical trial for critical limb ischemia. In addition, KSM will be granted stock options to acquire common shares in the capital of the Company to be granted in an amount equivalent to up to five percent (5%) of the Company's total issued and outstanding common shares.

It is anticipated that \$530,000 in consulting fees and \$30,000 in office rent will be paid out under this contract over the next six months, with additional amounts for reimbursable expenditures such as travel.

#### **Clinical Trial Costs**

The Company is committed to payments totaling approximately \$877,000 for activities related to our current clinical trial such as manufacturing, contract research, software and patient care. These payments are expected to be made over the next 12 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 30 to 60 days.

### **Contingencies**

In the ordinary course of operating, the Company may from time to time be subject to various claims or possible claims. Management believes that there are no claims or possible claims that if resolved would either individually or collectively result in a material adverse impact on the Company's financial position, results of operations, or cash flows. These matters are inherently uncertain, and management's view of these matters may change in the future.

### **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 and six months ended June 30, 2019, the Company incurred \$382,688 and \$788,146, respectively, of research and development expenses to a company related to Hemostemix by virtue of common management (June 30, 2018 - \$242,583 and \$366,384 for the three and six month periods).

The following includes all compensation to key management personnel:

The Company incurred \$314,704 and \$585,729, in consulting fees to the Chief Scientific Officer, Chief Medical Officer and the Management Contractor, who is providing a Chief Executive Officer, Chief Financial Officer, accountant, clinical staff and other services, during the three and six months ended June 30, 2019 (June 30, 2018 - \$343,234 and \$692,088 for the three and six month periods).

The Management Contractor was also reimbursed \$48,480 and \$87,611 in travel and office maintenance expense during the three and six months ended June 30, 2019 (June 30, 2018 - \$32,073 and \$38,654 for the three and six month periods). Additionally, the Management Contractor provides office space for the Company and \$30,000 of rental expense was included in lease and office maintenance (June 30, 2018 - \$Nil for the three and six month periods).

As at June 30, 2019, the Company had \$398,113 in accounts payable and accrued liabilities owing to the Management Company, the contract manufacturing company, and Chief Medical Officer (December 31, 2018 - \$390,542).

The Company recorded share-based compensation expense for the three and six months ended June 30, 2019 in the amount of \$180,038 and \$593,836 respectively (June 30, 2018 – \$525,327 and \$387,395 for the three and six month period) to key management personnel and the former management contract company.

## **FINANCIAL INSTRUMENTS & CAPITAL RISK MANAGEMENT**

Our financial instruments consist of cash and cash equivalents, other receivables and accounts payable and accrued liabilities. As at June 30, 2019, there are no significant differences between the carrying values of these amounts and their estimated market values.

### **Financial risk management**

The Company's financial risk management policies are established to identify and analyze the risks faced by the Company, to set acceptable risk tolerance limits and controls, and to monitor risks and adherence to limits. The financial risk management policies and systems are reviewed regularly to ensure they remain consistent with the objectives and risk tolerance acceptable to the Company and current market trends and conditions. The Company, through its training and management standards and procedures, aims to uphold a disciplined and constructive control environment in which all employees understand their roles and obligations.

#### *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 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.

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. 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 for the three months ended June 30, 2019 by approximately \$11,200.

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



Balances in foreign currencies at June 30, 2019 are as follows:

|                                       | US Dollars       |
|---------------------------------------|------------------|
|                                       | \$               |
| Cash and cash equivalents             | 2,879            |
| Accounts payable and accrued expenses | (373,917)        |
|                                       | <b>(371,038)</b> |

#### *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.

As at June 30, 2019, the Company has working capital deficit of \$1,735,672 (December 31, 2018 – positive working capital of \$487,799). As at June 30, 2019, the Company has an accumulated deficit of \$39,499,975 (December 31, 2018 - \$36,603,707) and is not yet generating operating cash flows. As such, there is material uncertainty about the ability of the Company to continue as a going concern. In order to continue as a going concern, the Company requires additional capital to fund ongoing operations and intends on continuing to raise additional funds through the issuance of equity and/or debt.

#### **Capital risk management**

The Company's objectives when managing capital are:

- ensuring sufficient liquidity to support its financial obligations and execute its operating and strategic plans;
- maintaining healthy liquidity reserves and access to capital; and
- minimizing the after-tax cost of capital while taking into consideration current and future industry, market and economic risks and conditions.

To assess its effectiveness in managing capital, management monitors certain key ratios to ensure they are within targeted ranges.

The Company defines its capital as its equity. Its capital management objectives and approach were unchanged during the quarter.

## **SUBSEQUENT EVENTS**

### **Cancellation of Non-Brokered Private Placement (“Other Debenture Offering”)**

On July 11, 2019, the Company announced that due to market conditions, it will not be proceeding with its previously announced non-brokered private placement of up to a maximum of \$6,000,000 principal amount of secured convertible debentures.

### **Cancellation of Second Tranche of Non-Brokered Private Placement of Convertible Debentures**

On July 11, 2019, the Company announced that it will not be having a second closing of its non-brokered private placement of up to a maximum of \$1,000,000 principal amount of secured convertible debentures. As announced on May 16, 2019, total gross proceeds of \$525,000 were raised pursuant to this offering.

### **Announcement of Loan Agreement**

Hemostemix entered into a loan agreement dated July 31, 2019 (the “Loan”) with J.M. Wood Investments Ltd. (“JMWI”) for a secured loan in an aggregate principal amount of up to \$2 million.

Under the terms of the loan, JMWI will advance a minimum amount of \$500,000 to the Company upon execution of the loan agreement. The loan bears interest at a rate of 12 per cent per annum and is secured by a general security agreement in favour of JMWI in respect of all of the personal property of the Company. The loan is repayable on a maturity date which is 12 months from the date of the first advance and the Company is entitled to prepay any amount outstanding under the loan without penalty. After Sept. 30, 2019, JMWI may provide the company with at least 60 days of written notice requiring repayment of the outstanding principal amount of the loan plus any accrued and unpaid interest. The proceeds of the loan will be used to finance the Company's current phase II clinical trial for critical limb ischemia, the Company's other clinical trial applications and for general working capital.

The Company is at arm's length with JMWI and JMWI is not a related party of the Company within the meaning of Multilateral Instrument 61-101. As at August 28, 2019, a total of \$925,746.90 has been advanced to Hemostemix under this Loan.

## **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 December 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**

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

To date, Hemostemix has not recorded any revenues from the sale of biopharmaceutical products or earning any licensing revenues, and, as a result, it faces a high risk of business failure. 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.

### **Ability to Continue as a Going Concern**

The Company's auditors' opinion on its December 31, 2018 financial statements includes an explanatory paragraph in respect of there being substantial doubt about its ability to continue as a going concern.

### **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. The

Company's technology will require significant research and development and preclinical and clinical testing prior to regulatory approval, if required, being obtained in the United States or other countries. The Company may not be able to obtain regulatory approvals, if required, to complete necessary clinical trials for its cell technology, or to commercialize it. The Company's technology may prove to have undesirable and unintended side effects, or other characteristics adversely affecting its safety, efficacy or cost-effectiveness could prevent or limit its use. The Company's technology may fail to provide its intended benefit, or achieve benefits equal to or better than its competitor's products at the time of testing or production and, if so, its business may fail.

### **Clinical Trial Risks**

The Company's clinical trials may fail to produce successful results or could be suspended due to unacceptable safety risks, which could cause its business to fail. Clinical trials are subject to extensive regulatory requirements, and are very expensive, time-consuming and difficult to design and implement, in part because they may be subject to rigorous regulatory requirements. The Company's products may fail to achieve necessary safety and efficacy endpoints during clinical trials. The Company believes that its clinical trials will take a substantial period of time to complete. Furthermore, failure can occur at any stage of the trials, and the Company could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including: unforeseen safety issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; and inability to monitor patients adequately during or after treatment. In addition, the Company or regulatory officials may suspend the Company's clinical trials at any time if it appears that the Company is exposing participants to unacceptable health risks. If the Company's clinical trials fail to produce successful results, or are suspended due to unacceptable safety risks, the Company's business may fail.

### **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.

### **Acceptance of Technology**

The Company's success depends on the acceptance of its stem cell technology by the medical community and consumers as a safe and effective solution. The success of its technology will depend on its acceptance by potential consumers and the medical community. Because its technology is new in the treatment of CLI, the long-term effects of using its new technology are unknown. The results of short-term clinical trials do not necessarily predict long-term clinical benefit or reveal adverse effects. If results obtained from future commercial experience indicate that its technology is not as safe or effective as other treatments, adoption of this technology by consumers and the medical community may suffer and its business will be harmed.

### **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 Key Man Insurance**

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

#### **No Anticipated Dividends**

The Company does not intend to pay dividends on any investment in the shares of stock of the Company. The Company has never paid any cash dividends and currently do not intend to pay any dividends for the foreseeable future. To the extent that the Company requires additional funding currently not provided for in its financing plan, its funding sources may prohibit the payment of a dividend. Because the Company does not intend to declare dividends, any gain on an investment in the Company will need to come through an increase in the stock's price. This may never happen and investors may lose all of their investment in the Company.

#### **ADDITIONAL DISCLOSURE FOR VENTURE ISSUERS WITHOUT SIGNIFICANT REVENUE**

The Company's main focus is to develop, 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.