

# **AMENDED**

# MANAGEMENT'S DISCUSSION AND ANALYSIS

# FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

Dated April 4, 2019

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# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

The following management's discussion and analysis ("MD&A") explains the variations in the consolidated operating results, financial position and cash flows of Sernova Corp. ("Sernova", the "Company", "We", "Us" or "Our") for the three months ended January 31, 2019 and 2018. This MD&A should be read in conjunction with the Company's unaudited interim condensed consolidated financial statements for the three months ended January 31, 2019 and 2018 and its audited consolidated financial statements and related notes for the years ended October 31, 2018 and 2017, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The Company's accounting policies under IFRS are set out in Note 3 of the audited consolidated financial statements for the years ended October 31, 2018 and 2017. All amounts are in Canadian dollars.

The information in this report is dated as of April 4, 2019.

#### FORWARD-LOOKING STATEMENTS

This MD&A contains "forward-looking statements" that reflect the Company's current expectations and projections about its future results. When used in this MD&A, the use of words such as "estimate", "project", "belief", "anticipate", "intend", "expect", "plan", "predict", "may", "should", "will", "consider", "anticipate", "objective" and the negative of these words or such variations thereon or comparable terminology, are intended to identify forward-looking statements and information. Forward-looking statements are, by their nature, not guarantees of the Company's future operational or financial performance and are subject to risks and uncertainties and other factors that could cause the Company's actual results, performance, prospects or opportunities to differ materially from those expressed in, or implied by, these forward-looking statements. No representation or warranty is intended with respect to anticipated future results, or that estimates, or projections will be sustained.

The Company's statements of "belief" concerning its product candidates are based primarily upon results derived to date from the Company's research and development programs. The Company also uses the term "demonstrated" in this MD&A to describe certain findings that it makes arising from its research and development including any pre-clinical and clinical studies that the Company has conducted to date.

Specifically, this MD&A contains forward-looking statements which include, but are not limited to, statements regarding:

- The Company's corporate strategies and objectives;
- The availability of various forms of financing;
- The initiation and completion of pre-clinical studies and clinical trials of our Cell Pouch<sup>TM</sup> for the treatment of insulin-dependent diabetes and other diseases;
- The preclinical studies and expected benefit of our hypo-thyroid program;
- The expected benefit of the Cell Pouch<sup>TM</sup> with therapeutic cells;
- The expected benefit of the European Commission's Horizon 2020 grant for our hemophilia program;
- The intention to protect therapeutic cells within the Cell Pouch from immune attack using local immune protection such as microencapsulation or other local immune protection technologies, or through the use of systemic antirejection regimens or a combination thereof;
- Sernova's intentions and ability to secure academic and pharmaceutical collaborations and to develop and implement partnering strategies; and
- The intention and ability to use human autograft cells or human donor cells for treatment and the intention to use human stem cell-derived cells or xenogeneic cells which are considered unlimited cell sources for our Cell Pouch for the potential treatment of chronic diseases;
- The intention and ability to obtain regulatory approval and commercialize the Cell Pouch for the treatment of insulin-dependent diabetes and other potential indications such as hemophilia and thyroid disease;

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- Expectations that the Cell Pouch technologies are unique and may become the standard of care in therapeutic cell transplantation if they prove to be safe and effective in clinical trials;
- Expectations with respect to the cost of Sernova's products, clinical trials and commercialization of our products;
- Sales and marketing strategy;
- Intentions regarding the development and protection of Sernova's intellectual property.
- General business and economic events

In developing the forward-looking statements in this MD&A, the Company has applied several material assumptions, including the availability of financing on reasonable terms, the Company's ability to form and maintain strategic alliances with other business entities and general business and economic conditions.

Forward-looking information is based on the reasonable assumptions, estimates, analysis and opinions of management made in light of its experience and perception of trends, current conditions and expected developments, as well as other factors that management believes to be relevant and reasonable in the circumstances at the date that such statements are made, but which may prove to be incorrect. We believe that the assumptions and expectations reflected in such forward-looking information are reasonable.

Key assumptions upon which the Corporation's forward-looking information are based include:

- our ability to manage our growth effectively;
- the absence of material adverse changes in our industry or the global economy;
- trends in our industry and markets;
- our ability to comply with current and future regulatory standards;
- our ability to protect our intellectual property rights;
- our continued compliance with third- party license terms and the non-infringement of third-party intellectual property rights;
- our ability to retain key personnel; and
- our ability to raise sufficient debt or equity financing to support our continued growth

There are a number of important factors that could cause Sernova's actual results to differ materially from those indicated or implied by forward-looking statements and information, including but not limited to: early stage development and scientific uncertainty, lack of product revenues and history of losses, additional financing requirements and access to capital, patents and proprietary technology, dependence on collaborative partners, licensors and others, government regulations, hazardous materials and environmental matters, rapid technological change, competition, reliance on key personnel, status of healthcare reimbursement, potential product liability and volatility of share price, absence of dividends and fluctuation of operating results. Such risks are further described under "Risk Factors" in this Annual Information Form. Potential investors and other readers are urged to consider these factors carefully in evaluating these forward-looking statements and information and are cautioned not to place undue reliance on them. Sernova has no responsibility, nor does it intend, to update these forward-looking statements and information, unless as otherwise required by law.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this MD&A or as of the date otherwise specifically indicated herein. Due to risks and uncertainties, including the risks and uncertainties described elsewhere in this MD&A, actual events may differ materially from current expectations. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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This MD&A has been prepared to help investors understand the financial performance of Sernova in the broader context of the Company's strategic direction, the risks and opportunities as understood by management, and some of the key metrics that are relevant to the Company's performance. This MD&A has been reviewed and approved by the Company's Audit Committee and the Board of Directors. The Company's Audit Committee includes three independent Directors who are financially knowledgeable.

#### ABOUT SERNOVA

Sernova Corp. is a clinical-stage regenerative medicine therapeutics company, focused on developing and commercializing our proprietary Cell Pouch and associated technologies including therapeutic cells and local immune protection. The Cell Pouch is a scalable, implantable, medical device, designed to create a vascularized tissue environment for the transplantation and engraftment of therapeutic cells, which then release proteins and/or hormones for the long-term treatment of a number of serious, chronic diseases such as diabetes, hemophilia and thyroid disease.

Therapeutic cells may be obtained directly from human autograft (self-cells) or allograft cells (non-self, donor cells), or derived from sources known to provide a virtually unlimited supply of cells such as stem cell-derived or xenogeneic (non-human) sources.

Implanted therapeutic cells may be protected within the Cell Pouch using systemic or local immune protection technologies such as microencapsulation or other local immune protection technologies being developed to create an immune privileged environment for protection of the Cell Pouch transplant from rejection.

Our initial studies have focused on the treatment of insulin-dependent diabetes through the transplantation of pancreatic islets, which control blood glucose levels. To date, we have successfully transplanted donor islets into our Cell Pouch to treat insulin-dependent diabetes in multiple animal models and conducted a proof of principle clinical study for the treatment of human subjects with diabetes receiving an islet transplant, protected by the standard of care antirejection drug regimen. In this study, results in a small cohort of patients have shown the Cell Pouch to be safe alone and when transplanted with human donor islets.

We are continuing the clinical investigation of the Cell Pouch with donor islets under an FDA IND (Investigational New Drug) allowance to conduct a human clinical study in the United States. We have initiated patient enrollment at the University of Chicago. Furthermore, pursuant to our strategy of obtaining sources of supplies for our therapeutic cells' applications, the Company secured a potential source of unlimited cells by entering into a license agreement with the University Health Network ("UHN") of Toronto, Canada. This license agreement gives us exclusive worldwide rights to certain patent-pending technologies that are related to the differentiation of stem cells into insulin-producing glucose- responsive therapeutic cells developed by UHN researchers. We continue to identify additional potential sources of cells which are not limited by donor availability through license agreements and/or partnerships. The Company is also investigating other diseases amenable to treatment with therapeutic cells such as Hemophilia A and thyroid disease.

## **Research and Development**

Our research and development efforts are focused principally on the development of the Cell Pouch in conjunction with various therapeutic cells for the treatment of chronic diseases and local immune protection technologies (e.g. microencapsulation) that may protect the therapeutic cells within the Cell Pouch from rejection by the body's immune system.

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Our objective is to advance our medical technologies through the various stages of preclinical and clinical development required to develop a commercial product. The programs we undertake may involve third-party collaborations and corporate partnerships in addition to our internal preclinical and clinical development efforts.

Our primary activities to achieve our goals include the following:

1. Conducting clinical trials required to gain marketing approval for the Cell Pouch System in countries that have a significant market opportunity. We developed our first therapeutic product for the treatment of insulin-dependent diabetes. Our first clinical trial, designed to demonstrate the proof of concept of the Cell Pouch and therapeutic cells in humans, was conducted in Canada.

With the encouraging findings of this first-in-human study, we designed a new clinical protocol and have initiated a clinical study of the Cell Pouch system in the United States at the University of Chicago. Sernova received US Food and Drug Administration (FDA) notice of allowance for its IND for this new clinical trial. The IRB (institutional ethics review board) cleared Sernova to begin this new Phase I/II (safety/efficacy) clinical study and screening and enrollment of patients is ongoing.

The trial is a Phase I/II prospective single-arm study of islets transplanted into patients with severe hypoglycemia unawareness implanted with the Cell Pouch prior to islet transplantation. The primary objective of the study is to demonstrate safety and tolerability of islet transplantation into the Cell Pouch. The secondary objective is to assess efficacy through a series of defined measures.

- 2. We are also developing a treatment that we believe could benefit the broader diabetes population using the Cell Pouch transplanted with locally immune protected cells from an unlimited source of cells such as glucose-responsive stem cell-derived cells or xenogeneic cells.
- 3. We also have ongoing research and development activities related to our proprietary Cell Pouch in the following areas:
  - a. Additional therapeutic indications including hemophilia and hypo-thyroid disease;
  - b. Establishing sources of therapeutic cells for transplantation within our Cell Pouch, including, depending on the clinical application, autologous cells, allogeneic cells such as donor cells and stem cell-derived cells as well as xenogeneic cells that could be used to treat significant numbers of patients with these chronic diseases;
  - c. Complementary technologies which may improve the safety and efficacy of cells within the Cell Pouch, including local immune protection technologies such as microencapsulation;
  - d. Proprietary processing and supply of therapeutic cells;
  - e. Ongoing international development of our intellectual property portfolio and development of new and/or licensing of intellectual property; and,
  - f. Establishing partnerships with medical device and/or pharmaceutical companies as well as academic institutions for the development of our products.

## **Recent Highlights**

In February 2018, Sernova announced that continuous glucose monitoring systems (CGM) (Medtronic, Northridge, CA) would be provided to patients in Sernova's US regenerative medicine clinical trial of its Cell Pouch. CGM is being used to track the function of the transplanted cells at multiple time points following transplantation into the Cell Pouch. Data from each period will be analyzed for mean glucose concentration,

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mean glucose variability, number and duration of hyperglycemic and hypoglycemic episodes, and total duration of hypoglycemia.

In May 2018, Sernova announced Mr. Sean Hodgins, CA, CPA, CPA (Illinois) joined Sernova as Chief Financial Officer.

In May 2018, Sernova announced Dr. Piotr Witkowski, M.D., Ph.D., as the Clinical Trial Principal Investigator for Sernova's new clinical study. Dr. Witkowski, at the University of Chicago site, will work closely with Sernova's team to conduct the clinical and regulatory aspects of the Cell Pouch trial. Dr. Witkowski is a published diabetes researcher and surgeon with a longstanding record in both basic science and clinical research pertaining to islet cell and abdominal organ transplantation. Under Dr. Witkowski's leadership, multidisciplinary research teams at the University of Chicago are currently conducting several studies designed to improve the quality and outcomes of islet cell transplantation in patients with T1D.

In May 2018, Sernova announced it received University of Chicago Institutional Review Board (IRB) approval to begin a new clinical protocol for the FDA-cleared human clinical trial to investigate the Cell Pouch for the treatment of type 1 diabetes (T1D) in individuals with hypoglycemia unawareness.

In July 2018, Sernova announced that patient screening and recruitment began at the University of Chicago clinical site in its regenerative medicine US clinical trial for diabetic patients with hypoglycemia unawareness.

In July 2018, the Corporation announced it closed a Private Placement for an aggregate total of \$2,754,000 and, in connection therewith, issued 11,016,000 Special Warrants.

In January 2019, the Company announced that three of seven patients had been enrolled in its U.S. Phase I/II clinical study of the Cell Pouch.

In January 2019, the Company announced the appointment of Dr. David Lillicrap, M.D., FRCPC, an internationally recognized leader in hematology, including hemophilia, and novel cell and gene therapy-based applications, to its Scientific Advisory Board (SAB).

# Research and Development Outlook for the 2019 Calendar Year

Our research and development program for 2019 includes the following:

- Continuing the clinical trial of our Cell Pouch in collaboration with JDRF under our US IND at the University of Chicago for patients with hypoglycemia unawareness using human donor islets and a standard of care antirejection drug regimen to further study the safety and efficacy of the device and islets. The Company is expecting to report preliminary safety data from Sernova's clinical study in the first half of 2019 and preliminary efficacy data in the second half of 2019;
- Submitting final documentation to the European Union to complete the HemAcure Horizon 2020 program to receive the final claim and to develop next steps which may include submission for further grant funding for a product development program for treatment of hemophilia A consisting of factor VIII releasing therapeutic cells transplanted within Sernova's Cell Pouch;
- Conducting preclinical proof of principal studies as part of a product development program for treatment of hypo-thyroid disease consisting of thyroid hormone releasing tissue transplanted within Sernova's Cell Pouch:
- Assessment of the quality characteristics including release criteria of cells being transplanted into the Cell Pouch;
- Producing human stem-cell-derived cells for diabetes and *in vivo* proof of principle assessment of these differentiated human stem cells for their safety and efficacy within Sernova's Cell Pouch for the treatment of insulin-dependent diabetes;

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- Assessing novel immune protection technologies for the transplanted Cell Pouch cells, to further develop
  and advance Sernova's therapeutic vision for diabetes and other diseases of a product consisting of
  immune protected therapeutic cells within the Cell Pouch; and
- Continue to collaborate with pharmaceutical and medical device companies as well as leading academic centers to assess safety and efficacy of our combined technologies in preclinical studies for potential negotiation of a licensing arrangement and commercial development partnership for our hemophilia and diabetes programs.

## Sernova's Cell Pouch System

The Cell Pouch is uniquely designed and patented to take into consideration the biological requirements of therapeutic cells. Our research demonstrates that vascularized tissue develops within the Cell Pouch environment when implanted beneath the skin or in other locations prior to transplantation of therapeutic cells. The design of the Cell Pouch, upon implantation, results in development of a biologically suitable environment consisting of vascularized tissue chambers for the placement of therapeutic cells for the potential treatment of diabetes, hemophilia and other diseases. In long-term pre-clinical evaluation, the Cell Pouch has been shown to maintain a stable, vascularized tissue environment prior to placement of these transplanted therapeutic cells. We believe these conditions are key for maintaining long-term survival and function of therapeutic cells. We have demonstrated in a series of ISO10993 biocompatibility studies and multiple animal studies that the Cell Pouch is biocompatible and safe. Long-term studies in multiple animal models have demonstrated that the islets become well-supported with microvessels as in their natural pancreatic environment following transplantation into the Cell Pouch. Benefits of the Cell Pouch are anticipated to be enhanced long-term therapeutic cell survival and function. It is crucial for therapeutic cells to have close contact with microvessels. For diabetes, as an example, this enables islets to monitor blood glucose levels and produce the appropriate amount of insulin throughout the day and night and after meals. We believe the Cell Pouch technologies achieve this ideal therapeutic/microvessel connection through alteration of the local environment and may allow for improved efficacy. For example, our studies have shown that islets transplanted into the Cell Pouch can control glucose levels in small and large animal models of diabetes over extended periods, and we believe this may also apply to other therapeutic cellular applications.

## **Development of the Cell Pouch in Diabetes**

According to the International Diabetes Federation, there are approximately 425 million people worldwide with diabetes and approximately 10% of these individuals have type-1 (insulin-dependent) diabetes. The primary treatment for subjects with type-1 diabetes is insulin injections by needle or insulin pump. The life of a patient with diabetes is consumed with attempting to control blood sugar levels to minimize the severe effects of diabetes which include heart and kidney disease, blindness and amputations. There is a significant need to improve the treatment of diabetic patients and to improve the quality of life of these individuals. Sernova believes an implantable medical device with a cell therapy approach for the treatment of diabetes could provide a significant improvement in the quality of life of patients as well as a substantial improvement in the potential efficacy and reduction of diabetes side effects in these patients. The goal of a cell therapy approach is essentially to replace the islet cells lost in the pancreas of diabetic patients in a retrievable device to return their blood sugar status to normal and to improve the quality of life of patients with diabetes.

Sernova's lead program is the clinical development of the Cell Pouch for the treatment of patients with insulindependent diabetes. By way of background, for diabetic patients with severe hypoglycemia unawareness, aside from the use of daily insulin injections, portal vein transplantation is the only cell-based treatment currently available. The treatment involves receipt of donor pancreata at specialized islet transplantation centres around

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the world. These pancreata are then put through a digestion process which is to isolate the insulin-producing islets from the pancreatic tissue. These pancreatic islets, often from multiple donors, are then infused into a patient's portal vein in the liver, followed by life-long administration of immunosuppressive drugs to inhibit rejection of the transplant.

It is encouraging that islet transplantation, even into the portal vein in humans when considered a first step proof of concept for diabetes cell therapy, may result in a reduction in the incidence of hypoglycemia unawareness, a reduced requirement for exogenous insulin and reduced diabetes-induced microvascular damage and potential insulin independence. These positive effects show the potential of cell therapy for diabetes.

There are issues with portal vein delivery of islets that we believe could be improved with Sernova's technologies. For example, following islet infusion with portal vein delivery, there is a significant initial reduction in surviving islets due to an immediate blood-mediated inflammatory reaction ("IBMIR"), which may damage and destroy a significant proportion of the islets infused into the portal vein. Due to IBMIR and other factors, up to three pancreata are required to treat a single patient and achieve a reduction in insulin injections using portal vein delivery. Also, the proportion of patients with insulin independence decreases over time, likely due to continued islet destruction with multiple etiologies. A further shortcoming of portal vein transplant is that infusion of cells into the portal vein is limited to donor islets and is not amenable to advanced technologies such as glucose-responsive insulin-producing stem cell-derived cells, similar to those licensed by Sernova, or xenogeneic cells being developed to overcome the limited supply of donor islet cells, as regulatory authorities have indicated, these cell technologies must be transplanted into an implantable and retrievable medical device.

With the encouraging initial results of islet transplantation, there is a need to develop an implantable and retrievable medical device that is highly vascularized for the placement and function of therapeutic cells including donor islets. Sernova's Cell Pouch is a minimally invasive, retrievable device which creates vascularized tissue chambers for the placement and long-term survival and function of therapeutic cells. Furthermore, the device was specifically designed to prevent fibrosis, a serious issue with previous implantable devices for therapeutic cells. As Sernova's first clinical indication, these donor islets transplanted into the Cell Pouch not only provide a means to optimize cell therapy within the Cell Pouch in humans while we develop unlimited supplies of cells for the Cell Pouch but as a potential therapeutic option for patients with hypoglycemia unawareness receiving an islet transplant.

We believe the Cell Pouch can alleviate a number of issues with portal vein transplantation. In the Cell Pouch, the therapeutic cells live within a tissue matrix surrounded by microvessels, similar to the islets' natural microenvironment in the pancreas rather than being subjected to a constant flow of blood with immune-reactive cells which is believed to lead to IBMIR. This reduced inflammatory response should enable improved islet survival and potentially lead to the need to implant fewer islets or other sources of insulin-producing cells. This could potentially enable the treatment of patients with diabetes with fewer donor pancreata than are currently being used in portal vein transplantation. In addition, known side effects from an infusion of cells into the portal vein such as portal vein hypertension, thrombosis, and liver steatosis (fatty liver), along with the costs of treating them, will be eliminated with the insulin-producing cells placed into the Cell Pouch.

Table I. Potential Benefits of the Cell Pouch Islet Transplant over the Portal Vein Islet Transplant

Characteristics	Cell Pouch <sup>TM</sup>	Portal Vein
		Transplant
Reduced Islet Mass	Yes	No
Tissue matrix to house islets	Yes	No
Vascularized Islets	Yes	No
Retrievable site	Yes	No
Future stem cell technologies	Yes	No
Minimally invasive site	Yes	No
Elimination of liver-associated toxicities	Yes	No
Elimination of IBMIR	Yes	No
Local immune protection of cells	Yes	No

Sernova's Cell Pouch was designed and patented to take into consideration the biological requirements of therapeutic cells. Our research demonstrates that highly vascularized tissue develops within the Cell Pouch environment when implanted below the skin or in other locations prior to transplantation of therapeutic cells. In long-term pre-clinical evaluation, the Cell Pouch has been shown to maintain a stable, vascularized tissue environment prior to placement of these transplanted therapeutic cells. We believe these conditions are key for maintaining long-term survival and function of therapeutic cells. We have demonstrated in a series of ISO10993 biocompatibility studies and multiple animal studies that the Cell Pouch is biocompatible and safe. Long-term studies in multiple animal models have demonstrated that the islets become well-supported with microvessels as in their natural pancreatic environment following islet transplantation into the Cell Pouch.

An independent pre-clinical study published in the journal Transplantation (Transplantation 2015 Nov: 99 (11):2294-300) demonstrated that the Cell Pouch with islets provided insulin independence for the length of the study (100 days) in a small animal model of diabetes using a marginal transplanted islet mass where over 95% of the animals achieved insulin independence. This study supports the concept that the Cell Pouch may require a smaller than anticipated number of cells to achieve efficacy, one of the parameters being investigated for further human clinical evaluation to achieve glucose control in patients with diabetes.

A proof-of-concept, first-in-human clinical study in Canada has demonstrated initial safety data for the Cell Pouch alone and with transplanted islets as well as survival of the well-vascularized islets within the Cell Pouch.

In summary, our human clinical results have shown the following important findings:

- First, the biocompatibility and a positive safety profile of the Cell Pouch have been shown in these subjects. Safety is the primary endpoint of the clinical study; and
- Second, the islets within the Cell Pouch, as shown by independent histological analysis, are well-vascularized, living within a natural tissue matrix and can make insulin, glucagon and somatostatin, key hormones in the control of blood glucose levels. We believe such revascularization of islets and islet metabolic function within Sernova's implantable medical device for therapeutic cells in humans in this patient population is an important step forward in the regenerative medicine field.

Based on these encouraging results as well as the learnings from this initial study, we developed a new clinical protocol to further address the safety as well as function of the Cell Pouch with therapeutic cells. Following peer review of the new clinical protocol, Sernova was awarded up to US\$2.45 million (≈\$3.2 million) grant under an agreement with the Juvenile Diabetes Research Foundation (JDRF). The grant is supporting our Cell Pouch diabetes clinical trial, which is being conducted at the University of Chicago under the direction of principal investigator, Dr. Piotr Witkowski.

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The clinical trial is a Phase I/II non-randomized, unblinded, single arm, company-sponsored trial, where diabetic subjects with hypoglycemia unawareness are being enrolled into the study under informed consent. Subjects are then implanted with Cell Pouches including several small sentinel pouches. Following the development of vascularized tissue chambers within the Cell Pouch, subjects are then stabilized on immunosuppression and placed on the donor transplant list. Upon receipt of a suitable donor pancreas and following isolation of islets, a dose of purified islets under strict release criteria is being transplanted into the Cell Pouches.

A sentinel pouch, also transplanted with islets, will be removed at approximately 90 days following transplant for an early assessment of the islet transplant. Subjects will be followed for safety and efficacy measures for approximately six months post-transplant. At that time, a decision will be made with regards to the transplant of a further second islet dose with subsequent safety and efficacy follow up. Patients will then be followed for one year. The primary objective of the study is to demonstrate the safety and tolerability of islet transplantation into the Cell Pouch. The secondary objective is to assess efficacy through a series of defined measures.

Our IND was allowed by the FDA December 2018 and approved by the University of Chicago Institutional Review Board (IRB) May 2018 to begin the study. We initiated subject recruitment and screening July 2018 and in January 2019 three of seven patients had been enrolled in the study.

We are continuing to advance our Cell Pouch technologies. While our current Cell Pouch clinical trial employs standard systemic immune protection regimens, in the future, the Cell Pouch may also accommodate novel local immune protection of therapeutic cells. Local immune protection of cells within the Cell Pouch using technologies such as microencapsulation or other technologies which house cells locally could result in a significant reduction or elimination of the need for anti-rejection drugs with their related side effects. In addition, local immune protection may provide a safer environment for the transplanted cells. The Cell Pouch is believed to be a suitable environment to support microencapsulated cells as the encapsulated cells are housed within the vascularized tissue matrix allowing vessels to be in very close contact with the islets as demonstrated in our preclinical studies of encapsulated islets. Other novel methods may also be employed to protect the transplanted cells from the immune system.

We believe the Cell Pouch can be used with a variety of sources of cells, such as glucose-responsive insulinproducing cells derived from stem cells or xenogeneic cells, addressing the limited availability of donors and allowing the extensive treatment of insulin-dependent diabetes. Sernova is working on these technologies including our licensed technology from UHN to provide an immune-protected cell-based therapeutic for all subjects with type-1 diabetes.

Thus, we believe our approach and its ease of use may provide an opportunity for the Cell Pouch to become the standard of care in therapeutic cell transplantation if it proves to be safe and effective in clinical trials. Sernova believes its technologies are unique in that the therapeutic cells have been proven to survive and function in a tissue matrix integrated with microvessels in close association with the therapeutic cells for potential treatment of chronic disease.

#### **Development of the Cell Pouch in Hemophilia**

We believe the Cell Pouch has multiple potential therapeutic applications. As part of this strategy to expand Cell Pouch clinical applications, we are evaluating Sernova's Cell Pouch for the treatment of patients with Hemophilia A.

One such approach involves taking a small blood sample from the patient, correcting the genetic defect in isolated cells and then expanding the cell numbers for placement into Sernova's Cell Pouch for constant release of factor VIII. Initial proof-of-concept studies were conducted by Sernova and a European team of experts forming the HemAcure consortium ("The Consortium"). The Consortium was successful in obtaining €5.6

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million (≈\$8.5 million), funded by a European Commission's Horizon 2020 grant, to develop a GMP (Good Manufacturing Practice) human cell product suitable for human clinical testing for the completion of safety and efficacy studies in the Cell Pouch as part of a regulatory package in preparation for human clinical testing.

The market for Hemophilia A is estimated at US\$15B/year, with an annual cost of up to US\$260,000 per patient. The current standard of care involves regular infusions of factor VIII, which achieves normal factor VIII blood levels for only a few hours at a time. The HemAcure consortium seeks to develop a product that will provide constant delivery of factor VIII to normalize blood levels (the "Program") in an effort to significantly improve the quality of life of patients suffering from Hemophilia A. The product being developed by the HemAcure consortium is expected to be highly disruptive to the current standard of care treatments for hemophilia A. The therapeutic goal of the Program is to use the patient's own cells corrected for the factor VIII gene. These cells placed in the implanted Cell Pouch are expected to release factor VIII on a continual basis at a rate that would be expected to reduce disease-associated hemorrhaging and joint damage. The constant delivery of factor VIII is also expected to reduce or eliminate the need for multiple weekly infusions which is the current standard of care using plasma-derived or recombinant, genetically engineered factor VIII for the prophylactic treatment of Hemophilia A.

We believe that the therapeutic potential to have a constant release of factor VIII from a Hemophilia A patient's own genetically corrected cells placed within the implanted Cell Pouch would be a very significant advancement in the treatment of hemophilia A. We believe Sernova's Cell Pouch with its vascularized tissue lined chambers for therapeutic cells, which has already been proven for islet safety and survival in human clinical assessment of diabetes, is an ideal, fully scalable medical device suitable for the potential treatment of Hemophilia A.

The preliminary preclinical proof of concept data used as a basis to support the foundation of the Horizon 2020 Grant was generated in a collaborative agreement between Medicyte GmbH under the FP7 ReLiver project, grant agreement 304961 and Sernova Corp where cryopreserved cells with the ex vivo inserted corrected gene for factor VIII were successfully shipped and assessed in Sernova's Cell Pouch at its headquarters in Canada. Regarding Sernova's participation in the consortium, the review of the HemAcure grant proposal stated that Sernova's participation was essential for carrying out the program because Sernova was the partner possessing the technology for the basis of the whole proposal, and which performed all the in vivo studies. At that time, the Cell Pouch had already been in development for more than six years and had already shown success in multiple small and large animal preclinical models and was in a first-in-human clinical trial for diabetes. The Cell Pouch was the only such device that, when implanted under the skin, was proven to become incorporated with blood vessel-enriched tissue-forming chambers for the placement of therapeutic cells, thus securing. Sernova as a key partner for the success of the Program.

In summary, the following developments have been achieved by the Consortium:

- In blood donated from patients with Hemophilia A, endothelial outgrowth cells to be corrected for the Factor VIII gene were isolated and grown successfully in a specialized Good Manufacturing Process (cGMP) compliant medium developed by the Consortium.
- Using a human Factor VIII gene insertion technique, the cells were corrected and confirmed to produce Factor VIII.
- A preliminary experiment showed these cells could release Factor VIII in the blood over time and improve blood clotting in an animal model of Hemophilia A, in preparation for transplant into the Cell Pouch.
- The corrected cells were proven to be successfully replicated through a production scale-up process. Following amplification, these cells maintained their normal healthy behaviour in producing Factor VIII. Additional safety metrics were achieved using established tests.
- The cells were then cryopreserved and shipped from the European partners to Sernova in North America

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- where they were shown to remain healthy through quality control testing in preparation for transplantation.
- The Cell Pouch manufactured under cGMP, and following implantation in the Hemophilia A animal model showed development of vascularized chambers suitable to receive the corrected cells.
- Following transplantation into the Cell Pouch in a Hemophilia A animal model, the patient's Factor VIII corrected cells survived at three months (the duration of the study).
- Initial results showed Factor VIII released from the cells in the Cell Pouch was detected in blood and notably, showed improved clotting when compared to the Hemophilia A animal control which did not receive human corrected cells.
- The steps of the cell production process were documented towards development of the cGMP manufacturing process for the corrected cells for future clinical use. An Instructions-for-Use document was also developed for implantation of the cGMP Cell Pouch, and transplantation of patient corrected Factor VIII producing cells applicable for future human testing in patients with Hemophilia A.

## **Developing the Cell Pouch for Additional Metabolic Disorders**

As the Company continues its work on diabetes and hemophilia indications, we are exploring new indications including a treatment for hypothyroid disease to further expand the application of our cell therapy platform technologies.

## Development of the Cell Pouch for Hypo-thyroid Disease

The thyroid gland controls how quickly the body uses energy, makes proteins, and sensitivity to other hormones. It participates in these processes by producing thyroid hormones, the principal hormones being triiodothyronine (T3) and thyroxine (T4). Hypothyroidism is a condition where the thyroid gland can't make enough hormone upsetting the normal balance of chemical reactions. If left untreated hypothyroidism can cause health problems such as obesity, joint pain, infertility, heart disease and eventually death. Common causes are autoimmune disease, radiation treatment, and surgical removal of the thyroid (thyroidectomy). Following thyroidectomy, patients require daily hormone replacement therapy with T4. Long-term T4 administration may be associated with significant morbidity and up to 50% of patients do not achieve adequate response to therapy.

To reduce the burden and risks of hypothyroidism, Sernova is conducting initial preclinical studies with our Cell Pouch in collaboration with Dr. Sam Wiseman at the University of British Columbia. The overall aim of the program is to evaluate the survival and function of thyroid tissue after implantation into the Cell Pouch to establish preclinical proof-of-concept of this novel approach to treat hypothyroidism.

## **Local Immune Protection & Other Complementary Technologies**

To broaden Sernova's local immune protection technologies, we continue to evaluate additional advanced technologies such as microencapsulation to reduce or eliminate the need for anti-rejection medications. We believe that microencapsulation of therapeutic cells within the Cell Pouch may provide a means to contain therapeutic cells within the Cell Pouch while providing close association of therapeutic cells with the required microvessels and tissue matrix. We believe this will enable long-term survival and function of cells for our disease indications.

#### **Alternative Sources of Cells**

Our transplantation technologies may incorporate autologous cells, donor cells or other sources of cells including therapeutic cells derived from human stem cells or derived from xenogeneic sources, depending on the clinical

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

indication under evaluation. As such, we will continue to work with academic collaborators and industry partners to identify and secure the required cells for our therapeutic indications. In this regard, Sernova has signed a license agreement with the UHN to gain access to worldwide, exclusive rights to certain patent-pending technologies for the advancement of glucose-responsive insulin-producing stem cells for treatment of patients with insulin-dependent diabetes. Process development and robust cell-production processes will provide a high standard of production of cells which consistently meets strict release criteria for evaluation of these cells in Sernova's Cell Pouch.

Sernova is also committed to working with pharmaceutical and academic partners to evaluate various insulin-producing cell technologies using different approaches, with the goal of combining Sernova and partner technologies to create best in class products. In this regard, Sernova has signed a number of agreements to test and evaluate several insulin-producing cell technologies in our Cell Pouch. The Company entered into a collaboration with an international pharmaceutical company to study Sernova's Cell Pouch in a large animal diabetes model. The collaboration involves the study of safety, survival and efficacy of locally immune protected therapeutic cells in our Cell Pouch in proof of concept studies with the goal to establish a future development and commercial partnership. Sernova plans to continue to develop multiple collaborations with pharmaceutical companies for its diabetes and hemophilia indications for establishment of potential long-term licensing and codevelopment relationships.

## Manufacturing

Our contract manufacturer has manufactured both our Cell Pouch and mini-Cell Pouch technologies (ISO13485; US FDA Quality System Regulations (QSR) 21 CFR 820; EU Medical Devices Regulation MDR 2017/745) for preclinical and clinical evaluation. Device specifications have been set, a semi-automated manufacturing process developed, and the product manufactured, packaged and sterilized under strict regulatory guidelines suitable for testing in clinical trials in North America and Europe to complete the manufacturing process. Sterilization verification studies were completed, and the product previously released for testing in our human clinical trial in Canada with Sernova's ITA (Investigational Testing Authorization) under the jurisdiction of Health Canada. A two-year packaging and product stability study has also been successfully completed demonstrating the stability of the product and packaging over this time-period. Furthermore, the manufacturing process has also been completed for the current US FDA IND (Investigational New Drug) application for our clinical study at the University of Chicago.

# **Intellectual Property**

Our patent portfolio currently consists of issued and pending patents in eight families covering our enabling platforms in important markets in North America, Europe and Asia. We strive to obtain broad claims in our patents, including exclusivity of our Cell Pouch device and related technologies in combination with a wide range of therapeutic cell technologies including glucose-responsive insulin-producing stem cell-derived cells and for the treatment of a number of chronic diseases. We intend to continue to expand our patent and licensing portfolio, through inventions developed internally as well as through strategic in-licensing, to maximize the commercial potential of our platform technologies.

#### RESULTS OF OPERATIONS

#### **Selected Financial Information**

Selected financial information from the statements of loss and comprehensive loss for the three months ended January 31, 2019 and 2018, were as follows:

	Three months ended January 31,	
	2019	2018
Research and development expenses	\$ 442,966	\$ 497,006
General and administrative expenses	\$ 277,907	\$ 272,187
Net loss and comprehensive loss for the period	\$ 723,750	\$ 766,355

For the three months ended January 31, 2019, the Company recorded a loss of \$723,750, which is comparable to the corresponding period in the prior year. The reduced loss compared to the same period in the prior year was primarily due to decreased research and development costs relating primarily to a decrease in the amount of manufacturing expenses and European patent related fees. In the first quarter of 2018, we incurred significant manufacturing costs in preparation for the initiation of our US clinical trial. This decrease was partially offset by increased general and administrative expenses related to increase investor relations expenses in the US associated with efforts to prepare the Company for a US listing and expanded capital raise efforts.

## **Research and Development Expenses**

Research and development expenditures for the three months ended January 31, 2019 and 2018, were as follows:

	Three months ended January 31,	
	2019	2018
Salaries, supplies and contract payments	\$ 355,820	\$ 340,335
Manufacturing costs	8,078	211,074
Patent fees and costs	53,829	135,325
Depreciation of property and equipment	16,160	15,315
Share-based compensation	34,079	84,188
	467,966	786,237
Contributions and tax credits	(25,000)	(289,231)
Total	\$ 442,966	\$ 497,006

For the three months ended January 31, 2019, we incurred total research and development expenses of \$442,966, a decrease of \$54,040 compared to the same period in the prior year. Excluding the impact of funding received, research and development expenses amounted to \$467,966 for the three months ended January 31, 2019, a decrease of \$318,271 compared to the same period in the prior year. The decrease was primarily due to a reduction in manufacturing costs which were completed in Q1 2018 in preparation for our US clinical trial. Patent fees also decreased by \$81,496 compared to the prior quarter. Contributions and tax credits decreased by \$264,231 compared

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

to the prior quarter as a result of the completion of the HemAcure Consortium funding which was finalized in fiscal Q4 2018.

## General and administrative expenses

General and administrative costs for the three months ended January 31, 2019 and 2018, were as follows:

	Three months ended January 31,	
	2019	2018
Salaries, benefits and consulting fees	\$ 54,329	\$ 62,438
Professional fees	15,783	24,270
Director fees and benefits	25,012	25,496
Investor relations	116,159	46,459
Travel and other costs	42,695	57,154
Depreciation of property and equipment	625	538
Share base compensation	23,304	55,832
Total	\$ 277,907	\$ 272,187

Total general and administrative expenses, for the three months ended January 31, 2019, increased by \$5,720, as compared to the same period in the prior year. This increase was primarily attributable to expanded investor relations activities in the United States which resulted in an increase in investor relations expenses of \$69,700 compared to the comparative quarter in 2018. This increase was partially offset by decreases in consulting fees, professional fees and share-based compensation.

#### Other items

	Three months ended January 31,	
	2019	2018
Finance income	\$ (1,862)	\$ (9,375)
Finance costs	2,075	3,359
Foreign exchange loss	2,664	3,178
Total	\$ 2,877	(\$ 2,838)

#### Finance income

Finance income, represented primarily by interest income earned on the Company's cash and marketable securities, was \$1,862 during the three ended January 31, 2018, compared to \$9,375 for the same period in the prior fiscal year. The decrease resulted from lower average balances of cash and marketable securities compared to the prior period.

#### Foreign exchange losses

Foreign exchange losses were \$2,664, for the three months ended January 31, 2019 compared to \$3,178 for the same period in the prior fiscal year. The foreign exchange losses are related to exchange losses on US payables funded with Canadian capital and strengthening US currency against the Canadian Dollar.

MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

#### Income taxes

Income taxes have not been recognized in profit and loss to date, as the Company has been incurring losses since inception, and it is not probable that future taxable profits will be available against which the accumulated tax losses can be utilized. Accordingly, the Company has substantial deferred tax assets that have not been recognized in the financial statements that would be available to shelter potential future taxable income from income taxes. See Note 11 to the Company's audited consolidated financial statements for the years ended October 31, 2018 and 2017, for further details related to the Company's income tax position.

## LIQUIDITY AND CAPITAL RESOURCES

Selected financial information from the statements of financial position as at January 31, 2019 and October 31, 2018, were as follows:

As at	January 31,	October 31,
	2019	2018
Cash and marketable securities	\$ 2,211,005	\$ 2,743,320
Total assets	3,099,812	3,605,188
Current liabilities	333,683	341,202
Share capital, warrants and contributed surplus	41,980,711	41,754,818
Deficit	\$(39,214,582)	\$(38,490,832)

As at January 31, 2019, the Company had cash and marketable securities of \$2,211,005 compared to \$2,743,320 as at October 31, 2018.

The Company does not have any debt or credit facilities.

We expect the Company's spending and capital requirements will increase as the Company advances its ongoing clinical trial. Some of the increased capital requirements are expected to be offset by the JDRF grant which was obtained specifically to help fund the clinical trial. Management believes that the Company has sufficient funds to continue to operate the business for the next twelve months.

## **Financing Activities**

In July 2018, the Company announced it closed a Private Placement for gross cash proceeds of \$2,754,000 and, in connection therewith, issued 11,016,000 Special Warrants.

Each Special Warrant converted, for no additional consideration, into one Unit ("Unit") of the Company. Each Unit consist of one common share and one common share purchase warrant ("Warrant") of the Company. Each Warrant will be exercisable into one share at \$0.35 per share for 24 months, subject to abridgement of the exercise period if the 20-day volume weighted price of the Company's shares exceeds \$0.50 per share. All securities issued in connection with the private placement were subject to a statutory hold period of four months. The Company compensated finders on a portion of the private placement, such compensation consisting of 7% in cash or 7% in finder warrants, or a combination thereof. The Company received approval of the TSX Venture Exchange on August 1, 2018. The Company agreed to file a final short form prospectus to qualify the distribution of the Units upon deemed conversion of the Special Warrants (the "Qualification") following the receipt of a final prospectus.

During the three months ended January 31, 2019, 1,250,000 stock options were exercised for gross cash proceeds of \$187,500 compared to the three months ended January 31, 2018, where 53,124 stock options were exercised for gross cash proceeds of \$10,078 and 465,600 warrants were exercised for gross cash proceeds of \$162,960.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

Historically, funding requirements have been met through the issuance of common shares from treasury and common share purchase warrants and stock options that are converted into common shares upon exercise. Management regularly monitors the capital markets and attempts to balance timing of new equity issues with the progress of our research and clinical development plan, general market conditions, and availability of capital. In addition, management actively targets additional sources of capital, such as grants and contributions, as well as collaborative partners which would assist in progressing our operations and research and clinical development programs.

We anticipate the cash requirements to fund our planned activities for fiscal 2019 will increase over the previous year. Our actual cash requirements for fiscal 2019 will depend on the clinical, pre-clinical, and collaboration activities that we ultimately undertake and the ability to secure partners, and non-dilutive funding in the form of government grants and receipt of ongoing funding from our JDRF grant for our US clinical trial.

The interim condensed consolidated financial statements have been prepared using IFRS that are applicable to a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business for the foreseeable future. The Company has experienced operating losses and cash outflows from operations since its inception, and accordingly, it will require ongoing financing in order to continue its research and development activities. In addition, it has not yet earned significant revenue or reached successful commercialization of its products. The Company will seek new funding from additional equity financings and/or licensing agreements and collaboration arrangements with development partners; however, there is no assurance that these funding initiatives will be successful.

#### Common Shares

The following table reflects the changes in the number of issued common shares from the most recent year ended October 31, 2018 to the date of this MD&A:

	Number of
	Common Shares
Balance as at October 31, 2018	159,971,348
Shares issued on the exercise of special warrants	11,016,000
Shares issued on the exercise of options	1,250,000
Balance as at January 31, 2019 and the date of this MD&A	172,237,348

#### Warrants

The following table reflects the changes in the number of issued warrants from the most recent year ended October 31, 2018 to the date of this MD&A:

	Weighted Average	
	Number of	Exercise Price
	Warrants	
Balance as at October 31, 2018	581,700	0.35
Issued on conversion of special warrants	11,016,000	0.35
Balance as at January 31, 2019 and the date of this MD&A	11,597,700	\$ 0.35

The warrants outstanding as at January 31, 2019 are described in Note 7 to the unaudited interim condensed consolidated financial statements for the three months ended January 31, 2019 and 2018.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

#### 2015 Incentive Plan

The Company has a 2015 Incentive Plan which has two components: (i) a rolling Share Option Plan ("Option Plan") and (ii) a Deferred Share Unit Plan ("DSU Plan"), (together the "Plan"). Further details on the Company's 2015 Incentive Plan are provided in Note 7 to the unaudited interim condensed consolidated financial statements for the three months ended January 31, 2019 and 2018.

The following table reflects the changes in the number of issued stock options from the most recent year ended October 31, 2017 to the date of this MD&A:

	Number of Options	Weighted Average
		Exercise Price
Balance as at October 31, 2018	9,005,000	\$ 0.23
Exercised	(1,250,000)	0.15
Expired	(50,000)	0.15
Balance as at January 31, 2019	7,705,000	\$ 0.23
Cancelled	(1,180,000)	0.24
Expired	(600,000)	0.15
Balance as at the date of this MD&A	5,925,000	\$ 0.24

The following table reflects the changes in the number of issued deferred share units (DSUs) from the most recent year ended October 31, 2017 to the date of this MD&A:

	Number of DSUs
Balance as at October 31, 2018, January 31, 2019 and the date of this MD&A	1,975,000

On August 14, 2017, the Board approved an amendment to the Company's Option Plan & Deferred Share Unit Plan (the "Incentive Plan") to increase the number of DSUs available by 660,222 to a maximum of 1,975,000. These additional DSUs were conditionally approved and granted subject to the Company obtaining shareholder approval and TSXV approval ("Exchange approval"). Subsequently, on March 19, 2018, the Board approved two further amendments to the Incentive Plan, subject to shareholder and Exchange approval, being: (a) an increase to 15% of the rolling number maximum of common shares available for reserve under the Incentive Plan for exercise of Options pursuant to the Option Plan component of the Incentive Plan; and (b) a further amendment to the DSU Plan component of the Incentive Plan to further increase the number of DSUs available by an additional 2,821,797 DSUs to a maximum fixed number total of 4,796,797 DSUs, which would represent 3% of the common shares at the date hereof. At the shareholder meeting of the Company held April 25, 2018 (the "2018 AGM") the shareholders approved, by majority vote of the disinterested shareholders of the Company, ordinary resolutions to amend the Company's Incentive Plan as follows: (a) to increase the rolling maximum percentage reserve of common shares for exercise of Options, pursuant to the Share Option Plan component of the Incentive Plan and for conversion of Deferred Share Units ("DSUs") pursuant to the Deferred Share Unit Plan component (the "DSU Plan") of the Incentive Plan, to a maximum of 15%; and (b) to increase the maximum number of common shares available for reserve for conversion of "DSUs" awarded pursuant to the DSU Plan.

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

At the 2018 AGM the shareholders also approved a resolution to ratify, confirm and approve the Incentive Plan, as it was anticipated to be amended and restated as of March 19, 2018, for continuation.

Both Incentive Plan amendments were shareholder approved subject to Exchange approval, and upon annual filing of the Option Plan component of the Incentive Plan, the TSXV chose to decline approval of the shareholder approved Incentive Plan amendments.

On March 25, 2019, the Board approved amendments to the Plan, subject to shareholder and Exchange approval, being (a) to amend the Incentive Plan to change the current rolling number maximum percentage, to a fixed number maximum plan representing 15% of the common shares of the Company issued and outstanding at the date of Board approval of the amended and restated Incentive Plan, which will allow for the reserve of up to an aggregate of 25,835,602 common shares for exercise of options pursuant to the stock option component of the Incentive Plan; and (b) a further amendment to the DSU component of the plan to further increase the number of DSUs available to a fixed number maximum of 5,167,120 representing 3% of the current and issued outstanding common shares of the Company.

## **COMMITMENTS AND CONTINGENCIES**

The Company expects to pay certain future costs related to its pre-clinical and clinical trials. Such payments are expected to include the cost of clinical staff and overhead thereon, trial insurance, and may include travel and a portion of drug or procedure—related expenses or transplantation expenses not covered by insurance. The total payments over the duration of the trial will be impacted by such factors as the rate of enrollment, the location in which the patient resides and the specifics of patient insurance.

By participating in the HemAcure consortium and accepting grant funding, the Company has committed to perform certain product development activities, as outlined in the grant agreement with the European Commission's Horizon 2020 program. While it is anticipated that the funding that has been received and further funding expected to be received by the Company will cover most of the costs expected to be incurred related to the planned product development activities, the actual amount of effort and the related costs may differ from what was expected and may be more than the maximum amounts the European Commission has agreed to cover. Accordingly, any excess costs required to complete the activities would become the Company's responsibility. Under the grant agreement, consortium members may also shift the funding allocated under the grant between members in order to cover excess costs, so the Company may ultimately receive a different amount of funding than currently expected. The project is subject to a number of risks and uncertainties, and in particular the risks outlined under the risk factor titled 'Dependence on collaborative partners, licensors, contract manufacturer and others', please refer to the risk factors discussed elsewhere in this MD&A.

In July 2016, the Company was awarded a US\$2.45 million (approximately \$3.2 million) grant under an agreement with JDRF. The grant supports a human clinical trial of Sernova's Cell Pouch<sup>TM</sup> for treatment of patients with type 1 diabetes at a major transplantation center in the United States. In August 2016, the Company received an initial funding payment from JDRF in the amount of US\$367,768 (\$480,783) as per the terms under the agreement. In November 2017, the Company received an interim payment in the amount of €226,603 (\$331,770). Pursuant to the agreement with JDRF, the Company has committed to perform certain clinical trial activities and to use commercially reasonable efforts to introduce a diabetes product into a major market. Further, the agreement creates an obligation for the Company to pay royalties to JDRF on any future net sales received by the Company from a diabetes product or in certain future license or disposition transactions limited to a certain percentage of funds received over time up to a prescribed limit related to the amount of the grant funding.

In October 2016, the Company entered into a collaboration with an international pharmaceutical company regarding a material transfer agreement to study Sernova's Cell Pouch safety, survival and efficacy of locally

# MANAGEMENT'S DISCUSSION AND ANALYSIS

#### FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

immune protected therapeutic cells in a large animal diabetes model. Pursuant to the collaboration agreement, the Company has committed to perform certain pre-clinical activities. This agreement included 50% cost sharing for the agreed studies. A payment in the amount of US\$185,778 (\$249,611) was received by the Company in December 2016.

The Company entered into a three-year lease effective September 1, 2017. Notwithstanding the term, the Company has the right to terminate the lease after the first anniversary by providing 90 days' written notice. Gross payments required under the new lease for the fiscal year ending October 31, 2019 amounts to \$67,025.

In November 2017, the Company received an interim payment in the amount of €226,603 (\$331,770) from the EU Horizon2020 grant program related to the HemAcure project based on achievement of program milestones.

## RELATED PARTY TRANSACTIONS

The key management personnel of the company are the Directors, the President and Chief Executive Officer and the Chief Financial Officer.

Amounts due to related parties, including amounts due to key management personnel, at the period-end are unsecured, interest free and settlement generally occurs in cash. There have been no guarantees provided or received for any related party receivables or payables. Included in accounts payable and accrued liabilities at January 31, 2019 was \$79,104 due to key management personnel (October 31, 2018 – \$61,356).

Compensation to key management personnel for the three months ended January 31, 2019 and 2018, was as follows:

	Three months ended January 31,	
	2019	2018
Salaries, benefits and consulting fees	\$ 89,575	\$ 103,896
Director fees and benefits	24,063	25,496
Share-based compensation	57,383	71,535
Total	\$ 171,021	\$ 200,927

Executive officers and directors participate in the Company's 2015 Incentive Plan, so they are eligible to receive stock options and deferred share units. Executive officers also participate in the Company's health benefits plan.

## SUMMARY OF QUARTERLY RESULTS

Selected quarterly data with respect to the statement of loss and comprehensive loss is set out below:

Fiscal		1st Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
Year					
2019	Net loss	\$ 723,750	-	-	-
	Net loss per share	\$ 0.00			
2018	Net loss	\$ 766,355	\$ 986,347	\$ 1,111,556	\$ 834,369
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.01	\$ 0.01
2017	Net loss	\$ 317,524	\$ 638,431	\$ 705,793	\$ 977,731
	Net loss per share	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.01

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

The marginally lower loss in the first quarter of 2019 is reflective of the Company's prior completion of key manufacturing costs incurred in preparation for the Company's clinical trial.

It is important to note that historical patterns of expenditures cannot be taken as an indication of future expenditures. The amount and timing of expenditures, and therefore liquidity and capital resources, may vary substantially from period to period depending on the business and research activities being undertaken at any one time and the availability of funding from investors and prospective collaborative partners.

## **OFF-BALANCE SHEET ARRANGEMENTS**

We do not have any off-balance sheet arrangements.

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with IFRS requires the Company to make judgements, estimates and assumptions that affect the application of accounting policies, the reported amounts of assets, liabilities and expenses, as well as the Company's ability to continue as a going concern. The estimates and assumptions made are continually evaluated and have been based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Such estimates and assumptions are inherently uncertain. Actual results could differ materially from these estimates and assumptions. Revisions to estimates are recognized in the period in which the estimate is revised and may impact future periods. A summary of the Company's significant accounting policies and estimates under IFRS is found in Note 3 of the Company's audited consolidated financial statements for the years ended October 31, 2018 and 2017.

Management has applied significant estimates and assumptions to the following:

#### Valuation of share-based compensation

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the expected: option life, volatility, risk-free interest rate, forfeiture rates, stock option exercise behaviors, dividend yield and corporate performance. Changes in these assumptions affect the fair value estimate for share-based compensation. The assumptions and models used for estimating fair value for share-based payment transactions are discussed in Note 7 of the audited consolidated financial statements for the years ended October 31, 2018 and 2017.

## INTERNAL CONTROLS OVER FINANCIAL REPORTING

As a result of the Company's limited administrative staffing levels, internal controls which rely on segregation of duties, in many cases, are not possible. Due to resource constraints and the present stage of the Company's development, the Company does not have sufficient size and scale to warrant the hiring of additional staff to address this potential weakness at this time. To help mitigate the impact of this, the Company is highly reliant on the performance of compensating procedures and senior management's review and approval.

As a venture issuer, the Company is not required to certify the design and evaluation of the Company's disclosure controls and procedure ("DC&P") and internal controls over financial reporting ("ICFR"), and as such has not

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

completed such an evaluation. Investors should be aware that inherent limitations on the ability of the certifying officers of a venture issuer to design and implement, on a cost-effective basis, DC&P and ICFR as defined in NI 52-109, may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

## **CHANGES IN ACCOUNTING POLICIES**

#### New standards and interpretations not yet effective

Standards issued, but not yet effective up to the date of issuance of the Company's interim condensed consolidated financial statements are listed below. This listing is of standards and interpretations issued, which the Company reasonably expects may be applicable at a future date. The Company intends to adopt those standards when they become effective.

As at November 1, 2017, the Company adopted IFRS 9, Financial Instruments (IFRS 9). The Company has elected to not restate comparative periods in the year of initial application of IFRS 9 relating to the transition for classification, measurement and impairment. As a result, the comparative information provided continues to be accounted for on a basis consistent with those followed in the most recent annual consolidated financial statements.

The Company assessed the classification and measurement of the financial instruments it held at the date of initial application of IFRS 9 (November 1, 2017) and has classified its financial instruments into the appropriate IFRS 9 categories. There were no changes to the carrying value of the Company's financial instruments resulting from this reclassification and accordingly there was no impact to the Company's opening balance of deficit as at November 1, 2017 as a result of the adoption of IFRS 9.

Certain pronouncements were issued by the IASB or International Financial Reporting Interpretation Committee that are mandatory for annual periods beginning after January 1, 2016 or later periods. Many of these updates are not applicable or are inconsequential to the Company and have been excluded from the discussion below. The remaining pronouncements are being assessed to determine their impact on the Company's results and financial position.

## IFRS 16 Leases

In January 2016, the IASB issued IFRS 16 *Leases* ("IFRS 16"), its new lease standard that requires lessees to recognize assets and liabilities for most leases on the statement of financial position. Lessees applying IFRS 16 will have a single accounting model for all leases, with certain exemptions. Lessor accounting is substantially unchanged. The new standard will be effective from January 1, 2019 with limited early application permitted. The Company is currently monitoring the development of this standard and assessing the impact that adoption of this standard may have on the interim condensed consolidated financial statements.

#### RISKS AND UNCERTAINTIES

An investment in our common shares involves a high degree of risk and should be considered speculative. An investment in our common shares should only be undertaken by those persons who can afford the total loss of their investment. You should carefully consider the risks and uncertainties listed below, as well as other information contained in this MD&A. The risks and uncertainties below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition and results of operations could be seriously harmed, and you could lose all or part of your investment. Further, if we fail to meet the expectations of the public market in any given period, the market price of our common shares could decline. We

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

operate in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of our control.

The following is a summary list of risks and uncertainties for the Company. For a detailed description of each risk and uncertainty, please refer to the annual Management's Discussion and Analysis for the years ended October 31, 2018 and 2017 as filed on SEDAR.

#### **Investment Risk**

- Volatility of share price, absence of dividends and fluctuation of operating results.
- Dilution.

#### **Issuer Risk**

- Early stage development and scientific uncertainty.
- We depend heavily on the success of our Cell Pouch platform.
- We do not expect to realize material revenues until, if and when, our medical technologies become commercially viable.
- Additional financing requirements and access to capital.
- We heavily rely on the capabilities and experience of our key executives and scientists and the loss of any of them could affect our ability to develop our products.
- Clinical trials are long, expensive and uncertain processes and Health Canada, FDA, European Union
  or other regulatory jurisdictions may ultimately not approve any of our products. We may never develop
  any commercial applications or products that generate revenues.
- Patents and proprietary technology.
- We may expend our limited resources to pursue particular research and development opportunities and fail to capitalize on others that may be more profitable or for which there is a greater likelihood of success.
- Dependence on collaborative partners, licensors, contract manufacturer and others.
- Employee misconduct or other improper activities.
- Lack of product revenues and history of losses.
- *Conflict of interest.*
- We are likely a "passive foreign investment company", which may have U.S. federal income tax consequences for U.S. shareholders.
- It may be difficult for non-Canadian investors to obtain and enforce judgements against us because of our Canadian incorporation and presence.
- As a foreign private issuer, we are not subject to certain United States securities law disclosure requirements that apply to a domestic United States issuer, which may limit the information which would be publicly available to our shareholders.

## **Industry Risk**

- Rapid technological change.
- Competition.
- Government regulations.
- *Hazardous materials and environmental matters.*
- Status of healthcare reimbursement.
- Potential product liability.
- Reliance on Information Technology.

MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2019 AND 2018

## **DIRECTORS AND OFFICERS**

Frank Holler, Chairman of the Board of Directors
Jeffrey Bacha, Director
James Parsons, Director
Bruce Weber, Director
Dr. Philip Toleikis, President, Chief Executive Officer and Director
Sean Hodgins, Chief Financial Officer

## ADDITIONAL INFORMATION

Additional information relating to the Company can be found on SEDAR at www.sedar.com.