



## **SERNOVA CORP**

**MANAGEMENT'S DISCUSSION AND ANALYSIS**

**FOR THE THREE AND SIX MONTHS ENDED  
APRIL 30, 2019 AND 2018**

Dated June 28, 2019

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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 and six months ended April 30, 2019 and 2018. This MD&A should be read in conjunction with the Company's unaudited interim condensed consolidated financial statements for the three and six months ended April 30, 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 June 28, 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 strategy and strategic objectives;
- The availability of various forms of external financing to fund the Company's ongoing liabilities and commitments;
- The expected benefits of the Cell Pouch™ for therapeutic cells;
- The conduct of pre-clinical studies and clinical trials of our Cell Pouch™ for the treatment of insulin-dependent diabetes;
- The preclinical studies and expected clinical benefit of our hypo-thyroid cell therapy program;
- The expected preclinical and clinical benefit of the cell therapy hemophilia A program and the benefits gained from the European Commission's Horizon 2020 hemophilia grant;
- 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;

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- 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;
- 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 of our Cell Pouch technologies;
- 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 MD&A. 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 for filing 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 are in the enrollment and treatment phase of the study and have announced transplantation of donor islets into the implanted Cell Pouch in the first patient 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 (Nostro CM, et al. Stem Cell Reports 2015;4(14):591). 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 within the Cell Pouch such as Hemophilia A and thyroid disease.

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#### **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.

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 are developing 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 review board) cleared Sernova to begin this new Phase I/II (safety/efficacy) clinical study.

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. Screening and enrollment of patients is ongoing.

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 postoperative hypothyroid 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.

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#### **Recent Highlights**

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

In February 2019, the Company announced that the first patient had been implanted with Sernova's Cell Pouch in its Phase I/II clinical trial for the treatment of hypoglycemia unawareness.

In April 2019, Sernova announced the first transplantation of therapeutic cells in the Cell Pouch for the Company's Phase I/II US clinical study for diabetes.

In April 2019, the Company announced a collaboration with Dr. Sam Wiseman, thyroid surgeon, researcher and Director of Research in the Department of Surgery at Providence Healthcare in Vancouver for the development of a Cell Therapy-based Program for the treatment of postoperative hypothyroidism.

In May 2019, Sernova announced the appointment of Deborah Brown to its Board of Directors and the approval by shareholders and the Exchange of the amended stock option plan.

In May 2019, Sernova received a milestone payment of US\$400,000 (CDN \$535,661) from the JDRF T1D Fund LLC related to the Research, Development and Commercialization Agreement with JDRF to help fund Sernova's Phase I/II Cell Pouch clinical trial at the University of Chicago.

#### **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

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therapeutic cells transplanted within Sernova's Cell Pouch;

- Conducting preclinical proof of principal studies as part of a product development program for treatment of postoperative hypothyroid disease consisting of thyroid hormone releasing tissue transplanted within Sernova's Cell Pouch;
- Assessing of the quality characteristics including release criteria of cells being transplanted into the Cell Pouch for our various therapeutic indications;
- 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;
- 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
- Continuing 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 chronic 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 (<https://www.idf.org/aboutdiabetes/what-is-diabetes/type-1-diabetes.html>). 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

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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 insulin-dependent 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 the world. These pancreata are then put through a digestion process 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.

As noted in Table 1, 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 lower the number of islets or other sources of insulin-producing cells that need to be implanted. Consequently, fewer donor pancreata than what are currently being used in portal vein transplantation would be required. In addition, known side effects of an infusion into the portal vein such as portal vein hypertension, thrombosis, and liver steatosis (fatty liver), along with the costs of treating them, are expected to be eliminated with the application of Sernova's Cell Pouch technology (see Table 1).



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

<b>Characteristics</b>	<b>Cell Pouch™</b>	<b>Portal Vein Transplant</b>
Reduced Islet Mass	Yes	No
Tissue matrix to house islets	Yes	No
Vascularized Islets	Yes	No
Retrievable site	Yes	No
Future stem cell derived 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 and glucagon, 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 small sentinel pouches. Following the development of vascularized tissue chambers within the Cell Pouch, subjects are then stabilized on immunosuppression and activated 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.

We announced our IND was allowed by the FDA in December 2018 and approved by the University of Chicago Institutional Review Board (IRB) in May 2018 to begin the study. We initiated subject recruitment and screening in July 2018 and in January 2019 three of seven patients had been enrolled in the study. We announced the first subject was implanted in February 2019 and subsequently, islets were transplanted in the Cell Pouch in April 2019 and the study is ongoing.

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 insulin-producing 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 therapeutics 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

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forming the HemAcure consortium ("The Consortium"). The Consortium was successful in obtaining €5.6 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.

According to a recent market analysis report (<https://www.grandviewresearch.com/industry-analysis/hemophilia-treatment-industry>), the global market is valued at USD 11.1 billion in 2018 and is expected to grow at a CAGR of 5.2% over forecast period to 2026. Furthermore, according to the World Federation of Hemophilia (WFH), the disease is more prevalent in males and about 1 in 5,000 neonates suffer from type A. Hemophilia is a rare genetic bleeding disorder estimated to have affected about 440,000 people globally as of 2018. The federation also mentions that about 75.0% of these individuals are either undiagnosed or receive inappropriate treatment.

The estimated patient annual cost of treatment is 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 shown success in multiple small and large animal preclinical models and was in a first-in-human clinical trial for diabetes. We believe the Cell Pouch was the only device that, when implanted under the skin, had at the time been shown 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, blood 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

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### **MANAGEMENT'S DISCUSSION AND ANALYSIS**

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#### 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 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.

#### **Development of the Cell Pouch for Postoperative Hypothyroidism**

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) Most thyroid operations are carried out for the treatment of thyroid nodules, which are very common (up to %65 prevalent) (PMID: 19041821) in the general population. Also, surgical thyroid removal may be recommended for patients with Grave's Disease (a type of Hyperthyroidism) and patients with large multinodular goiters. Thyroidectomy is also commonly performed for cancer diagnosis or treatment. Hypothyroidism inevitably occurs after total thyroidectomy and may also occur in up to 10% of people after thyroid lobectomy (Johner A, Griffith OL, Wood L, et al: Detection and Management of Hypothyroidism Following Thyroid Lobectomy: Evaluation of a Clinical Algorithm. *Ann of Surg One* 2011; 18(9):2548-2554) The American Thyroid Association (ATA) estimates that about 150,000 thyroidectomies are performed in the US yearly, and the majority of individuals undergoing a thyroid operation will be diagnosed with benign disease after their operation.

Following thyroidectomy, patients require daily hormone replacement therapy with T4. Even though post-operative thyroid hormone replacement seems simple, effective and safe, 30-50% of thyroxine users do not achieve adequate biochemical euthyroidism (1.Okosieme OE: Thyroid hormone replacement: current status and challenges. *Exp Opinon Phannacother* 2011; 12( 15):2315-2328) Moreover, it is recently evidenced that patients treated adequately with T4 still experienced a number of symptoms, including deficits in cognition and mood, their ability to focus, and their general mental well-being (Kansagra S, McCudden C, Willis M. The challenges and complexities of thyroid hormone replacement. *Laboratory Medicine* 2010; 41(6):338-48.). Then, long-term

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thyroid hormone administration may be associated with significant morbidity, and thus has many associated healthcare costs.

Sernova's approach in the treatment of postoperative hypothyroid disease is to auto-transplant healthy thyroid tissues of patients undergoing thyroidectomy into the pre-implanted vascularized Cell Pouch, to reduce the burden and risks of postoperative hypothyroidism. Sernova is conducting initial preclinical studies with our Cell Pouch in collaboration with Dr. Sam Wiseman at the University of British Columbia. This collaboration received funding by a Transplant Venture Grant awarded by the Transplant Research Foundation (TRF) 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. The collaboration will accelerate Sernova's research efforts and set the stage for the preparation of a regulatory submission for future clinical assessment of people suffering from postoperative hypothyroid disease with the aim to preserve thyroid function and improve patients' quality of life.

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

As the Company continues its work on current indications, we are exploring potential new rare disease indications to further expand the application of our cell therapy platform technologies.

#### **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 indication under evaluation. As such, we 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

**SERNOVA CORP.****MANAGEMENT'S DISCUSSION AND ANALYSIS****FOR THE THREE AND SIX MONTHS ENDED APRIL 30, 2019 AND 2018**

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companies for its diabetes and hemophilia indications for establishment of potential long-term licensing and co-development 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 established, 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, Cell Pouches were manufactured 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 twelve 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 and six months ended April 30, 2019 and 2018, were as follows:

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	Three months ended		Six months ended	
	2019	April 30, 2018	2019	April 30, 2018
Research and development expenses	\$301,649	\$524,518	\$744,614	\$1,021,524
General and administrative expenses	312,670	464,850	590,578	737,037
Loss and comprehensive loss for the period	\$613,356	\$986,350	\$1,337,104	\$1,752,705

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For the three months ended April 30, 2019, the Company recorded a loss of \$613,356. The reduced loss compared to the same period in the prior year of \$986,350 was primarily due to hitting a funding milestone on the Company's agreement with the Juvenile Diabetes Research Foundation (JDRF) associated with the US clinical study. The funding milestone was US \$400,000 (CDN \$535,661) which helps offset the research and development costs.

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For the six months ended April 30, 2019, the Company recorded a loss of \$1,337,104, compared to \$1,752,705 in the prior year. The decreased loss was also primarily due achieving a defined milestone with the US clinical study and the resulting recognition of the amount receivable of US \$400,000 (CDN \$535,661) from the Juvenile Diabetes Research Foundation (JDRF) which was subsequently received in May 2019.

**Research and Development Expenses**

Research and development expenditures for the three and six months ended April 30, 2019 and 2018, were as follows:

	Three months ended April 30,		Six months ended April 30,	
	2019	2018	2019	2018
Salaries, supplies and contract payment	\$746,206	\$356,807	\$1,102,026	\$697,142
Manufacturing costs	5,326	204,468	13,404	415,542
Patent fees and costs	54,646	49,933	108,475	185,258
Depreciation of property and equipment	15,303	15,355	31,462	30,670
Share-based compensation	26,044	76,324	60,123	160,512
JDRF and other funding contributions	(535,661)	(163,369)	(535,661)	(437,600)
Research and development tax credits	(10,215)	(15,000)	(35,215)	(30,000)
Total	\$301,649	\$524,518	\$744,614	\$1,021,524

For the three months ended April 30, 2019, we incurred total research and development expenses of \$301,649, a decrease of \$222,869 compared to the same period in the prior year of \$524,518. Excluding the impact of funding received, research and development expenses amounted to \$847,525 for the three months ended April 30, 2019, an increase of \$144,638 compared to the same period in the prior year. The increase was primarily due to the US clinical trial expenses with the University of Chicago.

Total research and development expenses, for the six months ended April 30, 2019, decreased to \$744,614 compared to \$1,021,524 for the prior fiscal year. Employee costs, supplies and contract payments, for the six months ended April 30, 2019, increased by \$404,884, compared to the equivalent period of the prior fiscal year. This increase is also primarily due to our US clinical trial expenses with the University of Chicago. The Company incurred \$13,404 in the six months ended April 30, 2019 in manufacturing costs regarding Sernova's Cell Pouch related to Sernova's preclinical and clinical programs compared to \$415,542 for the prior fiscal year as the major manufacturing costs have been completed. Contributions and tax credits increased to \$570,876 compared to \$467,600 during the prior fiscal period primarily due to the timing of the JDRF milestone payments.

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**General and administrative expenses**

General and administrative costs for the three and six months ended April 30, 2019 and 2018, were as follows:

	Three months ended April 30,		Six months ended April 30,	
	2019	2018	2019	2018
Salaries, benefit and consulting fees	\$ 48,229	\$ 62,400	\$ 102,560	\$ 124,838
Professional fees	48,101	163,108	63,883	187,378
Director fees and benefits	25,012	24,985	50,025	50,481
Investor relations	111,944	52,267	228,103	98,726
Travel and other costs	61,069	62,157	103,764	119,311
Depreciation of property and equipment	581	549	1,206	1,087
Shared-based compensation	17,734	99,384	41,037	155,216
<b>Total general and administrative expenses</b>	<b>\$ 312,670</b>	<b>\$ 464,850</b>	<b>\$ 590,579</b>	<b>\$ 737,037</b>

Total general and administrative expenses, for the three months ended April 30, 2019, decreased by \$152,180, as compared to the same period in the prior year. This decrease was primarily attributable to a decrease in professional fees. This decrease was partially offset by an increase in the expanded activity of investor relations, notably in the United States which resulted in an investor relation expense increase of \$59,677 compared to the comparative quarter in 2018.

Total general and administrative expenses, for the six months ended April 30, 2019, decreased by \$146,458 as compared to the same period in the prior year. Other than lower professional fees, lower cost of share-based compensation is attributed to the decrease. This decrease was also partially offset by an increase in the investor relations expense.

**Other items**

	Three months ended April 30,		Six months ended April 30,	
	2019	2018	2019	2018
Finance income	(\$4,174)	(\$7,660)	(\$6,036)	(\$17,035)
Finance costs	2,172	2,052	4,246	5,411
Foreign exchange (gain) loss	1,039	2,590	3,702	5,768
<b>Net Finance (Income) Costs</b>	<b>(\$963)</b>	<b>(\$3,018)</b>	<b>\$1,912</b>	<b>(\$5,856)</b>

**Finance income**

Finance income, represented primarily by interest income earned on the Company's cash and marketable securities, was \$4,174 during the three months ended April 30, 2019, compared to \$7,660 for the same period in the prior fiscal year. The finance income for the six months ended April 30, 2019 was \$6,036 compared to \$17,035 for the same six-month period in the prior fiscal year. The decrease resulted from lower average balances of cash and marketable securities compared to the prior period.



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#### Foreign exchange losses

Foreign exchange losses were \$1,039 for the three months ended April 30, 2019 compared to \$2,590 for the same period in the prior fiscal year. For the six months ended April 30, 2019, foreign exchange losses were \$3,702 compared to \$5,768 for the same six-month 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.

#### 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 April 30, 2019 and October 31, 2018, were as follows:

As at	April 30, 2019	October 31, 2018
Cash and marketable securities	\$ 1,618,967	\$ 2,743,320
Total assets	2,766,807	3,605,188
Current liabilities	570,254	341,202
Share capital, warrants and contributed surplus	42,024,489	41,754,818
Deficit	\$(39,827,936)	\$(38,490,832)

As at April 30, 2019, the Company had cash and marketable securities of \$1,618,967 compared to \$2,743,320 as at October 31, 2018.

The Company does not have any debt or credit facilities.

Total cash used for the six months ended April 30, 2019 was \$828,088 compared to \$1,245,883 for the six months ended April 30, 2018. Some of the increased capital requirements related to the US clinical study are offset by the JDRF grant which was obtained specifically to help fund the clinical trial, US \$400,000 (CDN \$535,661) of which was received subsequent to quarter end in May 2019. Management is of the opinion that sufficient working capital will be obtained from external financing to meet the Company's liabilities and from commitments as they become due, although there is a risk that additional financing will not be available on a timely basis or on terms acceptable to the Company. These factors indicate the existence of a material uncertainty that may cast significant doubt on the ability of the Company to continue as a going concern. These Financial Statements do not reflect any adjustments that may be necessary if the Company is unable to continue as a going concern.

#### 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

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### MANAGEMENT'S DISCUSSION AND ANALYSIS

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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.

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.

#### 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 April 30, 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:

	Number of Warrants	Weighted Average Exercise Price
Balance as at October 31, 2018	581,700	0.35
Issued on conversion of special warrants	11,016,000	0.35
Balance as at April 30, 2019 and the date of this MD&A	11,597,700	\$ 0.35

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The warrants outstanding as at April 30, 2019 are described in Note 7 to the unaudited interim condensed consolidated financial statements for the three months ended April 30, 2019 and 2018.

**2015 Incentive Plan**

The Company has an Incentive Plan (the "Incentive Plan") the terms of which were most recently approved by shareholders of the Company on April 26, 2019, and which has two components: (i) a Fixed Share Option Plan ("Option Plan") and (ii) a Deferred Share Unit Plan ("DSU Plan"). Further details on the Company's Incentive Plan are provided in Note 7 to the unaudited interim condensed consolidated financial statements for the three and six months ended April 30, 2019 and 2018.

The following table reflects the changes in the number of issued stock options from the most recent year ended October 31, 2018 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 April 30, 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, 2018 to the date of this MD&A:

	Number of DSUs
Balance as at October 31, 2018, April 30, 2019 and the date of this MD&A	1,975,000

On January 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. A fixed 20,668,482 representing 12% is reserved for the 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.

Both Incentive Plan amendments were approved by shareholders at the 2019 AGM and subsequently approved by the Exchange on May 13, 2019.

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### MANAGEMENT'S DISCUSSION AND ANALYSIS

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#### 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.

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 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 May 2019 the Company achieved a defined milestone with the US clinical study and as such recognized the amount receivable of US \$400,000 (CDN \$535,661). 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.

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. As at April 30, 2019 gross minimum payments, to the earliest termination date, amounted to \$76,791.

#### 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 April 30, 2019 was \$68,087 due to key management personnel (January 31, 2019 – \$79,104).

Compensation to key management personnel for the three and six months ended April 30, 2019 and 2018, was as follows:

	Three months ended April 30		Six months ended April 30	
	2019	2018	2019	2018
Salaries, benefits and consulting fees	\$ 123,300	\$ 160,644	\$ 265,376	\$ 234,541
Director fees and benefits	25,012	24,985	49,074	50,481
Share-based compensation	<u>43,778</u>	<u>115,088</u>	<u>101,160</u>	<u>186,662</u>
Total	<u>\$ 192,090</u>	<u>\$ 300,717</u>	<u>\$ 415,610</u>	<u>\$ 471,644</u>

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

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**SUMMARY OF QUARTERLY RESULTS**

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

Fiscal Year		1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
2019	Net loss	\$ 723,748	\$ 613,356	-	-
	Net loss per share	\$ 0.00	\$ 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

The marginally lower losses in the first and second quarters of 2019 are reflective of the Company's prior completion of key costs incurred during the third and fourth quarter of the 2018 fiscal year in preparation for the Company's clinical trial as well as recognizing the JDRF contribution milestone in the second quarter of 2019. The variability of the 2017 and 2018 quarterly losses were mostly attributable to manufacturing costs and the timing of contribution milestones as the employee and operating costs were relatively consistent.

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**

The Company does 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:

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### **MANAGEMENT'S DISCUSSION AND ANALYSIS**

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#### **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 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.

##### *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 is effective for the year ends commencing after December 31, 2018 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.

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

#### **Investment Risk**

***Volatility of share price, absence of dividends and fluctuation of operating results.*** Market prices for the securities of biotechnology companies, including ours, have historically been highly volatile. In the period ended April 30, 2019, our common shares traded on the TSX Venture Exchange, at a high of \$0.24 and a low of \$0.145 per share (2018 – a high of \$0.44 and a low of \$0.305 per share). Factors such as fluctuation of our operating results, announcements of technological innovations, patents or new commercial products by us or our 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 our common shares. Our common shares have been subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future. We have not paid dividends to date, and we do not expect to pay dividends in the foreseeable future.

***Dilution.*** We may sell additional equity securities in future offerings, including through the sale of securities convertible into equity securities, to finance our operations, acquisitions or projects, and issue additional common shares if outstanding warrants or stock options are exercised, which may result in dilution. As of the date of this MD&A, we had 5,9 million outstanding stock options convertible into common shares with an average exercise price of \$0.22 per share, 1,314,778 outstanding DSU's convertible into common shares and 11.6 million outstanding warrants convertible into common shares with an average exercise price of \$0.35 per share.

Our board of directors has the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, shareholders. Based on the need for additional capital to fund expected expenditures and growth, it is likely that we will issue additional securities to provide such capital. Such additional issuances may involve the issuance of a significant number of common shares at prices less than the current market price for our common shares.

Sales of substantial amounts of our securities, or the availability of such securities for sale, as well as the issuance of substantial amounts of our common shares upon the exercise of outstanding warrants, DSU's or stock options, could adversely affect the prevailing market prices for our securities and dilute our investors' earnings per share. A decline in the market prices of our securities could impair our ability to raise additional capital through the sale of securities should we desire to do so.

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#### **Reliance on Third Parties for Supply and Manufacture of Products**

Sernova relies on third parties for manufacturing its product candidates. Currently, Sernova does not have manufacturing facilities to independently manufacture its product candidates. Except for any contractual rights and remedies which Sernova may have with any future third-party manufacturers, Sernova may not have any control over the availability of its product candidates, their quality or cost. If for any reason, Sernova is unable to obtain third-party manufacturers on commercially acceptable terms, it may not be able to distribute its product candidates.

Medical device manufacturers are subject to ongoing periodic unannounced inspection by Health Canada, the FDA, and corresponding state and foreign agencies, including European agencies and their designees, to ensure strict compliance with GMPs and other government regulations. Sernova will not have complete control over its third-party manufacturers' compliance with these regulations and standards. Failure by either Sernova's third-party manufacturers or by Sernova to comply with applicable regulations could result in sanctions being imposed, including fines, injunctions, civil penalties, failure of the government to grant review of submissions or market approval of drugs, delays, suspension or withdrawal of approvals, product seizures or recalls, operating restrictions, facility closures and criminal prosecutions, any of which could negatively impact the business.

#### **Issuer Risk**

***Early stage development and scientific uncertainty.*** Our products are at an early stage of development. Significant additional investment in research and development, product validation, technology transfer to manufacturing, production scale-up, manufacturing, clinical testing, and regulatory submissions of such product candidates will be required prior to commercialization. There can be no assurance that any such products will be developed. The development and regulatory processes may require access to raw materials and inputs which may not be available to us in sufficient amounts or in a timely fashion to allow us 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 we are to complete the development of any product. It is not known whether any of these product 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 our investment in any such products will be recovered through sales or royalties.

***We depend heavily on the success of our Cell Pouch platform.*** All of our current product candidates involve the use of our Cell Pouch platform and are still in preclinical or clinical development. If we are unable to commercialize our product or experience significant delays in doing so, the business may be materially harmed.

We have committed significant resources to the development of our Cell Pouch platform. Our ability to generate product revenues, which is not expected to occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of our Cell Pouch platform and related therapeutic cells.

We are dependent on successful safety and efficacy of our Cell Pouch and therapeutic cells for our lead programs including the use of human or xenogeneic islets and stem cell-derived cells in combination with the Cell Pouch platform including cell immune protection to treat insulin-dependent diabetes and the use of Factor VIII releasing cells in combination with the Cell Pouch platform to treat severe hemophilia A. If we



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are unable to achieve safety and efficacy in these disease indications in preclinical and/or clinical studies the business may be materially harmed.

***Additional financing requirements and access to capital.*** We 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 our products. Management is of the opinion that sufficient working capital will be obtained from external financing to meet the Company's liabilities and commitments as they become due, although there is a risk that additional financing will not be available on a timely basis or on terms acceptable to the Company. These factors indicate the existence of a material uncertainty that may cast significant doubt on the ability of the Company to continue as a going concern. We may attempt to raise additional funds through public or private equity or debt financing, collaborations with other biopharmaceutical companies and/or from other sources, including non-governmental grants and loans and various government incentive programs. There can be no assurance that additional funding, however sourced, will be available on terms acceptable to us and which would foster the successful commercialization of our products.

***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.*** The loss of key members of our staff could harm us. We have employment agreements with our key staff members although such employment agreements do not guarantee their retention. We also depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial, medical, clinical and regulatory personnel, particularly as we expand our activities and seek regulatory approvals for clinical trials. We enter into agreements with our scientific and clinical collaborators and advisors, key opinion leaders and academic partners in the ordinary course of our business. We also enter into agreements with physicians and institutions who will recruit patients into our clinical trials on our behalf in the ordinary course of our business.

Notwithstanding these arrangements, we face significant competition for these types of personnel from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth. The loss of the services of any of our executive officers or other key personnel could potentially harm our business, operating results or financial condition.

***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.*** None of our product candidates have received regulatory approval for commercial use and sale in North America or any other jurisdiction. We cannot market any product in any jurisdiction until it has completed thorough pre-clinical testing and clinical trials in addition to that jurisdiction's extensive regulatory approval process. Approval in one country does not assure approval in another country. In general, significant research and development and clinical trials are required to demonstrate the safety and effectiveness of our product candidates before we can submit any regulatory applications for marketing approval.

Clinical trials are long, expensive and uncertain processes. Clinical trials may not be commenced or completed on schedule, and Health Canada or the FDA or any other regulatory body may not ultimately approve our product candidates for commercial sale. The clinical trials of any of our product candidates could be unsuccessful, which would prevent us from advancing, commercializing or partnering the product.

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Even if the results of our pre-clinical studies or clinical trials are initially positive, it is possible that we will obtain different results in the later stages of product development or that results seen in clinical trials will not continue with longer-term treatment. Positive results in early Phase I/II clinical trials may not be repeated in larger Phase I/II or Phase III clinical trials. We cannot be assured that our pre-clinical studies and clinical trials will generate positive results that allow us to move towards the commercial use and sale of our product candidates. Furthermore, negative results may cause our business, financial condition, or results of operations to be materially adversely affected.

For example, our Cell Pouch is in earlier clinical trials, and there is a long development path ahead which will take years to complete and is prone to the risks of failure inherent in the development process.

Preparing, submitting and advancing applications for regulatory approval is complex, expensive and time intensive and entails significant uncertainty. A commitment of substantial resources to conduct time-consuming research, pre-clinical and clinical trials will be required if we are to complete development of our products.

Clinical trials of our products require that we identify and enroll patients with the illness under investigation. We may not be able to enroll a sufficient number of appropriate patients to complete our clinical trials in a timely manner particularly in smaller indications and indications where there is significant competition for patients. If we experience difficulty in enrolling a sufficient number of patients to conduct our clinical trials, we may need to delay or terminate on-going clinical trials and will not accomplish objectives material to our success that could impact the price of our common shares. For example, delays in planned patient enrolment and other factors in our clinical trials or future trials may result in longer trials, increased costs or both.

In addition, unacceptable adverse side effects may occur at any time in the course of preclinical studies or human clinical trials or, if any product candidates are successfully developed and approved for marketing, during commercial use of any approved products. The appearance of any such unacceptable adverse side effects could interrupt, limit, delay or abort the development of any of our product candidates, or if previously approved, necessitate their withdrawal from the market. Furthermore, disease resistance or other unforeseen factors may limit the effectiveness of our potential products.

Our failure to develop safe, commercially viable products would substantially impair our ability to generate revenues and sustain our operations and would materially harm our business and adversely affect our share price. We may never achieve profitability.

***Patents and proprietary technology.*** Our success will depend in part on our 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 we will develop additional proprietary products that are patentable, that issued patents will provide us 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 our ability to conduct our business.

Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of our products, or design around the products patented by us. In addition, we 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 us, if at all. If we do not obtain such licenses, we could encounter delays in introducing one or more of our products to the market, while we attempt to design around such patents, or we could find that our development,

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manufacturing or sale of products requiring such licenses could be foreclosed. In addition, we could incur substantial costs in defending ourselves in suits brought against us on such patents or in suits where we attempt to enforce our patents against other parties.

Our ability to maintain the confidentiality of our technology may be crucial to our ultimate potential for commercial success. While we have adopted procedures designed to protect the confidentiality of our technology, no assurance can be given that such arrangements will be effective, that third parties will not gain access to our trade secrets or disclose our technology, or that we can meaningfully protect the rights to our trade secrets.

The pharmaceutical industry is characterized by extensive patent litigation. Other parties may have, or obtain in the future, patents and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization.

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions affecting the patentability of our inventions relating to our key products and the enforceability, validity, or scope of protection offered by our patents relating to our key products and may result in substantial monetary damages or result in significant delays in bringing our key products to market and/or preclude us from participating in the manufacture, use or sale of our key products or methods of treatment requiring licenses. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us.

***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.*** Because we have limited resources, we focus our research and development programs on therapeutic cell candidates for specific indications. As a result, we may forego or delay the pursuit of opportunities for other therapeutic cell candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and therapeutic cell candidates may not yield any commercially viable products.

We have based our research and development efforts on assessing various therapeutic cells within our Cell Pouch platform. As a result of pursuing the development of certain therapeutic cells within the Cell Pouch platform, the Company may fail to develop other therapeutic cells or address alternate scientific approaches that could offer greater commercial potential or for which there is a greater likelihood of success.

***Dependence on collaborative partners, licensors and others.*** We currently utilize technology which we have licensed and technology which has been developed by our own researchers. In particular, we are dependent upon our license to use certain technology provided under a sublicense agreement with UHN, dated September 9, 2015, for the development of our product candidates. While the company's licenses are in good standing, they may be terminated by the licensor if there is a breach of the license agreement.

Our activities will require us 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 our products. We intend to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that we will be able to establish such additional collaborations on favourable terms, if at all, or that our current or future collaborations will be successful.

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Failure to attract commercial partners for our products may cause us to incur 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.

Should any collaborative partner fail to develop, manufacture, or commercialize successfully any product to which it has rights, or any partner's product to which we will have rights, our 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 our competitors, as a means for developing treatments for the diseases targeted by our programs.

Furthermore, we may require licenses for certain technologies, and there can be no assurance that these licenses will be granted or, if granted, will not be terminated, or that they will be renewed on conditions acceptable to us. We intend 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. We 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.

We rely and will continue to rely on third parties to conduct some portions of our preclinical and clinical development activities. Preclinical activities include proof of concept and safety studies. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in our relationship with third parties, or if they are unable to provide quality services in a timely manner and at a reasonable cost, our active development programs will face delays. Further, if any of these third parties fail to perform as we expect or if their work fails to meet regulatory requirements, our testing could be delayed, cancelled or rendered ineffective.

We rely on a third-party contract manufacturer to manufacture our products. Health Canada and the FDA ensure the quality of products by carefully monitoring manufacturers' compliance with Good Manufacturing Practices regulations ("GMP"). Any manufacturing failures or delays or compliance issues could cause delays in the completion of our preclinical and clinical activities. There can be no assurances that our contract manufacturer will be able to meet our timetable and requirements. We have currently not contracted with alternate suppliers, in the event our contract manufacturer is unable to scale up production, or if they otherwise experience any other significant problems. If we are unable to arrange for alternative third-party manufacturing sources on commercially reasonable terms or in a timely manner, we may be delayed in the manufacture of our product. Further, contract manufacturers must operate in compliance with GMP and failure to do so could result in, among other things, the disruption of our product supplies. Our dependence upon third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop and deliver products on a timely and competitive basis.

***Employee misconduct or other improper activities.*** We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with Health Canada or FDA regulations, provide accurate information to those agencies, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in

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regulatory sanctions and serious harm to our reputation. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a substantial impact on our business and results of operations, including the imposition of substantial fines or other sanctions.

***Lack of product revenues and history of losses.*** To date, we have not recorded any revenues from the sale of cell therapy products. We expect to incur additional losses during the periods of research and development, clinical testing, and application for regulatory approval of our product candidates. For the six-months ended April 30, 2019, and 2018, we incurred losses of \$613,356 and \$986,347, respectively and had an accumulated deficit to April 30, 2019, of \$39.8 million. We expect to incur further losses unless and until such time as payments from corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund our continuing operations.

***Conflict of interest.*** Certain of our directors and senior officers may, from time to time, be employed by or affiliated with organizations which have entered into agreements with us. As disputes may arise between these organizations and us, or certain of these organizations may undertake or have undertaken research with our competitors, there exists the possibility for such persons to be in a position of conflict. Any decision or recommendation made by these persons involving us will be made in accordance with his or her duties and obligations to deal fairly and in good faith with us 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.

***We are likely a "passive foreign investment company," which may have adverse U.S. federal income tax consequences for U.S. shareholders.*** U.S. investors should be aware that we believe we were classified as a passive foreign investment company, or PFIC, during the tax years ended October 31, 2018, and 2017, and based on current business plans and financial expectations, we believe that we will be a PFIC for the current tax year and may be a PFIC in future tax years. If we are a PFIC for any year during a U.S. shareholder's holding period of our common shares, then such U.S. shareholder generally will be required to treat any gain realized upon a disposition of our common shares, or any so-called "excess distribution" received on our common shares, as ordinary income, and to pay an interest charge on a portion of such gain or distributions, unless the shareholder makes a timely and effective "qualified electing fund" election, or QEF Election, or a "mark-to-market" election with respect to our shares. A U.S. shareholder who makes a QEF Election generally must report on a current basis its share of our net capital gain and ordinary earnings for any year in which we are a PFIC, whether or not we distribute any amounts to our shareholders. A U.S. shareholder who makes the mark-to-market election generally must include as ordinary income each year the excess of the fair market value of the common shares over the shareholder's adjusted tax basis therein. Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of our common shares.

***It may be difficult for non-Canadian investors to obtain and enforce judgments against us because of our Canadian incorporation and presence.*** We are a corporation existing under the laws of the Province of Ontario, Canada. Several of our directors and officers, and several of the experts are residents of Canada, and all or a substantial portion of their assets, and all or a substantial portion of our assets are located outside the United States. Consequently, it may be difficult for holders of our securities who reside in the United States to effect service within the United States upon those directors and officers, and the experts who are not residents of the United States. It may also be difficult for holders of our securities who reside in the United States to realize in the United States upon judgments of courts of the United States predicated upon our civil liability and the civil liability of our directors, officers and experts under the United States federal securities laws.

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Investors should not assume that Canadian courts (i) would enforce judgments of United States courts obtained in actions against us or such directors, officers or experts predicated upon the civil liability provisions of the United States federal securities laws or the securities or "blue sky" laws of any state or jurisdiction of the United States or (ii) would enforce, in original actions, liabilities against us or such directors, officers or experts predicated upon the United States federal securities laws or any securities or "blue sky" laws of any state or jurisdiction of the United States. In addition, the protections afforded by Canadian securities laws may not be available to investors in the United States.

*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.* As a foreign private issuer, we are not required to comply with all the periodic disclosure requirements of the Exchange Act, and therefore, there may be less publicly available information about us than if we were a United States domestic issuer. For example, we are not subject to the proxy rules in the United States and disclosure with respect to our annual meetings will be governed by Canadian requirements.

#### Industry Risk

**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 our proposed products or technologies non-competitive, or that we 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 therapeutic effect as compared with products to be developed by us and could be more effective and less costly than the products to be developed by us. In addition, alternative forms of medical treatment may be competitive with our products.

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

**Government regulations.** Biotechnology and pharmaceutical companies operate in a high-risk regulatory environment. The manufacture and sale of therapeutic products are governed by numerous statutes and regulations in the United States, Canada and other countries where we intend to market our 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 our ability to utilize our technology, thereby adversely affecting our operations. Further, there can be no assurance that our product candidates prove to be safe and effective in clinical trials or receive the requisite regulatory

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approval. There is no assurance that we 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, impose similar restrictions.

***Hazardous materials and environmental matters.*** Certain of our research and development processes will involve the controlled use of hazardous materials. We are 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 our management 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, we could be held liable for damages and such liability could exceed our resources. We are not specifically insured with respect to this liability. Although our management believes that it currently complies in all material respects with applicable environmental laws and regulations, we may be required to incur significant costs to comply with environmental laws and regulations in the future. Furthermore, there can be no assurance that our operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

***Status of healthcare reimbursement.*** Our ability to successfully market certain 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 us to realize an acceptable return on our investment in product development.

***Potential product liability.*** Pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Product liability insurance is costly, and availability is limited and may not be available on terms which would be acceptable to us, 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 our products. A product liability claim brought against us, or withdrawal of a product from the market, could have a material adverse effect upon us and our financial condition.

***Reliance on Information Technology.*** Sernova is dependent on information technology systems, including Internet-based systems, for internal communication as well as communication with suppliers. Any significant disruption of these systems, whether due to computer viruses or other outside incursions, could materially and adversely affect Sernova's operations.

## **DIRECTORS AND OFFICERS**

Frank Holler, Chairman of the Board of Directors

Jeffrey Bacha, Director

James Parsons, Director

Deborah Brown, 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](http://www.sedar.com).