

# MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

Dated February 6, 2017

700 Collip Circle
The Stiller Centre, Suite 114
London, ON N6G 4X8
www.sernova.com

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

The following management's discussion and analysis ("MD&A") explains the variations in the consolidated operating results, financial position and cash flows of Sernova Corp. ("Sernova", the "Company", "We", "Us" or "Our") for the three months and years ended October 31, 2016 and 2015. This MD&A should be read in conjunction with the Company's audited consolidated financial statements for the years ended October 31, 2016 and 2015, 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, 2016 and 2015.

The information in this report is dated as of February, 6 2017.

### 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, forward looking statements can be identified by the use of words such as "may", or by words such as "will", "intend", "believe", "estimate", "consider", "expect", "anticipate", and "objective" or similar expressions and variations of such words. 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" with respect to its product candidates are based primarily upon results derived to date from the Company's research and development programs. The Company also uses the term "demonstrated" in this MD&A to describe certain findings that it makes arising from its research and development including any pre-clinical and clinical studies that the Company has conducted to date.

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

- The Company's corporate strategies and objectives;
- General business and economic events:
- The availability of various forms of financing such as private equity, government or non-profit agency funding and other programs;
- The initiation and completion of pre-clinical studies and clinical trials of our Cell Pouch<sup>TM</sup> for the treatment of insulin-dependent diabetes and other diseases;
- The expected benefit of the Cell Pouch TM with the rapeutic cells:
- The expected benefit of the European Commission's Horizon 2020 grant for our hemophilia program;
- The intention to protect therapeutic cells within the Cell Pouch<sup>TM</sup> 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;
- The intention 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<sup>TM</sup> for the potential treatment of chronic diseases;
- The intention 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 with respect to the cost of Sernova's products, clinical trials and commercialization of our products;

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

- Sales and marketing strategy;
- Sernova's intentions to secure academic and pharmaceutical collaborations and to develop and implement partnering strategies; and
- Intentions regarding the development and protection of Sernova's intellectual property.

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.

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.

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

### ABOUT SERNOVA

Sernova Corp. is a regenerative medicine company, focused on commercializing its proprietary Cell Pouch<sup>TM</sup> and associated technologies including therapeutic cells and local immune protection. The Cell Pouch<sup>TM</sup> is a scalable, implantable, medical device, designed to create a microvessel rich, 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. Depending on the clinical indication, the 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 from a stem cell derived or xenogeneic (non-human) source. Depending on the need, the therapeutic cells may be protected within the Cell Pouch<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> to be safe alone and when transplanted with human donor islets. The Company plans to continue clinical investigation of the Cell Pouch<sup>TM</sup> with donor islets. The Company has also secured a potential source of unlimited cells, through the signing of a license agreement with the University Health Network ("UHN") of Toronto, Canada to gain exclusive worldwide rights to certain patent-pending technologies that are related to the differentiation stem cells into insulin producing glucose-responsive therapeutic cells developed by UHN researchers. We continue to identify additional potential sources of cells which are not limited by donor availability. We intend to seek access through license agreements and/or partnerships, which can then be immune-protected within the Cell Pouch<sup>TM</sup> as a product to enable potential

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

treatment of people with diabetes. The Company is also investigating other diseases amenable to treatment with therapeutic cells such as hemophilia and thyroid disease.

# **Research and Development**

Sernova has been a development stage company since inception. Our research and development efforts are focused principally on the development of the Cell Pouch<sup>TM</sup> 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<sup>TM</sup> from immune system attack. We have not been profitable since inception, and we expect to continue to incur substantial losses as we continue our research and development efforts. We do not expect to realize material revenues until, if and when, our medical technologies become commercially viable; however, we continue to seek partnerships with pharmaceutical companies which we expect to result in substantial contributions to the development costs related to our products.

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. To achieve our goals, our primary activities include the following:

- 1. Conducting clinical trials required to gain marketing approval for the Cell Pouch<sup>TM</sup> System in countries that have a significant market opportunity. Our first product is being developed for the treatment of insulin-dependent diabetes. Our first clinical trial, designed to demonstrate the proof of concept of the Cell Pouch<sup>TM</sup> and therapeutic cells, was initiated in Canada and is ongoing. The treatment is the Cell Pouch<sup>TM</sup> transplanted with human donor islets, protected using the standard of care antirejection drug regimen, for subjects with insulin-dependent diabetes with hypoglycemia unawareness.
  - We are currently preparing for the conduct of an additional Phase I/II clinical study of our Cell Pouch<sup>TM</sup> in the United States in 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 also has a long-term goal of the treatment of diabetes using the Cell Pouch<sup>TM</sup> transplanted with locally immune protected cells from an unlimited source of cells such as glucose-responsive stem cell derived cells or xenogeneic cells and has work ongoing in these areas;
- 2. Conducting pre-clinical research programs in other therapeutic indications for our platform Cell Pouch<sup>TM</sup> technology including: hemophilia, thyroid disease, and other chronic diseases that require a hormone, protein or other factor which is missing or in short supply in the body;
- 3. Development of various sources of therapeutic cells for transplantation within our Cell Pouch<sup>TM</sup>, including, depending on the clinical application, autologous cells, allogeneic cells such as donor cells or glucose responsive stem cell derived cells that could be used to treat large numbers of patients as well as xenogeneic cells;
- 4. Identification and development of complementary technologies which may improve the safety and efficacy of cells within the Cell Pouch<sup>TM</sup>, including local immune protection technologies such as microencapsulation;
- 5. Manufacturing and supply of the Cell Pouch<sup>TM</sup> and the processing and supply of therapeutic cells;
- 6. Generation and/or licensing of intellectual property; and,
- 7. Developing partnerships with pharmaceutical companies for the development of our products.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

### Corporate Update for the years ended October 31, 2016 and 2015 and to the date of this MD&A

In February 2015, we announced that the patent offices in China, Israel, Singapore and New Zealand issued Notices of Allowance and issued patents to Sernova for its patent application entitled "Methods and Devices for Cellular Transplantation." These patents help protect Sernova's entire Cell Pouch System™, including the Cell Pouch™ itself, as well as the Cell Pouch™ combined with therapeutic cells and surgical tools for cell transplantation. These issued patents, in addition to patent rights already granted or actively being pursued in other countries, provide Sernova with patent protection through 2030.

In March 2015, we announced that Frank Holler was appointed Chairman of the Board and that Dr. George Adams was retiring as a director of Sernova at the end of his term and has stepped down as Chairman of the Board. Mr. Holler brings a wide-range of experience to his role as Sernova's Chairman of the Board as an active investor and successful entrepreneur.

In April 2015, we announced that the U.S. Patent and Trademark Office issued Sernova a patent that helps protect Sernova's entire Cell Pouch System<sup>™</sup>. This patent entitled "Methods and Devices for Cellular Transplantation" includes claims covering implantable polymer devices such as the Cell Pouch tell Pouch as well as methods using the same combined with therapeutic cells such as self-cells, donor cells, stem cell derived technologies and genetically modified cells as well as surgical tools for cell transplantation. This new patent provides Sernova with patent protection through 2030.

In September 2015, we announced the signing of a license agreement with the University Health Network (UHN) of Toronto, Canada to gain exclusive worldwide rights to certain patent-pending technologies developed by UHN researchers. These technologies relate to the development of stem cells into insulin producing glucose-responsive therapeutic cells for the treatment of patients with insulin-dependent diabetes.

In December 2015, the European Commission's Horizon 2020 program awarded a €5.6 million (approximately \$8.5 million) non-dilutive grant to the HemAcure consortium, which consists of Sernova Corp. and five European academic and private partners. The purpose is to advance the development of a GMP clinical grade factor VIII releasing therapeutic cell product in combination with Sernova's Cell Pouch™ for the treatment of severe hemophilia A, a serious genetic bleeding disorder caused by missing or defective factor VIII in the blood stream. The therapeutic goal of the product 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 significantly 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. In January 2016, the Company received an initial funding payment related to the grant in the amount of €566,607 (\$873,213).

In January 2016, we entered into a service agreement with the Centre for Commercialization of Regenerative Medicine ("CCRM") to establish, optimize and validate Sernova's licensed technology for creating stem cell derived therapeutic cells that produce insulin and are glucose responsive. Partnership with CCRM's expertise in developing production processes for cellular therapies is an important step in our plan to commercialize an unlimited supply of glucose responsive, insulin producing cells for the Cell Pouch System<sup>TM</sup> to be able to address the broader population of patients with insulin dependent diabetes.

In February 2016, we were selected as a member of the "2016 TSX Venture 50" from among the 1,791 companies listed on the TSX Venture Exchange as of December 31,2015.

In June 2016, we closed a \$4,200,000 non-brokered private placement. The offering consisted of 16,800,000 units sold at a price of \$0.25 per unit. Each unit consists of one common share and one common share purchase warrant, with each warrant entitling the holder thereto to purchase one common share of the company for a

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

period of 24 months at a price of \$0.35 per share, subject to abridgement of the exercise period with 30 days' notice to holders in the event that the twenty-day volume weighted average price of the Company's common share shares exceeds \$0.50.

In July 2016, we entered into a research funding agreement with the Juvenile Diabetes Research Foundation (JDRF), which will provide Sernova up to US \$2.45 million to support a Phase I/II safety and efficacy human clinical trial using Sernova's Cell Pouch™ technologies. The study is in preparation for an Investigational New Drug "IND" filing and will be conducted in the United States for treatment of patients with severe type 1 diabetes. The goal of the Phase I/II safety and efficacy study is to provide patients with a novel cell therapy treatment utilizing Sernova's proprietary Cell Pouch™ to reduce or eliminate the need for injections of exogenous insulin. 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 September 2016, we announced the appointment of Mr. Scott Langille as Chief Financial Officer "CFO". Mr. Langille's experience includes CFO of Tribute Pharmaceuticals, CFO of Virexx Medical Corp. Vice President at Biovail Pharmaceuticals and management positions at AltiMed Pharmaceuticals and Zimmer Canada.

In October 2016, the Company signed a collaboration with an international pharmaceutical company regarding a material transfer agreement to study Sernova's Cell Pouch<sup>TM</sup> for safety, survival and efficacy of locally immune protected therapeutic cells in a large animal diabetes model. This agreement included 50% cost sharing for the agreed studies. The first payment in the amount of US185,778 (\$249,611) was received in December 2016.

In November, 2016 we announced with CTI Clinical Trial and Consulting Services ("CTI"), a collaboration on regulatory matters respecting Sernova's Cell Pouch System<sup>TM</sup>. CTI as an expert in cell therapy, and immunology. CTI is supporting Sernova's clinical trial regulatory processes including submission of Sernova's regulatory package with the FDA for the recently announced JDRF supported clinical trial in patients with insulin-dependent diabetes.

In November 2016, we announced that we have retained Mackie Research Capital Corporation ("Mackie") to provide market making services to the company in compliance with the guidelines of the TSX Venture Exchange (the "TSXV").

#### Research and Development Outlook for the 2017 Calendar Year

Our product development program for 2017 includes the following:

- Continued clinical evaluation of the Cell Pouch<sup>TM</sup> in patients with insulin-dependent diabetes receiving an islet transplant;
- Conduct of collaborative IND-enabling cell production and preclinical studies for treatment of hemophilia A consisting of factor VIII releasing therapeutic cells transplanted within Sernova's Cell Pouch<sup>TM</sup> such as within the HemAcure consortium;
- Conduct of collaborative IND-enabling preclinical studies for treatment of hypo-thyroid disease consisting of thyroid hormone releasing tissue transplanted within Sernova's Cell Pouch<sup>TM</sup>;
- Production of human progenitor cells for diabetes derived from a stem cell source and *in vivo* proof of principle assessment of these differentiated human stem cells for their safety and efficacy within Sernova's Cell Pouch<sup>TM</sup> for the treatment of insulin-dependent diabetes;

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

- Assessment of novel microencapsulation technologies within the Cell Pouch<sup>TM</sup> cells, to further develop and advance Sernova's therapeutic vision for diabetes of a product consisting of locally immune protected therapeutic cells within the Cell Pouch<sup>TM</sup> using an unlimited source of cells for the future treatment of people with insulin-dependent diabetes; and,
- Continue to collaborate with pharmaceutical companies 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<sup>TM</sup>

The Cell Pouch<sup>TM</sup> was uniquely designed and patented to take into consideration the biological requirements of therapeutic cells. A tissue matrix rich in microvessels develops within the Cell Pouch<sup>TM</sup> environment when implanted subcutaneously or in other locations prior to transplantation of therapeutic cells. The Cell Pouch<sup>TM</sup> is believed to provide a unique and ideal environment consisting of vascularized tissue chambers for the placement of therapeutic cells, including insulin-producing islets (autograft and allograft), stem cell derived technologies and xenogenic technologies for potential treatment of diabetes, hemophilia and other diseases. In long-term pre-clinical evaluation, the Cell Pouch<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup>.

An independent pre-clinical study published in the journal Transplantation (Transplantation 2015 Nov: 99 (11):2294-300) demonstrated that the Cell Pouch<sup>TM</sup> 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<sup>TM</sup> may require a smaller than anticipated number of cells to achieve efficacy, one of the parameters under consideration for further human clinical evaluation to achieve glucose control in patients with diabetes.

Benefits of the Cell Pouch<sup>TM</sup> are anticipated to be enhanced long-term islet graft survival and function. It is important for islets to have close contact with microvessels 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<sup>TM</sup> technologies achieve this ideal islet/microvessel connection through alteration of the subcutaneous environment and should allow for improved glucose control. Our studies have shown that islets transplanted into the Cell Pouch<sup>TM</sup> can control glucose levels in small and large animal models of diabetes over extended periods.

### Clinical Development of the Cell Pouch<sup>TM</sup> in Diabetes

Sernova's lead program is the clinical development of the Cell Pouch<sup>TM</sup> for treatment of patients with insulindependent diabetes. A proof of concept, first in human clinical study to evaluate the Cell Pouch<sup>TM</sup> with human

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

donor islets, in insulin-dependent diabetic subjects with hypoglycemia unawareness who are receiving islet transplantation, has demonstrated safety of the Cell Pouch<sup>TM</sup> alone and with transplanted islets and survival of the well-vascularized islets within the Cell Pouch<sup>TM</sup>. Furthermore, the islets were shown in histological analysis to be able to make insulin, glucagon and somatostatin, key hormones in the control of blood glucose levels. With these encouraging results, the Company was awarded a US\$2.45 million (approximately \$3.2 million) grant under an agreement with JDRF. The grant supports a human clinical trial of Sernova's Cell Pouch<sup>TM</sup> for the treatment of patients with severe type 1 diabetes in the United States.

The Edmonton Protocol is the current standard of care cell-based treatment for insulin-dependent diabetic patients with hypoglycemia unawareness that involves infusing donor pancreatic islets, often from multiple donors, into a patient's liver portal vein, followed by life-long administration of immunosuppressive drugs to inhibit rejection of the transplant. Overall, benefits of islet transplantation may include a reduction in the incidence of hypoglycemia unawareness, a reduced requirement for exogenous insulin and reduced diabetes-induced microvascular damage and potential insulin independence. It is believed, however, following islet infusion that with portal vein delivery of islets, there is an initial significant reduction in surviving islets due to an immediate blood-mediated inflammatory reaction, which may damage and destroy a significant proportion of the islets infused into the portal vein. In addition, the proportion of patients with insulin-independence decreases over time likely due to continued islet destruction with multiple etiologies. A further limitation 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 or xenogeneic cells being developed to overcome the limited supply of donor islet cells, as these cell technologies must be transplanted into an implantable and retrievable medical device for safety reasons.

We believe the immediate blood-mediated inflammatory reaction ("IBMIR") may also be mitigated, using the Cell Pouch<sup>TM</sup>. The therapeutic cells live within a tissue matrix surrounded by microvessels similar to the islets' natural microenvironment in the pancreas rather than being bathed in a constant flow of blood with immune reactive cells. This reduced inflammatory response should enable improved islet survival and potentially lead to the need to implant fewer islets or other sources of insulin producing cells. In the case of donor islets, this could potentially enable patients with diabetes to be treated with fewer donor pancreata than are currently being used. It can take up to three pancreata to treat a single patient and achieve a reduction in insulin injections using the Edmonton Protocol.

The Cell Pouch<sup>TM</sup> enables islets to be transplanted subcutaneously or even in the omentum space, which we believe will offer significant advantages over portal vein delivery as it can be monitored, imaged and if required, retrieved and replaced. Known side effects from infusion of cells into the portal vein such as portal vein hypertension, thrombosis, and liver steatosis (fatty liver), along with the costs of treating them, will be eliminated as cells will not be placed in this location.

While the therapeutic cells within the Cell Pouch<sup>TM</sup> may function with systemic immune protection, it may also accommodate local immunoprotection technologies reducing or eliminating the need for lifelong systemic antirejection drug treatment. Local immune protection of islets such as microencapsulation could result in a significant reduction or elimination of the need for antirejection drugs and their ongoing prohibitive costs, as well as associated healthcare costs related to side effects of these drugs. In addition, local immunoprotection may provide a safer environment for the transplanted islets. The Cell Pouch<sup>TM</sup> is believed to be an ideal 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.

Finally, the Cell Pouch<sup>TM</sup> could 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

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

allowing the widespread treatment of insulin-dependent diabetes. Thus, we believe our approach and its ease of use may provide an opportunity for the Cell Pouch<sup>TM</sup> to become the standard of care in therapeutic cell transplantation, if it proves to be safe and effective in clinical trials. Sernova believes it has the only such device technology of its kind in which therapeutic cells have been proven to survive in a tissue matrix integrated with microvessels in close association with the therapeutic cells.

In our human clinical trial, subjects have been implanted with the Cell Pouch<sup>TM</sup>, which is allowed to incorporate with tissue and microvessels prior to transplantation of donor human islets. In this first-in-human study, to prevent islet graft rejection, patients have been treated with the state of the art standard of care Alemtuzumab-induction protocol and provided maintenance immunosuppression.

Our results have shown the following important findings:

- First, biocompatibility and a positive safety profile of the Cell Pouch<sup>TM</sup> have been shown in the patients. Safety is the primary endpoint of the clinical study;
- Second, the islets within the Cell Pouch<sup>TM</sup>, as shown by histological analysis, are well-vascularized, living within a natural tissue matrix and are able to make insulin, glucagon and somatostatin, key hormones in the control of blood glucose levels. We believe such revascularization of islets and islet metabolic function within an implantable medical device for therapeutic cells in humans in this patient population is a first in the regenerative medicine field; and,
- Based on these encouraging results from the study, we believe that Sernova's Cell Pouch<sup>TM</sup> may form a
  suitable environment for the survival and function of multiple types of therapeutic cells for a range of
  diseases.
- Based on these initial findings, we have established a collaboration through a grant from JDRF to
  continue human clinical evaluation of the Cell Pouch™ with human donor islets in the United States for
  which the Company is in active preparation in conjunction with CTI. The further clinical evaluation of
  our Cell Pouch™ technologies will assess the safety and efficacy of the Cell Pouch™ under optimized
  conditions.

# Developing the Cell Pouch $^{TM}$ for Other Indications

### Hemophilia

As part of our strategy to develop the Cell Pouch<sup>TM</sup> for various therapeutic indications, we are evaluating Sernova's Cell Pouch<sup>TM</sup> 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 have been conducted by Sernova and a European team of experts formed the HemAcure consortium ("The Consortium"). The Consortium was successful in obtaining €5.6 million (approximately \$8.5 million), funded by a European Commission's Horizon 2020 grant, to develop a GMP 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.

New Cell Pouch<sup>TM</sup> Indications for Metabolic Disorders

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

MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

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

To broaden Sernova's local immune protection technologies, we continue to evaluate additional advanced technologies such as microencapsulation. We believe that microencapsulation of therapeutic cells within the Cell Pouch<sup>TM</sup> may provide a means to contain therapeutic cells within the Cell Pouch<sup>TM</sup> 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 islets derived from xenogeneic sources, depending on the clinical indication under evaluation and the need for expanded numbers of cells for treatment of larger populations. As such, we will continue to work with academic collaborators and industry partners to identify and secure the required cells for our therapeutic indications. In this regard, Sernova has signed a license agreement with the UHN to gain access to worldwide, exclusive rights to certain patent-pending technologies developed by UHN researchers, for the advancement of glucose-responsive insulin-producing stem cells for the treatment of patients with insulin-dependent diabetes. Process development and cell-production processes will provide a high standard of production of cells which consistently meet strict release criteria for evaluation of these cells in Sernova's Cell Pouch<sup>TM</sup>.

Sernova is also committed to working with pharmaceutical and academic partners to evaluate various, insulin-producing cell technologies that use different approaches, with a goal of combining Sernova and partner technologies to create best in class products. In this regard, Sernova has signed several agreements to test and evaluate several insulin-producing cell technologies in our Cell Pouch<sup>TM</sup>. The Company signed a collaboration with an international pharmaceutical company regarding a material transfer agreement to study Sernova's Cell Pouch safety, survival and efficacy of locally immune protected therapeutic cells in a large animal diabetes model. Sernova plans to continue to develop multiple collaborations with pharmaceutical companies for its diabetes and hemophilia indications for establishment of potential long-term licensing and co-development relationships.

### **Manufacturing**

Our contract manufacturing process has enabled manufacture of both our Cell Pouch<sup>TM</sup> and mini-Cell Pouch<sup>TM</sup> technologies for preclinical and clinical evaluation in a number of clinical indications. Device specifications have been set, a semi-automated manufacturing process developed and the product manufactured, packaged and sterilized under strict regulatory guidelines (ISO 13485) suitable for testing in clinical trials in North America and Europe. Sterilization verification studies have been completed and the product has been released for assessment in human clinical trials by Health Canada and for potential clinical trials in other regulatory jurisdictions. A two-year packaging and product stability study has been successfully completed demonstrating stability of the product and packaging over this time-period.

### **Intellectual Property**

Our patent portfolio currently consists of issued and pending patents in eight families covering our enabling platforms. We strive to obtain broad claims in our patents, including exclusivity of our Cell Pouch<sup>TM</sup> device and related technologies in combination with a wide range of therapeutic cell technologies including glucoseresponsive insulin producing stem cell derived cells and to treat a number of chronic diseases. Importantly,

MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

our Cell Pouch<sup>TM</sup> patents extend to 2030. We intend to continue to expand our patent and licensing portfolio through proprietary internal inventions as well as strategic in-licensing, to maximize the commercial potential for our platform technologies.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

#### RESULTS OF OPERATIONS

	Three months end	led October 31,	Years e	ended October 31,	
(all amounts in Canadian Dollars)	2016	2015	2016 2		
Research and development expenses	(\$ 73,893)	\$ 497,047	\$ 1,199,346	\$ 1,793,218	
General and administrative expenses	265,859	394,866	1,302,222	1,092,470	
Loss and comprehensive loss for					
the period	\$ 166,308	\$ 866,116	\$ 2,499,622	\$ 2,859,477	

For the three months ended October 31, 2016, the Company recorded a loss of \$166,308 or \$0.00 per common share, compared to \$866,116 or \$0.01 per common share in the prior year, a decrease of \$699,808 or 80.8%. The reduced loss for the three months ended October 31, 2016 over the comparable period in the prior fiscal year, was due to funding received from the European Commission's Horizon 2020 grant and an initial funding payment from JDRF Therapeutics Fund, as well as lower general and administrative expenses due to one-time consulting expenses and fees related to listing on the OTC QB in the United States incurred in the three months ended October 31, 2015.

For the year ended October 31, 2016, the Company recorded a loss of \$2,499,622 or \$0.02 per common share, compared to \$2,859,477 or \$0.02 per common share in the prior year, a decrease of \$359,855 or 12.6%. The lower loss in the year ended October 31, 2016 over the comparable period in the prior fiscal year, was primarily due to funding received from the European Commission's Horizon 2020 grant and an initial funding payment from JDRF Therapeutics Fund offset in part by an increased spend on research and development activities relating to preclinical studies of therapeutic cells within Sernova's Cell Pouch<sup>TM</sup> as well as general and administrative expenses.

## **Research and Development Expenses**

Research and development expenditures for the three and the years ended October 31, 2016 and 2015, were as follows:

	Three months en	ded October 31,	Years ended October 31,		
(all amounts in Canadian Dollars)	2016	2015	2016	2015	
Salaries, supplies and contract payments	\$ 389,554	\$ 322,512	\$ 1,477,661	\$ 1,062,739	
Patent fees and costs	49,559	144,468	211,706	295,536	
Depreciation of property and equipment	1,776	1,189	7,104	4,756	
Amortization of intangible assets	_	_	_	492,075	
Share-based compensation	77,649	48,511	299,124	102,745	
Contributions and tax credits	(592,431)	(19,633)	(796,249)	(164,633)	
Total	\$ (73,893)	\$ 497,047	\$ 1,199,346	\$ 1,793,218	

Total research and development expenses, for the three months ended October 31, 2016, decreased by \$570,940 compared to the equivalent period of the prior fiscal year. Excluding the impact of funding received, research and development expenses amounted to \$518,538 during the three months ended October 31, 2016, an increase of \$1,858 compared to the equivalent period in the prior year.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

Excluding the impact of depreciation of property and equipment, and share-based compensation, all non-cash items, research and development expenses were (\$153,318) during the three months ended October 31, 2016, a decrease of \$600,665 compared to the equivalent period in the prior fiscal year. Salaries, supplies and contract payments, for the three months ended October 31, 2016, increased by \$67,042, compared to the equivalent period of the prior fiscal year. The increase was due to greater contract and research and development supply payments in the three months ended October 31, 2016, compared to the same period in the previous fiscal year. Patent fees and costs for the three months ended October 31, 2016, decreased by \$94,909 due to higher patent development expenses in the equivalent period of the prior fiscal year. Share-based compensation for the three months ended October 31, 2016, increased by \$29,138, due to greater stock-based compensation attached to the stock options granted in fiscal 2016, as compared to the grant in the prior fiscal year. Contributions and tax credits, for the three months ended October 31, 2016, increased by \$572,798, compared to the equivalent period of the prior fiscal year, due to higher tax credits, support from the European Commission's Horizon 2020 grant in the current year and an initial funding payment from JDRF Therapeutics Fund, LLC.

Total research and development expenses, for the year ended October 31, 2016, decreased by \$593,872 compared to the equivalent period of the prior fiscal year. Excluding the impact of funding received, research and development expenses amounted to \$1,995,595 during the year ended October 31, 2016, an increase of \$37,744 compared to the period year.

Excluding the impact of depreciation of property and equipment, amortization of intangible assets and sharebased compensation, all non-cash items, research and development expenses were \$893,118 during the year ended October 31, 2016, a decrease of \$300,524 compared to the equivalent period in the prior fiscal year. Salaries, supplies and contract payments, for the year ended October 31, 2016, increased by \$414,922, compared to the equivalent period of the prior fiscal year. The increase was due to greater salaries and research and development supplies and contract payments in the year ended October 31, 2016, compared to the same period in the previous fiscal year. Patent fees and costs for the year ended October 31, 2016, decreased by \$83,830 due to higher patent development expenses in the prior fiscal year. Amortization of intangible assets, for the year ended October 31, 2015, decreased by \$492,075, compared to the prior fiscal year, due to the intangible assets that were fully amortized at April 30, 2015. Share-based compensation for the year ended October 31, 2016, increased by \$196,379, due to greater stock-based compensation attached to the stock options granted in fiscal 2016, as compared to the grant in the prior fiscal year. Contributions and tax credits, for the year ended October 31, 2016, increased by \$631,616, compared to the prior fiscal year, due to higher tax credits, support from the European Commission's Horizon 2020 grant and an initial funding payment from JDRF Therapeutics Fund, LLC being recognized during the year ended October 31, 2016, compared to the amounts recognized in the previous fiscal year.

### General and administrative expenses

General and administrative costs for the three and years ended October 31, 2016 and 2015, were as follows:

	Three months ended October 31,		Years e	nded October 31,
(all amounts in Canadian Dollars)	2016	2015	2016	2015
Salaries, benefits and consulting fees	\$ 65,186	\$ 123,126	\$ 397,824	\$ 320,236
Professional fees	21,643	21,856	79,382	116,058
Director fees and benefits	25,453	31,225	101,749	115,895
Investor relations	44,254	100,312	198,563	212,869
Travel and other costs	26,149	27,569	153,175	148,612
Depreciation of property and equipment	115	138	460	231
DSU's issued for director compensation	29,981	27,517	130,459	38,284
Share-based compensation	53,078	63,123	240,610	140,285
Total	\$ 265,859	\$ 394,866	\$ 1,302,222	\$1,092,470

Total general and administrative expenses, for the three months ended October 31, 2016, decreased by \$129,007, as compared to the same period in the prior year. Excluding the impact of depreciation of property and equipment, DSU's issued for director compensation and share-based compensation, all non-cash items, total general and administrative expenses were \$182,685 during the three months ended October 31, 2016, a decrease of \$121,403 compared to the equivalent period in the prior fiscal year. Salaries, benefits and consulting fees, for the three months ended October 31, 2016, decreased by \$57,940 compared to the same period in the prior year, due one-time consulting expenses related to listing on the OTC QB in the United States incurred in the three months ended October 31, 2015. Investor relations expenses for the three months ended October 31, 2016, decreased by \$56,058 compared to the same period in the prior year, due to one-time consulting and fees associated with the OTCQB listing in the United States incurred in the three months ended October 31, 2015. Share-based compensation for the three months ended October 31, 2016, decreased by \$10,045, due to greater stock-based compensation attached to the stock options granted in fiscal 2015.

Total general and administrative expenses, for the year ended October 31, 2016, increased by \$209,752, as compared to the prior year. Excluding the impact of depreciation of property and equipment and share-based compensation, both non-cash items, general and administrative expenses was \$930,693 during the year ended October 31, 2016, an increase of \$17,023 compared to the prior fiscal year. Salaries, benefits and consulting fees, for the year ended October 31, 2016, increased by \$77,588 compared to the prior year, due to increased research and development. Professional fees, for the year ended October 31, 2016, decreased by \$36,676, compared to the prior year, primarily due to decreased consulting costs. Investor relations expenses, for the year ended October 31, 2016, decreased by \$14,306, compared to the prior year, primarily due to one-time consulting and fees associated with the OTCQB listing in the United States incurred in the year ended October 31, 2015. The expense related to DSU's issued for director's compensation increased by \$92,175 for the year ended October 31, 2016, compared to the prior year due to the fiscal 2015 grant being outstanding for a full year as well as the second DSU grant issued in March 2016. Share-based compensation for the year ended October 31, 2016, increased by \$100,325, due to greater stock-based compensation attached to the stock options granted in fiscal 2015 and 2016, as compared to only the grant in the 2015 fiscal year.

### Other items

	Three months	ended October 31	, Years of	Years ended October31,		
(all amounts in Canadian Dollars)	2016	2015	2016	2015		
Finance income	\$ (9,054)	\$ (7,674)	\$ (30,113)	\$ (31,995)		
Finance costs	2,654	789	9,693	3,351		
Foreign exchange loss (gain)	(19,258)	1,088	18,474	2,433		
Net finance income	\$ (25,658)	\$ (5,797)	\$ (1,946)	\$ (26,211)		

#### Finance income

Finance income, represented primarily by interest income earned on the Company's cash and marketable securities, was \$9,054 and \$30,113, during the three months and year ended October 31, 2016, respectively, compared to \$7,674 and \$31,995, for the same periods in the prior fiscal year. The increase during the three months ended October 31, 2016 compared to the equivalent period of the prior fiscal year was primarily related to higher interest income from an increased average balance of cash and marketable securities due to the Company's June 2016 private placement. The slight decrease during the year ended October 31, 2016 compared to the prior fiscal year was primarily due an increased average balance of cash and marketable securities due to the Company's June 2016 private placement offset by holding an increased cash position in more liquid accounts which yield a lower interest return.

### **Finance costs**

Finance costs, represented primarily by bank charges of \$2,654 and \$9,683, during the three months and year ended October 31, 2016, respectively, compared to \$789 and \$3,351, for the same periods in the prior fiscal year. The increase for the three months and the year ended October 31, 2016 compared to the e prior fiscal year was primarily due to a change in our investment accounts to highly liquid short term instruments. The fee being charged was negotiated down in Q3-2016, but remains higher than prior year costs.

### Foreign exchange loss (gain)

Foreign exchange loss (gain), represented by a (19,258) gain and 18,474 loss, for the three months and year ended October 31, 2016, respectively, compared to a loss of 1,088 and 2,433, for the same periods in the prior fiscal year. The gain for the three months ended October 31, 2016 compared to the equivalent period of the prior fiscal year was primarily due to foreign exchange gains incurred from a US\$367,768 payment received under an agreement with JDRF Therapeutics Fund, LLC in August 2016. The increased loss for the year ended October 31, 2016 compared to the prior fiscal year was primarily due to foreign exchange losses incurred from a 6566,507 payment received related to the European Commission's Horizon 2020 grant in January 2016.

### **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

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

have not been recognized in the financial statements that would be available to shelter potential future taxable income from income taxes. See Note 12 to the Company's audited consolidated financial statements for the years ended October 31, 2016 and 2015, 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 October 31, 2016 and October 31, 2015, were as follows:

	October 31,	October 31,
	2016	2015
Cash and marketable securities	\$ 5,899,451	\$ 2,880,963
Total assets	6,225,244	3,153,299
Current liabilities	846,274	199,850
Share capital, warrants and contributed surplus	37,531,696	32,606,553
Deficit	\$(32,152,726)	\$(29,653,104)

As at October 31, 2016, the Company had cash and marketable securities of \$5.9 million compared to \$2.9 million as at October 31, 2015. The increase in cash and marketable securities, total assets and share capital, warrants and contributed surplus relate primarily to a non-brokered private placement for gross cash proceeds of \$4,200,000 completed in June 2016. The offering consisted of 16,800,000 units sold at a price of \$0.25 per unit. The increase in current liabilities relates to the European Commission's Horizon 2020 program grant in the amount of \$655,324 (see Note 7). Management believes the Company has sufficient working capital to maintain its operations for at least the next twelve months.

The Company does not have any debt or credit facilities.

# **Financing Activities**

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™ technologies for treatment of hypoglycemia unawareness patients with severe type 1 diabetes at a major transplantation center in the United States. 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 a commitment for repayment by the Company following successful commercialization of a diabetes product. 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 June 2016, the Company completed a non-brokered private placement for gross cash proceeds of \$4,200,000. The offering consisted of 16,800,000 units sold at a price of \$0.25 per unit. Each unit consisted of one common share and one common share purchase warrant, with each warrant entitling the holder to purchase one common share of the Company for a period of 24 months at a price of \$0.35 per share, subject to abridgement of the exercise period with 30 days' notice to holders in the event that the twenty-day volume weighted price of the Company's common shares exceeds \$0.50. The warrants were ascribed a value of \$nil representing the difference between the issue price of the units and the fair market value of the shares received as part of the offering.

Costs associated with the private placement totaled \$258,324, including cash fees of \$200,121 and the issue of 521,850 finder's warrants valued at \$58,203, which have been deducted from the gross proceeds. Each finder's warrant entitles the holder to purchase one common share of the Company for a period of 24 months

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

at a price of \$0.35 per share, subject to the same hold and abridgement conditions as the warrants included in each unit of the offering.

The Company used the Black-Scholes pricing model to determine the fair value of the finder's warrants granted. The fair values have been estimated with the following assumptions:

Year ended October 31,	2016	2015
Dividend yield	0.0%	0.0%
Expected volatility	89.1%	110.2%
Risk free interest rate	0.5%	1.5%
Expected life of options	2.0 years	2.0 years

For the year ended October 31, 2016, 1,398,750 stock options were exercised for gross cash proceeds of \$333,000 and 131,528 warrants were exercised for gross cash proceeds of \$39,458.

In May 2015, the Company completed a non-brokered private placement for gross cash proceeds of \$1,600,000. The offering consisted of 8,888,889 units sold at a price of \$0.18 per unit. Each unit consisted of one common share and one common share purchase warrant, with each warrant entitling the holder to purchase one common share of the Company for a period of 24 months at a price of \$0.30 per share, subject to abridgement of the exercise period with 30 days' notice to holders in the event that the twenty-day volume weighted price of the Company's common shares exceeds \$0.50. The warrants were ascribed a value of \$nil representing the difference between the issue price of the units and the fair market value of the shares received as part of the offering.

Costs associated with the private placement totaled \$87,167, including cash fees of \$75,873 and the issue of 137,151 finder's warrants valued at \$11,294, which have been deducted from the gross proceeds. Each finder's warrant entitles the holder to purchase one common share of the Company for a period of 24 months at a price of \$0.30 per share, subject to the same hold and abridgement conditions as the warrants included in each unit of the offering.

For the year ended October 31, 2015, 1,455,000 stock options were exercised for gross cash proceeds of \$374,600.

In December 2015, the Company was awarded a  $\in$ 5.6 million (approximately \$8.5 million) non-dilutive grant by the European Commission's Horizon 2020 program, as part of a consortium. The Company expects to receive total funding in the amount of  $\in$ 944,178 (approximately \$1.4 million), representing its portion of the grant, based upon the terms of the grant agreement. In January 2016, the Company received an initial funding payment related to the grant in the amount of  $\in$ 566,507 (\$873,213).

Historically, funding requirements have been met through the issuance of common shares from treasury and common share purchase warrants 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 2017 will increase over the previous year. Our actual cash requirements for fiscal 2017 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.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

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

### **Common Shares**

The following table reflects the changes in the number of issued common shares from year ended October 31, 2015 to the date of this MD&A:

	Number of Common Shares
Balance as at October 31, 2015	141,821,720
Shares issued related to private placement	16,800,000
Shares issued on the exercise of stock options	1,398,750
Shares issued on the exercise of warrants	131,528
Performance escrow shares returned to treasury	(3,472,500)
Balance as at October 31, 2016 and to February 6, 2017	156,679,498

Pursuant to an agreement related to Sertoli Technologies Inc., the Company's obligation to release performance shares expired in August 2016 and 3,472,500 issued and outstanding performance escrow shares were returned to treasury and cancelled.

#### Warrants

The following table reflects the changes in the number of issued warrants from the ended October 31, 2015 to the date of this MD&A:

	Number of Warrants	Weighted Average Exercise Price
Balance as at October 31, 2015	19,026,040	\$ 0.35
Warrants issued related to private placement	17,321,850	0.35
Exercised	(131,528)	0.30
Expired	(10,000,000)	0.40
Balance as at October 31, 2016 and to February 6, 2017	26,216,362	\$ 0.33

The warrants outstanding as at October 31, 2016 are described in Note 8 to the audited consolidated financial statements for the three and twelve months ended October 31, 2016 and 2015.

# 2015 Incentive Plan

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

The Company has a 2015 Incentive Plan (the "Plan"), the terms of which were most recently approved by shareholders of the Company on April 29, 2016. The Plan includes both stock options and deferred share units ("DSU's"). Further details on the Company's 2015 Incentive Plan are provided in Note 8 to the audited consolidated financial statements for the three and twelve months ended October 31, 2016 and 2015.

The following table reflects the changes in the number of issued stock options from the ended October 31, 2015 to the date of this MD&A:

	Number of Options	Weighted Average	
		Exercise Price	
Balance as at October 31, 2015	8,873,750	\$ 0.19	
Granted	3,393,600	0.24	
Forfeited	(432,500)	0.25	
Exercised	(1,398,750)	0.15	
Balance as at October 31, 2016	10,436,100	0.21	
Granted	250,000	0.26	
Forfeited	(775,000)	0.24	
Balance as at February 6, 2017	9,911,100	\$ 0.21	

The following table reflects the changes in the number of issued deferred share units (DSU's) from the year ended October 31, 2015 to the date of this MD&A:

	Number of DSU's
D.1	<b>22.</b> 000
Balance as at October 31, 2015	625,000
Granted	450,000
Balance as at October 31, 2016 and February 6, 2017	1,075,000

### **COMMITMENTS AND CONTINGENCIES**

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

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

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

uncertainties, and in particular the risks outlined under the risk factor titled 'Dependence on collaborative partners, licensors, contract manufacturer and others', please refer to the risk factors discussed elsewhere in this MD&A.

In July 2016, the Company was awarded a US\$2.45 million (approximately \$3.2 million) grant under an agreement with JDRF. The grant supports a human clinical trial of Sernova's Cell Pouch<sup>TM</sup> for treatment of patients with severe 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. 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 lease commitment beginning on August 1, 2015, with remaining gross payments required under the lease of approximately \$51,000 related to the rental of laboratory space payable in the 2017 fiscal year. The lease also includes options for the Company to extend the lease for two additional one year periods.

### RELATED PARTY TRANSACTIONS

The key management personnel of the company are the Directors, the President and Chief Executive Officer and 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 October 31, 2016 was \$3,564 due to key management personnel (October 31, 2015 – \$2,121).

Compensation to key management personnel for the three and years ended October 31, 2016 and 2015, was as follows:

	Three months e	nded October 31,	Years ended October 31,		
(all amounts in Canadian Dollars)	2016	2015	2016	2015	
Salaries, benefits and fees	\$ 96,900	\$ 127,223	\$ 523,808	\$ 391,637	
Director fees and benefits DSU's issued for director	24,985	31,225	100,766	115,895	
compensation	29,982	27,517	130,459	38,284	
Share-based compensation	54,707	43,979	223,632	81,750	
Total	\$ 206,574	\$ 229,944	\$ 978,665	\$627,566	

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

#### SELECTED FINANCIAL INFORMATION

Selected financial information from the statements of loss and comprehensive loss for the three months and years ended October 31, 2016, 2015 and 2014 were as follows:

	Three months ended October 31,		Years ended October 31,		er 31,	
	2016	2015	2014	2016	2015	2014
Revenue	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Loss for the year	166,308	866,116	678,180	2,499,622	2,859,477	2,746,059
Basic and diluted loss						
for the year	0.00	0.01	0.01	0.02	0.02	0.02
Total assets	6,225,244	3,153,299	4,021,072	6,225,244	3,153,299	4,021,072
Total long-term						
financial liabilities	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -

### 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
2016	Net loss	\$ 676,450	\$ 691,917	\$ 964,947	\$ 166,308
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.01	\$ 0.00
2015	Net loss	\$ 630,294	\$ 676,212	\$ 666,855	\$ 886,116
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.00	\$ 0.01

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.

# EVENTS AFTER THE REPORTING PERIOD

In October 2016, the Company entered into a collaboration with an international pharmaceutical company regarding a material transfer agreement to study Sernova's Cell Pouch safety, survival and efficacy of locally immune protected therapeutic cells in a large animal diabetes model. This agreement included 50% cost sharing for the agreed studies. The first payment in the amount of US185,778 (\$249,611) was received by the Company in December 2016.

### **OFF-BALANCE SHEET ARRANGEMENTS**

We do not have any off-balance sheet arrangements.

MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

### **QUANTITATIVE & QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

### Fair value

IFRS 13 Fair Value Measurement provides a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs are those which reflect market data obtained from independent sources, while unobservable inputs reflect the Company's assumptions with respect to how market participants would price an asset or liability. These two inputs used to measure fair value fall into the following three different levels of the fair value hierarchy:

- Level 1 Quoted prices in active markets for identical instruments that are observable.
- Level 2 Quoted prices in active markets for similar instruments; inputs other than quoted prices that are observable and derived from or corroborated by observable market data.
- Level 3 Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

The hierarchy requires the use of observable market data when available.

The Company has classified its cash and marketable securities as Level 1.

Cash, marketable securities, amounts receivable, accounts payable and accrued liabilities, due within one year, are all short-term in nature and, as such, their carrying values approximate fair values.

### Risks

We are exposed to credit risk, liquidity risk, interest rate risk and foreign currency risk. Our Board of Directors has overall responsibility for the establishment and oversight of our risk management framework. The Audit Committee is responsible for reviewing our risk management policies.

#### Credit risk

Credit risk is the risk of loss to the Company if a counterparty to a financial instrument fails to meet its contractual obligations. The Company's credit risk is primarily attributable to cash and marketable securities and there is additional risk since those financial instruments are primarily held by a single counterparty. Management believes the risk of the counterparty, a Canadian Schedule A bank, failing to meet its obligations related to the cash and marketable securities held by the Company is remote. Amounts receivable are primarily composed of amounts due from the Canadian federal government.

# Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company is a development stage company and is reliant on external fundraising to support its operations. Once funds have been raised, the Company manages its liquidity risk by investing in cash and marketable securities to provide regular cash flow for its operations and monitoring actual and projected cash flows. As at October 31, 2016 and 2015, the Company had cash, cash equivalents and marketable securities of \$5,889,451 and \$2,880,963, respectively which are available to settle current liabilities of \$846,274 and \$199,850, respectively. The majority of the Company's accounts payable and accrued liabilities are due within three months or less.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

#### Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company holds its cash in bank accounts or guaranteed investment certificates with a fixed rate of interest and multiple maturity dates. The Company manages its interest rate risk by holding highly liquid short-term instruments and by holding its investments to a maturity date. For the years ended October 31, 2016 and 2015, the Company earned interest income of \$30,113 and \$31,995, respectively. Interest income is not significant to the Company's projected operational budget. A 1% change in the interest rate on cash and marketable securities for the year ended October 31, 2016 and 2015, would have a net impact on finance income of \$58,995 and \$28,810 respectively.

### Foreign currency risk

The Company is exposed to foreign currency risk on fluctuations in foreign exchange rates for any cash, amounts receivable or accounts payable and accrued liabilities that are denominated in foreign currencies. The Company's foreign currency risk is related to expenses denominated in United States dollars and Euros.

In December 2015, the Company was awarded a  $\in$ 5.6 million (approximately \$8.5 million) non-dilutive grant by the European Commission's Horizon 2020 program, as part of a consortium. The Company expects to receive total funding in the amount of  $\in$ 944,178 (approximately \$1.4 million), representing its portion of the grant, based upon the terms of the grant agreement. In January 2016, the Company received an initial funding payment related to the grant in the amount of  $\in$ 566,607 (\$873,213). A 10% change in the foreign exchange rate between the Canadian and the Euro would result in a fluctuation of \$65,532 in respect of the grant balance outstanding.

### 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, 2016 and 2015.

Management has applied significant estimates and assumptions to the following:

### Valuation of share-based compensation

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

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

share-based payment transactions are discussed in Note 8 of the audited consolidated financial statements for the years ended October 31, 2016 and 2015.

### 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 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.

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

## IFRS 9 Financial Instruments

In October 2010, the IASB published amendments to IFRS 9 *Financial Instruments* ("IFRS 9") which provides added guidance on the classification and measurement of financial liabilities. In July 2014, the IASB issued its final version of IFRS 9, which completes the classification and measurement, impairment and hedge accounting phases of the IASB's project to replace IAS 39 *Financial Instruments: Recognition and Measurement*. The final standard is mandatorily effective for annual periods beginning on or after January 1, 2018, with earlier application permitted. The Company has not yet assessed the impact of this standard on the consolidated financial statements.

### IFRS 15 Revenue from Contracts with Customers

In May 2014, the IASB issued IFRS 15 *Revenue from Contracts with Customers* ("IFRS 15"), which covers principles for reporting about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. In September 2015, the IASB issued an amendment to IFRS 15 reflecting a one-year deferral of the effective date of the standard to January 1, 2018. The Company has not yet assessed the impact of this standard on the consolidated financial statements.

MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

# IFRS 16 Leases

In January 2016, the IASB issued IFRS 16 *Leases* ("IFRS 16"), its new lease standard that requires lessees to recognize assets and liabilities for most leases on the statement of financial position. Lessees applying IFRS 16 will have a single accounting model for all leases, with certain exemptions. Lessor accounting is substantially unchanged. The new standard will be effective from January 1, 2019 with limited early application permitted. The Company has not yet assessed the impact of this standard on the consolidated financial statements.

MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

### 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 year ended October 31, 2016, our common shares traded on the TSX Venture Exchange, at a high of \$0.40 and a low of \$0.21 per share (2015 – a high of \$0.40 and a low of \$0.13 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 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 9.9 million outstanding stock options convertible into common shares with an average exercise price of \$0.21 per share, 1,075,000 outstanding DSU's convertible into common shares and 26 million outstanding warrants convertible into common shares with an average exercise price of \$0.33 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.

MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

#### **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 actually 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 or process candidates will meet applicable health regulatory standards and obtain required regulatory approvals, or whether such products can be produced in commercial quantities at reasonable costs and be successfully marketed, or if our investment in any such products will be recovered through sales or royalties.

We depend heavily on the success of our Cell Pouch<sup>TM</sup> platform. All of our current product candidates involve the use of our Cell Pouch<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> platform and related therapeutic cells.

We are dependent on successful safety and efficacy of our Cell Pouch<sup>TM</sup> 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<sup>TM</sup> platform including cell immune protection to treat insulin-dependent diabetes and the use of Factor VIII releasing cells in combination with the Cell Pouch<sup>TM</sup> platform to treat severe hemophilia A. If we are unable to achieve safety and efficacy in these disease indications in preclinical and/or clinical studies the business may be materially harmed.

# HemAcure consortium: forward looking statements

The HemAcure Consortium is the name of the consortium developing a product for hemophilia A. This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 667421. The consortium members include the University Hospital Wurzburg (Coordinating Institute), Integrierte Management Systeme IMS e.K., Universita del Piemonte Orientale "Amedeo Avogadro," Loughborough University, GABO:mi Gesellschaft für Ablauforganisation: milliarium mbH & Co. and Sernova Corp. The main objective of the HemAcure project is to develop and refine the tools and technologies for a novel ex vivo prepared cell based therapy within Sernova's prevascularized Cell Pouch to treat this bleeding disorder that should ultimately lead to improved quality of life of the patients.

The European Commission's Horizon 2020 program had awarded a Euro 5.6M (\$8.5M CAD) grant to the HemAcure Consortium to advance development of a GMP clinical grade Factor VIII releasing therapeutic cell product in combination with Sernova's Cell Pouch<sup>TM</sup> for the treatment of severe hemophilia A, a serious genetic bleeding disorder caused by missing or defective factor VIII in the blood stream. In February 2016, the Company also posted a link on Twitter.com to an article by Richard Mills entitled "Regenerative Medicine's Fountain of Youth" that appears on the website Aheadoftheherd.com. The Company has paid an

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

annual fee to Richard Mills to advertise the Company on the Aheadoftheherd.com website and to link articles and news releases about the Company on the Aheadoftheherd.com website.

In the news releases and the article, it is stated that a potential product from the HemAcure Consortium would be disruptive to the current standard of care, which involves regular infusions (approximately 3 times per week) of factor VIII and that the current market is estimated at approximately \$5 billion per year. In addition, the news releases and the article included the following forward looking statements (the "HemAcure FLI") with respect to the product being developed by the HemAcure Consortium that the Company is a part of:

- With successful safety and efficacy leading to regulatory approval to sell, a GMP clinical grade Factor VIII releasing therapeutic cell product in combination with Sernova's Cell Pouch<sup>TM</sup> could take over the current market and significantly improve patient quality of life, likely commanding a premium price; and
- Future revenues from this product stand to be significant, providing product diversification and more than a single billion dollar market.

Readers are cautioned that actual results may vary from the HemAcure FLI and should not to place undue reliance on those forward looking statements, which speak only as of the date initially disclosed and the date of this MD&A.

The following are the material factors or assumptions used to develop the HemAcure FLI:

• The global hemophilia market was valued at USD 9.3 billion in 2015 and is expected to grow at a CAGR of 5.6% over the forecast period. Hemophilia is a rare genetic bleeding disorder estimated to have affected about 400,000 people globally as of 2013. 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 Market Analysis by Type (Hemophilia A, Hemophilia B, Hemophilia C), By Treatment (On-demand, Prophylaxis), By Therapy (Replacement Therapy, Immune Tolerance Induction [ITI] Therapy, Gene Therapy), And Segment Forecasts to 2024. August, 2016 Grandview Research Report ID: 978-1-68038-989-0.

The following are the material risk factors that could cause actual results to differ materially from the HemAcure FLI.

- The HemAcure consortium may not be able to develop a GMP source of Factor VIII cells
- The preclinical safety and efficacy of Factor VIII producing cells in the Cell Pouch<sup>TM</sup> may not be sufficient to warrant clinical evaluation
- Clinical studies may not prove the combination of the Cell Pouch<sup>™</sup> and Factor VIII producing cells to be safe and efficacious and thus may not result in a commercial product.

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. Based on historical and future projected operations, we expect our current cash and marketable securities of \$5.9 million to enable us to fund our operating requirements for at least fiscal 2017. 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.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

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 Philip Toleikis, our President and Chief Executive Officer, or other 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.

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<sup>TM</sup> 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.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

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 compete 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, 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

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

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<sup>TM</sup> platform. As a result of pursuing the development of certain therapeutic cells within the Cell Pouch<sup>TM</sup> 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 agreements 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. 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 hold licenses for certain technologies and there can be no assurance that these licenses will not be terminated, or that they will be renewed on conditions acceptable to 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

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

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 fails 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 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 years ended October 31, 2016 and 2015, we incurred losses of \$2.5 million and \$2.9 million, respectively and had an accumulated deficit to October 31, 2016 of \$32.2 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

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

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, 2016 and 2015, and based on current business plans and financial expectations, we expect 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. 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.

MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

### **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 noncompetitive 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 is 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 labeling.

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 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.

# MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2016 AND 2015

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.

# **DIRECTORS AND OFFICERS**

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

### ADDITIONAL INFORMATION

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