



**Notice to Reader**

The MD&A for the year ended October 31, 2019, originally filed on February 14, 2020, is being refiled to correct the effective date to February 13, 2020, from February 12, 2020.

No other amendment has been made to any amount, balance or disclosure in the attached MD&A.

Dated: February 19, 2020



## **SERNOVA CORP**

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

**FOR THE YEARS ENDED  
OCTOBER 31, 2019 AND 2018**

Dated February 13, 2020

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## **SERNOVA CORP.**

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The following management's discussion and analysis (MD&A) explains the variations in the consolidated operating results, financial position and cash flows of Sernova Corp. (Sernova, the Company, We, Us or Our) for the three months and years ended October 31, 2019 and 2018. This MD&A should be read in conjunction with the Company's audited consolidated financial statements and related notes for the years ended October 31, 2019, and 2018, 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, 2019 and 2018. All amounts are in Canadian dollars.

The information in this report is dated as of February 13, 2020.

#### **FORWARD-LOOKING STATEMENT**

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

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

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

- The Company's corporate strategy and strategic objectives;
- The availability of various forms of external financing to fund the Company's ongoing liabilities and commitments;
- The expected benefits of the Cell Pouch™ for therapeutic cells and tissue;
- The conduct of preclinical studies and clinical trials of our Cell Pouch and Cell Pouch System for the treatment of insulin-dependent diabetes;
- The expected preclinical and clinical benefit of our hypothyroid cell therapy program;
- The expected preclinical and clinical benefit of the cell therapy hemophilia A program and the benefits gained from the completed work related to the European Commission Horizon 2020 grant received;
- The intention to protect therapeutic cells within the Cell Pouch from immune attack using local immune protection technologies, or using anti-rejection regimens or a combination thereof;
- Sernova's intentions and ability to secure academic and pharmaceutical / medtech collaborations to develop and implement partnering strategies and manage partnerships;
- The intention and ability to use human autograft cells or human donor allograft cells or tissues or xenogeneic cells for treatment and the intention to use human stem cell-derived cells, considered unlimited cell sources for our Cell Pouch and Cell Pouch System for the potential treatment of chronic diseases;
- The intention and ability to obtain regulatory clearance for clinical trials and marketing approval of the

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Cell Pouch or Cell Pouch System for the treatment of insulin-dependent diabetes, hemophilia, hypothyroid disease and other indications;

- Expectations that the Cell Pouch technologies are unique and may become the standard of care in therapeutic cell transplantation if they prove to be safe and effective in clinical trials;
- Expectations with respect to the cost of Sernova's products, clinical trials and commercialization of our products;
- Sales and marketing strategy of our Cell Pouch or Cell Pouch System and associated technologies;
- Intentions regarding the development and protection of Sernova's intellectual property;
- Intentions with respect to obtaining licenses for technologies related to the Cell Pouch System;
- The intention to develop next-generation Cell Pouch related technologies;
- Sufficient availability of Cell Pouch product for the conduct of preclinical studies, clinical trials and following marketing approval for commercial use; and
- General business and economic events.

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

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

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

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

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

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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 for filing by the Company's Audit Committee and the Board of Directors. The Company's Audit Committee includes three independent Directors who are financially knowledgeable.

#### **ABOUT SERNOVA**

Sernova Corp. is a clinical-stage regenerative medicine therapeutics company focused on developing and commercializing our proprietary Cell Pouch System with associated technologies including the Cell Pouch, cells or tissues and systemic and / or locally immune protected therapeutic cells and tissues. The Cell Pouch is a scalable, permanent implantable medical device, designed upon implantation to develop a vascularized tissue environment for the transplantation and engraftment of therapeutic cells or tissues, which then release the desired proteins and / or hormones for the long-term treatment of diabetes, hemophilia, hypothyroid disease and other severe, chronic diseases.

In preclinical studies to date, we have demonstrated proof of concept using therapeutic cells and tissues within the Cell Pouch related to the treatment of insulin-dependent diabetes, hemophilia and hypothyroid disease. Data from our research demonstrate that the Cell Pouch may provide a suitable environment allowing the transplant of therapeutic cells for the treatment of these and other chronic diseases.

Our initial clinical studies have focused on the treatment of insulin-dependent diabetes through the transplantation of pancreatic islets, which naturally control blood glucose levels in the body. Results of a proof-of-principal clinical trial in a small cohort of patients with insulin-dependent diabetes and hypoglycemia unawareness have shown the Cell Pouch to be safe prior to and following transplantation with human donor islets.

In 2018, we initiated a second clinical trial under a company-sponsored US Food and Drug Administration (US FDA) Investigational New Drug (IND) in the United States, which is funded in part through a collaboration with JDRF, the leading global organization funding type 1 diabetes (T1D) research. Preliminary trial findings based on a case study of the first patient support the safety of the Cell Pouch and survival and function of islets as demonstrated through fasting and glucose-stimulated blood levels of C-peptide from the islets transplanted into the Cell Pouch as well as indicators of blood glucose control as a potential treatment of T1D in patients with severe hypoglycemic events. These findings were presented by our Principal Investigator, Dr. Witkowski, during a peer-reviewed scientific meeting in July 2019 and in subsequent communications. Subjects continue to be enrolled, implanted with the Cell Pouch and transplanted with islets in this trial at the University of Chicago clinical site. Further trial information may be found at <https://www.clinicaltrials.gov/ct2/show/NCT03513939>.

Therapeutic cells or tissues for use in our Cell Pouch may be obtained directly from human autograft (self-cells or tissues) or allograft cells (similar non-self, human donor cells or tissues), xenogeneic (non-human species) or derived from sources such as human-derived stem cells differentiated into glucose responsive insulin producing cells that may provide a virtually unlimited supply of therapeutic cells to treat diseases using our Cell Pouch.

Our clinical and pre-clinical studies provide vital information to support our stem cell-derived technologies for the treatment of diabetes and hemophilia A. Pursuant to our strategy of obtaining sources of supply for our

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therapeutic cells applications, the Company entered into a license agreement with the University Health Network (UHN) of Toronto, Canada. This license agreement gives us exclusive worldwide rights to certain patented technologies that are related to the differentiation of stem cells into glucose-responsive insulin-producing therapeutic cells developed by UHN researchers (Nostro CM, et al. Stem Cell Reports 2015; 4(14):591). We are developing stem cell-derived technologies with the expectation to provide a virtually unlimited supply of cells for the treatment of diabetes. We are actively working through license agreements and / or pharmaceutical partnerships on sources of glucose responsive stem cell-derived cell technologies that are not limited by donor availability. The Company is also investigating other diseases amenable to treatment with therapeutic cells within the Cell Pouch such as hemophilia A, hypothyroid disease and other diseases where proteins, hormones or other factors are required to treat disease.

### **Research and Development**

Our research and development efforts are focused principally on the development of our Cell Pouch System in conjunction with various therapeutic cells and local immune protection technologies for the treatment of chronic disease in humans.

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

Our primary activities to achieve our goals include the following:

1. Conducting clinical trials required to gain marketing approval for the Cell Pouch System in countries that have a significant market opportunity. We are developing our first therapeutic product for the treatment of insulin-dependent diabetes;
2. Advancing a treatment that we believe could benefit the broader diabetes population consisting of the Cell Pouch transplanted with locally immune protected glucose-responsive stem cell-derived cells using our licensed technology; and
3. Ongoing research and development activities related to our proprietary Cell Pouch in the following areas:
  - a) Expanding our research into additional therapeutic indications including hemophilia and postoperative hypothyroid disease;
  - b) Establishing sources of therapeutic cells for transplantation within our Cell Pouch, such as autologous cells (self-cells) and allogeneic cells (stem cell-derived cells) to treat significant numbers of patients with these chronic diseases;
  - c) Identifying, evaluating and potentially in-licensing complementary technologies which may improve the safety and efficacy of cells within the Cell Pouch, including local immune protection technologies;
  - d) Continuing to develop proprietary processing and supply of therapeutic cells;
  - e) Ongoing international development of our intellectual property portfolio and development of new and / or licensing of intellectual property; and
  - f) Establishing partnerships with medical device and / or pharmaceutical companies as well as academic institutions for the development of our products and to advance our next-generation technologies.

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#### **Recent Highlights**

##### Research and Development

February 2020: We announced that the independent Data Safety Monitoring Board (DSMB) completed its first interim analysis of our active and ongoing “*Safety, Tolerability and Efficacy Study of Sernova's Cell Pouch™ for Clinical Islet Transplantation*” US Phase I/II clinical trial in patients with severe hypoglycemia unawareness (US Phase I/II Cell Pouch Clinical Trial) and that the DSMB did not raise any concerns regarding safety and recommended the continuation of the study.

October 2019: We announced the detection of enduring levels (measured up to 30 days and ongoing) of C-peptide, a biomarker of transplanted beta-cell insulin production, in the bloodstream of a fasting patient in our active US Phase I/II Cell Pouch Clinical Trial. The detection of fasting C-peptide in the bloodstream of our first patient combined with our earlier announced observation of glucose-stimulated C-peptide and other early efficacy indicators is believed to demonstrate a normalizing response of the Cell Pouch therapeutic cells to the body's varied need for insulin production. This is an important indicator and evidence of ongoing islet engraftment within the Cell Pouch.

July 2019: We announced the observation of initial safety as well as early indicators of efficacy, including glucose-stimulated C-peptide, insulin production and additional clinically meaningful measures of glucose control, in the first study patient of the US Phase I/II Cell Pouch Clinical Trial. Dr. Witkowski, Principal Investigator for the US Phase I/II Cell Pouch Clinical Trial, presented on Sernova's Cell Pouch technology and these preliminary findings at the 17th World Congress of the International Pancreas and Islet Transplantation Association (IPITA) in Lyon, France.

May 2019: We received an additional earned milestone payment of US\$400,000 (CDN \$535,661) from the Juvenile Diabetes Research Foundation, more formally JDRF Therapeutics Fund, LLC (JDRF) related to our “Research, Development and Commercialization Agreement” with JDRF that supports and helps fund our US Phase I/II Cell Pouch Clinical Trial at the University of Chicago.

April 2019: We announced the first transplantation of therapeutic cells in the Cell Pouch of the first implanted patient in our US Phase I/II Cell Pouch Clinical Trial. In addition, the Company announced a collaboration with Dr. Sam Wiseman, thyroid surgeon, researcher and Director of Research in the Department of Surgery at Providence Healthcare in Vancouver for the development of a cell therapy-based program for the treatment of postoperative hypothyroidism.

February 2019: We announced that the first patient in our US Phase I/II Cell Pouch Clinical Trial had been implanted with Sernova's Cell Pouch.

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

October 2018: We announced the achievements of the HemAcure Consortium, which the Company is an integral part of, and its progress developing a regenerative medicine approach to treat hemophilia A.

##### Corporate

October 2019: We announced the appointment of David Swetlow, CPA, CA as Chief Financial Officer of the Company and the grant of 750,000 stock options to an officer of the Company with an exercise price of \$0.21 per common share and ten-year expiry.

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September 2019: We announced the granting of 7,899,600 stock options to officers, employees, and consultants of the Company. These options have an exercise price of \$0.21 per share and have an expiry dates of September 13, 2022 or September 13, 2029. In addition, the cancellation of 660,222 DSUs held by and the issuance of 3,120,167 DSUs to directors of the Company was also announced.

August / September 2019: Over multiple closings, we completed a non-brokered private placement issuing 23,422,822 Units (Unit or Units) at \$0.20 per Unit, representing gross proceeds of \$4,684,564. Each Unit consists of one common share and one common share purchase warrant (Warrant), with each Warrant being exercisable into one common share at a price of \$0.30 per share for a period of 36 months. The Company paid legal costs and finders fees totaling \$144,338 and issued 391,125 finder warrants.

May 2019: We announced the appointment of Deborah Brown to our board of directors and the approval by shareholders and the TSX Venture Exchange (Exchange) of the Company's amended and restated stock option plan.

#### **Research and Development Outlook for 2020 Fiscal Year**

Our research and development program for our 2020 Fiscal Year is anticipated to include:

- Continuing to enroll, treat and obtain data on additional subjects in the US Phase I/II clinical trial of our Cell Pouch System under our US IND at the University of Chicago for patients with hypoglycemia unawareness in collaboration with JDRF;
- Continuing production of human stem-cell-derived islet cells as unlimited cell supply for ongoing *in vivo* safety and efficacy studies of these differentiated stem cells towards future clinical evaluation within our Cell Pouch for the treatment of insulin-dependent diabetes;
- Ongoing due diligence and preclinical assessment of novel immune protection technologies to secure rights to these technologies for our vision of developing immune protected therapeutic cells for diabetes and other clinical indications;
- Continuing research and development collaborations with key pharmaceutical and medical device companies in support of a potential licensing arrangement and commercial development partnership of our combined technologies for our diabetes and other programs; and
- Continuing our preclinical development program towards human clinical evaluation for the treatment of postoperative hypothyroid disease and hemophilia A consisting of Cell Pouch transplanted therapeutic tissue / cells.

#### **Sernova's Cell Pouch System**

Sernova's patented Cell Pouch technologies are uniquely designed to take into consideration the biological requirements of therapeutic cells. This is achieved through an 'organ-like' environment in which a vascularized tissue matrix for therapeutic cells develops upon implantation. Our unique approach provides for the ability for cells to be protected locally within the Cell Pouch or through systemic immune protection medications. We believe this unique approach helps prevent the issue of fibrosis that has plagued other implantable devices for cell therapy.

The Cell Pouch is uniquely designed to be scalable for various cell therapy applications such as diabetes, hemophilia and other chronic diseases. Our research demonstrates that these tissue chambers develop when implanted beneath the skin or in other locations. In long-term preclinical studies, the Cell Pouch maintained a stable, vascularized tissue environment prior to transplantation of therapeutic cells which we believe is key for maintaining long-term survival and function of therapeutic cells.



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We have demonstrated in a series of ISO 10993 biocompatibility studies and multiple animal studies that the Cell Pouch is biocompatible and safe. Long-term studies in several animal models have demonstrated that upon transplant the islets become well-supported with microvessels, similar to their natural pancreatic environment. An anticipated benefit of the Cell Pouch is enhanced long-term therapeutic cell survival and function which we believe is due in part to cells living in a natural tissue matrix within close contact of microvessels. For diabetes, as an example, this close vessel proximity enables islets to monitor blood glucose levels and produce the appropriate amount of insulin throughout the day and night and after meals. We believe the Cell Pouch technologies may achieve this ideal therapeutic/microvessel connection through alteration of the local environment. For example, our studies have shown that islets transplanted into the Cell Pouch can control blood glucose levels in small and large animal models of diabetes over extended periods, and have observed this also applies to other therapeutic cellular applications such as hemophilia A.

#### **Development of the Cell Pouch System for the Treatment of Diabetes**

In our current US Phase I/II clinical trial for hypoglycemia unawareness, enduring fasting and glucose-stimulated blood levels of C-peptide, a biomarker of insulin produced by islet cells, have been observed in addition to other efficacy indicators demonstrating a normalizing response of the Cell Pouch's therapeutic cells to the body's varied need for insulin production. We believe these findings are a significant achievement in the regenerative medicine therapeutics field and a first for an implanted prevascularized device with islet cells implanted under the skin. Our approach of testing the Cell Pouch with human donor islets in subjects with hypoglycemia unawareness, which is demonstrating encouraging initial results, is an important advance of our stepwise approach in leading to our ultimate diabetes technology solution involving immune protected stem cell-derived islet cells within our Cell Pouch for the treatment of all type 1 diabetes patients.

According to the International Diabetes Federation, there are approximately 463 million people worldwide with diabetes, and nearly 10% of these individuals have type 1 (insulin-dependent) diabetes (<https://www.idf.org/aboutdiabetes/type-1-diabetes.html>). The primary treatment for subjects with T1D is insulin injections by needle or insulin pump. The life of a patient with diabetes is consumed with attempting to control blood sugar levels to minimize the severe effects of diabetes which include heart and kidney disease, blindness, and amputations. There is a significant need to improve the treatment of diabetic patients and to improve the quality of life of these individuals. Sernova believes an implantable medical device with a cell therapy approach for the treatment of diabetes could provide a significant improvement in the quality of life of patients as well as a substantial improvement in the potential efficacy and reduction of diabetes side effects in these patients. The goal of a cell therapy approach is to replace the islets lost in the pancreas of diabetic patients in a retrievable device to return their blood sugar status to a healthy state and to improve their quality of life.

Sernova's lead program is the clinical development of the Cell Pouch for the treatment of patients with insulin-dependent diabetes. By way of background, for diabetic patients with severe hypoglycemia unawareness, aside from the use of daily insulin injections, portal vein transplantation is the only cell-based treatment currently available. The therapy involves receipt of donor pancreata at specialized islet transplantation centers around the world. These pancreata are then put through a digestion process to isolate the insulin-producing islets from the pancreatic tissue. These pancreatic islets, often from multiple donors, are then infused into a patient's portal vein in the liver, followed by life-long administration of immunosuppressive drugs to inhibit rejection of the transplant.

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

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

With the encouraging initial results of islet transplantation, there is a need to develop an implantable and retrievable medical device that is highly vascularized for the placement and function of therapeutic cells, including donor islets. Sernova’s Cell Pouch is a minimally invasive, retrievable device that creates vascularized tissue chambers for the placement and long-term survival and function of therapeutic cells. Furthermore, the device was specifically designed to prevent fibrosis, a serious issue with previous implantable devices for therapeutic cells. As Sernova’s first clinical indication, these donor islets transplanted into the Cell Pouch not only provide a means to optimize cell therapy within the Cell Pouch in humans providing safety and efficacy data to prepare for future clinical advancement of our glucose responsive stem cell derived cells for the Cell Pouch but as a potential therapeutic treatment for patients with hypoglycemia unawareness receiving an islet transplant.

As noted in Table 1 below, we believe the Cell Pouch can alleviate several existing issues with portal vein transplantation. In the Cell Pouch, the therapeutic cells live within a tissue matrix surrounded by microvessels, similar to the islets’ natural microenvironment in the pancreas rather than being subjected to a constant flow of blood with immune-reactive cells which is believed to lead to IBMIR. This reduced inflammatory response should enable improved islet survival, and potentially lower the number of islets or other sources of insulin-producing cells that need to be implanted. Consequently, fewer donor pancreata than what are currently being used in portal vein transplantation would be required. In addition, known side effects of an infusion into the portal vein such as portal vein hypertension, thrombosis, and liver steatosis (fatty liver), along with the costs of treating them, are expected to be eliminated with the application of Sernova’s Cell Pouch technology (see Table 1).

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

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

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Sernova's Cell Pouch was designed and patented to take into consideration the biological requirements of therapeutic cells. Our research demonstrates that highly vascularized tissue develops within the Cell Pouch environment when implanted below the skin or in other locations prior to transplantation of therapeutic cells. In long-term preclinical evaluation, the Cell Pouch has been shown to maintain a stable, vascularized tissue environment prior to the 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 ISO 10993 biocompatibility studies and multiple animal studies that the Cell Pouch is biocompatible and safe. Long-term studies in multiple animal models have demonstrated that the islets become well-supported with microvessels as in their natural pancreatic environment following islet transplantation into the Cell Pouch.

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

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

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

- The biocompatibility and a positive safety profile of the Cell Pouch in these subjects in which safety is the primary endpoint of the clinical study; and
- The islets within the Cell Pouch, as shown by independent histological analysis, are well-vascularized, living within a natural tissue matrix and can make insulin and glucagon, key hormones in the control of blood glucose levels.

We believe such revascularization of islets and islet metabolic function within Sernova's implantable medical device for therapeutic cells in humans in this patient population is an important step forward in the regenerative medicine field.

Based on these encouraging results as well as the learnings from this initial study, we developed a new clinical study entitled "*A Safety, Tolerability and Efficacy Study of Sernova's Cell Pouch for Clinical Islet Transplantation*" to further address the safety as well as function of the Cell Pouch with therapeutic cells. Following a peer review of the new clinical protocol, Sernova was awarded up to US\$2.45 million (~\$3.2 million) grant under an agreement with JDRF. The grant is supporting our Cell Pouch diabetes clinical trial, which is being conducted at the University of Chicago under the direction of Principal Investigator Dr. Witkowski, Director of the University of Chicago's Pancreatic, and Islet Transplant Program. Under Dr. Witkowski's leadership, multidisciplinary research teams at the University of Chicago are currently conducting several studies designed to improve the quality and outcomes of islet cell transplantation in patients with type 1 diabetes (T1D). Dr. Witkowski is a published diabetes researcher and surgeon with a longstanding record in both basic science and clinical research pertaining to islet cell and abdominal organ transplantation.

The clinical trial is a Phase I/II non-randomized, unblinded, single-arm, company-sponsored trial, where diabetic subjects with hypoglycemia unawareness are enrolled in the study under informed consent. A key inclusion criterion for subjects in this study is the absence of blood levels of C-peptide, measured through a glucose tolerance test, indicating that their pancreas produces no insulin. Subjects are then implanted with Cell Pouches including small sentinel pouches. Following the development of vascularized tissue chambers within the Cell Pouch, subjects are then stabilized on immunosuppression and activated on the donor transplant list. Upon

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receipt of a suitable donor pancreas and following isolation of islets, a dose of purified islets under strict release criteria is transplanted into the Cell Pouches.

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

We believe the Cell Pouch can be used with a variety of sources of cells, such as glucose-responsive insulin-producing cells derived from stem cells, addressing the limited availability of donors and allowing the extensive treatment of insulin-dependent diabetes. Using our extensive learnings of human donor islets within the Cell Pouch, Sernova is developing these technologies, including our licensed technology from UHN to provide an immune-protected cell-based therapeutics for all subjects with T1D.

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

#### **Development of the Cell Pouch for the Treatment of Hemophilia A**

We believe the Cell Pouch and Cell Pouch System has multiple potential therapeutic applications. As part of this strategy to expand Cell Pouch clinical applications, we are evaluating it for the post-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 our Cell Pouch for constant release of factor VIII. Initial proof-of-concept studies were conducted by Sernova and a European team of experts collectively forming the HemAcure Consortium (HemAcure Consortium). The HemAcure Consortium was successful in obtaining €5.6 million (~\$8.5 million), funded by a European Commission Horizon 2020 grant, to develop a Good Manufacturing Practices (cGMP) compliant human cell product suitable for human clinical testing for the completion of safety and efficacy studies in the Cell Pouch as part of a regulatory package in preparation for human clinical testing.

According to a recent market analysis report (<https://www.grandviewresearch.com/industry-analysis/hemophilia-treatment-industry>), the global hemophilia market is valued at USD 11.1 billion in 2018 and is expected to grow at a CAGR of 5.2% over the forecast period to 2026. Furthermore, according to the World Federation of Hemophilia (WFH), the disease is more prevalent in males, and about 1 in 5,000 neonates suffer from type A. Hemophilia is a rare genetic bleeding disorder estimated to have affected about 440,000 people globally as of 2018. The federation also mentions that about 75% of these individuals are either undiagnosed or receive inappropriate treatment.

According to a recent publication by the Alliance for Regenerative Medicine (ARM), the estimated annual cost of treatment for hemophilia A represents an average of US\$200,000 per patient. The current standard of care involves regular infusions of factor VIII, which achieves normal factor VIII blood levels for only a few hours at a time. The HemAcure Consortium seeks to develop a product that will provide constant delivery of factor VIII

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### **MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2019 AND 2018**

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to normalize blood levels (the "Program") in an effort to significantly improve the quality of life of patients suffering from hemophilia A. The product being developed by the HemAcure Consortium is expected to be highly disruptive to the current standard of care treatments for hemophilia A. The therapeutic goal of the Program is to use the patient's cells corrected for the factor VIII gene. These cells placed in the implanted Cell Pouch are expected to release factor VIII at a rate expected to reduce disease-associated hemorrhaging and joint damage. The continuous delivery of factor VIII is also expected to reduce or eliminate the need for multiple weekly infusions which is the current standard of care using plasma-derived or recombinant, genetically engineered factor VIII for the prophylactic treatment of hemophilia A.

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

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

The Company has completed its obligations for the HemAcure Consortium study and has received full payment in the amount of €1,019,378 (~\$1.48 million) of its portion of the 2020 Horizon Grant relating to this project.

In summary, the following developments were achieved by the HemAcure Consortium:

- In blood donated from patients with hemophilia A, blood endothelial outgrowth cells to be corrected for the factor VIII gene were isolated and grown successfully in a specialized cGMP compliant medium developed by the HemAcure Consortium;
- Using a human factor VIII gene insertion technique, the cells were corrected and confirmed to produce factor VIII;
- A preliminary experiment showed these cells could release factor VIII in the blood over time and improve blood clotting in an animal model of hemophilia A, in preparation for transplant into the Cell Pouch;
- The corrected cells were proven to be successfully replicated through a production scale-up process. Following amplification, these cells maintained their normal healthy behaviour in producing factor VIII. Additional safety metrics were achieved using established tests;
- The corrected cells were then cryopreserved and shipped from the European partners to Sernova in North America, where they were shown to remain healthy through quality control testing in preparation for transplantation;
- The Cell Pouch manufactured under cGMP, and following implantation in the hemophilia A animal model showed development of vascularized chambers suitable to receive the corrected cells;
- Following transplantation into the Cell Pouch in a hemophilia A animal model, the patient's factor VIII

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

#### **FOR THE YEARS ENDED OCTOBER 31, 2019 AND 2018**

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corrected cells survived at three months (the duration of the study);

- Initial results showed factor VIII released from the cells in the Cell Pouch was detected in blood and notably, showed improved clotting when compared to the hemophilia A animal control which did not receive human corrected cells; and
- The steps of the cell production process were documented towards development of the cGMP manufacturing process for the corrected cells for future clinical use. An Instructions-for-Use document was also developed for implantation of the Cell Pouch, and transplantation of patient corrected factor VIII producing cells applicable for future human testing in patients with hemophilia A.

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

The thyroid gland controls how quickly the body uses energy, makes proteins, and sensitivity to other hormones. It participates in these processes by producing thyroid hormones, the principal hormones being triiodothyronine (T3) and thyroxine (T4). Hypothyroidism is a condition where the thyroid gland can't make enough hormone upsetting the normal balance of chemical reactions. If left untreated, hypothyroidism can cause health problems such as obesity, joint pain, infertility, heart disease, and eventually death. Common causes are autoimmune disease, radiation treatment, and surgical removal of the thyroid (thyroidectomy). Most thyroid operations are carried out for the treatment of thyroid nodules, which are very common (up to 65% prevalence) (PMID: 19041821) in the general population. Also, surgical thyroid removal may be recommended for patients with Grave's Disease (a type of Hyperthyroidism) and patients with large multinodular goiters. Thyroidectomy is also commonly performed for cancer diagnosis or treatment. Hypothyroidism inevitably occurs after total thyroidectomy and may also occur in up to 10% of people after thyroid lobectomy (Johner A, Griffith OL, Wood L, et al: Detection and Management of Hypothyroidism Following Thyroid Lobectomy: Evaluation of a Clinical Algorithm. *Ann of Surg One* 2011; 18(9):2548-2554). The American Thyroid Association (ATA) estimates that about 150,000 thyroidectomies are performed in the US yearly, and most individuals undergoing a thyroid operation will be diagnosed with benign disease after their operation.

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

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

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### **MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2019 AND 2018**

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#### **Developing the Cell Pouch for the Treatment of Additional Disorders and Rare Diseases**

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

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

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

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

Our transplantation technologies may incorporate autologous cells, donor cells, or other sources of cells, including therapeutic cells derived from human stem cells or derived from xenogeneic sources, depending on the clinical indication under evaluation. As such, we continue to work with academic collaborators and industry partners to identify and secure the required cells for our therapeutic indications. In this regard, the Company has signed a license agreement with the UHN for worldwide, exclusive rights to certain patent-pending technologies for the advancement of glucose-responsive insulin-producing stem cells for treatment of patients with insulin-dependent diabetes and we have a collaboration agreement with a major pharmaceutical company to assess an advanced glucose-responsive stem cell technology in our Cell Pouch. Process development and robust cell-production processes will provide a high standard of production of cells that consistently meets strict release criteria for evaluation of these cells in the Cell Pouch.

Sernova is also working through collaboration with pharmaceutical partners to evaluate various insulin-producing cell technologies using different approaches intending to combine Sernova and partner technologies to create best in class therapeutic technologies in a potential licensing and marketing agreement. In this regard, we have signed a number of agreements to test and evaluate several insulin-producing cell technologies in our Cell Pouch. For example, we have signed a collaboration with an international pharmaceutical company to study Sernova's Cell Pouch in a large animal diabetes model. The collaboration involved the study of safety, survival, and efficacy of locally immune protected therapeutic islets in our Cell Pouch in proof-of-concept studies. Sernova plans to continue to develop multiple collaborations with pharmaceutical companies for its diabetes and other clinical indications to establish potential long-term licensing and co-development relationships. In addition to pharmaceutical companies, Sernova has entered into collaborations with various academic institutions relating to its Cell Pouch technologies.

#### **cGMP Manufacturing**

Our contract manufacturer has manufactured both our Cell Pouch and mini-Cell Pouch technologies (ISO 13485; US FDA Quality System Regulations (QSR) 21 CFR 820; EU Medical Devices Regulation MDR 2017/745 and Canadian Medical Device Regulation (CMDR)) for preclinical and clinical evaluation. Device specifications have been established, a semi-automated manufacturing process developed, and the product manufactured, packaged and sterilized under strict regulatory guidelines suitable for testing in clinical trials in North America and Europe to complete the manufacturing process. Sterilization verification studies were completed, and the product previously released for testing in our human clinical trial in Canada with Sernova's ITA (Investigational

## **SERNOVA CORP.**

### **MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2019 AND 2018**

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Testing Authorization) under the jurisdiction of Health Canada. A two-year has also been successfully completed demonstrating the stability of the product and packaging over this time period. Furthermore, Cell Pouches were also manufactured for the current US FDA IND application for our clinical study taking place at the University of Chicago. We anticipate additional manufacturing of the Cell Pouch will be required to supply the required product for the completion of our Phase I/II trial.

#### **Intellectual Property**

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

#### **Changes to our Board of Directors and Appointment of New Officer**

On May 21, 2019, we announced the appointment of Ms. Deborah Brown to our Board of Directors and the resignation of Bruce Weber. Ms. Brown brings extensive leadership experience and more than 20 years in senior management roles at several pharmaceutical companies and currently serves as a Managing Partner at Accelera Canada Ltd. She previously served as President of EMD Serono, a division of Merck KGaA; Executive Vice President at Serono US; General Manager, Director of Marketing, and Business Unit Director at Serono Canada; and Manager, International Regulatory at Pasteur Merieux Connaught. Ms. Brown is a former Board Chair of Rx&D (now Innovative Medicines Canada) and as a Director of the Board, oversaw the 100th anniversary of the association and the launch of the Canadian Innovation Timeline promoting the contributions Canadian researchers have made to the discovery and advancement of life science research. Ms. Brown is also a former board member of BIOTEC Canada. Ms. Brown holds an MBA from Ivey School of Business. She sits on the board of several corporate and not-for-profit organizations, including Life Sciences Ontario and the Hamilton / Burlington SPCA.

On October 24, 2019, we announced the appointment of David Swetlow, CPA, CA as Sernova's full-time Chief Financial Officer taking over from contract CFO Sean Hodgins, CPA, CA. As a veteran of the high tech and biotech / life sciences industries, Mr. Swetlow brings over 20 years of experience in various senior management, board and advisory roles for start-up, acceleration and high-growth stage companies, including multiple TSX and Nasdaq listed biotech public companies amongst them QLT Inc. and Protox Therapeutics Inc. (now Sopheris Bio, Inc).



**SERNOVA CORP.**MANAGEMENT'S DISCUSSION AND ANALYSIS  
FOR THE YEARS ENDED OCTOBER 31, 2019 AND 2018**RESULTS OF OPERATIONS****Selected Financial Information**

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

	Three months ended October 31,		Year ended October 31,	
	2019	2018	2019	2018
Research and development expenses	\$ 674,236	\$ 527,514	\$ 2,010,213	\$ 2,231,455
General and administrative expenses	1,121,407	308,154	1,997,926	1,474,980
Net loss and comprehensive loss	\$ 1,759,416	\$ 834,367	\$ 3,971,272	\$ 3,698,627

For the three months ended October 31, 2019, the Company recorded a net and comprehensive loss of \$1,759,416, an increase of \$925,049 or 111% compared to the same period in the prior year. The increase is attributable mainly to higher research and development costs with increased clinical trial and patent prosecution activities, and higher share-based compensation expense due to a catch up for approximately two and a half years of no DSU or stock option grants, with partial offset by additional grant contributions recognized during the final fiscal quarter. More detail on the impact of these factors is discussed below.

For the year ended October 31, 2019, the Company recorded a net and comprehensive loss of \$3,971,272, an increase of \$272,645 or 7% compared to the same period in the prior year. Although relatively comparable year over year, the components of the net and comprehensive loss varied between periods as further discussed below.

**Research and Development Expenses**

	Three months ended October 31,		Year ended October 31,	
	2019	2018	2019	2018
Salaries, supplies, contract payments	\$ 626,025	\$ 423,717	\$ 2,152,233	\$ 1,680,352
Manufacturing costs	512	19,045	13,917	568,927
Patent fees and costs	151,455	60,324	401,646	359,415
Depreciation	13,361	15,373	59,316	62,272
Share-based compensation	263,871	46,031	345,179	281,407
Grant contributions and tax credits	(380,988)	(36,976)	(962,078)	(720,918)
	\$ 674,236	\$ 527,514	\$ 2,010,213	\$ 2,231,455

For the three months ended October 31, 2019, the Company incurred net research and development (R&D) expenses of \$674,236, an increase of \$146,722 or 28% compared to the same period in the prior year. Excluding grant contributions recognized in Q4, R&D expenses increased 87% or \$490,734 to \$1,055,224. The primary factors for increased R&D costs were higher clinical trial costs commensurate with the advancement of the US Phase I/II Cell Pouch Clinical Trial; a higher level of patent prosecution activities and timing of ongoing patent maintenance fees; and share-based compensation costs associated with the stock options granted during the final quarter of the fiscal year.

Net R&D expenses for the year ended October 31, 2019 decreased \$221,242 or 10% to \$2,010,213 compared to the prior year. Total grant contributions and tax credits increased by \$241,160 or 33% to \$962,078 during the

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comparative period due to the timing of earned JDRF milestone and Horizon 2020 grant contributions. Excluding earned grant contributions recognized during the year ended October 31, 2019, total R&D costs were comparable to those for the prior year although the relativity of individual R&D costs varied. Personnel costs, clinical trial site and supplies costs increased by 28% or \$471,881, while manufacturing costs decreased by \$555,010 or 98% during the most recently completed fiscal year compared to the prior year. These changes reflect the increase in payments to the University of Chicago for study activities undertaken for the US Phase I/II Cell Pouch Clinical Trial and the higher level of manufacturing costs for the Cell Pouch incurred in the prior year in advance preparation for the commencement of the US Phase I/II Cell Pouch Clinical Trial.

**General and Administrative Expenses**

	Three months ended October 31,		Year ended October 31,	
	2019	2018	2019	2018
Salaries, benefit and consulting fees	\$ 113,107	\$ 44,669	\$ 273,106	\$ 325,483
Professional fees	38,861	115,193	124,742	331,097
Director fees and benefits	25,977	26,039	101,014	101,504
Investor relations	397,169	43,625	735,854	217,201
Travel and other costs	70,640	50,629	230,462	252,766
Depreciation	412	564	2,159	2,257
Share-based compensation - DSUs	200,945	16,011	227,190	121,288
Share-based compensation	274,296	16,152	303,399	123,384
	<b>\$1,121,407</b>	<b>\$ 312,882</b>	<b>\$1,997,926</b>	<b>\$1,474,980</b>

Total general and administrative (G&A) expenses for the three months ended October 31, 2019 increased by \$808,525 compared to the same period in the prior year. This increase was primarily attributable to the recognition of share-based compensation costs associated with stock options and DSUs granted during the final quarter as noted above, an increase in investor relations and communication fees for expanded activities; and higher corporate consulting fees; offset by a reduction in professional fees which vary from quarter to quarter depending on the services required during the specific period.

Total G&A expenses for the year ended October 31, 2019 increased by \$522,946 or 35% compared to the same period in the prior year. This increase was primarily attributable to the increase in investor relations costs, corporate communication fees and share-based compensation costs mentioned above for the quarter, with a partial offset for a reduction in professional fees.

**Other items**

	Three months ended October 31,		Year ended October 31,	
	2019	2018	2019	2018
Interest income	\$ (32,919)	\$ (5,189)	\$ (38,465)	\$ (27,749)
Finance costs	1,540	1,988	7,268	9,705
Foreign exchange (gain) loss	(4,847)	1,900	(5,670)	10,236
	<b>\$ (36,226)</b>	<b>\$ (1,301)</b>	<b>\$ (36,867)</b>	<b>\$ (7,808)</b>

## SERNOVA CORP.

### MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2019 AND 2018

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#### Interest income

Interest income earned on the Company's cash and marketable securities totaled \$32,919 and \$38,465 for the three months and year ended October 31, 2019, compared to \$5,189 and \$27,749, respectively, for the comparative periods in the prior year. The higher interest income is attributable to interest being earned on a higher average balance of cash with financing proceeds raised as well as a higher level of investment in interest bearing investments or yield versus the comparative period.

#### Foreign exchange (gain) losses

Foreign exchange gains were \$4,847 and \$5,670 for the three months and year ended October 31, 2019, compared to foreign exchange losses of \$1,900 and \$10,236, respectively, for the comparative periods in the prior year. Changes in foreign exchange gain and losses are directly attributable to fluctuations in the CDN / US exchange rate as the Company does not hedge its foreign currency needs.

#### Income taxes

Income taxes have not been recognized in profit and loss to date, as the Company has been incurring losses since inception, and it is not probable that future taxable profits will be available against which the accumulated tax losses can be utilized. Accordingly, the Company has substantial deferred tax assets that have not been recognized in the financial statements that would be available to shelter potential future taxable income from income taxes. For further details related to the Company's income tax position, refer to Note 11 – Income Taxes in the Company's audited consolidated financial statements for the years ended October 31, 2019 and 2018.

## LIQUIDITY AND CAPITAL RESOURCES

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

As at	October 31, 2019	October 31, 2018
Cash and marketable securities	\$ 3,804,137	\$ 2,743,320
Total assets	5,568,541	3,605,188
Current liabilities	686,823	341,202
Share capital, warrants and contributed surplus	47,343,822	41,754,818
Deficit	(\$ 42,462,104)	(\$ 38,490,832)

As at October 31, 2019, the Company had cash and marketable securities of \$3,804,137 compared to \$2,743,320 as at October 31, 2018. The increase in cash and marketable securities is attributable to the financing proceeds raised by the Company during the final quarter less cash used in operations during the 2019 fiscal year. The Company does not have any debt or credit facilities.

The Company's spending and capital requirements may increase as the Company advances its ongoing US Phase I/II Cell Pouch Clinical Trial. Some of the increased cash requirements related to this clinical trial will be offset by milestone draws against the Company's JDRF grant award. A milestone payment of US\$400,000 (\$535,662) was received during the year ended October 31, 2019. An additional milestone payment of US\$200,000 (\$263,200) was recorded during the year and included in amounts receivables as at October 31, 2019.

We have 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. The ability of the Company to continue as a going concern in the long-term depends upon its ability to develop profitable operations and to continue to raise adequate financing. The Company will seek new funding from additional

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equity financings and / or licensing agreements and collaborations with development partners. Management believes that the Company has sufficient cash to maintain its operations for at least the next twelve months from the statement of financial position date.

**Financing Activities**

In July 2018, the Company closed a private placement of 11,016,000 Special Warrants for gross cash proceeds of \$2,754,000. During fiscal 2019, each Special Warrant converted, for no additional consideration, into one Unit of the Company (2018 Unit or 2018 Units). Each 2018 Unit consisted of one common share and one common share purchase warrant. Each common share purchase warrant is exercisable into one common share at \$0.35 per share for 24 months, subject to acceleration of the exercise period expiry if the 20-day volume-weighted price of the Company's common shares exceeds \$0.50 per share. All securities issued in connection with the private placement were subject to a statutory hold period of four months. The Company compensated finders on a portion of the private placement, such compensation consisting of 7% in cash or 7% in finder warrants, or a combination thereof. The Company received approval of the Exchange on August 1, 2018. The Company filed a final short form prospectus to qualify the distribution of the 2018 Units upon the deemed conversion of the Special Warrants following the receipt of a final prospectus.

During the year ended October 31, 2019, 1,250,000 stock options were exercised for gross cash proceeds of \$187,500 compared to the exercise of 131,250 stock options and 465,600 warrants for gross cash proceeds of \$30,389 and \$162,960, respectively, during the prior year ended October 31, 2018.

Over multiple closings in August and September 2019, Sernova completed a non-brokered private placement issuing 23,422,822 Units (2019 Unit or 2019 Units) at \$0.20 per Unit, representing gross proceeds of \$4,684,564. Each 2019 Unit consisted of one common share and one common share purchase warrant, each warrant being exercisable into one common share at a price of \$0.30 per share for a period of 36 months. The Company incurred legal costs and finders' fees totaling \$144,338 and 391,125 finders warrants valued at \$55,172.

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

We anticipate our cash requirements to increase for fiscal 2020 to fund the US Phase I/II Cell Pouch Clinical Trial, planned activities and corporate initiatives compared to the most recently completed fiscal year. Our actual cash requirements for fiscal 2020 will depend on the preclinical, clinical and collaboration activities that we ultimately undertake and the ability to secure partners and non-dilutive funding in the form of grants, tax credits and earn additional milestone draws from our JDRF grant for the US Phase I/II Cell Pouch Clinical Trial.

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**Common Shares**

The following table reflects the changes in the number of issued common shares for the year ended October 31, 2019 to the date of this MD&A:

	Number of Common Shares
Balance as at October 31, 2018	159,971,348
Shares issued on conversion of Special Warrants	11,016,000
Shares issued pursuant to Units private placement	23,422,822
Shares issued on the exercise of stock options	1,250,000
Share issued for the equity-settlement of deferred stock units	284,944
Balance as at October 31, 2019 and the date of this MD&A	195,945,114

Further details on the common shares outstanding are provided in Note 7 – Common Shares and Warrants in the audited consolidated financial statements for the years ended October 31, 2019 and 2018.

**Warrants**

The following table reflects the changes in the number of issued warrants for the year ended October 31, 2019 and to the date of this MD&A:

	Number of Warrants	Weighted Average Exercise Price
Balance as at October 31, 2018	581,700	\$ 0.35
Warrants issued on conversion of special warrants	11,016,000	0.35
Warrants issued in conjunction with Unit financing	23,422,822	0.30
Finders warrants issued in conjunction with Unit financing	391,125	0.30
Balance as at October 31, 2019 and the date of this MD&A	35,411,647	\$ 0.32

Further details on the warrants outstanding are provided in Note 7 – Common Shares and Warrants in the audited consolidated financial statements for the years ended October 31, 2019 and 2018.

**SERNOVA CORP.**MANAGEMENT'S DISCUSSION AND ANALYSIS  
FOR THE YEARS ENDED OCTOBER 31, 2019 AND 2018**2015 Incentive Plan**

The Company has an incentive plan with two components: (i) a fixed Share Option Plan (Option Plan) and (ii) a Deferred Share Unit Plan (DSU Plan), (collectively the Incentive Plan). Further details on the Company's Incentive Plan are provided in Note 7 – Common Shares and Warrants in the audited consolidated financial statements for the years ended October 31, 2019 and 2018.

The following table reflects the changes in the number of issued stock options for the year ended October 31, 2019 and to the date of this MD&A:

	Number of Options	Weighted Average Exercise Price
Balance as at October 31, 2018	9,005,000	\$ 0.23
Issued	8,649,600	0.21
Exercised	(1,250,000)	0.15
Cancelled / forfeited	(1,180,000)	0.15
Expired	(650,000)	0.15
Balance as at October 31, 2019 and the date of this MD&A	14,574,600	\$ 0.22

The following table reflects the changes in the number of issued DSUs for the year ended October 31, 2019 and to the date of this MD&A:

	Number of DSUs
Balance as at October 31, 2018	1,975,000
DSUs canceled	(660,222)
DSUs issued	3,120,167
DSUs equity-settled	284,944
Balance as at October 31, 2019 and the date of this MD&A	4,150,001

Amendments to the Incentive Plan approved by shareholders of the Company at the last Annual General Meeting on April 26, 2019 and the Exchange on May 13, 2019 included: (a) changing the allowable number of options issuable being a rolling number with a maximum percentage to a fixed number maximum aggregate representing 15% of the common shares of the Company then issued and outstanding. The aggregate maximum of 25,835,602 common shares allowable under the Incentive Plan consists of: i) a maximum of 20,668,482 common shares reserved for the exercise of options pursuant to the Option Plan and ii) a maximum of 5,167,120 DSUs reserved under the DSU Plan component, representing 12% and 3% respectively of the then issued and outstanding common shares of the Company.

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### **MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2019 AND 2018**

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Further details on the stock options and DSUs outstanding are provided in Note 7 – Common Shares and Warrants in the audited consolidated financial statements for the years ended October 31, 2019 and 2018.

#### **DEFERRED GRANTS, COMMITMENTS AND CONTINGENCIES**

In December 2015, the HemAcure Consortium (which included the Company) was awarded a €5.6 million (approximately \$8.5 million) non-dilutive grant by the European Commission's Horizon 2020 Program. The Company expects to receive total funding in the amount of €1,019,378 (approximately \$1.48 million), representing its portion of the grant, based upon the terms of the grant agreement. In November 2017, the Company received an interim payment in the amount of €226,603 (\$331,770). All product development activities to be performed by the Company, as outlined in the grant agreement with the European Commission's Horizon 2020 Program, were completed by October 31, 2019. The Company's final funding claim of €226,268 (\$329,207), included in amounts receivable at October 31, 2019, passed audit by the European Commission and was collected subsequent to October 31, 2019 fiscal year end.

During 2016, the Company was awarded a US\$2.45 million (~\$3.2 million) grant under an agreement with JDRF. The grant supports the US Phase I/II Cell Pouch Clinical Trial 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 the US 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. A grant contribution of US\$200,000 (\$263,200) relating to milestone achievement was earned during the year ended October 31, 2019 (2018 - US\$400,000 (\$535,662)), and included in amounts receivable as at October 31, 2019 (October 31, 2018 – US\$nil (\$nil)). Remaining funding available to be advanced under the JDRF grant award totals approximately US\$1.48 million (\$1.95 million) as at October 31, 2019.

The Company expects to pay certain future costs related to its preclinical and clinical trials. Such payments are expected to include the cost of clinical staff and overhead thereon, clinical 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 clinical 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.

The Company entered into a three-year lease effective September 1, 2017. Notwithstanding the term, the Company has the right to terminate the lease after the first anniversary by providing 90 days' written notice. As at October 31, 2019, the remaining maximum gross lease payments total \$97,660 under the lease.

#### **RELATED PARTY TRANSACTIONS**

Key management personnel of the Company is composed of the Directors; the President and Chief Executive Officer; and the Chief Financial Officer.

Amounts due to related parties, including amounts due to key management personnel, at the period-end are unsecured, interest-free, and settlement generally occurs in cash. There have been no guarantees provided or received for any related party receivables or payables. Included in accounts payable and accrued liabilities at October 31, 2019 were amounts totaling \$56,978 due to key management personnel (October 31, 2018 – \$61,356).

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Compensation to key management personnel for the three months and years ended October 31, 2019 and 2018 were as follows:

	Three months ended October 31		Year ended October 31	
	2019	2018	2019	2018
Salaries, benefits and consulting fees	\$ 151,255	\$ 90,584	\$ 458,093	\$ 407,826
Director fees and benefits	25,977	26,038	101,014	101,504
Share-based compensation - DSUs	200,945	16,011	227,190	121,288
Share-based compensation	226,098	23,822	264,7012	153,512
	\$ 604,275	\$ 156,455	\$1,050,998	\$ 784,130

Key management personnel participate in the Company's Incentive Plan, so they are eligible to receive stock options and DSUs. The President and Chief Executive Officer and Chief Financial Officer also participate in the Company's health benefits plan.

**SUMMARY OF QUARTERLY RESULTS**

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

Fiscal Year		1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
2019	Net loss	\$ 723,748	\$ 613,356	\$ 874,750	\$ 1,759,418
	Net loss per share	\$ 0.00	\$ 0.00	\$ 0.01	\$ 0.01
2018	Net loss	\$ 766,355	\$ 986,347	\$ 1,111,556	\$ 834,369
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.01	\$ 0.01
2017	Net loss	\$ 317,524	\$ 638,431	\$ 705,793	\$ 977,731
	Net loss per share	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.01

Loss for the final quarter of the 2019 fiscal year increased significantly compared to the immediately preceding quarter and the comparable quarter of the prior year primarily due to incremental share-based compensation expense relating to stock options and DSUs granted during the final 2019 fiscal quarter. The higher loss for the third and fourth 2019 fiscal quarters also reflected higher costs commensurate with the increased activity level of the US Phase I/II Cell Pouch Clinical Trial and increased patent prosecution to expand and strengthen our patent portfolio. Lower quarterly losses during the first and second quarters of fiscal 2019, compared to the later quarters of fiscal 2018, reflected recognition of a JDRF grant contribution milestone in the second quarter of 2019 and the Company's completion of key activities during the 2018 fiscal year in advance preparation for the commencement of the US Phase I/II Cell Pouch Clinical Trial. The variability between 2018 and 2017 quarterly results was mostly attributable to manufacturing development costs and the timing of grant contribution claims or milestones earned as personnel and operating costs were relatively consistent.

It is important to note that historical patterns of expenditures cannot be taken as an indication of future expenditures. The amount and timing of expenditures, and therefore liquidity and capital resources, may vary



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substantially from period to period depending on the business and research activities being undertaken at any one time and the availability of funding from investors and prospective collaborative partners.

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

The Company does not have any off-balance sheet arrangements.

#### **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 Company's financial assets and financial liabilities, including cash, marketable securities, amounts receivable, accounts payable and accrued liabilities, are all short-term in nature being receivable or due within one year and 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 a single counterparty primarily holds those financial instruments. 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 government agencies and internationally recognized granting organizations.

##### 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, 2019, and 2018, the Company had cash, cash equivalents and marketable securities of

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\$3,804,137 and \$2,743,320, respectively which are available to settle current liabilities of \$686,823 and \$341,202, respectively. The majority of the Company's accounts payable and accrued liabilities are due within three months or less.

#### 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. For the years ended October 31, 2019 and 2018, the Company earned interest income of \$38,465 and \$27,749, respectively. Interest income is not significant to the Company's projected operational budget. A 100-basis point change in the interest rate on marketable securities for the year ended October 31, 2019 and 2018, would have a net impact on interest income of \$20,070 and \$10,235, respectively.

#### Foreign currency risk

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

In December 2015, the HemAcure Consortium was awarded a €5.6 million (~\$8.5 million) non-dilutive grant by the European Commission's Horizon 2020 Program. The Company expects to receive total funding in the amount of €1,019,378 (~\$1.48 million), representing its portion of the grant, based upon the terms of the grant agreement. The Company's final grant funding claim of €226,268 (\$329,207) is included in receivables as at October 31, 2019. A 10% change in the foreign exchange rate between the Canadian dollar and the Euro would result in a fluctuation of \$32,921 in respect of the remaining 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 – Significant Accounting Policies of the Company's audited consolidated financial statements for the years ended October 31, 2019 and 2018.

Management has applied significant estimates and assumptions to the following:

### **Going concern**

In the preparation of the consolidated financial statements, management is required to identify when events or conditions indicate that significant doubt may exist about the Company's ability to continue as a going concern. Significant doubt about the Company's ability to continue as a going concern would exist when relevant conditions and events, considered in the aggregate, indicate that the Company will not be able to meet its obligations as they become due for a period of at least, but not limited to, twelve months from the statement of

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financial position date. When the Company identifies conditions or events that raise potential for significant doubt about its ability to continue as a going concern, the Company considers whether its plans that are intended to mitigate those relevant conditions or events will alleviate the potential significant doubt.

The Company's ability to continue as a going concern for the next twelve months involves significant judgment. The Company will require ongoing financing in order to continue research and development activities, as it has not earned significant revenue or reached successful commercialization of its products. After considering its plans to mitigate the going concern risk, management has concluded that there are no material uncertainties related to events or conditions that may cast significant doubt upon the Company's ability to continue as a going concern for a period of at least, but not limited to, twelve months from the statement of financial position date.

**Valuation of share-based compensation and warrants**

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the expected: option life, volatility, risk-free interest rate, forfeiture rates, stock option exercise behaviors, dividend yield and corporate performance. Changes in these assumptions affect the fair value estimate for share-based compensation. The assumptions and models used for estimating fair value for share-based payment transactions are discussed in Note 7 – Share Capital and Warrants of the audited consolidated financial statements for the years ended October 31, 2019 and 2018.

**INTERNAL CONTROLS OVER FINANCIAL REPORTING**

As a result of the Company's limited administrative staffing, internal controls that rely on segregation of duties, in many cases, are not possible at this time. 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. 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 well as oversight by the board of directors.

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.

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#### **CHANGES IN ACCOUNTING POLICIES**

##### **New accounting standards adopted in the fiscal year**

###### *IFRS 15 Revenues from Contracts with Customers (IFRS 15)*

The adoption of IFRS 15 Revenue from Contracts with customers using the modified retrospective and the completed contract practical expedient approaches on November 1, 2018 (the date of initial application of IFRS 15) does result in a change in accounting policy. However, the adoption did not have a material impact on the financial statements, and as a result the 2018 comparatives are not required to be restated. The new standard replaces IAS 18, Revenue, IAS 11 Construction Contracts, and other interpretive guidance associated with revenue recognition. IFRS 15 provides a single model to determine how and when an entity should recognize revenue, as well as requiring entities to provide more informative, relevant disclosures in respect of its revenue recognition criteria. The modified retrospective approach results in the cumulative effect, if any, of adoption being recognized at the date of initial application. The Company currently has no product sales or significant sources of revenue, therefore there is no effect upon initial application.

##### **New standards and interpretations not yet effective**

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

###### *IFRS 16 Leases (IFRS 16)*

In January 2016, the IASB issued IFRS 16 *Leases*, its new lease standard that requires lessees to recognize assets and liabilities for most leases on the statement of financial position. Lessees applying IFRS 16 will have a single accounting model for all leases, with certain exemptions. Lessor accounting is substantially unchanged. The new standard is effective for annual periods beginning on or after January 1, 2019 with limited early application permitted. The Company plans to apply IFRS 16 effective November 1, 2019. The Company has an office and lab lease agreement which is expected to be recorded as a right-of-use asset and a lease liability under IFRS 16. The Company estimates at November 1, 2019, it will record a right-of use asset and related lease liability of approximately \$91,300.

#### **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.*

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#### **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. During the year ended October 31, 2019, our common shares traded on the TSX Venture Exchange at a high of \$0.28 and a low of \$0.145 per share (2018 – high of \$0.405 and low of \$0.19 per share). Factors such as fluctuation of our operating results, announcements of technological innovations, patents or new commercial products by us or our competitors, results of clinical testing, regulatory actions, or public concern over the safety of biopharmaceutical products and other factors could have a significant effect on the share price or trading volumes for our common shares. Our common shares have been subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future. We have not paid dividends to date, and we do not expect to pay dividends in the foreseeable future.

***Dilution.*** It is highly likely we will 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 14.6 million outstanding stock options convertible into common shares with an average exercise price of \$0.22 per share, 4.1 million outstanding DSU's convertible into common shares and 35.4 million outstanding warrants convertible into common shares with an average exercise price of \$0.32 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, DSUs 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.

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

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

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

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negatively impact the business.

#### **Issuer Risk**

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

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

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

We are dependent on successful safety and efficacy of our Cell Pouch and therapeutic cells for our lead programs including the use of human or xenogeneic islets and stem cell-derived cells in combination with the Cell Pouch platform including cell immune protection to treat insulin-dependent diabetes and the use of factor VIII releasing cells in combination with the Cell Pouch platform to treat severe hemophilia A. If we are unable to achieve safety and efficacy in these disease indications in preclinical and / or clinical studies the business may be materially harmed.

***We will likely need to raise substantial additional funding, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our research and development efforts or other operations.*** We will require substantial additional funds for further research and development, planned clinical testing, regulatory approvals, establishment of manufacturing capabilities and, if necessary, the marketing and sale of our products. Management is of the opinion that sufficient working capital will be obtained from external financing to meet the Company's liabilities and commitments as they become due, although there is a risk that additional financing will not be available on a timely basis or on terms acceptable to the Company. These factors indicate the existence of a material uncertainty that may cast significant doubt on the ability of the Company to continue as a going concern. We may attempt to raise additional funds through public or private equity or debt financing, collaborations with other biopharmaceutical companies and/or from other sources, including non-governmental grants and loans and various government incentive programs. There can be no assurance that additional funding, however, sourced, will be available on terms acceptable to us and which would allow the successful commercialization of our products.

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

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

***The regulatory approval processes of the US FDA, Health Canada, the European Medicines Agency (EMA), and regulators in other jurisdictions are lengthy, time-consuming and inherently unpredictable. If we, or our collaborators, are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, our business will be substantially harmed.*** The regulatory approval process is expensive, and the time required to obtain approval from the US FDA, Health Canada, EMA or other regulatory authorities in other jurisdictions to sell any product or combination therapy is uncertain and may take years. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of pre-clinical and clinical data necessary to gain approval may change during the course of our products' clinical development and may vary among jurisdictions. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and even if the pre-clinical studies show promising results and clinical trials are successfully completed, we cannot guarantee that the US FDA, Health Canada, EMA or other regulatory authorities in other jurisdictions will interpret the results as we do, and more trials, manufacturing-related studies or non-clinical studies could be required before we submit a product for approval. Many companies that have believed their product candidates or products performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. To the extent that the results of our studies and clinical trials are not satisfactory to the US FDA, Health Canada, EMA or other regulatory authorities in other jurisdictions for support of a marketing application, approval of any product(s) we develop may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product(s). It is also possible that neither our existing Cell Pouch System or any of our future products will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. Our products candidates could fail to receive regulatory approval for many reasons, including the following:

- the US FDA, Health Canada, EMA or other regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials;
- we or our collaborators may be unable to demonstrate to the satisfaction of the US FDA, Health Canada, EMA or other regulatory authorities that a product is safe and effective for its proposed indication;

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- the results of clinical trials may not meet the level of statistical significance required by the US FDA, Health Canada, EMA or other regulatory authorities for approval;
- we, or our collaborators, may be unable to demonstrate that a product's clinical and other benefits outweigh its safety risks;
- the US FDA, Health Canada, EMA or other regulatory authorities may disagree with our or our collaborators' interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our products may not be sufficient to support the submission of a Pre-market Approval (PMA) or other submission to obtain regulatory approval in the U.S. or elsewhere;
- the US FDA, Health Canada, EMA or other regulatory authorities may fail to approve the manufacturing processes, controls or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; and
- the approval policies or regulations of the US FDA, Health Canada, EMA or other regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

Even if we, or our collaborators, obtain approval for a particular product, regulatory authorities may grant approval contingent on the performance of costly post-approval clinical trials, or may approve a product with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product.

In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate in clinical trials that the product(s) we develop to treat those diseases are not only safe and effective, but may need to be compared to existing products, which may make it more difficult for our product candidates to receive regulatory approval or adequate reimbursement.

***Product development and associated clinical trials involves lengthy and expensive processes with uncertain timelines and uncertain outcomes. If clinical trials are prolonged, delayed or not completed, we, or our collaborators, may be unable to develop any commercial applications or products that generate revenues on a timely basis, if at all.*** Clinical trials are long, expensive, and uncertain processes. Clinical trials may not be commenced or completed on schedule, and the US FDA, Health Canada or any other regulatory body may not ultimately approve our Cell Pouch System or other products developed for commercial sale. Clinical trial outcomes are inherently uncertain, and failure can occur at any time during the clinical development process. The clinical trials for existing and / or future products could be unsuccessful, which would prevent us from advancing, commercializing, or partnering the product.

Even if the results of our preclinical 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 preclinical studies and clinical trials will generate positive results that allow us to move towards the commercial use and sale of our product candidates. Furthermore, negative results may cause our business, financial condition, or results of operations to be materially adversely affected.

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

Preparing, submitting and advancing applications for regulatory approval is complex, expensive and time-intensive and entails significant uncertainty. A commitment of substantial resources to conduct time-



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consuming research, preclinical and clinical trials will be required if we are to complete development of our products.

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

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

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

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

Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of our products or design around the products patented by us. In addition, we may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under such patents or proprietary rights will be available on terms acceptable to us, if at all. If we do not obtain such licenses, we could encounter delays in introducing one or more of our products to the market, while we attempt to design around such patents or we could find that our development, 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

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

***We may expend our limited resources to pursue particular research and development opportunities and fail to capitalize on others that may be more profitable or for which there is a greater likelihood of success.***

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

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

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

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

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

Furthermore, we may require licenses for certain technologies, and there can be no assurance that these licenses will be granted or, if granted, will not be terminated, or that they will be renewed on conditions acceptable to us. We intend to negotiate additional licenses in respect of technologies developed by other companies and academic institutions. Terms of license agreements to be negotiated may include, inter alia,

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a requirement to make milestone payments, which may be substantial. We will also be obligated to make royalty payments on the sales, if any, of products resulting from licensed technology and, in some instances, may be responsible for the costs of filing and prosecuting patent applications.

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

We rely on a third-party contract manufacturer to manufacture our products. Health Canada and the US FDA ensure the quality of products by carefully monitoring manufacturers' compliance with Good Manufacturing Practices regulations. 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.

***Acquisitions, joint ventures or other strategic transactions could disrupt our business, cause dilution to our shareholders and otherwise harm our business.*** We actively evaluate various strategic transactions on an ongoing basis, including the acquisition of other businesses, products or technologies as well as pursuing strategic alliances, joint ventures, licensing transactions or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with collaborators or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to pursuing strategic transactions and managing any such strategic alliances, joint ventures or acquisition integration challenges;
- dilution to our shareholders if we issue equity in connection with such transactions;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot

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predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

***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 US 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, 2019 and 2018, we incurred losses of \$3,971,272 and \$3,698,627, respectively and had an accumulated deficit to October 31, 2019 of \$42.4 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 that have entered into agreements with us. As disputes may arise between these organizations and us, or certain of these organizations may undertake or have undertaken research with our competitors, there exists the possibility for such persons to be in a position of conflict. Any decision or recommendation made by these persons involving us will be made in accordance with his or her duties and obligations to deal fairly and in good faith with us and such other organizations. In addition, as applicable, such directors and officers will refrain from voting on any matter in which they have a conflict of interest.

***Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.*** Global credit and financial markets experienced extreme disruptions at various points over the last decade, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary equity or debt financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and the market price of our common shares could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current collaborators, service providers, manufacturers and other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

***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, 2019, and 2018, and based on current business plans and financial expectations, we believe that we will be a PFIC for the current

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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.

#### **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

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### **MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEARS ENDED OCTOBER 31, 2019 AND 2018**

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may be competitive with our products.

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

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

**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.

**SERNOVA CORP.****MANAGEMENT'S DISCUSSION AND ANALYSIS  
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***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 that would be acceptable to us, if at all. An inability to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim brought against us, or withdrawal of a product from the market, could have a material adverse effect upon us and our financial condition.

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

**DIRECTORS AND OFFICERS**

Frank Holler, Chairman of the Board of Directors  
Jeffrey Bacha, Director  
James Parsons, Director  
Deborah Brown, Director  
Dr. Philip Toleikis, President, Chief Executive Officer, and Director  
David Swetlow, Chief Financial Officer

**ADDITIONAL INFORMATION**

Additional information relating to the Company can be found on SEDAR at [www.sedar.com](http://www.sedar.com).