



# **SERNOVA CORP.**

**MANAGEMENT'S DISCUSSION AND ANALYSIS**

**FOR THE THREE AND NINE MONTHS ENDED**

**JULY 31, 2020 AND 2019**

Dated September 23, 2020

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The following management's discussion and analysis (MD&A) explains the variations in the consolidated operating results, financial position, and cash flows of Sernova Corp. (Sernova, the Company, We, Us, or Our) for the three and nine months ended July 31, 2020, and 2019. This MD&A should be read in conjunction with the Company's unaudited interim condensed consolidated financial statements for the three and nine months ended July 31, 2020, and 2019 and its 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 – Significant Accounting Policies* 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 September 23, 2020, unless otherwise noted.

### **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 technologies and 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 (R&D), 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 benefits of our hypothyroid cell therapy program;
- the expected benefits of the cell therapy hemophilia A program and benefits gained from the completed work related to the European Commission Horizon 2020 Program grant received;
- the intention to protect therapeutic cells within the Cell Pouch from immune attack using local immune protection technologies such as conformal coating, microencapsulation and/or gene-editing approaches, or using systemic anti-rejection regimens or a combination thereof;
- Sernova's intentions and ability to secure academic and pharmaceutical/medtech collaborations

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- 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 diseases;
- the intention and ability to obtain regulatory clearance for clinical trials and marketing approval of the 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;
- the direct and indirect impact of the novel coronavirus (COVID-19) on our business and operations, including supply chain, manufacturing, research and development costs, clinical trials and patient enrollment, contracted service providers and employees; 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 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.

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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 "**RISKS AND UNCERTAINTIES**" in this MD&A. Potential investors and other readers are urged to consider these factors carefully in evaluating these forward-looking statements and information and are cautioned not to place undue reliance on them. Sernova has no responsibility, nor does it intend, to update these forward-looking statements and information, unless as otherwise required by law.

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

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 and systemic and / or locally immune protected therapeutic cells (human donor and stem cell-derived 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 provides a suitable environment allowing the transplantation, survival, and function of therapeutic cells for the potential treatment of these and other chronic diseases.

While we are developing stem cell-derived technologies for the treatment of diabetes, 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 severe hypoglycemia unawareness have shown the Cell Pouch to be safe prior to and following transplantation with human donor islets.

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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 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 (a biomarker of insulin produced by islet cells) 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. Piotr Witkowski, during a peer-reviewed scientific meeting in July 2019. In subsequent communications, additional positive findings have been reported, including confirmation of abundant insulin-producing vascularized islets in the sentinel Cell Pouch as assessed by an independent pathologist. 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 preclinical studies provide vital information to support our stem cell-derived technologies for the treatment of diabetes and hemophilia A and other clinical indications such as hypothyroid disease. Pursuant to our strategy of obtaining sources of supply for our 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 to overcome the limited supply of human donor islets.

Sernova is also developing local immune protection technologies with the goal of reducing or eliminating the need for immunosuppression antirejection medications for our cell therapy applications. In June 2020, we acquired cell encapsulation Conformal Coating Technology assets consisting of patents, patent applications, and know-how from Converge Biotech, Inc. In August 2020, we entered into an exclusive worldwide license with the University of Miami (UMiami) for the commercial rights to novel conformal coating immune protection technologies. The Conformal Coating Technology we acquired was developed by Dr. Alice Tomei and Dr. Jeffrey Hubbell as were the complementary UMiami technologies licensed along with Aaron Stock. Dr. Tomei is a leading international expert in immunoprotection and diabetes immunoengineering, of the renowned Diabetes Research Institute (DRI), a designated Center of Excellence at the University of Miami Miller School of Medicine. Dr. Hubbell is the Eugene Bell Professor of Tissue Engineering at the University of Chicago, and leading international researcher in immunoengineering. This exclusive worldwide license agreement broadens the technology scope of Sernova's immune protection conformal coating technologies and related intellectual property.

Furthermore, we have entered into a collaboration with AgeX Therapeutics, Inc. (AgeX) to utilize and evaluate its UniverCyte™ HLA-G gene-editing technology for our stem cell-derived cell technologies and programs as another therapeutic cells local immune protection approach. In addition to locally protecting human donor cells from immune system auto-response attack, Sernova's goal is to engineer and generate transplantable, universal immune-protected therapeutic cells for our cell therapy therapeutics

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total solution platform.

We are also developing collaborations with pharmaceutical companies and evaluating proprietary sources of glucose-responsive stem cell-derived cell technologies in combination with our Cell Pouch technologies with the goal of establishing long-term licensing and co-development relationships. Regarding our platform technologies, the Company continues to investigate other diseases amenable to treatment with therapeutic cells within the Cell Pouch where proteins, hormones, or other factors are required to treat disease.

### **Research and Development**

Our R&D efforts focus 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 and ultimately 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:

- conducting the series of 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;
- 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
- ongoing R&D activities related to our proprietary Cell Pouch in the following areas:
  - expanding our research into additional therapeutic indications including hemophilia A and postoperative hypothyroid disease;
  - 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;
  - 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;
  - developing acquired and in-licensed cellular local immune protection technologies;
  - establishing research collaborations for alternative cellular local immune protection technologies;
  - continuing to develop proprietary processing and supply of therapeutic cells;
  - ongoing international development of our intellectual property portfolio and development of new and / or licensing of intellectual property; and
  - 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

**September 2020:** We announced the completion of a \$3.7 million non-brokered private placement with proceeds to be used for clinical and R&D activities.

**September 2020:** We announced our President and CEO Dr. Philip Toleikis will be a member of the *Cell and Gene Therapies for Chronic Conditions* panel at the upcoming virtual 2020 Cell & Gene Meeting on the Mesa. Dr. Toleikis will also provide an update on Sernova's clinical and research programs as part of the 2020 Company Presentations segment of the annual conference.

**August 2020:** We announced entering into an exclusive worldwide license agreement with the University of Miami for additional local immune protection technologies. This licensing agreement expands Sernova's intellectual property portfolio and bolsters the Company's ability to develop best-in-class locally immune protected cell therapy solutions with the Sernova Cell Pouch.

**July 2020:** We announced the creation of a Global Advisory Board and the appointment of Dr. Anke M. Schulte. Dr. Schulte is an internationally acclaimed expert in diabetes and cell therapy regenerative medicine and a nineteen-year veteran of Sanofi, a global pharmaceutical leader.

**June 2020:** Our peer-reviewed abstract entitled "*Clinical Validation of the Implanted Pre-Vascularized Cell Pouch as a Viable, Safe Site for Diabetes Cell Therapy*" was presented at the American Diabetes Association's (ADA) Virtual 80<sup>th</sup> Scientific Sessions held June 12-16, 2020. The findings from assessments of patients implanted with the Cell Pouch and human donor islets support Sernova's Cell Pouch as a viable, safe site to provide diabetes cell therapy treatment.

**June 2020:** We acquired cellular local immune protection technology assets, more specifically intellectual property relating to a cell encapsulation technology utilizing a conformal coating approach, from Converge Biotech, Inc. This technology acquisition provides a pivotal component required for our total regenerative medicine cell therapy therapeutics solution platform and could accelerate our first-to-market strategy for T1D and significantly expand the number of treatable patients suffering from chronic diseases. To fund the acquisition, the Company issued unsecured convertible debentures for proceeds of \$1.0 million.

**May 2020:** We announced a research collaboration with AgeX Therapeutics, Inc. to engineer universal locally immune protected cell therapies for T1D and hemophilia A. The research collaboration will evaluate whether Sernova's pluripotent stem cell-derived pancreatic islet beta cells engineered with AgeX's UniverCyte technology can evade human immune detection.

**May 2020:** Achievements and positive results from the HemAcure Consortium's HemAcure Hemophilia Cell Therapy Program study of a novel, safe cell therapy approach, including our proprietary Cell Pouch, for the treatment of hemophilia A were presented at the American Society of Gene and Cell Therapy's 23rd Annual Meeting (ASGCT). Sernova's Cell Pouch transplanted with factor VIII corrected human cells showed robust functional blood clotting improvement demonstrating a novel first-in-class ex vivo gene therapy cell-based approach for the treatment of hemophilia A.

**February 2020:** We announced that the first treated patient in our current US Phase I/II clinical trial of the Cell Pouch with therapeutic cells for type 1 diabetes at the University of Chicago, had demonstrated survival of endocrine tissue (insulin-producing islets) in the sentinel Cell Pouch following 90 days transplant. This efficacy outcome, namely, survival of endocrine tissue in the sentinel Cell Pouch following 90 days transplant, is measured by positive staining of islets during histological analysis. This positive efficacy endpoint achievement is important because it is an indicator of transplanted islet health

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in the therapeutic Cell Pouches remaining in the subject, including the islets ability to produce insulin into the bloodstream.

**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.

### **Research and Development Outlook**

Our R&D program for the remainder of 2020 and into 2021, as applicable, 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 a potential unlimited cell supply for ongoing *in vivo* safety and efficacy studies in preparation for future clinical evaluation within our Cell Pouch for the treatment of insulin-dependent diabetes;
- formulating and proceeding with a development plan to the clinic for our recently acquired Conformal Coating Technology augmented by the now licensed UMiami technology as a local immune protection technology for human donor islets and stem cell-derived technologies for Sernova's clinical diabetes applications;
- evaluating AgeX's UniverCyte local immune protection technology for our hemophilia and diabetes cell therapy applications;
- continuing R&D collaborations with 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 programs towards human clinical evaluation for the treatment of postoperative hypothyroid disease and hemophilia A consisting of Cell Pouch transplanted therapeutic tissue / cells.

Refer to “Issuer Risk - *We face risks related to health epidemics and other outbreaks, which could significantly disrupt our operations and / or business.*” under “**RISKS AND UNCERTAINTIES**” of this MD&A.

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#### **Sernova Cell Pouch System**

Sernova's patented Cell Pouch System is designed to take into consideration the biological requirements of therapeutic cells. This is achieved through an 'organ-like' environment defined as a vascularized tissue matrix for therapeutic cells, which develops upon implantation. Our novel approach provides for the ability for therapeutic 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 prior-generation implantable cell therapy devices.

The Cell Pouch is designed to be scalable to match the required cell dose for the clinical application. Our research demonstrates that following Cell Pouch implantation under the skin or in other locations, vascularized tissue chambers develop within the device. 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.

We have demonstrated in a series of ISO 10993 biocompatibility studies, multiple animal studies and pilot human clinical trials 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. We have observed similar results in other therapeutic cell applications, such as hemophilia A.

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

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/what-is-diabetes/facts-figures.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 the Cell Pouch System may provide a significant improvement in the quality of life of patients as well as an improvement in the potential efficacy and reduction of diabetes-related 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 and cell therapy technologies 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. This approach involves the transplantation of pancreatic islets, often from multiple donors, which are infused into a patient's portal vein in the liver, followed by life-long administration of immunosuppressive drugs to inhibit rejection of the transplant.

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

There are significant issues with portal vein delivery of islets and potentially other cell technologies 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. 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.

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 walling off of the device within the body as a means of rejecting it, a serious issue with previous implantable devices for therapeutic cells. We believe that donor islets transplanted into the Cell Pouch may provide a means to optimize cell therapy for the treatment of diabetes. We also believe that data from our current clinical trial will provide the basis for future development of glucose-responsive stem cell-derived cells transplanted into the Cell Pouch as a life-changing treatment for patients with hypoglycemia unawareness.

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

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Table 1. 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                            |

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 previously 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 favorable safety profile of the Cell Pouch in these subjects; 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.

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#### **Type 1 Diabetes Clinical Trial for Hypoglycemia Unawareness**

Based on encouraging results and learnings from our first Cell Pouch clinical trial, we initiated a second clinical study - “*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 (~\$3.3 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 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. Subjects in this study do not have the ability to produce insulin in their pancreas, as shown in a glucose tolerance test by the lack of blood levels of C-peptide, a biomarker of insulin produced by islets. Subjects are then implanted with Cell Pouches, including small sentinel pouches. Following the development of vascularized tissue chambers within the Cell Pouch, subjects are then stabilized on immunosuppression and activated on the donor transplant list. Upon receipt of a suitable donor pancreas and following isolation of islets, a dose of purified islets under strict release criteria is 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 within the Cell Pouch. 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 have reported preliminary findings that support the safety, viability, and efficacy of the Cell Pouch System approach for the treatment of T1D. Following removal of a sentinel device transplanted with islets, and independently assessed by a pathologist, healthy abundant islets that were intimately associated with blood vessels housed in a natural tissue matrix, showing strong ability to produce insulin were observed. Of significant importance, fasting and glucose-stimulated blood levels of C-peptide and a reduction in the number of hypoglycemic unawareness events, HbA1c, and other efficacy indicators have been observed, suggesting a normalizing response of the Cell Pouch's therapeutic cells to the body's varied need for insulin production. We believe these early findings are an important achievement in the regenerative medicine therapeutics field and a first for an implanted prevascularized device with islet cells transplanted under the skin. These encouraging results using human donor islets in our Cell Pouch in subjects with hypoglycemia unawareness represents an important advance of our stepwise approach toward our ultimate goal of developing a treatment for all type 1 diabetes patients employing immune protected stem cell-derived islet cells within our Cell Pouch.

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

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donor islets within the Cell Pouch, Sernova is developing these technologies, including our licensed technology from the University Health Network, to provide an immune-protected cell-based therapeutic for all subjects with T1D.

Thus, we believe our approach and its ease of use may provide an opportunity for the Cell Pouch System to become the standard of care in therapeutic cell transplantation if it continues to demonstrate safety and efficacy 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.

#### **An Ex Vivo Gene Therapy Approach for Treatment of Rare Diseases: Cell Pouch System Treatment of Hemophilia A**

To expand the potential commercial opportunities for the Cell Pouch System, we are evaluating it for the treatment of hemophilia A.

Our 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 funded by a €5.6 million (~\$8.5 million) 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 11.8 billion in 2019 and is expected to grow at a compounded annual growth rate of 5.5% over the forecast period to 2027. Furthermore, according to the World Federation of Hemophilia ([WFH](#)), the disease is more prevalent in males, and about 1 in 10,000 newborns suffer from hemophilia 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's objective was to conduct research towards the development of a potential product that would provide constant delivery of factor VIII to normalize blood levels in an effort to significantly improve the quality of life of patients suffering from hemophilia A. The therapeutic approach developed and evaluated by the HemAcure Consortium could be highly disruptive to the current standard of care treatment for hemophilia A. The therapeutic goal is to use the patient's cells corrected for the factor VIII gene. These cells placed in an implanted Cell Pouch would release factor VIII at a rate expected to reduce disease-associated hemorrhaging and joint damage. The continuous delivery of factor VIII could also 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

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significant advancement in the treatment of hemophilia A and other diseases that can be treated with genetically engineered cells.

We believe Sernova's Cell Pouch with its vascularized tissue lined chambers for therapeutic cells, which has been established by early clinical evidence supporting islet safety and survival in human clinical assessment of diabetes, is an ideal, fully scalable medical device suitable for the potential treatment of a range of diseases that can be treated with genetically engineered cells. We believe that results of research undertaken by the HemaCure Consortium and supported by the Horizon 2020 grant provide preclinical proof-of-concept data to support further development of genetically engineered cell therapies in Sernova's Cell Pouch.

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 gene 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 gene corrected cells were proven to be successfully replicated through a production scale-up process. Following amplification, these cells maintained their normal healthy behavior 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 gene corrected cells;
- following transplantation into the Cell Pouch in a hemophilia A animal model, the patient's factor VIII gene corrected cells survived at three months (the duration of the study);
- initial results showed factor VIII released from the gene corrected 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
- cell production process steps 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 and other diseases.

The results of the HemAcure Consortium's research study were presented in a peer-reviewed abstract entitled "*Combined Gene and Cell Therapy for the Treatment of Hemophilia A within an Implantable Therapeutic Device*" at the ASGCT 23rd Annual Meeting on May 15, 2020. The abstract can be viewed at [https://www.asgct.org/global/documents/abstract-pdf-final-4-30?\\_zs=S2i4b&\\_zl=U9052](https://www.asgct.org/global/documents/abstract-pdf-final-4-30?_zs=S2i4b&_zl=U9052).

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

To further expand the potential commercial opportunities for the Cell Pouch System, Sernova is conducting preclinical research with our Cell Pouch for the treatment of postoperative hypothyroidism, 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. Our initial 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. 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 setting 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.

The thyroid gland controls how quickly the body uses energy, makes proteins, and sensitivity to other hormones, principally through the production of thyroid hormones, mainly triiodothyronine (T3) and thyroxine (T4).

Hypothyroidism is a condition where the thyroid gland does not produce sufficient hormones thereby 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). Patients may undergo surgical reduction (thyroid lobectomy) or complete removal of the thyroid gland (thyroidectomy) for treatment of several disorders such as thyroid nodules, which are very common (up to 65% prevalence) (PMID: 19041821) in the general population; Grave's Disease (a type of hyperthyroidism); and or 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. et al, *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; however, 30-50% of thyroxine users do not achieve adequate hormone levels (Okosieme, OE et al. *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, ability to focus, and general mental well-being (Kansagra, S. et al. *Laboratory Medicine* 2010; 41(6):338-48.). In addition, long-term thyroid hormone administration may be associated with significant morbidity, and thus has many associated healthcare costs.

Developing new treatments for postoperative hypothyroidism is an unmet medical need. We believe that thyroid tissue transplanted into an implanted Cell Pouch offers a potential novel approach that could improve the quality of life and outcomes of patients experiencing postoperative hypothyroidism. Results of our ongoing preclinical research will be evaluated as a foundation for possible future clinical trials using the Cell Pouch in combination with thyroid-hormone producing cells.

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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 other rare disease indications to expand the application of our cell therapy platform technologies further.

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

We believe that therapeutic cell encapsulation and other advanced technologies such as gene-editing of cells may protect therapeutic cells from immune system attack within the Cell Pouch while providing the means to enable close association of therapeutic cells with the required microvessels and tissue matrix. Such approaches may enable long-term survival and function of therapeutic cells within the Cell Pouch for the treatment of multiple disease indications while also allowing the reduction or elimination of immunosuppression medications and their associated side effects.

Consequently, development of cellular local immune protection technologies is an important pillar for our cell therapy therapeutics platform. During 2020, we have been successful in executing our strategy to secure local immune protection technologies for our platform.

Our approach of protecting cells in a safe manner locally within the Cell Pouch tissue matrix may represent a competitive advantage as a biologically compatible approach, which may accelerate the development of our therapeutic programs. We believe that we are now well-positioned to advance our total regenerative medicine cell therapy therapeutics solution platform to multiple clinical applications and broader patient populations.

#### Cell Encapsulation Approach (Conformal Coating)

On June 15, 2020, we acquired an innovative cellular local immune protection technology from Converge Biotech, Inc. Pursuant to an asset purchase agreement, we acquired all intellectual property for a conformal coating cell encapsulation technology (Conformal Coating Technology), including issued patents, patent applications, and know-how.

The Conformal Coating Technology consists of a thin proprietary coating layer that effectively cloaks coated therapeutic cells to protect them from an auto-response attack by one's own immune system post cell transplantation into the body.

The advantages and potential benefits of this cell encapsulating technology are as follows:

- provides protection of the therapeutic cells from immune system attack locally within the Cell Pouch chambers potentially avoiding the need for life-long immunosuppression medications, that are typically required after cell transplantation;
- enables close contact of the transplanted therapeutic cells with the vascularized tissue matrix within the Cell Pouch to enable more intimate interactions unlike standard microencapsulation technologies in which the capsules are significantly larger than the cells limiting required tissue interactions;
- improves the diffusion of small molecules and biomolecules (i.e., glucose, insulin, and other proteins or hormones), providing a physiological glucose-stimulated insulin response without delay that occurs with other encapsulation technologies; and
- due to the improved diffusion of biomolecules, it may require a smaller load of therapeutic cells to achieve the desired therapeutic effect in comparison to standard microcapsules.

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On August 4, 2020, we announced entering into an exclusive, worldwide license with the University of Miami for the commercial rights to novel complementary conformal coating immune protection technologies, which enables Sernova to broaden the intellectual property and technology scope of its immune protection conformal coating technologies.

#### Cell Tolerance Approach (Gene Editing)

On May 29, 2020, we entered into a research collaboration with AgeX Therapeutics, Inc. to investigate their UniverCyte gene-editing technology to generate transplantable, universal locally immune protected therapeutic cells for use in combination with our Cell Pouch to provide a total regenerative medicine cell therapy therapeutic solution for the treatment of T1D and hemophilia A. The goal of this collaboration is to evaluate the technology as a next-generation local immune protection approach for therapeutic cells or tissue transplanted into the Cell Pouch.

UniverCyte uses a novel modified form of HLA-G, a potent immunomodulatory molecule, to mask transplanted therapeutic cells from immune detection and attack. The research collaboration will evaluate whether Sernova's pluripotent stem cell-derived therapeutic cells engineered with the UniverCyte technology can evade human immune detection. Research will include UniverCyte modification of multiple cell types, including stem cell-derived islets, stem cell-derived human factor-VIII releasing cells as well as adult donor-derived factor-VIII releasing cells. We believe that the combination of these technologies could enable the transplantation of therapeutic cells in patients within an off-the-shelf manner using Sernova's Cell Pouch, without human leukocyte antigen (HLA) tissue matching or concurrent administration of immunosuppressive medications.

We may evaluate additional complementary technologies in the future to further broaden and enhance Sernova's technology platform and expand market penetration potential for our future product offerings.

#### **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. The Company has a license agreement with the UHN for worldwide, exclusive rights to certain patented and patent-pending technologies for the advancement of glucose-responsive insulin-producing stem cells for treatment of patients with insulin-dependent diabetes. Process development and robust cell-production processes will provide a high standard of production of cells that consistently meets strict release criteria for evaluation of these cells in the Cell Pouch.

Sernova is also working on expanding collaborations with international pharmaceutical partners to evaluate various insulin-producing cell technologies using different approaches combining Sernova and partner technologies to create best in class therapeutic. This includes collaborations with global pharmaceutical companies to assess advanced glucose-responsive stem cell technologies with our Cell Pouch technologies. In addition, a collaboration with an international pharmaceutical company to study Sernova's Cell Pouch in a large animal diabetes model has been successfully conducted. The collaboration involved the study of safety, survival, and efficacy of locally immune protected therapeutic islets in our Cell Pouch in a proof-of-concept study.

Sernova plans to continue to establish additional collaborations with pharmaceutical companies for its diabetes and other clinical indications with the end goal to establish potential long-term licensing and

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co-development relationships. In addition to pharmaceutical companies, Sernova has entered collaborations with various academic institutions relating to its Cell Pouch technologies.

**cGMP Manufacturing**

We manufacture 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 via a contract manufacturer. Device specifications have been established, a semi-automated manufacturing process developed, and the product manufactured, packaged, and sterilized under strict regulatory guidelines suitable for testing in clinical trials in North America and Europe to complete the manufacturing process. Sterilization verification studies were completed, and the product previously released for testing in our human clinical trial in Canada with Sernova's ITA (Investigational Testing Authorization) under the jurisdiction of Health Canada. A two-year test has also been successfully completed demonstrating the stability of the product and packaging over this time period. Furthermore, Cell Pouches were also manufactured for our clinical study taking place at the University of Chicago and additional manufacturing of the Cell Pouch is currently in process to supply the required product for the completion of our Phase I/II trial and other collaborations.

**Intellectual Property**

Our international patent portfolio currently consists of issued and pending patents in multiple families covering our platform and related enabling technologies in important markets in North America, South 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 also going forward with our acquired local immune protection conformal coating intellectual property and that recently licensed from UMiami, 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.

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**RESULTS OF OPERATIONS****Selected Financial Information**

The selected financial information provided below is derived from the Company's interim condensed consolidated financial statements.

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|                                     | <u>Three months ended July 31,</u> |            | <u>Nine months ended July 31,</u> |              |
|-------------------------------------|------------------------------------|------------|-----------------------------------|--------------|
|                                     | 2020                               | 2019       | 2020                              | 2019         |
| Research and development expenses   | \$ 616,551                         | \$ 586,023 | \$ 2,218,648                      | \$ 1,330,637 |
| General and administrative expenses | 569,922                            | 291,280    | 2,066,364                         | 881,859      |
| Loss and comprehensive loss         | 1,195,580                          | 874,750    | 4,290,772                         | 2,211,855    |

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For the three months ended July 31, 2020, we recorded a loss of \$1,195,580, an increase of \$320,830 compared to the same period in the prior year. In general, the increase in G&A costs reflects a scaling up of our operations and corporate activities. The year-over-year increase is mainly attributable to the addition of personnel to support the growth of the Company; expanded investor relations and communication initiatives; and the granting of stock options and DSUs during the final quarter of the 2019 fiscal year. The stock options and DSUs granted were the first grants in a few years, and several grants recognized multiple years of past services provided by the grantees.

For the nine months ended July 31, 2020, the Company recorded a loss of \$4,290,772, an increase of \$2,078,917 compared to the same period in the prior year. This reflects increases in both R&D and G&A costs attributable to the factors noted above for the latest quarter, as well as the advancement of our US Phase I/II Cell Pouch Clinical Trial; the timing of grant contributions earned; and additional investment in patent protection for our technologies. R&D and G&A costs can vary significantly between reporting periods due to differences in timing of expenditures as well as the level and status of specific research and corporate activities. Components of both R&D and G&A costs and changes from period to period are further discussed below.

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**Research and Development Expenses**

|   | Three months ended July 31, |            | Nine months ended July 31, |              |
|---|-----------------------------|------------|----------------------------|--------------|
|   | 2020                        | 2019       | 2020                       | 2019         |
| Personnel costs                           | \$ 171,180                  | \$ 187,151 | \$ 512,318                 | \$ 564,577   |
| Contract services and consulting          | 93,875                      | 162,099    | 860,601                    | 704,689      |
| Lab operations                            | 692                         | 46,884     | 11,114                     | 153,627      |
| Manufacturing costs                       | 94,788                      | -          | 168,709                    | 13,404       |
| Patent fees and costs                     | 164,827                     | 121,717    | 401,139                    | 230,192      |
| License fees                              | 20,117                      | 20,000     | 20,117                     | 20,000       |
| Other costs                               | 2,863                       | 22,708     | 34,235                     | 97,974       |
| Amortization and depreciation             | 64,046                      | 14,493     | 134,224                    | 45,955       |
| Share-based compensation                  | 70,519                      | 21,185     | 237,194                    | 81,309       |
|   | 683,907                     | 596,237    | 2,379,651                  | 1,911,727    |
| Less: grant contributions and tax credits | (13,650)                    | (10,214)   | (107,297)                  | (581,090)    |
| Less: COVID-19 wage subsidy               | (53,706)                    | -          | (53,706)                   | -            |
|   | \$ 616,551                  | \$ 586,023 | \$ 2,218,648               | \$ 1,330,637 |

For the three months ended July 31, 2020, the Company incurred net R&D expenses of \$616,551, an increase of \$30,528 compared to the prior year. Although net R&D expenses remained relatively constant, the composition of the latest quarter's R&D costs changed and included Cell Pouch manufacturing costs for additional clinical trial product inventory, less US Phase I/II Cell Pouch Clinical Trial related contract service costs due to timing of patient procedures performed, increased share-based compensation expense and higher amortization and depreciation. Higher share-based compensation expense reflects the incremental impact of expense associated with the stock options granted during the final quarter of the 2019 fiscal year. An increase in amortization and depreciation for R&D (and G&A below) is directly attributable to the adoption of IFRS 16 *Leases* and depreciation of the newly recognized right-of-use asset (refer to Note 3 – *Summary of Significant Accounting Policies* to the Company's interim condensed consolidated financial statements for the three and nine months ended July 31, 2020, and 2019), although offset by a reduction in rent expense of a similar amount previously charged to lab operations in the table above. Amortization and depreciation also increased during the three months ended July 31, 2020, with amortization expense recognition initiation relating to the recently acquired Conformal Coating Technology intangible assets.

Net R&D expenses for the nine months ended July 31, 2020, increased \$888,011 to \$2,218,648 compared to the prior year. Total grant contributions and tax credits decreased by \$473,793 from the comparative period primarily due to the timing of JDRF milestone grant contributions being earned, which varies based on certain protocol-based patient procedures performed by our clinical trial investigator. Excluding earned grant contributions recognized during the nine months ended July 31, 2020, total R&D costs increased 24% from the same period in the prior year with increased contract services, patent prosecution, share-based compensation costs, and amortization and depreciation expense being the primary factors. The increase in contract services costs incurred regarding our US Phase I/II Cell Pouch Clinical Trial reflects additional patient enrolment and procedures conducted at the clinical trial site and increased CRO activities commensurate with the progression of our clinical trial. The factors for increased share-based compensation and amortization and depreciation expense noted above for the latest quarter had the same effect on the nine months year to date results. Patent fees and costs can significantly vary each quarter depending on the timing and scope of patent portfolio activities, with quarters or periods of increased costs reflecting increased activities and / or the timing of annual patent maintenance fees becoming due.

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**General and Administrative Expenses**

|                                    | Three months ended July 31, |            | Nine months ended July 31, |            |
|------------------------------------|-----------------------------|------------|----------------------------|------------|
|                                    | 2020                        | 2019       | 2020                       | 2019       |
| Personnel costs                    | \$ 117,321                  | \$ 46,253  | \$ 364,899                 | \$ 139,813 |
| Consulting fees                    | 17,829                      | 56,076     | 155,767                    | 65,076     |
| Professional fees                  | 6,019                       | 21,997     | 50,809                     | 85,881     |
| Director fees and expenses         | 30,962                      | 25,012     | 86,748                     | 75,037     |
| Investor relations                 | 265,349                     | 66,306     | 902,559                    | 294,409    |
| Other costs                        | 37,610                      | 60,786     | 160,473                    | 164,548    |
| Depreciation                       | 6,164                       | 541        | 18,450                     | 1,748      |
| Share-based compensation - DSUs    | 49,800                      | 6,469      | 203,831                    | 26,246     |
| Share-based compensation - options | 38,868                      | 7,840      | 122,828                    | 29,101     |
|                                    | \$ 569,922                  | \$ 291,280 | \$2,066,364                | \$ 881,859 |

Total general and administrative (G&A) expenses for the three months ended July 31, 2020, increased by \$278,642 compared to the same period in the prior year. The year-over-year increase was primarily attributable to an increase in investor relations and communication fees for expanded activities, higher personnel costs relating to the addition of personnel consistent with the evolution of the Company's operations, and the incremental impact of share-based compensation costs for stock options and DSUs granted during the final quarter of the preceding fiscal year. The increase in depreciation is due to the adoption of IFRS 16 *Leases*, with a similar approximate reduction in rent expense included in other costs in the table above.

Total G&A expenses for the nine months ended July 31, 2020, increased by \$1,184,505 compared to the same period in the prior year. This increase was attributable to the same factors noted above for the current quarter and higher consulting fees due to additional business development and corporate initiatives, with a modest partial offset for a reduction in professional fees.

**LIQUIDITY AND CAPITAL RESOURCES**

The selected financial information provided below is derived from the Company's interim condensed consolidated financial statements.

| As at  | July 31,<br>2020 | October 31,<br>2019 |
|--|------------------|---------------------|
| Cash and short-term investments                  | \$ 1,529,177     | \$ 3,804,137        |
| Total assets                                     | 2,908,181        | 5,568,541           |
| Current liabilities                              | 748,448          | 686,823             |
| Non-current liabilities (convertible debentures) | 676,869          | -                   |
| Total liabilities                                | 1,425,317        | -                   |
| Share capital, warrants and contributed surplus  | 48,235,740       | 47,343,822          |
| Deficit  | (46,752,876)     | (42,462,104)        |

The Company's interim condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. As at July 31, 2020, the Company had working capital of \$966,936 (October 31, 2019 – \$4,630,216) and for the nine months ended July 31, 2020 had a negative

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cash flow from operations of \$2,855,453 (2019 - \$2,339,541), excluding grant contributions received in the amount of \$658,755 (2019 - \$535,436). The Company has experienced operating losses and net cash outflows from operations since its inception.

We anticipate our cash requirements will be higher for the next twelve months as we progress in our US Phase I/II Cell Pouch Clinical Trial, accelerate development of our local immune protection technology assets, advance research collaborations and execute upon strategic initiatives. Some of the increased cash requirements anticipated for the US Phase I/II Cell Pouch Clinical Trial will be offset by additional milestone achievement draws against the Company's JDRF grant award. However, the progression of and related spending for certain R&D activities and / or initiation of activities associated with new collaborations will be dependent on available cash resources.

Until such time as the Company's biotechnology therapeutic products are approved and available for sale, the Company's liquidity requirements and its ability to continue as a going concern and fund its R&D programs, strategic initiatives, and operations will be dependent on its ability to raise additional financing by selling additional equity, from common share purchase warrant and stock option exercise proceeds, from licensing agreements or strategic collaborations, from non-dilutive sources such as new research grants and / or from securing credit facilities. Future financing will depend on many factors, including, but not limited to, market conditions which are not within the Company's control and the market acceptance of its products. No assurance can be given that any such additional financing will be available or that, if available, it can be obtained on terms favourable to the Company. See section "**RISKS AND UNCERTAINTIES**" and "**CAPITAL MANAGEMENT, FINANCIAL INSTRUMENTS AND RISKS**" in this MD&A.

These material uncertainties may cast significant doubt about the Company's ability to continue as a going concern and realize its assets and discharge its liabilities and commitments in the normal course of business. The Company's ability to continue as a going concern is subject to management's ongoing ability to successfully raise additional financing and ultimately generate cash flow from the commercialization of its products. Failure to do so could have a material adverse effect on the Company's financial condition and financial performance.

If the going concern assumption was not appropriate for the interim condensed consolidated financial statements, adjustments would be necessary to the carrying value of assets and liabilities, the reported expenses, and the classifications used in the interim condensed consolidated statements of financial position. The interim condensed consolidated financial statements do not include adjustments that would be necessary if the going concern assumption was not appropriate.

#### **Financing Activities**

Since the end of the latest quarter and up to the date of this MD&A, we raised ~\$3.7 million through a non-brokered private placement with the issuance of 12,218,333 units at \$0.30 per unit (2020 Units). Each 2020 Unit consists of a common share and common share purchase warrant, with each common share purchase warrant being exercisable into one common share at a price of \$0.35 per share for a period of two years from the date of issue, subject to abridgment of the exercise period if the 10-day volume-weighted price of the Company's shares exceeds \$0.50 per share. All securities issued in connection with the private placement were subject to a statutory hold period of four months. No finders' fees or finders' warrants were paid or issued, respectively.

During the fiscal quarter ended July 31, 2020, through a non-brokered private placement we issued unsecured convertible debentures (Debentures) for an aggregate principal amount and gross proceeds of \$1,000,000. Proceeds were used to finance the acquisition of our Conformal Coating Technology

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intellectual property, discussed elsewhere in this MD&A. The Debentures are repayable on December 8, 2022, unless earlier converted or redeemed, and bear interest at a rate of 8% per annum payable semi-annually, in cash or common shares at the option of the Company. The holder has the right to convert the principle amount into common shares of the Company at a conversion price of \$0.25 per share. The Company may prepay all or a part of the principal amount before maturity based on certain conditions and paying an early redemption premium equal to 2% of the amount redeemed. In conjunction with the Debentures issuance, 3,000,000 non-transferable common share purchase warrants (Warrants) were issued with each Warrant being exercisable into one common share at a price of \$0.20 per share up to December 8, 2022. Issue costs totaling \$30,860 were incurred. No finders' fees or finders' warrants were paid or issued, respectively. For more information, see *Note 6 – Convertible Debentures* to the Company's interim condensed consolidated financial statements for the three and nine months ended July 31, 2020, and 2019. The Debentures and Warrants, and any securities into which they may be exchanged or converted, are subject to a four-month hold period in accordance with applicable securities regulations.

During the three and nine months ended July 31, 2020, 100,000 stock options were exercised for cash proceeds of \$21,000 compared to the exercise of 1,250,000 stock options for cash proceeds of \$187,500 during the first quarter of fiscal 2019. No common share purchase warrants were exercised during the three and nine months ended July 31, 2020, nor during the 2019 comparative periods.

In September 2019, the Company completed a non-brokered private placement issuing a total of 23,422,822 units at \$0.20 per unit (2019 Units) for gross proceeds of \$4,684,564. Each 2019 Unit consists of one common share and one common share purchase warrant, with each common share purchase warrant being exercisable into one common share at a price of \$0.30 per share for a period of 3 years. The Company incurred legal costs and finders' fees totaling \$144,338 and issued 391,125 finder warrants valued at \$55,172. The terms of the finder warrants were identical to those of the common share purchase warrants of the 2019 Units issued.

During the first quarter ended January 31st of the prior 2019 fiscal year, 11,016,000 special warrants were converted into units resulting in the issuance of 11,016,000 common shares and common share purchase warrants for no additional consideration.

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**Common Shares**

|   | Number of<br>Common Shares |
|---|----------------------------|
| Balance outstanding as at October 31, 2019                        | 195,945,114                |
| Shares issued upon options exercise                               | 100,000                    |
| Balance outstanding, as at July 31, 2020                          | 196,045,114                |
| Shares issued in conjunction with private placement of 2020 Units | 12,218,333                 |
| Balance outstanding as at the date of this MD&A                   | 208,263,447                |

Further details on the common shares outstanding are provided in *Note 7 – Common Shares and Warrants* to the interim condensed consolidated financial statements for the three and nine months ended July 31, 2020, and 2019.

**Common Share Purchase Warrants**

|   | Number of<br>Warrants | Weighted Average<br>Exercise Price |
|---|-----------------------|------------------------------------|
| Balance outstanding as at October 31, 2019  | 35,411,647            | \$ 0.32                            |
| Issued in conjunction with convertible debenture financing to fund technology acquisition | 3,000,000             | 0.20                               |
| Expiry of Warrants  | (581,700)             | (0.35)                             |
| Balance outstanding as at July 31, 2020   | 37,829,947            | 0.31                               |
| Issued in conjunction with 2020 Units private placement                                   | 12,218,333            | 0.35                               |
| Broker warrants issued for 2020 Units private placement                                   | 198,310               | 0.35                               |
| Balance outstanding as at the date of this MD&A   | 50,246,590            | \$ 0.32                            |

Further details on the warrants outstanding are provided in *Note 7 – Common Shares and Warrants* to the interim condensed consolidated financial statements for the three and nine months ended July 31, 2020, and 2019.

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**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* to the interim condensed consolidated financial statements for the three and nine months ended July 31, 2020, and 2019.

|   | Number of<br>Options | Weighted Average<br>Exercise Price |
|---|----------------------|------------------------------------|
| Balance outstanding as at October 31, 2019                            | 14,574,600           | \$ 0.22                            |
| Options exercised   | (100,000)            | \$ 0.21                            |
| Balance outstanding as at July 31, 2020, and the<br>date of this MD&A | 14,474,600           | \$ 0.22                            |

|   | Number of DSUs |
|---|----------------|
| Balance outstanding as at October 31, 2019, July 31,<br>2020, and the date of this MD&A | 4,150,001      |

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 13.2% and 2.6% respectively of the then issued and outstanding common shares of the Company.

Further details on the stock options and DSUs outstanding are provided in *Note 7 – Common Shares and Warrants* to the interim condensed consolidated financial statements for the three and nine months ended July 31, 2020, and 2019.

**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. All product development activities to be performed by the Company were completed by October 31, 2019. The Company's final funding claim of €226,268 (\$329,207), included in amounts receivable as at October 31, 2019, was collected during the first quarter of the current fiscal year. The Company received total grant funding of €1,019,378 (approximately \$1.48 million).

During 2016, the Company was awarded a US\$2.45 million (\$3.3 million) grant from 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

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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\$48,340 (\$66,348) relating to milestone achievement was earned and received during the three months ended April 30, 2020. Remaining funding available to be advanced under the JDRF grant award totals approximately US\$1.43 million (\$1.9 million) as at July 31, 2020.

The Company expects to pay certain future costs related to preclinical and clinical trial activities. Such payments are expected to include the cost of our clinical / R&D personnel and related overheads, for patient procedures performed and activities related to the US Phase I/II Cell Pouch Clinical Trial, CRO costs, additional Cell Pouch manufacturing, clinical trial insurance, and outsourced or lab work and testing, and may include travel and a portion of drug or procedure-related expenses or transplantation expenses not covered by patients' 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 July 31, 2020, the remaining maximum gross lease payments total \$9,766 under the lease. As the Company has not entered into a long-term extension of the lease, the lease will be deemed to have been renewed on September 1, 2020, on a month-to-month basis with minimum rent of \$10,000 per month and terminable upon 90 days prior written notice by either party.

**RELATED PARTY TRANSACTIONS**

Key management personnel of the Company are 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 July 31, 2020, were amounts totaling \$85,579 due to key management personnel (October 31, 2019 – \$56,978).

Compensation to key management personnel for the three and nine months ended July 31, 2020, and 2019 were as follows:

|   | Three months ended July 31, |                   | Nine months ended July 31, |                   |
|---|-----------------------------|-------------------|----------------------------|-------------------|
|   | 2020                        | 2019              | 2020                       | 2019              |
| Personnel costs and consulting services | \$ 146,152                  | \$ 85,373         | \$ 454,205                 | \$ 350,749        |
| Director fees and expenses              | 30,962                      | 25,012            | 83,525                     | 74,086            |
| Share-based compensation - DSUs         | 49,800                      | 6,469             | 203,831                    | 26,245            |
| Share-based compensation - options      | 46,022                      | 29,026            | 142,137                    | 110,410           |
|   | <u>\$ 272,936</u>           | <u>\$ 145,880</u> | <u>\$ 883,698</u>          | <u>\$ 561,490</u> |

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.

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**SUMMARY OF QUARTERLY RESULTS**

The following table presents unaudited selected financial information for the eleven most recently completed fiscal quarters:

| Fiscal Year |                | 1 <sup>st</sup> Quarter | 2 <sup>nd</sup> Quarter | 3 <sup>rd</sup> Quarter | 4 <sup>th</sup> Quarter |
|-------------|----------------|-------------------------|-------------------------|-------------------------|-------------------------|
| 2020        | Loss           | \$ 1,361,978            | \$ 1,733,214            | \$1,195,580             |                         |
|             | Loss per share | 0.01                    | 0.01                    | 0.01                    |                         |
| 2019        | Loss           | \$ 723,748              | \$ 613,356              | \$ 874,750              | \$ 1,759,418            |
|             | Loss per share | 0.00                    | 0.00                    | 0.01                    | 0.01                    |
| 2018        | Loss           | \$ 766,355              | \$ 986,347              | \$ 1,111,556            | \$ 834,369              |
|             | Loss per share | 0.00                    | 0.01                    | 0.01                    | 0.00                    |

Loss for the third quarter of our 2020 fiscal year decreased by 31% from the second quarter, reflecting the aggregate effect of a 40% and 19% decrease in R&D & G&A costs, respectively. The sequential quarter decrease in R&D costs primarily reflected less clinical investigator patient-procedures performed and on-site CRO activities for our US Phase I/II Cell Pouch Clinical Trial due to both timing and some temporary COVID-19 trial site access restrictions. The decrease in G&A costs reflects one-time costs for certain corporate initiatives incurred in the second quarter as well as managing costs with the onset of the COVID-19 pandemic.

The loss for the fourth quarter of fiscal 2019 was significantly higher compared to the immediately preceding quarters due to the incremental effect of a one-time share-based compensation expense totaling approximately \$481,600 and recorded for immediately vested stock options and DSUs granted during that fourth quarter.

Compared to more recent historical levels, the higher loss for the last four fiscal quarters, excluding the higher share-based compensation noted, reflects expected higher costs commensurate with the increased activity level of the US Phase I/II Cell Pouch Clinical Trial, increased patent prosecution for expanding and strengthening protection of our technology portfolio as well as adding and building core competencies internally to support our future activities. In addition, during the current and three immediately preceding quarters, costs associated with expanded investor relations and communication activities increased operating expenses and contributed to a higher loss. However, these investor relations and communications costs will start to decline during next quarter, i.e. the fourth and final quarter of fiscal 2020, as certain contracts will expire and will not be renewed.

Lower quarterly losses during the first and second quarters of fiscal 2019, compared to the later quarters of fiscal 2018, reflect 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 2019 and 2018 quarterly results was mostly attributable to manufacturing development costs and the timing of grant contribution claims or milestones earned as overall operating costs were otherwise relatively consistent.

It is important to note that historical patterns of expenditures cannot be taken as an indication of future expenditures. The amount and timing of expenditures, and therefore liquidity and capital resources, may vary substantially from period to period depending on the business and research activities being

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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.

#### **CAPITAL MANAGEMENT, FINANCIAL INSTRUMENTS AND RISKS**

##### **Capital Management**

Our objective in managing capital, consisting of shareholders' equity, cash, cash equivalents, and short-term investments being its primary components, is to ensure sufficient liquidity to fund R&D activities, corporate, administration and business development expenses and working capital requirements. This objective has remained the same as that of the previous year.

Over the past two years, our primary sources of liquidity have been capital raised from private placements of equity and unsecured convertible debentures and the exercise of common share purchase warrants and stock options, as well as grant contributions funding.

As our policy is to retain cash to keep funds available to finance the activities required to advance our product development, we do not currently pay dividends. We are not subject to any capital requirements imposed by any regulators or by any other external source.

##### **Financial Instruments and 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 short-term investments, 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 short-term investments 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 short-term investments to provide regular cash flow for its operations and monitoring actual and projected cash flows. As at July 31, 2020 and October 31, 2019, the Company had cash and short-term investments of \$1,529,177 and \$3,804,137, respectively available to settle current liabilities of \$748,448 and \$686,823, respectively. The majority of the Company's accounts payable and accrued liabilities are due within three months or less. With the adoption of IFRS 16 *Leases* (IFRS 16), an initial lease liabilities amount of \$91,268 was recorded as a current liability on November 1, 2019, of which \$9,645 remains in current liabilities as

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of July 31, 2020. Repayment of non-current outstanding unsecured convertible debentures with a face value of \$1,000,000 is due on December 8, 2022, in approximately 2.3 years.

#### **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 when possible. The Company manages its interest rate risk by holding highly liquid short-term instruments. For the three months ended July 31, 2020, and 2019, the Company earned interest income of \$11,607 and \$490, respectively. For the nine months ended July 31, 2020, and 2019, the Company earned interest income of \$35,874 and \$5,546, respectively. Interest income is not significant to the Company's projected operational budget. A 100-basis point change in the interest rate on short-term investments at July 31, 2020, and 2019, would have a net impact on interest income of \$14,312 and \$10,067, respectively, on an annualized basis.

In respect of financial liabilities, the Company's convertible debentures have a fixed interest rate of 8%.

#### **Foreign currency risk**

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

### **CRITICAL ACCOUNTING ESTIMATES**

The preparation of financial statements requires the Company to make judgments, 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, and 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. Furthermore, the full extent to which the novel coronavirus (COVID-19) pandemic will directly or indirectly impact the Company's estimates or results of operations will depend on future developments that are uncertain at this time. As events continue to evolve and additional COVID-19 information becomes available, the Company's estimates may change materially in future periods. 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 – Summary of 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**

Until such time as the Company's biotechnology therapeutic products are approved and available for sale, the Company's liquidity requirements will be dependent on its ability to raise additional financing by selling additional equity, from common share purchase warrant and stock option exercise proceeds, from licensing agreements or strategic collaborations and / or from securing credit facilities. The Company's future financing will depend on many factors, including, but not limited to, market conditions which are not

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within the Company's control and the market acceptance of its products. No assurance can be given that any such additional financing will be available or that, if available, it can be obtained on terms favorable to the Company. See *Note 13 – Capital Risk Management* and *Note 14 – Financial Instruments and Risk Management* to the Company's interim condensed consolidated financial statements for the three and nine months ended July 31, 2020.

These material uncertainties may cast significant doubt about the Company's ability to continue as a going concern and realize its assets and discharge its liabilities and commitments in the normal course of business. The Company's ability to continue as a going concern is subject to management's ongoing ability to successfully raise additional financing and ultimately generate cash flow from the commercialization of its products. Failure to do so could have a material adverse effect on the Company's financial condition and financial performance. Subsequent to the last quarter ended July 31, 2020, the Company closed a private placement of ~\$3.7 million, see *Note 15 - Events After The Reporting Period*.

If the going concern assumption was not appropriate for these interim condensed consolidated financial statements, adjustments would be necessary to the carrying value of assets and liabilities, the reported expenses, and the classifications used in the interim condensed consolidated statements of financial position. The interim condensed consolidated financial statements do not include adjustments that would be necessary if the going concern assumption was not appropriate.

#### **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.

#### **Discount rates**

The discount rate used for any impairment analysis and to calculate the net present value of the convertible debentures is based on management's best estimate of an appropriate industry peer group weighted average cost of capital and management's best estimate of the Company's risk levels. Changes in the general economic environment could result in significant changes to this estimate.

#### **Convertible instruments**

Convertible debentures are compound financial instruments which are accounted for separately by their components: a financial liability and an equity instrument. The financial liability, which represents the obligation to pay coupon interest on the convertible debenture in the future, is initially measured at its fair value and subsequently measured at amortized cost. The residual amount is accounted for as an equity instrument at issuance.

The identification of convertible debenture components is based on interpretations of the substance of the contractual arrangement and therefore requires judgement from management. The separation of the components affects the initial recognition of the convertible debenture at issuance and the subsequent recognition of interest on the liability component. The determination of the fair value of the liability is also based on a number of assumptions, including contractual future cash flows, discount rates and the presence of any derivative financial instruments.

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#### **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.

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

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

###### *IFRS 16 Leases*

On November 1, 2019, the Company adopted IFRS 16 using the modified retrospective approach measuring the right-of-use asset at an amount equal to the lease liability. This approach does not require restatement of prior period financial information as it recognizes the cumulative effect as an adjustment to opening retained earnings and applies the standard prospectively. The cumulative effect of initially applying IFRS 16 was recognized as a \$91,268 right-of-use asset with a corresponding lease liability. Refer to *Note 3 – Summary of Significant Accounting Policies* to the Company's interim condensed consolidated financial statements for the three and nine months ended July 31, 2020.

#### **RISKS AND UNCERTAINTIES**

*An investment in our common shares involves a high degree of risk and should be considered speculative. An investment in our common shares should only be undertaken by those persons who can afford the total loss of their investment. You should carefully consider the risks and uncertainties described below, as well as other information contained in this MD&A. The risks and uncertainties below are not the only ones we face.*

*Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition, and results of operations could be seriously harmed, and you could lose all or part of your investment. Further, if we fail to meet the expectations of the public market in any given period, the market price of our common shares could decline. We operate in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of our control.*

##### **Investment Risk**

***Volatility of share price, absence of dividends, and fluctuation of operating results.*** Market prices for the securities of biotechnology companies, including ours, have historically been highly volatile. During the nine months ended July 31, 2020, our common shares traded on the TSX Venture Exchange at a high

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of \$0.35 and a low of \$0.095 per share (2019 fiscal year – high of \$0.28 and low of \$0.145 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, stock options, and / or convertible debenture conversion rights are exercised, which may result in dilution. As of the date of this MD&A, we had 14.5 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, 50.2 million outstanding warrants with an average exercise price of \$0.32 per share and \$1.0 million of debentures convertible into 4.0 million common shares. On a fully diluted basis, we would have approximately 281 million common shares outstanding.

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

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#### **Issuer Risk**

*We face risks related to the COVID-19 pandemic, health epidemics, and other outbreaks, which could materially and adversely affect our business, financial condition, and results of operations.* In December 2019, COVID-19 emerged in Wuhan, China. During March 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. In response to the outbreak, governmental authorities around the world introduced various recommendations and measures to mitigate the spread of COVID-19, including restrictions on travel, border closures, quarantines, forced closures for certain types of public places and non-essential businesses and social distancing. The recommendations and measures are having a significant impact on the private sector and individuals, including unprecedented business, employment and economic disruptions.

The COVID-19 pandemic has impacted the Company's business to some extent. Our US Phase I/II Clinical Trial was impacted by the temporary COVID-19 related closure of the medical clinic at the University of Chicago and clinical trial and CRO personnel working remotely, which had the effect of slowing the screening of prospective trial participants, the conduct of patient procedures and some clinical trial data collation activities. The closure has been eased and the conduct of patient procedures has resumed. To make up time, efforts are underway at the clinical trial site to expedite the rescheduling of impacted patient procedures and patient enrollments that were varied states of progress when the site closure occurred. COVID-19 has also impacted the progression of some international research collaboration activities due to third-party facility access and travel restrictions; however, provisions are being made to minimize the impact on collaboration activities.

In response to the COVID-19 pandemic, we have implemented protocols and procedures for the safety and protection of our employees, contractors, service providers and collaborators. COVID-19 could further impact the Company's expected timelines and operations, or the operations of our CRO, our third-party service providers or suppliers and our contract manufacturer, as a result of quarantines, facility closures, travel and logistics restrictions and other limitations in connection with the outbreak. The most significant risks posed by the COVID-19 pandemic is that it could significantly impact the progress and completion of our US Phase I/II Clinical Trial and the advancement of our preclinical and collaborative research activities.

It is unknown how long the adverse conditions associated with COVID-19 will last and what the complete financial effect will be to the Company. Depending on the duration of the COVID-19 pandemic and actions taken or extended by federal, provincial, state or international governments and public health officials could result in:

- delays or difficulties in enrolling patients or retaining patients in our clinical trials if patients are affected by the virus or are unable to travel to our clinical trial site;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal, provincial or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- limitations on employee resources focused on the conduct of our preclinical studies and clinical trials, due to sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays or difficulties in clinical site initiation for new studies, including difficulties in recruiting clinical site investigators, clinical site staff and study subjects; and
- limited access to third-party laboratory facilities to conduct preclinical activities or progress our research collaborations.

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To the extent the COVID-19 pandemic, or other health epidemic or outbreak, adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in the "**RISKS AND UNCERTAINTIES**" section of this MD&A. Because of the highly uncertain and dynamic nature of events relating to the COVID-19 pandemic, it is not currently possible to estimate its impact on our business, results of operation and financial condition beyond that discussed above. However, these effects could have a material impact and we will continue to monitor the COVID-19 situation.

***Early-stage development and scientific uncertainty.*** Our products are at an early stage of development. Significant additional investment in R&D, 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 System platform.*** All of our current product candidates involve the use of our Cell Pouch System 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 System 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 System 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 System platform, including cell immune protection to treat insulin-dependent diabetes and the use of factor VIII releasing cells in combination with the Cell Pouch System 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 R&D efforts or other operations.*** We will require substantial additional funds for further R&D, 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

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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.

***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 preclinical and clinical data necessary to gain approval may change during the course of our products' clinical development and may vary among jurisdictions. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and even if the preclinical 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 preclinical 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 nor 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

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- 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;
- 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 preclinical 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 involve 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.

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

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

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

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

***We may expend our limited resources to pursue particular R&D 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 R&D 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 R&D programs and therapeutic cell candidates may not yield any commercially viable products.

We have based our R&D efforts on assessing various therapeutic cells within our Cell Pouch System platform. As a result of pursuing the development of certain therapeutic cells within the Cell Pouch System 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 sublicense agreement with UHN, dated September 9, 2015, for the development of stem-cell product candidates. In addition, we are dependent upon our license to use certain local immune protection technology provided under sublicense agreement with UMiami, dated July 28, 2020, for expanded protection of therapeutic cells placed inside our Cell Pouch. 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 favorable 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 successfully commercialize any product to which it has rights, or any partner's product to which we will have rights, our business may be adversely

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affected. Failure of a collaborative partner to continue to participate in any particular program could delay or halt the development or commercialization of products generated from such program. In addition, there can be no assurance that the collaborative partners will not pursue other technologies or develop alternative products either alone or in collaboration with others, including our competitors, as a means for developing treatments for the diseases targeted by our programs.

Furthermore, we may require licenses for certain technologies, and there can be no assurance that these licenses will be granted or, if granted, will not be terminated, or that they will be renewed on conditions acceptable to us. We intend to negotiate additional licenses in respect of technologies developed by other companies and academic institutions. Terms of license agreements to be negotiated may include, inter alia, a requirement to make milestone payments, which may be substantial. We will also be obligated to make royalty payments on the sales, if any, of products and payments on any sublicensing revenue derived from the 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, canceled, 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

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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, products or technologies.

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 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 R&D, clinical testing, and application for regulatory approval of our product candidates. For the three and nine months ended July 31, 2020, we incurred losses of \$1,195,580 and \$4,290,772 (2019 - \$874,750 and \$2,211,855) and had an accumulated deficit to July 31, 2020 of \$46.8 million. We expect to incur further losses unless and until such time as payments from corporate collaborations, product sales, and/or royalty payments generate sufficient revenues to fund our continuing operations.

***Conflict of interest.*** Certain of our directors and senior officers may, from time to time, be employed by or affiliated with organizations 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

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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 might 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 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 governed by Canadian law. 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.

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

#### **Industry Risk**

***Rapid technological change.*** The biotechnology and pharmaceutical industries are characterized by rapid and substantial technological change. There can be no assurance that developments by others will not render our proposed products or technologies non-competitive, or that we will keep pace with technological developments. Competitors have developed or are developing technologies that could be the basis for competitive products. Some of these products have an entirely different approach or means of accomplishing the desired therapeutic effect as compared with products to be developed by us and could be more effective and less costly than the products to be developed by us. In addition, alternative forms of medical treatment may be competitive with our products.

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

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

## **SERNOVA CORP.**

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

**FOR THE THREE AND NINE MONTHS ENDED JULY 31, 2020 AND 2019**

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materials cannot be completely eliminated. In the event of such an accident, we could be held liable for damages, and such liability could exceed our resources. We are not specifically insured with respect to this liability. Although our management believes that it currently complies in all material respects with applicable environmental laws and regulations, we may be required to incur significant costs to comply with environmental laws and regulations in the future. Furthermore, there can be no assurance that our operations, business, or assets will not be materially adversely affected by current or future environmental laws or regulations.

***Status of healthcare reimbursement.*** Our ability to successfully market certain therapeutic products may depend in part on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Significant uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement. Furthermore, challenges to the price of medical products and services are becoming more frequent. There can be no assurance that adequate third-party coverage will be available to establish price levels, which would allow us to realize an acceptable return on our investment in product development.

***Potential product liability.*** Pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Product liability insurance is costly, and availability is limited and may not be available on terms 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**

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|------------------------|--|
| Frank Holler           | Director and Chairman of the Board                               |
| Jeffrey Bacha          | Director and Compensation Committee Chair                        |
| James Parsons, CPA, CA | Director and Audit Committee Chair                               |
| Deborah Brown          | Director and Nominating and Corporate Governance Committee Chair |
| Dr. Philip Toleikis    | President, Chief Executive Officer, and Director                 |
| David Swetlow, CPA, CA | Chief Financial Officer  |

## **ADDITIONAL INFORMATION**

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