



SERNOVA CORP.

MANAGEMENT'S DISCUSSION AND ANALYSIS

**FOR THE YEARS ENDED
OCTOBER 31, 2021, AND 2020**

Dated February 14, 2022

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

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The following management's discussion and analysis (MD&A) explains the consolidated operating results, financial position, and cash flows of Sernova Corp. (Sernova, the Company, We, Us, or Our) for the three months and years ended October 31, 2021, and 2020. This MD&A should be read in conjunction with the Company's audited consolidated financial statements and related notes for the years ended October 31, 2021, and 2020, 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, 2021, and 2020. All amounts are in Canadian dollars. The information in this report is dated as of February 14, 2022, 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 to patients with the Cell Pouch™ transplanted with therapeutic cells or tissue;
- the conduct of preclinical studies and clinical trials of our Cell Pouch and Cell Pouch System™ for the treatment of insulin-dependent diabetes, thyroid disease, hemophilia A and other clinical indications, and the Company's ability to conduct its clinical studies;
- the expected benefits to patients of our Cell Pouch diabetes cell therapy program;
- the expected benefits to patients of our Cell Pouch thyroid disease cell therapy program;
- the expected benefits to patients of our Cell Pouch hemophilia A cell therapy program;
- the Company's intention to protect therapeutic cells within the Cell Pouch from immune

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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 and the expected benefits therefrom;

- the expected benefits of any next generation Cell Pouch System technologies;
- the Company's intentions and ability to secure academic and pharmaceutical / medtech collaborations to develop and implement partnering strategies and manage partnerships;
- the Company's intention and ability to use human autograft cells or tissues or human donor allograft cells 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 various diseases;
- the Company's 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 A, thyroid disease, and other diseases;
- the Company's intentions and ability to obtain Orphan Drug, Fast Track, Breakthrough Technology, Regenerative Medicine Advanced Therapy (RMAT), Accelerated Approval or Priority Review in the US, and similar regulatory designations in North America, Europe or other jurisdictions abroad, and the related impact on timeline estimates to conduct clinical trials and or obtain marketing approval for the Company's products;
- the Company's expectations that Sernova's technologies are unique and may become a standard of care in therapeutic cell transplantation if they continue to prove to be safe and effective in clinical trials;
- the Company's expectations with respect to the research and development of Sernova's products, clinical trials, and commercialization of our products;
- the Company's sales and marketing strategy for our technologies including Cell Pouch or Cell Pouch System and associated technologies;
- the Company's intentions regarding the development and protection of Sernova's intellectual property;
- the Company's intentions with respect to obtaining licenses for technologies compatible with the Cell Pouch System;
- the Company's intention to develop next-generation Cell Pouch or Cell Pouch System 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) and variants and any other further global health emergencies on our business and operations, including supply chain, manufacturing, research and development costs, clinical trials including patient enrollment, contracted service providers and employees; and
- the Company's 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.

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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:

- the Company's ability to manage its growth effectively;
- the expected benefits to patients of our technologies including Cell Pouch and Cell Pouch System cell therapy programs;
- the absence of material adverse changes in our industry or the global economy;
- trends in our industry and markets;
- the Company's ability to comply with current and future regulatory standards;
- the Company's ability to protect its intellectual property rights;
- the Company's continued compliance with third-party license terms and the non-infringement of third-party intellectual property rights;
- the Company's ability to attract and retain key personnel; and
- the Company's ability to raise sufficient equity or debt financing to support continued growth and operational needs.

There are a number of important factors that could cause Sernova's actual results to differ materially from those indicated or implied by forward-looking statements and information, including but not limited to: early-stage development and scientific uncertainty, lack of product revenues and history of losses, additional financing requirements and access to capital, patents and proprietary technology, dependence on collaborative partners, licensors, contract manufacturing organizations (CMOs) 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, fluctuation of operating results and the impacts of the continuing novel coronavirus (COVID-19) pandemic. 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 associated with COVID-19 and as 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

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Directors. The Company's Audit Committee includes two independent Directors and the Executive Chairman of the Company, who are all financially knowledgeable.

ABOUT SERNOVA

Sernova is a clinical-stage regenerative medicine therapeutics company focused on development and commercialization of our proprietary technologies, including Cell Pouch implantable device technologies and immune-protected therapeutic cells, herein termed Cell Pouch System. The Cell Pouch System is a technology platform, for the treatment of and a potential 'functional cure' for chronic debilitating diseases including type 1 diabetes (insulin-dependent diabetes or T1D), thyroid disease, and rare diseases such as hemophilia A. The Cell Pouch is a scalable, implantable, medical device, designed to create a highly vascularized organ-like environment for the transplantation and engraftment of therapeutic cells, which then release proteins and / or hormones into the microvasculature for the long-term treatment of various chronic diseases. The therapeutic cells used for therapeutic purposes may be autograft cells or tissues (self-cells / tissues) or allograft cells (non-self, donor cells) or allograft cells derived from sources known to provide a virtually unlimited supply of cells such as human stem cell-derived cells or from a xenogeneic (non-human) source. Furthermore, the therapeutic cells may be unmodified or may be genetically modified to produce their therapeutic product.

Our preclinical and clinical research studies to date support the safety and biocompatibility of the Cell Pouch and long-term survival and function of therapeutic cells transplanted into the vascularized Cell Pouch chambers. Our data demonstrates that, following implantation of the Cell Pouch deep under the skin or in other locations in the body, vascularized tissue incorporates through pores in the device forming fully enclosed vascularized tissue chambers. Upon transplantation of therapeutic cells into these vascularized chambers a natural tissue matrix forms around the cells along with microvessels to the cells, enabling them to engraft (survive and function). Thus, an anticipated benefit of the Cell Pouch is formation of a natural environment for the therapeutic cells that provides for enhanced long-term therapeutic cell survival and function. We believe this is due in part to the therapeutic cells living in a natural tissue matrix within close contact of microvessels. We believe our unique approach in providing a natural environment for therapeutic cells and its ease of use may provide an opportunity for Sernova's technologies including the Cell Pouch System to become the standard of care in therapeutic cell transplantation for multiple diseases if they continue to demonstrate safety, tolerability and clinical benefit in preclinical and clinical trials.

As noted in our latest Annual Information Form (AIF), filed under the Company's SEDAR profile at www.sedar.com on February 8, 2021, our research activities during the past three years have focused on the development of the Cell Pouch System platform as a potential new treatment for various therapeutic indications including T1D, hemophilia A, thyroid disease and additional chronic debilitating and rare diseases. We have also entered into strategic collaborations and acquired or in-licensed related technologies to expand and support our research efforts. Earlier history of the corporate development of the Company and its business is also available on SEDAR.

RECENT AND SELECT 2021 FY CORPORATE HIGHLIGHTS

(NOTE - recent R&D highlights are noted below under the relevant R&D program section)

February 2022: Echelon Capital Markets initiated coverage on Sernova and issued an analyst report with a Speculative Buy rating.

January 2022: iA Capital Markets (part of Industrial Alliance / iA Financial Group) initiated coverage on Sernova and issued an analyst report with a Speculative Buy rating.

January 2022: We participated in the LifeSci Partners Corporate Access Event, the H.C. Wainwright BIOCONNECT Virtual Conference and JP Morgan One-on-One Partnering meetings.

December 2021: We announced the appointment of investment industry executive Christopher Barnes as VP, Investors Relations. Mr. Barnes has over 20 years of experience in investor relations and capital markets, including institutional sales.

December 2021: We announced the appointment of Frank Holler, Sernova's Board Chairman, to the new role of Executive Chairman to augment our leadership team and further support our evolving corporate and R&D activities and objectives.

November 2021: We provided an investor presentation at Canaccord Genuity's MedTech, Diagnostics and Digital Health & Services Forum virtual event.

September 2021: We engaged New York based LifeSci Advisors LLC, a leading investor relations consultancy firm serving life science companies, to assist with elevating visibility and awareness of Sernova in the US markets and amongst institutional investors as well as targeted outreach initiatives.

August / September 2021: We provided an investor presentation at H.C. Wainwright's 23rd Annual Global Investment Conference and Canaccord Genuity's 41st Annual Growth Conference virtual events.

July 2021: We announced the results of Sernova's 2021 Annual General Meeting of Shareholders. All proposed resolutions, including the appointment of incumbent company directors and new director Dr. Mohammad Azab, were approved by a majority of shareholders.

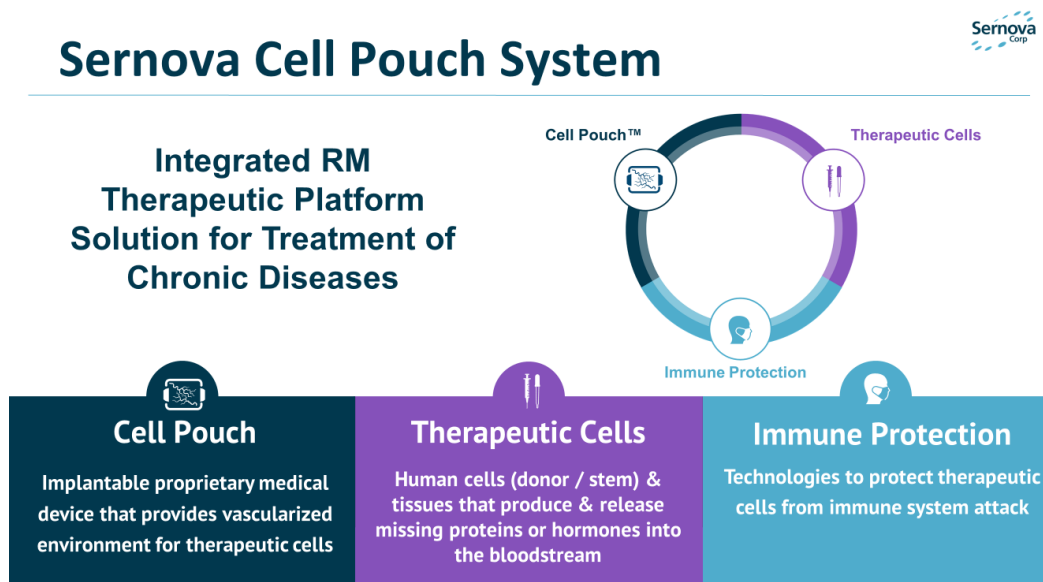
June 2021: We announced the appointment of pharmaceutical industry veteran Frank Shannon as VP Clinical Development and Regulatory Affairs. With over 25 years of experience, Mr. Shannon has served in senior level positions in the international medical device, pharmaceutical, and biologics industries.

May 2021: We presented Sernova's story and vision at the Global Partnership Family Office (GFPO) - HealthCare & Biotechnology TSX Showcase hosted by London, UK based International Deal Gateway. Sernova was one of five leading healthcare, biotechnology and life sciences companies put forward by the TMX Group and invited to present to GFPO investors in London, Geneva, Zurich and other key European markets at this virtual event.

March 2021: We announced the March 1st, 2021 closing of our \$20M upsized bought deal unit financing, and the full exercise of the 15% over-allotment option held by the underwriters, resulting in the issuance of 19,205,000 units at \$1.20 per unit for total proceeds of \$23 million.

BUSINESS OVERVIEW

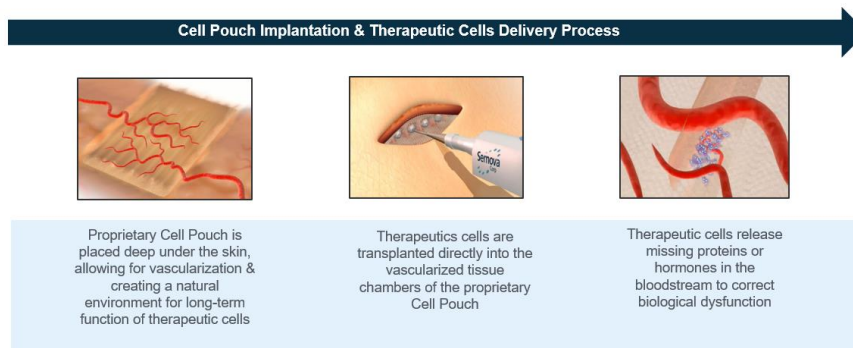
Sernova Cell Pouch System: A Platform Approach



Sernova's patented Cell Pouch System is designed to take into consideration the biological requirements of therapeutic cells. This is achieved through the establishment of an organ-like environment defined as a vascularized tissue matrix for therapeutic cells, which develops within the device chambers following implantation. Our novel approach seeks to provide for the ability for therapeutic cells to be protected locally from immune system attack within the Cell Pouch or through systemic immune protection medications. We believe this unique approach of allowing vascularized tissue incorporation into the device also helps prevent the issue of fibrosis that has plagued prior-generation implantable cell therapy devices and provides a biologically suitable environment for the engraftment and function of therapeutic cells.

The Cell Pouch is designed to be scalable to match the required cell dose for each clinical application. Our research demonstrates that following Cell Pouch implantation deep under the skin or in other locations, vascularized tissue chambers develop within the device. In long-term preclinical studies, it has been shown that the Cell Pouch maintains 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 believe Sernova's approach also solves potential issues of other competing implantable devices with therapeutic cells pre-inserted prior to the device being implanted into the body which may result in hypoxia, ischemia, cell death (resulting in poor engraftment) related to a lack of an integrated vascularized tissue environment into which cells are transplanted.

Biologically Compatible Delivery Process



We have demonstrated in a series of ISO 10993 biocompatibility studies, multiple animal studies, a pilot human clinical trial and an ongoing US Phase 1/2 clinical trial that the Cell Pouch is biocompatible and safe. Long-term studies in several animal models have demonstrated that following transplant, insulin-producing islets become well-supported with microvessels, similar to their natural pancreatic environment. An anticipated benefit of the Cell Pouch is enhanced short and long-term therapeutic cell survival and function, which we believe is due in part to cells being transplanted into a natural tissue matrix within close contact of microvessels. For diabetes, as an example, this close vessel proximity enables islets to continuously monitor blood glucose levels and produce the appropriate amount of insulin into the bloodstream. We believe the Cell Pouch platform technologies may achieve this ideal therapeutic / microvessel connection through interaction with the local tissue environment. Our preclinical 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 also observed encouraging preclinical results in other therapeutic cell applications, such as hemophilia A with corrected patient cells gene-edited to produce factor VIII, the missing protein preventing blood clotting, and hypothyroid disease with patient transplanted thyroid tissue with the goal to replace the function of the removed thyroid gland.

The cells transplanted into the Cell Pouch may be protected from immune system attack, when required, by systemic medications or through other local Cell Pouch immune protection technologies such as microencapsulation or conformal coating of cells. Microcapsules surrounding the cells have tiny pores, which have been shown to provide a means to allow nutrient and protein exchange within the local vascularized environment while preventing immune system attack. Conformal coating is a proprietary technology forming a cross-linked polymer coating around cells using a 'shrink wrap' approach that may also provide protection from immune system attack and has been shown to allow natural glucose and insulin flow in and out of cells, respectively, Sernova is also evaluating gene editing technologies for our stem cell-derived programs that may provide an alternative method of cellular immune protection. These approaches alone or in combination are anticipated to reduce or eliminate the requirement of anti-rejection medications targeted to our therapeutic cell applications across a range of disease indications.

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Thus, we believe our technology platform approach and its minimally invasive implantation approach through placement deep under the skin may provide an opportunity for the Cell Pouch System to become the standard of care for treatment of multiple diseases with the goal for a ‘functional cure’ if these technologies continue to demonstrate safety and clinical benefit in clinical trials and achieve marketing approval from regulatory agencies.

Pipeline – Life Cycle Iterations and Multiple Indications



Product Candidate	Therapeutic Cell Source	Immune Protection	Indication	Pre-Clinical	Phase 1/2	Phase 3	Market Approval Application
Cell Pouch System	Human donor islet cells	Immunosuppressives	Type 1 Diabetes				
2 nd Gen System	Human donor islet cells	Local immune protection					
3 rd Gen System	Stem cells	Local immune protection					
Cell Pouch System	Corrected patient cells	Auto geneic cells	Hemophilia A - Severe				
2 nd Gen System	Allograft immune protected stem cells	Local immune protection	Hemophilia A – All patients				
Cell Pouch System	Thyroid cells	Auto geneic cells	Thyroid Diseases / Hypothyroidism				
2 nd Gen System	Allograft immune protected stem cells	Local immune protection	Thyroid Diseases / Hypothyroidism				

Development of the Cell Pouch System Platform for the Treatment of Diabetes / T1D

The goals of our T1D program are to provide people with T1D the ability to better control their diabetes, an improved quality of life and ultimately a ‘functional cure’ to this disease.

According to the International Diabetes Federation ([IDF](#)), there are approximately 463 million people worldwide with diabetes, and nearly 10% of these individuals have T1D (insulin-dependent) diabetes where the cells in the pancreas that control blood sugar levels through release of insulin have stopped functioning or have died allowing blood sugar levels to rise resulting in short and long term debilitating effects of the disease. In particular, the market for people with diabetes who suffer from hypoglycemia unaware events represents a significant subpopulation of diabetic patients that could be addressed by Sernova’s approved products - depending on receiving final clearance from regulatory authorities following completion of clinical studies. The subset of people with T1D and hypoglycemia unawareness, affects about 17% of people with T1D according to diabetesnet.com.

The primary treatment for of T1D is insulin injections by needle or insulin pump. The life of a person with diabetes is consumed with the constant attempt to control blood sugar levels to minimize both the acute effects of hypoglycemia and severe long-term effects of diabetes, which include heart and kidney disease, blindness, and amputations. There is a critical need to improve the treatment of people with diabetes and to improve the quality of life of these individuals. Sernova believes its Cell Pouch System

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technologies may provide a significant improvement in the quality of life of these individuals as well as an improvement in the efficacy and reduction of diabetes-related side effects in these people relative to the current standard of care of insulin by needle injection or pump. The goal of the cell therapy approach for T1D is to replace the insulin-producing cells of people with diabetes that have been lost from the pancreas and to transplant them into a retrievable vascularized device to produce insulin and other needed regulatory hormones to improve the quality of life of patients with the ultimate goal to return blood sugar status to a healthy state.

Our most advanced development program involves the clinical development and validation of the Cell Pouch System for the treatment of people with T1D who suffer from unstable diabetes and severe life-threatening hypoglycemia unawareness. The current cell therapy treatment for portal vein transplantation, is transplantation of donor islets in the portal vein of the patient's liver. This first-generation cell therapy approach, which involves the transplantation of pancreatic donor islets, often from multiple donors, into a patient's portal vein in which islets lodge in the microvasculature of the liver. Life-long systemic immunosuppressive drugs are required to inhibit rejection of the transplant. A portal vein islet transplantation is the only cell therapy treatment available for this population of people with diabetes and is only occasionally offered to reduce the occurrence of severe hypoglycemic episodes when in these patients. Portal vein islet transplant is categorized as an experimental procedure by regulators, including the United States Food and Drug Administration (USFDA), and may only be administered under a clinical trial protocol.

It is encouraging that islet cell transplantation, even into the portal vein in humans, when considered a first step proof-of-concept for diabetes cell therapy treatment has shown some positive outcomes for diabetic patients. These positive effects demonstrate the potential of a cell therapy treatment approach for diabetes.

Despite the positive effects, there are a number of issues with portal vein delivery of either donor islets or stem cell derived technologies that we believe could be improved with Sernova's technologies. For example, following islet infusion with portal vein delivery, there is a significant reduction in the number of surviving islets due to an immediate blood-mediated inflammatory reaction (IBMIR), which may damage and destroy a substantial proportion of the islet cells infused into the portal vein. Due to this persistent death, often islets from multiple donor organs are required to achieve blood sugar control. Paradoxically, while a small dose of islets into the portal vein may be safe, undesirable portal vein hypertension, thrombosis, and liver steatosis (fatty liver) may occur following multiple cell transplants limiting the number of doses of cells that can be infused into the portal vein. A further shortcoming of portal vein transplant is that infusion of cells into the portal vein is currently limited to available donor islets and for safety reasons is not easily amenable to technologies such as glucose-responsive insulin-producing stem cell-derived cells, or xenogeneic cells being developed to overcome the limited supply of donor islet cells as these cells are not retrievable. The only way to explant liver infused cell technologies is to remove the liver, requiring a liver transplant, which becomes a life-threatening issue due to the lack of donor organs.

As noted in Table 1 below, we believe the Cell Pouch System can alleviate a number of important issues with portal vein transplantation. With the Cell Pouch System, the therapeutic cells live within a tissue matrix surrounded by microvessels, similar to the islets' natural microenvironment rather than being subjected to a constant flow of blood with immune-reactive cells, which is believed to lead to IBMIR. We believe Cell Pouch transplant will eliminate the portal infused inflammatory response enabling

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improved islet survival and to potentially lower the number of islets or other sources of insulin-producing cells that need to be transplanted. Consequently, in improving the cell therapy placement, fewer donor pancreata (a marginal islet cell dose) than what are currently being used for portal vein transplantation is anticipated to be required. In addition, known side effects of multiple infusions into the portal vein along with the costs of treating them are expected to be eliminated with the use of Sernova’s Cell Pouch System, especially as we develop glucose responsive stem cell-derived technologies (see Table 1).

Table 1. Potential Benefits of the Cell Pouch Islet Transplant over the Portal Vein Islet Transplant

Characteristics	Cell Pouch	Portal Vein Transplant
Marginal (small) islet number for efficacy	Yes	No
Tissue matrix to house islets	Yes	No
Improved vascularization of islets	Yes	No
Retrievable site	Yes	No
Safe stem cell-derived 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

While infusion of glucose responsive stem cell derived technologies into the portal vein may appear to be a solution to the limited supply of donor islets, the issues with portal vein transplant including IBMIR and the inability to retrieve the cells, if required, still remain.

With the encouraging initial results of portal vein islet transplantation, there is a need to develop a more suitable and retrievable environment for therapeutic cells. We believe an implantable and retrievable medical device that becomes highly vascularized when implanted into an appropriate area of the body for the placement and function of therapeutic cells, including donor islets and stem cell-derived technologies is a feasible and more sustainable approach. Sernova’s Cell Pouch is a minimally invasive, retrievable device that develops vascularized tissue chambers for the placement and long-term survival and function of therapeutic cells following implantation in the body and it is scalable to house different numbers of cells for the production of needed missing protein(s) or hormone(s).

Importantly, the Cell Pouch technologies are specifically and uniquely designed to be biocompatible featuring pores that incorporate with vascularized tissue, forming chambers to support the survival and function of therapeutic cells. A serious problem that may be encountered with other implanted therapeutic medical devices is the development of unwanted fibrosis in which the body treats the device as foreign and walls off the device with scar tissue resulting in starving of the cells of oxygen and nutrients. We believe the unique design of the Cell Pouch device prevents the formation of scar like fibrosis tissue following implantation enabling a suitable environment for the long-term survival and function of therapeutic cells.

As a novel approach beyond portal vein infusion of islets, we believe that islets (donor or stem cell derived) transplanted into the Cell Pouch may provide a better means to optimize cell therapy for the

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treatment of diabetes. Preliminary results in the most advanced treated patients in our current US Phase 1/2 Cell Pouch Clinical Trial using donor islets. We believe this may provide a basis for optimal development of glucose-responsive immune-protected stem cell-derived cells for transplant into the Cell Pouch as a life-changing treatment not only for diabetic patients suffering from severe hypoglycemia unawareness but also for the broader population, potentially involving millions of people suffering from T1D.

Sernova's Cell Pouch technologies are 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 following implantation 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.

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 initially anticipated number of cells (marginal islet dose) to achieve efficacy, one of the parameters being investigated and optimized in human clinical evaluation to achieve glucose control in patients with diabetes.

We have successfully manufactured our Cell Pouch at a medical device contract-manufacture facility in compliance with ISO13485, EU Medical Devices Regulation MDR 2017/745, United States Food and Drug Administration Quality System Regulations (QSR) 21 CFR 820 and Canadian Medical Device Regulation (CMDR).

We have also transplanted donor islets into our Cell Pouch treating insulin-dependent diabetes in multiple small and large animal models (syngeneic, autograft and allograft) of diabetes. As part of several collaborations with pharmaceutical companies we have also demonstrated that stem cell derived technologies in the Cell Pouch can provide long-term insulin independence in small animal models of diabetes. This is of key importance as we develop our technologies with a source of cells that has the potential to treat all patients with T1D.

Based on these encouraging preclinical results, we conducted a first-in-human proof of principle clinical study for the treatment of human diabetes subjects with hypoglycemia unawareness. Patients received donor islets, protected by the standard of care cell protection drug regimen in a Canadian study, approved by Health Canada. The approach of using human donor islets in the Cell Pouch enabled Sernova to understand the behaviour of transplanted insulin-producing cells in the Cell Pouch in humans as an initial step to the development of an immune-protected cell product to treat the larger treatable population of patients with diabetes.

This safety, tolerability proof-of-concept first-in-human clinical study we completed in Canada, demonstrated initial safety and tolerability results 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 showed 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, were well-vascularized, living within a natural tissue matrix, and able to make insulin, glucagon and other key hormones important in the control of blood glucose levels and hypoglycemic events.

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.

Type 1 Diabetes Phase 1/2 US Clinical Trial for Diabetic Subjects with Severe Hypoglycemia Unawareness

With the 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, tolerability as well as function of the Cell Pouch with therapeutic cells. 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. This clinical study is lending to our understanding of the relationship between the dose and dose density of islets in the Cell Pouch and safety and efficacy measures in patients with long standing T1D and hypoglycemia unawareness as we progress our development of a cell therapy approach to the treatment of T1D for all patients with diabetes. Continuous glucose monitoring (CGM), mixed meal tolerance tests and daily insulin use are used to track the function of the cells transplanted into the Cell Pouch and to assess efficacy measures at multiple time points during the course of the clinical trial.

Following a peer review of the new clinical protocol, Sernova was awarded up to US\$2.45 million (approximately \$3.0 million) grant under an agreement with JDRF. The grant is supporting our Cell Pouch Phase 1/2 diabetes clinical trial, which is being conducted at the University of Chicago in collaboration with Principal Investigator Dr. Witkowski, M.D., Ph.D., Director of the University of Chicago's Pancreatic, and Islet Transplant Program, who is a leading expert in diabetes and islet transplantation and 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.

This clinical trial is a Phase 1/2 non-randomized, unblinded, single-arm, company-sponsored trial to evaluate the safety and efficacy of the Cell Pouch as a potential treatment for diabetic patients with hypoglycemia unawareness (US Phase 1/2 Cell Pouch Clinical Trial).

Patients eligible for the study have long standing T1D, severe hypoglycemic unawareness and a history of severe hypoglycemic events despite optimized medical care, and also lack the ability to produce insulin from their pancreas, as shown in a glucose tolerance test by the lack of necessary blood levels of C-peptide, a quantitative biomarker of islet insulin production. The trial is designed to enroll seven (7) patients who are implanted with therapeutic Cell Pouches, and small sentinel pouches. Following the development of vascularized tissue chambers within the Cell Pouch, enrolled patients are stabilized on immunosuppression and activated on the donor transplant list. Upon receipt of a suitable donor pancreas and following isolation of islets, a small dose of purified islets under strict release criteria is transplanted into the Cell Pouches.

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A sentinel pouch, also transplanted with islets, is removed at approximately 90 days following transplant for an early assessment of islet function within the Cell Pouch. Our US Phase 1/2 Cell Pouch Clinical Trial study was designed so that subjects are followed for safety, tolerability 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 small islet dose with subsequent safety and efficacy follow-up. Patients are then followed for approximately one year and thereafter may receive a protocol-defined portal vein top-up dose of islets. The goal of providing several doses is to help us understand the relationship between dose and efficacy level as well as dose density in the Cell Pouches required to achieve maximum efficacy. Thereafter, Dr. Witkowski follows the patients longer term.

We have reported preliminary findings that support the safety, viability, and efficacy of the Cell Pouch System approach for the treatment of diabetic patients with severe hypoglycemia unawareness and the inability to produce their own insulin. Following removal of a sentinel device transplanted with islets and independently assessed by a pathologist, healthy abundant islets intimately associated with blood vessels housed in a natural tissue matrix were observed, showing the ability to produce insulin. Of significant importance, we have observed the following early diabetes improvement indicators. Fasting and glucose-stimulated blood levels of C-peptide (a biomarker of insulin produced by cells), a reduction in the number of severe hypoglycemic events, HbA1c, as well as other parameters have been observed in the most advanced trial patients. We believe these suggest a normalizing response of the Cell Pouch's therapeutic cells to the body's varied need for insulin production.

We believe these ongoing preliminary 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 goal of developing and optimizing a treatment for all T1D patients employing immune protected stem cell-derived islet clusters within our Cell Pouch.

We believe the Cell Pouch can be used with a variety of cell sources, 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 and we have demonstrated this in several pharmaceutical collaborations in small animal models of T1D. Using our extensive learnings of human donor islets within the Cell Pouch, Sernova is developing stem cell derived technologies including our licensed technology from the University Health Network in Toronto, Ontario to provide an immune-protected cell-based therapeutic for all subjects with insulin-dependent diabetes.

CGM used in this study supports the analysis of mean glucose concentration, mean glucose variability, number and duration of hyper and hypoglycemic episodes as well as total duration of hypoglycemia.

On July 3, 2019, we announced early findings in a preliminary analysis of the first patient in our US Phase 1/2 Cell Pouch Clinical Trial. Highlights of the preliminary findings included:

- no incidences of serious adverse events determined to be related to the Cell Pouch implant;
- the Cell Pouch was well-incorporated with vascularized tissue, which enabled successful transplant of the purified islets;
- the patient experienced stabilizing improvements in all glycemic control parameters as indicated CGM including an 87.5% reduction in hypoglycemic events from baseline collected

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over a two-week monitoring period; and

- presence of stimulated blood levels of C-peptide and insulin at the observed 90-day post-transplant point as indicated in a mixed meal tolerance test.

On October 16, 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 US Phase 1/2 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.

On February 13, 2020, we announced that the first patient treated in our US Phase 1/2 Cell Pouch Clinical Trial demonstrated survival of endocrine tissue (insulin-producing islets) in the sentinel Cell Pouch removed and assessed following 90 days after transplant and that the islets were confirmed to produce insulin.

On June 18, 2020, we announced the presentation of a peer-reviewed abstract "*Clinical Validation of the Implanted Pre-Vascularized Cell Pouch as a Viable, Safe Site for Diabetes Cell Therapy*" at the virtually hosted 80th Scientific Sessions of the American Diabetes Association (ADA). The data presented clinically demonstrate that the vascularized Cell Pouch provides a consistently safe and biologically suitable, retrievable environment for the transplantation and survival of functional islets.

On November 18, 2020, we provided a Clinical Update on our US Phase 1/2 Cell Pouch Trial, noting that 5 of 7 patients had been enrolled in the study defined by meeting the enrollment criteria and implanted with the Cell Pouch. Further, that these subjects were actively advancing through the transplantation phase of the study. We further announced that pre-screening was ongoing in order to recruit the final two patients in the study.

On January 15, 2021, we announced that Dr. Piotr Witkowski presented interim data from our US Phase 1/2 Cell Pouch Clinical Trial study at the American Society of Transplant Surgeons (ASTS) 21st Annual State of the Art Winter Symposium in a peer-reviewed abstract entitled "*Islet Allotransplantation Into Pre-Vascularized Sernova Cell Pouch – Preliminary Results from The University of Chicago*". Dr. Witkowski reported Sernova's Cell Pouch transplanted with insulin-producing cells in patients with T1D continues to show persistent islet function and clinically meaningful improvement in measures of glucose control and highlighted the following key points (as of November 2020):

- 5 of 7 patients had been enrolled in the study;
- 5 patients had been implanted with the Cell Pouch;
- 3 patients had received their first islet transplant;
- 2 patients had received their first and second islet transplant; and
- the remaining 2 patients were actively being pre-screened to complete enrolment for the trial.

Data from two transplanted patients who are furthest in the study and who have received a second islet transplant were further reported on by Dr. Witkowski. Importantly, these patients demonstrated improvement in clinical indices with reduction in daily injectable insulin requirement, along with the following additional clinical benefit indicators:

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- absence of life-threatening severe hypoglycemic events;
- sustained blood levels of C-peptide (a biomarker for insulin produced by cells in the Cell Pouch);
- reduction in HbA1c (a measure of long-term glucose control); and
- improvement in overall Continuous Glucose Monitoring (CGM) measured glucose control parameters (i.e., blood glucose 'Time in Range').

With clinical benefit demonstrated in these patients with Cell Pouch islets, the longest treated patient was later provided a single marginal infusion of islets (portal vein). We believe this top-up to the islets already received in the Cell Pouch contributed to this patient achieving and sustaining insulin independence for nine months (as of November 2020).

On February 18, 2021, we announced that an independent Data Safety Monitoring Board (DSMB) completed its second planned annual review of our US Phase 1/2 Cell Pouch Clinical Trial. The DSMB is an independent group of clinical research physicians who review the accumulated safety data throughout the clinical trial to safeguard the safety of the participating patients. The DSMB did not raise concerns regarding safety and recommended continuation of the study.

On April 6, 2021, President and CEO Dr. Toleikis as an invited presenter delivered an update on Sernova's Regenerative Medicine Therapeutics Platform and our diabetes program at the 2021 Cell and Gene Therapy Meeting on the Med virtual conference.

On June 5, 2021, Dr. Piotr Witkowski presented new preliminary data from our US Phase 1/2 Cell Pouch Clinical Trial at the American Transplant Congress (ATC) 2021 Virtual Connect conference. Dr. Witkowski's presentation entitled "*Islet Allograft Transplantation Into The Pre-Vascularized Sernova Cell Pouch™ Device - Preliminary Results Of The Phase 1/2 Prospective, Open-Label, Single-Arm Study At University of Chicago*" highlighted the following key points:

- 6 patients were enrolled and implanted with Cell Pouches and continued to meet the study's primary safety endpoint;
- 5 patients were transplanted with at least one dose of therapeutic cells (insulin producing islets) and were in different stages of the clinical trial; and
- positive fasting serum C-peptide had been detected in the bloodstream of 4 patients so far. (C-peptide is a biomarker for insulin produced by the islets in the Cell Pouch).

In addition to the continued confirmation of ongoing safety and tolerability in all currently enrolled patients, Dr. Witkowski provided further updates on the longest treated study patients. These patients have continued to show defined clinical benefit associated with ongoing efficacy indicators including:

- reduction / elimination in the need for daily injectable insulin;
- continued improvement, i.e. reduction/elimination, in Severe Hypoglycemic Events (SHE);
- persistent detection of fasting and stimulated C-peptide in patients' bloodstream;
- reduction in HbA1c; and
- continued improvement of glucose control determined through patient blinded Continuous

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Glucose Monitoring (CGM) and measured by reduction of Time Above Range (TAR) and increase of Time in Range (TIR).

On June 28, 2021, Dr. Piotr Witkowski and the Clinical Trial Team for our US Phase 1/2 Cell Pouch Clinical Trial presented additional data and patient observations from the ongoing study at the American Diabetes Association's 81st Scientific Sessions. Data was delivered in a poster presentation entitled "*Persistent graft function after allotransplantation into pre-vascularized Sernova Cell Pouch™ device: Preliminary results from the University of Chicago.*" Dr. Witkowski confirmed continued safety and tolerability in all six enrolled study patients. In addition, the two longest-treated patients continue to demonstrate clinical benefit in line with previously established key T1D efficacy indicators including reduction in HbA1c, reduction or elimination of severe hypoglycemic events (SHE), reduction or elimination of daily injectable insulin, detection of C-peptide in the patients' bloodstream, and improvement in glucose control as measured by CGM. The remaining patients are advancing through the study at different stages and their progress continues to be evaluated.

The most advanced patient has successfully completed the study protocol. Data from this patient supports the long-term safety of Sernova's Cell Pouch and, importantly, the patient then remained insulin independent (no requirement for injectable insulin) for approximately 15 months - with optimal glucose control.

On October 12, 2021, Dr. Toleikis provided a corporate update presentation at the Alliance of Regenerative Medicine (ARM) Cell and Gene Meeting on the Mesa virtual event.

On December 16, 2021, we announced that Dr. Piotr Witkowski would release updated interim data from our US Phase 1/2 Cell Pouch Clinical Trial study on January 13th, 2022, at the American Society of Transplant Surgeons (ASTS) 22nd Annual 'State of the Art' Winter Symposium from his peer-reviewed abstract entitled "*A Modified Approach for Improved Allotransplantation into the Pre-vascularized Sernova Cell Pouch*". Due to COVID-19 concerns, the ASTS conference was subsequently postponed to July 2022.

On January 10, 2022, with the postponement of the 2022 ASTS meeting, we reported on the highlights of Dr. Witkowski's updated interim data for our US Phase 1/2 Cell Pouch Clinical Trial as follows:

- ongoing safety and tolerability of Cell Pouch has been maintained in all study patients;
- islet transplantation to the Cell Pouch resulted in the establishment of new, measurable islet function documented by detectable levels of stimulated C-peptide in the first three patients, who completed the protocol-defined course of transplants;
- a supplemental, single intraportal islet transplant was sufficient for the first two patients to achieve and maintain sustained ongoing insulin independence and freedom from severe hypoglycemic events for over 21 and 2 months, respectively;
- the third transplanted patient recently completed their course of Cell Pouch transplants and a supplemental intraportal islet infusion, with favorable improvements in glucose control, near-normal levels of C-peptide, an absence of severe hypoglycemic events and reductions in daily insulin use;
- the other three enrolled study patients are progressing through the study protocol, as planned. All have received Cell Pouch implants and are at various stages of protocol-defined islet transplants

and follow-up; and

- the final (7th) study patient has been identified.

Recruitment, screening and enrollment finalization of the final (7th) study patient for our US Phase 1/2 Cell Pouch Clinical Trial continues and remains a top priority.

The preliminary results to-date for our US Phase 1/2 Cell Pouch Clinical Trial are very encouraging and are providing important information on the behaviour of our device with donor islets in real life situations in our study patients. As the therapeutic benefit of Sernova's Cell Pouch with donor islets for T1D continues to be demonstrated and validated, we progress in our ongoing pursuit of developing and commercializing a 'functional cure' for people with T1D using Sernova's Cell Pouch System technologies.

Further trial information may be found at <https://www.clinicaltrials.gov/ct2/show/NCT03513939>.

Development of the Cell Pouch System for the Treatment of Postoperative Hypothyroidism

The goals of our thyroid transplant program are to provide people with hypothyroid disease improvement in the natural thyroid hormone feedback loop, an improved quality of life and ultimately a 'functional cure' to this disease.

According to the American Thyroid Association (ATA), 20 million Americans currently live with thyroid disease, and 12% of Americans will develop a thyroid condition during their lifetime. The thyroid gland produces and secretes thyroid hormones that regulate the body's metabolism and is thus essential for life. Developing new treatments for thyroid disease is an unmet medical need. We believe that thyroid tissue transplanted into an implanted Cell Pouch offers a novel approach that could improve the quality of life and outcomes of patients experiencing postoperative hypothyroidism. Sernova's first approach in the treatment of hypothyroid disease is to transplant healthy thyroid tissue of patients undergoing thyroidectomy into the pre-implanted vascularized Cell Pouch with the goal to retrieve the natural feedback system for release of thyroid hormones.

The thyroid gland affects all critical body functions including heart rate, energy levels, and the rate at which energy is produced from nutrients. Its essential functions include control of 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 reported to occur in up to 65% of patients (PMID: 19041821); 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

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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. Published research indicates up to 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 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.

Results of our preclinical research is being used as a foundation for anticipated clinical trials using the Cell Pouch in combination with thyroid-hormone producing cells with the goal to preserve thyroid function and improve patient quality of life.

In this regard, Sernova has conducted preclinical research with our Cell Pouch for the treatment of postoperative hypothyroidism. To advance this platform technology, in collaboration with Dr. Sam Wiseman, BSc, MD, FRCSC, FACS, Professor, Faculty of Medicine, University of British Columbia and in part funded by a Transplant Venture Grant awarded by the Transplant Research Foundation (TRF) of British Columbia, we have assessed healthy human thyroid tissue transplanted into a previously implanted Cell Pouch in a preclinical model, in preparation of a clinical program. 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 proof-of-concept of this novel approach.

On April 30, 2019, we announced a collaboration with the University of British Columbia for development of a Cell Therapy-based program for the treatment of hypothyroidism under the direction of Dr. Sam Wiseman, thyroid surgeon and researcher, and the Director of Research in the Department of Surgery at Providence Healthcare in Vancouver, BC, Canada.

The results to date from this collaboration have been encouraging and support the potential of transplanted thyroid tissue to provide clinical benefit for the treatment of hypothyroidism.

On April 14, 2021, we announced the appointment of internationally renowned thyroid disease expert Dr. Sam Wiseman to Sernova's Scientific Advisory Board.

On April 28, 2021, Sernova hosted a virtual Thyroid Disease key opinion leader (KOL) event, led by internationally renowned expert Dr. Sam Wiseman, that highlighted the potential of our novel Cell Pouch cell therapy approach for the potential treatment of thyroid disease.

On January 27, 2022, we announced the publication of a peer reviewed preclinical study demonstrating positive results for our novel Cell Pouch System cell therapy approach to treat hypothyroidism and potentially avoid lifelong dependence on thyroid medication following surgical removal of the thyroid gland. The journal article entitled "Subcutaneous transplantation of human thyroid tissue into a pre-vascularized Cell Pouch™ device in a Mus musculus model: Evidence of viability and function for

thyroid transplantation” by lead author, Dr. Sam M. Wiseman BSc, MD, FRCSC, FACS, was published in the prestigious scientific journal PLOS ONE, January 20, 2022 edition.

We are currently preparing a regulatory submission to seek authorization to initiate a company sponsored first-in-world clinical trial for thyroid patients with significant unmet need requiring a cell transplantation approach. We plan to submit the application for this clinical trial in 2022 for study initiation pending clearance by regulatory authorities.

Development of the Cell Pouch System for the Treatment of Hemophilia A

The goals of our hemophilia program are to provide people with hemophilia A improvement in the natural production of FVIII in their bloodstream from FVIII corrected cells within the Cell Pouch, to reduce bleeds associated with this disease, an improved quality of life and ultimately a ‘functional cure’ to this disease.

Hemophilia A is a rare, serious genetic bleeding disorder caused by missing or defective clotting factor VIII in the bloodstream. A cellular genetic deficiency in factor VIII (FVIII) results in a reduced ability for blood to clot naturally resulting in increased bleeding. Bleeding can occur even in circumstances where small blood vessels naturally break and heal such as in joints, resulting in inflammatory arthritic type symptoms and joint damage in the Hemophilia A patient. To counteract this reduction in blood clotting, patients require frequent blood transfusions which put them at risk of acquiring blood-borne infections, such as HIV, hepatitis B and hepatitis C. The alternative is taking infusions of FVIII up to three times a week to maintain a blood level of FVIII that can reduce the bleeding.

According to a 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.

We believe that the therapeutic potential to have a constant release of FVIII from a hemophilia A patient’s own genetically corrected cells placed within the implanted Cell Pouch would be a very significant advancement in the treatment of hemophilia A and could be highly disruptive to the current standard of care treatment. We are evaluating the technology to expand the potential commercial opportunities for the Cell Pouch System. Corrected cells placed in an implanted Cell Pouch could release FVIII at a rate expected to reduce disease-associated hemorrhaging and joint damage. The continuous delivery of FVIII 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 FVIII as prophylaxis for the prevention of bleeding in patients with hemophilia A.

Sernova’s approach to the cell therapy treatment of hemophilia A involves taking a small blood sample from the patient, correcting the genetic defect in isolated cells in the laboratory, and then expanding the cell numbers and test safety before placement into our Cell Pouch for constant release of FVIII. We believe that the therapeutic potential to have a constant release of FVIII from a hemophilia A patient’s own genetically corrected cells placed within the implanted Cell Pouch would be a significant advancement in the treatment of hemophilia A and other diseases that can be treated with genetically engineered cells. The use of the Cell Pouch with therapeutic cells for hemophilia could reduce or eliminate the need for patients to take expensive infusions of FVIII, which is currently conducted on a regular basis for prophylactic treatment.

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Proof-of-concept studies were initiated during 2016 by Sernova and a European team of experts collectively forming the HemAcure Consortium (HemAcure Consortium). The aim of the HemAcure Consortium's three-year project was to develop a permanent, safe, therapeutic solution for those living with hemophilia A in the form of a novel ex vivo gene therapy, cell-based approach within Sernova's proprietary Cell Pouch. Our goal is to permanently replace missing clotting human FVIII in the patient's own Blood Outgrowth Endothelial Cells (BOECs) transplanted into the Cell Pouch. These corrected cells are to function to release FVIII into the bloodstream restoring the ability for blood clotting to occur during periods of bleeding. The HemAcure Consortium was funded by a €5.6 million (approximately \$8.5 million) European Commission Horizon 2020 grant (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.

The multi-year HemAcure Consortium project has been successfully completed, and the Company has completed its project collaboration obligations. We have received full payment in the amount of €1,019,378 (approximately \$1.48 million) for Sernova's portion of the Horizon 2020 Grant.

On May 19, 2020, the HemAcure Consortium presented the scientific results of the consortium's HemAcure Hemophilia Cell Therapy Program research, noted above, at the 23rd American Society of Gene & Cell Therapy (ASGCT) Annual Meeting. The results support the potential of using genetically corrected cells from a patient's own BOECs transplanted into the Cell Pouch to replace missing clotting human FVIII in patients with hemophilia A.

The following are the highlights of the results presented in the peer-reviewed abstract entitled "*Combined Gene and Cell Therapy for the Treatment of Hemophilia A within an Implantable Therapeutic Device*":

- BOECs were safely isolated and grown from a small sample of circulating peripheral blood of volunteer hemophilia A patients unable to express the required FVIII for clotting;
- to regain the function of the BOECs' ability to produce clotting FVIII, techniques were successful in safely inserting the gene responsible for the correction and production of human FVIII into the patient's BOECs, and these corrected cells were safely multiplied to increase their number;
- tests were conducted to ensure the safety, and the newly corrected BOECs produced enough human FVIII both in the laboratory and in an initial preclinical animal model deficient of FVIII. Human FVIII blood levels reached up to 10%, a therapeutically relevant level of FVIII;
- to further test cell dose-response, in the preclinical model of hemophilia A, animals originally unable to clot their blood were implanted with a vascularized Cell Pouch and transplanted in different groups with several different doses of human BOECs corrected for the ability to produce human FVIII;
- to assess the safety of the combined product, the Cell Pouch and corrected human FVIII BOECs derived from the volunteer participants with hemophilia A were examined using histological analyses. Importantly, histology showed healthy tissue represented by the presence of stromal growth and new blood vessel formation within the Cell Pouch;
- histological investigation of the transplanted Cell Pouch sections demonstrated long-term survival of human FVIII BOECs present within the vascularized Cell Pouch achieved through

co-staining for blood vessels (von Willebrand Factor stain) and the presence of the patients corrected human cells (HLA-ABC stain);

- in both experimental doses, human FVIII was detected in circulating peripheral blood up to 4 months following transplantation, with more human FVIII present in peripheral blood using the higher dose of corrected BOECs; and
- data further confirmed functional clotting improvement in the blood at the four months time point where FVIII BOECs transplanted into the hemophilia A mouse model restored the animal's FVIII activity at a therapeutic level in the Cell Pouch.

During December 2021, the results of the HemAcure Consortium's study were published in a journal article entitled "*Efficient and Safe Correction of Hemophilia A by Lentiviral Vector-Transduced BOECs in an Implantable Device (Sernova's Cell Pouch™)*" in the prestigious scientific journal *Molecular Therapy: Methods & Clinical Development*, Volume 23.

We believe these published results demonstrate the potential of our Cell Pouch System to provide a novel approach for the treatment of hemophilia A using an ex vivo gene therapy, cell-based technology that could lead to improved efficacy and quality of life of people suffering from hemophilia A.

The proposed hemophilia A therapy is paving the way for future human clinical testing in hemophilia A patients using Sernova's Cell Pouch transplanted with genetically corrected FVIII releasing cells developed by the HemAcure Consortium team.

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

We are exploring the potential use of our technology for the treatment of other rare disease indications to further expand the application of our Cell Pouch and cell therapy platform technologies further.

On January 28, 2021, we provided a Collaborations Update highlighting Sernova now has multiple research collaboration agreements with global pharmaceutical companies. In this regard, Sernova is deploying its in-house cell therapy expertise and proprietary Cell Pouch technologies in combination with proprietary therapeutic cell assets designated by the pharmaceutical collaborators to conduct proof of concept studies for a number of potential clinical indications. These collaborations with leaders in the pharma industry build upon our business strategy to develop a portfolio of therapeutic technologies to realize the full potential of Sernova's regenerative medicine platform. We believe partnering with multiple pharmaceutical companies not only will expand our therapeutic treatment potential but also provides a de-risked approach for Sernova as we develop our technologies and bring new therapies to patients with the goal to provide people with a functional cure for multiple chronic and rare diseases. To date we have obtained encouraging results assessing various stem cell-derived technologies for a number of clinical indications and are continuing to advance these collaborations with the goal of achieving long-term development partnerships.

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 vascularized environment 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 the 2020 fiscal year, we secured by acquisition and licensing local immune protection technologies for our Cell Pouch cell therapy 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.

Cellular Conformal Coating Approach

The goals of our conformal coating program are to provide people protection of transplanted therapeutic cells without the need for life long antirejection medications by providing a cellular local immune protection of their transplanted cells, resulting in an improved quality of life.

In June 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 technology (Conformal Coating Technology), including issued patents, patent applications and know-how. This technology acquisition provides a pivotal component required for our regenerative medicine therapeutics platform and could accelerate our first-to-market strategy for T1D and significantly expand the number of treatable patients suffering from chronic diseases.

The Conformal Coating Technology consists of a thin proprietary coating layer designed to surround therapeutic cells with the goal 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 Conformal Coating Technology are anticipated 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 currently 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
- 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.

In August 2020, we announced entering into an exclusive, worldwide license with the University of Miami (UMiami) 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.

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In September 2021, we announced a collaboration with the University of Miami and Dr. Alice Tomei, a leading international expert in immunoprotection and diabetes management from the renowned Diabetes Research Institute (DRI) at the University of Miami Miller School of Medicine, to validate our Conformal Coating Technology in combination with therapeutic cells in Sernova's Cell Pouch for T1D. Under the terms of the agreement, the Company has committed to fund a one-year budget of up to US\$833,154 (approximately \$1,052,357). Dr. Tomei is one of the original inventors of the Conformal Coating Technology that has been developed and optimized over 12 years with her dedicated team. This important collaboration is multifaceted in nature and designed to advance for the first time locally immune protected cells within the Cell Pouch with the goal of advancing these technologies into clinical trials without the need for immune suppression technologies. We believe successful development of this combination technology could meet an unmet need in a much broader population of people with T1D who seek a 'functional cure' for their diabetes without the need to take life-long immunosuppression medications.

Subsequent to the collaboration announcement, in September 2021 we hosted an information session webinar "*The Ultimate Combination of Two Proven Technologies as a Potential Functional Cure for Type 1 Diabetes and Other Chronic Diseases*". The webinar featured Dr. Tomei, who spoke about the use of our Conformal Coating Technology as a technology approach for local cellular immune protection. The webinar is available on the Sernova website at www.sernova.com/investor/#News_Releases/ or at <https://youtu.be/U57fkmsBT7k>.

Cell Tolerance Approach (Gene Editing)

In May 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 FVIII releasing cells as well as adult donor-derived FVIII 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.

Sernova's Access to Multiple Sources of Therapeutic 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.

Pursuant to our strategy of obtaining sources of supply for our therapeutic cell 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 and patent-pending technologies for the advancement of glucose-responsive insulin-producing stem cells for treatment of patients with insulin-dependent diabetes. 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. 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 expanding its 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 therapeutics. 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 xenogeneic therapeutic islets in our Cell Pouch in a proof-of-concept study.

We have demonstrated long-term insulin independence in several collaborations with global pharmaceutical partners using advanced stem cell-derived diabetes technologies within the Cell Pouch in accepted animal models of T1D. This work supports the concept that the Cell Pouch combined with an advanced stem cell source meant to provide an unlimited supply of therapeutic cells could provide a solution for millions of people with T1D.

Sernova plans to continue to establish and develop additional collaborations with pharmaceutical and medtech companies for its diabetes and other clinical indications with the end goal to have long-term licensing and / or co-development relationships. In addition to pharmaceutical companies, Sernova has entered collaborations with various academic institutions relating to its Cell Pouch technologies for next-generation products.

Sernova Acquisitions and Collaborations

AgeX Collaboration

On May 29, 2020, Sernova announced a collaboration with AgeX Therapeutics, Inc. ("AgeX"), a biotechnology company developing therapeutics for human aging and regeneration, where Sernova would utilize AgeX's UniverCyte™ gene technology to generate immune-protected universal therapeutic cells for use in combination with Sernova's Cell Pouch for treatment of T1D diabetes and hemophilia A. Sernova's goal is to eliminate the need for immunosuppressive medications following Cell Pouch cell transplantation.

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The research collaboration is evaluating whether Sernova's pluripotent stem cell-derived pancreatic islet beta cells engineered with AgeX's UniverCyte technology can evade human immune detection. The complementary combination of technologies could enable the transplantation of therapeutic cells in patients with T1D in an off-the-shelf manner using Sernova's Cell Pouch, without human leukocyte antigen (HLA) tissue matching or concurrent administration of immunosuppressive medications. With a similar intent, pluripotent stem cell-derived or adult donor-derived human Factor VIII-releasing cells modified with AgeX's UniverCyte will be evaluated in Sernova's hemophilia A program.

Under the terms of the agreement, Sernova is granted a time-limited, non-exclusive research license by AgeX. A commercial license for Sernova to utilize UniverCyte to engineer cellular products for therapeutic and commercial purposes may be negotiated between the companies pending successful study outcomes.

The UniverCyte technology aims to mask therapeutic cells derived from pluripotent stem cells or adult donors from human immune detection to allow for off-the-shelf cellular products without the need for immunosuppressant medications, which may have potent side effects, or HLA-matching between donor and patient. UniverCyte uses a novel, modified form of HLA-G, a potent immunomodulatory molecule, which in nature protects an unborn child from their mother's immune system. In almost all human cells, native HLA-G expression is silenced after birth. AgeX's modified HLA-G shows evidence of being resistant to this silencing, thereby potentially allowing for long-term, stable and high expression of the immunomodulatory effect.

This collaboration is allowing Sernova to further identify and evaluate technologies complementary to Sernova's Cell Pouch therapeutic platform and to expand Sernova's immune protection offerings with potential benefit over current immunosuppressive strategies for regenerative medicinal therapeutics. As of the date of this MD&A, the collaboration has been extended to continue the evaluation of the HLA-G technology with stem cell derived cells within Sernova's Cell Pouch. Success with the preclinical evaluation could lead to a licensing agreement and clinical evaluation of the technology in a diabetes stem cell derived program.

Conformal Coating Technology

In June 2020, Sernova completed the acquisition of cellular local immune protection technology from Converge Biotech, Inc. ("Converge"), as a strategic accelerator for expansion of Sernova's total regenerative medicine cell therapy therapeutics platform. Sernova acquired all intellectual property associated with Converge's Conformal Coating Technology.

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 a patient's own immune system following cell transplantation into the body. The technology was developed by Dr. Tomei and Dr. Hubbell. Dr. Tomei, of the renowned Diabetes Research Institute (DRI), a designated Center of Excellence at the University of Miami Miller School of Medicine, is a leading international expert in immunoprotection and diabetes immunoengineering. Dr. Hubbell is the Eugene Bell Professor of Tissue Engineering at the University of Chicago and a leading international researcher in immunoengineering.

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In August 2020, Sernova announced it had entered into an exclusive, worldwide license with the University of Miami for the commercial rights to the novel conformal coating immune protection technologies, further developed by Dr. Tomei.

This exclusive worldwide license agreement broadens the technological scope of Sernova's immune protection conformal coating technologies and related intellectual property. Furthermore, it adds to the series of our recent strategic acquisitions and collaborations building on the Company's goal of protecting Sernova's therapeutic cells or tissues transplanted into Sernova's Cell Pouch from a detrimental auto-immune system response while eliminating the need for immunosuppressive drugs in treated patients.

In addition to filing an international patent application following further encouraging research supporting the Conformal Coating Technology in islets and stem cell derived technologies at the University of Miami, a collaborative research plan advancing the Conformal Coating Technology in combination with therapeutic cells within Cell Pouch as well as the scale up of the Conformal Coating Technology has been developed in support of advancing the combined technologies to the clinic with locally immune protected therapeutic cells with the goal to eliminate the need for antirejection medications. The anticipated clinical evaluation of this combined technology is expected to enable expansion of the diabetic patient population to be treated with Sernova's technologies.

On September 16th, 2021, we announced an extensive development collaboration with Dr. Tomei and the University of Miami to validate our Conformal Coating Technology in combination with therapeutic cells in Sernova's Cell Pouch for T1D. This important collaboration is multifaceted in nature and designed to advance locally immune protected cells within the Cell Pouch into clinical use, without the need for immunosuppression medications. The multifaceted work being conducted in this collaboration is well under way and we are pleased with the progress to date with the Sernova and UMiami collaboration teams.

The preliminary positive results reported to date in patients for T1D, implanted with Sernova's Cell Pouch and transplanted with islets, continue to validate our cell therapy therapeutics approach. These collaborations position Sernova's advancing cell therapies to include locally immune protected stem cell-derived cells as a leader in the development of a potential 'functional cure' for all patients with diabetes and other chronic diseases.

Pharmaceutical Company Collaborations

The goal of our pharmaceutical collaborations is to gain access to new therapeutic cell technologies to build Sernova's pipeline and to gain access to unlimited supplies of stem cell-derived technologies to expand our treatable populations.

Sernova has multiple active research collaboration agreements with global pharmaceutical companies. In this regard, Sernova is deploying its in-house cell therapy expertise and proprietary Cell Pouch technologies in combination with proprietary therapeutic cell assets designated by the pharmaceutical collaborators. The research collaborations follow the ongoing clinical success of our Cell Pouch technologies in diabetes and reflect the value and evolving recognition of our technologies and cell therapy platform. These important partnerships with leaders in the pharma industry build upon our business strategy to develop a portfolio of products to realize the full potential of Sernova's regenerative medicine therapeutic platform by extending and broadening its application to new therapeutic areas and

modalities. We believe partnering with multiple pharmaceutical companies not only will expand our therapeutic treatment potential but also provides a de-risked approach for Sernova as we develop our technologies and bring new therapies to patients with the goal to provide people with a functional cure for multiple chronic and rare diseases.

We have now shown in our collaborations with two advanced glucose responsive stem cell derived technologies in combination with Sernova's Cell Pouch that the combination achieved long-term insulin independence in small animal models of T1D. The research work and business discussions with our global pharma research collaborators are continuing.

Protection of Proprietary Intellectual Property

Sernova has filed international patent applications related to the Cell Pouch System to protect its intellectual property rights related to its therapeutic programs. We have been successful at achieving patent claims in multiple countries around the world.

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 for 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 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.

Sernova will continue to protect the commercial therapeutic applications of its discoveries and inventions. In addition, the Company has developed technologies, which it may elect to keep as trade secrets and not publicly disclose in patent applications.

Research and Development (R&D)

Our R&D efforts focus principally on the development of our Cell Pouch System cell therapy platform in conjunction with various therapeutic cells and local immune protection technologies for the treatment of major and rare diseases in humans.

Our overall objective is to advance our medical technologies through the various stages of preclinical and clinical development and ultimately to provide commercial products to patients. 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 overall objective and related goals include the following:

- conducting the series of clinical trials required to gain eventual 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 T1D and severe hypoglycemic events;
- advancing a treatment that we believe could benefit the broader diabetes population consisting of the Cell Pouch transplanted with locally immune protected insulin producing stem cell-

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- derived cells using our licensed technology; and
- ongoing R&D activities related to our proprietary Cell Pouch in the following areas:
 - continuing our research into additional therapeutic indications such as 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;
 - developing acquired and in-licensed cellular local immune protection technologies;
 - establishing research collaborations to assess 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 (medtech) and / or pharmaceutical companies as well as academic institutions for the development of our products and to advance our next-generation technologies.

Research and Development Outlook

With the Bought Deal Financing completed early March 2021, the following funding was earmarked for the following R&D initiatives and precursor activities:

Initiative	\$ (millions)
Advance Sernova's diabetes clinical development program, including US Phase 1/2 Cell Pouch clinical trial.	\$2.0
Combine Conformal Coating Technology in Cell Pouch for diabetes immune protected islet and stem cell-derived programs in preparation for clinical trials.	2.0
Expand Sernova's diabetes clinical development program with Conformal Coating Technology.	2.5
Advance Cell Pouch thyroid replacement therapy through preclinical development and into a clinical trial.	2.5
Advance gene editing technologies for Sernova's rare disease program such as hemophilia.	2.0
Advance partnership activities with pharmaceutical companies towards business development agreements for diabetes stem cell technologies and rare diseases.	0.6
Intellectual property / patent prosecution and maintenance.	1.0
Capital expenditures for R&D programs.	0.5
Total	\$13.1

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To date, our R&D efforts and programs are progressing as planned.

The above intermediary project initiatives and supplemental activities are anticipated to be completed within 12 months or up to a couple years depending on the specific final scope and initiation timing of each. Their outcomes will help shape and refine our ultimate future clinical strategy and validate next steps direction for our various programs to progress them into or through the clinic toward regulatory approval in an optimal manner. Additional resources and funding will be allocated and committed to subsequent R&D efforts and specific clinical development programs and activities, such as pivotal studies, once the outcomes are available, assessed and concluded upon.

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.

RESULTS OF OPERATIONS

Selected Financial Information

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

	Three months ended October 31,		Year ended October 31,	
	2021	2020	2021	2020
Research and development expenses	\$ 1,891,639	\$ 539,985	\$ 4,637,989	\$ 2,758,633
General and administrative expenses	566,188	434,767	2,298,518	2,501,131
Loss and comprehensive loss	2,175,343	1,030,536	6,965,539	5,321,308

For the three months ended October 31, 2021, we recorded a loss of \$2,175,343, an increase of \$1,144,807 compared to the same period in the prior year. This 111% increase was primarily attributable to the combined effect of a 250% increase (\$1,351,654) in R&D costs and a 30% increase (\$131,421) in G&A expenses. The increases in R&D and G&A expenses are the net result of several factors which are discussed in detail below.

For the year ended October 31, 2021, the Company recorded a loss of \$6,965,539, an increase of \$1,644,231 compared to the same period in the prior year. This 31% increase was primarily attributable to the combined effect of a 68% increase (\$1,879,356) in R&D costs with partial offset by a 8% reduction (\$202,613) in G&A costs. The changes are discussed in detail below.

Components of both R&D and G&A costs and changes from period to period are further discussed below. 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.

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Research and Development Expenses

	Three months ended October 31,		Year ended October 31,	
	2021	2020	2021	2020
Personnel costs	\$ 450,513	\$ 190,700	\$ 1,271,948	\$ 703,017
Contract services and consulting	1,244,870	473,566	3,022,244	1,334,168
Lab operations	16,952	26,854	122,892	37,967
Manufacturing costs	325,870	33,550	389,191	202,259
Patent fees and costs	72,114	82,921	529,041	484,060
License fees	29,880	(97)	39,880	20,020
Other costs	7,738	1,321	27,085	35,558
Amortization and depreciation	78,647	70,042	258,966	204,265
Share-based compensation	15,455	51,274	96,463	288,468
Total	2,242,039	930,131	5,757,710	3,309,782
Less: contributions and tax credits	(350,400)	(390,146)	(1,119,721)	(551,149)
Net	\$ 1,891,639	\$ 539,985	\$ 4,637,989	\$ 2,758,633

For the three months ended October 31, 2021, the Company incurred net R&D expenses of \$1,891,639, a 250% increase from the comparative period and commensurate with the continued advancement of our R&D initiatives and the US Phase 1/2 Cell Pouch Clinical Trial. Of the total R&D quarterly costs net increase of \$1,351,654, some components changed more significantly, and some had an offsetting effect. As expected with more enrolled patients in total and advancing through the more extensive and costly protocol-based procedures, for instance the transplantation of islet cells into Cell Pouch or the portal vein as a marginal dose top-up, costs incurred for contract services provided at the clinical trial site and for CRO activities have increased significantly from the comparative period. The increase in personnel costs was attributable to R&D team new hires, higher salaries, bonus and recruiting costs. Manufacturing and patent costs historically tend to vary significantly, depending on the timing of specific activity and project initiation, progress or completion coupled with annual patent maintenance fees periodically becoming due. During the final quarter of fiscal year 2021, year-over-year manufacturing costs were higher with a new Cell Pouch production run in progress versus no production during the comparative period. The reduction in share-based compensation reflects diminishing expense for the 2019 granted stock options as full vesting gets progressively closer. Contributions and tax credits include cost recoveries totaling \$81,557 related to activities for our pharmaceutical company collaborations.

Total and net R&D expenses for the year ended October 31, 2021, increased 74% to \$5,757,710 and 68% to \$4,637,989, respectively, compared to the prior year. Several of the factors noted above for the most recently completed quarter had a similar effect on the full fiscal year period. The increase in contract services and consulting costs for our US Phase 1/2 Cell Pouch Clinical Trial reflects additional patient enrolment and the overall number of procedures conducted at the clinical trial site as well as CRO activities commensurate with the progression of the clinical trial. Contributions and tax credits increased by \$568,572, or approximately doubled, due to the timing of JDRF milestone grant contributions being earned based upon the completion of specific protocol-driven patient procedures by our principal investigator combined with cost recoveries (\$182,149) associated with our pharmaceutical company collaborations as noted above. Around mid year 2020, a smaller Cell Pouch production run was

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completed compared to that noted above as being in progress during Q4 2021. The increase in amortization and depreciation is directly related to the incremental cost amortization of our Q3 2020 Conformal Coating Technology acquisition, i.e. a full twelve months during fiscal 2021 versus only five months during fiscal year 2020.

General and Administrative Expenses

	Three months ended October 31,		Year ended October 31,	
	2021	2020	2021	2020
Personnel costs	\$ 178,050	\$ 119,707	\$ 728,379	\$ 484,607
Consulting and professional fees	98,308	20,112	315,936	226,688
Director fees and expenses	75,513	38,255	239,293	125,004
Investor relations	108,849	141,175	551,946	1,043,735
Other costs	76,308	45,122	332,794	205,590
Depreciation	6,096	2,513	8,238	20,965
Share-based compensation – DSUs	15,122	38,843	90,186	242,674
Share-based compensation – options	7,942	29,040	31,746	151,868
	\$ 566,188	\$ 434,767	\$ 2,298,518	\$ 2,501,131

For the three months ended October 31, 2021, total G&A expenses increased by \$131,421 from the comparative period. The 30% year-over-year increase included some G&A cost components that changed significantly and others with an offsetting effect. Changes included: i) increased personnel costs attributable to additional hires and higher market adjusted salaries; ii) a decrease in investor relations costs with cost savings realized from contracts that previously expired or were not renewed and iii) more business development activities and legal services led to higher consulting and professional fees costs. In addition, share-based compensation expense declined reflecting the impact of graduated vesting associated with the last grant of outstanding stock options and DSUs in 2019 getting progressively closer to completing their respective multi-year vesting periods.

Total G&A expenses for the year ended October 31, 2021 declined by \$202,613 from the comparative period. This 8% decrease was attributable to the same factors noted above for the current quarter, most notably a 47% reduction in investor relations costs. Higher cash incentive compensation awarded earlier during the 2021 fiscal year for objectives achieved contributed further to the change in personnel costs on a year-over-year comparative basis. Director fees and expenses were also higher resulting from the cumulative effect of earlier effected market-based director fee adjustments and the addition of a new independent paid member to the Board of Directors. Other costs increased from the prior year due to a significant increase in the Company's annual stock exchange sustaining fees and incremental fees or costs associated with a significant increase in the number of registered shareholders and listing on the Deutsche Börsethe Xetra institutionally focused trading platform in Europe. No annual granting of stock options and DSUs employee, management or director grants since the 2019 fiscal year also compounded the decline in share-based compensation expense comparatively for the year. Amidst the COVID-19 environment and related continued uncertainties ahead we continue to monitor and manage costs closely.

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LIQUIDITY AND CAPITAL RESOURCES

The selected financial information provided below is derived from the Company’s audited consolidated financial statements.

As at	October 31, 2021	October 31, 2020
Cash	\$ 27,874,198	\$ 3,949,412
Total assets	29,820,344	5,725,524
Current liabilities	1,475,871	878,075
Non-current liabilities	275,979	702,612
Total liabilities	1,751,850	1,580,687
Share capital, warrants and contributed surplus	82,817,445	51,928,249
Deficit	(54,748,951)	(47,783,412)

The Company’s audited consolidated financial statements have been prepared assuming the Company will continue as a going concern. As at October 31, 2021, the Company had working capital of \$26,851,474 (October 31, 2020 – \$3,727,208) and for the year ended October 31, 2021 had a negative cash flow from operations of \$6,843,744 (2020 - \$3,939,199), excluding grant contributions received in the amount of \$871,799 (2020 - \$658,755). The Company has experienced operating losses and net cash outflows from operations since its inception.

We anticipate increased cash requirements for the next twelve months as we progress in our US Phase 1/2 Cell Pouch Clinical Trial, accelerate development of our local immune protection technology assets, prepare for and initiate our first thyroid clinical trial, advance research collaborations and execute upon strategic initiatives. Some of the increased cash requirements anticipated for the US Phase 1/2 Cell Pouch Clinical Trial may be offset by additional milestone achievement draws against the Company’s JDRF grant award.

Until such time as the Company’s products are approved and available for sale and profitable operations are developed, its liquidity requirements and ability to continue as a going concern are subject to management’s ongoing ability to successfully raise additional working capital and ultimately generate cash flow from the commercialization of its products. Future financing will depend on many factors, including, but not limited to, market conditions that 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. Failure to do so could have a material adverse effect on the Company’s financial condition and financial performance. See section “**RISKS AND UNCERTAINTIES**” and “**CAPITAL MANAGEMENT, FINANCIAL INSTRUMENTS AND RISKS**” in this MD&A.

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

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Financing Activities

Since the end of the reporting period ended October 31, 2021, and up to the date of this MD&A, cash proceeds of \$1,303,475 million have been received for the exercise of common share purchase warrants and stock options.

During the year ended October 31, 2021:

- (i) cash proceeds of \$23,046,000 were received from a brokered bought deal offering (Offering) of 19,205,000 units, including the full exercise of the underwriters' 15% over-allotment option, at the issue price of \$1.20 per unit (2021 Units). Each 2021 Unit consists of a common share and one common share purchase warrant, with each common share purchase warrant being exercisable into one common share at a price of \$1.70 per share until March 1, 2023, subject to abridgment of the exercise period if the ten-day volume-weighted price of the Company's common shares exceeds \$3.05 per share. As consideration for services provided in connection with the Offering, the Company paid to the underwriters: a cash commission of \$1,452,981, a corporate finance fee of 384,100 2021 Units (Corporate Finance Fee Units) and 1,210,818 broker warrants (also referred to as compensation options), where each broker warrant upon exercise entitles the holder to purchase one 2021 Unit at \$1.20 until March 1, 2023 (Broker Warrant). The Corporate Finance Fee Units and Broker Warrants issued were valued at \$460,920 and \$2,350,924, respectively. The value of the Broker Warrants was determined using the Geske Model. Share issuance costs totalling \$466,915 were also incurred and paid. The value of the Broker Warrants was determined using the Geske Model with the following assumptions: volatility of 129%, a risk-free interest rate of 0.3%, an expected life of two years, a dividend yield of 0% and no forfeiture;
- (ii) cash proceeds of \$8,777,772 were received from the exercise of common share purchase warrants and stock options for a combined 29,141,731 common shares;
- (iii) 138,980 common shares were issued as settlement for \$40,110 of interest accrued on the convertible debentures; and
- (iv) upon receipt of a conversion notice from the holder of the Debentures, the outstanding principal of \$1.0 million was converted into 4,000,000 common shares, at the fixed conversion price of \$0.25 per common share. No additional consideration was received for the conversion into common shares.

During the year ended October 31, 2020, 100,000 stock options were exercised for proceeds of \$21,000 and no share purchase warrants were exercised during the same period.

During the final quarter of the year ended October 31, 2020, we closed a non-brokered private placement on September 22, 2020, with the issuance of 12,218,333 units at \$0.30 per unit (2020 Units), for gross proceeds of \$3,665,500, of which \$244,367 was allocated to the related common share purchase warrants issued using the residual value approach. Each 2020 Unit consisted 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 until September 22, 2022, subject to abridgment of the exercise period if the ten-day volume-weighted price of the Company's shares exceeds \$0.50 per share and the Company elects to trigger the abridgment by issuing a notice to warrant holders (Abridgment Notice). All securities issued in connection with the private placement were subject to a statutory hold period of four months. The Company incurred legal costs and finders' fees totaling \$92,148 and issued 198,310 finder warrants valued at \$29,366. The value of these finders' warrants was determined using the Black-Scholes Model

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based on the following assumptions: an exercise price of \$0.35 per common share, expected life of two years, volatility of 113% and a risk-free interest rate of 0.26%. The terms of the finder warrants were the same as those of the common share purchase warrants of the 2020 Units issued. As of the date of this MD&A, no Abridgment Notice has been issued by the Company although the \$0.50 share price threshold has been surpassed and the Company’s share continues to trade at higher levels.

During the third fiscal quarter ended July 31, 2020, through a non-brokered private placement we issued the 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 intellectual property, discussed elsewhere in this MD&A. The Debentures holder was granted the right to convert the principal amount into common shares of the Company at a fixed conversion price of \$0.25 per share, at any time up to the repayment date, and such right was exercised during the most recently completed quarter as noted above. The Debentures were repayable on December 8, 2022, unless earlier converted or redeemed, and interest at a rate of 8% per annum was payable semi-annually, in cash or common shares at the option of the Company. In conjunction with the Debentures issuance, 3,000,000 non-transferable common share purchase warrants (Debenture Warrants) were issued with each Debenture Warrant being exercisable into one common share at a price of \$0.20 per share up to December 8, 2022. Issue costs totaling \$30,896 were incurred. No finders’ fees or finders’ warrants were paid or issued, respectively. The Debentures and Debenture Warrants, and any securities into which they may be exchanged or converted, were subject to a four-month hold period in accordance with applicable securities regulations. For more information, see *Note 9 – Convertible Debentures* to the Company’s audited consolidated financial statements for the years ended October 31, 2021, and 2020.

Common Shares

	Number of Common Shares
Balance outstanding as at October 31, 2020	208,263,447
Issued in conjunction with a prospectus offering of units	19,205,000
Issued in conjunction with a corporate finance fee for a prospectus offering of units	384,100
Issued upon exercise of stock options	4,239,365
Issued upon exercise of warrants	24,902,366
Issued upon conversion of convertible debentures	4,000,000
Issued for payment of convertible debentures interest	138,980
Balance outstanding, as at October 31, 2021	261,133,258
Issued upon exercise of stock options	125,000
Issued upon exercise of warrants	1,004,000
Balance outstanding as at the date of this MD&A	262,262,258

Further details on the common shares outstanding are provided in *Note 10 – Common Shares and Warrants* to the audited consolidated financial statements for the years ended October 31, 2021, and 2020.

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Warrants

	Number of Warrants	Weighted Average Exercise Price
Balance outstanding as at October 31, 2020	50,246,590	\$ 0.32
Issuance in conjunction with a prospectus offering of units	19,589,100	1.70
Issuance of broker warrants	1,210,818	1.20
Exercised	(24,902,366)	(0.31)
Balance outstanding as at October 31, 2021	46,144,142	0.93
Exercised	(1,004,000)	(1.27)
Issued	100,000	1.70
Balance outstanding as at the date of this MD&A	45,240,142	\$ 0.92

Further details on the common share purchase warrants outstanding are provided in *Note 10 – Common Shares and Warrants* to the audited consolidated financial statements for the years ended October 31, 2021, and 2020.

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 10 – Common Shares and Warrants* to the audited consolidated financial statements for the years ended October 31, 2021, and 2020.

	Number of Options	Weighted Average Exercise Price
Balance outstanding as at October 31, 2020	14,474,600	\$ 0.22
Granted	100,000	1.40
Exercised	(4,239,365)	(0.22)
Canceled / forfeited	(1,442,735)	(0.21)
Balance outstanding as at October 31, 2021	8,892,500	0.24
Exercised	(125,000)	(0.23)
Granted	13,575,484	1.32
Balance outstanding as at the date of this MD&A	22,342,984	\$ 0.90

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	Number of DSUs
Balance outstanding as at October 31, 2020, and 2021	4,150,001
Granted	1,360,000
Balance outstanding as at the date of this MD&A	5,510,001

The Company initiated its Incentive Plan in 2015, with the latest amendments thereto approved by shareholders of the Company on June 30, 2021. The aggregate maximum of 38,746,536 common shares allowable under the Incentive Plan consists of: (i) a maximum of 30,997,229 common shares reserved for the exercise of share options pursuant to the Option Plan and (ii) a maximum of 7,749,307 DSUs reserved under the DSU Plan component, representing 12.5% and 2.5% respectively of the then issued and outstanding common shares of the Company.

Further details on the share options and DSUs outstanding are provided in *Note 10 – Common Shares and Warrants* to the audited consolidated financial statements for the years ended October 31, 2021, and 2020.

COMMITMENTS AND CONTINGENCIES

During the 2016 fiscal year, the Company was awarded a US\$2.45 million (approximately \$3.0 million) grant from JDRF. The grant supports the US Phase 1/2 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. Contributions relating to milestone achievements totaling US\$581,160 (\$724,182) were earned during the year ended October 31, 2021 (2020 – US\$332,730 (\$442,844)). Remaining funding available to be earned under the JDRF grant award totals approximately US\$0.57 million (\$0.70 million) as at October 31, 2021, and the date of this MD&A. The Company is required to pay royalties to JDRF as a percentage of any future net sales received from such diabetes product or in certain future license or disposition transactions up to an aggregate maximum of four times the aggregate amount of JDRF grant funding received. A bonus amount equal to the total amount of grant funding received is also payable to JDRF on two aggregate net sales thresholds if they are achieved. Given the early and inconclusive stage of development of the diabetes product, the royalty is not probable at this time and therefore no liability has been recorded.

During the 2021 fiscal year, the Company entered into research collaborations with international pharmaceutical companies to evaluate the collaborator's stem cell assets in our Cell Pouch for proof-of-concept studies. Successful studies may lead to future development and commercial partnership opportunities. Under the terms of the collaboration agreements, the Company has committed to perform certain preclinical activities which the collaboration parties will provide funding enabling the Company to fully recover costs incurred. Of the total US\$205,490 (\$261,439) of funding received during the year, US\$150,563 (\$191,549) was recorded as a research and development cost recovery contribution in the statement of loss and comprehensive loss with the remainder of US\$54,927 (\$69,890) recorded as research collaboration advances in current liabilities as at October 31, 2021.

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

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patient procedures performed and activities related to the US Phase 1/2 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. We enter into contracts and agreements in the normal course of business, including for research and development activities, consulting and other services. As at October 31, 2021, the Company has contract commitments totally approximately \$5,386,000, of which approximately \$3,728,000 is expected to be paid over the next twelve months. The majority of these contractual obligations are cancelable at any time by us, generally upon prior written notice to the service provider or vendor. In addition, the Company has minimum annual royalty payment obligations of approximately \$30,000 for third party licensing agreements.

Effective September 1, 2021, the Company entered into a two-year lease for both its existing office premises and lab facilities and additional office space at a rate of \$14,000 per month, with a 2% increase on the anniversary of the lease agreement. Under the terms of the lease, the Company has an option to extend the lease term for an additional twelve months, up to August 31, 2024, with a minimum of ninety days advance written notice of its intent to extend occupancy. As of October 31, 2021, remaining undiscounted lease payment obligations total \$486,147, of which \$168,560 is payable over the next twelve months.

RELATED PARTY TRANSACTIONS

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

Amounts due to related parties, including amounts due to key management personnel, at the period-end are unsecured, interest-free, and settlement generally occurs in cash. There have been no guarantees provided or received for any related party receivables or payables. Included in accounts payable and accrued liabilities at October 31, 2021, were amounts totaling \$217,880 due to key management personnel (October 31, 2020 – \$103,699).

Compensation to key management personnel for the reporting period was as follows:

	Three months ended October 31,		Year ended October 31,	
	2021	2020	2021	2020
Personnel costs	\$ 293,757	\$ 170,935	\$ 1,109,986	\$ 625,140
Director fees and costs	79,884	38,255	241,673	121,780
Share-based compensation - DSUs	15,123	38,844	90,186	242,675
Share-based compensation - options	9,720	32,798	57,986	174,935
	\$ 398,484	\$ 280,832	\$ 1,499,831	\$ 1,164,530

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 twelve most recently completed fiscal quarters:

Fiscal Year		1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter
2021	Loss	\$ 1,492,232	\$ 1,666,966	\$ 1,630,998	\$ 2,175,343
	Loss per share	0.01	0.01	0.01	0.01
2020	Loss	\$ 1,361,978	\$ 1,733,214	\$ 1,195,580	\$ 1,030,536
	Loss per share	0.01	0.01	0.01	0.01

Quarterly losses have trended higher over the course of fiscal year 2021 and overall compared to prior years, reflecting the ongoing overall growth of the Company and the advancement of our R&D programs and commensurate with increased activities and support for our US Phase 1/2 Cell Pouch Clinical Trial.

R&D costs have increased 68% year-over-year compared to fiscal year 2020. Quarterly clinical trial costs have particularly increased due to additional patient enrollment, a corresponding increase in the number of patient protocol-based procedures performed, the conduct of individual patient trial procedures being more expensive the further a patient advances along the study protocol and associated with incremental clinical trial support activities internally and conducted by our study CRO and other service providers. Corporate objectives-based bonuses awarded during the fiscal year 2021 second quarter also contributed to higher costs. Cell Pouch manufacturing development and production activities during the last quarter of fiscal year 2021 and fiscal year 2020 second quarter significantly contributed to higher R&D costs in those particular quarters. Other factors contributing to higher recent quarterly losses include increased patent costs as well as adding personnel and building core competencies internally to support our future activities.

In the final quarter of our fiscal year 2019, costs associated with expanded investor relations and communication activities significantly increased operating expenses and contributed to higher quarterly losses. However, as most contracts expired or were not renewed during the final quarter of fiscal year 2020, cost savings began to be realized during the fourth quarter of fiscal year 2020 and continued to have a positive effect on all 2021 fiscal year quarterly costs and results.

It is important to note that historical patterns of expenditures cannot be taken as an indication of future expenditures. The amount and timing of expenditures, and therefore liquidity and capital resources, may vary substantially from period to period depending on the business and research activities being undertaken at any one-time and the availability of funding from investors and prospective collaborative partners. Grants earned are also dependent on the completion of specific subsets of patient procedures which can vary significantly from quarter to quarter.

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 a prospectus offering, a private placement, the issuance of unsecured convertible debentures and the exercise of common share purchase warrants and stock options, combined with 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. Excess cash is invested in accordance with the Company's investment policy, as established by the Company's Audit Committee. The primary objectives of the investment policy, in order of priority, are preservation of capital, liquidity and return on investment.

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 from time to time is remote. Amounts receivable at October 31, 2021, are composed of amounts due from Canadian federal government agencies and \$224,349 from JDRF.

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 October 31, 2021, the Company had working capital cash of \$26,851,474 (October 31, 2020 - \$3,727,208). The majority of the Company's accounts payable and accrued liabilities are due within three months or less. During the year ended October 31, 2021, an initial lease liabilities amount of \$411,185 was recorded as a liability relating to the aforementioned new office space and lab facilities lease in accordance with IFRS 16 *Leases*. As of October 31, 2021, remaining undiscounted minimum lease payment obligations total \$486,147, of which \$168,560 is payable over the next twelve months. Repayment of the non-current unsecured convertible debentures with a face value of \$1,000,000

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outstanding as at October 31, 2020 - that would have been due on December 8, 2022 - will no longer be required with the January 18, 2021 conversion of the convertible debentures by the holder into 4,000,000 common shares of the Company at the fixed price of \$0.25 per share.

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. Interest income varies from period to period depending on average cash balances on hand and changes in short-term market yields. Interest income is not significant to the Company's projected operational budget and related rate fluctuations are not significant to the Company's risk assessment.

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 grant contributions 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 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, 2021, and 2020.

Going concern

Our consolidated financial statements have been prepared assuming that the Company will continue as a going concern. We have incurred losses and negative cashflow since inception. A comprehensive loss of \$6,965,539 was incurred during the year ended October 31, 2021, and the Company has an accumulated deficit of \$54,748,951. As at October 31, 2021, we had working capital of \$26,851,474.

Until our biotechnology therapeutic products are approved and available for sale and profitable operations

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are developed, our liquidity requirements will be dependent on our ability to continue to obtain adequate financing. Failure to do so could have a material adverse effect on the Company's financial condition and financial performance. During the year ended October 31, 2021, we completed a \$23 million financing, which is anticipated to fund our operating plan for a period of at least twelve months. Future financing will depend on many factors, including, but not limited to, market conditions which are not within our control, and ultimately the market acceptance of our 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 *Note 17 – Capital Risk Management* and *Note 18 – Financial Instruments and Risk Management* to the Company's audited consolidated financial statements for the years ended October 31, 2021, and 2020.

Estimated useful life of long-lived assets

Judgement is used to estimate each component of a long-lived asset's useful life and is based on an analysis of all pertinent factors including, but not limited to, the expected use of the asset and in the case of an intangible asset, contractual provisions that enable renewal or extension of the asset's legal or contractual life without substantial cost, and renewal history. If the estimated useful lives were incorrect, it could result in an increase or decrease in the annual amortization expense, and future impairment charges or recoveries.

Impairment of long-lived assets

Long-lived assets are reviewed for impairment upon the occurrence of events or changes in circumstances indicating that the carrying value of the asset may not be recoverable. For the purpose of measuring recoverable amounts, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). The recoverable amount is the higher of an asset's fair value less costs to sell and value in use (being the present value of the expected future cash flows of the relevant asset or cash-generating unit). An impairment loss is recognized for the amount by which the asset's carrying value exceeds its recoverable amount. Management evaluates impairment losses for potential reversals when events or circumstances warrant such consideration.

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. Any directly attributable transaction costs are allocated to the liability and equity components in proportion to their initial carrying amounts. Subsequent to initial recognition, the liability component of a compound financial instrument is measured at amortized cost using the effective interest method. The equity component of a compound financial instrument is not re-measured subsequent to initial recognition. Upon conversion, the carrying value of the equity portion is transferred to common shares.

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

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also based on several assumptions, including contractual future cash flows, discount rates and the presence of any derivative financial instruments.

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.

Valuation of share-based payments compensation and warrants

The Company measures the cost of equity-settled transactions 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 and dividend yield. Changes in these assumptions affect the fair value estimate for share-based compensation and warrants. The assumptions and models used for estimating fair value for share-based payment transactions are discussed in *Note 10 – Share Capital and Warrants* to the audited consolidated financial statements for the years ended October 31, 2021, and 2020 and the audited consolidated financial statements for the years ended October 31, 2020, and 2019.

Valuation of equity units issued

The Company uses the residual value method with respect to the measurement of shares and warrants issued as part of units. The residual value method first allocates value to the most readily measurable component based on fair value and then the residual value, if any, to the other component(s) as applicable. Estimating fair value of a component may include the use of market prices or selection of an appropriate valuation model and related data inputs including the expected option life, volatility, risk-free interest rate, forfeiture rates and dividend yield. The assumptions and approach used for estimating fair value of equity units' components are discussed in *Note 3 – Summary of Significant Accounting Policies* and *Note 10 – Share Capital and Warrants* to the audited consolidated financial statements for the years ended October 31, 2021, and 2020.

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 during the current fiscal year

None

New accounting standards and interpretations not yet adopted

In January 2020, the IASB issued amendments to Presentation of financial statements ("IAS 1") to provide a more general approach to the classification of liabilities under IAS 1 based on the contractual arrangements in place at the reporting date. The amendments to IAS 1 are effective for annual reporting periods beginning on or after January 1, 2023. The company is currently evaluating the potential impacts of adoption.

There are no other standards, interpretations or amendments to existing standards that are not yet effective that are expected to have a material impact on the consolidated financial statements of the Company.

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 year ended October 31, 2021, our common shares traded on the TSX Venture Exchange at a high of \$2.87 and a low of \$0.26 per share (2020 fiscal year – high of \$0.35 and low of \$0.095 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

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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 approximately 22.3 million outstanding stock options convertible into common shares with an average exercise price of \$0.90 per share; approximately 5.5 million outstanding DSU's convertible into common shares; and approximately 45.2 million outstanding warrants with an average exercise price of \$0.92 per share (including 1.1 million Broker Warrants convertible into units of one common share and one common share purchase warrant therefore 2.2 million common share equivalents for purposes of determining the number of fully diluted common shares below). On a fully diluted basis, we would have approximately 336.5 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 secure 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 USFDA, and corresponding state and foreign agencies, including European agencies and their designees, to ensure strict compliance with GMPs and other government regulations. Sernova will not have complete control over its third-party manufacturers' compliance with these regulations and standards. Failure by either Sernova's third-party manufacturers or by Sernova to comply with applicable regulations could result in sanctions being imposed, including fines, injunctions, civil penalties, failure of the government to grant review of submissions or market approval of drugs, delays, suspension, or withdrawal of approvals, product seizures or recalls, operating restrictions, facility closures and criminal prosecutions, any of which could negatively impact the business.

Issuer Risk

We face risks related to the ongoing 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 ongoing COVID-19 pandemic has impacted the Company's business to some extent. Early on during the pandemic, our US Phase 1/2 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 subsequently eased with COVID-19 safety provisions and the conduct of patient procedures resuming. Thereafter, efforts were made and continue at the clinical trial site to expedite any impacted patient procedures in various stages of progress and the completion of patient enrollment. However, with the subsequent emergence and escalation of COVID-19 variants, the scheduling and timing of some remaining patient procedures has been and may continue to be unpredictably impacted due to changes in operating room (OR) availability due to everchanging restrictions or the reluctance of some non-local study patients to travel to the University of Chicago clinical trial site until the current COVID-19 variant infection surge subsides. COVID-19 has also impacted the progression of some international research collaboration activities due to third-party facility access and travel restrictions; however, provisions have been and continue to be made as required 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 and continue to make adjustments in response to changing government regulations and directives. COVID-19 and emergence of variants 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 ongoing COVID-19 pandemic is that it could significantly impact the progress and completion of our US Phase 1/2 Clinical Trial and the advancement of our preclinical and collaborative research activities.

It is unknown how long the adverse conditions associated with COVID-19 and subsequent variants will last and what the complete financial effect will be to the Company. Depending on the duration of the ongoing 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,

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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.

To the extent the continuing 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 continuing 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 ongoing COVID-19 pandemic 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, the use of thyroid tissue in combination with the Cell Pouch System and the use of factor VIII releasing cells in combination with the Cell Pouch System to treat severe hemophilia A. If we are unable to achieve

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safety and efficacy in one or more of these disease indications in preclinical and/or clinical studies the business may be materially harmed.

We will 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 potential existence of a future material uncertainty that may cast significant doubt on the ability of the Company to continue as a going concern. We may attempt to raise additional funds through public or private equity or debt financing, collaborations with other biopharmaceutical companies and / or from other sources, including non-governmental grants and loans and various government incentive programs. There can be no assurance that additional funding, however sourced, will be available on terms acceptable to us and which would allow the successful commercialization of our products.

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 USFDA, 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 USFDA, 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

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even if the preclinical studies show promising results and clinical trials are successfully completed, we cannot guarantee that the USFDA, 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 USFDA, 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 USFDA, Health Canada, EMA or other regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials;
- we or our collaborators may be unable to demonstrate to the satisfaction of the USFDA, 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 significance required by the USFDA, 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 USFDA, 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 USFDA, 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 USFDA, Health Canada, EMA, or other regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

If we, and or potential partners, pursued Orphan Drug, Fast Track, Breakthrough Technology, Regenerative Medicine Advanced Therapy (RMAT), Accelerated Approval or Priority Review in the US, or similar preferential regulatory designation(s) in any other jurisdiction abroad, that could be beneficial to expedite the conduct, completion or review of a clinical study, marketing approval for a product and or restrict post approval market competition, there is no assurance that any such designation could be successfully secured. If unsuccessful in obtaining, development and clinical timelines, cost estimates, market opportunities and or commercialization / go-to-market strategies for a product under development or a product to be developed in the future could be significantly and unfavourably impacted.

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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 USFDA, 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 clinical trials may not be repeated in larger pivotal clinical trials. We cannot be assured that our preclinical studies and clinical trials will generate positive results that allow us to move towards the commercial use and sale of our product candidates. Furthermore, negative results may cause our business, financial condition, or results of operations to be materially adversely affected.

For example, our Cell Pouch 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 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,

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during commercial use of any approved products. The appearance of any such unacceptable adverse side effects could interrupt, limit, delay, or abort the development of any of our product candidates, or if previously approved, necessitate their withdrawal from the market. Furthermore, disease resistance or other unforeseen factors may limit the effectiveness of our potential products.

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

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

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

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

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

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions affecting the patentability of our inventions relating to our key products and the enforceability, validity, or scope of 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.

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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 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

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

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

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

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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.

Product liability claims are an inherent risk of the Company's business, and if the Company's clinical trial and product liability insurance prove inadequate, product liability claims may harm its business. Human therapeutic products involve an inherent risk of product liability claims and associated adverse publicity. Although the Company currently carries what it believes to be adequate product liability and clinical trial insurance, there can be no assurance that the Company will be able to maintain its current insurance, or obtain other insurance as required, on acceptable terms, with adequate coverage in the future against potential liabilities or at all. Insurance covering product liability claims becomes increasingly expensive as a product candidate moves through the development pipeline to commercialization. An inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could have a material adverse effect on the Company's business. If a product is withdrawn or a product liability claim was brought against the Company, it could significantly damage the Company's reputation and prevent or inhibit the commercialization of its products currently under development or product candidates in the future (licensed or owned) or negatively impact existing or future collaborations.

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 USFDA 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 year ended October 31, 2021, we incurred losses of \$6,965,539 (2020 - \$5,321,308) and had an accumulated deficit to October 31, 2021, of approximately \$55 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

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with our competitors, there exists the possibility for such persons to be in a position of conflict. Any decision or recommendation made by these persons involving us will be made in accordance with his or her duties and obligations to deal fairly and in good faith with us and such other organizations. In addition, as applicable, such directors and officers will refrain from voting on any matter in which they have a conflict of interest.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition. Global credit and financial markets experienced extreme disruptions at various points over the last decade, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it 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, 2021, and 2020, and based on current business plans and financial expectations, we believe that we may be a PFIC for the current tax year and immediate 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 (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.

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.

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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 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.

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DIRECTORS AND OFFICERS

Frank Holler	Director and Chair 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 Governance Committee Chair
Dr. Mohammad Azab	Director
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.