SERNOVA CORP.

MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE YEARS ENDED

OCTOBER 31, 2023 AND 2022

Dated January 26, 2024

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

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, 2023, and 2022. This MD&A should be read in conjunction with the Company's Annual Information Form (AIF) dated January 26, 2024 and its audited consolidated financial statements and related notes for the years ended October 31, 2023, and 2022, which have been prepared in accordance with IFRS Accounting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

The Company's accounting policies under IFRS are set out in Note 3 – *Material Accounting Policies* of the audited consolidated financial statements for the years ended October 31, 2023, and 2022. All amounts are in Canadian dollars. The information in this report is dated as of January 26, 2024, 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" 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. Without limitation, this MD&A contains forward-looking statements pertaining to:

- our corporate strategy, strategic objectives, R&D plans, projections and cash requirements;
- the availability of financing to fund our ongoing operations, liabilities and R&D activities;
- the function, potential benefits, tolerability profile, effectiveness and safety of Cell Pouch™ transplanted with therapeutic cells or tissue;
- the timing, cost and results of preclinical and clinical studies to treat insulin-dependent diabetes, hypothyroid disease and or hemophilia A with the Cell Pouch System™;
- the expected benefits to type 1 diabetes (T1D) patients implanted with Cell Pouch™ and human donor islets or induced pluripotent stem cell (iPSC) derived islet-like clusters (ILCs);
- the timing and success of IND enabling preclinical studies, IND submission and obtaining regulatory clearance to commence a Phase 1/2 trial combining iPSC-derived ILCs with Cell Pouch™ in conjunction with the Evotec Collaboration (defined below);
- the protection of therapeutic cells within Cell Pouch™ from immune system attack using local immune protection technologies, such as conformal coating, gene-editing, tolerance, or using a systemic anti-rejection regimen or a combination thereof, and the expected benefits;
- our intention and ability to use human autograft cells or tissues or human donor allograft cells or xenogeneic (non-human) cells for treatment, coupled with the expectation that the

use of stem cell-derived cells (i.e., iPSCs) could provide a virtually unlimited cell supply for Cell Pouch™ to treat various diseases;

- our expectations to secure collaborations and partnerships to research, develop, commercialize and market our product candidates;
- our regulatory strategies and ability to obtain regulatory clearance for clinical trials and marketing approval for our product candidates;
- our ability to obtain Orphan Drug (for rare diseases), Fast Track, Breakthrough Technology, Regenerative Medicine Advanced Therapy (RMAT), Accelerated Approval or Priority Review in the US, and similar regulatory designations in other jurisdictions, and expediting clinical trials or marketing approval for product candidates;
- our belief that our technologies are unique and could become a standard of care in therapeutic cell transplantation, if they prove to be safe and effective in clinical trials;
- our intentions regarding the development and protection of our intellectual property;
- our intention to manage, optimally allocate and or reduce spending in certain areas to permit greater financial resources to be applied to R&D projects;
- obtaining licenses for technologies complementary to or with the Cell Pouch System™;
- securing cGMP manufacturing facilities for our cell therapy programs; and
- the benefits of developing next-generation Cell Pouch™ or Cell Pouch System™ technologies.

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

Forward-looking information is based on the reasonable assumptions, estimates, analysis, and opinions of management made based on experience and perception of trends, current conditions, and expected developments, and 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 the assumptions and expectations reflected in such forward-looking information are reasonable.

Key assumptions upon which our forward-looking information are based include:

- our ability to obtain additional financing in the future on acceptable terms;
- the Company's future R&D plans proceeding substantially as currently envisioned;
- the expected benefits to patients of our product candidates and technologies, including Cell Pouch™ and Cell Pouch System™ cell therapy programs in combination with therapeutic cells;
- our ability, or that of partners, to receive regulatory approval for our product candidates;
- our ability to protect our intellectual property rights, and continued compliance with third-party license terms and the non-infringement of third-party intellectual property rights;
- our and our partner Evotec's ability to successfully complete all necessary preparatory work to file an IND for iPSC-derived ILCs in combination with Cell Pouch™ and any applicable ancillary technologies;
- our partner Evotec's successful and timely completion of iPSC-derived ILC development, including scale-up and manufacturing, to support planned clinical trials;
- our ability to supply Cell Pouches, therapeutic cells and or any complementary technologies

comprising a product for the conduct of preclinical studies, clinical trials and commercial use following marketing approval of a product candidate;

- our ability to conduct and complete clinical trials, including our active T1D Phase 1/2 study;
- our ability to attract and retain key personnel;
- our ability to successfully manage, optimally allocate and or reduce spending in certain areas to allow more financial resources to be applied to R&D activities;
- our ability to successfully commercialize and license our assets; and
- manage growth effectively; and the absence of material adverse changes in our industry or the global economy, including any impact of the Hamas-Israel and Russia-Ukraine conflicts, and any lingering effect of the COVID-19 pandemic or emergence of other pathogens on our business and operations, including supply chain, manufacturing, research and development costs, clinical trials including patient enrollment, contracted service providers and employees.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements and information, including but not limited to the following risks and uncertainties: early-stage development and scientific uncertainty; R&D activities not achieving the desired outcomes; management of growth; lack of product revenues and history of losses; volatility of share price and access to capital to meet additional funding requirements; patents and proprietary technology; finding pharma partners to license product candidates; dependence on collaborative partners, licensors, contract research organizations (CROs), contract manufacturing organizations (CMOs) and others; government regulations; hazardous materials and environmental matters; rapid technological change; competition; reliance on and retention of key personnel; status of healthcare reimbursement; potential product liability; economic conditions; and the impact or lingering effects of the COVID-19 pandemic or emergence of other pathogens. Such risks are further described under "**RISKS AND UNCERTAINTIES**" in this MD&A or under *"RISK FACTORS"* in our most recently filed AIF available on our profile at www.sedarplus.ca. 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 global business conditions 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 our strategic direction, the risks and opportunities as understood by management, and some of the key metrics that are relevant to our performance. This MD&A has been reviewed and approved for filing by the Company's Audit Committee and the Board of Directors. The Company's Audit Committee consists of three independent Directors, who are all considered to be "financially literate" as defined in NI 52-110.

GLOBAL ECONOMIC AND BUSINESS CONDITIONS

General market conditions resulting from high inflation, high interest rates, global supply chain issues, the Hamas-Israel and Russia-Ukraine conflicts, COVID-19, US bank failures, general economic uncertainty and other macroeconomic factors, as well as market conditions affecting companies in the life sciences industry in general, may impact our business, financial position and financial performance.

We face various risks related to public health issues, including epidemics, pandemics, and other outbreaks, such as the lingering effects of the COVID-19 pandemic or emergence of other pathogens. The effects and potential effects include, but are not limited to, their impact on general economic conditions, trade and financial markets, changes in current or potential clinical trial participants behavior and continuity in business operations, creates significant uncertainty. In addition, the COVID-19 pandemic may cause an increase in costs resulting from our efforts to mitigate the effects or in general. Even as the COVID-19 pandemic has subsided, we may suffer an adverse impact on our business due to any or prolonged continuance of the global economic effect of the pandemic or emergence of other pathogens, including any economic recession that has occurred or may occur in the future.

The extent, duration and impact of both the current Hamas-Israel and Russia-Ukraine conflicts, related sanctions, and any resulting market disruptions or instability could be significant and potentially have a substantial negative impact on the global economy and our business for an unknown period of time. Any such volatility and disruptions may also magnify the impact of other financial market risks and uncertainties described herein.

ABOUT SERNOVA

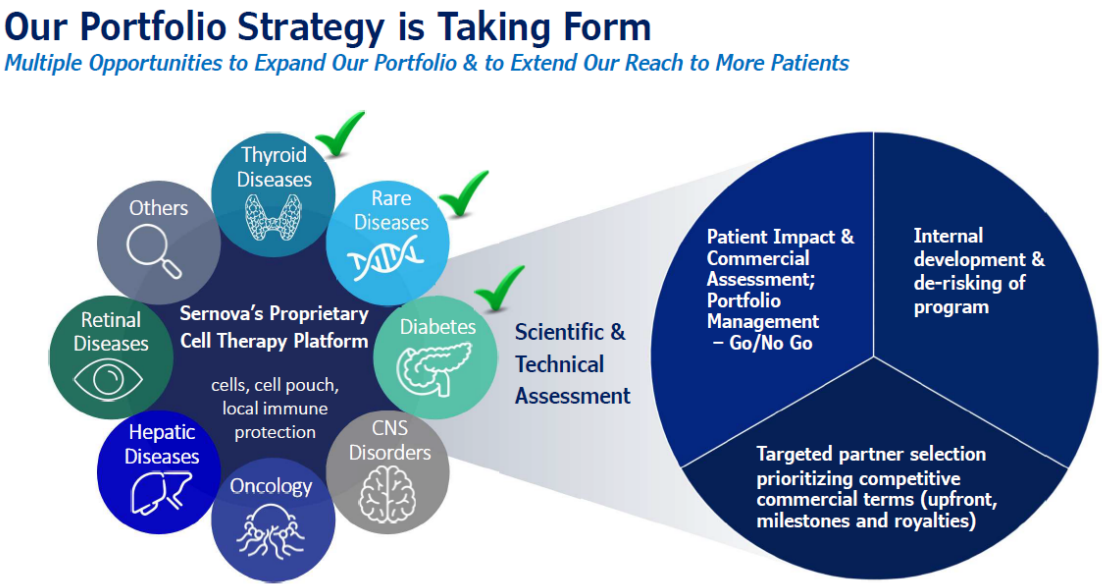
Sernova is a publicly listed (TSX:SVA | OTCQB:SEOVF | FSE / XETRA:PSH) clinical-stage cell therapeutics company focused on development and commercialization of its proprietary platform and associated technologies, including Cell Pouch™ implantable device technologies and immune-protected therapeutic cells, herein termed Cell Pouch System™. Sernova is well positioned to develop assets pre-clinically and to the point of conducting phase 1 and 2 studies, at which time Sernova aims to partner and or license its assets. This intention does not preclude Sernova from progressing assets through later stages of development, including Phase 3 studies and licensure, internally. The Cell Pouch System™ is a technology platform being developed for the treatment of and a potential 'functional cure' for chronic debilitating diseases including type 1 diabetes (insulin-dependent diabetes or T1D), hypothyroid disease, and rare diseases such as hemophilia A among others. 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, hormones or other factors into the bloodstream for the long-term treatment of various chronic diseases. Depending on the clinical indication under evaluation, the therapeutic cells used for therapeutic purposes may be autograft cells or tissues (self-cells / tissues) or allograft cells (non-self, donor cells) or cells derived from sources known to provide a virtually unlimited supply of cells such as 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 effect. We continue to work with academic collaborators and industry partners to identify and secure favorable cell candidates for our therapeutic indications.

Our preclinical and clinical research studies to date support the safety and biocompatibility of 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™, 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 develops providing microvascularization of the transplanted 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 graft survival and function. We believe this is due in part to the therapeutic cells living in a natural vascularized tissue matrix allowing close contact with the transplanted cells.

As noted in our latest AIF, filed under the Company's SEDAR+ profile at www.sedarplus.ca, 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 and hypothyroid disease. We have also entered into strategic collaborations and acquired, in-licensed or obtained an exclusive option to in-license related technologies to expand and support our research efforts. Earlier corporate development history of the Company and its business is available on SEDAR+.

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.



SELECT RECENT HIGHLIGHTS

September 2023: We announced the appointment of biotech and pharma industry veteran Cynthia Pussinen as Chief Executive Officer (CEO) and a member of the Board of Directors of Sernova and that Dr. Philip Toleikis, who was President and CEO since 2009 assumed the position of Chief Technology Officer and continued as a member of the Board of Directors.

September 2023: Veteran dealmaker and strategic leader Modestus Obochi, Ph.D., MBA, commenced the role of Chief Business Officer for Sernova.

September 2023: We announced an update on our Conformal Coating Technology development activities with Dr. Alice Tomei of the University of Miami, Miller School of Medicine in combination with our Cell Pouch™. Select highlights of the update were as follows:

- results from pre-clinical studies demonstrated that conformally coated islets transplanted into the pre-vascularized Cell Pouch™ achieved normal blood glucose control and reversed the effects of T1D in a syngeneic rat model of T1D;
- conformally coated islets show normal responsiveness to glucose and fully regulated insulin production transplanted in the Cell Pouch™;
- treated animals achieved full insulin independence (return to normal glucose levels); and
- in optimization studies in T1D animal models transplanted with conformally coated allogeneic islets in an implanted Cell Pouch™, subjects treated with a single selective immune response agent achieved sustained normalized blood glucose levels during the study period.

October 2023: We announced the presentation of additional preclinical data for our conformal coating immune protection technology program by Dr. Tomei at the International Pancreas and Islet Transplant Association (IPITA) - International Xenotransplantation Association (IXA) - Cell Transplant and Regenerative Medicine Society (CTRMS) Joint Congress in San Diego, CA. The podium presentation, entitled "*Transplantation of Conformal Coated Islets in a Pre-Vascularized Cell Pouch™ Device for Beta Cell Replacement in Diabetic Rats*" was part of the Islet Transplantation: Engineering the Islet Site Session, highlighted key advancements in the refinement of the coating composition and process and outcomes of preclinical studies with Sernova's Cell Pouch™. Refer to the ***Cellular Conformal Coating Approach and Development*** section below in this MD&A for more information on the advancements and findings presented.

October 2023: We announced the presentation of further positive interim clinical data and update for our ongoing Phase 1/2 T1D Clinical Trial, by the study's Principal Investigator Dr. Piotr Witkowski, at the IPITA–IXA–CTRMS Joint Congress in San Diego, CA. Dr. Witkowski's oral presentation entitled "*Islet allotransplantation into pre-vascularized Sernova Cell Pouch™ - Lessons learned from the first patient cohort*" as part of the Islet Transplantation: Engineering the Islet Site Session. Highlights noted:

- all six patients of the fully enrolled first cohort (Cohort A) successfully implanted with the 8-channel Cell Pouch™ with post-transplant data available for periods of 6 months to 3.5 years;
- five of six patients in Cohort A discontinued insulin therapy (insulin independent) following islet transplantation into the Cell Pouch™ and modest islet top-up via portal vein. All 6 patients achieved HbA1c non-diabetic range values (<6.5%) with current durations of out to 3.5 years;
- in the study's second cohort (Cohort B), the first six of seven planned patients had the higher capacity 10-channel Cell Pouch™ implanted and five patients have received a first islet transplant;
- stable fasting and stimulated serum C-peptide levels were observed following a single islet transplant into the 10-channel Cell Pouch™ in the first assessable Cohort B patient who subsequently achieved insulin independence with a modest portal vein top-up.

Refer to the ***Type 1 Diabetes Phase 1/2 Clinical Trial for Patients with T1D, Severe Hypoglycemic Episodes and Hypoglycemia Unawareness (Phase 1/2 T1D Clinical Trial)*** section below in this MD&A for more information on the findings presented.

November 2023: We announced the granting by the US Food and Drug Administration (US FDA) of both Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) for our Hemophilia A program. ODD provides certain benefits, including tax credits for qualified clinical

testing, waiver or partial payment of US FDA application fees and seven years of market exclusivity, if the product is approved for marketing upon completion of clinical testing. Upon approval of a Hemophilia A product for pediatric use, RPDD would provide a priority review voucher for a subsequent marketing application for a different product. The priority review voucher may be redeemed, transferred, or sold. Refer to the ***Development of the Cell Pouch System™ for the Treatment of Hemophilia A / Hemophilia Program*** section below in this MD&A for more information.

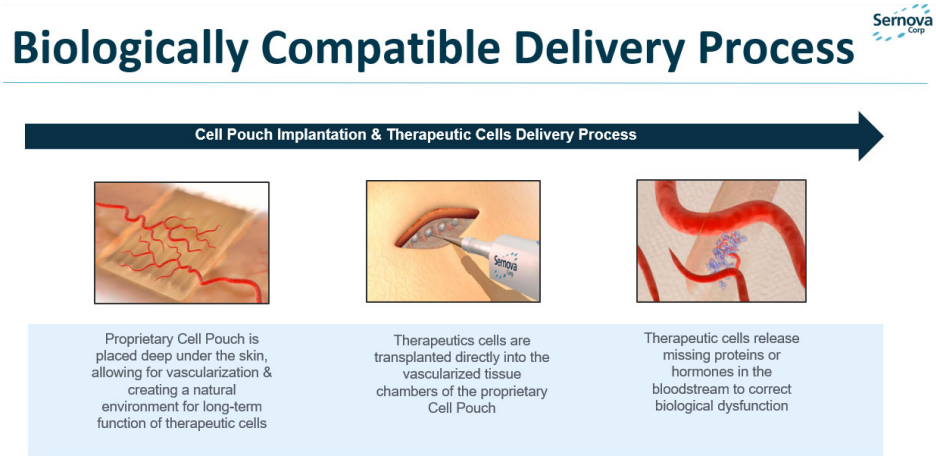
The Company continues to build out its virtual data room to provide prospective partners and institutional investors with information and materials concerning the Company upon the signing of a confidentiality agreement. To date, multiple potential partners and institutional investors have entered into confidentiality agreements and viewed the information contained therein.

BUSINESS OVERVIEW

Sernova Cell Pouch System™: A Platform Technology 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. We believe this unique approach of encouraging vascularized tissue incorporation into the device may also help prevent fibrosis that plagues other implantable cell therapy devices and provides a biologically optimal 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 for optimized therapeutic effect. Our preclinical research demonstrated that following Cell Pouch™ implantation, vascularized tissue chambers develop within the device. Long-term preclinical studies have shown that the Cell Pouch™ creates a stable, vascularized, native-tissue environment prior to transplantation of therapeutic cells, which we believe is key for maintaining long-term survival and function of therapeutic cell grafts. We believe Sernova's approach also addresses the potential issues of other competing implantable devices wherein therapeutic cells are pre-inserted prior to the device being implanted into the body which may result in hypoxia, ischemia, and cell death (resulting in poor engraftment). These issues relate to the lack of an integrated vascularized tissue environment into which cells are transplanted.

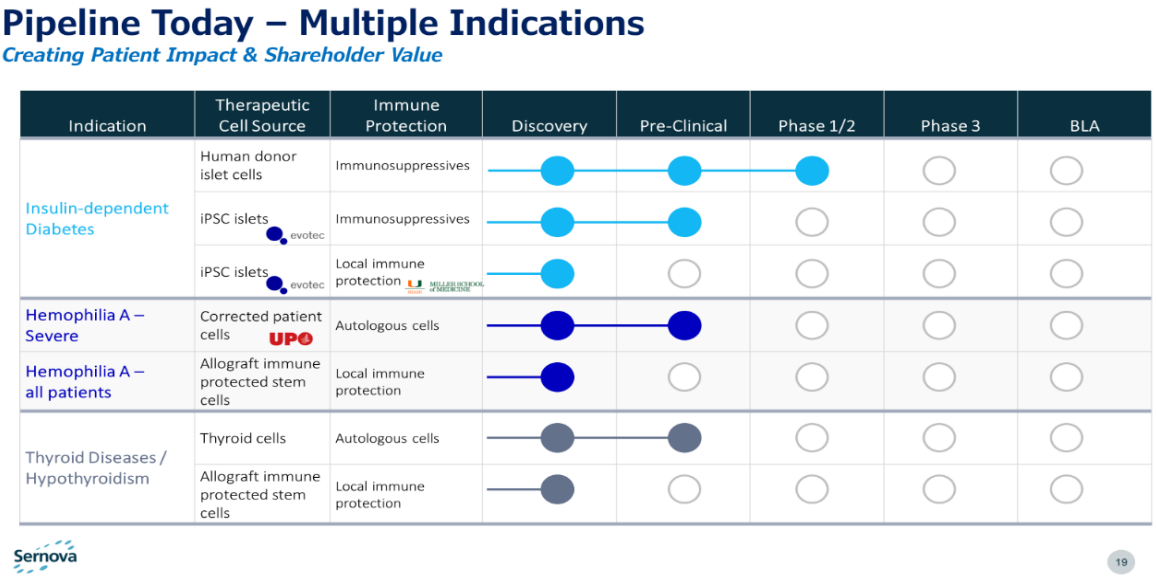


Data from a series of ISO 10993 biocompatibility studies, multiple preclinical studies, a pilot human clinical trial and our ongoing Phase 1/2 T1D Clinical Trial demonstrate that the Cell Pouch™ is biocompatible and well-tolerated. These data further demonstrate that the Cell Pouch™ platform technology establishes a required cell-to-microvessel interaction to support the viability and function of therapeutic cells via the Cell Pouch™-mediated local tissue environment. In preclinical studies, an observed benefit of Cell Pouch™ was 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 in close contact with microvessels. Our preclinical studies have shown that human donor islets transplanted into Cell Pouch™ can control blood glucose levels in small and large animal models of diabetes over extended periods. Long-term studies in several animal models have demonstrated that following transplant, insulin-producing islets become well-supported with microvessels, as occurs in their natural pancreatic environment. As a potential "functional cure" for diabetes, this close vessel proximity enables islets to continuously monitor blood glucose levels and release the appropriate amount of insulin into the bloodstream. We have also recently demonstrated that ILCs of iPSC cells transplanted into the Cell Pouch™ can control blood glucose levels in small animal models of diabetes. Similar results have been observed for other potential therapeutic applications. For example, we have demonstrated that patient cells gene-edited to produce factor VIII and transplanted into the Cell Pouch™ are effective in restoring blood clotting in a preclinical animal model of hemophilia A. Furthermore, in a preclinical animal model we have demonstrated that explanted thyroid tissue transplanted into the Cell Pouch™ allows for restoration of normal hormone levels for triiodothyronine (T3) and thyroxine (T4). We believe these data demonstrate the potential of our Cell Pouch System™ to address significant unmet medical needs across a range of therapeutic indications.

The cells transplanted into Cell Pouch™ may be protected from immune system attack, when required, by systemic immunosuppressive anti-rejection medications, therapeutics that promote tolerance of the immune system to transplanted cells, or through other Sernova immune protection technologies such as microencapsulation or conformal coating of cells. Microcapsules surrounding the cells have tiny pores, which have been shown in preclinical studies to provide a means to allow nutrient and protein exchange within the local vascularized environment while preventing immune system attack. Conformal coating is an exclusively licensed 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 in preclinical studies to allow natural exchange of glucose and insulin between conformally coated cells and systemic blood. Sernova is also evaluating gene editing technologies for our stem cell-derived programs and other approaches such as promoting immune system tolerance to transplanted cells that may provide an alternative method of local cellular immune protection. These approaches alone or in combination are anticipated to reduce or eliminate the requirement of systemic immunosuppressive anti-rejection medications, across a range of disease indications.

Thus, we believe our technology platform approach and its minimally invasive implantation approach may provide an opportunity for the Cell Pouch System™ to become the standard of care for the treatment of multiple diseases with the goal of a 'functional cure'.

The graphic below represents the progress to date of our active research and clinical development programs combined with the envisioned potential future longer-term expansion of our Hemophilia and Thyroid Programs to include immune protected stem cells as the therapeutic cell source.



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 immune protection technologies for the treatment of major and rare diseases in humans. The vast majority of the Company's direct R&D costs over the last three fiscal years have been related to Sernova's Diabetes Program, which is the Company's lead R&D program.

Our overall objective is to advance our programs through the various stages of preclinical and clinical development to Phase 3 licensure-enabling studies. Final clinical development as well as product commercialization, marketing approval and distribution would be achieved through securing commercial partners. 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 R&D objectives and related goals include the following:

- conducting or supporting the clinical trials required to gain eventual marketing approval for the Cell Pouch System™ in countries that have a significant market opportunity. Our current Phase 1/2 T1D Clinical Trial is utilizing human donor islets;
- completion of preclinical IND enabling activities followed by clinical testing of the combination of Evotec iPSC-derived ILCs and Sernova technologies to overcome the limited supply issue of human donor islets. We believe this would expand the availability of treatment to millions of diabetics, versus thousands; and simultaneously expand the value of our assets; and
- ongoing R&D activities related to our proprietary Cell Pouch™ in the following areas:
  - continuing R&D and preclinical work that could support IND filings for additional therapeutic indications such as postoperative hypothyroid disease and hemophilia A;
  - developing, assessing and optimizing our cellular immune protection technologies;
  - collaboration with industry and academic partners to assess new technologies and evolve product development activities for new product and clinical indication opportunities;
  - assessing new therapeutic cell sources in additional potential therapeutic indications of interest; and

- expansion of our intellectual property portfolio.

Refer to specific sections below for more details of progress and the next activities and milestones for each of our R&D programs and related initiatives.

Development of the Cell Pouch System™ Platform for the Treatment of 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, the reduction of debilitating complications, and ultimately a 'functional cure' for this disease.

According to the International Diabetes Federation (IDF), there are approximately 537 million people worldwide with diabetes, and nearly 10% of these individuals have T1D (https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html) where the cells in the pancreas that control blood sugar levels through controlled 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. Approximately 17% of people with T1D suffer from hypoglycemia unawareness events characterized by onset of hypoglycemia without any warning symptoms (www.diabetesnet.com). This significant proportion of diabetic patients is at risk of sudden and severe low blood sugar reactions that may become fatal without the intervention of another person. The safe management of this at-risk population could be addressed by Sernova's products – following successful completion of clinical studies and regulatory approval.

The primary treatment for T1D to help control blood sugar levels is insulin injections by needle or insulin pump. The life of a person with diabetes is consumed with constant monitoring and frequent treatments in an 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 both improve treatments for diabetic people and to enhance their quality of life. We believe our Cell Pouch System™ may provide an efficacy advantage and reduction of diabetes-related side effects in these people relative to the current standard of care, leading to significant improvements in their quality of life. The ultimate goal of our cell therapy approach for T1D is to return blood sugar regulation to a normal healthy state.

In some countries, the current cell therapy is transplantation of donor islets into the portal vein of the patient's liver. This first-generation cell therapy approach 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 this irreversible transplant. A portal vein islet transplant is the only cell therapy treatment approach possible for this population of people with diabetes and is only occasionally offered to reduce the occurrence of severe hypoglycemic episodes in these patients. Portal vein islet transplant remains categorized as an experimental procedure by some regulators, including the US FDA, and may only be administered under a clinical trial protocol.

It is encouraging that islet cell transplantation, even into the portal vein in humans, has shown some positive outcomes for diabetic patients. These positive effects demonstrate the potential of a standardized 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 IBMIR, large quantities of islets, often 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, which are typically required to achieve efficacy. This limits the number of doses of cells that can be infused into the portal vein during a patient's lifetime. A further shortcoming of portal vein transplant is that infusion of cells into the portal vein is not easily amenable to technologies such as glucose-responsive insulin-producing stem cell-derived cells, that are being developed to overcome the limited supply of donor islet cells. When infused into the liver, these cells are not retrievable if there is an islet product safety or tolerability issue. The only way to explant liver-infused cell technologies is to perform a liver transplant, which becomes a life-threatening issue due to the lack of donor organs.

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 life-threatening severe hypoglycemic episodes. 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 integrated with microvessels, similar to the islets' natural pancreatic environment rather than being subjected to immersion in blood with immune-reactive cells, which is believed to lead to IBMIR. We believe islet transplant to Cell Pouch™ may eliminate the inflammatory response observed after portal vein infusion, enabling improved islet survival. Improved islet survival and engraftment potentially lowers the number of islets required for each transplant. Consequently, by transplanting islets into the Cell Pouch™, rather than the portal vein, fewer islets, and therefore fewer donor pancreata are anticipated to be required to achieve glucose control for each recipient, thereby potentially increasing the availability of these life-sustaining organs. In addition, the known side effects of multiple islet infusions into the portal vein are expected to be eliminated with the use of Sernova's Cell Pouch System™. These benefits are expected to be further magnified by Sernova's development of glucose responsive stem cell-derived ILC technologies.

Table 1 - Potential Benefits of Cell Pouch™ Islet Transplant

Characteristics	Cell Pouch™ Transplant	Portal Vein Transplant
Islets housed in a vascularized tissue matrix	Yes	No
Confirmed vascularization of islets	Yes	No
Retrievable site	Yes	No
Retrievable site for stem cell-derived and gene-edited cells, providing a safety benefit	Yes	No
Minimally invasive subcutaneous site	Yes	No
Prevention of liver-associated toxicities	Yes	No
Prevention of IBMIR	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. The Cell Pouch™ is a minimally invasive, retrievable device for the placement and long-term survival and function of therapeutic cells for the production of needed, but missing protein(s) or hormone(s).

Importantly, Cell Pouch™ technologies are specifically and uniquely designed to be biocompatible, featuring pores that incorporate with vascularized tissue to form fully enclosed chambers with central void spaces for placement 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™ prevents the formation of fibrotic tissue following implantation, facilitating the long-term survival and function of transplanted 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 treatment of diabetes. The data gained from our current clinical study using donor islets is being used to provide a basis for advancement of glucose-responsive immune-protected stem cell-derived cells for transplant into the Cell Pouch™. We believe stem cell-derived islets have the potential to treat 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. In long-term preclinical evaluation, 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 an 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 Cell Pouch™ may require a smaller than initially anticipated dose of cells (marginal islet dose) with a lower overall cell density per Cell Pouch™ channel, in order to achieve efficacy. This parameter is being investigated and optimized in human clinical evaluations testing the ability of Cell Pouch™ and transplanted islets to achieve glucose control in patients with diabetes.

We have manufactured our Cell Pouch™ at a US-based medical device contract-manufacturing 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). In our current Phase 1/2 T1D Clinical Trial with donor islets, we are testing additional sizes of Cell Pouch™ that will enable us to further optimize islet dosing and dose density which we believe may lead to enhanced patient outcomes with the Cell Pouch System™. In addition to preparing for a potential T1D pivotal study with donor islets, the current Phase 1/2 T1D Clinical Trial is informing planned trials with the Evotec iPSC-derived ILC technology.

To validate our Cell Pouch System™ technologies in preparation for clinical evaluation for T1D, in addition to safety studies of Cell Pouch™ alone we successfully transplanted donor islets into the Cell Pouch™, in multiple small and large animal models (syngeneic, autograft and allograft) of diabetes. The reversal of diabetes in these studies provided proof of concept of the Cell Pouch System™ to support clinical evaluation of the Cell Pouch™ with donor islets. Based on the preclinical results with donor islets, we conducted a first-in-human proof-of-concept (POC) clinical study for the treatment of human

subjects with diabetes and hypoglycemia unawareness. Patients received donor islets, protected by the standard of care immunosuppressives for a first in human Canadian safety study, cleared by Health Canada. The approach of using human donor islets in the Cell Pouch™ has 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 stem cell product to treat the larger treatable population of patients with diabetes.

We believe that the ability of Cell Pouch™ to revascularize transplanted islets and restore their metabolic function is a significant breakthrough in the cell therapeutics field for this fragile patient population.

While donor islets provide a first Cell Pouch System™ therapeutic cell source and potential product to treat patients with the most significant unmet need - those with severe hypoglycemic events and hypoglycemia unawareness - our goal is to offer effective treatment to the broader general patient population of millions of people with diabetes. Consequently, we sought out an ethically derived, advanced iPSC-derived ILC technology with high potential for successful commercialization. We have demonstrated that iPSC-derived ILCs can provide long-term insulin independence in an animal model of diabetes when transplanted into the Cell Pouch™. We believe iPSC-derived ILCs have superior commercial opportunity compared to progenitor embryonic stem cell-derived cells as the latter technologies are currently prohibited for human use in certain regulatory jurisdictions. Furthermore, fully differentiated ILCs may provide required insulin to patients sooner following transplantation than early progenitor islet technologies which may take many months to mature following transplantation prior to producing therapeutic levels of insulin in the body.

We chose Evotec's iPSC technology for this transformative component of our therapeutics platform based on multiple scientific, regulatory, manufacturing capabilities, business and commercial factors. We believe the Evotec Collaboration will secure a virtually unlimited supply of ethically derived, advanced glucose-responsive, insulin-producing ILCs, eliminating the limitation of a restrictive supply of donor islets for product commercialization. We also believe that this technology broadens and strengthens our appeal to strategic partners for business development and/or M&A opportunities with our cell therapy platform and the Company overall. Evotec's iPSC-derived ILCs in combination with the Cell Pouch™ and immune protection technologies is a priority in our clinical development plans and product pipeline. For more information on Evotec's iPSC technology and current status of our iPSC Program status, refer to the *Significant Acquisitions, In-Licensing and Collaborations* section within this MD&A.

Our partner, Evotec, continues to optimize and advance the process development for and scale up of iPSC-derived ILCs which will be used in additional IND enabling studies, clinical testing and subsequent commercial supply following regulatory submissions and approvals. Sernova's goal is to ensure a production process that is as close to commercial ready as possible, before going into a first in human trial to avoid and or limit any costly changes and delays in the future. Evotec has recently provided updated timelines for delivery of the more optimized ILCs. We now anticipate initiating the Phase 1/2 clinical trial evaluating the Cell Pouch™ with iPSC-derived ILCs for treatment of T1D in the fourth quarter of 2025.

We also anticipate introducing local immune protection technologies into the diabetes program to develop additional product offerings and are conducting preclinical development studies with anticipated future clinical development activities with human donor islets and or iPSC-derived ILCs.

We continue to advance our clinical studies with our end goal of product approval and registration of all product offerings for the diabetic market.

Type 1 Diabetes Phase 1/2 Clinical Trial for Patients with T1D, Severe Hypoglycemic Episodes and Hypoglycemia Unawareness (Phase 1/2 T1D Clinical Trial)

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 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 defining our understanding of the relationship of treatment response to the dose and dose-density of islets transplanted into the Cell Pouch™. Continuous glucose monitoring (CGM), mixed meal tolerance tests and changes in daily insulin use are efficacy measures used to track the function of the cells transplanted into Cell Pouch™ at key time points throughout the clinical trial. The use of CGM in this study supports the analysis of serum glucose concentrations and variability, the number, severity and duration of both high and low glycemic episodes.

Following a peer review of the new clinical protocol, Sernova was awarded up to US$2.5 million (approximately $3.4 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 Cell Pouch™ as a potential treatment for diabetic patients with hypoglycemia unawareness.

Patients eligible for the study have long standing T1D, hypoglycemia unawareness and a history of severe hypoglycemic events despite optimized medical care. These patients lack the ability to produce insulin from their pancreas, as evidenced by undetectable blood levels of C-peptide in response to a glucose tolerance test. C-peptide is a quantitative biomarker of endogenous insulin production by islets. In this trial, eligible patients are implanted with therapeutic Cell Pouches and small sentinel Cell 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 isolation of the islets under strict release criteria, a marginal dose of the purified islets is transplanted into the vascularized tissue channels of the pre-implanted Cell Pouches.

A sentinel pouch is transplanted with islets concurrently with the therapeutic Cell Pouches and then retrieved by the surgeon approximately 90 days following transplantation. Sentinel Cell Pouches are subjected to histological assessment of islet survival and function within the Cell Pouch™. Following a period of 45 days to six months post-transplant, the clinical investigator determines if a second small islet dose will be transplanted followed by a subsequent 45 day to six-month safety and efficacy follow-up period. Patients are then followed for approximately one year. Patients not demonstrating optimal therapeutic benefit are eligible to receive a protocol-defined marginal dose portal vein top-up of donor islets. The goal of providing up to three doses of islets is to determine the relationship between therapeutic effect and both total islet dose and density within the Cell Pouch™.

Interim analyses have resulted in the development and implementation of higher capacity 10-channel Cell Pouches, that provide >50% more islet capacity relative to the 8-channel Cell Pouches used for the first cohort in our Phase 1/2 T1D Clinical Trial with the additional potential for reduced islet density.

The transition to this new larger Cell Pouch™ and the amended protocol enables optimized dosing and shorter efficacy evaluation periods to ultimately decrease time to key efficacy endpoints. These endpoint measures include survival of transplanted islet cells, proportion of patients with a reduction of severe hypoglycemic episodes, and proportion of patients with an improvement in HbA1c. We believe the higher dose of islets at a lower cell density will further enhance graft function. Subjects who complete the study protocol continue long-term follow-up by their investigator physician.

We believe these preliminary findings from the ongoing, adaptive-design trial support the safety, viability, and efficacy of the Cell Pouch System™ approach following protocol-defined islet transplants for the treatment of patients with T1D, hypoglycemia unawareness and severe hypoglycemic episodes.

At key timepoints during the trial, islet-transplanted sentinel devices are removed and subjected to histological assessment by an independent pathologist. In several patients, and from multiple timepoints, healthy and abundant insulin-producing islets have been observed in the sentinel Cell Pouches. These islets have been observed to be intimately associated with blood vessels within the native-tissue matrix. Of significant importance, observations have been reported reflective of early diabetes improvement in the most advanced trial patients: fasting and glucose-stimulated blood levels of C-peptide (a biomarker of insulin produced by cells), reduction in the number of severe hypoglycemic episodes, reduction in HbA1c, and other metabolic parameters. These indicators were further improved with the protocol-defined supplemental islet transplant to portal vein, following which subjects rapidly converted to insulin independence. We believe these indicators suggest a cumulative effect of islet transplants to Cell Pouch™ that facilitate conversion to a non-diabetic state with a minimal supplemental dose via the portal vein. It is for these reasons that we introduced the higher capacity 10-channel Cell Pouch™ to accommodate what we have calculated to be the optimal total dose of high-quality purified islets required to potentially achieve insulin independence.

We believe these preliminary findings are an important achievement in the cell therapeutics field and a first for an implanted device transplanted with donor islets. These results from transplanted human donor islets in Cell Pouch™ represents an important advance toward our goal of developing an optimized treatment for all insulin-dependent diabetic patients by employing immune protected iPSC-derived ILCs within our Cell Pouch™.

We believe 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 using small animal models of T1D. We are leveraging our extensive learnings of human donor islets within the Cell Pouch™ as we develop our iPSC-derived beta cell technologies, along with Evotec, to provide an immune-protected cell-based therapeutic suitable for all people with insulin-dependent diabetes.

Advancements with the T1D study and additional findings over the past year are summarized below.

On November 3, 2022, we announced the adoption of a protocol amendment, approved by the University of Chicago Institutional Review Board (IRB) and without objection from US FDA, to add a second cohort of up to seven patients to test the aforementioned enhanced capacity 10-channel Cell Pouch™ and potentially optimize patient outcomes. The amendment was based on promising positive interim data to date from our clinical study informing on islet dose and density. The amendment enables us to proceed with a strategically optimized protocol potentially reducing the time required for patient treatment while accelerating potential secondary endpoint efficacy achievement with more optimal dosing. We have engaged a clinical trial recruitment partner with extensive experience and success in

accelerating T1D clinical trial patient enrollment to expedite recruiting and patient enrollment and we expect to report on interim data from the second cohort with the enhanced capacity Cell Pouches in 2023. On November 17, 2022, we provided an update that the first two patients of the second cohort have been implanted with the enhanced 10-channel Cell Pouch™.

On March 8, 2023, we announced that the first two patients enrolled in the second cohort of our Phase 1/2 T1D Clinical Trial received their first islet transplant into the higher capacity Cell Pouch™. Additionally, a third enrolled patient has now been implanted with the higher capacity Cell Pouch™ and awaits islet transplantation. Execution of enrollment acceleration strategies by the experienced clinical trial recruitment agency partner we have engaged are proving to be very successful. Enrollment for the recently added second cohort is already approximately half completed (three of up to seven patients). Recruitment of the remaining patients for the second cohort is continuing.

On June 24, 2023, the Research Team from Dr. Piotr Witkowski's laboratory at the University of Chicago for our Phase 1/2 T1D Clinical Trial presented updated positive data from the ongoing study at the American Diabetes Association's 83rd Scientific Sessions in San Diego, California. Updated data was presented in an oral podium presentation, "*Islet Allotransplantation into Pre-vascularized Sernova Cell Pouch—Early Results from the University of Chicago"*.

The presentation discussed the first eleven patients enrolled across two cohorts in the clinical trial and reconfirmed the safety of Cell Pouch™ up to more than four years following implant. To date, five patients in the first cohort of six subjects who have completed the clinical trial protocol have experienced insulin independence for periods ranging from six months to greater than three years. The sixth patient in the first cohort has only recently completed the protocol-defined islet transplants and awaits assessment of their islet graft function.

In addition, updates were provided for the second cohort with the recently implemented 10-channel Cell Pouch™ with more than 50% greater transplant capacity than the previous 8-channel system. Five of the seven patients have been enrolled in the second cohort and implanted with the higher capacity Cell Pouch™. Three of the five patients enrolled have each received a first islet transplant to their implanted Cell Pouches. The first evaluable patient in the second cohort has demonstrated persistent fasting and stimulated serum C-peptide levels following a single islet transplant into the pre-vascularized 10-channel Cell Pouch™.

Other findings from the interim clinical update:

- long-term surgical implantation of the Cell Pouch™ continues to be well tolerated with a favorable safety profile in patients receiving either 8 or 10-channel Cell Pouches;
- five of the six patients in the first cohort achieved insulin independence following supplemental islet transplants via the portal vein that were below the typical intraportal islet dose, indicating that islet graft function in the 8-channel Cell Pouch™ is supporting ongoing glucose control;
- histological assessment of sentinel Cell Pouches excised at ≥90 days post-transplant revealed surviving functional islets in five of six patients in the first cohort; and
- the first patient in the second cohort developed persistent neutropenia requiring cessation of immunotherapy to enable the neutropenia to resolve. The third patient who received a first islet transplant awaits their first islet graft assessment.

On October 26, 2023, Principal Investigator Dr. Witkowski presented updated positive data from the ongoing study at the IPITA–IXA–CTRMS Joint Congress in San Diego, CA. Updated data was

presented in an oral podium presentation, "*Islet allotransplantation into pre-vascularized Sernova Cell Pouch - Lessons learned from the first patient cohort*", as part of the Islet Transplantation: Engineering the Islet Site Session. Enrollment in the first cohort (Cohort A), utilizing the 8-channel Cell Pouch™, is complete with post-transplant data available for periods of follow-up ranging from six months to three and a half years. The second cohort (Cohort B), that began enrolling in November 2022 and utilizing the higher capacity Cell Pouch™ with a revised and better-tolerated immunosuppressive regimen, has enrolled at a significantly faster pace that Cohort A with six of the planned seven patients successfully implanted with Cell Pouch™.

Interim results from Cohort A demonstrated successful implantations of the 8-channel Cell Pouch™ in the six treated patients that were well tolerated with no seromas and no unexpected AEs (adverse events), chronic pain or discomfort. Data showed histological evidence of surviving and functional islets and positive fasting and stimulated serum C-peptide (a measure of islet insulin secretion) in patients who maintained optimal immunosuppression. All six patients eventually received supplemental, marginal-dose islet infusions via the portal vein with the first five having achieved sustained insulin independence. All six Cohort A patients achieved HbA1c values in the non-diabetic range (<6.5%) with persistent serum fasting and stimulated C-peptide levels for current durations out to three and a half years.

In Cohort B, six of the planned seven patients have been implanted with the higher capacity 10-channel Cell Pouch™, without complications. Among the six patients that have been implanted, five have completed at least one of the two protocol-defined islet transplants to Cell Pouch™. The first assessable patient in Cohort B following the first Cell Pouch™ islet transplant showed persistent fasting and stimulated serum C-peptide, with stable BETA-2 scores (a measure of islet graft function) that continued at Day 180 following their first islet transplant to Cell Pouch™. The same patient showed modest but favorable improvements in HbA1c from 7.5% at baseline to 6.9% also at Day 180. Unexpectedly, the day following the second islet transplant to Cell Pouch™ for this patient, results from a sample of the islets taken from the donor pancreas on the day of transplant came back positive for the yeast Candida albicans. Out of an abundance of caution, the Cell Pouches containing the contaminated islets were immediately removed. The Cell Pouches that were previously transplanted with the first dose of uncontaminated, healthy islets were not removed and continued to function as anticipated. Explantation of the Cell Pouches containing the contaminated islets was completed without complications and the patient fully recovered without any wound or systemic blood infection, demonstrating the designed retrievability of the transplanted Cell Pouch™. Following recovery, this patient received a modest intraportal islet transplant and remains insulin independent.

The revised immunosuppression protocol, used in Cohort B, continues to demonstrate favorable protection for the islet grafts with no donor islet rejection or donor-specific antibodies (DSAs) observed under the new regimen. Recruitment of the final patient (seventh) in Cohort B was recently completed. The Company anticipates additional Cohort B clinical findings relating to the larger 10-channel Cell Pouch™ towards the end of the first quarter of calendar year 2024.

Results from the combined cohorts will help guide decisions on the next clinical development steps for our T1D Program, including our current donor islet study and further support advancement of our iPSC-ILC therapy into the clinic.

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 / Thyroid Programs

The goal of our thyroid cell therapy program is to provide people with hypothyroid disease an improvement in the natural thyroid hormone feedback loop, 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 is essential for life as it produces and secretes thyroid hormones that regulate the body's metabolism. The development of new treatments for patients with unsatisfactory control of the thyroid hormone feedback loop may satisfy this 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 following thyroidectomy. Sernova's first approach in the treatment of hypothyroid disease is to take healthy tissue from each patient's own thyroid gland - removed during a thyroidectomy – and transplant that tissue into the pre-implanted vascularized Cell Pouch™. The goal is to restore the natural feedback system for release of thyroid hormones from each patient's own thyroid tissue.

The thyroid gland affects all critical body functions including heart rate, energy levels, and the rate at which energy is produced from nutrients. Essential functions of the thyroid gland include control of how quickly the body uses energy, makes proteins, and sensitivity to other hormones, principally through the production of the thyroid hormones triiodothyronine (T3) and thyroxine (T4) in response to elevating levels of thyroid stimulating hormone (TSH).

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 diseases, radiation treatment, and surgical removal of the thyroid (thyroidectomy). Patients may undergo surgical reduction (thyroid lobectomy) or complete removal of the thyroid gland (total thyroidectomy) for treatment of several disorders such as thyroid nodules, which are reported to occur in up to 65% of patients observed upon autopsy (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 Thyroid Association estimates that 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 and most patients are treated with daily Levothyroxine, a synthetic T4. Published research indicates up to 50% of synthetic thyroxine users do not achieve adequate T3 and T4 hormone levels (Okosieme, OE et al. Expert Opin Pharmacother 2011; 12(15):2315-2328). Moreover, it is evidenced that patients treated with T4 still experienced several symptoms of hypothyroidism, 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.). Results of our preclinical research are being used as a foundation for anticipated clinical trials using Cell Pouch in combination with thyroid-hormone producing cells with the goal to preserve or recover normal T3 and T4 thyroid regulation and improve patient quality of life.

Sernova has conducted preclinical research with its Cell Pouch™ for the treatment of postoperative hypothyroidism in collaboration with Dr. Sam Wiseman, BSc, MD, FRCSC, FACS, Professor, Faculty of Medicine at the University of British Columbia, Director of Research in the Department of Surgery at Providence Healthcare in Vancouver, BC, Canada and, in part, funded by a Transplant Venture Grant awarded by the Transplant Research Foundation (TRF) of British Columbia. Sernova has assessed healthy human thyroid tissue transplanted into a previously implanted Cell Pouch™ in a preclinical model, in preparation for a clinical program. Our planned initial clinical approach to 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 restore thyroid regulation and reduce the burden and risks of postoperative hypothyroidism. The overall aim of the program is to evaluate the survival and function of thyroid tissue after implantation into the Cell Pouch™ to establish proof-of-concept of this novel approach. The current results from this collaboration support the potential for Cell Pouch™ transplanted with thyroid tissue to provide clinical benefit for the treatment of hypothyroidism.

On January 27, 2022, we announced the publication of a peer reviewed preclinical study demonstrating positive results of a 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. Wiseman, a leading surgeon, researcher and internationally renowned expert in the management of thyroid and parathyroid disease, was published in the scientific journal, *PLOS ONE*, January 20, 2022 edition. In this study, thyroid tissue from patients undergoing surgery for treatment of benign disease was transplanted into Sernova Cell Pouches that had been previously implanted into laboratory mice. The aim of the study was to investigate the long-term survival of human thyroid tissue in the Cell Pouch™ and evaluate the ability of these thyroid transplants to release thyroid hormones into the bloodstream. The study confirmed that the human thyroid tissue transplanted into the Cell Pouch™ survived and released human thyroglobulin into the bloodstream, with no adverse effects for the three-months duration of the study. Thyroglobulin was used as a biomarker efficacy measure in this study as it is the precursor of thyroid hormones.

On January 30, 2023, we announced results from an additional POC preclinical study that demonstrated auto-transplantation of thyroid tissue into the Cell Pouch™ can compensate for removal of the thyroid gland (total thyroidectomy), restoring normal thyroid hormone levels with the normal production of T3 and T4 thyroid hormones in response to naturally elevating TSH.

We are now completing a final IND enabling preclinical study to support advancement of the program to clinical trials for this novel approach to the prevention of postoperative hypothyroidism. Simultaneously, we are preparing documentation to support a clinical trial application. The aforementioned preclinical study is progressing well. If study results continue as expected, we anticipate to expedite an IND filing – pending favorable findings of expanded market research currently being conducted and sufficient financial resources being available to commence a clinical trial. Discussions have continued with regulatory authorities and regulatory pathways for clinical development in each target jurisdiction have been determined.

Development of the Cell Pouch System™ for the Treatment of Hemophilia A / Hemophilia Program

Our hemophilia program targets a comprehensive therapy that corrects factor VIII (FVIII) production in people with hemophilia A. The use of FVIII corrected cells, transplanted to the vascularized pre-

implanted Cell Pouch™, is intended to reduce or eliminate bleeds associated with hemophilia A, thereby providing a 'functional cure' and improved quality of life.

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 FVIII results in a reduced ability for blood to clot naturally resulting in increased bleeding, even in circumstances where small blood vessels naturally break and heal such as in joints, resulting in inflammatory arthritic type symptoms and joint damage. 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 and a disruptive approach to the current standard of care treatment for hemophilia A. 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 for the prophylactic treatment of hemophilia A. This approach is analogous to that used for CAR T-cell therapy as a validated therapeutic approach where a patient's own cells are collected from a blood sample and then modified, multiplied and placed back into the patient's body to treat the target disease.

Sernova's approach to the cell therapy treatment of hemophilia A involves obtaining a blood sample from the patient and correcting the genetic defect in certain isolated cells so the cells produce the required FVIII. The cell numbers are then expanded for placement into our Cell Pouch™, that has been previously implanted into the patient. We believe the therapeutic potential to have a constant release of FVIII from a hemophilia A patient's own genetically corrected cells in the Cell Pouch™ would be a significant advancement in the treatment of hemophilia A and other diseases that can be treated with genetically engineered cells that are maintained within a contained, retrievable, and replaceable, organ-like environment. Sernova's therapeutic approach could reduce or eliminate the need for patients to take expensive life-long infusions of FVIII to reduce or prevent the deleterious effects of this disease.

In the development of this novel technology, multi-year product development and POC studies have been conducted and successfully completed by Sernova and a European team of experts collectively forming the HemAcure Consortium (HemAcure Consortium). The aim of the HemAcure Consortium 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™. This combination therapy strives to replace missing clotting human FVIII in the patient's own Blood Outgrowth Endothelial Cells (BOECs) transplanted into the Cell Pouch™. These corrected cells function to release FVIII into the bloodstream restoring the ability for blood clotting to occur preventing uncontrolled 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 to enable the completion of safety and efficacy studies in the Cell Pouch™ as part of a regulatory package in preparation for human clinical testing.

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 scientific journal *Molecular Therapy: Methods & Clinical Development, Volume 23*.

The publication highlighted a therapeutic approach that includes use of the patient's own cells obtained from a blood sample, which are then modified using a lentiviral vector-mediated gene transfer procedure using the B-domain deleted form of FVIII under the control of an endothelial-specific promoter and subsequently transplanted within Sernova's vascularized Cell Pouch™ into a mouse model of hemophilia A. These cells then provide a continuous therapeutic release of factor VIII into the bloodstream. The publication highlighted the successful demonstration of safety and long-term improvement in blood clotting in a hemophilia A mouse model.

We believe the published preclinical results demonstrate the potential of 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.

We have entered into a collaboration with a leading European academic center to optimize the cellular factor VIII production in the gene editing manufacturing process as well as Cell Pouch™ dosing in a preclinical model of hemophilia A. We anticipate, in collaboration with this leading European academic center, to complete IND-enabling studies in 2024 and in early 2025, pending the receipt of supportive data, IND filing efforts will be initiated immediately.

On November 27, 2023, we announced that the US FDA had granted both Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) for Sernova's Hemophilia A program. The US FDA grants orphan designation, also referred to as orphan status, to therapies intended for the treatment of rare diseases that affect fewer than 200,000 people in the US. This designation provides certain benefits, including tax credits for qualified clinical testing, waiver or partial payment of FDA application fees and up to seven years of market exclusivity, if approved. Separately, RPDDs are granted for rare diseases that primarily affect children under 18 years old with recipients of this designation being awarded a Priority Review Voucher (that can be used for a subsequent marketing application for a different product) upon approval of the Company product for the treatment of Hemophilia A in pediatric patients. The priority review voucher may be redeemed by the holder, transferred, or sold. Over time Priority Review Vouchers have been sold to third parties for amounts of up to US$350 million. Recently, several Priority Review Voucher sales have occurred with the majority sold for around US$100 million, including at least three sold during 2023.

Our proposed 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.

Local Immune Protection & Other Complementary Technologies

We believe that encapsulation (conformal coating technologies) and other advanced technologies such as gene-editing may protect therapeutic cells from immune system attack within the Cell Pouch™ vascularized environment while providing the means to enable direct communication between therapeutic cells and microvessels within the established tissue matrix. We believe such approaches may enable long-term survival and function of therapeutic cells in Cell Pouch™, with transient or even no need for immunosuppressive medications. Consequently, development of cellular local immune protection technologies is an important pillar for our cell therapeutics platform. During 2020, we secured

exclusive rights to local immune protection technologies for our Cell Pouch™ cell therapy platform via acquisition and licensing agreements.

Our approach of providing immune protection for cells locally, within the Cell Pouch™ tissue matrix, is anticipated to be a competitive advantage and accelerate development of our therapeutic programs. We continue to evaluate additional immune protection technology approaches. We believe we are well-positioned to advance our total cell-based therapeutics platform to multiple clinical applications and broader patient populations.

Cellular Conformal Coating Approach and Development

The goal of our conformal coating program is to apply local immune protection to transplanted therapeutic cells to avoid the current need for life long anti-rejection medications. This technology would improve overall outcomes and quality of life for patients through freedom from the maintenance and side-effects of immunosuppressive agents. We expect to accomplish this by providing local immune protection that shields therapeutic cells from detection and attack by a patient's own immune system.

During 2020, we acquired an innovative cellular local immune protection technology. 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 cell therapy 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 cross-linked polymer 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 following cell transplantation;
- enables close contact of the transplanted therapeutic cells with the vascularized tissue matrix within the Cell Pouch™ chambers to enable more intimate interactions;
- enables the diffusion of small molecules and biomolecules (i.e. glucose, insulin, and other proteins or hormones), to provide a physiological glucose-stimulated insulin response without delay that occurs with other encapsulation technologies; and
- due to the improved diffusion of biomolecules relative to other encapsulated technologies, it may require a smaller load of therapeutic cells to achieve the desired therapeutic effect in comparison to standard microcapsules.

Further to our Conformal Coating Technology acquisition, we secured 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.

The complementary technology is further being developed through a collaboration with the UMiami and Dr. Alice Tomei, a leading international expert in immunoprotection and diabetes management from the renowned Diabetes Research Institute 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, we have committed to fund up to a total of US$1.81 million ($2.51 million), of which US$1.60 million ($2.21 million) has been incurred as of October 31, 2023. Technology optimization and further preclinical validation work is progressing as expected and continuing. Dr. Tomei is one of the original inventors of the Conformal Coating Technology that has been developed and optimized over more than a decade 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 life long immune suppression technologies. We believe successful development of this combination technology could meet an unmet need in a 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, 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 cellular immune protection.

Our R&D group has been working closely with Dr. Tomei's team to advance the collaboration as well as the scale up processes to manufacture sufficient coated cells for clinical applications. We have substantially increased our knowledge regarding the combination of conformally coated islets in the Cell Pouch™ and have gathered important information about the criteria needed to release the combined product for clinical use.

On September 7, 2023, we provided an update on our conformal coating development activities at UMiami with Dr. Tomei. The following advancements and findings were reported on:

- pre-clinical studies have demonstrated that conformally coated islets transplanted into the pre-vascularized Cell Pouch™ achieved normal blood glucose control and reversed the effects of T1D in a syngeneic rat model of T1D. The treated animals achieved insulin independence (return to normal glucose levels). These findings demonstrate that the conformal coating technology supports efficient glucose detection and insulin release kinetics in coated cells transplanted to Cell Pouch™;
- in additional optimization studies in T1D animal models transplanted with conformally coated allogeneic islets to pre-implanted Cell Pouch™, subjects treated with a single selective immunomodulatory agent achieved sustained, normalized blood glucose levels during the study period. These findings support our product approach of eliminating the need for the immunosuppressive medication cocktails typically used for islet transplant patients and which are frequently associated with unwanted side effects;
- assays have been identified and studies conducted to develop and validate product release criteria for the conformal coating. Release testing is conducted for the finished coated islet product to ensure quality, safety, and efficacy potential, prior to the transplantation of conformally coated islets into Cell Pouch™. Long-term in vitro stability and durability studies have also been successfully completed;
- through a design and manufacturing partner, Sernova is developing a bench-top, scalable, fully automated and GMP-compatible cell coating system. The clinical-scaled system is designed for compatible installation in both industrial and clinical GMP cell manufacturing facilities to facilitate GMP coating islets and islet analogues for testing in clinical trials; and

- Sernova is undertaking a standard array of biocompatibility studies and is completing an allogeneic optimization study using conformally coated islets in the Cell Pouch™ with the addition of a selective immunomodulatory agent which has proven effective in our ongoing Phase 1/2 T1D Clinical Trial study. A single agent provided intermittently with the conformal coating technology would be a significant advancement in the field of cellular immune protection.

On October 27, 2023, additional preclinical data for our conformal coating immune protection technology program was presented by Dr. Tomei at the IPITA-IXA-CTRMS Joint Congress in San Diego, CA. Dr. Tomei's podium presentation, "*Transplantation of Conformal Coated Islets in a Pre-Vascularized Cell Pouch™ Device for Beta Cell Replacement in Diabetic Rats*", was part of the Islet Transplantation: Engineering the Islet Site Session, and highlighted key advancements in the refinement of the coating composition and process and outcomes of preclinical studies with Sernova's Cell Pouch™. The following advancements and finding were reported on:

- the final conformal coating composition exhibits significantly improved cell compatibility and overall biocompatibility, representing evolution across years of process development work and preclinical testing;
- coating process enhancements resulted in a 500% increase in conformal coating production capacity (number of starting islets to be coated) and an 89% overall islet encapsulation yield (ratio of conformal coated islets to initial islets). These enhancements have a direct positive impact on the in vitro and in vivo efficacy of the coated islets;
- final conformal coated product was purified using a process to contain 98% conformal coated islets and only 2% empty capsules. This enables an increase in the number of functional coated islets that are transplanted within the Cell Pouch™ chambers and minimization of graft volume;
- using these composition and process development improvements, the coated islets were tested, in combination with the Cell Pouch™, in a syngeneic gold standard animal model of T1D to assess the safety and efficacy of the combined product and confirmed:
    - the biocompatibility of the coated islets within the Cell Pouch™, histologically demonstrating healthy islets within the vascularized tissue matrix;
    - the normal physiological transfer of glucose-stimulated insulin from the conformal coated islets within the Cell Pouch™; and
    - diabetic animals that received conformal coated islets within the Cell Pouch™ exhibited controlled blood glucose to non-diabetic levels - which reversed upon removal of the Cell Pouch™ - proving function of the conformal coated islets.
- a series of pilot studies using conformal coated islets, in combination with the Cell Pouch, in an allogeneic rat model of T1D established the optimal conditions to achieve diabetes reversal. These conditions, which are being used in confirmatory allogeneic studies in additional upcoming preclinical work, included:
    - drug kinetic studies identified the optimal dose and frequency of a single selective immune response agent to be used in combination with conformal coated islets; and
    - islet dose-dependent glucose control was demonstrated using conformal coated islets in the Cell Pouch™ with the selective immune response agent.
- release criteria essential for clinical manufacturing have been developed, including coating conformality, completeness, stiffness, thickness and selective permeability. Using these criteria, the conformal coating material showed long term mechanical stability, durability and selective permeability to insulin and glucose molecules but not to antibodies or inflammatory cells. These

are key requirements for long-term function of the conformal coating technology in vivo; and

- significant progress was achieved in manufacturing of the coating scale up equipment. Prototype devices have been manufactured and being tested. Final system design will provide fully automated, GMP-compliant coating applied to transplantable coated islets. The system function will involve conformal coating, washing, counting and production monitoring.

Cell Pouch™ Surgical Kit and Accessories

We are in the process of developing implantation instruments to ensure the safety, quality and consistency of tissue pocket formation and Cell Pouch™ placement for optimal graft performance. We have completed an initial design phase. The implantation instruments are currently undergoing prototype functionality and integrity testing.

We are also in the process of developing transplantation instruments to ensure the safety, quality and consistency of cell and tissue preparations and their transplantation Cell Pouch™ tissue chambers. The design program has been initiated for the transplantation instruments, and prototype testing for standardized cell and tissue handling and loading procedures is in progress.

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 stem cells or derived from xenogeneic (non-human) 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.

As part of our ongoing strategy to develop and provide an unlimited supply of insulin producing cells to patients, we are developing stem cell-derived technologies and or acquiring or securing access to associated intellectual property with the expectation to have commercial rights to provide a virtually unlimited supply of cells for the treatment of diabetes to overcome the limited supply of human donor islets. Pursuant to this strategy, the Company entered into a license agreement with the University Health Network in Toronto, Ontario, 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.

As otherwise mentioned in this MD&A, we are collaborating with global pharmaceutical partners to evaluate various cell technologies using different approaches combining Sernova and other technologies with the goal of creating best-in-class therapeutics. We have demonstrated long-term insulin independence in several collaborations using advanced iPSC stem cell-derived technologies within the Cell Pouch™ in accepted animal models of T1D. This work supported the concept of the Cell Pouch™ combined with an advanced stem cell source meant to provide an unlimited supply of therapeutic cells to treat a significant number of T1D subjects. After the assessment of the results from the collaboration activities, we pursued and came to terms with Evotec for access to their iPSC-derived ILC technology, expanding our access to stem cell-derived technologies.

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.

Significant Acquisitions, In-Licensing and Collaborations

Exclusive License Option for Advanced iPSC Beta Cells for Islet Replacement Therapy / iPSC Program

On May 16, 2022, we entered into a strategic partnership with Evotec, a global life science company and leading developer of iPSC cell technologies for therapeutic applications, with the goal to develop a best-in-class cell therapy treatment for people living with insulin-dependent diabetes. Together we will combine and leverage our respective technologies and scientific expertise to develop an implantable iPSC-based beta cell (islet-like clusters) replacement therapy (iPSC Program) to provide an off-the shelf unlimited insulin-producing cell source to treat patients with insulin-dependent diabetes.

The Evotec Collaboration combines our Cell Pouch System™ with complementary technologies and Evotec's iPSC-based beta cells for clinical development and commercialization. We believe that incorporating Evotec's glucose responsive insulin-producing, iPSC-derived ILC beta cells within our Cell Pouch™ platform creates the potential to provide a 'functional cure' for the significant number of people worldwide suffering from diabetes through this scalable, off-the-shelf product.

With its long-standing beta cell development program, Evotec has demonstrated the ability to reliably generate high quality, stable, human iPSC-derived beta cells using its proprietary process for producing ILCs in a quality-controlled, scalable, bioreactor process. These ILCs have been demonstrated to be functionally equivalent to primary human islets in their ability to normalize blood glucose levels in *in vivo* models of T1D for approximately one year, which was the length of the study.

After continued development and optimization of its iPSC technologies and evaluation of the commercial and development landscapes for implantable medical devices, Evotec concluded that the Cell Pouch™ is the optimal device component to complement its field-leading iPSC technologies in a complete treatment solution for T1D. Similarly, based on data from our collaborations with other prospective partners, Sernova concluded that Evotec had the ideal, ethically derived iPSC beta cell technology with the greatest potential to become a highly successful commercial product in combination with Sernova's proprietary technologies.

The Evotec Collaboration provides us with a worldwide exclusive option to license Evotec's iPSC-based beta cells for use in treating both type 1 and type 2 diabetes.

On January 10, 2023, we provided an update on the progress of our collaboration with Evotec SE (NASDAQ:EVO | FSE:EVT) for the development and commercialization of an iPSC-based beta cell replacement therapy for diabetes (Evotec Collaboration). The Evotec Collaboration combines Evotec's iPSC-derived ILCs with Sernova's implantable Cell Pouch™ device for the treatment of patients with T1D. Significant achievements included:

- development of a robust, cost-efficient, scalable, highly controlled iPSC differentiation protocol with the ability to cryopreserve and store batches of differentiated islet-cell clusters;
- demonstration of excellent ILC survival under standard pharmaceutical shipping conditions and following transplantation;
- demonstration of consistent long-term insulin independence with no hypoglycemic events and consistent safety profiles in a gold standard T1D preclinical model with Evotec's iPSC-derived ILCs transplanted in Sernova's Cell Pouch™;
- iPSC-derived ILC manufacturing scale-up and technology transfer activities to Evotec's iPSC GMP facility are well under way in preparation for manufacture of clinical and commercial iPSC-derived ILCs supply; and

- interactions with experts to support design of a Phase 1/2 clinical trial.

On April 24, 2023, preclinical data for Sernova's iPSC Program and the Evotec Collaboration was externally presented for the first time. The oral podium presentation, "*Manufacturing Of Human Islet-like Clusters (ILCs) From iPSCs and Functional Testing of an ILC and Cell Pouch Combination In Vivo*", occurred at the 4th International Pancreas and Islet Transplant Association (IPITA) / Harvard Stem Cell Institute (HSCI) / Juvenile Diabetes Research Fund (JDRF) Summit. Key highlights of the data presented included:

- Evotec's scalable GMP manufacturing process has been designed to produce iPSC-derived ILCs with high insulin-producing beta cell content as well as glucagon and somatostatin (produced by alpha cells and delta cells, respectively), similar to human islets;
- Evotec ILCs are cryopreserved at a late-intermediate stage of differentiation allowing for a cost-effective large-scale manufacturing process to optimize both pre and post-implantation durability and enabling storage of mass volumes and cost efficient on-demand worldwide delivery as required, which we believe represent major advantages over competing cell therapies in development;
- results from a standard T1D preclinical model with Evotec's ILCs implanted into Sernova's Cell Pouch™ demonstrated robust and durable insulin independence with blood C-peptide levels and glucose tolerance test results equivalent to a test group with human islets; and
- an additional T1D study with Evotec's ILCs demonstrated sustained normalization of blood sugar levels in diabetic mice throughout the 320-day term of the study.

As part of our Evotec Collaboration and iPSC Program, development work including multiple preclinical studies have been completed to date establishing proof of concept and progressing iPSC-derived ILC production process development, tech transfer and scaleup. Based on learnings from work completed to date, additional process related development will be conducted to further optimize the ILC component of our combined product candidate prior to commencing further and final IND enabling studies and the anticipated Phase 1/2 clinical study for the treatment of T1D with Cell Pouch™ and iPSC-derived ILCs.

Accordingly, IND enabling work and activities will continue during 2024 and into 2025 in support of an envisioned IND submission. With the expansion and extension of preclinical activities, initiation of the planned Phase 1/2 clinical trial is now anticipated in late 2025. From the start, optimal therapeutic product design has been the focus and goal of the product development for the iPSC-derived ILCs to enable the earliest possible clinical testing of as near ready to final commercial product as part of the combined product candidate. While this approach can impact early project timelines, there are longer term benefits and advantages, one being reduced risk of regulatory agencies requesting more or varied preclinical studies or product candidate rework being required at a later stage of clinical development, which would be very costly and time consuming.

Costs for iPSC IND enabling activities will continue to be incurred through 2024 and into 2025 with progression of the latest planned preparatory activities toward a now projected IND filing and associated regulatory clearance during late 2025 for a Phase 1/2 iPSC T1D clinical trial of Cell Pouch™ with Evotec's iPSC-derived ILC technology. We expect the clinical trial study would be initiated as quickly as possible after regulatory clearance was obtained.

Research Collaboration with AstraZeneca

On May 3, 2023, we announced our research collaboration with AstraZeneca to evaluate novel potential therapeutic cell applications. AstraZeneca is exploring the use of Sernova's Cell Pouch System™ as a potential platform for integration with its development of the next wave of innovative cell therapies for various indications. The preclinical research outcomes will determine the feasibility of potential therapeutic applications and subsequent product development opportunities and activities between the two companies. AstraZeneca is covering the costs of the feasibility assessment studies.

Pharmaceutical and Life Sciences Company Collaborations

The goal of our collaborations with pharmaceutical and life sciences companies is to establish new cell therapeutic products to provide potential 'functional cures' for diseases involving replacement of missing proteins or hormones through the combination of Sernova and collaborator technologies. The collaborations may result in the in-licensing or out-licensing of technologies or co-development of therapeutic products. These collaborations may also result in other M&A activities between Sernova and the collaborator companies.

In this regard, we are deploying our in-house cell therapy expertise and proprietary Cell Pouch™ technologies in combination with proprietary therapeutic cell assets designated by pharmaceutical or life science company collaborators, such as AstraZeneca noted above. 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 pharmaceutical industry build upon our business strategy to develop a portfolio of products to realize the full potential of Sernova's cell therapeutics 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 us 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.

Protection of Proprietary Intellectual Property

We have filed international patent applications related to Cell Pouch™ and the Cell Pouch System™ to protect our intellectual property rights related to our 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 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.

We will continue to protect the commercial therapeutic applications of our discoveries and inventions. In addition, we have developed technologies which we may elect to keep as trade secrets and not publicly disclose in patent applications.

SELECTED ANNUAL INFORMATION

	Year ended October 31, 2023	Year ended October 31, 2022	Year ended October 31, 2021
Expenses			
Research and development	$ 32,042,533	$ 16,896,624	$ 4,637,989
General and administrative	8,459,060	7,857,137	2,298,518
Total expenses	40,501,593	24,753,761	6,936,507
Other Expense (Income)			
Interest income	(1,500,222)	(577,285)	(70,552)
Finance costs	32,075	118,002	58,368
Foreign exchange loss (gain)	(35,926)	126,058	41,216
Net other income	(1,504,073)	(333,225)	29,032
Loss and comprehensive loss	$ 38,997,520	$ 24,420,536	$ 6,965,539
Basic and diluted loss per common share	$ 0.13	$ 0.09	$ 0.03

	As at October 31, 2023	As at October 31, 2022	As at October 31, 2021
Total assets	$ 22,106,815	$ 52,484,921	$ 29,820,344
Total non-current financial liabilities	$ –	$ 136,123	$ 275,979

RESULTS OF OPERATIONS

For the three months ended October 31, 2023, we recorded a loss of $11,703,658, an increase of $3,493,236 compared to the same period in the prior year. The increase was driven mainly by an increase in R&D costs, moderated by the offsetting effect of a decrease in non-cash share-based compensation expense. As otherwise more fully described in this MD&A, the R&D cost increase was significantly influenced by our active iPSC Program collaboration with Evotec, which was at an earlier stage during the prior year's comparative quarter, and an increase in patient related costs due to increased patient enrollment in the Phase 1/2 T1D Clinical Trial over the prior year's comparative quarter with the opening and recruitment of a second patient cohort and related expenses as existing and additional patients progressed through the trial protocol.

For the year ended October 31, 2023, we recorded a loss of $38,997,520, an increase of $14,576,984 compared to the prior year. Similar to the fourth quarter, higher R&D costs associated with the advancement of our iPSC Program was the primary year-over-year loss increase driver. Increased costs were partially offset by a decrease in non-cash share-based compensation due to the vesting of stock options and DSUs granted during the first quarter of the comparative fiscal year which included non-recurring "catch-up" of awards for two fiscal years in combination with initial grants to new employees. These grants had an incremental effect on share-based compensation for the comparative period by a one-time amount of approximately $2.4 million that is not applicable in the current year.

Period to period R&D and G&A cost changes are further discussed below.

As at October 31, 2023, total assets were $22,106,815 compared to $52,484,921 as at October 31, 2022. The decrease is primarily due to funds used to finance our operating activities.

Research and Development Expenses

The primary focus of our R&D activities during both the three months and year ended October 31, 2023 was the testing and development of the Cell Pouch System™ platform and associated technologies predominantly in relation to our lead program - Diabetes. Consequently, the vast majority of the Company's direct R&D expenditures during these periods were related to our Diabetes Program and included activities and costs associated with (i) our ongoing Phase 1/2 T1D Clinical Trial, (ii) our Evotec Collaboration / iPSC Program, (iii) Cell Pouch™ manufacturing and (iv) Conformal Coating Technology collaboration and development.

For the three months ended October 31, 2023, the Company incurred net R&D expenses of $9,675,848, a $3,132,272 increase from the comparative period. The increase reflects the progression of the iPSC Program and Evotec Collaboration, which was at an earlier stage in the comparative period; higher costs for the Phase 1/2 T1D Clinical Trial reflecting a higher number of enrolled study patients with the addition of a second patient cohort coupled with the protocol progression of all study patients; and higher personnel costs with the expansion of our R&D team, including related recruiting costs. The increase in R&D expenses is partially offset by a reduction in manufacturing costs and share-based compensation as discussed above.

Net R&D costs increased by $15,145,909 to $32,042,533 for the year ended October 31, 2023 over the comparative period, with the same factors driving the increase as described above for the latest quarter offset by a decrease in share-based compensation due to the incentive grants described above and their one-time expense impact in the comparative period.

General and Administrative Expenses

For the three months ended October 31, 2023, total G&A expenses of $2,135,747 approximated those of the comparative period although specific G&A expense components within varied and had an offsetting effect. Personnel costs increased with the expansion of our senior leadership team. This increase in G&A Expenses was partially offset by a similar reduction in share-based compensation with that discussed above under R&D Expenses.

Total G&A expenses of $8,459,060 for the year ended October 31, 2023 increased by a modest $601,923 from the comparative period despite specific components of total G&A expenses varying significantly and having an offsetting effect. Cost increases were primarily attributable to significant one-time proxy solicitation services and other expenses related to the Company's contested annual general meeting in the second quarter of this fiscal year, higher personnel costs for additional hires and related recruiting costs, and incremental investor relations and communication activities. These cost increases were offset by an overall decrease in share-based compensation expense due to the grants described above and their one-time expense impact in the first quarter of the comparative period.

SUMMARY OF QUARTERLY RESULTS

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

	Year ended October 31, 2023				Year Ended October 31, 2022			
	Q4 $	Q3 $	Q2 $	Q1 $	Q4 $	Q3 $	Q2 $	Q1 $
Loss	11,703,658	9,931,704	9,346,772	8,015,386	8,210,422	5,831,492	4,919,687	5,458,935
Loss per share	0.04	0.03	0.03	0.03	0.03	0.02	0.02	0.02

During the latter part of fiscal year 2022 and continuing over fiscal year 2023, quarterly losses have trended higher reflecting the ongoing overall growth of the Company and the advancement of our R&D programs, particularly with the initiation of our iPSC Program research collaboration with Evotec during the second quarter of fiscal year 2022 and increased study patient activities for our Phase 1/2 T1D Clinical Trial as described above in this MD&A.

Scale up and a generally higher level of iPSC Program activities has resulted in increased R&D costs since the third quarter of fiscal year 2022 compared to earlier fiscal quarters. Costs for iPSC IND enabling activities will be regularly incurred until planned preparatory activities are completed.

Quarterly clinical trial costs have trended upwards since late in fiscal year 2022 as expected due to additional patient enrollment, including the initiation of a second patient cohort in the first quarter of the current 2023 fiscal year; an increase in the number of patient protocol-based procedures performed for all patients; the conduct of individual patient trial procedures being more expensive the further a patient advances along the study protocol; and incremental clinical trial support activities internally and conducted by our study CRO and other service providers. Other factors contributing to up trending quarterly losses include increased costs for the expansion of our leadership team; addition of personnel and building core competencies internally to support our corporate and R&D programs, priorities, and activities.

Fiscal year 2022 quarterly losses also increased significantly due to non-cash share-based compensation expense recognized as discussed above in this MD&A. However, share-based compensation expense for fiscal year 2023 relating to these stock option and DSU grants is significantly less comparatively as is typical through the progression of and into the later stages of the full vesting schedule for specific incentive grants. The recently completed fourth quarter included share-based compensation expense for stock options granted to our new Chief Executive Officer and Chief Business Officer.

Over the quarters presented above, the vast majority of the Company's direct R&D costs have been related to our Diabetes Program, which is Sernova's lead R&D program. 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 R&D and corporate activities being undertaken.

RELATED PARTY TRANSACTIONS

There were no related party transactions other than for the payment of and accruals for compensation to key management personnel of the Company in the ordinary course of business for the year ended October 31, 2023, with the exception of a combined reimbursement totaling $92,744 to two of the Company's Directors for non-recurring expenses related to the 2023 annual general meeting of shareholders. The non-recurring amounts were recorded as expense during the second quarter ended April 30, 2023. Refer to Note 10 – *Related Party Transactions* in our audited consolidated financial statements for further information.

LIQUIDITY AND CAPITAL RESOURCES

The Company's audited consolidated financial statements have been prepared assuming we will continue as a going concern. We have incurred losses and generated negative cashflow from operations since inception. As at October 31, 2023, we had an accumulated deficit of $118,167,007 (2022 - $79,169,487) and working capital of $11,431,210 (October 31, 2022 – $46,350,475) and for the year ended October 31, 2023 generated negative cashflow from operations of $30,339,117 (2022 – $14,421,398), excluding grant contributions received in the amount of $510,170 (2022 – $224,168). During the year ended October 31, 2023, capital expenditures were $99,259 (2022 – $329,000) as we equipped new personnel and upgraded or replaced certain equipment in our laboratory to support our R&D priorities.

Until the Company's biotechnology therapeutic products are approved and available for sale and profitable operations are developed, our liquidity requirements will be dependent on our ability to continue to obtain additional funding as required. We must secure sufficient funding to cover R&D expenditures to advance program initiatives that are planned for the next twelve months. Failure to do so could have material adverse effect on our financial condition and may cause us to defer or reduce planned expenditures. At this time, no assurance can be given that such funding will be available or can be obtained on favorable terms. Management is working towards securing funding from lenders and strategic alliances, but there can be no assurance as to when or whether the Company will succeed establishing such credit facilities or complete any strategic alliances. Consequently, raising additional equity capital in the future may be required, but is subject to market conditions and is not within the Company's control. As a result, material uncertainty exists which may cast significant doubt on the Company's ability to continue as a going concern and realize its assets and discharge its liabilities in the normal course of business. Refer to sections "**RISKS AND UNCERTAINTIES**" and "**CAPITAL MANAGEMENT, FINANCIAL INSTRUMENTS AND RISKS**" in this MD&A.

If the going concern assumption was not appropriate for the audited 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, and these adjustments could be material. The audited consolidated financial statements do not include adjustments that would be necessary if the going concern assumption was not appropriate.

Financing Activities

During the year ended October 31, 2023, there were no changes to the Company's share capital.

During the comparative year ended October 31, 2022, the Company:

- received proceeds of $16,230,478 from the exercise of common share purchase warrants and stock options and the corresponding issuance of 29,254,524 common shares; and

- closed a non-brokered private placement as part of an exclusive global strategic partnership with Evotec, issuing a total of 12,944,904 common shares at a price of $1.57 and 2,709,800 unconditional common share purchase warrants which were fully exercised at a price of $2.50 per share, for gross proceeds of $20,323,500 and $6,774,500 respectively. Total gross proceeds received from Evotec's investment into the Company were $27,098,000, before deducting issuance costs totalling $44,322.

Common Shares

	Number of common shares
Balance outstanding as at October 31, 2022, October 31, 2023 and the date of this MD&A	303,332,686

Warrants

	Number of warrants	Weighted average exercise price
Balance outstanding as at October 31, 2022	20,136,918	$ 1.67
Expired	(20,136,918)	(1.67)
Balance outstanding as at October 31, 2023 and the date of this MD&A	–	$ –

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).

	Number of options	Weighted average exercise price
Balance outstanding as at October 31, 2022	22,285,984	$ 0.91
Granted	8,738,613	0.95
Cancelled	(338,334)	(0.62)
Forfeited	(612,081)	(1.21)
Balance outstanding as at October 31, 2023	30,074,182	$ 0.92
Conditionally granted	200,000	0.80
Cancelled	(24,585)	1.30
Balance outstanding as at the date of this MD&A	30,249,597	$ 0.92

	Number of DSUs
Balance outstanding as at October 31, 2022, October 31, 2023 and 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. Under the Incentive Plan, the Board of Directors may grant stock options to directors, officers, employees or consultants of the Company and deferred share units to directors and officers of the Company up to an aggregate fixed maximum of 38,746,536 of the Company's issued and outstanding common shares, representing approximately 12.8% of the common shares outstanding as at October 31, 2023. The remaining balance available for grant under the Incentive Plan as of October 31, 2023 is 995,088 which is reserved for the issuance of stock options.

COMMITMENTS AND CONTINGENCIES

The Company was previously awarded a US$2.5 million (approximately $3.40 million) grant under an agreement with JDRF Therapeutics Fund LLC (JDRF). The grant supports a Phase 1/2 clinical trial of Sernova's Cell Pouch™ for treatment of patients with T1D. Pursuant to the agreement, 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$239,010 ($326,932) were earned during the year ended October 31, 2023 (2022 – US$281,160 ($369,976). Remaining funding available to be earned under the JDRF grant award totals approximately US$0.05 million ($0.07 million) as at October 31, 2023. 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.

In May 2022, the Company entered into an exclusive global strategic partnership with Evotec for the development and commercialization of an iPSC-based beta cell replacement therapy with the goal to provide an unlimited insulin-producing cell source to treat patients with insulin-dependent diabetes. The Company has committed to pay future milestone and royalty payments to Evotec pursuant to the occurrence of certain events as set forth in the Evotec collaboration agreement (the "Evotec Agreement"). Under the terms of the Evotec Agreement, the preclinical development program(s) will be jointly funded up to IND with the Company's share of potential costs capped at a maximum of approximately US$25.0 million ($34.7 million). The latest project costs forecast provided by Evotec is under review by the Company. It is anticipated the total project cost and the Company's commitment portion will increase, although currently under discussion with Evotec. The Evotec Agreement is cancellable by the Company with notice, subject to certain terms and conditions. iPSC Program costs of US$13,812,276 ($18,615,546) were incurred during the year ended October 31, 2023, respectively (2022 – US$5,635,624 ($7,420,725). The amount of joint iPSC Program costs originally incurred by Evotec and subsequently recharged to the Company was recorded in research and development expenses in the consolidated statement of loss, and the reimbursement of iPSC Program costs originally incurred by the Company was recorded as a reduction of research and development expenses in the consolidated statement of loss. Total iPSC Program costs of US$17,759,233 ($23,781,061) have been incurred since the commencement of the initiative up to the end of the most recently completed quarter ended October 31, 2023. The joint iPSC Program project budget and forecasted costs are regularly reviewed by the Company and our partner Evotec.

We enter into contracts and agreements in the normal course of business, including for R&D activities, consulting, and other services. The majority of these contractual obligations are cancelable by us at any time, generally upon prior written notice to the service provider or vendor. In addition, we have

minimum annual royalty payment obligations of approx. $32,000 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% annual increase thereafter for the duration of the lease period including any extension. Pursuant to the terms of the lease, the Company exercised its option to extend the lease term for an additional 12 months up to August 31, 2024. Subsequent to completion of the October 31, 2023 fiscal year, the Company entered into a successor lease for office premises and lab space at the same facility at a rate of $14,010 per month with a 3% annual increase thereafter for the duration of the lease period, including up to two 12-month extensions at our option. The new three-year lease is effective January 1, 2024, and if we were to exercise both 12-month extension options the lease term would extend to December 31, 2028.

The following table summarizes our significant future contractual obligations as at October 31, 2023:

	Payment due by period				
Contractual obligations[1][2]	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Lease obligations[3]	$ 145,650	$ 145,650	$ –	$ –	$ –
Purchase obligations[4]	6,095,995	2,186,027	3,277,692	632,276	–
Other[5]	95,000	95,000	–	–	–
	$ 6,336,645	$ 2,426,677	$ 3,277,692	$ 632,276	$ –

NOTES
(1) Contractual obligations in the above table do not include amounts in accounts payable and accrued liabilities on our statement of financial position as at October 31, 2023.
(2) Contingent milestone and royalty payments under collaboration agreements noted above are not included in the table.
(3) Includes operating lease obligations for office and laboratory facilities.
(4) Purchase obligations include cancellable and non-cancellable contracts including agreements related to the conduct of our clinical trial, preclinical studies, and manufacturing activities.
(5) Includes amounts related to a retention arrangement with a key employee.

OFF-BALANCE SHEET ARRANGEMENTS

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

CAPITAL MANAGEMENT, FINANCIAL INSTRUMENTS AND RISKS

This section provides disclosures relating to the nature and extent of our exposure to risks arising from financial instruments, including credit risk, liquidity risk, interest rate risk and foreign currency risk, and how we manage those risks.

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. Our credit risk is primarily attributable to cash and marketable securities, in excess of insured amounts, held or invested at financial institutions including Canadian chartered banks and financial service firms. We actively review the risk of the financial institutions and or the counterparty to the underlying financial instruments held failing to meet its obligations and adjust our marketable securities investments if and when any undue risk is identified. Amounts receivable at

October 31, 2023 are composed of amounts due from Canadian federal government agencies and international industry collaborators with full collection expected.

Liquidity risk

Liquidity risk is the risk that we will not be able to meet our financial obligations as they fall due. We are a development stage company and are reliant on external fundraising to support our operations. Once funds have been raised, we manage our liquidity risk by investing our cash resources in high interest savings accounts or marketable securities to provide regular cash flow for our operations and monitoring actual and projected cash flows. As at October 31, 2023, we had working capital of $11,431,210 (October 31, 2022 – $46,350,475). Refer to **LIQUIDITY AND CAPITAL RESOURCES** section of this MD&A for more information.

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. We hold our cash in bank accounts and manage our interest rate risk by holding cash in high yield savings accounts or highly liquid short-term investments. With increases in global interest rates over the last year and higher average investment balances, interest income has become more significant to our projected operational budget although rate fluctuations are not significant to our risk assessment. Note 16(c) to the audited consolidated financial statements for the year ended October 31, 2023 provides an indication of our interest rate risk exposure as at that date.

Foreign currency risk

Foreign currency risk is the risk that future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. We are exposed to foreign currency risk on fluctuations in foreign exchange rates for any cash, amounts receivable, accounts payable and accrued liabilities and grant contributions that are denominated in foreign currencies. Our foreign currency risk is primarily related to expenses denominated in United States dollars. Fluctuations in the United States dollar exchange rate could have a significant impact on our results. Note 16(d) to the audited consolidated financial statements for the year ended October 31, 2023 provides information on our significant foreign exchange currency exposures as at that date.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements requires us to make judgments, estimates, and assumptions that affect the application of accounting policies, the reported amounts of assets, liabilities, and expenses, as well as our 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.

Refer to the Company's audited consolidated financial statements for the years ended October 31, 2023 and 2022 for discussions on our material accounting policies and significant estimates. Management considers that the following judgements and estimates are most important in assessing, understanding and evaluating our annual audited consolidated financial statements:

Going Concern

The use of the going concern basis of preparation of the financial statements is a critical judgement. At the end of each reporting period, Management assesses the basis of preparation of the financial statements. The financial statements have been prepared on a going concern basis in accordance with IFRS. The going concern basis of presentation assumes that the Corporation will continue its operations for the foreseeable future and can realize its assets and discharge its liabilities and commitments in the normal course of business. Refer to **LIQUIDITY AND CAPITAL RESOURCES** section of this MD&A for more information.

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. The fair value of equity instruments is subject to the limitations of the Black-Scholes option pricing model ("Black-Scholes Model"), as well as other pricing models for equity instruments involving compound options. An estimate requires determining the most appropriate data inputs for the relevant valuation model, including the expected option life, share price volatility, risk-free interest rate and dividend yield, and application of a forfeiture rate as applicable. Changes in these subjective data input assumptions can materially affect the fair value estimate for share-based payments compensation and warrants.

Accrued expenses related to research and development costs

The Company's determination of accrued research and development (R&D) costs at each reporting period requires significant judgement, as estimates are based on a number of factors, including Management's knowledge of the R&D programs and associated timelines, invoicing to date from third-party contract service providers, and the terms and conditions in the contractual arrangements. The completeness and accuracy of accrued expenses related to R&D costs are subject to risk of estimation uncertainty related to services having been received where invoices are not received from third parties in a timely manner prior to the issuance of the audited consolidated financial statements. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust R&D expenses in subsequent periods.

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.

INTERNAL CONTROLS OVER FINANCIAL REPORTING

The Company's management is responsible for establishing and maintaining disclosure controls and procedures (DC&P), as defined in NI 52-109. Management has designed such DC&P to provide reasonable assurance that material information with respect to the Company is made known to them and information required to be disclosed by the Company in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the specified time periods and in compliance with applicable securities legislation and guidelines.

The Company's management is responsible for establishing and maintaining internal controls over financial reporting (ICFR), as defined in NI 52-109 and have designed such ICFR to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with IFRS.

There have been no changes in the Company's ICFR during the year ended October 31, 2023, that have materially affected, or are reasonably likely to materially affect, the Company's ICFR.

CHANGES IN ACCOUNTING POLICIES

New accounting standards adopted during the current period

IAS 1 Presentation of Financial Statements
As at November 1, 2022, the Company adopted amendments made to International Accounting Standard 1 *Presentation of Financial Statements* (IAS 1). IAS 1 provides a more general approach to the classification of liabilities based on the contractual arrangements in place at the reporting date and does not impact the amount or timing of recognition. The adoption of this amendment did not have a material impact on the audited consolidated financial statements.

As at November 1, 2022, the Company adopted amendments made to IAS 1 and IFRS Practice Statement 2 *Making Materiality Judgements* in which guidance and examples are provided to help entities apply materiality judgements to accounting policy disclosures. The adoption of this amendment did not have a material impact on the audited consolidated financial statements.

IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors
As at November 1, 2022, the Company adopted amendments made to International Accounting Standard 8 *Accounting Policies, Changes in Accounting Estimates and Errors* (IAS 8) which introduces a new definition of 'accounting estimates'. The amendments clarify the distinction between changes in accounting estimates and changes in accounting policies and the correction of errors. Also, the amendments clarify how entities use measurement techniques and inputs to develop accounting estimates. The adoption of this amendment did not have a material impact on the audited consolidated financial statements.

IAS 12 Income taxes
As at November 1, 2022, the Company adopted amendments made to International Accounting Standard 12 *Income Taxes* (IAS 12). IAS 12 was amended so that it no longer applies to transactions that give rise to equal and offsetting temporary differences. As a result, companies will need to recognize a deferred tax asset and a deferred tax liability for temporary differences arising on initial recognition of a lease and a decommissioning provision. The amendments apply to annual reporting periods beginning

on or after January 1, 2023, with earlier application permitted. The adoption of this amendment did not have a material impact on the audited consolidated financial statements.

New accounting standards and interpretations not yet adopted

None

RISKS AND UNCERTAINTIES

We are a clinical stage biotechnology company that operates in an industry that is dependent on several factors that include the capacity to raise additional capital on reasonable terms, obtain positive results of clinical trials, obtain positive results of clinical trials without serious adverse or inappropriate side effects, obtaining marketing authorization for products and ultimately market acceptance of its product.

An investment in our common shares is subject to several risks and uncertainties and being high risk in nature should be considered speculative. Several of the factors, risks and uncertainties are outside the control of the Company's management. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. An investor should carefully consider the risks and uncertainties described below, as well as other information contained in this MD&A. If any of such described risks occur, or if others occur, our business, operating results and financial condition could be seriously harmed and adversely impacted, and investors could lose all or part of their investment.

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, 2023, our common shares traded on the Toronto Stock Exchange at a high of $1.26 and a low of $0.70 per share (2022 fiscal year – high of $2.22 and low of $0.69 per share). Factors such as general market conditions, biotech sector investment sentiment, fluctuation of our operating results, announcements of technological innovations, patents or new commercial products by us or our competitors, results of clinical testing, regulatory actions, or public concern over the safety of biopharmaceutical products and other factors could have a significant effect on the share price or trading volumes for our common shares. Our common shares have been subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future. We have not paid dividends to date, and we do not expect to pay dividends in the foreseeable future.

Dilution. It is highly likely we will sell additional equity securities in future offerings, including through the sale of securities convertible into equity securities, to finance our operations, acquisitions, or projects, and issue additional common shares if outstanding warrants and stock options are exercised, which may result in dilution.

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 Manufacture and Supply 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.

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

Issuer Risk

Our activities may be impacted by the spread of COVID-19 or other virus outbreaks. The COVID-19 pandemic or any future emergence and spread of similar pathogens could have an adverse impact on global economic conditions (including monetary policy and inflation) which may adversely impact the Company's operations and the operations of the Company's suppliers, contractors and service providers, and may negatively impact future fiscal periods in the event of prolonged disruptions associated with the pandemic. A sustained slowdown in global growth or demand, or a significant slowdown, could result in delays in clinical trial activities, delays and difficulty in enrolling patients in clinical trial activities, interruptions in clinical activities and increased government regulations, all of which may negatively impact the Company's business and financial condition. In addition, any future emergence and spread of COVID-19 or similar pathogens, could have a material adverse impact on global economic conditions, which may adversely impact: the market price of the Company's Common Shares, the Company's operations, its ability to raise equity financing.

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 Corporation'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 Corporation. These factors indicate the potential existence of a future material uncertainty that may cast significant doubt on the ability of the Corporation 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. Refer to **LIQUIDITY AND CAPITAL RESOURCES** section of this MD&A.

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 candidate. 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.

The Company expects to incur substantial expenditures in connection with the development of its product candidates. If Sernova fails to successfully develop and sell all or any of its resulting products then the Company will not earn any return on its investment, which will adversely affect the Company's results of operations and could adversely affect the market price of the common shares. Sernova's success in developing and selling new products will depend upon multiple factors, including:

- ability to develop safe and effective products and receive regulatory approval;
- acceptance of the product by the medical community and by patients and third-party payors;
- inherent development risks, such as the product proving to be unsafe or unreliable, or not having the anticipated efficacy;
- ability to develop repeatable processes to manufacture new products in sufficient quantities; and
- ability to market and sell its products, either on its own or through a third-party.

If any of these factors cannot be overcome, we may not be able to develop and introduce the Company's product candidates, if approved, in a timely or cost-effective manner, which could adversely affect the Company's future growth and results of operations. Our failure to develop the Company's product candidates could adversely affect the market price of the Company's common shares.

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 FVIII

releasing cells in combination with the Cell Pouch System™ platform to treat severe hemophilia A. If we are unable to achieve safety and efficacy in one or more of these disease indications in preclinical and / or clinical studies the business may be materially harmed.

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 ofany of our executive officers or other key personnel could potentially harm our business, operating results, or financial condition.

The regulatory approval processes of the US FDA, Health Canada, the European Medicines Agency ("EMA"), and regulators in other jurisdictions are lengthy, time-consuming, and inherently unpredictable. If we, or our collaborators, are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, our business will be substantially harmed. The regulatory approval process is expensive, and the time required to obtain approval from the US FDA, Health Canada, EMA, or other regulatory authorities in other jurisdictions to sell any product or combination therapy is uncertain and may take years. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of our products' clinical development and may vary among jurisdictions. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and even if the preclinical studies show promising results and clinical trials are successfully completed, we cannot guarantee that the US FDA, Health Canada, EMA, or other regulatory authorities in other jurisdictions will interpret the results as we do, and more trials, manufacturing-related studies or non-clinical studies could be required before we submit a product for approval. Many companies that have believed their product candidates or products performed satisfactorily in preclinical studies, and clinical trials have nonetheless failed to obtain marketing approval of their products. To the extent that the results of our studies and clinical trials are not satisfactory to the US FDA, Health Canada, EMA, or other regulatory authorities in other jurisdictions for support of a marketing application, approval of any product(s) we develop may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product(s). It is also possible that neither our existing Cell Pouch System™ nor any of our future products will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. Our products candidates could fail to receive regulatory approval for many reasons, including the following:

- the US FDA, Health Canada, EMA or other regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials;
- we or our collaborators may be unable to demonstrate to the satisfaction of the US FDA, Health Canada, EMA or other regulatory authorities that a product is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of significance required by the US FDA, Health Canada, EMA or other regulatory authorities for approval;
- we, or our collaborators, may be unable to demonstrate that a product's clinical and other benefits outweigh its safety risks;
- the US FDA, Health Canada, EMA or other regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our products may not be sufficient to support the submission of a Market Authorization Application or other submission to obtain regulatory approval in the United States or elsewhere;
- the US FDA, Health Canada, EMA or other regulatory authorities may fail to approve the manufacturing processes, controls or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; and
- the approval policies or regulations of the US FDA, Health Canada, EMA, or other regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

If we, and or potential partners, pursued Orphan Drug, Fast Track, Breakthrough Technology, 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 unfavorably impacted where such preferential regulatory designations may have been factored into approval timelines and projections.

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

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

Product development and associated clinical trials involve lengthy and expensive processes with uncertain timelines and uncertain outcomes. If clinical trials are prolonged, delayed, or not completed, we, or our collaborators, may be unable to develop any commercial applications or products that generate revenues on a timely basis, if at all. Clinical trials are long, expensive, and uncertain processes. Clinical trials may not be commenced or completed on schedule, and the US FDA, Health Canada, or any other regulatory body may not ultimately approve our Cell Pouch System™ or

other products developed for commercial sale. Clinical trial outcomes are inherently uncertain, and failure can occur at any time during the clinical development process. The clinical trials for existing and or future products could be unsuccessful, which would prevent us from advancing, commercializing, or partnering the product.

Even if the results of our preclinical studies or clinical trials are initially positive, it is possible that we will obtain different results in the later stages of product development or that results seen in clinical trials will not continue with longer-term treatment. Positive results in early clinical trials may not be repeated in larger 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, 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.

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 Corporation 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, have an option to license or that has been developed internally 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 on access to the iPSC technology being developed under the Evotec Collaboration and Evotec's successful and timely completion of iPSC-derived ILCs development, including scale-up and manufacturing. We are also 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 Corporation'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 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 third-party contract manufacturers to manufacture our products. Health Canada and the US FDA ensure the quality of products by carefully monitoring manufacturers' compliance with Good Manufacturing Practices regulations. Any manufacturing failures or delays or compliance issues could cause delays in the completion of our preclinical and clinical activities. There can be no assurances that our contract manufacturers 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.

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 Corporation's business, and if the Corporation'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 Corporation currently carries what it believes to be adequate product liability and clinical trial insurance, there can be no assurance that the Corporation 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 Corporation's business. If a product is withdrawn or a product liability claim was brought against the Corporation, it could significantly damage the Corporation'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

US FDA regulations, provide accurate information to those agencies, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a substantial impact on our business and results of operations, including the imposition of substantial fines or other sanctions.

Lack of product revenues and history of losses. To date, we have not recorded any revenues from the sale of cell therapy products. We expect to incur additional losses during the periods of R&D, clinical testing, and application for regulatory approval of our product candidates. For the year ended October 31, 2023, we incurred losses of $38,997,520 (2022 - $24,420,536) and had an accumulated deficit as of October 31, 2023 of $118,167,007. We expect to incur further losses unless and until such time as payments from corporate collaborations, product sales, and or royalty payments generate sufficient revenues to fund our continuing operations.

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

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition. Global credit and financial markets experienced extreme disruptions at various points over the last decade, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it 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.

Reliance on Information Technology. Despite the implementation of security measures, our internal computer systems, and those of our third parties on which we rely, are vulnerable to damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to our systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorism has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have

increased. Should a material system failure or security breach occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed.

We are likely a "passive foreign investment company" (PFIC) which may have adverse U.S. federal income tax consequences for shareholders in the United States (U.S.). 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, 2023, and 2022, and based on current business plans and financial expectations, we believe that we may be a PFIC for the current tax year and the 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.

Management of Growth. The Company could experience growth that could put a significant strain on each of the Company's managerial, operational and financial resources. The Company must implement and constantly improve its operational and financial systems and expand, train and manage its employee base to manage growth. In addition, the Company expects that its operational and management systems will face increased strain as a result of the expansion of the Company's technologies. The Company might not be able to effectively manage the expansion of its operations and systems, and its procedures and controls might not be adequate to support its operations. In addition, management might not be able to make and execute decisions rapidly enough to exploit market opportunities for the expansion of the Company's technologies. If the Company is unable to manage its growth effectively, its business, results of operations and financial condition will suffer. Failure to effectively manage growth could also result in difficulty in launching new technology or enhancing existing technology, declines in quality or end-user satisfaction, increases in costs or other operational difficulties, and any of these difficulties could have a material adverse effect on its business, prospects, financial condition, results of operations and cash flows.

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. We may be unable to compete against other companies and research institutions with greater financial and other resources.

Government regulations. Biotechnology and pharmaceutical companies operate in a high-risk regulatory environment. The manufacture and sale of therapeutic products are governed by numerous statutes and regulations in the United States, Canada, and other countries where we intend to market our products. The subject matter of such legislation includes approval of manufacturing facilities, controlled

research, and testing procedures, review, and approval of manufacturing, preclinical and clinical data prior to marketing approval, as well as regulation of marketing activities, notably advertising and labeling.

The process of completing clinical testing and obtaining required approvals is likely to take several years and require the expenditure of substantial resources. Furthermore, there can be no assurance that the regulators will not require modification to any submissions, which may result in delays or failure to obtain regulatory approvals. Any delay or failure to obtain regulatory approvals could adversely affect our ability to utilize our technology, thereby adversely affecting our operations. Further, there can be no assurance that our product candidates prove to be safe and effective in clinical trials or receive the requisite regulatory approval. There is no assurance that we will be able to timely and profitably produce its products while complying with all the applicable regulatory requirements. Foreign markets, other than the United States and Canada, impose similar restrictions.

Hazardous materials and environmental matters. Certain of our R&D processes will involve the controlled use of hazardous materials. We are subject to federal, provincial, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of such materials and certain waste products. Although our management believes that its procedures for handling and disposing of such materials comply with the standards prescribed, the risk of accidental contamination or injury from these 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.

DIRECTORS AND OFFICERS

Brett Whalen	Director, Chair of the Board and Compensation Committee
James Parsons, CPA, CA	Director, Chair of the Audit and Nomination and Governance Committees
Dr. Dan Mahony	Director
Dr. Steven Sangha	Director
Bertram von Plettenberg	Director
Cynthia Pussinen	Chief Executive Officer and Director
Dr. Philip Toleikis	Chief Technology Officer and Director
Gary Floyd, LLB	Corporate Secretary
David Swetlow, CPA, CA	Chief Financial Officer
Dr. Modestus Obochi, MBA	Chief Business Officer

ADDITIONAL INFORMATION

Additional information relating to the Company can be found on SEDAR+ at www.sedarplus.ca.