SERNOVA CORP.

MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE MONTHS ENDED

JANUARY 31, 2023 AND 2022

Dated March 15, 2023

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The following management's discussion and analysis (MD&A) explains the consolidated operating results, financial position, and cash flows of Sernova Corp. (Sernova, the Company, We, Us, or Our) for the three months ended January 31, 2023, and 2022. This MD&A should be read in conjunction with the Company's Annual Information Form (AIF) dated January 26, 2023 and its interim condensed consolidated financial statements and related notes for the three months ended January 31, 2023, and 2022, which have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

The Company's accounting policies under IFRS are set out in *Note 3 – Significant Accounting Policies* of the audited consolidated financial statements for the years ended October 31, 2022, and 2021. All amounts are in Canadian dollars. The information in this report is dated as of March 15, 2023, unless otherwise noted.

FORWARD-LOOKING STATEMENT

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

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

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

- the Company's corporate strategy and strategic objectives;
- the availability of various forms of external financing to fund the Company's ongoing operations, liabilities and commitments;
- the expected benefits to patients with Cell Pouch™ transplanted with therapeutic cells or tissue;
- the conduct of preclinical studies and clinical trials of our Cell Pouch System™ for the treatment of insulin-dependent diabetes, hypothyroid disease, hemophilia A and other clinical indications, and the Company's ability to conduct its clinical studies;
- the expected benefits to patients of our Cell Pouch diabetes, hypothyroid disease and hemophilia A cell therapy programs;
- the expected benefits to patients with type 1 diabetes (T1D) implanted with Cell Pouch and human donor islets and or induced pluripotent stem cell (iPSC) derived islet-like clusters;
- the Company's intention to protect therapeutic cells within Cell Pouch from immune 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 therefrom;

- the expected benefits of any next generation Cell Pouch System and or other delivery technologies;
- the expectation of successful development up to an IND submission and beyond combined with the expected benefits of using iPSC derived islet-like clusters in combination with Cell Pouch and ancillary technologies within the Evotec Collaboration (defined hereafter);
- the Company's intentions and ability to secure academic and pharmaceutical / medtech collaborations to develop and implement partnering strategies and manage partnerships;
- the Company's intention and ability to use human autograft cells or tissues or human donor allograft cells or xenogeneic cells for treatment, and the intention to use human stem cell-derived cells (i.e. iPSCs), considered unlimited cell sources for our Cell Pouch and Cell Pouch System for the potential treatment of various diseases;
- the Company's intention and ability to obtain regulatory clearance for clinical trials and marketing approval of the Cell Pouch or Cell Pouch System for the treatment of insulin-dependent diabetes, hemophilia A, thyroid disease, and other diseases;
- the Company's intentions and ability to obtain Orphan Drug (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 North America, Europe or other jurisdictions abroad, and the related impact on timeline estimates to conduct clinical trials or obtain marketing approval for the Company's products;
- the Company's expectations that Sernova's technologies are unique and may become a standard of care in therapeutic cell transplantation if they prove to be safe and effective in clinical trials;
- the Company's expectations with respect to the research and development of Sernova's products, clinical trials, and commercialization of our products;
- the Company's commercialization strategy for our technologies including Cell Pouch or Cell Pouch System and associated technologies;
- the Company's intentions regarding the development and protection of Sernova's intellectual property;
- the Company's intentions with respect to obtaining licenses for technologies compatible with the Cell Pouch System;
- the Company's intention to develop next-generation Cell Pouch or Cell Pouch System related technologies;
- the Company's ability to secure cGMP manufacturing facilities for its cell therapy programs;
- sufficient availability of Cell Pouch product for the conduct of preclinical studies, clinical trials, and following marketing approval for commercial use;
- the direct and indirect impact of the novel coronavirus (COVID-19) and variants and any other further global health emergencies on our business and operations, including supply chain, manufacturing, research and development costs, clinical trials including patient enrollment, contracted service providers and employees; and
- the Company's general business and economic conditions.

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

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

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

- the Company's ability to manage its growth effectively;
- the expected benefits to patients of our technologies including Cell Pouch and Cell Pouch System cell therapy programs;
- the absence of material adverse changes in our industry or the global economy;
- trends in our industry and markets;
- the Company's ability to comply with current and future regulatory standards;
- the Company's ability to protect its intellectual property rights;
- the Company's continued compliance with third-party license terms and the non-infringement of third-party intellectual property rights;
- the Company's ability to complete all necessary preparatory work to file an IND for iPSC derived islet-like clusters in combination with Cell Pouch and any applicable ancillary technologies;
- the Company's ability to supply Cell Pouches, therapeutic cells and or any complementary technologies comprising a product;
- the Company's ability to effectively conduct and manage clinical trials;
- the Company's ability to attract and retain key personnel; and
- the Company's ability to raise sufficient equity or debt financing to support continued growth and operational needs.

There are a number of important factors that could cause Sernova's actual results to differ materially from those indicated or implied by forward-looking statements and information, including but not limited to: early-stage development and scientific uncertainty, management of growth, lack of product revenues and history of losses, additional financing requirements and access to capital, patents and proprietary technology, dependence on collaborative partners, licensors, contract research organizations (CROs), contract manufacturing organizations (CMOs) and others, government regulations, hazardous materials and environmental matters, rapid technological change, competition, reliance on key personnel, status of healthcare reimbursement, potential product liability and volatility of share price, absence of dividends, fluctuation of operating results and the impacts of the COVID-19 pandemic or related outbreaks, and economic conditions. Such risks are further described under "**RISK FACTORS AND UNCERTAINTIES**" in this MD&A or under *"RISK FACTORS"* in our most recently filed Annual Information Form (AIF) available on www.sedar.com. Potential investors, and other readers are urged to consider these factors carefully in evaluating these forward-looking statements and information and are cautioned not to place undue reliance on them. Sernova has no responsibility, nor does it intend, to update these forward-looking statements and information unless as otherwise required by law.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this MD&A or as of the date otherwise specifically indicated herein. Due to risks and uncertainties, including the risks and uncertainties associated with COVID-19 and as described elsewhere in this MD&A, actual events may differ materially from current expectations. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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

COVID-19 PANDEMIC

The COVID-19 pandemic continues to cause significant financial market and social disruption. The Company cannot presently predict the scope and severity of any potential business shutdowns or disruptions related to COVID-19, the impact of any new variants nor the impact of the vaccines that are now accessible. If the Company or any of the third parties with whom it engages, were to experience shutdowns or other business disruptions due to the pandemic, its ability to conduct its business in the manner and on the timelines presently planned could be materially and negatively impacted. The Company will continue to monitor developments of the pandemic and continuously assess its potential further impact on its operations to prevent any disruptions to the conduct of its business and clinical trials. In the event of a prolonged continuation of the pandemic, it is not clear what the potential impact may be on the Company's business, financial position and financial performance.

ABOUT SERNOVA

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

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 forms around the cells along with microvessels to the cells, enabling them to engraft (survive and function).

Thus, an anticipated benefit of the Cell Pouch is formation of a natural environment for the therapeutic cells that provides for enhanced long-term therapeutic cell survival and function. We believe this is due in part to the therapeutic cells living in a natural tissue matrix within close contact of microvessels.

We believe our unique approach in providing a natural environment for therapeutic cells and its ease of use may provide an opportunity for Sernova's technologies including the Cell Pouch System to become the standard of care in therapeutic cell transplantation for multiple diseases if they continue to demonstrate safety, tolerability and clinical benefit in preclinical and clinical trials.

As noted in our latest AIF, filed under the Company's SEDAR profile at www.sedar.com on January 26, 2023, our research activities during the past three years have focused on the development of the Cell Pouch System platform as a potential new treatment for various therapeutic indications including T1D, hemophilia A, thyroid disease and additional chronic debilitating and rare diseases. We have also entered into strategic collaborations and acquired, in-licensed or obtained an exclusive option to in-license related technologies to expand and support our research efforts. Earlier history of the corporate development of the Company and its business is also available on SEDAR.

RECENT QUARTER HIGHLIGHTS

R&D HIGHLIGHTS

March 2023: We announced that the first two patients enrolled in the second cohort of our Phase 1/2 T1D Clinical Trial (defined herein) received their first islet transplant into the higher capacity 10-channel Cell Pouch. Additionally, a third enrolled patient has now been implanted with the higher capacity 10-channel Cell Pouch and awaits islet transplant. Enrollment for the recently added second cohort is already approximately half completed (three of up to seven patients).

January 2023: We announced an update on the progress in our collaboration with Hamburg, Germany based 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 has to date resulted in the following significant achievements:

- 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 islet-like cluster 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 islet-like clusters transplanted in Sernova's Cell Pouch;
- iPSC islet-like cluster 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 islet-like clusters supply; and
- interactions with experts to support design of a Phase 1/2 clinical trial.

Activities will continue in preparation for the anticipated IND filing and clinical study initiation.

November 2022: We announced the approval of a protocol amendment for our Phase 1/2 T1D Clinical Trial, adding a second cohort of up to seven patients and incorporating a larger capacity 10 channel Cell Pouch and optimized dose of transplanted donor islets . It was also announced that we have engaged a clinical trial recruitment agency to assist with expediting patient enrollment and the first two patients of

the second cohort have been implanted with the new 10 channel Cell Pouch.

June 2022: Updated interim data from our ongoing Phase 1/2 T1D Clinical Trial was presented on June 6th, 2022, as an oral podium presentation "*Modified Approach for Improved Islet Allotransplantation into Prevascularized Sernova Cell PouchTM Device: Preliminary Results of the Phase I/II Clinical Trial at University of Chicago"* at the American Diabetes Association (ADA) 82nd Scientific Sessions, held in New Orleans, LA. Key observations included the following:

- surgical implantation of Cell Pouch continues to be generally well tolerated with a favorable safety profile;
- the first three patients with long standing T1D and serious hypoglycemia events (SHE), presented positive serum C-peptide values confirming active insulin production after islet transplantation into the Cell Pouch;
- a supplemental marginal dose islet transplantation via the portal vein was sufficient to allow those three patients to achieve and maintain insulin independence, ranging at the time of presentation from 3 months to over 2 years;
- the insulin independent patients have HbA1c in the normal range; and
- immunosuppression for three additional patients on the study who did not maintain optimal levels has been resolved, enabling those patients to receive further protocol-defined islet transplants.

Another key finding from the interim clinical update was that decreasing the density of the islets transplanted into the Cell Pouch resulted in greater stimulated serum C-peptide levels. As well, we identified cumulative dosing amounts that has led to insulin independence in patients. Consequently, we believe implementing a higher capacity Cell Pouch that allows for increased dosing at a reduced islet density will optimize patient efficacy outcomes.

May 2022: We announced entering into an exclusive global strategic partnership with Evotec SE, the leading developer of iPSC cell technologies for therapeutic applications, for the development and commercialization of an iPSC-based beta cell replacement therapy for diabetes. The Evotec Collaboration is a transformative partnership for Sernova that will combine our proprietary Cell Pouch System, which has demonstrated Phase 1/2 clinical proof-of-concept using human donor islets, and related technologies with Evotec's iPSC-based beta cells (islet-like clusters). We believe incorporating Evotec's insulin-producing, ethically derived islet-like clusters into Sernova's Cell Pouch platform creates the potential to provide a 'functional cure' for millions of people suffering from diabetes using an off-the shelf cGMP manufactured, scalable product.

CORPORATE HIGHLIGHTS

January 2023: We attended the J.P. Morgan 41st Annual Healthcare Conference in San Francisco, CA (JPM) and engaged with pharma and biotech companies during the BIO Partnering sessions and other corporate meetings. We also met with and provided a corporate update to analysts and bankers as well as current and potential US investors during LifeSci Partners' 12th Annual Corporate Access Event hosted concurrently at JPM.

December 2022: As part of a planned leadership succession process and management team expansion, we announced that after a successful 13-year tenure leading the Company through the development of its pioneering Cell Pouch System and ensuing growth, current President and Chief Executive Officer Dr. Philip Toleikis will assume the new position of Chief Technology Officer once a new Chief

Executive Officer has been recruited and joins the Company. A comprehensive executive search process is underway.

October 2022: We announced the appointment of KPMG LLP, Chartered Professional Accountants as new auditor of the Company. There were no reservations in the Company's former auditor's audit reports for any financial period during which they were our auditor nor were there any "reportable events" (as the term is defined in National Instrument 51-102 - Continuous Disclosure Obligations).

September 2022: We announced full exercise of the remaining common share purchase warrants expiring in September 2022. Combined with the full exercise of remaining common share purchase warrants expiring in August 2022, total proceeds of $16,136,728 were received during the fiscal year.

September 2022: We announced the appointment of Daniel Mahony, Ph.D. to our Board of Directors, effective September 30th, 2022. Dr. Mahony is Entrepreneur-in-Residence at Evotec SE (Evotec) and is also responsible for managing Evotec's equity investment portfolio. Dr. Mahony brings over 25 years of global healthcare investment, management and research experience covering biotechnology, medical technology, and healthcare service sectors.

September 2022: We closed the second and final tranche of Evotec's strategic investment private placement with the effective exercise of an unconditional common share purchase warrant for 2,709,800 common shares at a price of $2.50 per share for total proceeds of $6,774,500.

June 2022: On June 2nd, 2022, trading of the Company's common shares commenced on the Toronto Stock Exchange (TSX:SVA) with its graduation from the TSX Venture Exchange (TSXV). Concurrently, the Company voluntarily delisted its common shares from the TSXV.

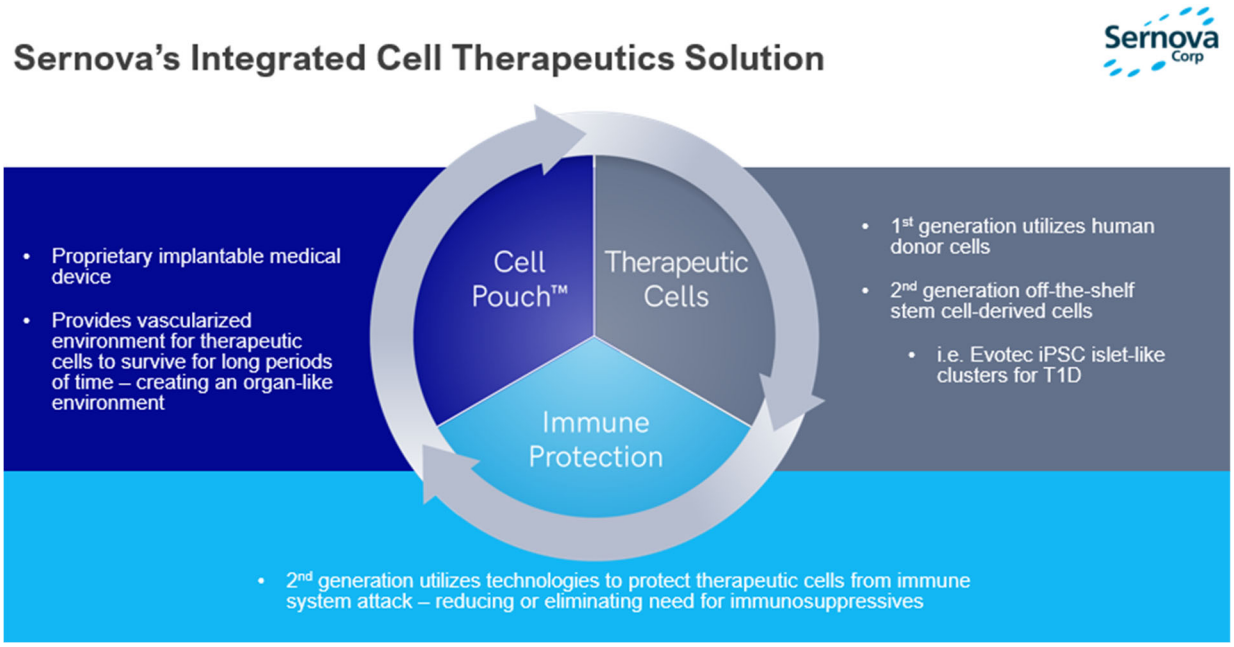
May 2022: Concurrent with entering into the Evotec Collaboration noted above, Evotec made a strategic equity investment commitment totaling approximately $27 million of proceeds for the Company. The first tranche of 12,944,904 common shares at a price of $1.57 per share for gross proceeds of $20,323,500 was closed.

May 2022: We announced engaging New York based LifeSci Communications, a global life science and medical technologies-focused communications and marketing agency. LifeSci Communications will assist Sernova to expand and elevate its profile through strategic communications and public relations. Sernova is also working with affiliate LifeSci Advisors LLC, a leading investor relations consultancy firm serving life science companies, providing institutional investor communications and capital markets outreach services in support of the Company's U.S. capital markets objectives.

April / May 2022: We presented Sernova's vision and progress at a number of investment and healthcare industry conferences including: Alliance of Regenerative Medicine's Cell Gene Therapy Meeting on the Med in Barcelona, Spain; Roth Capital's Canada Corporate Access Day in New York, NY; the JDRF-NIH-FDA Beta Cell Replacement Workshop in Bethesda, MD; and the H.C. Wainwright Global Investment Conference in Miami Beach, FL.

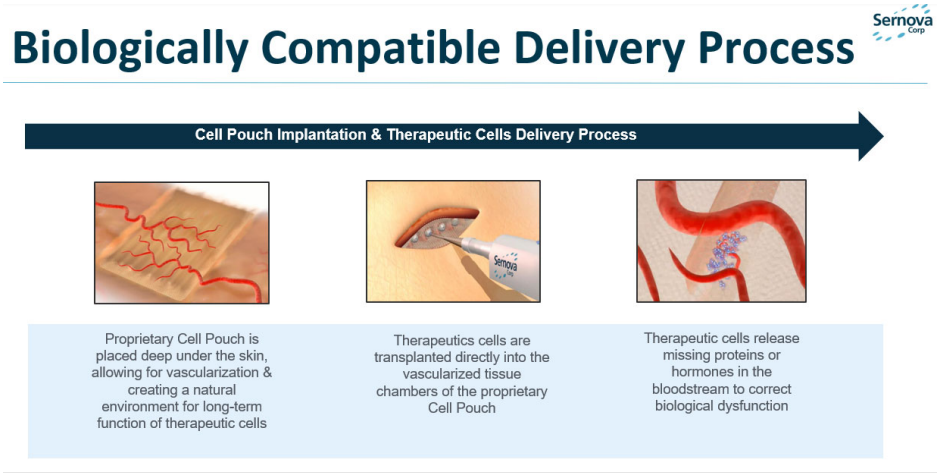
BUSINESS OVERVIEW

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 also helps 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. Our research demonstrates 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.

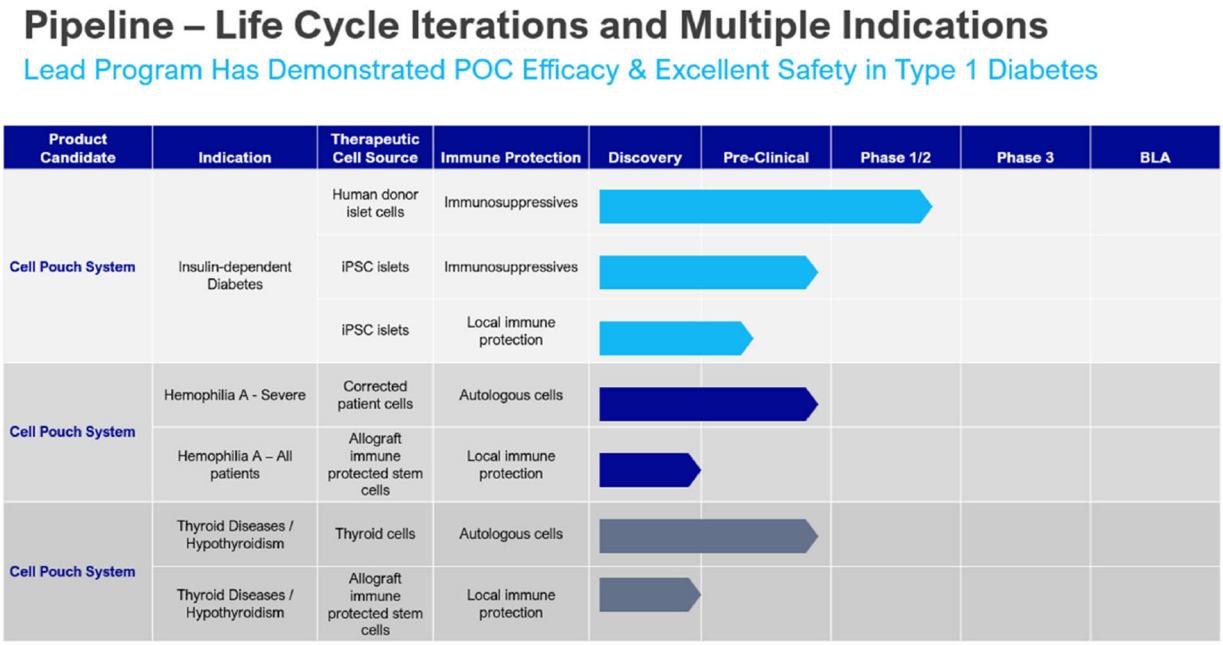


Data from a series of ISO 10993 biocompatibility studies, multiple animal studies, a pilot human clinical trial and our ongoing Phase 1/2 T1D Clinical Trial demonstrate that the Cell Pouch is biocompatible and safe. These data further demonstrate that the Cell Pouch platform technology establishes a required cell-to-microvessel interaction to support the viability and function of therapeutic cells via the Cell Pouch-medicated local tissue environment. An anticipated advantage of Cell Pouch is enhanced short and long-term therapeutic cell survival and function, which we believe is due in part to cells being transplanted into a natural tissue matrix in close contact with microvessels. Our preclinical studies have shown that human donor islets transplanted into the 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 produce the appropriate amount of insulin into the bloodstream. We have also recently demonstrated that islet-like clusters 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 production of normal hormone levels triiodothyronine (T3) and thyroxine (T4). We believe these data demonstrate that 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 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 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 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'.



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

The goals of our T1D program are to provide people with T1D the ability to better control their diabetes, an improved quality of life, the reduction of debilitating disease side effects and complications, and ultimately a 'functional cure' to 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 (insulin-dependent) diabetes (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. In particular, the sub-set of people with diabetes who suffer from hypoglycemia unawareness events represents a significant proportion of diabetic patients that could be addressed by Sernova's products – following regulatory approval. About 17% of people with T1D suffer from hypoglycemia unawareness, according to diabetesnet.com.

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 improve treatments for diabetic people and to improve the quality

of life for these individuals. Sernova believes its 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 goal of Sernova's cell therapy approach for T1D is to improve the quality of life of patients with the ultimate goal to return blood sugar regulation to a normal healthy state.

Our most advanced development program involves the clinical development and validation of the Cell Pouch System for the treatment of people with T1D who suffer from unstable diabetes and life-threatening severe hypoglycemic episodes. In some countries, the current cell therapy is transplantation of donor islets in 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 United States Food and Drug Administration (USFDA), and may only be administered under a clinical trial protocol.

It is encouraging that islet cell transplantation, even into the portal vein in humans, 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 a 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.

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 a Cell Pouch, rather than the portal vein, fewer islets, and therefor fewer donor pancreata are anticipated to be required to achieve glucose control for each recipient, thereby increasing the availability of these life-sustaining organs. In addition, the known side effects of multiple islet infusions into the portal vein, along with the risks and costs associated with their treatment 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 Cell Pouch therapy with our glucose responsive stem cell-derived technologies. (see Table 1).

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

Characteristics	**Cell Pouch**	**Portal Vein Transplant**
Smaller islet dose to achieve efficacy	Yes	No
Tissue matrix to house islets	Yes	No
Improved vascularization of islets	Yes	No
Retrievable site	Yes	No
Safe site for stem cell-derived cells	Yes	No
Minimally invasive subcutaneous site	Yes	No
Elimination of liver-associated toxicities	Yes	No
Elimination of IBMIR	Yes	No
Safer local immune protection of cells	Yes	No

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

With the encouraging initial results of portal vein islet transplantation, there is a need to develop a more suitable and retrievable environment for therapeutic cells. We believe an implantable and retrievable medical device that becomes highly vascularized when implanted into an appropriate area of the body for the placement and function of therapeutic cells, including donor islets and stem cell-derived technologies is a feasible and more sustainable approach. Sernova's Cell Pouch is a minimally invasive, retrievable device 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 device 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 U.S. medical device contract-manufacture facility in compliance with ISO13485, EU Medical Devices Regulation MDR 2017/745, United States Food and Drug Administration Quality System Regulations (QSR) 21 CFR 820 and Canadian Medical Device Regulation (CMDR). 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 islet-like cluster 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 encouraging 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.

Our initial Canadian safety and tolerability clinical study demonstrated encouraging results for the Cell Pouch alone and with transplanted islets.

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

- the biocompatibility and a favorable safety profile of Cell Pouch in these subjects; and
- independent histological analysis demonstrated that the islets within the Cell Pouch were well-vascularized within a natural tissue matrix, and readily producing insulin, glucagon and other key hormones important in the control of blood glucose levels and prevent hypoglycemic events.

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 islet-like cluster technology with high potential for successful commercialization. We have demonstrated that ethically derived iPSC stem cell-derived islet-like clusters can provide long-term insulin independence in an animal model of diabetes when transplanted into the Cell Pouch. We believe ethically derived induced pluripotent stem cells (iPSCs) derived islet-like clusters have superior commercial opportunity compared to progenitor embryonic stem cell-derived cells as the latter technologies are currently prohibited for human use certain regulatory jurisdictions. Furthermore, fully differentiated islet-like clusters will provide required insulin to patients sooner following transplantation than early progenitor islet technologies which may take months to mature following transplantation and produce 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. The Evotec Collaboration secures a potentially virtually unlimited supply of ethically derived, advanced glucose-responsive, insulin-producing islet-like clusters, eliminating the limitation of a restrictive supply of donor islets for product commercialization. We 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 islet-like clusters 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, refer to the *Significant Acquisitions, In-Licensing and Collaborations During or Since the 2022 Fiscal Year* section within this MD&A.

The Company also anticipates introducing local immune protection technologies into the diabetes program to develop additional product offerings and is conducting preclinical development studies with anticipated future clinical development activities with human donor islets and or iPSC islet-like cluster stem cell derived technologies.

As the Company advances its clinical studies, the Company's end goal is 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$2.45 million (approximately $3.27 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 under the revised protocol also 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 Dr. Witkowski.

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 (November 2022) the higher capacity 10-channel Cell Pouch to accommodate what we have calculated to be the optimal full dose of high-quality purified islets required to potentially achieve insulin independence and eliminate the need for intraportal islet transplantation.

We believe these preliminary findings are an important achievement in the cell therapeutics field and a first for an implanted prevascularized device with islet cells. These encouraging results using human donor islets in our Cell Pouch in subjects with hypoglycemia unawareness represents an important advance of our stepwise approach toward our goal of developing and optimizing a treatment for all T1D patients employing immune protected stem cell-derived iPSC islet-like clusters 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. Leveraging our extensive learnings of human donor islets within the Cell Pouch, we are using knowledge gained as we develop iPSC beta cell technologies 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 January 10, 2022, we reported on the highlights of Dr. Witkowski's updated interim data for Sernova's Phase 1/2 T1D Clinical Trial as follows:

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

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

On March 17, 2022, we announced that after having completed its third annual review of our ongoing Phase 1/2 T1D Clinical Trial, the DSMB recommended continuation of the clinical study according to the study plan.

On June 6, 2022, 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 82nd Scientific Sessions in New Orleans, LA. Updated data was presented in an oral podium presentation, "*Modified Approach for Improved Islet Allotransplantation into Prevascularized Sernova Cell PouchTM Device: Preliminary Results of the Phase I/II Clinical Trial at University of Chicago"* [Abstract 306-OR].

The presented data reviewed the six patients who lived with long-standing insulin dependent T1D and hypoglycemia unawareness prior to study treatment that underwent both Cell Pouch implantation and islet transplantation. Graft function was measured by blood glucose, patient insulin usage, and C-peptide, a widely used measure of islet function. The first three patients achieved complete and sustained insulin independence. Three additional patients in the study did not maintain optimal immunosuppression, however this was resolved enabling those patients to receive further protocol-defined islet transplants.

Key highlights included:

- the first three patients have been insulin independent for over 2 years, 6 months, and 3 months, respectively;
- those first three patients with islets transplanted into the Cell Pouch subsequently presented positive serum C-peptide values confirming active insulin production by the Cell Pouch islet grafts; and
- the Cell Pouch was well tolerated with implant durations exceeding 35 months.

Key findings from the interim clinical update:

- surgical implantation of the Cell Pouch was found to be well tolerated with a favorable safety profile;
- all patients who had favorable immunosuppression achieved complete insulin independence:
    - first three transplanted patients presented positive serum C-peptide values confirming active insulin production after islet transplantation into the Sernova Cell Pouch;
    - supplemental marginal dose islet transplantation via the portal vein was sufficient to allow those three patients to achieve and maintain insulin independence for over 2 years, 6 months, and 3 months, respectively; and
    - insulin independent patients have HbA1c in the normal range.
- Dr. Witkowski further optimized outcomes in the ongoing clinical trial:
    - replacing patients' own plasma with serum as the islet suspension medium;
    - decreasing the concentration of islet suspensions transplanted to Cell Pouch resulted in greater stimulated C-peptide; and
    - the Cell Pouch implantation procedure was optimized with two shorter incisions to minimize infection risk and enhance healing.

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 USFDA, to add a second cohort of up to seven patients to test the aforementioned enhanced capacity 10 channel Cell Pouch and further 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 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 further 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.

Results from the combined cohorts will help guide the design of Sernova's pivotal study, which would support an anticipated BLA submission to the USFDA and accelerate our iPSC stem cells 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

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. 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 recover 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).

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 about 150,000 thyroidectomies are performed in the US yearly, and most individuals undergoing a thyroid operation will be diagnosed with benign disease after their operation.

Following thyroidectomy, patients require daily hormone replacement therapy with T4. Published research indicates up to 50% of thyroxine users do not achieve adequate hormone levels (Okosieme, OE et al. Expert Opin Pharmacother 2011; 12(15):2315-2328). Moreover, it is evidenced that patients treated 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 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 proof of concept 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 in an animal model with the production of triiodothyronine (T3) and thyroxine (T4).

We are completing preclinical studies to enable advancement to clinical trials for this novel approach to the prevention of post-operative hypothyroidism. Simultaneously, Sernova is preparing documentation to support a clinical trial application. Furthermore, the Company has commissioned an independent market assessment of the hypothyroid indication for this initial and next generation stem cell-derived technology. Documentation has been submitted to the regulatory authorities to determine how the product will be regulated, whether through the device or combination product process. Interactions with regulators are ongoing towards a final determination of product classification for this proposed therapeutic approach. Our goal is to apply for regulatory authorization to initiate an early phase clinical trial for patients with planned thyroidectomy for benign disease.

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

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

Hemophilia A is a rare, serious genetic bleeding disorder caused by missing or defective clotting factor VIII in the bloodstream. A cellular genetic deficiency in 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 in the treatment of hemophilia A 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. 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 proof-of-concept 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.

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

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

- BOECs were safely isolated and grown from a small sample of circulating peripheral blood of volunteer hemophilia A patients unable to express the required FVIII for clotting;
- to regain the function of the BOECs' ability to produce clotting FVIII, techniques were successful in safely inserting the gene responsible for the correction and production of human FVIII into the patient's BOECs, and these corrected cells were safely multiplied to increase their number;
- tests were conducted to ensure the safety, and the newly corrected BOECs produced enough human FVIII both in the laboratory and in an initial preclinical animal model deficient of FVIII. FVIII blood levels reached up to 10%, a therapeutically relevant level of FVIII;
- to further test cell dose-response, in the preclinical model of hemophilia A, animals originally unable to clot their blood were implanted with a Cell Pouch and in separate groups transplanted with two different doses of human BOECs corrected for the ability to produce human FVIII;
- to assess the safety of the combined product, the Cell Pouch and corrected human FVIII BOECs derived from the volunteer participants with hemophilia A were examined using histological analyses. Importantly, histology showed healthy tissue represented by the presence of stromal growth and new blood vessel formation within the Cell Pouch;
- further histological investigation of the transplanted Cell Pouch sections demonstrated long-term survival of human FVIII BOECs present within the vascularized Cell Pouch achieved through co-staining for blood vessels (von Willebrand Factor stain) and the presence of the patients corrected human cells (HLA-ABC stain) in a preclinical animal model;
- in both experimental doses, human FVIII was detected in circulating peripheral blood up to 4 months following transplantation, with more human FVIII present in peripheral blood using the higher dose of corrected BOECs; and
- data further confirmed functional clotting improvement in the blood at the four months' time

point where FVIII BOECs transplanted into the hemophilia A mouse model restored the animal's FVIII activity at a therapeutic level in the Cell Pouch.

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

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

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

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

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

To date, we have had research collaborations with multiple major pharmaceutical companies, deploying its in-house cell therapy expertise and proprietary Cell Pouch technologies in combination with proprietary therapeutic cell assets designated by the pharmaceutical collaborators to conduct proof of concept studies for additional potential clinical indications. These collaborations with leaders in the pharmaceutical industry build upon our business strategy to develop a portfolio of therapeutic technologies to realize the full potential of Sernova's cell therapeutics platform. We believe collaborating / partnering with multiple pharmaceutical and life science companies will not only expand our therapeutic treatment potential but also provides a de-risked approach for Sernova as we develop our technologies and bring new therapies to patients with the goal to provide people with a 'functional cure' for multiple chronic and rare diseases. To date we have obtained encouraging results assessing various stem cell-derived technologies for a number of clinical indications and we are continuing to advance select collaborations with the goal of achieving long-term development partnerships. It is not expected that all collaboration opportunities and efforts will lead to product and or licensing opportunities, as we are seeking specific outcomes and may test assets and technologies of multiple third parties for the same or a similar targeted product or indication opportunity. Collaboration activity with third parties is in progress and continuing.

Local Immune Protection & Other Complementary Technologies

We believe that encapsulation 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. 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 regenerative medicine cell therapy therapeutics platform to multiple clinical applications and broader patient populations.

Cellular Conformal Coating Approach

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 antirejection 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 regenerative medicine therapeutics platform and could accelerate our first-to-market strategy for T1D and significantly expand the number of treatable patients suffering from chronic diseases.

The Conformal Coating Technology consists of a thin proprietary 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 two-year agreement, the Company committed to fund the first-year budget of up to US$833,154 (approximately $1,137,172). Technology optimization and further preclinical validation work is progressing as expected and continuing, with the associated second year budget awaiting finalization but anticipated to be similar to that of the first year noted above. Dr. Tomei is one of the original inventors of the Conformal Coating Technology that has been developed and

optimized over twelve years with her dedicated team. This important collaboration is multifaceted in nature and designed to advance for the first time locally immune protected cells within the Cell Pouch with the goal of advancing these technologies into clinical trials without the need for 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. The webinar is available at https://www.sernova.com/investor/#News_Releases and https://youtu.be/U57fkmsBT7k.

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.

Gene Editing Approaches

Sernova is continuing to identify, evaluate and or negotiate to obtain access to technologies complementary to Sernova's Cell Pouch therapeutic platform and to expand Sernova's immune protection offerings with potential benefit over current immunosuppressive strategies for cell therapeutics and to expand market penetration potential for our future product offerings.

Sernova's Access to Multiple Sources of Therapeutic Cells

Our transplantation technologies may incorporate autologous cells, donor cells, or other sources of cells, including therapeutic cells derived from human stem cells or derived from xenogeneic sources, depending on the clinical indication under evaluation. As such, we continue to work with academic collaborators and industry partners to identify and secure the required cells for our therapeutic indications.

We are developing stem cell-derived technologies with the expectation to provide a virtually unlimited supply of cells for the treatment of diabetes to overcome the limited supply of human donor islets. Pursuant to our strategy of obtaining sources of supply for our therapeutic cell applications, the Company entered into a license agreement with the University Health Network 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 mentioned above, Sernova is also expanding its collaborations with global pharmaceutical partners to evaluate various cell technologies using different approaches combining Sernova and partner technologies with the goal to create best-in-class therapeutics.

We have demonstrated long-term insulin independence in several collaborations with global pharmaceutical partners using advanced iPSC stem cell-derived diabetes 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,

Sernova pursued and came to terms with Evotec regarding access to their iPSC derived islet-like cluster technology for Sernova.

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 During or Since the 2022 Fiscal Year

Exclusive License Option for Leading Advanced iPSC Beta Cells for Islet Replacement Therapy

On May 16, 2022, we entered into an exclusive global strategic partnership with Evotec, the global life science company and leading developer of iPSC cell technologies for therapeutic applications, 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 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. Incorporating Evotec's insulin-producing, ethically derived islet-like cluster 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 islet-like clusters in a quality-controlled, scalable, bioreactor process. These islet-like clusters 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 and ongoing.

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 Sernova 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 Evotec Collaboration - refer to the *R&D Highlights* section within this MD&A for more information.

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 a series of 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, Sernova is deploying its 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. 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

Sernova has filed international patent applications related to Cell Pouch and the Cell Pouch System to protect its intellectual property rights related to its therapeutic programs. Sernova has 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.

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

Research and Development (R&D)

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

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

Our primary activities to achieve our overall objective and related goals include the following:

- conducting the series of clinical trials required to gain eventual marketing approval for the Cell Pouch System in countries that have a significant market opportunity. We are developing our first therapeutic product for the treatment of T1D and severe hypoglycemic events

utilizing human donor islets;

- advancing a treatment that we believe could potentially treat millions of people with diabetes consisting of the Cell Pouch System using immune protected Evotec iPSCs and our owned, licensed or controlled technologies; and
- ongoing R&D activities related to our proprietary Cell Pouch in the following areas:
    - continuing our research and development of additional therapeutic indications such as hemophilia A and postoperative hypothyroid disease;
    - developing therapeutic cell sources for transplantation within our Cell Pouch, such as autologous cells (self-cells) and allogeneic cells (stem cell-derived cells) to treat patients with these chronic diseases;
    - identifying, evaluating and potentially in-licensing complementary technologies which may improve the safety and efficacy of cells within the Cell Pouch:
    - establishing research collaborations to assess alternative cellular immune protection technologies;
    - developing acquired and in-licensed cellular local immune protection technologies;
    - continuing to develop proprietary processing and supply of therapeutic cells;
    - ongoing international development of our intellectual property portfolio and development of new and or licensing of intellectual property; and
    - establishing partnerships with medical device (medtech) and or pharmaceutical companies as well as academic institutions for the development of our products and to advance our next-generation technologies.

RESULTS OF OPERATIONS

For the three months ended January 31, 2023, we recorded a loss of $8,015,386, an increase of $2,556,451 / 47% 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 and higher interest income. The R&D cost increase was significantly influenced by our new iPSC Program collaboration with Evotec, which commenced after the prior year's comparative quarter.

The vesting of stock options and DSUs granted during the first quarter of the comparative fiscal year had the effect of increasing share-based compensation expense for the comparative Q1 2022 period by a one-time amount of approximately $2.4 million that is not applicable to the most recently completed quarter. Excluding the effect of non-cash share-based compensation expense for all periods, the latest quarter's loss of $7,074,119 increased by 232% versus the comparative period. Total cash expenses, which excludes share-based compensation, amortization and depreciation expenses and interest expense on lease liabilities, related to R&D and G&A were $6,957,202 for the three months ended January 31, 2023 (2022 – $2,024,219). Period to period R&D and G&A cost changes are further discussed below.

As at January 31, 2023, total assets were $46,960,432 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 Company incurred net R&D expenses of $6,911,250 for the three months ended January 31, 2023, a $3,741,745 / 118% increase from the comparative period. Excluding the effect of non-cash share-based compensation expense, the latest quarter's net R&D costs of $6,487,799 increased by $5,014,723 / 340% compared to the prior year. The increase reflects iPSC Program development activities inclusion versus none in the comparative period; higher costs for the Phase 1/2 T1D Clinical Trial reflecting a

higher number of enrolled study patients coupled with the protocol progression of all study patients; and higher personnel costs with the expansion of our R&D team and recruiting costs.

General and Administrative Expenses

For the three months ended January 31, 2023, total G&A expenses decreased by $590,329 / 26% from the comparative period. Excluding the effect of the non-cash share-based compensation expense, the latest quarter's net G&A costs of $1,179,339 increased by $521,986 / 79% compared to the same period in the prior year. This normalized increase reflects incremental costs related to: higher personnel costs for additional hires and recruiting costs; increased professional services provided; incremental investor relations and communication activities; and increased business development and conference costs with COVID-19 pandemic related travel restrictions having eased.

Amidst the ongoing growth of the Company and the uncertain capital markets, we continue to manage our costs closely.

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				Year ended October 31, 2021		
	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2
	$	$	$	$	$	$	$	$
Loss	8,015,386	8,210,422	5,831,492	4,919,687	5,458,935	2,175,343	1,630,998	1,666,966
Loss per share	0.03	0.03	0.02	0.02	0.02	0.01	0.01	0.01

As of the beginning and furthermore during the latter part of fiscal year 2022, quarterly losses have trended higher reflecting the ongoing overall growth of the Company and the advancement of our R&D programs, particularly with increased study patient activities for our Phase 1/2 T1D Clinical Trial and initiation of our iPSC Program research collaboration with Evotec during the second quarter of fiscal year 2022.

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. Thereafter, it is anticipated costs will be incurred for clinical development of Cell Pouch with Evotec's iPSC technology.

Quarterly clinical trial costs during fiscal year 2022 trended up as expected due to additional patient enrollment; 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. Additional and new Cell Pouch manufacturing development and production activities during the last quarter of fiscal year 2021 contributed to higher R&D costs

than prior, and since then activities have continued at a similar level during most subsequent quarters. Other factors contributing to up trending quarterly losses include increased costs for the addition of personnel and building core competencies internally to support our corporate and R&D programs priorities and activities.

Compared to the quarters of fiscal year 2021, 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 will be significantly less comparatively as is typical through the progression of and into the later stages of the full vesting period for specific incentive grants.

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

During the three months ended January 31, 2023, and 2022, there were no related party transactions other than for the payment of compensation to key management personnel of the Company in the ordinary course of business. Refer to Note 5 – *Related Party Transactions* in our interim condensed consolidated financial statements for further information.

LIQUIDITY AND CAPITAL RESOURCES

The Company's interim condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. As at January 31, 2023, the Company had working capital of $39,272,420 (October 31, 2022 – $46,350,475) and for the three months ended January 31, 2023 had a negative cash flow from operations of $5,470,592 (2022 - $1,938,430), excluding grant contributions received in the amount of $347,908 (2022 - $224,168). The Company has experienced operating losses and net cash outflows from operations since its inception.

During the three months ended January 31, 2023, capital expenditures were $71,835 (2022 - $243,784) as we continue to upgrade or replace equipment in our laboratory to support our R&D priorities.

Until such time as our biotechnology therapeutic products are approved and available for sale and profitable operations are developed, our liquidity requirements and ability to continue as a going concern are subject to management's ongoing ability to successfully raise additional working capital and ultimately generate cash flow from the commercialization of its products. Failure to do so could have a material adverse effect on the Company's financial condition and financial performance. During the year ended October 31, 2022, we raised proceeds of $20,279,178 from a private placement financing and $16,136,728 from the exercise of common share purchase warrants. Cash and marketable securities on hand of approximately $44.5 million as at January 31, 2023 are anticipated to fund our operating plan for a period of at least twelve months. Future financing will depend on many factors, including, but not limited to, market conditions that are not within the Company's control and the market acceptance of its products. No assurance can be given that any such additional financing will be available or that, if available, it can be obtained on terms favourable to the Company. See section "**RISKS AND UNCERTAINTIES**" and "**CAPITAL MANAGEMENT, FINANCIAL INSTRUMENTS AND RISKS**" in this MD&A.

If the going concern assumption was not appropriate for the consolidated financial statements, adjustments would be necessary to the carrying value of assets and liabilities, the reported expenses,

and the classifications used in the consolidated statements of financial position. The consolidated financial statements do not include adjustments that would be necessary if the going concern assumption was not appropriate.

Financing Activities

During the three months ended January 31, 2023, there were no changes to the Company's share capital.

During the comparative three months ended January 31, 2022, the Company received proceeds of $1,303,475 from the exercise of common share purchase warrants and stock options and the corresponding issuance of 1,129,000 common shares.

Common Shares

	Number of common shares
Balance outstanding as at October 31, 2022, January 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, and January 31, 2023	20,136,918	$ 1.67
Expired	(20,136,918)	$ 1.67
Balance outstanding as at 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	22,770,984	$ 0.92
Granted	120,000	0.80
Cancelled / forfeited	(225,000)	(0.22)
Balance outstanding as at January 31, 2023 and the date of this MD&A	22,665,984	$ 0.93

	Number of DSUs
Balance outstanding as at October 31, 2022, January 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. The aggregate maximum of 38,746,536 common shares allowable under the Incentive Plan consists of: (i) a maximum of 30,997,229 common shares reserved for the exercise of share options pursuant to the Option Plan and (ii) a maximum of 7,749,307 DSUs reserved under the DSU Plan component, representing 12.5% and 2.5% respectively of the then issued and outstanding common shares of the Company.

COMMITMENTS AND CONTINGENCIES

The Company was previously awarded a US$2.45 million (approximately $3.27 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. No contributions relating to milestones achievements were earned during the three months ended January 31, 2023 (2022 – $nil). Remaining funding available to be earned under the JDRF grant award totals approximately US$0.29 million ($0.39 million) as at January 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 SE for the development and commercialization of an iPSC-based beta cell replacement therapy ("iPSC Program") 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 million. The Evotec Agreement is cancellable by the Company with notice, subject to certain terms and conditions. iPSC Program costs of US$3,477,200 ($4,697,956) were incurred during the three months ended January 31, 2023 (2022 – $nil). 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.

We enter into contracts and agreements in the normal course of business, including for research and development activities, consulting, and other services. The majority of these contractual obligations are cancelable at any time by us, generally upon prior written notice to the service provider or vendor. In addition, the Company has minimum annual royalty payment obligations of approximately $30,000 for third party licensing agreements.

Effective September 1, 2021, the Company entered into a two-year lease for both its existing office premises and lab facilities and additional office space at a rate of $14,000 per month with a 2% annual increase thereafter for the duration of the lease period including any extension. Under the terms of the lease, the Company has an option to extend the lease term for an additional 12 months, up to August 31, 2024.

The following table summarizes our significant future contractual obligations as at January 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]	$ 274,747	$ 172,788	$ 101,959	$ –	$ –
Purchase obligations[4]	3,585,119	2,166,730	1,418,389	–	–
Other[5]	228,000	228,000	–	–	–
	$ 4,087,867	$ 2,567,518	$ 1,520,348	$ –	$ –

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 January 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 is identified. Amounts receivable at January 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 January 31, 2023, we had working capital of $39,272,420 (October 31, 2022 - $46,350,475).

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 9(c) to the interim condensed consolidated financial statements for the three months ended January 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 9(d) to the interim condensed consolidated financial statements for the three months ended January 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 the Company to make judgments, estimates, and assumptions that affect the application of accounting policies, the reported amounts of assets, liabilities, and expenses, as well as the Company's ability to continue as a going concern. The estimates and assumptions made are continually evaluated and have been based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Such estimates and assumptions are inherently uncertain, and actual results could differ materially from these estimates and assumptions. Revisions to estimates are recognized in the period in which the estimate is revised and may impact future periods.

Refer to the Company's audited consolidated financial statements for the years ended October 31, 2022 and 2021 for discussions on our accounting policies and significant estimates that are most important in assessing, understanding and evaluating our interim condensed consolidated financial statements.

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 three months ended January 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 interim condensed 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 interim condensed 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 interim condensed 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 interim condensed 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, and in the Company's most recently filed AIF available on www.sedar.com. 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.

Early Stage

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

Additional Capital Requirements

The Company has incurred annual losses over several years, and it plans on continuing to make significant expenditures to support its business growth and may require additional funds to respond to business challenges, including the need to expand sales and marketing activities, develop new processing technologies to enhance its existing technology, enhance its operating infrastructure, and acquire complementary businesses and technologies. Accordingly, the Company may need to engage in equity or debt financings to secure additional funds. If the Company raises additional funds through further issuances of equity or convertible debt securities, the Company's existing shareholders could suffer significant dilution, and any new equity securities the Company issues could have rights, preferences, and privileges superior to those of holders of the Company shares. Any debt financing secured by the Company in the future could involve restrictive covenants relating to its capital raising activities and other financial and operational matters, which might make it more difficult for it to obtain additional capital and to pursue business opportunities.

The Company can provide no assurance that sufficient debt or equity financing will be available on reasonable terms or at all to support its business growth and to respond to business challenges and failure to obtain sufficient debt or equity financing when required could have a material adverse effect on its business, prospects, financial condition, results of operations and cash flows.

The Company expects its cash reserves will be reduced due to future operating losses and working capital requirements, and it cannot provide certainty as to how long the Company's cash reserves will last or that it will be able to access additional capital when necessary. The Company expects to incur continued losses and generate negative cash flow until it can produce sufficient revenues to cover its costs. The Company may never become profitable. Even if it does achieve profitability, the Company may be unable to sustain or increase its profitability in the future.

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.

Economic Conditions

Current and future unfavorable economic conditions could negatively impact the Company's financial viability. Unfavorable economic conditions could also increase the Company's financing costs, decrease net income, or increase net loss, limit access to capital markets and negatively impact any of the availability of credit facilities to the Company.

For further information on important risks and uncertainties that could impact our business, please refer to the "*RISK FACTORS*" section of our most recent AIF, and included or discussed in our other periodic public filings, such as previous Management's Discussion and Analysis, filed on SEDAR at www.sedar.com.

DIRECTORS AND OFFICERS

Frank Holler	Director and Executive Chair of the Board
Jeffrey Bacha	Director and Compensation Committee Chair
James Parsons, CPA, CA	Director and Audit Committee Chair
Deborah Brown	Director and Nomination and Governance Committee Chair
Dr. Mohammad Azab	Director
Dr. Dan Mahony	Director
Dr. Philip Toleikis	President, Chief Executive Officer, and Director
Gary Floyd	Corporate Secretary
David Swetlow, CPA, CA	Chief Financial Officer

ADDITIONAL INFORMATION

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