



SERNOVA CORP.

MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE AND NINE MONTHS ENDED

JULY 31, 2023 AND 2022

Dated September 12, 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 and nine months ended July 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 and nine months ended July 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 September 12, 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:

- our corporate strategy, strategic objectives, future plans and projections;
- the availability of various forms of external financing to fund our 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 our ability to conduct clinical studies;
- the expected benefits to patients of our Cell Pouch applications for our diabetes, hypothyroid disease and hemophilia A 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 (ILCs);
- our intention to protect therapeutic cells within Cell Pouch from immune attack using local

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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 Investigational New Drug (IND) submission and beyond combined with the expected benefits of using iPSC derived ILCs in combination with Cell Pouch and ancillary technologies within the Evotec Collaboration (defined hereafter);
- the timing of IND enabling pre-clinical studies and regulatory clearance of the subject IND;
- our intentions and ability to secure academic and pharmaceutical / medtech collaborations to develop and implement partnering strategies and manage partnerships;
- our 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 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;
- our 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;
- our 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 our products;
- our expectations that our 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;
- our expectations with respect to the research and development of our products, clinical trials, and commercialization of our products, including with respect to timing;
- our commercialization strategy for our technologies including Cell Pouch or Cell Pouch System and associated technologies coupled with the ability to commercialize our product candidates, pending regulatory clearance;
- our intentions regarding the development and protection of our intellectual property;
- our intentions with respect to obtaining licenses for technologies compatible with the Cell Pouch System;
- our intention to develop next-generation Cell Pouch or Cell Pouch System related technologies;
- our ability to secure cGMP manufacturing facilities for our cell therapy programs;
- sufficient availability of Cell Pouch product, therapeutic cells, iPSCs and iPSC derived ILCs, as applicable, for the conduct of preclinical studies, clinical trials, and commercial use following marketing approval;
- the direct and indirect impact or lingering effect 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
- our general business and economic conditions.

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

Forward-looking information is based on the reasonable assumptions, estimates, analysis, and opinions of management made 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 our forward-looking information are based include:

- the expected benefits to patients of our product candidates and technologies including Cell Pouch and Cell Pouch System cell therapy programs in combination with therapeutic cells;
- the absence of material adverse changes in our industry or the global economy, including the impact of the Russia-Ukraine conflict and any lingering effect of the COVID-19 pandemic on our business and operations even after the World Health Organization (WHO) has declared it is no longer a global health emergency;
- the effect of macroeconomic conditions, including rising interest rates and inflation, on our operations;
- trends in our industry and markets;
- the speed of regulatory review and clearance;
- our ability to comply with current and future regulatory standards;
- our ability to protect our intellectual property rights;
- our continued compliance with third-party license terms and the non-infringement of third-party intellectual property rights;
- our ability to complete all necessary preparatory work to file an IND for iPSC derived ILCs in combination with Cell Pouch and any applicable ancillary technologies;
- our ability to supply Cell Pouches, therapeutic cells and or any complementary technologies comprising a product;
- our ability to effectively conduct and manage clinical trials;
- our ability to attract and retain key personnel;
- our ability to manage its growth effectively; and
- our 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 our 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 or lingering effects of the COVID-19 pandemic or related outbreaks, and economic conditions. Such risks are further described under “**RISK**

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FACTORS AND UNCERTAINTIES" in this MD&A or under "*RISK FACTORS*" in our most recently filed Annual Information Form (AIF) available on www.sedarplus.ca. Potential investors, and other readers are urged to consider these factors carefully in evaluating these forward-looking statements and information and are cautioned not to place undue reliance on them. Sernova has no responsibility, nor does it intend, to update these forward-looking statements and information unless as otherwise required by law.

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

This MD&A has been prepared to help investors understand the financial performance of Sernova in the broader context of our strategic direction, the risks and opportunities as understood by management, and some of the key metrics that are relevant to our performance. This MD&A has been reviewed and approved for filing by the Company's Audit Committee on behalf of the Board of Directors. The Company's Audit Committee consists of three independent Directors, who are all considered to be "financially literate" as defined in NI 52-110.

GLOBAL ECONOMIC AND BUSINESS CONDITIONS

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

We face various risks related to public health issues, including epidemics, pandemics, and other outbreaks, such as the lingering effects of the COVID-19 pandemic. The effects and potential effects of the COVID-19 pandemic, including, but not limited to, its impact on general economic conditions, trade and financial markets, changes in current or potential clinical trial participants behavior and continuity in business operations, creates significant uncertainty. In addition, the COVID-19 pandemic may cause an increase in costs resulting from our efforts to mitigate the effects. Even as the COVID-19 pandemic subsides, with the WHO declaring on May 5th, 2023 it is no longer a global health emergency, we may suffer an adverse impact on our business due to any or prolonged continuance of the global economic effect of the pandemic, including any economic recession that has occurred or may occur in the future.

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

Financial institution failures could impair our ability to access our cash, cash equivalents and marketable securities and to timely pay key vendors and others. For example, on March 10, 2023, Silicon Valley Bank (SVB) was placed into receivership with the Federal Deposit Insurance Corporation (FDIC), which resulted in all funds held at SVB being temporarily inaccessible by SVB's customers. Although we did not have any funds in SVB nor other institutions that have also since closed, we cannot guarantee that the banks or other financial institutions that hold our funds will not experience similar issues. If any with whom we have banking relationships enter receivership or become insolvent in the future, we may

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be unable to access, and we may lose, some or all of our then existing cash, cash equivalents and marketable securities to the extent those funds are not insured or otherwise protected by the Canadian Deposit Insurance Corporation (CDIC) or other regulating bodies. In addition, in such circumstances we might not be able to timely pay key vendors and others. Any delay in our ability to access our cash, cash equivalents, and marketable securities (or the loss of some or all of such funds) or to timely pay key vendors and others could have a material adverse effect on our operations and cause us to need to seek additional capital or sooner if and when planned.

In addition, investor concerns regarding the US or international financial systems could result in less favorable commercial financing terms or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on favorable terms, or at all, and could have material adverse impacts on our liquidity, our business, financial condition and or results of operations.

ABOUT SERNOVA

Sernova is a publicly listed (TSX:SVA | OTCQB:SEOVF | FSE / XETRA:PSH) clinical-stage cell therapeutics company focused on development and commercialization of our proprietary platform and associated 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), hypothyroid disease, and rare diseases such as hemophilia A among others. The Cell Pouch is a scalable, implantable, medical device, designed to create a highly vascularized organ-like environment for the transplantation and engraftment of therapeutic cells, which then release proteins, hormones or other factors into the bloodstream for the long-term treatment of various chronic diseases. The therapeutic cells used for therapeutic purposes may be autograft cells or tissues (self-cells / tissues) or allograft cells (non-self, donor cells) or cells derived from sources known to provide a virtually unlimited supply of cells such as stem cell-derived cells or from a xenogeneic (non-human) source. Furthermore, the therapeutic cells may be unmodified or may be genetically modified to produce their therapeutic effect.

Our preclinical and clinical research studies to date support the safety and biocompatibility of Cell Pouch and long-term survival and function of therapeutic cells transplanted into the vascularized Cell Pouch chambers. Our data demonstrates that following implantation of the Cell Pouch, vascularized tissue incorporates through pores in the device forming fully enclosed vascularized tissue chambers. Upon transplantation of therapeutic cells into these vascularized chambers a natural tissue matrix develops providing microvascularization of the transplanted cells, enabling them to engraft (survive and function). Thus, an anticipated benefit of the Cell Pouch is formation of a natural environment for the therapeutic cells that provides for enhanced long-term graft survival and function. We believe this is due in part to the therapeutic cells living in a natural vascularized tissue matrix allowing close contact with the transplanted cells.

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.sedarplus.ca 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, hypothyroid disease. We have also entered into strategic collaborations and acquired, in-

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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.

SELECT RECENT HIGHLIGHTS

April 2023: We announced the first presentation of preclinical data for Sernova's iPSC Program in conjunction with our collaboration with Hamburg, Germany based Evotec SE (Evotec) for the development and commercialization of an iPSC-based beta cell replacement therapy for diabetes (Evotec Collaboration). The Evotec Collaboration combines Evotec's iPSC derived ILCs with Sernova's implantable Cell Pouch device for the treatment of patients with T1D. The oral podium presentation, "*Manufacturing Of Human Islet-like Clusters (ILCs) From iPSCs and Functional Testing of an ILC and Cell Pouch Combination In Vivo*", occurred at the 4th International Pancreas and Islet Transplant Association (IPITA) / Harvard Stem Cell Institute (HSCI) / Juvenile Diabetes Research Fund (JDRF) Summit. Key highlights of the data presented included:

- Evotec's scalable GMP manufacturing process has been designed to produce iPSC-derived ILCs with high insulin-producing beta cell content as well as glucagon and somatostatin (produced by alpha cells and delta cells, respectively), similar to human islets;
- Evotec ILCs are cryopreserved at a late-intermediate stage of differentiation allowing for a cost-effective large-scale manufacturing process to optimize both pre and post-implantation durability and enabling storage of mass volumes and cost efficient on-demand worldwide delivery as required, which we believe represent major advantages over competing cell therapies in development;
- results from a T1D preclinical model in mice with Evotec's ILCs implanted into Sernova's Cell Pouch demonstrated robust and durable insulin independence with blood C-peptide levels and glucose tolerance test results equivalent to a test group with human islets;
- an additional T1D study with Evotec's ILCs demonstrated sustained normalization of blood sugar levels in diabetic mice throughout the 320-day term of the study; and
- IND filing and Phase 1/2 clinical program initiation with Sernova's Cell Pouch and Evotec's iPSC derived ILCs are on track for 2024.

Activities are continuing in preparation for the anticipated IND filing and regulatory clearance to initiate a Phase 1/2 clinical study in 2024.

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

May 2023: We announced the appointment of Mr. Brett Whalen as Chair of the Company's Board of Directors and the retirement of directors Ms. Deborah M. Brown and Dr. Mohammad Azab.

June 2023: We announced updated interim positive clinical results from our ongoing Phase 1/2 T1D Clinical Trial. The Research Team from Principal Investigator Dr. Piotr Witkowski's laboratory at the University of Chicago presented at the American Diabetes Association's 83rd Scientific Sessions in San Diego, California an oral podium presentation, "*Islet Allograft Transplantation into Pre-vascularized Sernova Cell Pouch—Early Results from the University of Chicago*", updating patient progress in the study.

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The presentation discussed the first eleven patients enrolled across two cohorts in the clinical trial and reconfirmed the safety of Cell Pouch up to more than four years following implant. To date, five patients in the first cohort of six subjects who have completed the clinical trial protocol have experienced insulin independence for periods ranging from six months to greater than three years. The sixth patient in the first cohort has only recently completed the protocol-defined islet transplants and awaits assessment of their islet graft function. The first evaluable patient in the second cohort has demonstrated persistent fasting and stimulated serum C-peptide levels following a single islet transplant into the pre-vascularized 10-channel Cell Pouch. Refer to the *Type 1 Diabetes Phase 1/2 Clinical Trial for Patients with T1D, Severe Hypoglycemic Episodes and Hypoglycemia Unawareness (Phase 1/2 T1D Clinical Trial)* section below in this MD&A for more information on the findings presented.

July 2023: We announced the expansion of our leadership team with the appointment of veteran dealmaker and strategic leader Modestus Obochi, Ph.D., MBA, as Chief Business Officer effective September 8, 2023.

September 2023: We announced the appointment of biotech and pharma industry veteran Cynthia Pussinen as Chief Executive Officer (CEO) and a member of the Board of Directors of Sernova and that Dr. Philip Toleikis, prior President and CEO, will assume the position of Chief Technology Officer and remain a member of the Board of Directors.

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

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

Dr. Tomei will provide a detailed update on the Conformal Coating Technology in a podium presentation at the 2023 IPITA-IXA-CTRMS Joint Congress in San Diego from October 26-29, 2023.

BUSINESS OVERVIEW

Sernova Cell Pouch System: A Platform Technology Approach

Sernova's patented Cell Pouch System is designed to take into consideration the biological requirements of therapeutic cells. This is achieved through the establishment of an organ-like environment defined as a vascularized tissue matrix for therapeutic cells, which develops within the device chambers following implantation. We believe this unique approach of encouraging vascularized tissue incorporation into the device may also help prevent fibrosis that plagues other implantable cell therapy devices and provides a biologically optimal environment for the engraftment and function of therapeutic cells.

The Cell Pouch is designed to be scalable to match the required cell dose for each clinical application for optimized therapeutic effect. Our preclinical research demonstrated that following Cell Pouch implantation, vascularized tissue chambers develop within the device. Long-term preclinical studies

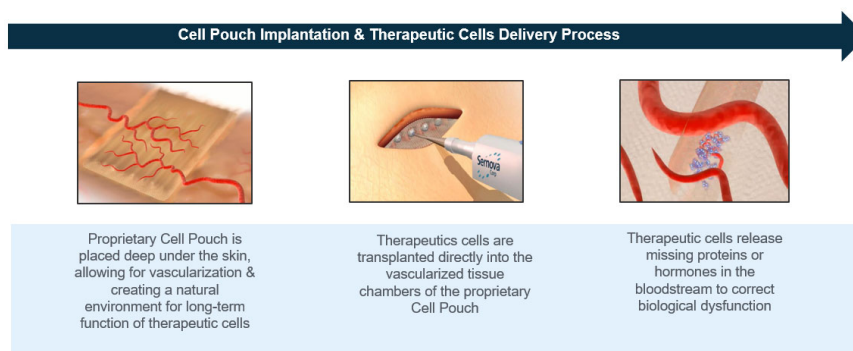
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have shown that the Cell Pouch creates a stable, vascularized, native-tissue environment prior to transplantation of therapeutic cells, which we believe is key for maintaining long-term survival and function of therapeutic cell grafts. We believe Sernova's 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.

Biologically Compatible Delivery Process



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

The cells transplanted into Cell Pouch may be protected from immune system attack, when required, by systemic immunosuppressive anti-rejection medications, therapeutics that promote tolerance of the immune system to transplanted cells, or through other Sernova immune protection technologies such as

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microencapsulation or conformal coating of cells. Microcapsules surrounding the cells have tiny pores, which have been shown in preclinical studies to provide a means to allow nutrient and protein exchange within the local vascularized environment while preventing immune system attack. Conformal coating is an exclusively licensed proprietary technology forming a cross-linked polymer coating around cells using a ‘shrink wrap’ approach that may also provide protection from immune system attack and has been shown in preclinical studies to allow natural exchange of glucose and insulin between conformally coated cells and systemic blood. Sernova is also evaluating gene editing technologies for our stem cell-derived programs and other approaches such as promoting immune system tolerance to transplanted cells that may provide an alternative method of local cellular immune protection. These approaches alone or in combination are anticipated to reduce or eliminate the requirement of systemic immunosuppressive anti-rejection medications, across a range of disease indications.

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

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

Pipeline – Life Cycle Iterations and Multiple Indications

Product Candidate	Indication	Therapeutic Cell Source	Immune Protection	Discovery	Pre-Clinical	Phase 1/2	Phase 3	BLA
Cell Pouch System	Insulin-dependent Diabetes	Human donor islet cells	Immunosuppressives	▶				
		iPSC islets	Immunosuppressives	▶				
		iPSC islets	Local immune protection	▶				
Cell Pouch System	Hemophilia A - Severe	Corrected patient cells	Autologous cells	▶				
	Hemophilia A – all patients	Allograft immune protected stem cells	Local immune protection	▶				
Cell Pouch System	Thyroid Diseases / Hypothyroidism	Thyroid cells	Autologous cells	▶				
	Thyroid Diseases / Hypothyroidism	Allograft immune protected stem cells	Local immune protection	▶				

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

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

According to the International Diabetes Federation (IDF), there are approximately 537 million people worldwide with diabetes, and nearly 10% of these individuals have T1D (<https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html>) where the cells in the pancreas that control blood sugar levels through controlled release of insulin have stopped functioning or have died, allowing blood sugar levels to rise resulting in short and long-term debilitating effects of the disease. Approximately 17% of people with T1D suffer from hypoglycemia unawareness events

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characterized by onset of hypoglycemia without any warning symptoms (www.diabetesnet.com). This significant proportion of diabetic patients is at risk of sudden and severe low blood sugar reactions that may become fatal without the intervention of another person. The safe management of this at-risk population could be addressed by Sernova's products – following successful completion of clinical studies and regulatory approval.

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

In some countries, the current cell therapy is transplantation of donor islets 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 (US FDA), and may only be administered under a clinical trial protocol.

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

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

Our most advanced development program involves the clinical development and validation of the Cell Pouch System for the treatment of people with T1D who suffer from unstable diabetes and life-threatening severe hypoglycemic episodes. As noted in Table 1 below, we believe the Cell Pouch System can alleviate a number of important issues with portal vein transplantation. With the Cell Pouch

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

Table 1 - Potential Benefits of Cell Pouch Islet Transplant

Characteristics	Cell Pouch Transplant	Portal Vein Transplant
Islets housed in a vascularized tissue matrix	Yes	No
Confirmed vascularization of islets	Yes	No
Retrievable site	Yes	No
Retrievable site for stem cell-derived and gene-edited cells, providing a safety benefit	Yes	No
Minimally invasive subcutaneous site	Yes	No
Prevention of liver-associated toxicities	Yes	No
Prevention of IBMIR	Yes	No

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

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

Importantly, Cell Pouch technologies are specifically and uniquely designed to be biocompatible, featuring pores that incorporate with vascularized tissue to form fully enclosed chambers with central void spaces for placement of therapeutic cells. A serious problem that may be encountered with other implanted therapeutic medical devices is the development of unwanted fibrosis in which the body treats the device as foreign and walls off the device with scar tissue resulting in starving of the cells of oxygen and nutrients. We believe the unique design of the Cell Pouch prevents the formation of fibrotic tissue following implantation, facilitating the long-term survival and function of transplanted therapeutic cells.

As a novel approach beyond portal vein infusion of islets, we believe that islets (donor or stem cell-derived) transplanted into the Cell Pouch may provide a better means to optimize cell therapy for the treatment of diabetes. The data gained from our current clinical study using donor islets is being used to provide a basis for advancement of glucose-responsive immune-protected stem cell-derived cells for

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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-manufacturing facility in compliance with ISO13485, EU Medical Devices Regulation MDR 2017/745, United States Food and Drug Administration Quality System Regulations (QSR) 21 CFR 820 and Canadian Medical Device Regulation (CMDR). In our current Phase 1/2 T1D Clinical Trial with donor islets, we are testing additional sizes of Cell Pouch that will enable us to further optimize islet dosing and dose density which we believe may lead to enhanced patient outcomes with the Cell Pouch System. In addition to preparing for a potential T1D pivotal study with donor islets, the current Phase 1/2 T1D Clinical Trial is informing planned trials with the Evotec iPSC derived ILC technology.

To validate our Cell Pouch System technologies in preparation for clinical evaluation for T1D, in addition to safety studies of Cell Pouch alone we successfully transplanted donor islets into the Cell Pouch, in multiple small and large animal models (syngeneic, autograft and allograft) of diabetes. The reversal of diabetes in these studies provided proof of concept of the Cell Pouch System to support clinical evaluation of the Cell Pouch with donor islets. Based on the preclinical results with donor islets, we conducted a first-in-human proof-of-concept (POC) clinical study for the treatment of human subjects with diabetes and hypoglycemia unawareness. Patients received donor islets, protected by the standard of care immunosuppressives for a first in human Canadian safety study, cleared by Health Canada. The approach of using human donor islets in the Cell Pouch has enabled Sernova to understand the behaviour of transplanted insulin-producing cells in the Cell Pouch in humans as an initial step to the development of an immune-protected stem cell product to treat the larger treatable population of patients with diabetes.

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

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

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fully differentiated ILCs may provide required insulin to patients sooner following transplantation than early progenitor islet technologies which may take many months to mature following transplantation prior to producing therapeutic levels of insulin in the body.

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

The completion of IND enabling preclinical studies, filing of an IND submission, regulatory clearance of the subject IND and initiation of a Phase 1/2 clinical trial study with Sernova's Cell Pouch and Evotec's iPSC derived ILCs remain on track for 2024.

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

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

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

With the encouraging results and learnings from our first Cell Pouch clinical trial, we initiated a second clinical study - "*A Safety, Tolerability and Efficacy Study of Sernova's Cell Pouch™ for Clinical Islet Transplantation*" - to further address the safety, tolerability as well as function of Cell Pouch with therapeutic cells. The primary objective of the study is to demonstrate the safety and tolerability of islet transplantation into the Cell Pouch. The secondary objective is to assess efficacy through a series of defined measures. This clinical study is defining our understanding of the relationship of treatment response to the dose and dose-density of islets transplanted into the Cell Pouch. Continuous glucose monitoring (CGM), mixed meal tolerance tests and changes in daily insulin use are efficacy measures used to track the function of the cells transplanted into Cell Pouch at key time points throughout the clinical trial. The use of CGM in this study supports the analysis of serum glucose concentrations and variability, the number, severity and duration of both high and low glycemic episodes.

Following a peer review of the new clinical protocol, Sernova was awarded up to US\$2.5 million (approximately \$3.2 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.

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

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

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

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

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accommodate what we have calculated to be the optimal total dose of high-quality purified islets required to potentially achieve insulin independence.

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

We believe Cell Pouch can be used with a variety of cell sources, such as glucose-responsive insulin-producing cells derived from stem cells, addressing the limited availability of donors and allowing the extensive treatment of insulin-dependent diabetes and we have demonstrated this in several pharmaceutical collaborations using small animal models of T1D. We are leveraging our extensive learnings of human donor islets within the Cell Pouch as we develop our iPSC-derived beta cell technologies, along with Evotec, to provide an immune-protected cell-based therapeutic suitable for all people with insulin-dependent diabetes.

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

On November 3, 2022, we announced the adoption of a protocol amendment, approved by the University of Chicago Institutional Review Board (IRB) and without objection from US FDA, to add a second cohort of up to seven patients to test the aforementioned enhanced capacity 10-channel Cell Pouch and potentially optimize patient outcomes. The amendment was based on promising positive interim data to date from our clinical study informing on islet dose and density. The amendment enables us to proceed with a strategically optimized protocol potentially reducing the time required for patient treatment while accelerating potential secondary endpoint efficacy achievement with more optimal dosing. We have engaged a clinical trial recruitment partner with extensive experience and success in accelerating T1D clinical trial patient enrollment to expedite recruiting and patient enrollment and we expect to report on interim data from the second cohort with the enhanced capacity Cell Pouches in 2023. On November 17, 2022, we provided an update that the first two patients of the second cohort have been implanted with the enhanced 10-channel Cell Pouch.

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

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

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

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first cohort has only recently completed the protocol-defined islet transplants and awaits assessment of their islet graft function.

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

Other findings from the interim clinical update:

- long-term surgical implantation of the Cell Pouch continues to be well tolerated with a favorable safety profile in patients receiving either 8 or 10-channel Cell Pouches;
- five of the six patients in the first cohort achieved insulin independence following supplemental islet transplants via the portal vein that were below the typical intraportal islet dose, indicating that islet graft function in the 8-channel Cell Pouch is supporting ongoing glucose control;
- histological assessment of sentinel Cell Pouches excised at ≥ 90 days post-transplant revealed surviving functional islets in five of six patients in the first cohort;
- the first patient in the second cohort developed persistent neutropenia requiring cessation of immunotherapy to enable the neutropenia to resolve. The third patient who received a first islet transplant awaits their first islet graft assessment; and
- a further update on the second cohort of the clinical trial is expected in H2 2023.

With the expansion of our Phase 1/2 T1D Clinical Trial in November 2022 to include a second cohort of study patients, we remain on track to be able to provide an update on the clinical trial and second cohort patients before the end of H2 2023.

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

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

Development of the Cell Pouch System for the Treatment of Postoperative Hypothyroidism / Thyroid Program

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

According to the American Thyroid Association (ATA), 20 million Americans currently live with thyroid disease, and 12% of Americans will develop a thyroid condition during their lifetime. The thyroid gland is essential for life as it produces and secretes thyroid hormones that regulate the body's metabolism. The development of new treatments for patients with unsatisfactory control of the thyroid hormone feedback loop may satisfy this unmet medical need. We believe that thyroid tissue transplanted into an implanted Cell Pouch offers a novel approach that could improve the quality of life and outcomes of patients experiencing postoperative hypothyroidism following thyroidectomy. Sernova's first approach in the treatment of hypothyroid disease is to take healthy tissue from each patient's own

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thyroid gland - removed during a thyroidectomy – and transplant that tissue into the pre-implanted vascularized Cell Pouch. The goal is to restore the natural feedback system for release of thyroid hormones from each patient's own thyroid tissue.

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

Hypothyroidism is a condition where the thyroid gland does not produce sufficient hormones, thereby upsetting the normal balance of chemical reactions. If left untreated, hypothyroidism can cause health problems such as obesity, joint pain, infertility, heart disease, and eventually death. Common causes are autoimmune diseases, radiation treatment, and surgical removal of the thyroid (thyroidectomy). Patients may undergo surgical reduction (thyroid lobectomy) or complete removal of the thyroid gland (total thyroidectomy) for treatment of several disorders such as thyroid nodules, which are reported to occur in up to 65% of patients observed upon autopsy (PMID: 19041821); Grave's Disease (a type of hyperthyroidism); and or large multinodular goiters. Thyroidectomy is also commonly performed for cancer diagnosis or treatment.

Hypothyroidism inevitably occurs after total thyroidectomy and may also occur in up to 10% of people after thyroid lobectomy (Johner, A. et al, *Ann of Surg One* 2011; 18(9):2548-2554). The American Thyroid Association estimates that 150,000 thyroidectomies are performed in the US yearly, and most individuals undergoing a thyroid operation will be diagnosed with benign disease after their operation.

Following thyroidectomy, patients require daily hormone replacement therapy with synthetic T4. Published research indicates up to 50% of synthetic 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

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potentially avoid lifelong dependence on thyroid medication following surgical removal of the thyroid gland. The journal article entitled “*Subcutaneous transplantation of human thyroid tissue into a pre-vascularized Cell Pouch™ device in a Mus musculus model: Evidence of viability and function for thyroid transplantation*” by lead author, Dr. Wiseman, a leading surgeon, researcher and internationally renowned expert in the management of thyroid and parathyroid disease, was published in the scientific journal, *PLOS ONE*, January 20, 2022 edition. In this study, thyroid tissue from patients undergoing surgery for treatment of benign disease was transplanted into Sernova Cell Pouches that had been previously implanted into laboratory mice. The aim of the study was to investigate the long-term survival of human thyroid tissue in the Cell Pouch and evaluate the ability of these thyroid transplants to release thyroid hormones into the bloodstream. The study confirmed that the human thyroid tissue transplanted into the Cell Pouch survived and released human thyroglobulin into the bloodstream, with no adverse effects for the three-months duration of the study. Thyroglobulin was used as a biomarker efficacy measure in this study as it is the precursor of thyroid hormones.

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

We are now completing a final IND enabling preclinical study to advance the program to clinical trials for this novel approach to the prevention of postoperative hypothyroidism. Simultaneously, we are preparing documentation to support a clinical trial application. Discussions have continued with regulatory authorities who have taken considerably longer than expected to pre-determine how the product will be regulated and, therefore, the most efficient regulatory pathway for each jurisdiction.

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

Our hemophilia program targets a comprehensive therapy that corrects factor VIII (FVIII) production in people with hemophilia A. The use of FVIII corrected cells, transplanted to the vascularized pre-implanted Cell Pouch, is intended to reduce or eliminate bleeds associated with hemophilia A, thereby providing a ‘functional cure’ and improved quality of life.

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

According to a publication by the Alliance for Regenerative Medicine ([ARM](#)), the estimated annual cost of treatment for hemophilia A represents an average of US\$200,000 per patient.

We believe that the therapeutic potential to have a constant release of FVIII from a hemophilia A patient’s own genetically corrected cells placed within the implanted Cell Pouch would be a very significant advancement and a disruptive approach to the current standard of care treatment for hemophilia A. Corrected cells placed in an implanted Cell Pouch could release FVIII at a rate expected to reduce disease-associated hemorrhaging and joint damage. The continuous delivery of FVIII could also reduce or eliminate the need for multiple weekly infusions, which is the current standard of care using plasma-derived or recombinant, genetically engineered FVIII for the prophylactic treatment of

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hemophilia A. This approach is analogous to that used for CAR T-cell therapy as a validated therapeutic approach where a patient's own cells are collected from a blood sample and then modified, multiplied and placed back into the patient's body to treat the target disease.

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

In the development of this novel technology, multi-year product development and POC studies have been conducted and successfully completed by Sernova and a European team of experts collectively forming the HemAcure Consortium (HemAcure Consortium). The aim of the HemAcure Consortium three-year project was to develop a permanent, safe, therapeutic solution for those living with hemophilia A in the form of a novel ex vivo gene therapy, cell-based approach within Sernova's proprietary Cell Pouch. This combination therapy strives to replace missing clotting human FVIII in the patient's own Blood Outgrowth Endothelial Cells (BOECs) transplanted into the Cell Pouch. These corrected cells function to release FVIII into the bloodstream restoring the ability for blood clotting to occur preventing uncontrolled bleeding. The HemAcure Consortium was funded by a €5.6 million (approximately \$8.5 million) European Commission Horizon 2020 grant (Horizon 2020 Grant) to develop a Good Manufacturing Practices (cGMP) compliant human cell product to enable the completion of safety and efficacy studies in the Cell Pouch as part of a regulatory package in preparation for human clinical testing.

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

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

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

We have entered into a collaboration with a leading European academic center to optimize the cellular Factor VIII production in the gene editing manufacturing process as well as Cell Pouch dosing in a preclinical model of hemophilia A and pending the research outcome, support a potential future IND submission for the first hemophilia A clinical study with the Cell Pouch System.

The proposed therapy is paving the way for future human clinical testing in hemophilia A patients using

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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.

To date, we have had research collaborations with multiple major pharmaceutical companies deploying our in-house cell therapy expertise and proprietary Cell Pouch technologies in combination with proprietary therapeutic cell assets designated by the pharmaceutical collaborators to conduct POC 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 our 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 (conformal coating technologies) and other advanced technologies such as gene-editing may protect therapeutic cells from immune system attack within the Cell Pouch vascularized environment while providing the means to enable direct communication between therapeutic cells and microvessels within the established tissue matrix. We believe such approaches may enable long-term survival and function of therapeutic cells in Cell Pouch, with transient or even no need for immunosuppressive medications. Consequently, development of cellular local immune protection technologies is an important pillar for our cell therapeutics platform. During 2020, we secured exclusive rights to local immune protection technologies for our Cell Pouch cell therapy platform via acquisition and licensing agreements.

Our approach of providing immune protection for cells locally, within the Cell Pouch tissue matrix, is anticipated to be a competitive advantage and accelerate development of our therapeutic programs. We continue to evaluate additional immune protection technology approaches. We believe we are well-positioned to advance our total 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 anti-rejection medications. This technology would improve overall outcomes and quality of life for patients through freedom from the maintenance and side-effects of immunosuppressive agents. We expect to accomplish this by providing local immune protection that shields therapeutic cells from detection and attack by a patient's own immune system.

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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, we have committed to fund up to a total of US\$1.38 million (\$1.82 million), of which US\$1.36 million (\$1.79 million) has been incurred as of July 31, 2023. Technology optimization and further preclinical validation work is progressing as expected and continuing. Dr. Tomei is one of the original inventors of the Conformal Coating Technology that has been developed and optimized over more than a decade with her dedicated team. This important collaboration is multifaceted in nature and designed to advance for the first time locally immune protected cells within the Cell Pouch with the goal of advancing these technologies into clinical trials without the need for life long immune suppression technologies. We believe successful development of this combination technology could meet an unmet need in a broader population of people with T1D who seek a 'functional cure' for their diabetes without the need to take life-long immunosuppression medications.

Subsequent to the collaboration announcement, we hosted an information session webinar "The Ultimate Combination of Two Proven Technologies as a Potential Functional Cure for Type 1 Diabetes and Other Chronic Diseases". The webinar featured Dr. Tomei, who spoke about the use of our

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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.

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

- pre-clinical studies conducted demonstrated that conformally coated islets transplanted into the pre-vascularized Cell Pouch achieved normal blood glucose control and reversed the effects of T1D in a syngeneic rat model of T1D. The treated animals achieved insulin independence (return to normal glucose levels). These findings demonstrate that the conformal coating technology supports efficient glucose detection and insulin release kinetics in coated cells transplanted to Cell Pouch;
- in additional optimization studies in T1D animal models transplanted with conformally coated allogeneic islets to pre-implanted Cell Pouch, subjects treated with a single selective immunomodulatory agent achieved sustained, normalized blood glucose levels during the study period. These findings support our product approach of eliminating the need for the immunosuppressive medication cocktails typically used for islet transplant patients and which are frequently associated with unwanted side effects;
- assays have been identified and studies conducted to develop and validate product release criteria for the conformal coating. Release testing is conducted for the finished coated islet product to ensure quality, safety, and efficacy potential, prior to the transplantation of conformally coated islets into Cell Pouch. Long-term in vitro stability and durability studies have also been successfully completed;
- through a design and manufacturing partner, Sernova is developing a bench-top, scalable, fully automated and GMP-compatible cell coating system. The clinical-scaled system is designed for compatible installation in both industrial and clinical GMP cell manufacturing facilities to facilitate GMP coating islets and islet analogues for testing in clinical trials; and
- Sernova is undertaking a standard array of biocompatibility studies and is completing an allogeneic optimization study using conformally coated islets in the Cell Pouch with the addition of a selective immunomodulatory agent which has proven effective in our ongoing Phase 1/2 T1D Clinical Trial study. A single agent provided intermittently with the conformal coating technology would be a significant advancement in the field of cellular immune protection.

Access to Multiple Sources of Therapeutic Cells

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

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

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

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

Significant Acquisitions, In-Licensing and Collaborations During or Since Our Last Fiscal Year

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

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, with the goal to develop a best-in-class cell therapy treatment for people living with insulin-dependent diabetes. Together we will combine and leverage our respective technologies and scientific expertise to develop an implantable iPSC-based beta cell (islet-like clusters) replacement therapy (iPSC Program) to provide an off-the shelf unlimited insulin-producing cell source to treat patients with insulin-dependent diabetes.

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

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

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complete treatment solution for T1D. Similarly, based on data from our collaborations with other prospective partners, Sernova concluded that Evotec had the ideal, ethically derived iPSC beta cell technology with the greatest potential to become a highly successful commercial product in combination with Sernova's proprietary technologies.

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

On January 10, 2023, we provided an update on the progress 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 had 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 ILC survival under standard pharmaceutical shipping conditions and following transplantation;
- demonstration of consistent long-term insulin independence with no hypoglycemic events and consistent safety profiles in a gold standard T1D preclinical model with Evotec's iPSC-derived ILCs transplanted in Sernova's Cell Pouch;
- iPSC derived ILC manufacturing scale-up and technology transfer activities to Evotec's iPSC GMP facility are well under way in preparation for manufacture of clinical and commercial iPSC derived ILCs supply; and
- interactions with experts to support design of a Phase 1/2 clinical trial.

On April 24, 2023, preclinical data for Sernova's iPSC Program and the Evotec Collaboration was externally presented for the first time. The oral podium presentation, "*Manufacturing Of Human Islet-like Clusters (ILCs) From iPSCs and Functional Testing of an ILC and Cell Pouch Combination In Vivo*", occurred at the 4th IPITA / HSCI / JDRF Summit. Refer to the SELECT RECENT HIGHLIGHTS section within this MD&A for more information on the findings presented.

The filing of an IND submission, regulatory clearance of the subject IND and initiation of a Phase 1/2 clinical trial study with Sernova's Cell Pouch and Evotec's iPSC derived ILCs remain on track for 2024.

Pharmaceutical and Life Sciences Company Collaborations

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

In this regard, we are deploying our in-house cell therapy expertise and proprietary Cell Pouch technologies in combination with proprietary therapeutic cell assets designated by pharmaceutical or life science company collaborators. 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

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expand our therapeutic treatment potential but also provides a de-risked approach for us as we develop our technologies and bring new therapies to patients with the goal to provide people with a functional cure for multiple chronic and rare diseases.

Protection of Proprietary Intellectual Property

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

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

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

Research and Development (R&D)

Our R&D efforts focus principally on the development of our Cell Pouch System cell therapy platform in conjunction with various therapeutic cells and immune protection technologies for the treatment of major and rare diseases in humans. The vast majority of the Company's direct R&D costs over the last three fiscal years have been related to Sernova's Diabetes Program, which is the Company's lead R&D program.

Our overall objective is to advance our 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 R&D objectives and related goals include the following:

- conducting the clinical trials required to gain eventual marketing approval for the Cell Pouch System in countries that have a significant market opportunity. Our first clinical trial for the treatment of T1D and severe hypoglycemic events is utilizing human donor islets;
- combining Evotec iPSC derived ILCs and Sernova technologies, including the Cell Pouch System, to potentially expand the market opportunity and availability of our T1D treatment to millions of people with diabetes; and
- ongoing R&D activities related to our proprietary Cell Pouch in the following areas:
 - continuing R&D of additional therapeutic indications such as postoperative hypothyroid disease and hemophilia A;
 - assessing and developing our Cell Pouch System cellular immune protection technologies;

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- collaboration with industry and academic partners to assess new technologies and evolve product development activities for new clinical opportunities;
- assessing new therapeutic cell sources in additional potential therapeutic indications of interest; and
- expansion of our intellectual property portfolio.

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

RESULTS OF OPERATIONS

For the three months ended July 31, 2023, we recorded a loss of \$9,931,704, an increase of \$4,100,212 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. As otherwise more fully described in this MD&A, the R&D cost increase was significantly influenced by our active iPSC Program collaboration with Evotec, which was in early stages during the prior year's comparative quarter, and an increase in patient related costs due to increased patient enrollment in the Phase 1/2 T1D Clinical Trial over the prior year's comparative quarter and related expenses as patients progress through the trial.

For the nine months ended July 31, 2023, we recorded a loss of \$27,293,862, an increase of \$11,083,748 compared to the same period in the prior year. Similar to the third quarter, higher R&D costs associated with the advancement of our iPSC Program was the primary year-to-date loss increase driver. Increased costs were partially offset by a decrease in non-cash share-based compensation due to the vesting of stock options and DSUs granted during the first quarter of the comparative fiscal year. These grants had an incremental effect on share-based compensation for the comparative period by a one-time amount of approximately \$2.4 million that is not applicable in the current period.

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

As at July 31, 2023, total assets were \$33,203,107 compared to \$52,484,921 as at October 31, 2022. The decrease is primarily due to funds used to finance our operating activities.

Research and Development Expenses

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

For the three months ended July 31, 2023, the Company incurred net R&D expenses of \$8,427,684, a \$4,422,176 increase from the comparative period. The increase reflects the progression of the iPSC Program and Evotec Collaboration, which was in early stages in the comparative period; higher costs for the Phase 1/2 T1D Clinical Trial reflecting a higher number of enrolled study patients with the addition of a second patient cohort coupled with the protocol progression of all study patients; recording of an estimated provision for certain potential exceptional Phase 1/2 T1D Clinical Trial patient costs incurred that may not be covered by or recoverable from patient and or third-party insurance providers; and finally, higher personnel costs with the expansion of our R&D team and related recruiting costs.

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The increase in R&D expenses is partially offset by a reduction in share-based compensation as discussed above.

Net R&D costs increased by \$12,013,637 to \$22,366,685 for the nine months ended July 31, 2023 over the comparative period, with the same factors driving the increase as described above for the latest quarter offset by a decrease in share-based compensation due to the incentive grants described above and their one-time expense impact in the first quarter of the comparative period.

General and Administrative Expenses

For the three months ended July 31, 2023, total G&A expenses of \$1,845,980 approximated those of the comparative period although specific G&A expense components within varied and had an offsetting effect. Public company expenses were significantly lower due to one-time TSX main board graduation application fees incurred in the comparative period, however this reduction was offset by additional consulting and professional fees which vary from period to period.

Total G&A expenses of \$6,323,313 for the nine months ended July 31, 2023 increased by a modest \$374,427 from the comparative period despite specific components of total G&A expenses varying significantly and having an offsetting effect. Cost increases were primarily attributable to significant one-time proxy solicitation services and other expenses related to the Company's contested annual general meeting in the second quarter of this fiscal year, higher personnel costs for additional hires and related recruiting costs, and incremental investor relations and communication activities. These cost increases were offset by an overall decrease in share-based compensation expense due to the grants described above and their one-time expense impact in the first quarter of the comparative period.

SUMMARY OF QUARTERLY RESULTS

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

	Year ended October 31, 2023			Year Ended October 31, 2022				Year ended October 31, 2021
	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
	\$	\$	\$	\$	\$	\$	\$	\$
Loss	9,931,704	9,346,772	8,015,386	8,210,422	5,831,492	4,919,687	5,458,935	2,175,343
Loss per share	0.03	0.03	0.03	0.03	0.02	0.02	0.02	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 the initiation of our iPSC Program research collaboration with Evotec during the second quarter of fiscal year 2022 and increased study patient activities for our Phase 1/2 T1D Clinical Trial as described above in this MD&A.

Scale up and a generally higher level of iPSC Program activities has resulted in increased R&D costs since the third quarter of fiscal year 2022 compared to earlier fiscal quarters. Costs for iPSC IND enabling activities will be regularly incurred until planned preparatory activities are completed in 2024.

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

Quarterly clinical trial costs have trended upwards since fiscal year 2022 as expected due to additional patient enrollment, including the initiation of a second patient cohort in the first quarter of the current 2023 fiscal year; an increase in the number of patient protocol-based procedures performed for all patients; the conduct of individual patient trial procedures being more expensive the further a patient advances along the study protocol; and incremental clinical trial support activities internally and conducted by our study CRO and other service providers. Other factors contributing to up trending quarterly losses include increased costs for the 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 schedule for specific incentive grants.

Over the quarters presented above, the vast majority of the Company's direct R&D costs have been related to our Diabetes Program, which is Sernova's lead R&D program. R&D and G&A costs can vary significantly between reporting periods due to differences in timing of expenditures as well as the level and status of specific R&D and corporate activities being undertaken.

RELATED PARTY TRANSACTIONS

There were no related party transactions other than for the payment of and accruals for compensation to key management personnel of the Company in the ordinary course of business for the three and nine months ended July 31, 2023, with the exception of a combined reimbursement totaling \$92,744 to two of the Company's Directors for non-recurring expenses related to the 2023 annual general meeting of shareholders. The non-recurring amounts were recorded as expense during the second quarter ended April 30, 2023. Refer to Note 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 we will continue as a going concern. As at July 31, 2023, we had working capital of \$22,078,994 (October 31, 2022 – \$46,350,475) and for the nine months ended July 31, 2023 had a negative cash flow from operations of \$18,987,705 (2022 - \$9,667,92), excluding grant contributions received in the amount of \$347,908 (2022 - \$224,168). We have experienced operating losses and net cash outflows from operations since its inception.

During the nine months ended July 31, 2023, capital expenditures were \$99,259 (2022 - \$310,454) as we continue to equip new personnel and 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

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material adverse effect on our 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 \$31.0 million as at July 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 our control and the market acceptance of our products. No assurance can be given that any such additional financing will be available or that, if available, it can be obtained on terms favourable to the Company. See 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 interim condensed consolidated financial statements, adjustments would be necessary to the carrying value of assets and liabilities, the reported expenses, and the classifications used in the consolidated statements of financial position. The interim condensed consolidated financial statements do not include adjustments that would be necessary if the going concern assumption was not appropriate.

Financing Activities

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

During the comparative nine months ended July 31, 2022, the Company:

- i) received proceeds of \$3,757,004 from the exercise of common share purchase warrants and stock options and the corresponding issuance of 9,179,088 common shares; and
- ii) closed on May 16, 2022 a non-brokered private placement as part of an exclusive global strategic partnership with Hamburg, Germany based Evotec SE (“Evotec”), issuing a total of 12,944,904 common shares at a price of \$1.57 and 2,709,800 unconditional common share purchase warrants. The gross proceeds from this private placement were \$20,323,500, before deducting issuance costs totalling \$44,322. Each common share purchase warrant is exercisable into one common share at a price of \$2.50 per share until August 31, 2022, subject to abridgment of the exercise period if the five-day volume-weighted price of the Company's common shares exceeds \$2.50 per share, representing guaranteed future proceeds of \$6,774,500.

Common Shares

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

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Warrants

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

Incentive Plan

The Company has an incentive plan with two components: (i) a fixed Share Option Plan (Option Plan) and (ii) a Deferred Share Unit Plan (DSU Plan) (collectively the Incentive Plan).

	Number of options	Weighted average exercise price
Balance outstanding as at October 31, 2022	22,245,984	\$ 0.92
Granted	5,999,047	1.05
Cancelled	(325,000)	(0.58)
Forfeited	(860,434)	(1.19)
Balance outstanding as at July 31, 2023	27,059,597	\$ 0.94
Granted	3,030,000	0.79
Balance outstanding as at the date of this MD&A	30,089,597	\$ 0.92

	Number of DSUs
Balance outstanding as at October 31, 2022, July 31, 2023 and the date of this MD&A	5,510,001

The Company initiated its Incentive Plan in 2015, with the latest amendments thereto approved by shareholders of the Company on June 30, 2021. Under the Incentive Plan, the Board of Directors may grant stock options to directors, officers, employees or consultants of the Company and deferred share units to directors and officers of the Company up to an aggregate fixed maximum of 38,746,536 of the Company's issued and outstanding common shares, representing approximately 12.8% of the common shares outstanding as at July 31, 2023. The maximum fixed number of common shares to be reserved for options exercise and DSUs conversion under the Incentive Plan is 32,951,591 and 5,794,945, respectively, after the Board of Directors' approval on July 28, 2023 of the transfer and reduction of 1,954,362 common shares reserved for DSU conversion and a corresponding increase in the number of common shares reserved for options exercise.

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COMMITMENTS AND CONTINGENCIES

The Company was previously awarded a US\$2.5 million (approximately \$3.23 million) grant under an agreement with JDRF Therapeutics Fund LLC (JDRF). The grant supports a Phase 1/2 clinical trial of Sernova's Cell Pouch for treatment of patients with T1D. Pursuant to the agreement, the Company has committed to perform certain clinical trial activities and to use commercially reasonable efforts to introduce a diabetes product into the US market. Contributions relating to milestone achievements totaling US\$98,430 (\$129,701) were earned during the three and nine months ended July 31, 2023 (2022 – US\$nil (\$nil) and US\$148,430 (\$189,872), respectively). Remaining funding available to be earned under the JDRF grant award totals approximately US\$0.19 million (\$0.25 million) as at July 31, 2023. The Company is required to pay royalties to JDRF as a percentage of any future net sales received from such diabetes product or in certain future license or disposition transactions up to an aggregate maximum of four times the aggregate amount of JDRF grant funding received. A bonus amount equal to the total amount of grant funding received is also payable to JDRF on two aggregate net sales thresholds if they are achieved. Given the early and inconclusive stage of development of the diabetes product, the royalty is not probable at this time and therefore no liability has been recorded.

In May 2022, the Company entered into an exclusive global strategic partnership with Evotec for the development and commercialization of an iPSC-based beta cell replacement therapy with the goal to provide an unlimited insulin-producing cell source to treat patients with insulin-dependent diabetes. The Company has committed to pay future milestone and royalty payments to Evotec pursuant to the occurrence of certain events as set forth in the Evotec collaboration agreement (the "Evotec Agreement"). Under the terms of the Evotec Agreement, the preclinical development program(s) will be jointly funded up to IND with the Company's share of potential costs capped at a maximum of approximately US\$25 million (\$33 million). Support activities and the preparation for as well as the submission of the Evotec Collaboration IND is anticipated to be completed during the later half of calendar year 2024. The Evotec Agreement is cancellable by the Company with notice, subject to certain terms and conditions. iPSC Program costs of US\$3,373,669 (\$4,463,816) and US\$9,711,484 (\$13,024,501) were incurred during the three and nine months ended July 31, 2023, respectively (2022 – US\$2,102,652 (\$2,671,603) and US\$2,858,570 (\$3,635,508), respectively). The amount of joint iPSC Program costs originally incurred by Evotec and subsequently recharged to the Company was recorded in research and development expenses in the consolidated statement of loss, and the reimbursement of iPSC Program costs originally incurred by the Company was recorded as a reduction of research and development expenses in the consolidated statement of loss. Total iPSC Program costs of US\$13,836,559 (\$18,433,372) have been incurred since the commencement of the initiative up to the end of the most recently completed quarter ended July 31, 2023.

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 Company is in discussion with the landlord concerning the longer-term extension of the lease and availability of other space within the same facilities.

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

Contractual obligations ⁽¹⁾⁽²⁾	Payment due by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Lease obligations ⁽³⁾	\$ 189,068	\$ 174,502	\$ 14,566	\$ –	\$ –
Purchase obligations ⁽⁴⁾	6,377,719	2,340,743	3,170,497	866,479	–
	\$ 6,566,787	\$ 2,515,245	\$ 3,185,063	\$ 866,479	\$ –

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 July 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.

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 July 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 July 31, 2023, we had working capital of \$22,078,994 (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 and nine months ended July 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 and nine months ended July 31, 2023 provides information on our significant foreign exchange currency exposures as at that date.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements requires us to make judgments, estimates, and assumptions that affect the application of accounting policies, the reported amounts of assets, liabilities, and expenses, as well as our ability to continue as a going concern. The estimates and assumptions made are continually evaluated and have been based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Such estimates and assumptions are inherently uncertain, and actual results could differ materially from these estimates and assumptions. Revisions to estimates are recognized in the period in which the estimate is revised and may impact future periods.

Refer to the Company's audited consolidated financial statements for the years ended October 31, 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.

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There have been no changes in the Company's ICFR during the three months ended July 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

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MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE AND NINE MONTHS ENDED JULY 31, 2023, AND 2022

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.sedarplus.ca. 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 Development and Scientific Uncertainty

Our product candidates 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 or approved. The development and regulatory processes may require access to raw materials and inputs which may not be available to us in sufficient amounts or in a timely fashion to allow us to complete the development or receive regulatory approval of any product or process. A commitment of substantial time and resources is required to conduct research and clinical trials if we are to complete the development of any product candidate. It is not known whether any of these product candidates will meet applicable health regulatory standards and obtain required regulatory approvals, or whether such products can be produced in commercial quantities at reasonable costs and be successfully marketed, if approved, or if our investment in any such products will be recovered through sales or royalties.

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

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

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

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

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MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE AND NINE MONTHS ENDED JULY 31, 2023, AND 2022

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, 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.sedarplus.ca.

SERNOVA CORP.**MANAGEMENT'S DISCUSSION AND ANALYSIS****FOR THE THREE AND NINE MONTHS ENDED JULY 31, 2023, AND 2022**

DIRECTORS AND OFFICERS

Brett Whalen	Director, Chair of the Board and Compensation Committee
James Parsons, CPA, CA	Director, Chair of the Audit and Nomination and Governance Committees
Dr. Dan Mahony	Director
Dr. Steven Sangha	Director
Bertram von Plettenberg	Director
Cynthia Pussinen	Chief Executive Officer and Director (as of September 1, 2023)
Dr. Philip Toleikis	Chief Technology Officer and Director
	President and Chief Executive Officer (up to September 1, 2023)
Gary Floyd, LLB	Corporate Secretary
David Swetlow, CPA, CA	Chief Financial Officer
Dr. Modestus Obochi, MBA	Chief Business Officer

ADDITIONAL INFORMATION

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