



SERNOVA CORP.

MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE AND SIX MONTHS ENDED
APRIL 30, 2024 AND 2023

Dated June 14, 2024

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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 six months ended April 30, 2024, and 2023. This MD&A should be read in conjunction with the Company's Annual Information Form (AIF) dated January 26, 2024 and its audited consolidated financial statements and related notes for the years ended October 31, 2023, and 2022, which have been prepared in accordance with IFRS Accounting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

The Company's accounting policies under IFRS are set out in Note 3 – *Material Accounting Policies* of the audited consolidated financial statements for the years ended October 31, 2023, and 2022. All amounts are in Canadian dollars. The information in this MD&A is dated as of June 14, 2024, unless otherwise noted.

FORWARD-LOOKING STATEMENT

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

The Company's statements of "belief" concerning its technologies and product candidates are based primarily upon results derived to date from the Company's research and development programs. The Company also uses the term "demonstrated" to describe certain findings that it makes arising from its research and development (R&D), including any preclinical and clinical studies that the Company has conducted to date. Without limitation, this MD&A contains forward-looking statements pertaining to:

- our corporate strategy, strategic objectives, R&D plans, projections and cash requirements;
- the availability of financing to fund our ongoing operations, liabilities and R&D activities;
- the function, potential benefits, tolerability profile, effectiveness and safety of Cell Pouch™ transplanted with therapeutic cells or tissue;
- the timing, cost and results of preclinical and clinical studies to treat insulin-dependent diabetes, hypothyroid disease and or hemophilia A with the Cell Pouch System™;
- the expected benefits to type 1 diabetes (T1D) patients implanted with Cell Pouch™ and human donor islets or induced pluripotent stem cell (iPSC) derived islet-like clusters (ILCs);

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- the timing and success of IND enabling preclinical studies, IND submission and obtaining regulatory clearance to commence a Phase 1/2 trial combining iPSC derived ILCs with Cell Pouch™ in conjunction with the Evotec Collaboration (defined below);
- the protection of therapeutic cells within Cell Pouch™ from immune system attack using local immune protection technologies, such as, gene-editing, tolerance, or using a systemic anti-rejection regimen or a combination thereof, and the expected benefits;
- our intention and ability to use human autograft cells or tissues or human donor allograft cells or xenogeneic (non-human) cells for treatment, coupled with the expectation that the use of ethically derived stem cell-derived cells (i.e., iPSCs) could provide a virtually unlimited cell supply for Cell Pouch™ to treat various diseases;
- our expectations to secure collaborations and partnerships to research, develop, commercialize and market our product candidates;
- our regulatory strategies and ability to obtain regulatory clearance for clinical trials and marketing approval for our product candidates;
- our ability to obtain Orphan Drug (for rare diseases), Fast Track, Breakthrough Technology, Regenerative Medicine Advanced Therapy (RMAT), Accelerated Approval or Priority Review in the US, and similar regulatory designations in other jurisdictions, and expediting clinical trials or marketing approval for product candidates;
- our belief that our technologies are unique and could become a standard of care in therapeutic cell transplantation, if they prove to be safe and effective in clinical trials;
- our intentions regarding the development and protection of our intellectual property;
- our intention to manage, optimally allocate and or reduce spending in certain areas to permit greater financial resources to be applied to R&D projects;
- obtaining licenses for technologies complementary to or with the Cell Pouch System™;
- securing cGMP manufacturing facilities for our cell therapy programs; and
- the benefits of developing next-generation Cell Pouch™ or Cell Pouch System™ technologies.

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

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

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Key assumptions

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

- our ability to obtain additional financing in the future on acceptable terms;
- our future R&D plans proceeding substantially as currently envisioned;
- the expected benefits to patients of our product candidates and technologies, including Cell Pouch™ and Cell Pouch System™ cell therapy programs in combination with therapeutic cells;
- our ability, or that of partners, to receive regulatory approval for our product candidates;
- our ability to protect our intellectual property rights, and continued compliance with third-party license terms and the non-infringement of third-party intellectual property rights;
- our and our partner Evotec's ability to successfully complete all necessary preparatory work to file an IND for iPSC derived ILCs in combination with Cell Pouch™ and any applicable ancillary technologies;
- our partner Evotec's successful and timely completion of iPSC derived ILC development, including scale-up and manufacturing, to support planned clinical trials;
- our ability to supply Cell Pouches, therapeutic cells and or any complementary technologies comprising a product for the conduct of preclinical studies, clinical trials and commercial use following marketing approval of a product candidate;
- our ability to conduct and complete clinical trials, including our active T1D Phase 1/2 study;
- our ability to attract, hire and retain key personnel;
- our ability to successfully manage, optimally allocate and or reduce spending in certain areas to allow more financial resources to be applied to R&D activities;
- our ability to successfully commercialize and license our assets;
- our ability to manage growth effectively; and
- the absence of material adverse changes in our industry or the global economy, including any impact of the Hamas-Israel and Russia-Ukraine conflicts, and any lingering effect of the COVID-19 pandemic or emergence of other pathogens on our business and operations, including supply chain, manufacturing, research and development costs, clinical trials including patient enrollment, contracted service providers and employees.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements and information, including but not limited to the following risks and uncertainties: early-stage development and scientific uncertainty; R&D activities not achieving the desired outcomes; management of growth; lack of product revenues and history of losses; volatility of share price and access to capital to meet additional funding requirements; patents and proprietary technology; finding pharma partners to license product candidates; dependence on collaborative partners, licensors, contract research organizations (CROs), contract development manufacturing organizations (CDMOs) and others; government regulations; hazardous materials and environmental matters; rapid

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technological change; competition; reliance on and retention of key personnel; status of healthcare reimbursement; potential product liability; economic conditions; and the impact or lingering effects of the COVID-19 pandemic or emergence of other pathogens. Such risks are further described under “**RISKS AND UNCERTAINTIES**” in this MD&A or under “*RISK FACTORS*” in our most recently filed AIF available on our profile at www.sedarplus.ca.

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

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

This MD&A has been prepared to help investors understand the financial performance of Sernova in the broader context of our strategic direction, the risks and opportunities as understood by management, and some of the key metrics that are relevant to our performance. This MD&A has been reviewed and approved for filing by the Company's Audit Committee and the Board of Directors. The Company's Audit Committee consists of three independent Directors, who are all considered to be “financially literate” as defined in National Instrument 51-110 – *Audit Committees*.

GLOBAL ECONOMIC AND BUSINESS CONDITIONS

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

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

The extent, duration and impact of both the current Hamas-Israel and Russia-Ukraine conflicts, related sanctions, and any resulting market disruptions or instability could be significant and potentially have a substantial negative impact on the global economy and our business for an

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unknown period. Any such volatility and disruptions may also magnify the impact of other financial market risks and uncertainties described herein.

ABOUT SERNOVA

Sernova is a publicly listed (TSX:SVA | OTCQB:SEOVF | FSE / XETRA:PSH) clinical-stage cell therapeutics company focused on development and commercialization of its proprietary platform and associated technologies, including Cell Pouch™ implantable delivery vehicle technologies and immune-protected therapeutic cells, herein termed Cell Pouch System™. Sernova is well positioned to develop assets pre-clinically and to the point of conducting phase 1 and 2 studies, at which time the Company aims to partner and or license its assets. This intention does not preclude Sernova from internally progressing assets through later stages of development, including Phase 3 studies and licensure.

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 function as a delivery vehicle for therapeutic cells and tissues. Once implanted, it creates a highly vascularized organ-like environment for the transplantation and engraftment of therapeutic cells or tissues, which then release proteins, hormones or other factors into the bloodstream for the long-term treatment of various chronic diseases.

Depending on the clinical indication under evaluation, the therapeutic cells may be autograft cells or tissues (self-cells / tissues) or allograft cells (non-self, donor cells) or cells derived from sources known to provide a virtually unlimited supply of cells such as stem cell-derived cells or from a xenogeneic (non-human) source. Furthermore, the therapeutic cells may be unmodified or may be genetically modified to produce their therapeutic effect. We continue to work with academic collaborators and industry partners to identify and secure favorable cell candidates for our therapeutic indications.

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

As noted in our latest AIF, filed under the Company's SEDAR+ profile at www.sedarplus.ca, our research activities during the past three years have focused on the development of the Cell Pouch System™ platform as a potential new treatment for various therapeutic indications including T1D, hemophilia A and post operative hypothyroid disease. We have also entered into strategic collaborations and acquired, in-licensed or obtained an exclusive option to in-

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license related technologies to expand and support our research efforts. Earlier corporate development history of the Company and its business is available on SEDAR+.

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

SELECT RECENT HIGHLIGHTS

March 2024: We announced that Nicholas J. Rossettos, CPA has joined Sernova on a consulting basis as interim Chief Financial Officer (CFO) while we have initiated a formal search for a permanent CFO. Mr. Rossettos replaced our former CFO, David Swetlow, whose employment was terminated for cause.

April 2024: We announced positive clinical and platform portfolio updates confirming key priorities which include our lighthouse program in insulin dependent Type 1 Diabetes plus our intention to advance IND filing for our post-operative hypothyroidism program.

Data from a patient in Cohort 2 of our T1D program confirms histologic evidence of long-term (one year) robust survival of abundant human donor islets throughout the Cell Pouch. Cohort 2 patients treated with an advanced immunosuppression protocol avoided graft rejection and experienced minimal side effects in comparison to those patients observed in Cohort 1. None of the six patients in Cohort 2 treated with the advanced regimen have tested positive for donor specific antibodies (DSAs), a marker of graft rejection, in comparison to three of six patients who developed DSAs under the conventional immunosuppression regimen in Cohort 1.

We also reported that April 2024 marks the four-year anniversary of the first patient in Cohort 1 of this Phase 1/2 study who celebrated insulin independence and normalized blood sugar levels, based on two transplants of human donor islets to the Cell Pouch plus a marginal portal vein top up.

We announced the appointment of Dr. Bernd Muehlenweg as Evotec's nominee for our Board of Directors and the retirement of Mr. Bertram von Plettenberg from the Board.

Lastly, we announced the retirement of Chief Technology Officer, Dr. Philip Toleikis along with progress on strategic transformation efforts including a restructuring of operations and a workforce reduction of approximately 35%. Following a review of our therapeutic pipeline and emerging opportunities for the Cell Pouch system platform technologies, we announced that we will pause new investments into the conformal coating program and will continue to evaluate alternative approaches to obviate the need for immunosuppressive regimens for allogeneic therapies.

We also confirmed the completion and closure of all internal investigation efforts, previously announced with respect to our former CFO and potentially a second employee. No new findings were revealed and there will be no further action on the matter. The investigation confirmed that there have been no securities violations and that findings bore no material impact on our financial statements.

May 2024: We announced the appointment of Jonathan Rigby to our Board of Directors.

BUSINESS OVERVIEW

Sernova Cell Pouch System™: A Platform Technology Approach

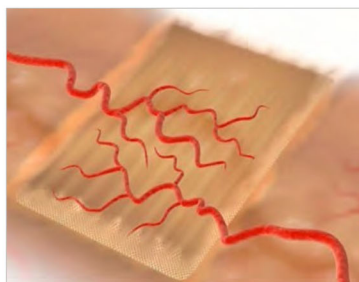
Sernova's patented Cell Pouch System™ is designed to take into consideration the biological requirements of therapeutic cells. This is achieved through the establishment of an organ-like environment defined as a vascularized tissue matrix for therapeutic cells, which develops within the device chambers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

The Cell Pouch™ is designed to be scalable to match the required cell dose for each clinical application for optimized therapeutic effect. Our preclinical research demonstrated that following Cell Pouch™ implantation, vascularized tissue chambers develop within the device. Long-term preclinical studies have shown that the Cell Pouch™ creates a stable, vascularized, native-tissue environment prior to transplantation of therapeutic cells, which we feel is key for maintaining long-term survival and function of therapeutic cell grafts.

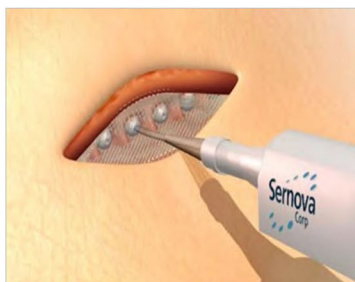
We believe Sernova's approach also addresses the potential issues of other competing implantable devices wherein therapeutic cells are pre-inserted prior to the device being implanted into the body which may result in hypoxia, ischemia, and cell death (resulting in poor engraftment). These issues relate to the lack of an integrated vascularized tissue environment into which cells are transplanted.

Cell Pouch + Therapeutic Provides Organ-Like Environment

Creates vascularized tissue chambers to allow optimal engraftment of therapeutic cells



- Cell Pouch is placed deep under the skin in a short procedure
- Vascularized tissue chambers develop, enabling long-term survival and function of therapeutic cells



- After 3 weeks, therapeutic cells can be transplanted into the vascularized tissue chambers enabling rapid engraftment within tissue matrix



- Therapeutic cells are responsive to endogenous regulation and able to correct biologic dysfunctions by producing missing proteins or hormones

Development of tool kit enabling consistent pouch placement & therapeutic payload transplantation is underway



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We have manufactured our Cell Pouch™ at a US-based medical device contract-manufacturing facility in compliance with ISO13485, EU Medical Devices Regulation MDR 2017/745, United States Food and Drug Administration Quality System Regulations (QSR) 21 CFR 820 and Canadian Medical Device Regulation (CMDR). In our current Phase 1/2 T1D Clinical Trial with human donor islets, we are testing additional sizes of Cell Pouch™ that will enable us to further optimize islet dosing and dose density which may lead to enhanced patient outcomes with the Cell Pouch System™.

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 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 iPSC-derived ILCs 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 hemophilic patient cells that have been 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. Sernova is 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.

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’.

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Research and Development (R&D)

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 Today – Multiple Indications

Impacting patients around the world

Indication	Therapeutic Cell Source	Discovery	Pre-Clinical	Phase 1/2	Phase 3	BLA
Insulin-dependent Diabetes	Human donor islet cells <i>serves as proof of concept for iPSC study</i>	●	●	●	●	●
	iPSC islets 	●	●	○	○	○
Hemophilia A	Corrected patient cells Autologous 	●	●	○	○	○
Hemophilia A	Allograft immune protected stem cells	●	○	○	○	○
Thyroid Diseases / Post Operative Hypothyroidism	Thyroid cells Autologous	●	●	○	○	○
	Allograft immune protected stem cells	●	○	○	○	○

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

Our overall objective is to advance our programs through the various stages of preclinical and clinical development to Phase 3 licensure-enabling studies. Final clinical development, including pivotal study conduct, as well as product commercialization, marketing approval and distribution would be achieved through securing commercial partners. The programs we undertake may involve internal preclinical and clinical development efforts in addition to third-party collaborations and corporate partnerships. Our primary activities to achieve our overall R&D objectives and related goals include the following:

- conducting or supporting the clinical trials required to gain eventual marketing approval for the Cell Pouch System™ in countries that have a significant market opportunity;
- completion of preclinical IND enabling activities followed by clinical testing of the combination of Evotec iPSC derived ILCs and Sernova technologies to overcome the limited supply issue of human donor islets. We expect this would expand the availability of treatment to millions of diabetics, versus thousands; and simultaneously expand the value of our assets; and

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- ongoing R&D activities related to our proprietary Cell Pouch™ in the following areas:
 - continuing R&D and preclinical work that could support IND filings for additional therapeutic indications such as postoperative hypothyroid disease and hemophilia A;
 - developing, assessing and optimizing cellular immune protection technologies;
 - collaboration with industry and academic partners to assess new technologies and evolve development activities for new product and clinical indication opportunities;
 - assessing new therapeutic cell sources in additional potential therapeutic indications of interest; and
 - expansion of our intellectual property portfolio.

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

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

Type 1 Diabetes Background

Type 1 diabetes is an autoimmune condition that destroys the insulin-producing beta cells in the islets of the pancreas. These cells control blood glucose levels. Currently, there is no cure for type 1 diabetes. The goals of our T1D program are to provide people with T1D the ability to better control their diabetes, an improved quality of life and health, 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. Nearly 10% of these individuals have T1D (<https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html>) a condition where the cells in the pancreas that control blood sugar levels through controlled release of insulin have stopped functioning or have died, thereby allowing blood sugar levels to rise resulting in short and long-term debilitating effects of the disease. Hypoglycemia or low blood glucose levels can happen if there is difficulty balancing insulin, diet and exercise. Severe hypoglycemia can cause loss of consciousness, coma and seizures. Approximately 17% of people with T1D suffer from episodes of hypoglycemia unawareness characterized by onset of hypoglycemia without any symptoms or physiological warning signs (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 both this at-risk and general population of T1D patients could be addressed by Sernova's products – following successful completion of clinical studies and regulatory approval.

The primary standard of care for T1D is insulin therapy, a treatment that has existed for more than 100 years. Insulin works to aid in controlling blood sugar levels and is delivered via insulin injections by needle or by an insulin pump. The life of a person with diabetes is consumed with constant monitoring and frequent treatments to control blood sugar levels to minimize both the acute effects of hypoglycemia and severe long-term effects of diabetes, which include cardiovascular 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.

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We believe our Cell Pouch System™ may provide an efficacy advantage and reduction of diabetes-related side effects in patients, relative to the current standard of care, leading to significant improvements in their health outcomes and quality of life. The goal of our cell therapy approach for T1D is to return blood sugar regulation to a normal healthy state.

Cell Therapy Treatments & Type 1 Diabetes

Over the past years, there have been advancements made in the cell therapy field with respect to treating T1D. In some countries, current cell therapy treatment includes transplantation of human donor islets into the portal vein of the patient's liver. This first-generation cell therapy approach involves the transplantation of human donor pancreatic islets, often from multiple donors, into a patient's portal vein after which the 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.

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 several issues with portal vein delivery of either human donor islets or stem cell derived technologies that we anticipate 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, which 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.

Sernova's Cell Pouch + Cell Therapy Approach for Type 1 Diabetes

Sernova's most advanced 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, the Cell Pouch System™ holds the potential to alleviate several important issues with portal vein transplantation. With the Cell Pouch System™, the therapeutic cells live within a tissue matrix integrated with microvessels, which is 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.

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We expect that islet transplant to Cell Pouch™ may eliminate the inflammatory response observed after portal vein infusion, enabling improved islet survival and engraftment which 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 human donor islets, the issues with portal vein transplant including IBMIR and the inability to retrieve the cells, if required, 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 human donor islets and stem cell-derived technologies is a feasible and more sustainable approach. The Cell Pouch™ is a minimally invasive, retrievable delivery mechanism that functions as a home for 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. Based on trial results to date we are confident that the unique design of the Cell Pouch™ will continue to prevent the formation of fibrotic tissue following implantation, facilitating the long-term survival and function of transplanted therapeutic cells.

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As a novel approach beyond portal vein infusion of islets, 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 human donor islets is being used to provide a basis for advancement of glucose-responsive immune-protected stem cell-derived cells for transplant into the Cell Pouch™. We believe stem cell-derived islets have the potential to treat millions of people suffering from T1D. Sernova's Cell Pouch™ technologies are designed and patented to take into consideration the biological requirements of therapeutic cells. In long-term preclinical evaluation, Cell Pouch™ has been shown to maintain a stable, vascularized tissue environment prior to the placement of these transplanted therapeutic cells.

A 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, to achieve efficacy. This parameter is being investigated and optimized in human clinical evaluations testing the ability of Cell Pouch™ plus transplanted islets to achieve glucose control in patients with diabetes.

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 pre-clinical small and large animal diabetes models (syngeneic, autograft and allograft). The reversal of diabetes in these pre-clinical studies provided proof of concept of the Cell Pouch System™ to support clinical evaluation of the Cell Pouch™ with human 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 human donor islets, protected by 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 behavior 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.

It is our opinion 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.

T1D Human donor islets and iPSC Islet Like Clusters (ILCs)

While human donor islets provide an initial therapeutic cell source and potential product to treat those patients with the most significant unmet need - people 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.

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In 2022, Sernova and Evotec formed a strategic partnership around Evotec's iPSC technology. This transformative component of our therapeutics platform is based on multiple scientific, regulatory, manufacturing capabilities, business and commercial factors. We anticipate 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 human 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 status of our iPSC Program status, refer to the *Significant Acquisitions, In-Licensing and Collaborations* section within this MD&A.

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

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 expect iPSC derived ILCs will represent a 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.

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

We continue to advance our clinical studies with an 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)

Following encouraging results and learnings from our first Cell Pouch™ clinical trial that was initiated at the University of Alberta in 2012, 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 human donor islet therapeutic cells. 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. 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.

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Following a peer review of the new clinical protocol, Sernova was awarded a grant, up to US\$2.5 million (approximately \$3.28 million CAD), under an agreement with The Juvenile Diabetes Research Foundation, or JDRF. The grant is supporting our Cell Pouch™ Phase 1/2 diabetes clinical trial, which was initiated in 2018 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. Dr. Witkowski is a leading expert in diabetes and islet transplantation as well as a published diabetes researcher and surgeon with a longstanding record in both basic science and clinical research pertaining to islet cell and abdominal organ transplantation.

This clinical 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.

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 an immunosuppressive regimen 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 human 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™.

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

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subjects rapidly converted to insulin independence.

We feel these indicators suggest a cumulative effect of islet transplants to Cell Pouch™ that facilitate conversion to a non-diabetic state with a minimal supplemental dose via the portal vein. It is for these reasons that we introduced the higher capacity 10-channel Cell Pouch™ to accommodate what we have calculated to be the optimal total dose of high-quality purified islets required to potentially achieve insulin independence. The higher capacity 10-channel Cell Pouches 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 10-channel Cell Pouch is being used in Cohort 2 of our on-going Phase 1/2 T1D human donor islet study.

T1D Phase 1/2 Human Donor Islet Clinical Study: Preliminary Findings & Data

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

We believe these preliminary findings from the ongoing, adaptive-design trial 1) 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 and, 2) are an important achievement in the cell therapeutics field and a first for an implanted device transplanted with human donor islets. These results from transplanted human donor islets in Cell Pouch™ represent 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™.

The Cell Pouch™ could 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 October 26, 2023, Principal Investigator Dr. Witkowski presented updated positive data from the ongoing study at the IPITA–IXA–CTRMS Joint Congress in San Diego, CA. Updated data was presented in an oral podium presentation, *"Islet allotransplantation into pre-vascularized Sernova Cell Pouch - Lessons learned from the first patient cohort"*, as part of the Islet Transplantation: Engineering the Islet Site Session. Enrollment in the first cohort, utilizing the 8-channel Cell Pouch™, is complete with post-transplant data available for periods of follow-up ranging from six months to three and a half years. The second cohort, that began enrolling in November 2022 and utilizing the higher capacity Cell Pouch™ with a revised and

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better-tolerated immunosuppressive regimen, has enrolled at a significantly faster pace than Cohort A with six of the planned seven patients successfully implanted with Cell Pouch™.

Interim results from Cohort 1 demonstrated successful implantations of the 8-channel Cell Pouch™ in the six treated patients that were well tolerated with no seromas and no unexpected AEs (adverse events), chronic pain or discomfort. Data showed histological evidence of surviving and functional islets and positive fasting and stimulated serum C-peptide (a measure of islet insulin secretion) in patients who maintained optimal immunosuppression. All six patients eventually received supplemental, marginal-dose islet infusions via the portal vein with the first five having achieved sustained insulin independence. All six Cohort 1 patients achieved HbA1c values in the non-diabetic range (<6.5%) with persistent serum fasting and stimulated C-peptide levels for current durations of three and a half years at the time of the IPITA presentation.

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

We believe that the Cell Pouch's proven ability to fully contain the therapeutic payload along with complete retrievability of said payload are critical factors for the safe delivery of manufactured cell therapies, including genetically modified and xenogeneic cell lines.

The patient who experienced the transplant of islets contaminated with *Candida albicans* subsequently had a modest dose of islets transplanted by the portal vein and converted to insulin independence 30 days later. The limited number of islets transplanted via the portal vein and the rapid conversion to insulin independence indicate a substantial contribution of the first islet transplant to Cell Pouch to the patient's restoration of blood glucose control. Furthermore, removal and histological analysis of the original transplanted Cell Pouches from this patient, 1 year after transplant, revealed abundant insulin producing islets in all chambers of the excised Cell Pouches providing further evidence that Cell Pouch supports the survival and function of transplanted donor islets in patients with T1D. As of the date of this MD&A, five patients in the first cohort of six subjects who have completed the clinical trial protocol have experienced insulin independence for periods ranging from one year to almost

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four years. All six patients in the first cohort have achieved HbA1c levels in the non-diabetic (<6.5%) as defined by the American Diabetes Association.

Recruitment of the final patient previously determined to be the seventh Cohort 2 subject was recently terminated due to a previously undisclosed eligibility criterion. Recruitment of the 7th patient in Cohort 2 has recommenced. The Company anticipates additional Cohort 2 clinical findings relating to the larger 10-channel Cell Pouch™ to be available for analysis over the course of calendar year 2024.

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

Additional trial information may be found at [clinicaltrials.gov](https://www.clinicaltrials.gov) using the following link:

<https://www.clinicaltrials.gov/ct2/show/NCT03513939>.

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

The goal of our thyroid cell therapy program is to restore the natural thyroid hormone feedback loop to prevent hypothyroid disease in patients undergoing thyroidectomy.

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. Thyroid tissue transplanted into an implanted Cell Pouch™ could offer a novel approach that might improve the quality of life and outcomes of patients experiencing postoperative hypothyroidism following thyroidectomy. Sernova's first approach in the treatment of hypothyroid disease is to take healthy tissue from each patient's own thyroid gland - removed during a thyroidectomy – and transplant that tissue into the pre-implanted vascularized Cell Pouch™. The goal is to restore the natural feedback system for release of thyroid hormones from each patient's own thyroid tissue.

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

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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 receive a laboratory-confirmed diagnosis of benign disease after their operation.

Following thyroidectomy, patients require daily hormone replacement therapy, and most patients are treated with daily Levothyroxine, a synthetic T4. Published research indicates up to 50% of synthetic thyroxine users do not achieve adequate T3 and T4 hormone levels (Okosieme, OE et al. *Expert Opin Pharmacother* 2011; 12(15):2315-2328). Moreover, it is evidenced that patients treated with T4 still experienced several symptoms of hypothyroidism, including deficits in cognition and mood, ability to focus, and general mental well-being (Kansagra, S. et al. *Laboratory Medicine* 2010; 41(6):338-48.). Results of our preclinical research are being used as a foundation for anticipated clinical trials using Cell Pouch in combination with thyroid-hormone producing cells with the goal to preserve or recover normal T3 and T4 thyroid regulation and improve patient quality of life.

Sernova has conducted preclinical research with its Cell Pouch™ for the treatment of postoperative hypothyroidism in collaboration with Dr. Sam Wiseman, BSc, MD, FRCSC, FACS, Professor, Faculty of Medicine at the University of British Columbia, Director of Research in the Department of Surgery at Providence Healthcare in Vancouver, BC, Canada and, in part, funded by a Transplant Venture Grant awarded by the Transplant Research Foundation (TRF) of British Columbia.

In preparation for a clinical program, Sernova has assessed healthy human thyroid tissue transplanted into a previously implanted Cell Pouch™ in a preclinical model. Our planned initial clinical approach to the treatment of postoperative hypothyroid disease is to auto-transplant healthy thyroid tissues of patients undergoing thyroidectomy into the pre-implanted vascularized Cell Pouch™, to restore thyroid regulation and reduce the burden and risks of postoperative hypothyroidism. The overall aim of the program is to evaluate the survival and function of thyroid tissue after implantation into the Cell Pouch™ to establish proof-of-concept of this novel approach. The current results from this collaboration support the potential for Cell Pouch™ transplanted with thyroid tissue to provide clinical benefit for the treatment of hypothyroidism.

On January 27, 2022, we announced the publication of a peer reviewed preclinical study demonstrating positive results of a novel Cell Pouch System™ cell therapy approach to treat hypothyroidism and potentially avoid lifelong dependence on thyroid medication following surgical removal of the thyroid gland. The journal article entitled "*Subcutaneous transplantation of human thyroid tissue into a pre-vascularized Cell Pouch™ device in a Mus musculus model: Evidence of viability and function for thyroid transplantation*" by lead author, Dr. Wiseman, a leading surgeon, researcher and internationally renowned expert in the management of thyroid and parathyroid disease, was published in the scientific journal, *PLOS ONE*, January 20, 2022 edition. In this study, thyroid tissue from patients undergoing surgery for treatment of benign disease was transplanted into Sernova Cell Pouches that had been previously implanted into laboratory mice.

The aim of the study was to investigate the long-term survival of human thyroid tissue in the Cell Pouch™ and to evaluate the ability of these thyroid transplants to release thyroid

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hormones into the bloodstream. The study confirmed that the human thyroid tissue transplanted into the Cell Pouch™ survived and released human thyroglobulin into the bloodstream, with no adverse effects for the three-months duration of the study. Thyroglobulin was used as a biomarker efficacy measure in this study as it is the precursor of thyroid hormones.

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

We are now completing a final IND enabling preclinical study to support advancement of the program to clinical trials for this novel approach to the prevention of postoperative hypothyroidism. Simultaneously, we are preparing documentation to support a clinical trial application. We plan to expedite an IND filing – pending sufficient financial resources being available to commence a clinical trial. Discussions have continued with regulatory authorities and regulatory pathways for clinical development in each target jurisdiction have been determined.

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

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

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 puts them at risk of acquiring blood-borne infections, such as HIV, hepatitis B and hepatitis C. The alternative is 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.

The therapeutic potential of a constant release of FVIII from a hemophilia A patient's own genetically corrected cells, placed within the implanted Cell Pouch™, could represent a significant advancement and a disruptive approach to the current standard of care treatment for 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. This approach involves placement of corrected cells into an implanted Cell Pouch™, which could release FVIII at a rate expected to reduce disease-associated hemorrhaging and joint damage. The continuous delivery of FVIII could also reduce or eliminate the need for multiple weekly infusions, which is the current standard of care using plasma-derived or recombinant, genetically engineered FVIII for the prophylactic treatment of hemophilia A. This approach is analogous to that used for CAR T-cell therapy as a validated therapeutic approach where a

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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. . This therapeutic route 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 CAD) 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. In 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 results of a pre-clinical mouse study of our 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 of the B-domain deleted form of FVIII under the control of an endothelial-specific promoter. These cells were subsequently transplanted in 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. In this collaboration, we anticipate, conducting development work including IND-enabling studies in 2024 and 2025, and, pending supportive data, IND filing efforts will be initiated immediately, thereafter.

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On November 27, 2023, we announced that the US FDA had granted both Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) for Sernova's Hemophilia A program. The US FDA grants orphan designation, also referred to as orphan status, to therapies intended for the treatment of rare diseases that affect fewer than 200,000 people in the US. This designation provides certain benefits, including tax credits for qualified clinical testing, waiver or partial payment of FDA application fees and up to seven years of market exclusivity, if approved.

Separately, RPDDs are granted for rare diseases that primarily affect children under 18 years old with recipients of this designation being awarded a Priority Review Voucher (that can be used for a subsequent marketing application for a different product) upon approval of the Company product for the treatment of Hemophilia A in pediatric patients. The priority review voucher may be redeemed by the holder, transferred, or sold. Over time Priority Review Vouchers have been sold to third parties for amounts of up to US\$350 million. Recently, several Priority Review Voucher sales have occurred with the majority sold for around US\$100 million, including at least three sold during 2023.

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

Local Immune Protection & Other Complementary Technologies

We predict that encapsulation and other advanced technologies such as gene-editing may protect therapeutic cells from immune system attack within the Cell Pouch™ vascularized environment, while providing the means to enable direct communication between therapeutic cells and microvessels within the established tissue matrix. We anticipate that such approaches may enable long-term survival and function of therapeutic cells in the 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, Sernova secured exclusive rights, through an asset purchase agreement, to local immune protection know how, for our Cell Pouch™ cell therapy platform. We continue to evaluate additional immune protection technology solutions.

Our approach of providing immune protection for cells locally, within the Cell Pouch™ tissue matrix, is anticipated to be both a competitive advantage and a way to accelerate development of our therapeutic programs.

Cell Pouch™ Surgical Kit and Accessories

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

We are also in the process of developing transplantation instruments to ensure the safety, quality and consistency of cell and tissue preparations and their transplantation into the Cell Pouch™ tissue chambers. The design program has been initiated for the transplantation

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instruments, and prototype testing for standardized cell and tissue handling and loading procedures is in progress.

Collaboration and Business Development Efforts

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

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

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

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

Significant Acquisitions, In-Licensing and Collaborations

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

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

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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.

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 April 24, 2023, preclinical data for Sernova's iPSC Program and the Evotec Collaboration was externally presented for the first time. The oral podium presentation, "*Manufacturing Of Human Islet-like Clusters (ILCs) From iPSCs and Functional Testing of an ILC and Cell Pouch Combination In Vivo*", occurred at the 4th International Pancreas and Islet Transplant Association (IPITA) / Harvard Stem Cell Institute (HSCI) / Juvenile Diabetes Research Fund (JDRF) Summit. As part of our Evotec Collaboration and iPSC Program, development work including multiple preclinical studies have been completed to date establishing proof of concept and progressing iPSC derived ILC production process development, tech transfer and scaleup. Based on learnings from work completed to date, additional process related development will be conducted to further optimize the ILC component of our combined product candidate prior to commencing further and final IND enabling studies and the anticipated Phase 1/2 clinical study for the treatment of T1D with Cell Pouch™ and iPSC derived ILCs. For additional development program details, please refer to ***Sernova's Cell Pouch + Cell Therapy Approach for Type 1 Diabetes*** section in this MD&A for more information.

Costs for iPSC IND enabling activities will continue to be incurred across 2024 and 2025 with progression of the latest planned preparatory activities toward a now projected IND filing and associated regulatory clearance during late 2025 for a Phase 1/2 iPSC T1D clinical trial of Cell Pouch™ with Evotec's iPSC derived ILC technology. We anticipate initiating the clinical trial soon after regulatory clearance is obtained.

Research Collaboration with AstraZeneca

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

Pharmaceutical and Life Sciences Company Collaborations

The goal of our collaborations with pharmaceutical and life science 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.

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In this regard, we are deploying our in-house cell therapy expertise and proprietary Cell Pouch™ technologies in combination with proprietary therapeutic cell assets designated by pharmaceutical or life science company collaborators, such as AstraZeneca noted above. The research collaborations follow the ongoing clinical success of our Cell Pouch™ technologies in diabetes and reflect the value and evolving recognition of our technologies and cell therapy platform. These important partnerships with leaders in the pharmaceutical industry build upon our business strategy to develop a portfolio of products to realize the full potential of Sernova's cell therapeutics platform by extending and broadening its application to new therapeutic areas and modalities. Partnering with multiple pharmaceutical companies will not only expand our therapeutic treatment opportunities but could also provide 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 licensed from UMiami, for the treatment of several 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 Sernova's 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.

RESULTS OF OPERATIONS

For the three months ended April 30, 2024, we recorded a loss of \$9,943,484, an increase of \$596,712 compared to the same period in the prior year. The increase was largely attributable to R&D expenses related to our lead program and other income and expense. The higher loss from other income and expenses resulted from a decrease in interest income, consistent with the decrease in cash as funds were used to finance our operating activities, and an increase in foreign exchange loss. The overall increase in net loss was partially offset by a decrease in G&A expenses.

For the six months ended April 30, 2024, we recorded a loss of \$19,686,583, an increase of \$2,324,425 compared to the same period in the prior year. The larger loss was primarily a result of higher R&D and G&A expenses due to increased costs associated with the advancement of our iPSC Program and personnel costs including higher headcount throughout the current period coupled with separation payments and related legal fees

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associated with the reduction in workforce that took place during the current period. In addition and consistent with the second quarter, there was a decrease in interest income in line with the decrease in cash and marketable securities.

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

As at April 30, 2024, total assets were \$11,765,522 compared to \$22,106,815 as at October 31, 2023. 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 the three months ended April 30, 2024 was the testing and development of the Cell Pouch System™ platform and associated technologies predominantly in relation to our lead program – Type 1 Diabetes. Consequently, the vast majority of our direct R&D expenditures during this period were related to our Diabetes Program and included activities and costs associated with our ongoing Phase 1/2 T1D clinical trial and our Evotec Collaboration / iPSC program.

For the three months ended April 30, 2024, we incurred net R&D expenses of \$7,709,017, a \$681,266 increase from the comparative period. The increase reflects higher personnel costs, increased collaboration costs with Evotec and higher share-based compensation expense. Personnel costs and share-based compensation increased due to a combination of higher headcount throughout the current period over the prior period as well as separation payments incurred upon the retirement of a senior officer and reduction of workforce which occurred at the end of the current period.

Compared to the six months ended April 30, 2023, net R&D costs increased by \$1,011,020 for the six months ended April 30, 2024. The factors driving the increase are largely the same as the factors mentioned above.

General and Administrative Expenses

For the three months ended April 30, 2024, we incurred total G&A expenses of \$2,089,500, a \$690,678 decrease from the comparative period. The decrease was due mainly to lower share-based compensation as a result of significant stock option forfeitures in the current period and non-recurring acceleration of DSU vesting in the prior period for former directors. Additionally, the decrease reflects significantly lower public company expenses due to non-recurring proxy solicitation services and other expenses related to the Company's contested annual general meeting in the comparative period. The overall decrease of G&A expenses was offset by higher legal and professional fees in the current period related to an internal investigation initiated by the Board of Directors for which the matter has been concluded.

Total G&A expenses for the six months ended April 30, 2024, increased by \$398,845 from the comparative period. The increase was largely attributable to higher legal and professional fees as noted above as well as higher personnel costs with the expansion of the senior leadership team in the fourth quarter of fiscal year 2023 and an increase in market research activities to assess potential future indications for our Cell Pouch System™ platform.

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SUMMARY OF QUARTERLY RESULTS

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

	Year ending October 31, 2024		Year ended October 31, 2023				Year ended October 31, 2022	
	Q2	Q1	Q4	Q3	Q2	Q1	Q4	Q3
	\$	\$	\$	\$	\$	\$	\$	\$
Loss	9,943,484	9,743,099	11,703,658	9,931,704	9,346,772	8,015,386	8,210,422	5,831,492
Loss per share	0.03	0.03	0.04	0.03	0.03	0.03	0.03	0.02

During the latter part of fiscal year 2022 and continuing over fiscal year 2023 and 2024, 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.

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. Costs for iPSC IND enabling activities will be regularly incurred until planned preparatory activities are completed. Costs may vary based on stage of the program and extent of planned activities and related materials requirements. Quarterly clinical trial costs have trended upwards since late in fiscal year 2022 as expected due to additional patient enrollment, including the initiation of a second patient cohort in the first quarter of the 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 at certain time points during the study protocol; and incremental clinical trial support activities internally and conducted by our study CRO and other service providers. Clinical trial costs decreased in the first half of the 2024 fiscal year as a result of the initial completion of patient recruitment and timing of patient trial procedures. Other factors contributing to up trending quarterly losses include increased personnel costs for the expansion of our leadership team in the fourth quarter of fiscal year 2023 and the effect of separation payments in the second quarter of fiscal year 2024.

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.

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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 six months ended April 30, 2024. Refer to Note 6 – *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. We have incurred losses and generated negative cashflow from operations since inception. As at April 30, 2024, we had an accumulated deficit of \$137,853,590 (October 31, 2023 – \$118,167,007) and working capital deficit of \$6,373,215 (October 31, 2023 – working capital of \$11,431,210) and for the six months ended April 30, 2024 generated negative cashflow from operations of \$11,486,963 (2023 – \$14,512,461), excluding grant contributions received in the amount of \$193,038 (2023 – \$347,908).

During the six months ended April 30, 2024, capital expenditures were \$nil (2023 – \$89,551).

Until the Company's biotechnology therapeutic products are approved and available for sale and profitable operations are developed, our liquidity requirements will be dependent on our ability to continue to secure additional funding to meet our current short-term financial obligations and to fund research and development expenditures. Failure to do so could have material adverse effect on our financial condition. Until sufficient financing is obtained, we plan to defer or reduce planned expenditures. At this time, no assurance can be given that such funding will be available or that, if available, it can be obtained on favorable terms. Consequently, raising additional equity capital in the future may be required, but is subject to market conditions and is not within our control. As a result, material uncertainty exists which may cast significant doubt on our ability to continue as a going concern and realize our assets and discharge our liabilities in the normal course of business. Refer to sections "**RISKS AND UNCERTAINTIES**" and "**CAPITAL MANAGEMENT, FINANCIAL INSTRUMENTS AND RISKS**" in this MD&A.

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

Financing Activities

During the six months ended April 30, 2024 we received proceeds of \$15,750 from the exercise of stock options and the corresponding issuance of 75,000 common shares.

There were no changes to the Company's share capital during the comparative six months ended April 30, 2023.

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Common Shares

	Number of common shares
Balance outstanding as at October 31, 2023	303,332,686
Issued upon exercise of stock options	75,000
Balance outstanding as at April 30, 2024	303,407,686
Issued upon conversion of deferred share units	205,000
Balance outstanding as of the date of this MD&A	303,612,686

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, 2023	30,074,182	\$ 0.92
Granted	400,000	0.73
Exercised	(75,000)	(0.21)
Forfeited	(1,351,508)	(1.17)
Cancelled	(5,448,669)	(1.15)
Balance outstanding as at April 30, 2024	23,599,005	\$ 0.85
Cancelled	(140,000)	(1.20)
Balance outstanding as at the date of this MD&A	23,459,005	\$ 0.85

	Number of DSUs
Balance outstanding as at October 31, 2023 and April 30, 2024	5,510,001
Converted	(205,000)
Balance outstanding as at the date of this MD&A	5,305,001

The Company initiated its Incentive Plan in 2015, with the latest amendments thereto approved by shareholders of the Company on April 30, 2024. 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. The total number of common shares available for issuance under the Company's Incentive Plan is 45,511,153. The remaining balance available for grant under the Incentive Plan as of April 30, 2024 is 14,159,882 which is reserved for the issuance of stock options.

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COMMITMENTS AND CONTINGENCIES

The Company was previously awarded a US\$2.45 million (approximately \$3.28 million CAD) grant under an agreement with JDRF Therapeutics Fund LLC (JDRF). The grant supports a Phase 1/2 clinical trial of Sernova's Cell Pouch™ for treatment of patients with T1D. Pursuant to the agreement, the Company has committed to perform certain clinical trial activities and to use commercially reasonable efforts to introduce a diabetes product into the US market. No contributions relating to milestone achievements were earned during the three and six months ended April 30, 2024 (2023 – \$nil). Remaining funding available to be earned under the JDRF grant award totals US\$0.05 million (approximately \$0.07 million) as at April 30, 2024. 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 originally anticipated to be approximately US\$25.0 million (\$34.4 million CAD). The latest project costs forecast provided by Evotec is under review by the Company. It is anticipated the total project cost and the Company's commitment portion will increase.

The Evotec Agreement is cancellable by the Company with notice, subject to certain terms and conditions. iPSC Program costs of US\$3,146,482 (\$4,323,216) and US\$6,428,788 (\$8,692,890) were incurred during the three and six months ended April 30, 2024, respectively (2023 – US\$2,994,472 (\$4,064,101) and US\$6,471,671 (\$8,762,057), 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\$23,982,234 (\$32,198,657) have been incurred since the commencement of the initiative up to the end of the most recently completed quarter ended April 30, 2024. The joint iPSC Program project budget and forecasted costs are regularly reviewed by the Company and our partner Evotec.

We enter into contracts and agreements in the normal course of business, including for R&D activities, consulting, and other services. The majority of these contractual obligations are cancelable by us at any time, generally upon prior written notice to the service provider or vendor. In addition, we have minimum annual royalty payment obligations of approx. \$32,000 for third party licensing agreements.

Effective December 31, 2023, the Company terminated its lease for existing office premises and lab space which resulted in a gain on disposal of right-of-use asset and lease liabilities of

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\$18,862 upon derecognition of the right-of-use asset and lease liability. Effective January 1, 2024, the Company entered into a successor three-year lease for office premises and lab space at the same facility at a rate of \$14,010 per month, with a 3% increase on the anniversary of the lease agreement. Under the terms of the lease, the Company has two option periods to extend the lease term for an additional twelve months each, up to December 31, 2028. As of April 30, 2024, remaining undiscounted lease payment obligations total \$836,520 assuming the Company exercises both options, of which \$169,800 is payable over the next twelve months.

The following table summarizes our significant future contractual obligations as at April 30, 2024:

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⁾	\$ 836,520	\$ 169,800	\$ 540,576	\$ 126,144	\$ —
Purchase obligations ⁽⁴⁾	4,897,145	1,594,104	3,213,770	89,271	—
Other	—	—	—	—	—
	\$ 5,733,665	\$ 1,763,904	\$ 3,754,346	\$ 215,415	\$ —

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 April 30, 2024.
- (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 risk is identified. Amounts receivable at April 30, 2024 are composed of amounts due from

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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 April 30, 2024, we had working capital deficit of \$6,373,215 (October 31, 2023 – working capital \$11,431,210). Additional financing is required for the Company to meet its short-term financial obligations, refer to **LIQUIDITY AND CAPITAL RESOURCES** section of this MD&A for more information.

Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. We hold our cash in bank accounts and manage our interest rate risk by holding cash in high yield savings accounts or highly liquid short-term investments. With increases in global interest rates over the last year and higher average investment balances, interest income has become more significant to our projected operational budget although rate fluctuations are not significant to our risk assessment. Note 10(c) to the interim condensed consolidated financial statements for the three and six months ended April 30, 2024 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 10(d) to the interim condensed consolidated financial statements for the three and six months ended April 30, 2024 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.

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

INTERNAL CONTROLS OVER FINANCIAL REPORTING

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

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

There have been no changes in the Company's ICFR during the three months ended April 30, 2024, 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

None

New accounting standards and interpretations not yet adopted

A number of new standards, and amendments to standards and interpretations, have been issued but are not yet effective. None of these are expected to have a material effect on future financial statements.

RISKS AND UNCERTAINTIES

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

An investment in our common shares is subject to several risks and uncertainties and being high risk in nature should be considered speculative. Several of the factors, risks and uncertainties are outside the control of the Company's management. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. An investor should carefully consider the risks and uncertainties described below, as well as other information contained in this MD&A, and in the Company's most

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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.

We will need to raise substantial additional funding, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit, or terminate our R&D efforts or other operations. We will require substantial additional funds for further R&D, planned clinical testing, regulatory approvals, establishment of manufacturing capabilities, and, if necessary, the marketing and sale of our products. Management is of the opinion that sufficient working capital will need to be obtained from external financing to meet our liabilities and commitments as they become due, although there is a risk that additional financing will not be available on a timely basis or on acceptable terms. These factors indicate a material uncertainty that may cast significant doubt on our ability to continue as a going concern. We may attempt to raise additional funds through public or private equity or debt financing, collaborations with other biopharmaceutical companies and / or from other sources, including non-governmental grants and loans and various government incentive programs. There can be no assurance that additional funding, however sourced, will be available on terms acceptable to us and which would allow the successful commercialization of our products. Refer to **LIQUIDITY AND CAPITAL RESOURCES** section of this MD&A.

We have debt owed to Evotec which affects our liquidity and may impact our ability to raise funds or raise funds on favourable terms. We currently owe Evotec approximately \$14.3 million in accounts payable pursuant to the Evotec Agreement. Evotec has agreed the Company does not need to commence payment for at least approximately \$6.7 million of the amounts due to Evotec until January 2025. Working capital and/or funds raised from future financings will be required to repay these amounts to Evotec which are funds we will be unable to allocate to its clinical trials, research and development. There is no guarantee we will be able to raise sufficient capital or access other capital to repay Evotec.

We have negative cash flow from operating activities and may never become profitable. Our business has incurred losses since its inception. Although we expect to become profitable, there is no guarantee that will happen, and we may never become profitable. We currently have a negative operating cash flow and may continue to have a negative operating cash flow for the foreseeable future. To date, we have not generated any revenues and a large portion of our expenses are related to the completion of our current phase I/II clinical trial including contractual commitments and supporting personnel costs. Our ability to generate additional revenues and potential to become profitable will depend largely on our ability to obtain approval for and commercialize our biotechnology therapeutic products. There can be no assurance that any such events will occur or that we will ever become profitable. Even if we do achieve profitability, we cannot predict the level of such profitability. If we sustain losses over an extended period of time, we may be unable to continue our business.

Our prospects depend on the success of our product candidates which are at early-stages of development and are subject to scientific uncertainty. Our products are at an early stage of development. Significant additional investment in R&D, product validation, technology transfer to manufacturing, production scale-up, manufacturing, clinical testing, and regulatory submissions of such product candidates will be required prior to commercialization. There can be no assurance that any such products will be developed. The development and

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

We expect to incur substantial expenditures in connection with the development of our product candidates. If we fail to successfully develop and sell all or any of our resulting products then we will not earn any return on our investment, which will adversely affect our results of operations and could adversely affect the market price of the common shares. Our success in developing and selling new products will depend upon multiple factors, including:

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

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

We rely heavily on the capabilities and experience of key executives and scientists and the loss of any of them could affect our ability to develop our products. The loss of key members of Company staff could harm us. We have employment agreements with key staff members although such employment agreements do not guarantee their retention. We also depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to the Company. In addition, management believes our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial, medical, clinical and regulatory personnel, particularly as we expand our activities and seek regulatory approvals for clinical trials. We enter into agreements with scientific and clinical collaborators and advisors, key opinion leaders and academic partners in the ordinary course of our business. We also enter into agreements with physicians and institutions who will recruit patients into our clinical trials on our behalf in the ordinary course of our business.

Notwithstanding these arrangements, we face significant competition for these types of personnel from other companies, research and academic institutions, government entities and other organizations. We cannot predict its success in hiring or retaining the personnel required for continued growth. The loss of the services of any of our executive officers or other key personnel could potentially harm our business, operating results or financial condition.

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We expect to expand our organization and, as a result, we may encounter difficulties in management our growth, which could disrupt our operations. At a future point in time, we could experience growth that might put a significant strain on each of our managerial, operational and financial resources. We must implement and constantly improve its operational and financial systems and expand, train and manage its employee base to manage growth. In addition, we expect that our operational and management systems will face increased strain because of the expansion of our technologies. We might not be able to effectively manage the expansion of our operations and systems, and our procedures and controls might not be adequate to support our operations. In addition, management might not be able to make and execute decisions rapidly enough to exploit market opportunities for the expansion of our technologies. If we are unable to manage our growth effectively, our 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 our business, prospects, financial condition, results of operations and cash flows.

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 MD&A, filed on SEDAR+ at www.sedarplus.ca.

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DIRECTORS AND OFFICERS

Brett Whalen	Director, Chair of the Board
James Parsons, CPA, CA	Director, Chair of the Audit Committee
Dr. Bernd Muehlenweg	Director
Dr. Steven Sangha	Director
Jonathan Rigby	Director
Cynthia Pussinen	Chief Executive Officer and Director
Gary Floyd, LLB	Corporate Secretary
Nicholas Rossettos, CPA	Interim 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.