



## **ANNUAL INFORMATION FORM**

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Unless otherwise indicated  
all information in this Annual Information Form  
is presented as at and for the financial year ended October 31, 2023

January 26, 2024

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## CURRENCY AND MEASUREMENT

Unless otherwise indicated, all references to “dollars” or the use of the symbol “\$” are to Canadian dollars, all references to “US dollars” or “US\$” are to United States dollars.

## DOCUMENTS INCORPORATED BY REFERENCE

Information has been incorporated by reference in this Annual Information Form from documents filed with securities commissions or similar authorities in Canada. Copies of the documents incorporated herein by reference are available under the Company’s profile on the System for Electronic Document Analysis and Retrieval (SEDAR) which can be accessed at [www.sedarplus.ca](http://www.sedarplus.ca).

## FORWARD-LOOKING STATEMENTS

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

The Company’s statements of “belief” concerning its technologies and product candidates are based primarily upon results derived to date from the Company’s research and development programs. The Company also uses the term “demonstrated” in this document 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 AIF contains forward-looking statements pertaining to:

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

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

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

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

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

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

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

following marketing approval of a product candidate;

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

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements and information, including but not limited to the following risks and uncertainties: early-stage development and scientific uncertainty; R&D activities not achieving the desired outcomes; management of growth; lack of product revenues and history of losses; volatility of share price and access to capital to meet additional funding requirements; patents and proprietary technology; finding pharma partners to license product candidates; dependence on collaborative partners, licensors, contract research organizations (CROs), contract manufacturing organizations (CMOs) and others; government regulations; hazardous materials and environmental matters; rapid technological change; competition; reliance on and retention of key personnel; status of healthcare reimbursement; potential product liability; economic conditions; and the impact or lingering effects of the COVID-19 pandemic or emergence of other pathogens. Such risks are further described under “**RISK FACTORS**” in this AIF or under “*RISK AND UNCERTAINTIES*” in our Management’s Discussion and Analysis (MD&A). Potential investors, and other readers are urged to consider these factors carefully in evaluating these forward-looking statements and information and are cautioned not to place undue reliance on them. Sernova has no responsibility, nor does it intend, to update these forward-looking statements and information unless as otherwise required by law.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document 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 document, actual events may differ materially from current expectations. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

### **USE OF MARKET AND INDUSTRY DATA**

This AIF includes market and industry data that has been obtained from third party sources, including industry publications, as well as industry data prepared by the Company’s management on the basis of its knowledge of and experience in the industry in which the Company operates (including management’s estimates and assumptions relating to the industry based on that knowledge). Management’s knowledge of the industry has been developed through its experience and lengthy participation in the industry. Management believes that its industry data is accurate and that its estimates and assumptions are reasonable, but there is no assurance as to the accuracy or completeness of this data. Third party sources generally state that the information contained therein has been obtained from sources believed to be reliable, but there is no assurance as to the accuracy or completeness of included information. Although management believes it to be reliable, the Company’s management has not independently verified any of the data from third party

sources referred to in this AIF or ascertained the underlying economic assumptions relied upon by such sources.

## **CORPORATE STRUCTURE**

### **General**

In this document, references to the “Company”, “Sernova”, “we”, “us”, and “our” refer to Sernova Corp. and references to “Common Shares” refer to common shares of the Company.

Sernova Corp. was initially incorporated under the *Company Act* (British Columbia) on August 19, 1998, under the name of “Pheromone Sciences Corp.”. Effective May 29, 2001, the Company was continued under the *Canada Business Corporations Act* (CBCA). Effective November 1, 2001 the Company was amalgamated with 3927849 Canada Inc. to form a new amalgamated corporation under the name “Pheromone Sciences Corp.” pursuant to s. 185 of the CBCA. The Company’s Articles stipulate a minimum of 3 and maximum of 15 directors and grants the Board of Directors (Board) the authority, between annual shareholder meetings, to appoint one or more additional directors of the Company to serve until the next annual shareholder meeting. The additional number of directors is limited to a maximum of 1/3 of the number of directors elected at the previous shareholder meeting. On September 20, 2006, the Company filed Articles of Amendment to change its name to Sernova Corp.

The Company’s registered office is at Suite 1500, 1055 West Georgia Street, Vancouver, British Columbia, Canada V6E 4N7, and its current head office is at 700 Collip Circle, Suite 114, London, Ontario, Canada N6G 4X8. The Company’s head office telephone number is (519) 858-5126, and fax number is (519) 858-5099. Its email address is [info@sernova.com](mailto:info@sernova.com), and the address of its website is [www.sernova.com](http://www.sernova.com). The Corporate Records of the Company are kept at Suite 1500, 1055 West Georgia Street, Vancouver, British Columbia, Canada V6E 4N7.

The financial year end date of the Company is October 31. The Company’s most recently completed financial year is October 31, 2023. The audited consolidated financial statements and related management discussion and analysis for the October 31, 2023 financial year-end are filed under the Company’s SEDAR+ profile at [www.sedarplus.ca](http://www.sedarplus.ca).

### **Intercorporate Relationships**

Sernova (US) Corp. is a wholly owned subsidiary of Sernova Cop. and was incorporated in the State of Delaware on November 28, 2023, resulting from the conversion from a State of Nevada corporation which was originally incorporated as Sertocell Biotechnology (US) Corp. on June 14, 2006. Its registered office is located at 1209 Orange Street, Wilmington, New Castle County, Delaware 19801 and is registered at 155 Federal Street, Suite 700, Boston, MA 02110 as a foreign corporation to do business in the Commonwealth of Massachusetts. On August 27, 2023, Sernova (US) Corp. changed its name from Sertocell Biotechnology (US) Corp.

## **DESCRIPTION AND GENERAL DEVELOPMENT OF THE BUSINESS**

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

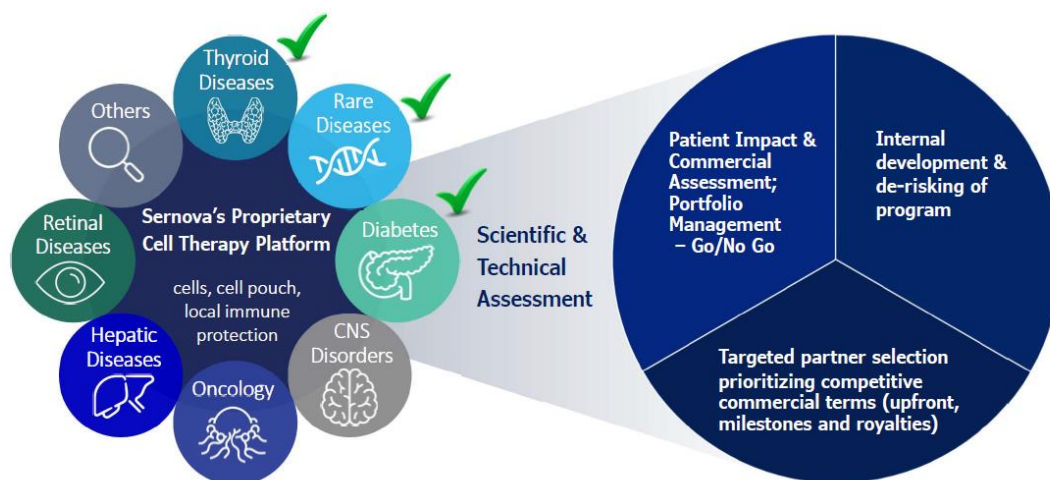
later stages of development, including Phase 3 studies and licensure, internally. The Cell Pouch System™ is a technology platform being developed for the treatment of and a potential ‘functional cure’ for chronic debilitating diseases including type 1 diabetes (insulin-dependent diabetes or T1D), hypothyroid disease, and rare diseases such as hemophilia A among others. The Cell Pouch™ is a scalable, implantable, medical device, designed to create a highly vascularized organ-like environment for the transplantation and engraftment of therapeutic cells, which then release proteins, hormones or other factors into the bloodstream for the long-term treatment of various chronic diseases. Depending on the clinical indication under evaluation, the therapeutic cells used for therapeutic purposes may be autograft cells or tissues (self-cells / tissues) or allograft cells (non-self, donor cells) or cells derived from sources known to provide a virtually unlimited supply of cells such as stem cell-derived cells or from a xenogeneic (non-human) source. Furthermore, the therapeutic cells may be unmodified or may be genetically modified to produce their therapeutic effect. We continue to work with academic collaborators and industry partners to identify and secure favorable cell candidates for our therapeutic indications.

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

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

## Our Portfolio Strategy is Taking Form

*Multiple Opportunities to Expand Our Portfolio & to Extend Our Reach to More Patients*



During the past three years, our research activities have focused on the development the Cell Pouch System™ as a potential new treatment for various therapeutic indications including T1D, hemophilia, hypothyroid disease and additional chronic debilitating and rare diseases. We have also entered into



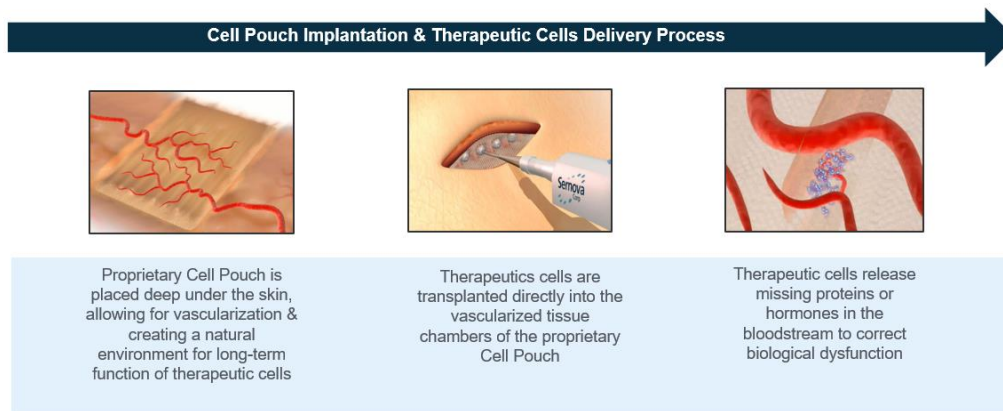
strategic collaborations and acquired or in-licensed related technologies to expand and support our research efforts.

### ***Sernova Cell Pouch System™: A Platform Technology Approach***

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

The Cell Pouch™ is designed to be scalable to match the required cell dose for each clinical application. Our research demonstrates that following Cell Pouch™ implantation deep under the skin or in other locations, vascularized tissue chambers develop within the device. Long-term preclinical studies have shown that the Cell Pouch™ creates a stable, vascularized, native-tissue environment prior to transplantation of therapeutic cells, which we believe is key for maintaining long-term survival and function of therapeutic cell grafts. We believe Sernova’s approach also addresses the potential issues of other competing implantable devices wherein therapeutic cells are pre-inserted prior to the device being implanted into the body which may result in hypoxia, ischemia, and cell death (resulting in poor engraftment). These issues relate to the lack of an integrated vascularized tissue environment into which cells are transplanted.

## **Biologically Compatible Delivery Process**



Data from a series of ISO 10993 biocompatibility studies, multiple preclinical studies, a pilot human clinical trial and our ongoing Phase 1/2 T1D human donor islet Clinical Trial demonstrate that the Cell Pouch™ is biocompatible and well-tolerated. These data further demonstrate that the Cell Pouch™ platform technology establishes a required cell-to-microvessel interaction to support the viability and function of therapeutic cells via the Cell Pouch™-mediated local tissue environment. In preclinical studies, an observed benefit of Cell Pouch™ was enhanced short and long-term therapeutic cell survival and function, which we believe is due in part to cells being transplanted into a natural tissue matrix in close contact with microvessels. Our preclinical studies have shown that human donor islets transplanted into Cell Pouch™ can control blood glucose levels in small and large animal models of diabetes over extended periods. Long-term studies in several animal models have demonstrated that following transplant, insulin-producing islets become well-supported with microvessels, as occurs in their natural



pancreatic environment. As a potential “functional cure” for diabetes, this close vessel proximity enables islets to continuously monitor blood glucose levels and release the appropriate amount of insulin into the bloodstream. We have also recently demonstrated that ILCs of iPSC cells transplanted into the Cell Pouch™ can control blood glucose levels in small animal models of diabetes. Similar results have been observed for other potential therapeutic applications. For example, we have demonstrated that patient cells gene-edited to produce factor VIII and transplanted into the Cell Pouch™ are effective in restoring blood clotting in a preclinical animal model of hemophilia A. Furthermore, in a preclinical animal model we have demonstrated that explanted thyroid tissue transplanted into the Cell Pouch™ allows for restoration of normal hormone levels for triiodothyronine (T3) and thyroxine (T4). We believe these data demonstrate the potential of our Cell Pouch System™ to address significant unmet medical needs across a range of therapeutic indications.





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

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

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

# Pipeline Today – Multiple Indications

Creating Patient Impact & Shareholder Value

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



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

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

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

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

In some countries, the current cell therapy is transplantation of donor islets into the portal vein of the patient’s liver. This first-generation cell therapy approach involves the transplantation of pancreatic donor islets, often from multiple donors, into a patient’s portal vein in which islets lodge in the microvasculature of the liver. Life-long systemic immunosuppressive drugs are required to inhibit rejection of this irreversible transplant. A portal vein islet transplant is the only cell therapy treatment approach possible for this population of people with diabetes and is only occasionally offered to reduce the occurrence of severe hypoglycemic episodes in these patients. Portal vein islet transplant remains categorized as an experimental procedure by some regulators, including the US FDA, and may only be administered under a clinical trial protocol.

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

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

islet cells. When infused into the liver, these cells are not retrievable if there is an islet product safety or tolerability issue. The only way to explant liver-infused cell technologies is to perform a liver transplant, which becomes a life-threatening issue due to the lack of donor organs.

Our most advanced development program involves the clinical development and validation of the Cell Pouch System™ for the treatment of people with T1D who suffer from unstable diabetes and life-threatening severe hypoglycemic episodes. As noted in Table 1 below, we believe the Cell Pouch System™ can alleviate a number of important issues with portal vein transplantation. With the Cell Pouch System™, the therapeutic cells live within a tissue matrix integrated with microvessels, similar to the islets’ natural pancreatic environment rather than being subjected to immersion in blood with immune-reactive cells, which is believed to lead to IBMIR. We believe islet transplant to Cell Pouch™ may eliminate the inflammatory response observed after portal vein infusion, enabling improved islet survival. Improved islet survival and engraftment potentially lowers the number of islets required for each transplant. Consequently, by transplanting islets into the Cell Pouch™, rather than the portal vein, fewer islets, and therefore fewer donor pancreata are anticipated to be required to achieve glucose control for each recipient, thereby potentially increasing the availability of these life-sustaining organs. In addition, the known side effects of multiple islet infusions into the portal vein are expected to be eliminated with the use of Sernova’s Cell Pouch System™. These benefits are expected to be further magnified by Sernova’s development of glucose responsive stem cell-derived ILC technologies.

Table 1 - Potential Benefits of Cell Pouch™ Islet Transplant

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

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

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

Importantly, Cell Pouch™ technologies are specifically and uniquely designed to be biocompatible, featuring pores that incorporate with vascularized tissue to form fully enclosed chambers with central void spaces for placement of therapeutic cells. A serious problem that may be encountered with other implanted therapeutic medical devices is the development of unwanted fibrosis in which the body treats the device as foreign and walls off the device with scar tissue resulting in starving of the cells of oxygen and nutrients.

We believe the unique design of the Cell Pouch™ prevents the formation of fibrotic tissue following implantation, facilitating the long-term survival and function of transplanted therapeutic cells.

As a novel approach beyond portal vein infusion of islets, we believe that islets (donor or stem cell-derived) transplanted into the Cell Pouch™ may provide a better means to optimize cell therapy for the treatment of diabetes. The data gained from our current clinical study using donor islets is being used to provide a basis for advancement of glucose-responsive immune-protected stem cell-derived cells for transplant into the Cell Pouch™. We believe stem cell-derived islets have the potential to treat millions of people suffering from T1D.

Sernova's Cell Pouch™ technologies are designed and patented to take into consideration the biological requirements of therapeutic cells. In long-term preclinical evaluation, Cell Pouch™ has been shown to maintain a stable, vascularized tissue environment prior to the placement of these transplanted therapeutic cells.

An independent preclinical study published in the journal "*Transplantation*" (Transplantation 2015 Nov: 99 (11):2294-300) demonstrated that the Cell Pouch™ with islets provided insulin independence for the length of the study (100 days) in an animal model of diabetes using a marginal transplanted islet mass where over 95% of the animals achieved insulin independence. This study supports the concept that Cell Pouch™ may require a smaller than initially anticipated dose of cells (marginal islet dose) with a lower overall cell density per Cell Pouch™ channel, in order to achieve efficacy. This parameter is being investigated and optimized in human clinical evaluations testing the ability of Cell Pouch™ and transplanted islets to achieve glucose control in patients with diabetes.

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

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

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

While donor islets provide a first Cell Pouch System™ therapeutic cell source and potential product to treat patients with the most significant unmet need - those with severe hypoglycemic events and hypoglycemia unawareness - our goal is to offer effective treatment to the broader general patient population of millions of people with diabetes. Consequently, we sought out an ethically derived, advanced iPSC-derived ILC technology with high potential for successful commercialization. We have demonstrated that iPSC-derived

ILCs can provide long-term insulin independence in an animal model of diabetes when transplanted into the Cell Pouch™. We believe iPSC-derived ILCs have superior commercial opportunity compared to progenitor embryonic stem cell-derived cells as the latter technologies are currently prohibited for human use in certain regulatory jurisdictions. Furthermore, fully differentiated ILCs may provide required insulin to patients sooner following transplantation than early progenitor islet technologies which may take many months to mature following transplantation prior to producing therapeutic levels of insulin in the body.

We chose Evotec's iPSC technology for this transformative component of our therapeutics platform based on multiple scientific, regulatory, manufacturing capabilities, business and commercial factors. We believe the Evotec Collaboration will secure a virtually unlimited supply of ethically derived, advanced glucose-responsive, insulin-producing ILCs, eliminating the limitation of a restrictive supply of donor islets for product commercialization. We also believe that this technology broadens and strengthens our appeal to strategic partners for business development and/or M&A opportunities with our cell therapy platform and the Company overall. Evotec's iPSC-derived ILCs in combination with the Cell Pouch™ and immune protection technologies is a priority in our clinical development plans and product pipeline. For more information on Evotec's iPSC technology and current status of our iPSC Program status, refer to the *Significant Acquisitions, In-Licensing and Collaborations* section within this AIF. Our partner, Evotec, continues to optimize and advance the process development for and scale up of iPSC-derived ILCs which will be used in additional IND enabling studies, clinical testing and subsequent commercial supply following regulatory submissions and approvals. Sernova's goal is to ensure a production process that is as close to commercial ready as possible, before going into a first in human trial to avoid and or limit any costly changes and delays in the future. Evotec has recently provided updated timelines for delivery of the more optimized ILCs. We now anticipate initiating the Phase 1/2 clinical trial evaluating the Cell Pouch™ with iPSC-derived ILCs for treatment of T1D in the fourth quarter of 2025.

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

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

### ***Type 1 Diabetes Phase 1/2 US Clinical Trial for Patients with T1D, Severe Hypoglycemic Episodes and Hypoglycemia Unawareness***

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

Following a peer review of the new clinical protocol, Sernova was awarded up to US\$2.5 million (approximately \$3.2 million) grant under an agreement with JDRF. The grant is supporting our Cell Pouch™ Phase 1/2 diabetes clinical trial, which is being conducted at the University of Chicago in collaboration with Principal Investigator Dr. Witkowski, M.D., Ph.D., Director of the University of Chicago's Pancreatic, and Islet Transplant Program, who is a leading expert in diabetes and islet transplantation and a published diabetes researcher and surgeon with a longstanding record in both basic

science and clinical research pertaining to islet cell and abdominal organ transplantation.

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 (US Phase 1/2 Cell Pouch™ Clinical Trial).

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

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

Interim analyses have resulted in the development and implementation of higher capacity 10-channel Cell Pouches, that provide >50% more islet capacity relative to the 8-channel Cell Pouches used for the first cohort in our US Phase 1/2 Cell Pouch™ Clinical Trial with the additional potential for reduced islet density. The transition to this new larger Cell Pouch™ and the amended protocol enables optimized dosing and shorter efficacy evaluation periods to ultimately decrease time to key efficacy endpoints. These endpoint measures include survival of transplanted islet cells, proportion of patients with a reduction of severe hypoglycemic episodes, and proportion of patients with an improvement in HbA1c. We believe the higher dose of islets at a lower cell density will further enhance graft function. Subjects who complete the study protocol continue long-term follow-up by their investigator physician.

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

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



insulin independence.

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

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

On January 15, 2021, we announced that Dr. Piotr Witkowski, the principal investigator in our clinical trial presented interim data from the clinical trial at the American Society of Transplant Surgeons (ASTS) 21st Annual State of the Art Winter Symposium in an abstract entitled “*Islet Allograft Transplantation Into Pre-Vascularized Sernova Cell Pouch – Preliminary Results From The University of Chicago*”. Dr. Witkowski reported Sernova’s Cell Pouch™ transplanted with insulin-producing cells in patients with T1D continues to show persistent islet function and clinically meaningful improvement in measures of glucose control.

Data from two transplanted patients who are furthest in the study and who have received a second islet transplant were focused on. Importantly, these patients are showing defined clinical benefit with a clinically meaningful reduction in daily injectable insulin requirement, along with the following additional clinical benefit indicators:

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

On February 18, 2021, we announced that an independent DSMB completed its second planned annual review of our US Phase 1/2 Cell Pouch™ Clinical Trial and did not raise concerns regarding safety and recommended continuation of the study.

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

In addition to the continued confirmation of ongoing safety and tolerability in all 6 currently enrolled patients, Dr. Witkowski provided further updates on the longest treated study patients. These patients have continued to show defined clinical benefit associated with ongoing efficacy indicators including:

- reduction / elimination in the need for daily injectable insulin;
- continued improvement, i.e. reduction/elimination, in Severe Hypoglycemic Events (SHE);
- persistent detection of fasting and stimulated C-peptide in patients’ bloodstream;

- reduction in HbA1c; and
- continued improvement of glucose control determined through patient blinded CGM and measured by reduction of Time Above Range (TAR) and increase of Time in Range (TIR).

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

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

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

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

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

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

On June 6, 2022, the Research Team from Dr. Piotr Witkowski's laboratory at the University of Chicago for our US Phase 1/2 Cell Pouch™ Clinical Trial presented updated positive data from the ongoing study at the American Diabetes Association's 82nd Scientific Sessions in New Orleans, LA. Updated data was presented in an oral podium presentation, "*Modified Approach for Improved Islet Allograft Transplantation into Prevascularized Sernova Cell Pouch™ Device: Preliminary Results of the Phase I/II Clinical Trial at University of Chicago*" [Abstract 306-OR].

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

Key highlights included:

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

Key findings from the interim clinical update:

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

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

endpoint efficacy achievement with more optimal dosing. We have engaged a clinical trial recruitment partner with extensive experience and success in accelerating T1D clinical trial patient enrollment to expedite recruiting and patient enrollment and we expect to report on interim data from the second cohort with the enhanced capacity Cell Pouches in 2023. On November 17, 2022, we provided an update that the first two patients of the second cohort have been implanted with the enhanced 10 channel Cell Pouch™. Recruitment of the second cohort is continuing.

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

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

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

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

Other findings from the interim clinical update:

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

On October 26, 2023, Principal Investigator Dr. Witkowski presented updated positive data from the ongoing study at the IPITA–IXA–CTRMS Joint Congress in San Diego, CA. Updated data was presented in an oral podium presentation, “*Islet allograft transplantation into pre-vascularized Sernova Cell Pouch –*

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

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

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

The revised Immunosuppression protocol, used in Cohort B, continues to demonstrate favorable protection for the islet grafts with no donor islet rejection or donor-specific antibodies (DSAs) observed under the new regimen. Recruitment of the final patient (seventh) in Cohort B was recently completed. The Company anticipates additional Cohort B clinical findings relating to the larger 10-channel Cell Pouch™ towards the end of the first quarter of calendar year 2024. Results from the combined cohorts will help inform the design of Sernova’s pivotal study, which would support an anticipated BLA submission to the US FDA and accelerate our iPSC stem cells into the clinic.

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

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

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

According to the American Thyroid Association (ATA), 20 million Americans currently live with thyroid disease, and 12% of Americans will develop a thyroid condition during their lifetime. The thyroid gland is essential for life as it produces and secretes thyroid hormones that regulate the body’s metabolism. The

development of new treatments for patients with unsatisfactory control of the thyroid hormone feedback loop may satisfy this unmet medical need. We believe that thyroid tissue transplanted into an implanted Cell Pouch™ offers a novel approach that could improve the quality of life and outcomes of patients experiencing postoperative hypothyroidism. Sernova's first approach in the treatment of hypothyroid disease is to take healthy tissue from each patient's own thyroid gland— removed during a thyroidectomy – and transplant that tissue into the pre-implanted vascularized Cell Pouch™. The goal is to recover the natural feedback system for release of thyroid hormones from each patient's own thyroid tissue.

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

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

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

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

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

The following describes significant events during the past three years related to the development of the Cell Pouch™ for the treatment of Postoperative Hypothyroidism.

On January 27, 2022, we announced the publication of a peer reviewed preclinical study demonstrating positive results of a novel Cell Pouch System™ cell therapy approach to treat hypothyroidism and potentially avoid lifelong dependence on thyroid medication following surgical removal of the thyroid gland. The journal article entitled “*Subcutaneous transplantation of human thyroid tissue into a pre-vascularized Cell Pouch™ device in a Mus musculus model: Evidence of viability and function for thyroid transplantation*” by lead author, Dr. Wiseman, a leading surgeon, researcher and internationally renowned expert in the management of thyroid and parathyroid disease, was published in the scientific journal, *PLOS ONE*, January 20, 2022 edition. In this study, thyroid tissue from patients undergoing surgery for treatment of benign disease was transplanted into Sernova Cell Pouches that had been previously implanted into laboratory mice. The aim of the study was to investigate the long-term survival of human thyroid tissue in the Cell Pouch™ and evaluate the ability of these thyroid transplants to release thyroid hormones into the bloodstream. The study confirmed that the human thyroid tissue transplanted into the Cell Pouch™ survived and released human thyroglobulin into the bloodstream, with no adverse effects for the three-months duration of the study. Thyroglobulin was used as a biomarker efficacy measure in this study as it is the precursor of thyroid hormones.

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

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

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

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

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

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

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



We believe that the therapeutic potential to have a constant release of FVIII from a hemophilia A patient's own genetically corrected cells placed within the implanted Cell Pouch™ would be a very significant advancement in the treatment of hemophilia A and a disruptive approach to the current standard of care treatment for hemophilia A. Corrected cells placed in an implanted Cell Pouch™ could release FVIII at a rate expected to reduce disease-associated hemorrhaging and joint damage. The continuous delivery of FVIII could also reduce or eliminate the need for multiple weekly infusions, which is the current standard of care using plasma-derived or recombinant, genetically engineered FVIII for the prophylactic treatment of hemophilia A. This approach is analogous to that used for CAR T-cell therapy as a validated therapeutic approach where a patient's own cells are collected from a blood sample and modified, scaled-up and placed back into the body to treat disease.

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

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

The following describes significant events during the past three years related to the development of the Cell Pouch™ for the treatment of hemophilia A.

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

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

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

We have entered into a collaboration with a leading European academic center to optimize the cellular factor VIII production in the gene editing manufacturing process as well as Cell Pouch™ dosing in a preclinical model of hemophilia A. We anticipate, in collaboration with this leading European academic center, to complete IND-enabling studies in 2024 and in early 2025, pending the receipt of supportive data, IND filing efforts will be initiated immediately. On November 27, 2023, we announced that the US FDA had granted both Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) for Sernova's Hemophilia A program. The US FDA grants orphan designation, also referred to as orphan status, to therapies intended for the treatment of rare diseases that affect fewer than 200,000 people in the US. This designation provides certain benefits, including tax credits for qualified clinical testing, waiver or partial payment of FDA application fees and up to seven years of market exclusivity, if approved. Separately, RPDDs are granted for rare diseases that primarily affect children under 18 years old with recipients of this designation being awarded a Priority Review Voucher (that can be used for a subsequent marketing application for a different product) upon approval of the Company product for the treatment of Hemophilia A in pediatric patients. The priority review voucher may be redeemed by the holder, transferred, or sold. Over time Priority Review Vouchers have been sold to third parties for amounts of up to US\$350 million. Recently, several Priority Review Voucher sales have occurred with the majority sold for around US\$100 million, including at least three sold during 2023.

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

### ***Local Immune Protection & Other Complementary Technologies***

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

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

### ***Cellular Conformal Coating Approach and Development***

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

During June 2020, we acquired an innovative cellular local immune protection technology. Pursuant to an asset purchase agreement, we acquired all intellectual property for a conformal coating cell technology (Conformal Coating Technology), including issued patents, patent applications and know-how. This technology acquisition provides a pivotal component required for our cell therapy therapeutics platform and could accelerate our first-to-market strategy for T1D and significantly expand the number of treatable patients suffering from chronic diseases.

The Conformal Coating Technology consists of a thin proprietary cross-linked polymer coating layer designed to surround therapeutic cells with the goal to protect them from an auto-response attack by one's own immune system post cell transplantation into the body.

The advantages and potential benefits of Conformal Coating Technology are anticipated as follows:

- provides protection of the therapeutic cells from immune system attack locally within the Cell Pouch™ chambers potentially avoiding the need for life-long immunosuppression medications, that are currently required following cell transplantation;
- enables close contact of the transplanted therapeutic cells with the vascularized tissue matrix within the Cell Pouch™ chambers to enable more intimate interactions;
- enables the diffusion of small molecules and biomolecules (i.e. glucose, insulin, and other proteins or hormones), to provide a physiological glucose-stimulated insulin response without delay that occurs with other encapsulation technologies; and
- due to the improved diffusion of biomolecules relative to other encapsulation technologies, it may require a smaller load of therapeutic cells to achieve the desired therapeutic effect in comparison to standard microcapsules.

Shortly after our Conformal Coating Technology acquisition, we secured an exclusive, worldwide license with the University of Miami (UMiami) for the commercial rights to novel complementary conformal coating immune protection technologies, which enables Sernova to broaden the intellectual property and technology scope of its immune protection conformal coating technologies.

In September 2021, we announced a collaboration with the UMiami and Dr. Alice Tomei, a leading international expert in immunoprotection and diabetes management from the renowned Diabetes Research Institute at the University of Miami Miller School of Medicine, to validate our Conformal Coating Technology in combination with therapeutic cells in Sernova's Cell Pouch™ for T1D. Under the terms of the agreement, we have committed to fund up to a total of US\$1.81 million (\$2.51 million), of which US\$1.60 million (\$2.21 million) has been incurred as of October 31, 2023. Technology optimization and further preclinical validation work is progressing as expected and continuing, with the associated second year budget awaiting finalization but anticipated to be similar to that of the first year noted above. Dr. Tomei is one of the original inventors of the Conformal Coating Technology that has been developed and optimized over twelve years with her dedicated team. This important collaboration is multifaceted in nature and designed to advance for the first time locally immune protected cells within the Cell Pouch™ with the goal of advancing these technologies into clinical trials without the need for life long immune suppression technologies. We believe successful development of this combination technology could meet an unmet need in a broader population of people with T1D who seek a 'functional cure' for their diabetes without the need to take life-long immunosuppression medications.

Subsequent to the collaboration announcement, in September 2021 we hosted an information session webinar "*The Ultimate Combination of Two Proven Technologies as a Potential Functional Cure for Type 1 Diabetes and Other Chronic Diseases*". The webinar featured Dr. Tomei, who spoke about the use of our Conformal Coating Technology as a technology approach for local cellular immune protection.

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

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

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

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

- the final conformal coating composition exhibits significantly improved cell compatibility and overall biocompatibility, representing evolution across years of process development work and preclinical testing;
- coating process enhancements resulted in a 500% increase in conformal coating production capacity (number of starting islets to be coated) and an 89% overall islet encapsulation yield (ratio of conformal coated islets to initial islets). These enhancements have a direct positive impact on the in vitro and in vivo efficacy of the coated islets;

- final conformal coated product was purified using a process to contain 98% conformal coated islets and only 2% empty capsules. This enables an increase in the number of functional coated islets that are transplanted within the Cell Pouch™ chambers and minimization of graft volume;
- using these composition and process development improvements, the coated islets were tested, in combination with the Cell Pouch™, in an established syngeneic animal model of T1D to assess the safety and efficacy of the combined product and confirmed:
  - the biocompatibility of the coated islets within the Cell Pouch™, histologically demonstrating healthy islets within the vascularized tissue matrix;
  - the normal physiological transfer of glucose-stimulated insulin from the conformal coated islets within the Cell Pouch™; and
  - diabetic animals that received conformal coated islets within the Cell Pouch™ exhibited controlled blood glucose to non-diabetic levels - which reversed upon removal of the Cell Pouch™ - proving function of the conformal coated islets.
- a series of pilot studies using conformal coated islets, in combination with the Cell Pouch™, in an allogeneic rat model of T1D established the optimal conditions to achieve diabetes reversal. These conditions, which are being used in confirmatory allogeneic studies in additional upcoming preclinical work, included:
  - drug kinetic studies identified the optimal dose and frequency of a single selective immune response agent to be used in combination with conformal coated islets; and
  - islet dose-dependent glucose control was demonstrated using conformal coated islets in the Cell Pouch™ with the selective immune response agent.
- release criteria essential for clinical manufacturing have been developed, including coating conformality, completeness, stiffness, thickness and selective permeability. Using these criteria, the conformal coating material showed long term mechanical stability, durability and selective permeability to insulin and glucose molecules but not to antibodies or inflammatory cells. These are key requirements for long-term function of the conformal coating technology in vivo; and
- significant progress was achieved in manufacturing of the coating scale up equipment. Prototype devices have been manufactured and being tested. Final system design will provide fully automated, GMP-compliant coating applied to transplantable coated islets. The system function will involve conformal coating, washing, counting and production monitoring.

### ***Cell Pouch™ Surgical Kit and Accessories***

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

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

### ***Access to Multiple Sources of Therapeutic Cells***

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

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

As otherwise mentioned in this AIF, 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.

### ***Corporate Developments***

On January 25, 2021, Sernova announced the early conversion by the holder of the outstanding \$1 million convertible debenture, due December 2022, into equity of the Company and that proceeds of approximately \$4.3 million had been received from the recent exercise of warrants.

On February 4, 2021, Sernova announced its shares had been accepted for trading on Xetra, the electronic trading system of Deutsche Börse AG in Germany, under the ticker-symbol: PSH. Xetra is the first and primary choice for institutional investors with its significantly higher liquidity and narrower price spreads.

On March 1, 2021, Sernova completed a \$20M upsized bought deal unit financing, co-lead by Leede Jones Gable Inc. and Canaccord Genuity Corp., and the full exercise of the 15% over-allotment option held by the underwriters, resulting in the issuance of 19,205,000 units at \$1.20 per unit for total proceeds of \$23 million. Each unit consisted of one common share and one warrant. Each warrant will entitle the holder thereof to purchase one common share at an exercise price of \$1.70 at any time up to 24 months following closing, subject to abridgment of the exercise period if the 10-day volume-weighted average price of the Company's common shares exceeds \$3.05 per common share with 30-days advance notice.

On May 4, 2021, Sernova announced that seasoned pharmaceutical industry executive, Dr. Mohammad Azab, MB ChB, MSc, MBA, was nominated to its Board. Dr. Azab has more than 30 years of experience in clinical research, business management and led the global development of several drugs currently approved in oncology and other therapeutic areas.

On June 30, 2021, Sernova announced the appointment of pharmaceutical industry veteran Frank Shannon as VP Clinical Development and Regulatory Affairs. With over 25 years of experience, Mr. Shannon has served in senior level positions in the international medical device, pharmaceutical, and biologics industries.

On December 2, 2021, Sernova announced that Frank Holler, member and chairman of the Sernova board of directors, will assume a new role of Executive Chair in order to augment the current leadership team and further support Sernova's evolving corporate and R&D activities and objectives.

On December 14, 2021, Sernova announced the appointment of Christopher Barnes as Vice President, Investor Relations. With a track record of 23 years of experience in both investor relations and capital markets, Mr. Barnes will lead the execution of Sernova's investor relations strategy and communications activities.

On December 14, 2021, the Board granted 13,575,484 stock options to certain officers, employees and consultants of the Company with each option being exercisable into one common share at a price of \$1.32 per share for a period of 5 years and granted 1,360,000 DSUs to its non-management directors.

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

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

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

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

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

In October 2022, we announced the appointment of KPMG LLP, Chartered Professional Accountants as new auditor of the Company. There were no reservations in the Company's former auditor's audit reports for any financial period during which they were our auditor nor were there any "reportable events" (as the term is defined in National Instrument 51-102 - Continuous Disclosure Obligations). The appointment of KPMG LLP was subsequently approved by Shareholders at the Company's annual meeting held on April 27, 2023.

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



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

In September 2023, we announced the appointment of biotech and pharma industry veteran Cynthia Pussinen as Chief Executive Officer (CEO) and a member of the Board of Directors of Sernova and that Dr. Philip Toleikis, prior President and CEO, was assuming the position of Chief Technology Officer and continuing as a member of the Board of Directors. In addition, veteran dealmaker and strategic leader Modestus Obochi, Ph.D., MBA, officially commenced in the role of Chief Business Officer for Sernova.

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

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

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

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

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

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

- development of a robust, cost-efficient, scalable, highly controlled iPSC differentiation protocol with the ability to cryopreserve and store batches of differentiated islet-cell clusters;
- demonstration of excellent ILC survival under standard pharmaceutical shipping conditions and following transplantation;
- demonstration of consistent long-term insulin independence with no hypoglycemic events and

consistent safety profiles in a gold standard T1D preclinical model with Evotec's iPSC-derived ILCs transplanted in Sernova's Cell Pouch™;

- iPSC derived ILC manufacturing scale-up and technology transfer activities to Evotec's iPSC GMP facility are well under way in preparation for manufacture of clinical and commercial iPSC derived ILCs supply; and
- interactions with experts to support design of a Phase 1/2 clinical trial.

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

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

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

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

Costs for iPSC IND enabling activities will continue to be incurred through 2024 and into 2025 with progression of the latest planned preparatory activities toward a now projected IND filing and associated regulatory clearance during late 2025 for a Phase 1/2 iPSC T1D clinical trial of Cell Pouch™ with Evotec's

iPSC-derived ILC technology. We expect the clinical trial study would be initiated as quickly as possible after regulatory clearance was obtained.

#### *Conformal Coating Technology Acquisition*

As noted above, Sernova completed its June 2020 acquisition of cellular local immune protection technology as a strategic accelerator for expansion of Sernova's total cell therapeutics platform. Sernova acquired intellectual property associated with the Conformal Coating Technology.

As otherwise described within this AIF, the Conformal Coating Technology consists of a thin proprietary cross-linked polymer coating layer that is designed to cloak therapeutic cells to protect them from an auto-response attack by a patient's own immune system following cell transplantation into the body.

#### *Conformal Coating Technology In-License Expansion*

On August 4, 2020, Sernova announced it had entered into an exclusive, worldwide license with the University of Miami for the commercial rights to additional novel Conformal Coating Technology developed by Dr. Tomei.

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

In addition to filing an international patent application following further encouraging research supporting the Conformal Coating Technology in islets and stem cell-derived technologies at the University of Miami, a collaborative research plan was developed advancing the Conformal Coating Technology in combination with therapeutic cells within Cell Pouch™.

#### *Conformal Coating Technology Collaboration*

On September 16, 2021, Sernova announced that it had entered into a research agreement with UMiami to validate its Conformal Coating Technology in combination with therapeutic cells in Sernova's Cell Pouch™ for T1D. This important collaboration is multifaceted in nature and designed to advance locally immune protected cells within the Cell Pouch™ and the scale up of the Conformal Coating Technology with the objective to conduct clinical testing in the future.

#### *Research Collaboration with AstraZeneca*

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

## ***Clinical Testing, Product Development, Regulatory, Marketing and Commercialization of Sernova's Human Therapeutic Products and Cell Therapy Platform***

### ***Market Opportunity for the Cell Pouch System™ and Cell Therapy Platform Applications***

The global insulin market is expected to grow from USD \$21.11 billion in 2022 to USD \$25 billion by 2030, at a CAGR of 2.14% during the forecast period 2022-2030<sup>1</sup>. The cell therapy market for T1D is considerably higher than for that predicted for use of insulin alone. The anticipation is that unlike insulin injections alone, a cell therapy approach has the potential to reduce the debilitating side effects of the disease including blindness, heart and kidney disease and amputations that result in the major healthcare costs of T1D. The reduction of these side effects with a cell therapy approach is expected to result in an increased market potential for the cell therapy approach. Furthermore, this market is also expected to be dependent in part on the duration, also referred to as durability, of the cell therapy therapeutic effect in patients.

A recently reported market size for all diabetes treatments was estimated at USD \$43.6B for 2022, growing to USD \$55.3B in 2029<sup>2</sup>, with the T1D market accounting for an estimated USD \$11.8B (2024) and growing to USD \$19.9B by 2028<sup>3</sup>. The Company believes the Cell Pouch™ diabetes therapeutic platform under development for treatment of patients with insulin-dependent diabetes could gain significant market share upon successful completion of clinical development and believes, upon achievement of regulatory approval, may become the new standard of care worldwide for diabetes in patients currently taking insulin.

The global hemophilia market size was estimated at USD \$12.6 billion in 2022 and is expected to grow at a compound annual growth rate (CAGR) of 6.6% from 2023 to 2030. Hemophilia A held the highest share of 74.16% in 2022 in the hemophilia market<sup>4</sup>, with an annual cost of up to US\$200,000 per patient. Sernova seeks to develop a product that will provide constant delivery of FVIII to normalize blood levels in an effort to significantly improve the quality of life of patients suffering from hemophilia A and reduce the debilitating side effects of the disease, similar to its treatment for T1D. Currently the standard of care for hemophilia A patients requires regular infusions of FVIII on a weekly basis to maintain FVIII levels.

The global thyroid gland disorder treatment market was valued at US\$3.6 billion in 2020<sup>5</sup>. An estimated 150,000 thyroidectomies are performed each year in the United States alone. Sernova's approach in the treatment of hypothyroid disease is to transplant the remaining healthy thyroid cells of patients undergoing thyroidectomy into the pre-implanted vascularized Cell Pouch™ and replace the current standard of care of oral medications which either fail to achieve appropriate levels of thyroid hormone or result in patients often suffering from side effects including weight gain, depression, headaches, and cardiovascular disease, resulting in negative impacts on quality of life, and costs to the healthcare system.

### ***Regulatory Approval and Certification***

All commercial applications of the Sernova Cell Pouch System™ (i.e. Cell Pouch™ medical device, therapeutic cells, cellular immune protection) and resulting testing and evaluation thereof are subject to substantial regulation and rigorous approval procedures by Health Canada, the US FDA, the EU and other

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<sup>1</sup> "Insulin Market Size by Product type (Rapid-Acting Insulin, Combination Insulin, Long-Acting Insulin, Biosimilar, and Others), Application (Type 1 Diabetes, and Type 2 Diabetes), Type, Distribution Channel, Global Industry Analysis, Share, Growth, Trends and Forecast 2022 to 2030." The Brainy Insights. Accessed January 19, 2024. <https://www.thebrainyinsights.com/report/insulin-market-13032>.

<sup>2</sup> "Diabetes Treatment Market, Global Outlook and Forecast 2023-2030" by 24MarketReports.

<sup>3</sup> The Business Research Company's "Type 1 Diabetes Global Market Report 2024".

<sup>4</sup> Grand View Research, "Hemophilia Market Size, Share & Trends Analysis Report by Type (Hemophilia A), By Treatment Type (On-demand), By Therapy (Gene Therapy & Monoclonal Antibodies), By Distribution Channel, By Region, And Segment Forecasts, 2023 – 2030".

<sup>5</sup> Al-Qurayshi Z et al. Association of Surgeon Volume with Outcomes and Cost Savings Following Thyroidectomy: A National Forecast. JAMA Otolaryngol Head Neck Surg. 2016 Jan;142(1):32-9; Dark Horse Consulting, 2022.

international regulatory agencies, as we develop our products through to marketing approval in the jurisdictions in which Sernova or its strategic partners intend to sell these cell therapy therapeutic products.

Sernova will evaluate and as available pursue Orphan Drug, Fast Track, Breakthrough Technology, Regenerative Medicine Advanced Therapy (RMAT), Accelerated Approval or Priority Review in the US, and similar regulatory designations in North America, Europe, or other jurisdictions abroad, to expedite the conduct of clinical trials, the review of regulatory submissions and or obtain marketing approval for its products and technologies.

The markets for Sernova's technologies are worldwide to coincide with its patented jurisdictions, however, are initially focused on North America and Europe. Sernova is ensuring we meet regulatory standards of the various jurisdictions in which we plan to be marketing our technologies. While many countries throughout the world provide reciprocal approval based upon the receipt by an innovator of an FDA approval, Sernova will ensure it accounts for any differences between countries in regulatory requirements.

Sernova conducts GMP manufacturing of its Cell Pouch™ and rigorous pre-clinical testing of its technologies in relevant animal models of disease to evaluate biocompatibility, safety / efficacy of these technologies. The results of these studies, along with a GMP compliant manufacturing dossier, and extensive clinical documentation are submitted to one or more of the regulatory authorities, i.e. US FDA or Health Canada, as part of an Investigational New Drug (IND) application (for US FDA) or Investigational Testing Authorization (ITA) (for Health Canada), which must be cleared by the respective regulatory authorities prior to initiation of clinical testing in humans. A similar process occurs for clinical product testing in other countries.

Typically, for our regenerative medicine combination products, the clinical evaluation process involves several Phases. For our combination medical device/cell therapies a Phase 1/2 (safety and efficacy), clinical evaluation is initially conducted with a small number of human subjects who have the disease to establish a safety profile, and potential efficacy parameters. Clinical evaluation patient number may then be increased to include a larger number of patients to further assess safety and efficacy parameters. A Phase 3 study may then be conducted, typically at multiple clinical sites to provide enough data to demonstrate the efficacy and safety in a larger population. The number of subjects in the clinical studies will depend on several factors including the overall size of the patient population with the disease. For example, some clinical indications designated orphan status indications may require smaller numbers of patients for product approval.

In the United States, as an example, preclinical and clinical results from the clinical studies are submitted to the US FDA in the form of a New Drug Application (NDA) and require approval before the product can commence commercial sales. In responding to an NDA, the US FDA may grant marketing approval, request additional information, or deny the application if the US FDA determines that the application does not satisfy its regulatory approval criteria. While it is typical that the Company would interact with regulatory authorities on a regular basis through the clinical trial process, this is not a guarantee that approvals from the US FDA for its product candidates will be granted on a timely basis, if at all. Similar regulatory procedures are in place in countries outside the United States.

#### *Commercial Marketing Plans and Strategies*

Following product marketing approval from the various regulatory authorities, Sernova's therapeutic products will require establishment of global marketing and distribution channels. To maximize benefit to shareholders, Sernova intends to license to, or enter into strategic alliances with pharmaceutical entities that are equipped to market Sernova's products through their established distribution networks. The Company may license or sublicense some or all of its patent rights to one or more such companies to achieve the fullest development, marketing and distribution of its products. These potential agreements are anticipated to provide significant benefit to the Company in terms of upfront payments, milestone payments and

royalties. To this end, the Company intends to continue to develop and improve its proprietary technologies and expand the applications of its technologies in the healthcare markets. Furthermore, Sernova will continue its business development activities with the major pharmaceutical and medical device companies who have established sales forces in the therapeutic areas that Sernova is focused on.

#### *Pricing and Reimbursement*

Therapeutic products are largely reimbursed based on third-party insurers. In the United States, concurrent with approval for commercialization of such therapeutic products by the US FDA, each therapeutic product is assigned a product code or CPT (Current Procedural Terminology code). Each product code and CPT is then assigned a reimbursement level by the Centers for Medicare and Medicaid Services (CMS). Third party insurance payers typically establish a specific fee to be paid for each code submitted. Third party payer reimbursement policies are generally determined with reference to the reimbursement for CPT codes for Medicare patients which themselves are determined on a national basis by CMS.

In parallel with this reimbursement scheme in the United States, other countries have substantially similar reimbursement procedures that will be followed. As we develop our products towards expected marketing approval Sernova plans to establish, reimbursement schemes which are intended to provide ultimate financial payment for Sernova's products consistent with its business plan.

#### *Collaboration and Commercialization Agreements*

To increase market exposure of its products and to capitalize on a partner's potential clinical development competencies, market position, and distribution capabilities, the Company may advance its technologies in conjunction with collaborative commercial partners who will fund further product development incorporating Sernova's technologies and possibly a combination of Sernova's technologies and the commercial partner's technologies. In addition, collaborations may enable the Company to gain access to new therapeutic cell technologies in additional indications to build Sernova's pipeline and to gain access to unlimited supplies of stem cell-derived technologies to expand targeted treatable populations.

These collaborative arrangements may provide for jointly funded product development and contemplate a licensing arrangement (which may be entered into at the same time as the development program or at a later date) under which, if a project is commercialized by the collaborative partner, Sernova could potentially receive license fees, royalty payments from product sales and manufacturing revenue. Sernova management believes that such arrangements with major commercial partners could serve to speed development of our programs, provide non-dilutive capital and assist Sernova in attracting additional licensing arrangements on favorable terms.

#### *Human Healthcare Products Competition*

There are pharmaceutical companies (large and small) that are developing and/or marketing various products for diabetes, hemophilia and other relevant disease indications including thyroid and other genetic and/or immunological disorders and diseases for which Sernova is developing products. While we believe Sernova's cell therapeutic technologies are unique and may provide significant benefit to patients, over the current approved products, these Companies may become collaborators or even competitors with Sernova as new products are developed. From a competitive perspective, Sernova expects competition from these companies as they develop different and or novel approaches to the treatment of these diseases. Although the markets Sernova is entering are quite large, some of these approaches may directly compete with the technologies that Sernova is currently developing.

In the competitive environment that is the human pharmaceutical industry, those companies that complete clinical trials, obtain regulatory approval and commercialize their therapeutic products first may enjoy certain competitive advantages. Sernova believes that it will develop its cell therapy technologies with characteristics that may enable them, if fully developed, to have a significant market impact. Several major

pharmaceutical companies have significant programs to develop treatments of T1D, hemophilia and thyroid disease.

### ***cGMP Manufacturing***

We manufacture our Cell Pouch™ and mini-Cell Pouch™ technologies (ISO 13485; US FDA Quality System Regulations (QSR) 21 CFR 820; EU Medical Devices Regulation MDR 2017/745, and Canadian Medical Device Regulation (CMDR)) for preclinical and clinical evaluation via a contract manufacturer. Device specifications have been established, a semi-automated manufacturing process developed, and the product manufactured, packaged, and sterilized under strict regulatory guidelines suitable for testing in clinical trials in North America and Europe to complete the manufacturing process. Sterilization verification studies were completed, and the product previously released for testing in our human clinical trial in Canada with Sernova's ITA (Investigational Testing Authorization) under the jurisdiction of Health Canada. A two-year test has also been successfully completed demonstrating the stability of the product and packaging over this time period.

The Cell Pouch™ is scalable and can be manufactured in different sizes for the same or different therapeutic indications / applications. Our initial manufacturing run of the new expanded size 10 plug Cell Pouch™ has been completed. We believe the 10 plug Cell Pouch™ will be able to host the combined payload of transplanted therapeutic cells that has enabled our most advanced clinical trial patients to achieve insulin independence under our current US Phase 1/2 Cell Pouch™ Clinical Trial protocol.

Our collaboration partner Evotec as part of our agreement is responsible for manufacturing the iPSC derived islet-like clusters for clinical studies and commercial supply. Evotec has a GMP iPSC manufacturing facility in Europe and is in the process of scaling up the production as well as completing tech transfer to the facility in preparation for anticipated clinical trials and future commercial production of the islet-like clusters. Evotec has developed a cryopreservation technique which may allow the developed islet-like clusters to be stored in significant quantities for an extended period of time prior to site delivery and transplant into patients. We believe this approach is best-in-class and enables commercially viable and cost-effective production of the islet-like clusters with a supply chain that is unique and provides competitive advantage in the field.

### ***Protection of Proprietary Intellectual Property***

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

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

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



## ***Employees***

As at October 31, 2023, we had twenty-six full-time employees including management, research and development staff and finance and administrative staff. We also use consultants and outside contractors to carry on many of our activities, including preclinical testing, manufacturing, clinical and regulatory affairs and clinical trials.

## ***Legal Proceedings***

The Company is not a party to any legal proceedings or regulatory actions nor does the Company anticipate becoming party to any such proceedings or regulatory actions.

## **RISK FACTORS**

Prospects for companies in the biotechnology industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in biotechnology companies should be regarded as speculative. Biotechnology research and development involves a significant degree of risk. An investor should carefully consider the risks and uncertainties described below, as well as other information contained in this AIF. The risks and uncertainties described below are not an exhaustive list. Additional risks and uncertainties not presently known to the Company or that the Company believes to be immaterial may also adversely affect the Company's business. If any one or more of the following risks occur, the Company's business, financial condition and results of operations could be seriously harmed. Further, if the Company fails to meet the expectations of the public market in any given period, the market price of the Company's common shares could decline.

### **Investment Risk**

***Volatility of share price, absence of dividends, and fluctuation of operating results.*** Market prices for the securities of biotechnology companies, including ours, have historically been highly volatile. During the year ended October 31, 2023, our common shares traded on the Toronto Stock Exchange at a high of \$1.26 and a low of \$0.70 per share (2022 fiscal year – high of \$2.22 and low of \$0.69 per share). Factors such as general market conditions, biotech sector investment sentiment, fluctuation of our operating results, announcements of technological innovations, patents or new commercial products by us or our competitors, results of clinical testing, regulatory actions, or public concern over the safety of biopharmaceutical products and other factors could have a significant effect on the share price or trading volumes for our common shares. Our common shares have been subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future. We have not paid dividends to date, and we do not expect to pay dividends in the foreseeable future.

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

Our Board of Directors has the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, shareholders. Based on the need for additional capital to fund expected expenditures and growth, it is likely that we will issue additional securities to provide such capital. Such additional issuances may involve the issuance of a significant number of common shares at prices less than the current market price for our common shares.

Sales of substantial amounts of our securities, or the availability of such securities for sale, as well as the issuance of substantial amounts of our common shares upon the exercise of outstanding warrants, DSUs, or stock options, could adversely affect the prevailing market prices for our securities and dilute our investors'

earnings per share. A decline in the market prices of our securities could impair our ability to raise additional capital through the sale of securities should we desire to do so.

### **Reliance on Third Parties for Manufacture and Supply of Products**

*Sernova relies on third parties to manufacture its product candidates.* Currently, Sernova does not have manufacturing facilities to independently manufacture its product candidates. Except for any contractual rights and remedies which Sernova may have with any future third-party manufacturers, Sernova may not have any control over the availability of its product candidates, their quality, or cost. If, for any reason, Sernova is unable to secure third-party manufacturers on commercially acceptable terms, it may not be able to distribute its product candidates.

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

### **Issuer Risk**

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

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

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

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

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

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

***We depend heavily on the success of our Cell Pouch System™ platform.*** All of our current product candidates involve the use of our Cell Pouch System™ platform and are still in preclinical or clinical development. If we are unable to commercialize our product or experience significant delays in doing so, the business may be materially harmed.

We have committed significant resources to the development of our Cell Pouch System™ platform. Our ability to generate product revenues, which is not expected to occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of our Cell Pouch System™ platform and related therapeutic cells.

We are dependent on successful safety and efficacy of our Cell Pouch™ and therapeutic cells for our lead programs, including the use of human or xenogeneic islets and stem cell-derived cells in combination with the Cell Pouch System™ platform, including cell immune protection to treat insulin-dependent diabetes, the use of thyroid tissue in combination with the Cell Pouch System™ and the use of FVIII releasing cells in combination with the Cell Pouch System™ platform to treat severe hemophilia A. If we are unable to achieve safety and efficacy in one or more of these disease indications in preclinical and / or clinical studies the business may be materially harmed.

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

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

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

- the US FDA, Health Canada, EMA or other regulatory authorities may disagree with the design or implementation of our or our collaborators’ clinical trials;
- we or our collaborators may be unable to demonstrate to the satisfaction of the US FDA, Health Canada, EMA or other regulatory authorities that a product is safe and effective for its proposed indication;

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

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

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

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

***Product development and associated clinical trials involve lengthy and expensive processes with uncertain timelines and uncertain outcomes. If clinical trials are prolonged, delayed, or not completed, we, or our collaborators, may be unable to develop any commercial applications or products that generate revenues on a timely basis, if at all.*** Clinical trials are long, expensive, and uncertain processes. Clinical trials may not be commenced or completed on schedule, and the US FDA, Health Canada, or any other regulatory body may not ultimately approve our Cell Pouch System™ or other products developed for commercial sale. Clinical trial outcomes are inherently uncertain, and failure can occur at any time during the clinical development process. The clinical trials for existing and or future products could be unsuccessful, which would prevent us from advancing, commercializing, or partnering the product.

Even if the results of our preclinical studies or clinical trials are initially positive, it is possible that we will obtain different results in the later stages of product development or that results seen in clinical trials will not continue with longer-term treatment. Positive results in early clinical trials may not be repeated in larger clinical trials. We cannot be assured that our preclinical studies and clinical trials will generate positive results that allow us to move towards the commercial use and sale of our product candidates. Furthermore, negative results may cause our business, financial condition, or results of operations to be materially adversely affected. For example, our Cell Pouch System™ is in earlier clinical trials, and there is a long development path ahead, which will take years to complete and is prone to the risks of failure inherent in the development process.

Preparing, submitting and advancing applications for regulatory approval is complex, expensive, and time-intensive and entails significant uncertainty. A commitment of substantial resources to conduct time-consuming research, preclinical, and clinical trials will be required if we are to complete the development of our products.

Clinical trials of our products require that we identify and enroll patients with the illness under investigation. We may not be able to enroll a sufficient number of appropriate patients to complete our clinical trials in a timely manner, particularly in smaller indications and indications where there is significant competition for patients. If we experience difficulty in enrolling patients to conduct our clinical trials, we may need to delay or terminate on-going clinical trials and will not accomplish objectives material to our success that could impact the price of our common shares. For example, delays in planned patient enrolment and other factors in our clinical trials or future trials may result in longer trials, increased costs, or both.

In addition, unacceptable adverse side effects may occur at any time in the course of preclinical studies or human clinical trials or, if any product candidates are successfully developed and approved for marketing, during commercial use of any approved products. The appearance of any such unacceptable adverse side effects could interrupt, limit, delay, or abort the development of any of our product candidates, or if previously approved, necessitate their withdrawal from the market. Furthermore, disease resistance or other unforeseen factors may limit the effectiveness of our potential products.

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

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

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

Our ability to maintain the confidentiality of our technology may be crucial to our ultimate potential for commercial success. While we have adopted procedures designed to protect the confidentiality of our

technology, no assurance can be given that such arrangements will be effective, that third parties will not gain access to our trade secrets or disclose our technology, or that we can meaningfully protect the rights to our trade secrets.

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

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions affecting the patentability of our inventions relating to our key products and the enforceability, validity, or scope of protection offered by our patents relating to our key products and may result in substantial monetary damages or result in significant delays in bringing our key products to market and / or preclude us from participating in the manufacture, use or sale of our key products or methods of treatment requiring licenses. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us.

***We may expend our limited resources to pursue particular R&D opportunities and fail to capitalize on others that may be more profitable or for which there is a greater likelihood of success.*** Because we have limited resources, we focus our R&D programs on therapeutic cell candidates for specific indications. As a result, we may forego or delay the pursuit of opportunities for other therapeutic cell candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future R&D programs and therapeutic cell candidates may not yield any commercially viable products.

We have based our R&D efforts on assessing various therapeutic cells within our Cell Pouch System™ platform. As a result of pursuing the development of certain therapeutic cells within the Cell Pouch System™ platform, the Corporation may fail to develop other therapeutic cells or address alternate scientific approaches that could offer greater commercial potential or for which there is a greater likelihood of success.

***Dependence on collaborative partners, licensors, and others.*** We currently utilize technology that we have licensed, have an option to license or that has been developed internally by our own researchers. In particular, we are dependent upon our license to use certain technology provided under sublicense agreement with UHN, dated September 9, 2015, for the development of stem-cell product candidates. In addition, we are dependent on access to the iPSC technology being developed under the Evotec Collaboration and Evotec's successful and timely completion of iPSC-derived ILCs development, including scale-up and manufacturing. We are also dependent upon our license to use certain local immune protection technology provided under sublicense agreement with UMiami, dated July 28, 2020, for expanded protection of therapeutic cells placed inside our Cell Pouch™. While the Corporation's licenses are in good standing, they may be terminated by the licensor if there is a breach of the license agreement.

Our activities will require us to enter into various arrangements with corporate and academic collaborators, licensors, licensees, and others for the research, development, clinical testing, manufacturing, marketing, and commercialization of our products. We intend to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that we will be able to establish such additional collaborations on favorable terms, if at all, or that our current or future collaborations will be successful. Failure to attract commercial partners for our products may cause us to incur substantial clinical testing, manufacturing, and commercialization costs prior to realizing any revenue from product sales or result in delays or program discontinuance if funds are not available in sufficient quantities.

Should any collaborative partner fail to develop, manufacture, or successfully commercialize any product to which it has rights, or any partner's product to which we will have rights, our business may be adversely affected. Failure of a collaborative partner to continue to participate in any particular program could delay or halt the development or commercialization of products generated from such program. In addition, there can be no assurance that the collaborative partners will not pursue other technologies or develop alternative products either alone or in collaboration with others, including our competitors, as a means for developing treatments for the diseases targeted by our programs.

Furthermore, we may require licenses for certain technologies, and there can be no assurance that these licenses will be granted or, if granted, will not be terminated, or that they will be renewed on conditions acceptable to us. We intend to negotiate additional licenses in respect of technologies developed by other companies and academic institutions. Terms of license agreements to be negotiated may include, inter alia, a requirement to make milestone payments, which may be substantial. We will also be obligated to make royalty payments on the sales, if any, of products and payments on any sublicensing revenue derived from the licensed technology and, in some instances, may be responsible for the costs of filing and prosecuting patent applications.

We rely and will continue to rely on third parties to conduct some portions of our preclinical and clinical development activities. Preclinical activities include proof-of-concept and safety studies. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring, and project management. If there is any dispute or disruption in our relationship with third parties, or if they are unable to provide quality services in a timely manner and at a reasonable cost, our active development programs will face delays. Further, if any of these third parties fail to perform as we expect or if their work fails to meet regulatory requirements, our testing could be delayed, canceled, or rendered ineffective.

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

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

- disruption in our relationships with collaborators or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;



- retention of key employees;
- diversion of management time and focus from operating our business to pursuing strategic transactions and managing any such strategic alliances, joint ventures or acquisition integration challenges;
- dilution to our shareholders if we issue equity in connection with such transactions;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses, products or technologies.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks, and the particular economic, political, and regulatory risks associated with specific countries. Also, the anticipated benefit of any strategic alliance, joint venture, or acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing, or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

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

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

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

collaborations, product sales, and or royalty payments generate sufficient revenues to fund our continuing operations.

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

***Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.*** Global credit and financial markets experienced extreme disruptions at various points over the last decade, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it might make any necessary equity or debt financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and the market price of our common shares could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current collaborators, service providers, manufacturers, and other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

***Reliance on Information Technology.*** Despite the implementation of security measures, our internal computer systems, and those of our third parties on which we rely, are vulnerable to damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to our systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorism has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Should a material system failure or security breach occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed.

***We are likely a “passive foreign investment company” (PFIC) which may have adverse U.S. federal income tax consequences for shareholders in the United States (U.S.).*** U.S. investors should be aware that we believe we were classified as a passive foreign investment company, or PFIC, during the tax years ended October 31, 2023, and 2022, and based on current business plans and financial expectations, we believe that we may be a PFIC for the current tax year and the immediate future tax years. If we are a PFIC for any year during a U.S. shareholder’s holding period of our common shares, then such U.S. shareholder generally will be required to treat any gain realized upon a disposition of our common shares, or any so-called “excess distribution” received on our common shares, as ordinary income, and to pay an interest

charge on a portion of such gain or distributions, unless the shareholder makes a timely and effective “qualified electing fund” election (QEF Election) or a “mark-to-market” election with respect to our shares. A U.S. shareholder who makes a QEF Election generally must report on a current basis its share of our net capital gain and ordinary earnings for any year in which we are a PFIC, whether or not we distribute any amounts to our shareholders. A U.S. shareholder who makes the mark-to-market election generally must include as ordinary income each year the excess of the fair market value of the common shares over the shareholder’s adjusted tax basis therein. Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common shares.

***It may be difficult for non-Canadian investors to obtain and enforce judgments against us because of our Canadian incorporation and presence.*** We are a corporation governed by Canadian law. Several of our directors and officers, and several of the experts are residents of Canada, and all or a substantial portion of their assets, and all or a substantial portion of our assets are located outside the United States. Consequently, it may be difficult for holders of our securities who reside in the United States to effect service within the United States upon those directors and officers, and the experts who are not residents of the United States. It may also be difficult for holders of our securities who reside in the United States to realize in the United States upon judgments of courts of the United States predicated upon our civil liability and the civil liability of our directors, officers, and experts under the United States federal securities laws.

Investors should not assume that Canadian courts (i) would enforce judgments of United States courts obtained in actions against us or such directors, officers or experts predicated upon the civil liability provisions of the United States federal securities laws or the securities or “blue sky” laws of any state or jurisdiction of the United States or (ii) would enforce, in original actions, liabilities against us or such directors, officers or experts predicated upon the United States federal securities laws or any securities or “blue sky” laws of any state or jurisdiction of the United States. In addition, the protections afforded by Canadian securities laws may not be available to investors in the United States.

***As a foreign private issuer, we are not subject to certain United States securities law disclosure requirements that apply to a domestic United States issuer, which may limit the information which would be publicly available to our shareholders.*** As a foreign private issuer, we are not required to comply with all the periodic disclosure requirements of the Exchange Act, and therefore, there may be less publicly available information about us than if we were a United States domestic issuer. For example, we are not subject to the proxy rules in the United States, and disclosure with respect to our annual meetings will be governed by Canadian requirements.

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

## **Industry Risk**

***Rapid technological change.*** The biotechnology and pharmaceutical industries are characterized by rapid and substantial technological change. There can be no assurance that developments by others will not render our proposed products or technologies non-competitive, or that we will keep pace with technological developments. Competitors have developed or are developing technologies that could be the basis for competitive products. Some of these products have an entirely different approach or means of accomplishing the desired therapeutic effect as compared with products to be developed by us and could be more effective and less costly than the products to be developed by us. In addition, alternative forms of medical treatment may be competitive with our products.

***Competition.*** Technological competition from pharmaceutical companies, biopharmaceutical companies, and universities is intense and is expected to increase. Potential competitors for us have or may develop product development capabilities or financial, scientific, marketing, and human resources exceeding ours. Competitors may develop products before we can develop our products, obtain regulatory approval for such products more rapidly than us, or develop products which are more effective than those which we intend to develop. Research and development by others may render our proposed technology or products obsolete or non-competitive or produce treatments or cures superior to any therapy developed or to be developed by us, or otherwise preferred to any therapy developed by us. We may be unable to compete against other companies and research institutions with greater financial and other resources.

***Government regulations.*** Biotechnology and pharmaceutical companies operate in a high-risk regulatory environment. The manufacture and sale of therapeutic products are governed by numerous statutes and regulations in the United States, Canada, and other countries where we intend to market our products. The subject matter of such legislation includes approval of manufacturing facilities, controlled research, and testing procedures, review, and approval of manufacturing, preclinical and clinical data prior to marketing approval, as well as regulation of marketing activities, notably advertising and labeling.

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

***Hazardous materials and environmental matters.*** Certain of our R&D processes will involve the controlled use of hazardous materials. We are subject to federal, provincial, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of such materials and certain waste products. Although our management believes that its procedures for handling and disposing of such materials comply with the standards prescribed, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for damages, and such liability could exceed our resources. We are not specifically insured with respect to this liability. Although our management believes that it currently complies in all material respects with applicable environmental laws and regulations, we may be required to incur significant costs to comply with environmental laws and regulations in the future. Furthermore, there can be no assurance that our operations, business, or assets will not be materially adversely affected by current or future environmental laws or regulations.

***Status of healthcare reimbursement.*** Our ability to successfully market certain therapeutic products may depend in part on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Significant uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement. Furthermore, challenges to the price of medical products and services are becoming more frequent. There can be no assurance that adequate third-party coverage will be available to establish price levels, which would allow us to realize an acceptable return on our investment in product development.

***Potential product liability.*** Pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Product liability insurance is costly, and availability is limited and may not be available on terms that would be acceptable to us, if at all. An inability to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim brought against us, or withdrawal of a product from the market, could have a material adverse effect upon us and our financial condition.

## **DIVIDENDS**

There are no restrictions in Sernova's Articles, By-Laws or elsewhere, which would prevent the Company from paying dividends. No dividends have been declared or paid on the Common Shares in the last four fiscal years, and it is not expected that dividends will be declared or paid in the immediate or foreseeable future. The Board policy is to reinvest all available funds in operations. The Board will reassess this policy from time to time. Any decision to pay dividends on the common shares of Sernova will be made by the Board based on the assessment of, among other factors, earnings, capital requirements and the operating and financial condition of the Company.

## **DESCRIPTION OF CAPITAL STRUCTURE**

The Company is authorized to issue an unlimited number of voting and participating Common Shares without par value. As at October 31, 2023 and the date of this AIF there were 303,332,686 Common Shares issued and outstanding.

Each Common Share carries one vote at all shareholder meetings of the Company whether ordinary or special, and may participate in any dividends declared by Sernova's board or directors. The Common Shares carry the right to receive a proportionate share of Sernova's assets available for distribution to the holders of the Common Shares upon liquidation, dissolution or winding up of the Company. The Common Shares do not have any special liquidation, pre-emptive or conversion rights.

The Company has a fixed Share Option Plan (SOP) and a Deferred Share Unit Plan (DSU Plan) (together, Incentive Plan). On May 14, 2021, the Board approved the Company's amended and restated Incentive Plan, which was amended to change fixed number maximum of the SOP and DSU Plan components to a combined 15% of the then issued and outstanding Common Shares, for an aggregate total of 38,746,536 Common Shares available for reservation pursuant to the Incentive Plan. At the Company's annual shareholder meeting held June 30, 2021 the disinterested shareholders approved: (i) the amended and restated Incentive Plan and (ii) the increase to the fixed number maximum of Common Shares available for reserve under the Incentive Plan to 38,746,536.

## MARKET FOR SECURITIES

### Trading Price and Volume

The Common Shares are listed under the symbol “SVA” and during the financial year traded on the TSX. The following table sets out the high and low sale prices and the volume of trading of the Common Shares on the TSX for the months indicated:

Period	High (\$)	Low (\$)	Volume
November 2022	1.00	0.74	1,965,719
December 2022	1.00	0.69	2,494,068
January 2023	1.28	0.79	3,716,263
February 2023	1.21	0.90	1,713,981
March 2023	1.15	0.83	3,870,855
April 2023	0.95	0.78	1,743,584
May 2023	1.15	0.82	1,493,703
June 2023	1.10	0.80	2,028,377
July 2023	1.04	0.90	2,274,001
August 2023	0.92	0.71	1,341,183
September 2023	0.91	0.74	1,147,115
October 2023	0.82	0.68	1,778,405
November 2023	0.82	0.68	1,841,341
December 2023	0.77	0.61	2,938,215

The Common Shares are also listed under the symbol “SEOVF” on the OTCQB Venture Market, under the symbol “PSH” on the Frankfurt Stock Exchange and on Xetra, the electronic trading system of Deutsche Börse AG in Germany, also under the ticker-symbol “PSH”.

### Prior Sales

The following table summarizes details of each class of securities that is outstanding but not listed or quoted on a marketplace issued by the Company during the year ended October 31, 2023.

Date of Issuance	Exercise Price	Number of Securities	Description of Security
February 2, 2023	\$1.18	780,613	Stock option
April 25, 2023	\$0.84	1,595,000	Stock option
April 25, 2023	\$1.20	1,470,000	Stock option
May 30, 2023	\$0.87	153,000	Stock option
June 1, 2023	\$0.85	20,000	Stock option
June 5, 2023	\$0.83	20,000	Stock option
June 12, 2023	\$0.88	30,000	Stock option
July 24, 2023	\$0.96	1,000,000	Stock option
July 28, 2023	\$1.20	630,000	Stock option
September 5, 2023	\$0.79	3,000,000	Stock option
October 19, 2023	\$0.74	40,000	Stock option

## DIRECTORS AND OFFICERS

### Name, Occupation and Security Holding

The following table sets out the name, residence, position with Sernova and principal occupations for the previous five years of each of the directors and executive officers of Sernova, as well as the period during which each has been a director and/or an officer of Sernova and the number of Common Shares of the corporation beneficially owned by each, directly or indirectly, or over which each exercised control or direction, as at October 31, 2023.

Name, Position and Residence	Principal Occupation Last Five Years <sup>(4)</sup>	Director/Officer Since	Common Shares <sup>(4)</sup>
<b>Brett A. Whalen</b> <sup>(2)</sup> <i>Director, Board Chair</i> Ontario, Canada	Private investor; Director, NextSource Materials Inc. since July 2020; Director and Chairman, Monitor Ventures Inc, since October 2013 and April 2014, respectively; sixteen years at Dundee Corporation with last position VP, Portfolio Manager from January 2013 to September 2018.	Director: April 2023  Board Chair: April 2023	2,650,000
<b>James T. Parsons, CPA, CA</b> <sup>(1)(3)</sup> <i>Director</i> Ontario, Canada	Life sciences industry consultant and corporate director; former Chief Financial Officer of Trillium Therapeutics Inc. from August 2011 to its acquisition by Pfizer in November 2021; Director, DiaMedica Therapeutics since October 2015; Director, Oncolytics Biotech Inc. since June 2022.	April 2012	284,728
<b>Dr. Daniel Mahony</b> <sup>(1)(2)</sup> <i>Director</i> London, England	Senior Partner at Novo Holdings since January 2024; Chairman, Trellus Health plc since March 2021; Chair of UK BioIndustry Association since January 2022; former Entrepreneur-in Residence at Evotec from October 2021 to February 2023; former Co-Head of Healthcare at Polar Capital from October 2007 to September 2021.	September 2022	Nil
<b>Dr. Steven S. Sangha</b> <sup>(3)</sup> <i>Director</i> British Columbia, Canada	President and CEO, professional dental corporation since 2001; Principal Partner of family office / private investment company since 1998; Corporate Advisor, Better Life Inc since June 2023; Director, Goldhills Holding Ltd. since November 2022; Director, Blockchaink2 Corp. since September 2020.	April 2023	12,166,900

Name, Position and Residence	Principal Occupation Last Five Years <sup>(4)</sup>	Director/Officer Since	Common Shares <sup>(4)</sup>
<b>Bertram T. von Plettenberg</b> <sup>(1)(2)</sup> <i>Director</i> Kussnacht, Switzerland	Independent business consultant focusing on project development and management of active investments; a Founding Partner and CEO of CMF AG from 1999 to 2022.	April 2023	1,576,600
<b>Cynthia Pussinen</b> <i>Chief Executive Officer, Director</i> Connecticut, USA	Chief Executive Officer of the Company since September 2023; Chief Technical Officer, Spark Therapeutics, Inc. from February 2021 to December 2022; Global Vice President and General Manager, Life Sciences and Specialty Chemicals at Honeywell from 2019 to 2020; Executive Vice President, Technical Development and Operations at Actinium Pharmaceuticals, Inc from 2018 to 2019.	Officer and Director: September 2023	Nil
<b>Dr. Philip M. Toleikis</b> <sup>(5)</sup> <i>Chief Technology Officer, Director</i> Ontario, Canada	Chief Technology Officer of the Company since September 2023; President and CEO of the Company from April 2009 to August 2023.	Officer: April 2009 Director: June 2009	5,273,598
<b>David Swetlow, CPA, CA</b> <i>Chief Financial Officer</i> British Columbia, Canada	Chief Financial Officer of the Company since October 2019; business consultant to life science and technology companies; Director and Audit / Risk Committee member, Saskatchewan Science Centre from April 2018 to April 2021.	October 2019	65,000
<b>Dr. Modestus Obochi</b> <i>Chief Business Officer</i> Illinois, USA	Chief Business Officer of the Company since September 2023; Advisor, 2Flo Ventures, LLC since August 2022; Board Member, Temprian Therapeutics since August 2022; EVP, Strategy and Business Development and General Manager, API Solutions at Phlow Corporation from November 2020 to September 2023; Investment Committee Member, Accel-Rx (Canada's Health Science Accelerator) from January 2015 to August 2020; President and CEO and Board Member, Coeptis Therapeutics from February 2019 to March 2020; Strategy and Business Development Executive, Pfenex Inc from September 2017 to February 2019.	September 2023	Nil



Notes:

1. Member of the Audit Committee of the Board. Mr. Parsons is the Chair of the Audit Committee.
2. Member of the Compensation Committee of the Board. Mr. Whalen is the Chair of the Compensation Committee.
3. Member of the Nomination and Governance Committee of the Board. Mr. Parsons is the Chair of the Nomination and Governance Committee.
4. The information as to principal occupation and shares beneficially owned or over which control or direction is exercised is not within the knowledge of the Company, and therefore has been furnished by each director individually.
5. The number of Common Shares reported by Dr. Toleikis includes 352,071 Common Shares which are owned indirectly by him through PM Toleikis & Associates Consulting Inc.

### **Term of Office**

The term of office of each director of Sernova expires at the end of the annual meeting of shareholders each year. The next annual shareholder meeting of the Company is expected to be held on April 25, 2024.

### **Director and Officer Share Ownership**

As at January 26, 2024, the directors and executive officers of Sernova, as a group, owned or exercised control and direction over 22,016,826 Common Shares (2022 – 7,104,972), being approximately 7.3% (2022 – 2.3%) of the issued Common Shares on a non-diluted basis.

The information as to principal occupation, business or employment and Common Shares beneficially owned, directly or indirectly, or controlled is based on information furnished by the respective directors and executive officers and from information available at [www.sedi.ca](http://www.sedi.ca).

### **CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS**

To the knowledge of the Company, and except as otherwise set out herein, no director or executive officer, or any shareholder holding a sufficient number of securities of the Company to materially influence control of the Company: (a) is, as at January 26, 2024, or has been within the last ten years, a director, or a chief executive officer or a chief financial officer of a company (including Sernova Corp.) which, while the director or executive officer was acting in such capacity, (i) was subject to a cease trade or similar order or was refused an exemption prescribed by securities legislation for more than 30 consecutive days, (ii) has, after the termination of duties as a director or executive officer, been subject to a cease trade or similar order or been denied an exemption under securities legislation for more than 30 consecutive days due to an event that took place while that person was in office, or (iii) has, while the director or executive officer held that office or within a year of ceasing to act in that capacity, become bankrupt, made a proposal under any bankruptcy or insolvency legislation, made a proposal under any legislation relating to bankruptcy or insolvency, or was subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver-manager or trustee appointed to hold his assets, or (b) within the ten preceding years, became bankrupt, made a proposal under any bankruptcy or insolvency legislation, made a proposal under any legislation relating to bankruptcy or insolvency, or became subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver-manager or trustee appointed to hold the assets of the director, officer or shareholder, or (c) has been the subject of (i) a penalty or sanction imposed by a court relating to securities legislation or by a securities regulatory authority or entered into a settlement agreement with it, or (ii) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor making an investment.

## **CONFLICTS OF INTEREST**

Certain directors or officers of the Company are also directors, officers or shareholders of other companies and conflicts of interest may arise between their duties as a director or officer of the Company and their duties as a director, officer or shareholder of other companies. All potential conflicts of interest must be disclosed in accordance with the requirements of the *Canada Business Corporations Act*, and the directors and officers in question are required to comply with their legal obligations as well as all contractual provisions binding them. To the knowledge of the Company, no conflict of interest arose during the year ended October 31, 2022, or currently exists.

## **PROMOTERS**

On September 29, 2021, Sernova announced the engagement of New York based LifeSci Advisors LLC (LifeSci), a leading investor relations consultancy firm serving life science companies, to assist with elevating visibility and awareness of Sernova in the US markets and amongst institutional investors as well as targeted outreach initiatives. LifeSci's contract was for a fixed term of 12 months, from October 2021 to September 2022. Since the expiry of the contract term, services have continued on a month-to-month basis. LifeSci has reduced its monthly fees billing to the Company to US\$10,000 plus expenses.

## **INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Other than the transactions described below, no (a) director or executive officer of the Company, (b) person or company that is the direct or indirect beneficial owner of, or who exercises control or direction over, more than 10% of any class or series of the Company's outstanding securities, and (c) an associate or affiliate of any of the persons or companies referred to in (a) or (b), during the three most recently completed financial years or during the current financial year, has had any material interest, direct or indirect, in any transaction which has materially affected or would materially affect the Company.

On March 1, 2021, Sernova closed its bought deal financing of \$23 million led by Canaccord Genuity Corp. and Leede Jones Gable Inc. as co-lead underwriters. 19,205,000 units were issued (including the exercise in full of the underwriters' over-allotment option) at a price of \$1.20 per unit, with each unit consisting of one common share and one warrant. Each warrant is exercisable into one common share at a price of \$1.70 per common share for a period of 24 months, subject to abridgement of the exercise period if the 10-day volume weighted average trading price of the Company's common shares exceeds \$3.05 per common share. Executive officer David Swetlow, Chief Financial Officer of the Company, purchased 65,000 units in this financing. The out-of-the-money warrants expired unexercised on March 1, 2023.

## **TRANSFER AGENT AND REGISTRAR**

The Company's registrar and transfer agent is TSX Trust Company, located at Suite 1600, 1066 West Hastings Street, Vancouver, BC V6E 3X1.

## **MATERIAL CONTRACTS**

Other than contracts that were entered into in the ordinary course of business, as at October 31, 2023, the Company has not entered into any material contracts in the most recently completed financial year or before the most recently completed financial year that are still in effect, except as set out below.

- In August 2020, Sernova entered into worldwide license with the University of Miami, for the commercial rights to novel conformal coating immune protection technologies, which was

developed by Dr. Alice Tomei and her team at the Diabetes Research Institute, a designated Center of Excellence at the University of Miami Miller School of Medicine. This exclusive worldwide license agreement broadens the technological scope of Sernova's immune protection conformal coating technologies and related intellectual property.

- In May 2022, Sernova entered into an agreement with a subsidiary of Evotec SE for the Evotec Collaboration, to develop and commercialize products for the treatment of insulin-dependent diabetes, including type 1 and 2, incorporating Evotec's iPSC technologies. The agreement provides Sernova with an exclusive worldwide license option to Evotec's advanced iPSC derived islet-like clusters and associated technologies.

## **INTERESTS OF EXPERTS**

### **Names of Experts**

The Company's auditors are KPMG LLP, Chartered Professional Accountants, who have prepared an independent auditors' report dated January 26, 2024, in respect of the Company's audited annual consolidated financial statements for the two most recent fiscal years ended October 31, 2023, and October 31, 2022. KPMG LLP has advised that they are independent with respect to the Company within the meaning of the CPABC Code of Professional Conduct.

### **Interests of Experts**

To the knowledge of management of the Company, none of the persons above held, at the time of or after such person prepared the statement, report or valuation, any registered or beneficial interests, direct or indirect, in any securities or other property of the Company or of one of its associates or affiliates or is or is expected to be elected, appointed or employed as a director, officer or employee of the Company or of any associate or affiliate of the Company.

## **ADDITIONAL INFORMATION**

Additional information regarding directors' and officers' remuneration and indebtedness, principal holders of the Company's securities and securities authorized for issuance under equity compensation plans is contained in the management information circular for Sernova dated March 15, 2023, a copy of which is available under the Company's SEDAR+ profile at [www.sedarplus.ca](http://www.sedarplus.ca).

Additional financial information relating to Sernova is included in the Company's consolidated audited financial statements for the Company's fiscal years ended October 31, 2023, and October 31, 2022, together with the accompanying auditor's report and management's discussion and analysis (the "Annual Financials"). Copies of the Annual Financials, Sernova's most current interim financial statements and management's discussion and analysis, and a copy of this Annual Information Form, as well as additional information relating to the Company, may be found under Sernova's SEDAR+ profile at [www.sedarplus.ca](http://www.sedarplus.ca).

## APPENDIX A

### National Instrument 52-110 “*Audit Committees*” (“NI 52-110”) FORM 52-110F1 - AUDIT COMMITTEE INFORMATION REQUIRED IN AN AIF

#### I. The Audit Committee Charter

The Audit Committee (the “Audit Committee”) is a committee of the Board of Directors (the “Board”) of Sernova Corp. (the “Corporation”).

The audit committee has a charter (the “Audit Committee Charter”) that sets out its mandate and responsibilities.

The primary function of the Audit Committee is to assist the Board in fulfilling its financial reporting and control responsibilities to the shareholders of the Corporation and the investment community. The external auditors will report directly to the Audit Committee. The Audit Committee’s primary duties and responsibilities are:

- overseeing the integrity of the Corporation’s financial statements and reviewing the financial reports and other financial information provided by the Corporation to any governmental body or the public and other relevant documents;
- recommending the appointment and reviewing and appraising the audit efforts of the Corporation’s external auditor, overseeing the external auditor’s qualifications and independence and providing an open avenue of communication among the external auditor, financial and senior management and the Board;
- serving as an external and objective party to oversee and monitor the Corporation’s financial reporting process and internal controls, the Corporation’s processes to manage business and financial risk, and its compliance with legal, ethical and regulatory requirements;
- encouraging continuous improvement of, and fostering adherence to, the Corporation’s policies, procedures and practices at all levels.

#### II. Composition

The Audit Committee shall consist of a minimum of three directors of the Corporation, including the Chair of the Audit Committee, all of whom shall be “independent” directors as such term is defined in National Instrument 52-110 (“NI 52-110”). All members shall, to the satisfaction of the Board, be “financially literate” as defined in NI 52-110.

The members of the Audit Committee shall be appointed by a resolution of the Board at the annual organizational meeting of the Board. The Board may remove a member of the Audit Committee at any time in its sole discretion by resolution of the Board. Unless a Chair is elected by the full Board of Directors, the members of the Audit Committee may designate a Chair by majority vote of the full membership of the Audit Committee.

The Chair’s responsibilities shall include (i) providing leadership to enhance the effectiveness and focus of the Audit Committee, (ii) calling and chairing meetings of the Audit Committee ensuring that the Audit Committee meets on a regular basis, at least quarterly, (iii) setting with the Chief Financial Officer the agenda for each meeting, (iv) ensuring that the Audit Committee receives adequate and regular updates from management on all matters necessary for the Audit Committee to discharge its responsibilities, including but not limited to matters regarding audits, financial statements, MD&A, press releases, and

procedures for disclosure of financial information and disclosure controls, (v) acting as liaison between the Audit Committee and the external auditors with respect to the annual audit and (vi) acting as liaison between the Audit Committee and the Board including reporting regularly to the Board on all proceedings and deliberations of the Audit Committee. The Chair shall also appoint a Secretary of the Audit Committee who need not be a director.

### **III. Duties and Responsibilities**

1. The Audit Committee shall:

- (a) Review and recommend to the Board for approval the annual audited financial statements.
- (b) Review with financial management and the external auditor the Corporation's financial statements, MD&A's and earnings releases to be filed with regulatory bodies such as securities commissions prior to filing or prior to the release of earnings. Review of quarterly results with the external auditor will be at the discretion of the Audit Committee.
- (c) Review documents referencing, containing or incorporating by reference the annual audited consolidated financial statements or interim financial results (e.g., prospectuses, press releases with financial results and Annual Information Form ("AIF") – when applicable) prior to their public release.

2. The Audit Committee, in fulfilling its mandate, will:

- (a) Periodically review the adequacy and effectiveness of the internal controls and procedures in place which allow the Chief Executive Officer and the Chief Financial Officer to certify financial statements and other disclosure documents as required under securities laws.
- (b) Recommend to the Board of Directors the selection of the external auditor, consider the independence and effectiveness and approve the fees and other compensation to be paid to the external auditor.
- (c) Monitor the relationship between management and the external auditor including reviewing any management letters or other reports of the external auditor, and discussing and resolving any material differences of opinion or disagreements between management and the external auditor.
- (d) Review and discuss, on an annual basis, with the external auditor all significant relationships they have with the Corporation to determine their independence and report to the Board of Directors.
- (e) Review and approve requests for any management consulting engagement to be performed by the external auditor and be advised of any other study undertaken at the request of management that is beyond the scope of the audit engagement letter and related fees.
- (f) Review the performance of the external auditor and approve any proposed discharge and replacement of the external auditor when circumstances warrant. Consider with management the rationale for employing accounting/auditing firms other than the principal external auditor.
- (g) Periodically consult with the external auditor out of the presence of management about significant risks or exposures, internal controls and other steps that management has taken

to control such risks, and the fullness and accuracy of the organization's financial statements. Particular emphasis should be given to the adequacy of internal controls to expose any payments, transactions, or procedures that might be deemed illegal or otherwise improper.

- (h) Arrange for the external auditor to be available to the Audit Committee and the full Board of Directors as needed. Ensure that the auditors report directly to the Audit Committee and are made accountable to the Board and the Audit Committee, as representatives of the shareholders to whom the auditors are ultimately responsible.
- (i) Directly oversee the work of the external auditors engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services.
- (j) Pre-approve any permissible non-audit engagements of the external auditors, in accordance with applicable legislation.
- (k) Review and approve hiring policies for employees or former employees of the past and present external auditors.
- (l) Review the scope of the external audit, including the fees involved.
- (m) Review the report of the external auditor on the annual audited financial statements.
- (n) Review problems found in performing the audit, such as limitations or restrictions imposed by management or situations where management seeks a second opinion on a significant accounting issue.
- (o) Review major positive and negative observations of the auditor during the course of the audit.
- (p) Review with management and the external auditor of the Corporation's critical accounting policies, including the impact of alternative accounting policies and key management estimates and judgments that can materially affect the financial results.
- (q) Review emerging accounting issues and their potential impact on the Corporation's financial reporting.
- (r) Review with management, the external auditors and legal counsel, any litigation, claims or other contingency, including tax assessments, which could have a material effect upon the financial position or operating results of the Corporation, and whether these matters have been appropriately disclosed in the financial statements.
- (s) Review the conclusions reached in the evaluation of management's internal control systems by the external auditors, and management's responses to any identified weaknesses
- (t) Review with management their approach to controlling and securing corporate assets (including intellectual property) and information systems, the adequacy of staffing of key functions and their plans for improvements.
- (u) Review annually the code of ethics and legal and regulatory requirements that, if breached, could have a significant impact on the Corporation's published financial reports or reputation.

- (v) Review with management relationships with regulators, and the accuracy and timeliness of filing with regulatory authorities (when and if applicable).
  - (w) Review annually the business continuity plans for the Corporation.
  - (x) Review the annual audit plans of the external auditors of the Corporation.
  - (y) Review annually general insurance coverage of the Corporation to ensure adequate protection of major corporate assets including but not limited to D&O and if applicable, Key Person coverage. The identification of Key Persons is reassessed from time to time.
  - (z) Review the effectiveness of the Company's risk management system to assure that material risks are identified, and appropriate risk management processes are in place.
  - (aa) Satisfy itself that adequate procedures are in place for the review of the Corporation's public disclosure of financial information (other than the documents under section 1(b) above) extracted or derived from the Corporation's financial statements and must periodically assess the adequacy of such procedures.
  - (bb) Perform such other duties as consistent with this Charter, the Company's Articles and applicable securities legislation and policies that the Board or the Committee determines are necessary or appropriate.
  - (cc) Assist in the preparation of the disclosure required to be included in the Corporation's AIF in accordance with Form 52-110F1.
  - (dd) Establish procedures for:
    - (i) the receipt, retention and treatment of complaints received by the Corporation regarding accounting, internal controls, or auditing matters; and
    - (ii) the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or audit matters.
3. The Audit Committee may engage and communicate directly and independently with outside legal and other advisors for the Audit Committee as required and the Corporation will provide for appropriate funding, as determined by the Audit Committee, to pay any such legal or other advisors. The Corporation will also pay ordinary administrative expenses of the Audit Committee that are necessary or appropriate in carrying out its duties.
  4. On a yearly basis, the Audit Committee will review the Audit Committee Charter and where appropriate recommend changes to the Board of Directors.

#### **IV. Delegation**

The Audit Committee may delegate authority to one or more members or subcommittees when deemed appropriate, provided that the actions of any such members or subcommittees must be reported to the full Committee no later than at its next scheduled meeting.

#### **V. Secretary**

The Secretary of the Audit Committee will be appointed by the Chair.

## **VI. Meetings**

1. The Audit Committee shall meet at such times and places as the Audit Committee may determine, but no less than four times per year. At least annually, the Audit Committee shall meet separately with management and with the external auditors. Additionally, the Audit Committee may request any officer or other employee of the Corporation, counsel to the Corporation or any representative of the independent auditor, to meet with one or more members of the Audit Committee, or with counsel to another advisor to the Committee.
2. Meetings may be conducted with members present, in person, by telephone or by video conference facilities.
3. A resolution in writing signed by all the members of the Audit Committee is valid as if it had been passed at a meeting of the Audit Committee.
4. Meetings of the Audit Committee shall be held from time to time as the Audit Committee or the Chairman of the Audit Committee shall determine upon 48 hours notice to each of its members. The notice period may be waived by a quorum of the Audit Committee.
5. The external auditors or any member of the Audit Committee may also call a meeting of the Audit Committee.
6. The Board shall be kept informed of the Audit Committee's activities by a report, including copies of minutes, at the next board meeting following each Audit Committee meeting.

## **VII. Quorum**

Quorum for the transaction of business at any meeting of the Audit Committee shall be a majority of the number of members of the Audit Committee present in person or by telephone or other telecommunication device that permits all persons participating in the meeting to speak and hear each other. No business may be transacted by the Audit Committee except at a meeting of its members at which a quorum of the Audit Committee is present.

### **Composition of the Audit Committee**

The Audit Committee, at the present time, is comprised of Chair James Parsons, Dr. Daniel Mahony and Bertram von Plettenberg. Each member is financially literate and all members of the Audit Committee are independent directors. The Audit Committee will be reconstituted upon the election of directors at the forthcoming annual meeting of shareholders.

### **Relevant Education and Experience**

**James T. Parsons** is a life sciences consultant and director. He was previously Chief Financial Officer of Trillium Therapeutics Inc. (TSX/NASDAQ:TRIL) from August 2011 to its acquisition by Pfizer in November 2021 for US\$2.2 billion. Mr. Parsons has a broad background in the life sciences industry across therapeutics, diagnostics and device companies. Mr. Parsons has extensive experience in strategic planning, financing, contract negotiation, investor relations, risk management, corporate governance and public company management. Mr. Parsons also serves on the board of directors of DiaMedica Therapeutics (NASDAQ:DMAC) where he is chair of their audit committee and Oncolytics Biotech Inc (NASDAQ:ONCY). He has a Master of Accounting degree from the University of Waterloo and is a Chartered Professional Accountant and Chartered Accountant.

**Dr. Daniel Mahony** became a Senior Partner at Novo Holdings in January 2024 and has also served as Chairman of Trellus Health plc (AIM:TRLS), a digital health company, since March 2021. Dr. Mahony brings over 25 years of global healthcare investment, management and research experience covering



biotechnology, medical technology, and healthcare service sectors. Dr. Mahony was previously Entrepreneur-in-Residence at Evotec, from October 2021 to February 2023, where he was responsible for managing Evotec's equity investment portfolio. Prior to joining Evotec, he served as the Co-head of Healthcare at Polar Capital where he launched the firm's healthcare investment business in 2007 and grew it to over \$4 billion of assets under management. Prior to Polar Capital, he was head of European healthcare research at Morgan Stanley, an analyst at ING Barings Furman Selz in New York, and a postdoctoral research scientist at DNAX Research Institute in California. Dr. Mahony holds multiple industry leadership positions. He currently chairs the board of the BioIndustry Association (BIA), the industry trade association for UK life sciences, and holds non-executive directorships at the Wellcome Sanger Institute and Keepabl. In November 2022, Dr. Mahony was appointed as the UK Life Sciences Investment Envoy by the UK Government. Dr. Mahony was awarded a first-class, honours degree in biochemistry from Oxford University and received his doctorate degree from Cambridge University.

**Bertram von Plettenberg** is an independent business consultant focusing on project development, and management of active investments. Between 1999 and 2022, Mr. von Plettenberg worked as founding partner and CEO of Munich, Germany based CMF AG, a consulting and corporate finance firm, dedicated to advisory work in the fields of general corporate management, restructurings, M&A, Venture Capital, and Private Equity, areas in which he had also worked before setting up CMF AG. Mr. von Plettenberg studied law at ICADE in Madrid, Spain and received an MBA from Institut Européen d'Administration des Affaires (INSEAD) in Fontainebleau, France.

Each Audit Committee member has gained financial literacy through his/her previous working and educational experience and has a significant understanding of the life sciences business which the Corporation engages in and has an appreciation for the relevant accounting principles for that business.

#### **Reliance on Certain Exemptions**

At no time since the commencement of the Corporation's most recently completed fiscal year has the Corporation relied on the exemptions in section 2.4 (*De Minimis Non-audit Services*), section 3.2 (*Initial Public Offerings*), section 3.4 (*Events Outside Control of Member*), section 3.5 (*Death, Disability or Resignation of Audit Committee Member*) or Part 8 (*Exemptions*).

#### **Reliance on the Exemption in Subsection 3.3(2) or Section 3.6**

At no time since the commencement of the Corporation's most recently completed fiscal year has the Corporation relied on the exemption in subsection 3.3(2) (*Controlled Companies*) or section 3.6 (*Temporary Exemption for Limited and Exceptional Circumstances*).

#### **Reliance on Section 3.8**

At no time since the commencement of the Corporation's most recently completed fiscal year has the Corporation relied on section 3.8 (*Acquisition of Financial Literacy*).

#### **Audit Committee Oversight**

At no time since the commencement of the Corporation's most recently completed fiscal year was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the Board of Directors.

#### **Pre-Approval Policies and Procedures**

The Audit Committee has adopted a policy requiring pre-approval by the Audit Committee for the engagement of non-audit services by the Corporation's external auditors, which policy is contained in the Audit Committee Charter referenced above.

## External Auditor Service Fees (By Category)

The fees paid by the Company to its auditors in the last two fiscal years, by category, are as follows:

<b>Financial Year Ending</b>	<b>Audit Fees<sup>(1)</sup></b>	<b>Audit-Related Fees<sup>(2)</sup></b>	<b>Tax Fees<sup>(3)</sup></b>	<b>All Other Fees<sup>(4)</sup></b>
October 31, 2023	\$327,338	\$Nil	\$Nil	\$48,685
October 31, 2022	\$187,250	\$Nil	\$Nil	\$Nil

Notes:

1. “Audit Fees” include, where applicable, fees necessary to perform the annual audit and the quarterly review of the Company’s consolidated financial statements. Audit Fees include fees for the review of tax provisions and for accounting consultations on matters reflected in the financial statements. Audit Fees include audit and other attest services required by legislation or regulation, such as comfort letters, consents, reviews of securities filings and statutory audits.
2. “Audit-Related Fees” include, where applicable, services that are traditionally performed by the auditor. These audit-related services include employee benefits audits, due diligence assistance, accounting consultants on proposed transactions, internal control reviews and audit or attest services not required by legislation or regulation.
3. “Tax Fees” include, where applicable, fees for all tax services other than those included in “Audit Fees” and “Audit Related Fees”. This category includes fees for tax compliance, tax planning and tax advice. Tax planning and tax advice includes Assistance with tax audits and appeals, tax advice related to mergers and acquisitions, and requests for rulings or technical advice from tax authorities.
4. “All Other Fees” includes, where applicable, all other non-audit services.