



ANNUAL INFORMATION FORM

SERNOVA CORP.

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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, 2022

January 26, 2023

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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.sedar.com.

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.

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

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

- the Company's intention to protect therapeutic cells within Cell Pouch from immune attack using local immune protection technologies such as conformal coating, gene-editing, tolerance, or using a systemic anti-rejection regimen or a combination thereof and the expected benefits therefrom;
- the expected benefits of any next generation Cell Pouch System technologies;
- the expectation of successful development up to an IND submission and beyond combined with the expected benefits of using iPSC derived islet-like-clusters in combination with Cell Pouch and ancillary technologies within the Evotec Collaboration (defined hereafter);
- the Company's intentions and ability to secure academic and pharmaceutical / medtech collaborations to develop and implement partnering strategies and manage partnerships;
- the Company's intention and ability to use human autograft cells or tissues or human donor allograft cells or xenogeneic cells for treatment, and the intention to use human stem cell-derived cells (i.e., iPSCs), considered unlimited cell sources for our Cell Pouch and Cell Pouch System for the potential treatment of various diseases;
- the Company's intention and ability to obtain regulatory clearance for clinical trials and marketing approval of the Cell Pouch or Cell Pouch System for the treatment of insulin-dependent diabetes, hemophilia A, thyroid disease, and other diseases;
- the Company's intentions and ability to obtain Orphan Drug (for rare diseases), Fast Track, Breakthrough Technology, Regenerative Medicine Advanced Therapy (RMAT), Accelerated Approval or Priority Review in the US, and similar regulatory designations in North America, Europe or other jurisdictions abroad, and the related impact on timeline estimates to conduct clinical trials or obtain marketing approval for the Company's products;
- the Company's expectations that Sernova's technologies are unique and may become a standard of care in therapeutic cell transplantation if they prove to be safe and effective in clinical trials;
- the Company's expectations with respect to the research and development of Sernova's products, clinical trials, and commercialization of our products;
- the Company's commercialization strategy for our technologies including Cell Pouch or Cell Pouch System and associated technologies;
- the Company's intentions regarding the development and protection of Sernova's intellectual property;
- the Company's intentions with respect to obtaining licenses for technologies compatible with the Cell Pouch System;
- the Company's intention to develop next-generation Cell Pouch or Cell Pouch System related technologies;
- the Company's ability to secure cGMP manufacturing facilities for its cell therapy programs;
- sufficient availability of Cell Pouch product for the conduct of preclinical studies, clinical trials, and following marketing approval for commercial use;
- the direct and indirect impact of the novel coronavirus (COVID-19) and variants and any other further global health emergencies on our business and operations, including supply chain,

manufacturing, research and development costs, clinical trials including patient enrollment, contracted service providers and employees; and

- the Company's general business and economic conditions.

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

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

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

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

There are a number of important factors that could cause Sernova's actual results to differ materially from those indicated or implied by forward-looking statements and information, including but not limited to: early-stage development and scientific uncertainty, lack of product revenues and history of losses, additional financing requirements and access to capital, patents and proprietary technology, dependence on collaborative partners, licensors, contract research organizations (CROs), contract manufacturing organizations (CMOs) and others, government regulations, hazardous materials and environmental matters, rapid technological change, competition, reliance on key personnel, status of healthcare reimbursement, potential product liability and volatility of share price, absence of dividends, fluctuation of operating results and the impacts of the continuing novel coronavirus (COVID-19) pandemic or related outbreaks. Such risks

are further described under “**RISK FACTORS**” in this AIF or under “*RISK FACTORS AND UNCERTAINTIES*” in our Management’s Discussion and Analysis. 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 COVID-19 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

Name, Address and Incorporation

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, and the address of its website is 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, 2022. The audited financial statements and related management discussion and analysis for the October 31, 2022 financial year-end are filed under the Company's SEDAR profile at www.sedar.com.

DESCRIPTION AND GENERAL DEVELOPMENT OF THE BUSINESS

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

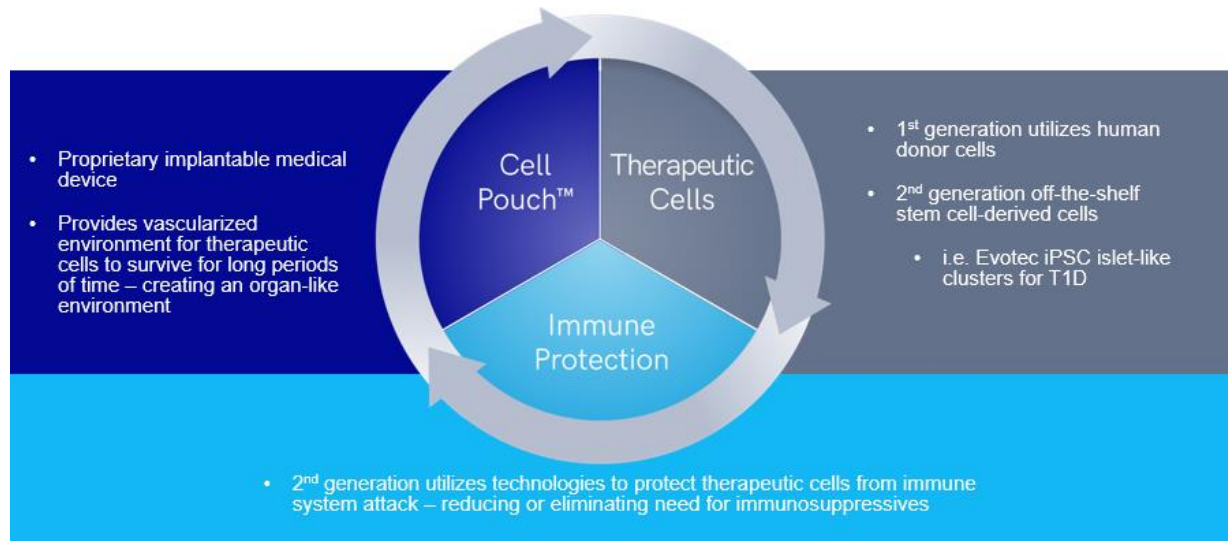
Our preclinical and clinical research studies to date support the safety and biocompatibility of Cell Pouch and long-term survival and function of therapeutic cells transplanted into the vascularized Cell Pouch chambers. Our data demonstrates that, following implantation of a Cell Pouch deep under the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

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

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

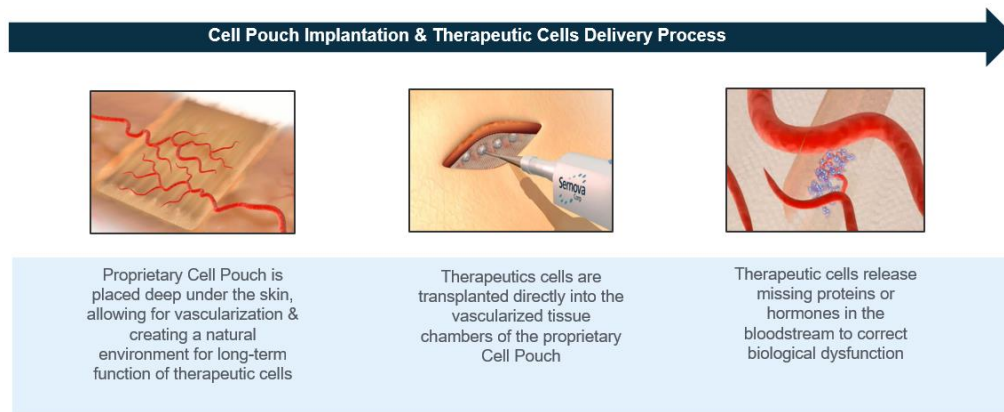
Sernova's Integrated Cell Therapeutics Solution



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



We have demonstrated in a series of ISO 10993 biocompatibility studies, multiple animal studies, a pilot human clinical trial and our ongoing US Phase 1/2 clinical trial that the Cell Pouch is biocompatible and safe. 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. An anticipated benefit of Cell Pouch is enhanced short and long-term therapeutic cell survival and function, which we believe is due in part to cells being transplanted into a natural tissue matrix in close contact of microvessels. For diabetes, this close vessel proximity enables islets to continuously monitor blood glucose levels and produce the appropriate amount of insulin into the bloodstream. The Cell Pouch platform technology appears to achieve this ideal islet-to-microvessel interaction via the Cell Pouch-mediated local tissue environment. Our preclinical studies have shown that islets transplanted into the Cell Pouch can control blood glucose levels in small and large animal models of diabetes over extended periods. We have also observed encouraging preclinical results in other therapeutic cell applications, such as hemophilia A with corrected patient cells gene-edited to produce factor VIII, the missing protein preventing blood clotting, and hypothyroid disease with patient transplanted thyroid tissue with the goal to replace the function of the removed thyroid gland.

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

Thus, we believe our technology platform approach and its minimally invasive implantation approach through placement deep under the skin 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'.

Pipeline – Life Cycle Iterations and Multiple Indications

Lead Program Has Demonstrated POC Efficacy & Excellent Safety in Type 1 Diabetes

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

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

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

According to the International Diabetes Federation (IDF), there are approximately 537 million people worldwide with diabetes, and nearly 10% of these individuals have T1D (insulin-dependent) diabetes (<https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html>) where the cells in the pancreas that control blood sugar levels through controlled release of insulin have stopped functioning or have died, allowing blood sugar levels to rise resulting in short and long-term debilitating effects of the disease. In particular, the sub-set of people with diabetes who suffer from hypoglycemia unawareness events represents a significant proportion of diabetic patients that could be addressed by Sernova’s products – following regulatory approval. About 17% of people with T1D suffer from hypoglycemia unawareness, according to diabetesnet.com.

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

Our most advanced development program involves the clinical development and validation of the Cell Pouch System for the treatment of people with T1D who suffer from unstable diabetes and life-threatening severe hypoglycemic episodes. In some countries, the current cell therapy is transplantation of donor islets

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

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

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

As noted in Table 1 below, we believe the Cell Pouch System can alleviate a number of important issues with portal vein transplantation. With the Cell Pouch System, the therapeutic cells live within a tissue matrix integrated with microvessels, similar to the islets' natural pancreatic environment rather than being subjected to immersion in blood with immune-reactive cells, which is believed to lead to IBMIR. We believe islet transplant to Cell Pouch may eliminate the inflammatory response observed after portal vein infusion, enabling improved islet survival. Improved islet survival and engraftment potentially lowers the number of islets required for each transplant. Consequently, by transplanting islets into 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 increasing the availability of these life-sustaining organs. In addition, the known side effects of multiple islet infusions into the portal vein, along with the risks and costs associated with their treatment are expected to be eliminated with the use of Sernova's Cell Pouch System. These benefits are expected to be further magnified by Sernova's development of Cell Pouch therapy with our glucose responsive stem cell-derived technologies. (see Table 1).

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

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

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

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

Importantly, Cell Pouch technologies are specifically and uniquely designed to be biocompatible featuring pores that incorporate with vascularized tissue to form fully enclosed chambers with central void spaces for placement of therapeutic cells. A serious problem that may be encountered with other implanted therapeutic medical devices is the development of unwanted fibrosis in which the body treats the device as foreign and walls off the device with scar tissue resulting in starving of the cells of oxygen and nutrients. We believe the unique design of the Cell Pouch device prevents the formation of scar like fibrotic tissue following implantation for the long-term survival and function of 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 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 a small 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) resulting in a lower overall Cell Pouch cell density to achieve efficacy, one of the parameters being investigated and optimized in human clinical evaluation to achieve glucose control in patients with diabetes.

We have manufactured our Cell Pouch at a U.S. medical device contract-manufacture facility in compliance with ISO13485, EU Medical Devices Regulation MDR 2017/745, USFDA Quality System Regulations (QSR) 21 CFR 820 and Canadian Medical Device Regulation (CMDR). 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, including our current US Phase 1/2 Cell Pouch Clinical Trial T1D study with donor islets and in preparation for next step studies with the Evotec iPSC beta cell technology.

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

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

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

- the biocompatibility and a favorable safety profile of Cell Pouch in these subjects; and
- the islets within the Cell Pouch, as shown by independent histological analysis, were well-vascularized, living within a natural tissue matrix, and able to make insulin, glucagon, and other key hormones important in the control of blood glucose levels and hypoglycemic events.

We believe such revascularization of islets and islet metabolic function within Sernova's implantable medical device for therapeutic cells in humans in this patient population is an important step forward in the cell therapy therapeutics field.

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, our goal is to have and enable the Cell Pouch System to offer treatment to the broader general patient population of millions of people with diabetes. Consequently, we sought out an ethically derived advanced iPSC beta cell technology with the potential to be successfully commercialized. With the proprietary assets of multiple pharmaceutical companies, we demonstrated that ethically derived iPSC stem cell-derived beta cells can provide long-term insulin independence in small animal models of diabetes when transplanted into the Cell Pouch. We believe ethically derived induced pluripotent stem cells - iPSCs - are superior to progenitor embryonic stem cell-derived cells as embryonic cell derived technologies are not allowed in certain regulatory jurisdictions limiting their use in patients and potential commercial viability. Furthermore, fully differentiated islet-like clusters could provide required insulin to patients sooner than progenitor islet technologies.

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 secures a virtually unlimited supply of ethically derived advanced iPSCs and eliminates the limitation of a restrictive supply of donor islets for product commercialization. We believe that this 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 iPSCs in combination with

the Cell Pouch and immune protection technologies is a priority in our future clinical development plans and product pipeline. For more information on Evotec's iPSC technology, refer to the "*Significant Acquisitions, In-Licensing and Collaborations*" section within this AIF.

Type 1 Diabetes Phase 1/2 US Clinical Trial for Patients with T1D and Severe 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\$2.45 million (approximately \$3.35 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, severe hypoglycemic unawareness and a history of severe hypoglycemic events despite optimized medical care, and lack the ability to produce insulin from their pancreas, as shown in a glucose tolerance test by the lack of necessary blood levels of C-peptide, a quantitative biomarker of islet insulin production. Eligible patients are implanted with therapeutic Cell Pouches, and small sentinel 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 pre-implanted Cell Pouches.

A sentinel pouch, also transplanted with islets, is removed at approximately 90 days following transplant for an early assessment of islet function within the Cell Pouch. Following three to six months post-transplant the clinical investigator determines if a second small islet dose will be transplanted followed by a subsequent 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 dose of donor islets. The goal of providing up to three doses of islets is to determine the relationship between therapeutic effect and both islet dose and dose density in 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. The transition to this new larger Cell Pouch under the revised 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 Dr. Witkowski.

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

At key timepoints during the trial, islet-transplanted sentinel devices are removed and subjected to histological assessment by an independent pathologist. In several patients, and from multiple timepoints, healthy and abundant insulin-producing islets have been observed in the sentinel Cell Pouches 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 recently introduced, in November 2022, the noted higher capacity 10 channel Cell Pouch to accommodate what we believe to be the optimal full dose of islets required to potentially eliminate the need for intraportal islet transplantation.

We believe these preliminary findings are an important achievement in the cell therapeutics field and a first for an implanted prevascularized device with islet cells, transplanted deep under the skin. These encouraging results using human donor islets in our Cell Pouch in subjects with hypoglycemia unawareness represents an important advance of our stepwise approach toward our goal of developing and optimizing a treatment for all T1D patients employing immune protected stem cell-derived iPSC islet-like-clusters within our Cell Pouch.

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

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 October 16, 2019, we announced the detection of enduring levels (measured up to 30 days and ongoing) of C-peptide, a biomarker of transplanted beta-cell insulin production, in the bloodstream of a fasting patient in our US Phase 1/2 Cell Pouch Clinical Trial. The detection of fasting C-peptide in the bloodstream of our first patient, combined with our earlier announced observation of glucose-stimulated C-peptide and other early efficacy indicators, is believed to demonstrate a normalizing response of the Cell Pouch therapeutic cells to the body's varied need for insulin production. This is an important indicator and evidence of ongoing islet engraftment within the Cell Pouch. On February 10, 2020, we announced that an independent Data Safety Monitoring Board (DSMB) completed its first interim analysis of our clinical trial. The DSMB is an independent group of clinical research experts who review the accumulated safety data throughout the clinical trial to safeguard the safety and interests of participating patients while ensuring the scientific validity and integrity of the trial. This interim analysis was the first of three planned DSMB reviews of this clinical trial. The DSMB did not raise any concerns regarding safety and recommended continuation of the study.

On February 13, 2020, we announced that the first patient treated in the clinical trial demonstrated survival of endocrine tissue (insulin-producing islets) in the sentinel Cell Pouch following 90 days after transplant and that the islets were confirmed to produce insulin.

On June 18, 2020, the Company announced it had presented its abstract *“Clinical Validation of the Implanted Pre-Vascularized Cell Pouch as a Viable, Safe Site for Diabetes Cell Therapy”* the virtual presentation of the 80th Scientific Sessions of the American Diabetes Association (ADA). The data presented clinically demonstrated that the vascularized Cell Pouch provides a consistently safe and biologically suitable, retrievable environment for the transplantation and survival of functional islets.

On November 18, 2020, we provided a Clinical Update on our US Phase 1/2 Cell Pouch Trial, noting that 5 of 7 patients had been enrolled in the study defined by meeting the enrollment criteria and implanted with the Cell Pouch. Further, that these subjects were actively advancing through the transplantation phase of the study.

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 Allotransplantation 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 Allotransplantation 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 Allotransplantation 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 USFDA, to add a second cohort of up to seven patients to test the aforementioned enhanced capacity 10 channel Cell Pouch and further optimize patient outcomes. The amendment was based on promising positive interim data to date from our

clinical study informing on islet dose and density. The amendment enables us to proceed with a strategically optimized protocol reducing the time required for patient treatment while accelerating potential secondary endpoint efficacy achievement with more optimal dosing. We have engaged a clinical trial recruitment partner with extensive experience and success in accelerating T1D clinical trial patient enrollment to expedite recruiting and patient enrollment and we expect to report on interim data from the second cohort with the enhanced capacity Cell Pouches in 2023. On November 17, 2022, we provided an update that the first two patients of the second cohort have been implanted with the enhanced 10 channel Cell Pouch. Recruitment of the second cohort is continuing.

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

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

Development of the Cell Pouch System for the Treatment of Postoperative Hypothyroidism

The 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. Its essential functions include control of how quickly the body uses energy, makes proteins, and sensitivity to other hormones, principally through the production of the thyroid hormones triiodothyronine (T3) and thyroxine (T4).

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

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

Following thyroidectomy, patients require daily hormone replacement therapy with T4. Published research indicates up to 50% of thyroxine users do not achieve adequate hormone levels (Okosieme, OE et al. Expert

Opin Pharmacother 2011; 12(15):2315-2328). Moreover, it is evidenced that patients treated with T4 still experienced several symptoms of hypothyroidism, including deficits in cognition and mood, ability to focus, and general mental well-being (Kansagra, S. et al. Laboratory Medicine 2010; 41(6):338-48.). Results of our preclinical research are being used as a foundation for anticipated clinical trials using Cell Pouch in combination with thyroid-hormone producing cells with the goal to preserve or recover normal thyroid regulation and improve patient quality of life.

Sernova has conducted preclinical research with our 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. We have 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 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.

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

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

The goals of our hemophilia program are to provide people with hemophilia A improvement in the natural

production of factor VIII (FVIII) in their bloodstream from FVIII corrected cells within the Cell Pouch, to reduce bleeds associated with this disease, an improved quality of life and ultimately a ‘functional cure’ to this disease.

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

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

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

On May 19, 2020, the HemAcure Consortium presented the scientific results of the consortium’s HemAcure Hemophilia Cell Therapy Program research, noted above, at the 23rd American Society of Gene & Cell

Therapy (ASGCT) Annual Meeting. The results support the potential of using genetically corrected cells from a patient's own BOECs transplanted into the Cell Pouch to replace missing clotting human FVIII in patients with hemophilia A.

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

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

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

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

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

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

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

On January 28, 2021, we provided a Collaborations Update highlighting Sernova had multiple active research collaborations with major pharmaceutical companies. In this regard, Sernova is deploying its in-house cell therapy expertise and proprietary Cell Pouch technologies in combination with proprietary therapeutic cell assets designated by the pharmaceutical collaborators to conduct proof of concept studies for additional potential clinical indications. These collaborations with leaders in the pharmaceutical industry build upon our business strategy to develop a portfolio of therapeutic technologies to realize the full potential of Sernova's cell therapeutics platform. We believe collaborating / partnering with multiple pharmaceutical and life science companies will not only expand our therapeutic treatment potential but also provides a de-risked approach for Sernova as we develop our technologies and bring new therapies to patients with the goal to provide people with a 'functional cure' for multiple chronic and rare diseases. To date we have obtained encouraging results assessing various stem cell-derived technologies for a number of clinical indications and we are continuing to advance select collaborations with the goal of achieving long-term development partnerships.

Local Immune Protection & Other Complementary Technologies

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

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.

In 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.

In August 2020, we announced entering into 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 two-year agreement, the Company committed to fund the first-year budget of up to US\$833,154 (approximately \$1,137,172). Technology optimization and further preclinical validation work is progressing as expected and continuing, with the associated second year budget awaiting finalization but anticipated to be similar to that of the first year noted above. Dr. Tomei is one of the original inventors of the Conformal Coating Technology that has been developed and optimized over twelve years with her dedicated team. This important collaboration is multifaceted in nature and designed to advance for the first time locally immune protected cells within the Cell Pouch with the goal of advancing these technologies into clinical trials without the need for life long immune suppression technologies. We believe successful development of this combination technology could meet an unmet need in a broader population of people with T1D who seek a 'functional cure' for their diabetes without the need to take life-long immunosuppression medications.

Subsequent to the collaboration announcement, 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. The webinar is available on the Sernova website at www.sernova.com/investor/#News_Releases/ or at <https://youtu.be/U57fkmsBT7k>.

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

Cell Tolerance Approach (Gene Editing)

In May 2020, we entered into a research collaboration with AgeX Therapeutics, Inc. to investigate their UniverCyte gene-editing technology to generate such transplantable therapeutic cells for use in combination with our Cell Pouch to provide a total cell therapy therapeutic solution for the treatment of chronic diseases. The goal of this collaboration was to evaluate the technology as one of several potential next-generation local immune protection approaches for therapeutic cells or tissue transplanted into the Cell Pouch. The research collaboration was extended into fiscal year 2022 and the initial evaluation work was concluded during the recently completed 2022 fiscal year.

UniverCyte uses a novel modified form of HLA-G, a potent immunomodulatory molecule, which may mask transplanted therapeutic cells from immune detection and attack. The objective of the research collaboration was to evaluate whether stem cell-derived therapeutic cells engineered with the UniverCyte technology could potentially evade human immune detection. The approach of HLA-G is one of a number of immune evasive mechanisms that alone or in combination could enable the transplantation of therapeutic cells in patients within an off-the-shelf manner using Sernova's Cell Pouch, without human leukocyte antigen (HLA) tissue matching or permanent concurrent administration of immunosuppressive medications. We continue to evaluate these mechanisms to find the optimal solution, in light of the complex human immune system.

This work is allowing Sernova to further identify and evaluate technologies complementary to Sernova's Cell Pouch therapeutic platform and to expand Sernova's immune protection offerings with potential benefit over current immunosuppressive strategies for cell therapeutics and to expand market penetration potential for our future product offerings.

Sernova's Access to Multiple Sources of Therapeutic Cells

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

We are developing stem cell-derived technologies with the expectation to provide a virtually unlimited supply of cells for the treatment of diabetes to overcome the limited supply of human donor islets. Pursuant to our strategy of obtaining sources of supply for our therapeutic cell applications, the Company entered into a license agreement with the University Health Network in Toronto, Ontario, Canada. This license agreement gives us exclusive worldwide rights to certain patented and patent-pending technologies for the advancement of glucose-responsive insulin-producing stem cells for treatment of patients with insulin-dependent diabetes. As mentioned above, Sernova is also expanding its collaborations with global pharmaceutical partners to evaluate various cell technologies using different approaches combining Sernova and partner technologies with the goal to create best-in-class therapeutics.

In addition, a collaboration with an international pharmaceutical company to study Sernova's Cell Pouch in a large animal diabetes model has been successfully conducted. The collaboration involved the study of safety, survival, and efficacy of locally immune protected xenogeneic therapeutic islets in our Cell Pouch in a proof-of-concept study.

We have demonstrated long-term insulin independence in several collaborations with global pharmaceutical partners using advanced iPSC stem cell-derived diabetes technologies within the Cell Pouch in accepted animal models of T1D. This work supported the concept of the Cell Pouch combined with an advanced stem cell source meant to provide an unlimited supply of therapeutic cells to treat a significant number of T1D subjects. These collaborations resulted in Sernova and Evotec coming to terms on an iPSC derived beta cell technology for Sernova.

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

Corporate Developments

On September 23, 2020, Sernova announced the completion of an oversubscribed \$3.7 million non-brokered private placement. 12,218,333 units were issued at \$0.30 per unit, with each unit consisting of one common share and one warrant. Each warrant entitles the holder to acquire one common share at \$0.35 per common share for a period of 24 months, subject to abridgment of the exercise period if the 10-day volume-weighted average price of the Company's common shares exceeds \$0.50 per common share. The Company also issued 198,310 warrants and paid a total of \$59,493 to qualified finders. The hold period of four months for all securities issued in connection with this private placement expired January 23, 2021.

On November 2, 2020, Sernova announced that it had obtained TSX Venture Exchange (Exchange) approval to extend the expiry date of 11,016,000 outstanding share purchase warrants. The new expiry dates of the subject warrants, which were to expire on November 14, 2020, and November 21, 2020, are February 12, 2021, and February 19, 2021. All other terms and conditions, including the exercise price of \$0.35 per share, remain the same. The subject share purchase warrants were subsequently fully exercised.

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 3, 2021, Sernova announced entering into an agreement for a \$10 million bought deal unit financing co-lead by Leede Jones Gable Inc. and Canaccord Genuity Corp. 8,350,000 units will be issued at a price of \$1.20 per unit with each unit consisting 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 February 4, 2021, Sernova announced the upsizing of the \$10 million bought deal unit financing announced on February 3, 2021 to \$20 million. 16,700,000 units will be issued upon closing. All terms of the upsized offering remain the same.

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 February 25, 2021, Sernova announced that the TSX Venture Exchange recognized Sernova as a 2021 Venture 50 company, showcasing the top 50 performing listed companies. The Venture 50 are the top ten companies listed on TSX Venture Exchange in each of five major industry sectors – mining, energy & energy services, clean technology & life sciences, diversified industries and technology – based on a ranking formula with equal weighting given to market cap growth, trading volume amount and share price appreciation.

On March 1, 2021, Sernova completed a \$20M upsized bought deal unit financing, 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.

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 September 29, 2021, Sernova announced the engagement of New York based LifeSci Advisors LLC, 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.

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.

On February 24, 2022, Sernova announced that the TSX Venture Exchange had again recognized Sernova as a top 50 performing listed company as part of its 2022 TSX Venture Top 50 list. Sernova ranked #1 in the Clean Technology and Life Sciences category.

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

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

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

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 30th, 2022. Dr. Mahony is Entrepreneur-in-Residence at Evotec SE (Evotec) and is also responsible for managing Evotec's equity investment portfolio. Dr. Mahony brings over 25 years of global healthcare investment, management and research experience covering biotechnology, medical technology, and healthcare service sectors.

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).

In December 2022, as part of a planned leadership succession process and management team expansion, we announced that after a successful 13-year tenure leading the Company through the development of its pioneering Cell Pouch System and ensuing growth, current President and Chief Executive Officer Dr. Philip Toleikis will assume the new position of Chief Technology Officer once a new Chief Executive Officer has been recruited and joins the Company. A comprehensive executive search process is underway.

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

Significant Acquisitions, In-Licensing and Collaborations

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

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

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

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

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

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

Conformal Coating Technology Acquisition

As note 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.

Gene Editing Collaboration

As noted above, during May 2020 Sernova announced a collaboration with AgeX Therapeutics, Inc. ("AgeX"), a biotechnology company developing therapeutics for human aging and regeneration, where Sernova would utilize AgeX's UniverCyte™ gene technology to generate immune-protected universal therapeutic cells for use in combination with Sernova's Cell Pouch for treatment of T1D diabetes and

hemophilia A. Sernova's goal is to reduce or eliminate the need for immunosuppressive medications following Cell Pouch cell transplantation.

Under the initial terms of the agreement, Sernova was granted a time-limited, non-exclusive research license by AgeX. The research collaboration was extended into fiscal year 2022 and the initial evaluation work was concluded during the recently completed 2022 fiscal year. Whether a licensing agreement and clinical evaluation of the technology in a diabetes stem cell-derived program is ultimately pursued will depend on the final assessment of the work completed and any future additional preclinical evaluation deemed necessary to be undertaken, as well as access to other third-party gene-editing technologies now or in the future by the Company.

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 human insulin market accounted for US\$22 billion in 2019. 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.

In this regard as of 2021, the global annual cost of diabetes was evaluated at US\$966 billion. The Company believes the Cell Pouch diabetes therapeutic platform under development for treatment of patients with insulin-dependent diabetes will 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 market for the orphan indication hemophilia A represents an estimated US\$11.8 billion annually, 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\$2.3 billion in 2020. 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 USFDA, the EU and other 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 in 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. USFDA or Health Canada, as part of an Investigational New Drug (IND) application (for USFDA) 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 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 FDA may grant marketing approval, request additional information, or deny the application if the 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 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 major medical device and or 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 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 favourable terms.

Currently Sernova has multiple active research collaboration agreements with global pharma companies with Sernova deploying its in-house cell therapy expertise and proprietary Cell Pouch technologies in combination with proprietary therapeutic cell assets designated by the pharma collaborators. We believe these collaborations reflect the value and evolving recognition of our technologies and cell therapy platform. These important collaborations with leaders in the pharmaceutical industry build upon our business strategy to develop a portfolio of products to realize the full potential of Sernova's cell therapy therapeutic platform by extending and broadening its application to new therapeutic areas and modalities. We believe partnering with multiple pharmaceutical companies not only will expand our therapeutic treatment potential but also provides a de-risked approach for Sernova as we develop our technologies and bring new therapies to patients with the goal to provide people with a functional cure for multiple chronic and rare diseases.

We have now shown in our collaborations with two advanced glucose responsive stem cell-derived technologies in combination with Sernova's Cell Pouch that the combination achieved long-term insulin independence in small animal models of T1D. Non-diabetes potential indications with another global pharma company's stem cell-derived technologies are also under evaluation. The research work and business discussions with our global pharma research collaborators are continuing.

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 human 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; USFDA 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 Cell Pouch System to further 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 aggressively 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.

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, 2022, our common shares traded on the TSX Venture Exchange and TSX Exchange at a high of \$2.22 and a low of \$0.69 per share (2021 fiscal year – high of \$2.87 and low of \$0.26 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 Supply and Manufacture 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.

Medical device manufacturers are subject to ongoing periodic unannounced inspection by Health Canada, the USFDA, 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

We face risks related to the ongoing COVID-19 pandemic, health epidemics, and other outbreaks, which could materially and adversely affect our business, financial condition, and results of operations. In December 2019, COVID-19 emerged in Wuhan, China. During March 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. In response to the outbreak, governmental authorities around the world introduced various recommendations and measures to mitigate the spread of COVID-19, including restrictions on travel, border closures, quarantines, forced closures for certain types of public places and non-essential businesses and social distancing. The recommendations and measures are having a significant impact on the private sector and individuals, including unprecedented business, employment and economic disruptions.

The ongoing COVID-19 pandemic has impacted the Company's business to some extent. Early on during the pandemic, our US Phase 1/2 Clinical Trial was impacted by the temporary COVID-19 related closure of the medical clinic at the University of Chicago and clinical trial and CRO personnel working remotely, which had the effect of slowing the screening of prospective trial participants, the conduct of patient procedures and some clinical trial data collation activities. The closure subsequently eased with COVID-19 safety provisions and the conduct of patient procedures resuming. Thereafter, efforts were made at the clinical trial site to expedite any impacted patient procedures in various stages of progress and the completion of patient enrollment. However, with the subsequent (re)emergence and (re)escalation of COVID-19 variants, the scheduling and timing of some remaining patient procedures has been and may continue to be unpredictably impacted due to changes in OR (operating room) availability due to everchanging restrictions or the reluctance of some non-local study patients to travel to the University of Chicago clinical trial site during periods of increased prevalence or resurgence of COVID-19 infections. COVID-19 has also impacted the progression of some international research collaboration activities due to third-party facility access and travel restrictions or limitations; however, provisions have been and continue to be made as required to minimize the impact on collaboration activities and conditions in general have improved.

In response to the COVID-19 pandemic, we have implemented protocols and procedures for the safety and protection of our employees, contractors, service providers and collaborators, and continue to make adjustments in response to changing government regulations and directives. COVID-19 and the emergence of variants could further impact the Company's expected timelines and operations, or the operations of our CRO, our third-party service providers or suppliers and our contract manufacturer, as a result of quarantines, facility closures, travel and logistics restrictions and other limitations in connection with the outbreak. The most significant risks posed by the ongoing COVID-19 pandemic is that it could significantly impact the progress and completion of our US Phase 1/2 Clinical Trial and the advancement of our preclinical and collaborative research activities.

It is unknown how long the adverse conditions associated with COVID-19 and subsequent variants will last and what the complete financial effect will be to the Company. Depending on the duration of the ongoing COVID-19 pandemic and actions taken or extended by federal, provincial, state or international governments and public health officials could result in:

- delays or difficulties in enrolling patients or retaining patients in our clinical trials if patients are affected by the virus or are unable to travel to our clinical trial site;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal, provincial or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- limitations on employee resources focused on the conduct of our preclinical studies and clinical trials, due to sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays or difficulties in clinical site initiation for new studies, including difficulties in recruiting clinical site investigators, clinical site staff and study subjects; and
- limited access to third-party laboratory facilities to conduct preclinical activities or progress our research collaborations.

To the extent the ongoing COVID-19 pandemic, or other health epidemic or outbreak, adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this Risk Factors section. Because of the highly uncertain and dynamic nature of events relating to the continuing COVID-19 pandemic, it is not currently possible to estimate its impact on our business, results of operations and financial condition beyond that discussed above. However, these effects could have a material impact and we will continue to monitor the ongoing COVID-19 pandemic situation.

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. It is not known whether any of these product candidates will meet applicable health regulatory standards and obtain required regulatory approvals, or whether such products can be produced in commercial quantities at reasonable costs and be successfully marketed, or if our investment in any such products will be recovered through sales or royalties.

We 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 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 Company'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 Company. These factors indicate the potential existence of a future material uncertainty that may cast significant doubt on the ability of the Company to continue as a going concern. We expect that our existing combined cash and marketable securities as at October 31, 2022 of \$49,776,054 will enable us to fund our current operating plan requirements for at least the next twelve months. 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.

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 USFDA, 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 USFDA, 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 USFDA, 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 USFDA, 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 USFDA, 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 USFDA, 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 USFDA, 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 USFDA, 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 USFDA, 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 USFDA, 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 unfavourably 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 USFDA, 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 Company 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. 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 Company'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 a third-party contract manufacturer to manufacture our products. Health Canada and the USFDA 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 manufacturer 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 Company's business, and if the Company'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 Company currently carries what it believes to be adequate product liability and clinical trial insurance, there can be no assurance that the Company 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 Company's business. If a product is withdrawn or a product liability claim was brought against the Company, it could significantly damage the Company'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 USFDA 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, 2021, we incurred losses of \$24,420,536 (2021 - \$6,965,539) and had an accumulated deficit as of October 31, 2022 of \$79,169,487. 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 (US). US 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, 2022, and 2021, 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 US shareholder’s holding period of our common shares, then such US 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 US 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 US 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 US shareholder should consult its own tax advisors regarding the PFIC rules and the US 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.

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.

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, 2022 there were 303,332,686 Common Shares issued and outstanding. At as the date of this AIF, there were 303,332,686.

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; (ii) the increase to the fixed number maximum of Common Shares available for reserve under the SOP to 30,997,229 Common Shares and (iii) the increase to the fixed number maximum of Common Shares available for reserve for conversion of DSUs to 7,749,307 Common Shares.

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-V (from November 2021 – June 1, 2022) and TSX (from June 2, 2022 onwards). The following table sets out the high and low sale prices and the volume of trading of the Common Shares on the TSX-V and TSX for the months indicated:

Period	High (\$)	Low (\$)	Volume
November 2021	1.62	1.22	4,102,694
December 2021	2.03	1.26	5,875,503
January 2022	2.22	1.31	13,989,570
February 2022	1.74	1.30	3,770,094
March 2022	1.51	1.345	4,146,444
April 2022	1.57	1.33	2,753,182
May 2022	1.80	1.33	5,208,712
June 2022	1.59	0.94	6,025,762
July 2022	1.28	1.06	1,525,346
August 2022	1.21	0.98	1,716,697
September 2022	1.17	0.81	2,995,281
October 2022	0.86	0.69	2,377,155
November 2022	1.00	0.74	1,965,719
December 2022	1.00	0.69	2,494,068

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

For information related to the 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, 2022, refer to the “*Liquidity and Capital Resources*” section of our Management’s Discussion and Analysis.

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, 2022.

Name, Position and Residence	Principal Occupation Last Five Years⁽⁴⁾	Director/Officer Since	Common Shares⁽⁴⁾
Frank A. Holler⁽²⁾⁽³⁾ <i>Director, Board and Executive Chair</i> British Columbia, Canada	President and CEO of Ponderosa Capital Inc. since May 2003; Director, Theratechnologies Inc. since June 2021; Director and Chairman of the Board, Harvest One Cannabis (now Delivra Health Brands Inc.) since September 2018; former Director of Xenon Pharmaceuticals from 1999 to June 2021.	Director: February 2014 Executive Chairman: December 2021	666,666
Jeffrey A. Bacha⁽¹⁾⁽²⁾ <i>Director</i> British Columbia, Canada	Executive Chairman of Rakovina Therapeutics Inc. since September 2020; CEO of Edison Oncology Holding Corp. since August 2018; Co-Founder, former Chief Executive Officer and former Chairman of DelMar Pharmaceuticals, Inc. (now Kintara Therapeutics, Inc.) from 2010 to 2017.	October 2008	614,980
Dr. Philip M. Toleikis⁽⁵⁾ <i>President and Chief Executive Officer, Director</i> Ontario, Canada	President and CEO of the Company since April 2009.	Officer: April 2009 Director: June 2009	5,273,598
James T. Parsons, CA, CPA⁽¹⁾ <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
Deborah M. Brown⁽¹⁾⁽³⁾ <i>Director</i> Ontario, Canada	Lead, Strategic Partnerships at EVERSANA Life Science Services, LLC since July 2021; Managing Partner of Accelera Canada (acquired by EVERSANA) from May 2017 to July 2021; Director, Oncolytics Biotech Inc. since November 2017; Director, Cardiol Therapeutics Inc. from September 2018 to September 2021.	April 2019	200,000

Name, Position and Residence	Principal Occupation Last Five Years ⁽⁴⁾	Director/Officer Since	Common Shares ⁽⁴⁾
Dr. Mohammad Azab ⁽²⁾⁽³⁾ <i>Director</i> California, United States	Chairman of the Board of Astex Pharmaceuticals, Inc. since November 2020; former President and Chief Medical Officer of Astex Pharmaceuticals, Inc. from July 2009 to November 2020; Director, Xenon Pharmaceuticals since January 2003; Director, Durect Company since January 2021.	June 2021	Nil
Dr. Daniel Mahony <i>Director</i> Milton, England	Entrepreneur-in Residence at Evotec since October 2021; former Co-Head of Healthcare at Polar Capital from October 2007 to September 2021.	September 2022	Nil
David Swetlow, CA, CPA <i>Chief Financial Officer</i> British Columbia, Canada	Chief Financial Officer of the Company since October 2019; business transformation consultant to life science and technology companies; Director and Audit / Risk Committee member, Saskatchewan Science Centre from April 2018 to April 2021; Saskatchewan Institute Council Member of the Canadian Association of Management Consultants (CMC) as Public Representative appointed by the Government of Saskatchewan, from September 2014 to August 2019.	October 2019	65,000

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. Bacha is the Chair of the Compensation Committee.
3. Member of the Nomination and Governance Committee of the Board. Ms. Brown 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 be held on April 27, 2023.

Director and Officer Share Ownership

As at January 26, 2023, the directors and executive officers of Sernova, as a group, owned or exercised control and direction over 7,104,972 Common Shares (2021 – 6,799,971), being approximately 2.3% (2021 – 2.6%) 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.

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, 2023, 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.

Frank A. Holler was previously the Chairman & CEO of BC Advantage Funds (“Advantage”), a venture capital fund investing in emerging technology companies. On July 5, 2013 one of Advantage’s publicly traded portfolio companies, Allon Therapeutics Inc. (Allon), made a proposal to its creditors under the *Bankruptcy and Insolvency Act*, and a reorganization of its share structure was approved by the Supreme Court of British Columbia. Following such approval, all of the issued and outstanding shares of Allon were acquired by Paladin Labs Inc. The common shares of Allon were delisted from the Toronto Stock Exchange on June 28, 2013. Mr. Holler was a director of Allon and ceased to be a director of that company effective July 16, 2013.

On December 23, 2013 a privately held Advantage portfolio company, Contech Enterprises Inc., made a proposal to its creditors under the *Bankruptcy and Insolvency Act*, and a reorganization of its capital structure was approved by the Supreme Court of British Columbia on January 26, 2015. This proposal was intended to facilitate a financing by a new lender and a debt restructuring that, together, would enable the company to carry on its business profitability for the foreseeable future. However, on March 6, 2015, the Court of Appeal overturned the approval of the proposal by the Supreme Court and placed the company into bankruptcy. Mr. Holler was a director of Contech Enterprises and ceased to be a director of that company effective March 6, 2015.

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 is for a period of 12 months, from October 2021 to September 2022, with monthly remuneration of US\$17,500 plus expenses. Contract renewal is in progress, during which time the contract is continuing on a month-to-month basis.

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 September 23, 2020, Sernova closed a non-brokered private placement of \$3.7 million. 12,218,333 units were issued at a price of \$0.30 per unit, with each unit consisting of one common share and one common share purchase warrant, which each common share purchase warrant exercisable into one common share at \$0.35 per common share for a period of 24 months, subject to abridgment of the exercise period if the 10-day volume-weighted average price of the Company's common shares exceeds \$0.50 per common share. The following directors participated in the private placement:

- Deborah M. Brown – 100,000 units
- Frank A. Holler – 83,333 units
- James T. Parsons – 10,000 units
- Jeffrey A. Bacha – 16,666 units
- Philip. M. Toleikis – 45,002 units

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.

All warrants issued to directors related to the September 23, 2020 private placement noted above, aggregating 255,001, were exercised during the year ended October 31, 2022.

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, 2022, 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, 2022, in respect of the Company's audited annual consolidated financial statements for the two most recent fiscal years ended October 31, 2022, and October 31, 2021. Results for the year ended October 31, 2021 were audited by predecessor auditor Davidson & Company, LLP. 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 January 26, 2023, a copy of which is available under the Company's SEDAR profile at www.sedar.com.

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, 2022, and October 31, 2021, 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.sedar.com.

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 review and recommend to the Board for approval:
 - (a) 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) 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 – when applicable) prior to their 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) 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 major 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) 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 set and pay the compensation of such advisors.
 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. Secretary

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

V. 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.
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.

VI. 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.

Composition of the Audit Committee

The Audit Committee, at the present time, is comprised of Messrs. Deborah Brown, Jeffrey Bacha and James Parsons. 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

Deborah M. Brown is currently Lead, Strategic Partnerships at EVERSANA Life Science Services, LLC prior to which she was a Partner at Accelera Canada Ltd (acquired by EVERSANA Life Science Services, LLC). Ms. Brown has extensive leadership experience with more than 20 years in senior management roles. She served as President of EMD Serono, a division of Merck KGaA, Executive Vice President at Serono US, General Manager, Director of Marketing, and Business Unit Director at Serono Canada and Manager, International Regulatory at Pasteur Merieux Connaught. Ms. Brown is a former Board Chair and Director of Rx&D and former Board Director of BIOTEC Canada. Mr. Brown holds an MBA from Ivey School of Business and completed the ICD.D designation in 2019. She sits on the board of several corporate and not-for-profit organizations including Oncolytics Biotech Inc (NASDAQ:ONCY).

Jeffrey A. Bacha, BSc, MBA currently serves as executive chairman of Rakovina Therapeutics Inc., a biopharmaceutical company focused on the development of novel DNA-damage response inhibitors for the treatment of cancer. He also serves as chief executive officer of Edison Oncology Holding Corp. a company

he co-founded in 2018 to develop and commercialize new cancer treatments. From 2010 to 2017, Mr. Bacha served as chief executive officer and chairman of DelMar Pharmaceuticals (now Kintara Therapeutics, Inc., NASDAQ:KTRA) a company he co-founded in 2010. Mr. Bacha and led the company's growth from founding through initiation of pivotal registration-directed clinical trials and its listing on NASDAQ. Since 2005 until founding Del Mar Pharmaceuticals, Mr. Bacha has consulted with a number of life sciences companies and served as Executive Vice President, Corporate Affairs and Chief Operating Officer of Clera Inc. From 2002 through 2005 Mr. Bacha served as President and Founding CEO of Inimex Pharmaceuticals, where he was responsible for establishing the company's research & development team and leading venture capital financing and grant funding efforts which raised more than \$35 million to support the company's research programs. From 1999 to 2002, Mr. Bacha served as vice president, corporate development of Inflazyme Pharmaceuticals Ltd. Prior to his operating roles, Mr. Bacha previously served as senior manager and director of KPMG Health Ventures. He holds an MBA from the Goizueta Business School at Emory University and a degree in BSc (BioPhysics) from the University of California, San Diego.

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.

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:

Financial Year Ending	Audit Fees⁽¹⁾	Audit-Related Fees⁽²⁾	Tax Fees⁽³⁾	All Other Fees⁽⁴⁾
October 31, 2022	\$187,250	\$Nil	\$Nil	\$Nil
October 31, 2021	\$81,000	\$2,300	\$11,000	\$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.