ANNUAL INFORMATION FORM

SERNOVA CORP.

700 Collip Circle, Suite 114
London, Ontario
Canada, N6G 4X8

E-mail: info@sernova.com
www.sernova.com

Unless otherwise indicated
all information in this Annual Information Form
is presented as at and for the financial year ended October 31, 2024

December 23, 2024

TABLE OF CONTENTS

CURRENCY AND MEASUREMENT

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

DOCUMENTS INCORPORATED BY REFERENCE

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

FORWARD-LOOKING STATEMENTS

This Annual Information Form (AIF) contains forward-looking statements within the meaning of applicable securities laws. All statements contained herein that are not clearly historical in nature are forward-looking, and the words "anticipate", "believe", "expect", "project", "potential", "estimate", "plan", "predict", "may", "will", "could", "leading", "intend", "objective", "contemplate", "consider", "shall" and similar expressions are generally intended to identify forward-looking statements. 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.

Forward-looking statements in this AIF include, but are not limited to, statements with respect to:

- our corporate strategy, strategic objectives, R&D plans, projections and cash requirements;
- the availability of financing to fund our ongoing operations, liabilities and R&D activities;
- the function, potential benefits, tolerability profile, duration of benefit, effectiveness and safety of Cell Pouch™ transplanted with therapeutic cells or tissue;
- the timing, cost and results of preclinical and clinical studies to treat insulin-dependent diabetes, hypothyroid disease and or hemophilia A with the Cell Pouch System™;
- the expected benefits to type 1 diabetes (T1D) patients implanted with Cell Pouch™ and human donor islets or induced pluripotent stem cell (iPSC) derived islet-like clusters (ILCs);
- the timing and success of IND enabling preclinical studies, IND submission and obtaining regulatory clearance to commence a Phase 1/2 trial combining iPSC derived ILCs with Cell Pouch™ in conjunction with the Evotec Collaboration (defined below);
- the protection of therapeutic cells within the Cell Pouch™ from immune system attack using local immune protection technologies, or using a systemic anti-rejection regimen or a combination thereof, and the expected benefits;
- our intention and ability to use human autograft cells or tissues or human donor allograft cells for treatment, coupled with the expectation that the use of ethically derived stem cell-derived cells (i.e., iPSCs) could provide a virtually unlimited cell supply for Cell Pouch to treat various diseases;
- our expectations to secure collaborations and partnerships to research, develop, commercialize and market our product candidates;
- our regulatory strategies and ability to obtain regulatory clearance for clinical trials and

marketing approval for our product candidates;

- our ability to obtain Orphan Drug (for rare diseases), Fast Track, Breakthrough Technology, Regenerative Medicine Advanced Therapy (RMAT), Accelerated Approval or Priority Review in the US, and similar regulatory designations in other jurisdictions, and expediting clinical trials or marketing approval for product candidates;
- our belief that our technologies are unique and could become a standard of care in therapeutic cell transplantation, if they prove to be safe and effective in clinical trials;
- our intentions regarding the development and protection of our intellectual property;
- obtaining licenses for technologies complementary to or with the Cell Pouch System™;
- securing cGMP manufacturing facilities for our cell therapy programs; and
- the benefits of developing next-generation Cell Pouch™ or Cell Pouch System™ technologies.

All forward-looking statements reflect our beliefs and assumptions based on information available at the time the assumption was made. These forward-looking statements are not based on historical facts but rather on management's expectations regarding future activities, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities. By its nature, forward-looking information involves numerous assumptions, inherent risks and uncertainties, both general and specific, known and unknown, that contribute to the possibility that the predictions, forecasts, projections or other forward-looking statements will not occur. Factors which could cause future outcomes to differ materially from those set forth in the forward-looking statements include, but are not limited to:

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

impact of the Hamas-Israel and Russia-Ukraine conflicts, and any lingering effect of the COVID-19 pandemic or emergence of other pathogens on our business and operations, including supply chain, manufacturing, research and development costs, clinical trials including patient enrollment, contracted service providers and employees.

Such risks are further and more fully described under the heading "Risk Factors" in this AIF and in our most recently filed Management Discussion and Analysis (MD&A) available on our profile at www.sedarplus.ca.

Although the forward-looking statements contained in this AIF are based upon what our management believes to be reasonable assumptions, we cannot assure readers that actual results will be consistent with these forward looking statements.

Any forward-looking statements represent our estimates only as of the date of this MD&A and should not be relied upon as representing our estimates as of any subsequent date. We undertake no obligation to update any forward looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events, except as may be required by securities legislation.

USE OF MARKET AND INDUSTRY DATA

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

CORPORATE STRUCTURE

General

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

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

The Company's registered office is at Suite 1500, 1055 West Georgia Street, Vancouver, British Columbia, Canada V6E 4N7, and its current head office is at 700 Collip Circle, Suite 114, London, Ontario, Canada N6G 4X8. The Company's head office telephone number is (519) 858-5184. 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, 2024. The audited consolidated financial statements and related management discussion and analysis for the October 31, 2024 financial year-end are filed under the Company's SEDAR+ profile at www.sedarplus.ca.

Intercorporate Relationships

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

DESCRIPTION AND GENERAL DEVELOPMENT OF THE BUSINESS

Sernova is a clinical-stage biotechnology company focused on advancing regenerative medicine in the treatment of chronic diseases. The company's primary asset is its proprietary Cell Pouch, a bio-hybrid organ system which is designed to enhance the delivery of cell therapy to better replicate natural body functions. The Cell Pouch creates a vascularized, organ-like environment that promotes the longevity and functionality of therapeutic cells and ensures containment for retrievability.

Currently, Sernova's Cell Pouch bio-hybrid organ system is in a Phase 1/2 clinical trial with human donor islets in patients with type 1 diabetes, an autoimmune disorder in which the body's immune system destroys its own insulin-producing pancreatic beta cells. In addition to type 1 diabetes, we are pursuing research in other chronic conditions including hypothyroidism, a potentially life-threatening condition caused by a dysfunctional thyroid gland with no or limited ability to release key hormones that regulate the metabolic process. There currently is no cure for hypothyroidism and patients may require lifelong treatment.

Our business strategy is focused on establishing partnerships with companies in the regenerative medicine space that complement our technology, primarily those that are developing therapeutic cells for chronic conditions with no cure, to jointly develop and commercialize our products. In 2022, we entered into a strategic partnership with Evotec to develop induced Pluripotent Stem Cell (iPSC)-based islet-like cell clusters to treat insulin-dependent diabetes.

RESEARCH & DEVELOPMENT

Cell Pouch Bio-Hybrid Organ System

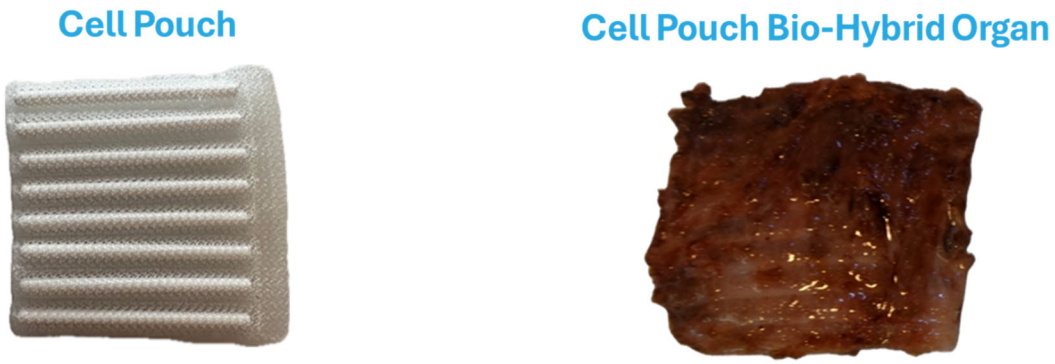
The Cell Pouch bio-hybrid organ system is a scaffold structure made of non-degradable polymers, formed into small cylindrical chambers, each of which contain a non-adherent rod. It is specifically and uniquely designed to be biocompatible and therefore, when implanted upon the abdominal muscle, vascularized

tissue integrates into the mesh of the Cell Pouch, surrounding the non-adherent rods in as little as four weeks, as demonstrated in clinical studies. Once vascularized, the rods are removed, leaving fully formed tissue chambers for the transplantation of therapeutic cells including Islets of Langerhans (islets). The bio-hybrid organ system forms an environment rich in microvessels that support engraftment of the transplanted islets resulting in a bio-hybrid pancreatic organ. *See Figure 1.* The therapeutic cells are then responsive to endogenous regulation and able to correct biological dysfunctions by producing the proteins and/or hormones that a patient is lacking.

Our clinical evidence shows that the unique design of the Cell Pouch prevents the formation of fibrotic tissue following implantation, which is supported by data from our ongoing clinical study in patients with type 1 diabetes which have shown that our Cell Pouch enables long-term survival and function of transplanted islets beyond 5 years.

Our bio-hybrid organ system is manufactured and produced at a US-based medical device contract manufacturing facility in compliance with ISO13485, EU Medical Devices Regulation MDR 2017/745, United States Food and Drug Administration Quality System Regulations (QSR) 21 CFR 820 and Canadian Medical Device Regulation (CMDR).

Figure 1



Type 1 Diabetes

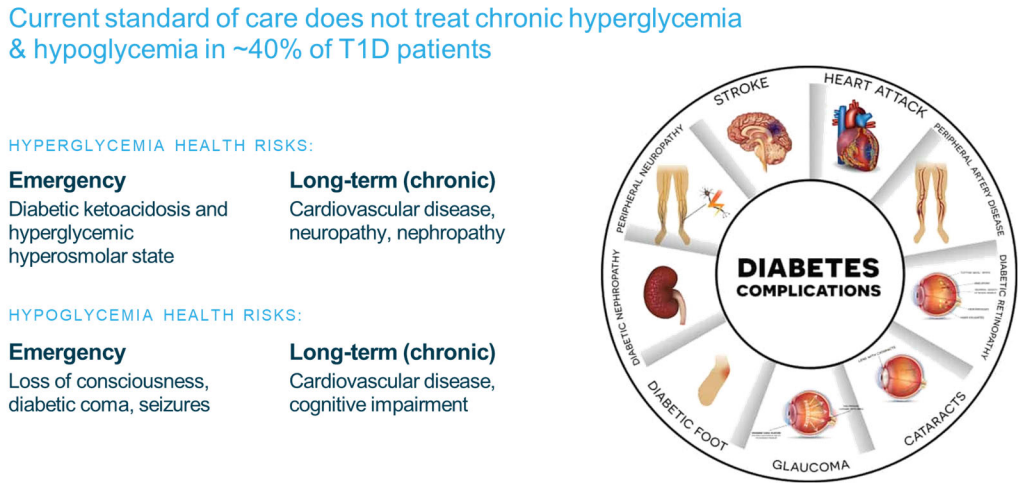
Insulin, glucagon, and somatostatin are hormones secreted by beta, alpha, and delta cells, respectively, in the pancreas. Together, they are responsible for maintaining proper function of the glucose cycle which underpins the body's energy balance, cellular function, and overall health. As the body's primary source of energy, homeostasis of glucose in the bloodstream is critical.

Type 1 diabetes is an irreversible autoimmune disorder in which the body's immune system mistakenly destroys insulin-producing beta cells in the pancreas. This results in disruption of the glucose cycle which can cause serious, acute health risks such as hyperglycemia and hypoglycemia, the latter of which accounts for 10% of deaths in people with T1D. T1D patients are at risk of longer-term health complications that can be severe, life changing and often life threatening. These health risks include cardiovascular disease, kidney disease, neuropathy, ophthalmic issues, and stroke, among other serious conditions. *See Figure 2.*

The lack of pancreatic beta cells in T1D patients also leads to the dysfunction of glucagon-producing alpha cells and somatostatin-producing delta cells. Glucagon is responsible for triggering the release of glycogen, which is a form of glucose that is stored in the liver and skeletal muscles. These stores provide

a continuous source of energy for the body such as during fasting periods between meals. Somatostatin regulates the production of both insulin and glucagon by acting directly upon neighboring beta and alpha cells in the pancreas. When the function of alpha and/or beta cells are disrupted in people with T1D, the delta cells can no longer respond to their usual signals, and therefore, are unable to regulate the glucose cycle.

Figure 2



Phase 1/2 Clinical Trial in Type 1 Diabetes

Sernova's lead clinical trial is a Phase 1/2 study investigating our bio-hybrid organ system with human donor islet cells as a functional cure for type 1 diabetes. The study is designed to assess both the safety and tolerability of transplanting pancreatic islets into our bio-hybrid organ system in individuals who experience hypoglycemia unawareness and have a history of severe hypoglycemic episodes. Hypoglycemia unawareness, which occurs when a person cannot recognize the onset of low blood sugar symptoms, can be life-threatening if onset occurs in the absence of another person who can assist during a hypoglycemic episode.

By transplanting islets into our bio-hybrid organ system, the study aims to restore glucose-regulating capabilities and potentially reduce these events. Additionally, the study seeks to establish specific islet release criteria, which will help define the quality and characteristics of the islet product prior to transplantation. These criteria are intended to predict clinical transplant success, an outcome that will be evaluated through predefined efficacy measures. We expect the study to contribute critical insights into both the safety of islet transplantation within the bio-hybrid organ system, and its potential to improve blood glucose stability in T1D patients at risk for severe hypoglycemia.

The trial includes participants aged 18-65 with T1D who experience hypoglycemic unawareness and severe hypoglycemic episodes, and who are eligible for donor islet transplantation. The trial is currently divided into two cohorts. Cohort A involved six patients who received the first-generation 8-channel Cell Pouch. Cohort B is evaluating seven patients transplanted with an optimized 10-channel Cell Pouch, which has a 56% greater islet capacity than the Cell Pouch used in Cohort A. Patients are implanted with four Cell Pouches, subcutaneously upon the surface of the abdominal muscle. Approximately six weeks later - allowing time to establish a stable immunosuppression therapy for the patient - islets are transplanted into the pre-vascularized tissue chambers of two of the four implanted Cell Pouches. If the patient has not attained optimal clinical benefit by 90 days following the islet transplant to Cell Pouch, the

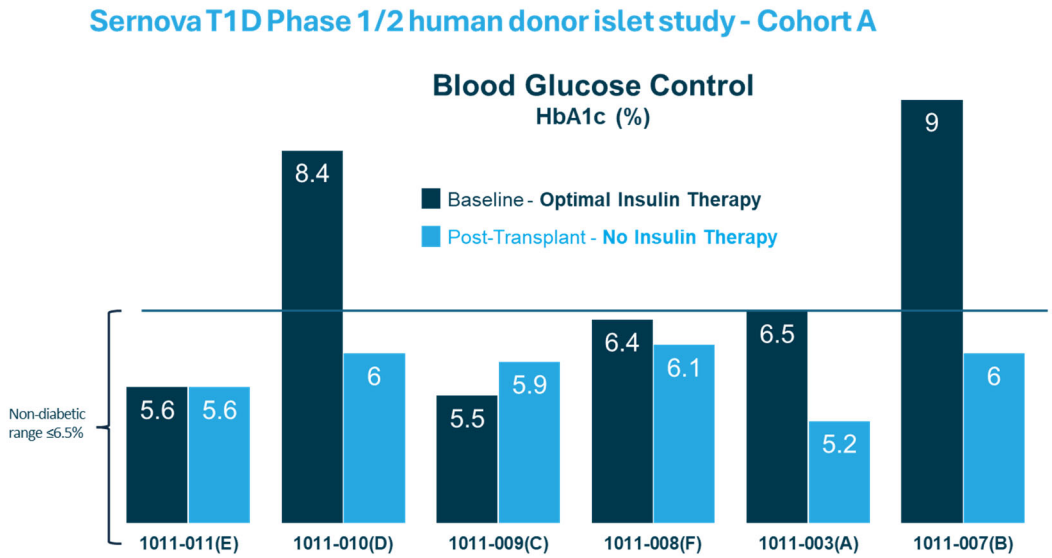
patient is eligible to receive a second islet transplant to the remaining two Cell Pouches. Patients who remain dependent on insulin more than 6 months after the second islet transplant to Cell Pouch may qualify for a third transplant via the portal vein. Safety and efficacy are assessed throughout the 12 months following the last islet transplant and those subjects who retain implants will be followed for at least three years. The key endpoints for this Phase 1/2 trial include continuous glucose monitoring (time in range), production of C-peptide, insulin use, HbA1c levels, and the frequency of severe hypoglycemic episodes.

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, as well as the number, severity and duration of both high and low glycemic episodes.

Data from Phase 1/2 clinical trial in T1D

In Cohort A of our Phase 1/2 clinical trial, all 6 of the patients enrolled achieved sustained insulin independence after combined islet transplantation into the Cell Pouch bio-hybrid organ system and intraportally. The first patient to be treated in the trial experienced sustained insulin independence for more than 4 years accompanied by blood sugar levels in the non-diabetic range (HbA1c ≤6.5%). Importantly, histological data from the explanted bio-hybrid organ confirmed abundant, well-vascularized, functioning islets consisting of cells producing insulin, glucagon and somatostatin, throughout all chambers, 5 years after being transplanted to the Cell Pouch. Additionally, after being in the body for more than 5 years, a pathology examination found no evidence of detrimental fibrotic tissue, material degradation or changes in the architecture of the Cell Pouch.

Figure 3



(HbA1c levels of all six patients in Cohort A of the Phase 1/2 clinical trial prior to treatment and following implantation of the Cell Pouch Bio-hybrid Organ System)

Additional Programs - Hypothyroidism and Hemophilia A

In pre-clinical studies we have been exploring the use of our bio-hybrid organ system in thyroid disease and hemophilia A. Hypothyroidism is a thyroid disease that, like diabetes, impacts cardiovascular and metabolic health. Hemophilia A is a bleeding disorder in which the patient's cells do not produce the necessary factors for blood to clot normally. Similar to T1D, both hypothyroidism and hemophilia A are chronic and life-limiting conditions that require lifelong monitoring and multiple daily treatments. We have demonstrated in animal models that explanted thyroid tissue transplanted into our bio-hybrid organ system allows for restoration of normal hormone levels for triiodothyronine (T3) and thyroxine (T4). We are currently planning to file an Investigation New Drug (IND) application to pursue its potential as a treatment to prevent hypothyroidism in human subjects. We have also shown that cells from hemophilia A patients that have been gene-edited to produce factor VIII and transplanted into the Cell Pouch are effective in restoring blood clotting in a preclinical animal model of hemophilia A.

Local Immune Protection & Other Complementary Technologies

In addition to our clinical work, we are exploring immune protection and other technologies to improve the safety and efficacy of our potential treatment solution for type 1 diabetes and other chronic illnesses, to overcome the current challenges faced in the field of cell therapy and regenerative medicine. This includes the necessity of immunosuppressive therapy to prevent islet cell apoptosis that is a feature of type 1 and type 2 diabetes and also occurs after islet transplantation due to the immune system's response to foreign cells.

Development Pipeline

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

Corporate Developments

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 was 12,944,904 common shares at a price of $1.57 per share for gross proceeds of

$20,323,500. The second and final tranche of Evotec's strategic investment private placement was closed in September 2022 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.

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

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

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

In May 2023, we announced our research collaboration with AstraZeneca to evaluate novel potential therapeutic cell applications. The preclinical research outcomes will determine the feasibility of potential therapeutic applications and subsequent product development opportunities and activities between the two companies. AstraZeneca is covering the costs of the feasibility assessment studies.

In August 2024, we announced the appointment of Jonathan Rigby as Chief Executive Officer of Sernova Corp. Mr. Rigby joined the Board of Directors in May 2024 and was appointed as Executive Chairman in July 2024.

In September 2024, we closed an oversubscribed non-brokered private placement through the issuance of 20,852,100 units at $0.25 per unit for gross proceeds of over $5.2 million. Each unit comprises one common share and one common share purchase warrant which is exercisable for one common share at a price of $0.30 per common share for 18 months. The common share purchase warrant is subject to acceleration of the exercise period on 30 days notice to warrant holders in the event that the 20-day volume weighted average price of our common shares exceeds $0.50 per share.

Significant Acquisitions, In-Licensing and Collaborations

Evotec iPSC Program

In May 2022, Sernova entered into an agreement to acquire an option for an exclusive global license to Evotec's Induced Pluripotent Stem Cell (iPSC)-based islet-like clusters for use with our bio-hybrid organ system to create an off-the-shelf treatment for type 1 and type 2 diabetes. Off-the-shelf allogeneic approaches based on iPSCs offer significant advantages compared to both autologous and donor-derived allogeneic therapies. This includes a virtually unlimited supply of therapeutic cells, consistent quality of final product and on demand product availability to patients. With its long-standing beta cell development program, Evotec has demonstrated the ability to reliably generate high quality, stable, human iPSC-derived beta cells using its proprietary process for producing ILCs in a quality-controlled, scalable, bioreactor process. These ILCs have been demonstrated to be functionally equivalent to primary human islets in their ability to normalize blood glucose levels in *in vivo* models of T1D for approximately one year, which was the length of the study.

Additional Collaborations

On May 3, 2023, we announced a research collaboration with AstraZeneca to evaluate novel potential therapeutic cell applications. AstraZeneca is exploring the use of Sernova's Cell Pouch System™ as a potential platform for integration with its development of the next wave of innovative cell therapies for various indications.

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

There are approximately 1.6 million people in the US that live with T1D and around 64,000 new cases diagnosed each year. Globally, there are close to 9 million T1D patients and the number of new cases diagnosed annually is approximately 149,000. In 2021, health expenditures for diabetes were estimated to be approximately $966 billion on a global basis and is projected to increase by over 100% by 2030 to between $2.2 and $2.5 trillion by 2030. This accounts for both direct medical costs including insulin, insulin delivery systems, and treatment of acute and chronic complications, as well as indirect costs such as lost productivity due to illness or premature death. The current standard of care is based on disease management and is an inefficient means to reduce costs or comorbidities that are associated with life-long T1D. Cell therapeutics such as our Cell Pouch Bio-hybrid Organ System have the potential to provide a functional cure for patients with T1D which could create a significant market opportunity by enabling the restoration of patients' glucose cycle and therefore mitigating the ongoing costs and long-term comorbidities.

The global thyroid gland disorder treatment market was valued at US$3.6 billion in 2020[1]. 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.

The global hemophilia market size was estimated at US $12.6 billion in 2022 and is expected to grow at a compound annual growth rate (CAGR) of 6.6% from 2023 to 2030. Hemophilia A held the highest share of 74.2% in 2022 in the hemophilia market[2], 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.

Regulatory Approval and Certification

All commercial applications of the Sernova Cell Pouch Bio-hybrid Organ System™ (i.e. Cell Pouch™, therapeutic cells, cellular immune protection) and resulting testing and evaluation thereof are subject to substantial regulation and rigorous approval procedures by the U.S. Food and Drug Administration (FDA), Health Canada the EU and other international regulatory agencies, as we develop our products through to

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

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

marketing approval in the jurisdictions in which Sernova or its strategic partners intend to sell these cell therapy 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 Canada, 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, however, we are initially focused on North America, Europe, and the Middle East. Sernova is ensuring we meet regulatory standards of the various jurisdictions in which we plan to market 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 and 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. FDA or Health Canada, as part of an Investigational New Drug (IND) application (for FDA) or Investigational Testing Authorization (ITA) (for Health Canada), which must be cleared by the respective regulatory authorities prior to initiation of clinical testing in humans. A similar process occurs for clinical product testing in other countries.

Typically, for our regenerative medicine combination products, the clinical evaluation process involves several Phases. For our combination medical device/cell therapies a Phase 1/2 (safety and efficacy), clinical evaluation is initially conducted with a small number of human subjects who have the disease to establish a safety profile, and potential efficacy parameters. Clinical evaluation patient numbers 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 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 favorable terms.

Competition

Sernova operates in the regenerative medicine and cell therapy space where there is growing innovation and research capabilities. In our current stage, we view our primary competition as cell therapies that are focused on improved treatments for type 1 diabetes, beyond daily disease management with exogenous insulin, glucose supplements, and other pharmaceuticals or devices that are common with today's most effective options. We believe our bio-hybrid organ system is a differentiated product among our competition given its demonstrated ability to create a localized environment for cells that becomes fully vascularized, promoting cell functionality and longevity. This compares to other cell therapies in clinical development for T1D that deliver cells through the portal vein or otherwise without a retrievable containment system.

Key competitors include companies developing alternative delivery platforms for cell therapies, such as encapsulation technologies and gene-editing solutions that modify beta cells to avoid immune rejection. Additionally, firms using stem cell-derived beta cells, including those from induced pluripotent stem cells (iPSCs), pose significant competition, especially as these solutions progress in clinical trials. Sernova's

partnership with Evotec to use iPSC-derived beta cells aims to position the Cell Pouch System as a potentially curative solution by providing a fully contained and retrievable, organ-like environment for these cells, which differentiates it from conventional islet transplantation methods.

The competitive landscape is also shaped by regulatory challenges and the high costs associated with developing and commercializing cell therapies.

cGMP Manufacturing

We manufacture our Cell Pouch technologies in conformance with (ISO 13485; FDA Quality System Regulations (QSR) 21 CFR 820; EU Medical Devices Regulation MDR 2017/745, and Canadian Medical Device Regulation (CMDR)) for preclinical and clinical evaluation via a contract manufacturer. Device specifications have been established, a semi-automated manufacturing process developed, and the product manufactured, packaged, and sterilized under quality controls applicable for testing in clinical trials in North America and Europe.

The Cell Pouch™ is scalable and is manufactured in different sizes for the same or different therapeutic indications / applications.

Our collaboration partner Evotec is responsible for manufacturing the iPSC derived islet-like clusters for clinical studies and commercial supply. Evotec has established a GMP cell therapy manufacturing facility in Europe where we anticipate producing supplies of iPSC-derived islet-like clusters for the treatment of trial participants with T1D.

Intellectual Property

Sernova's intellectual property (IP) portfolio is a critical asset underpinning its strategic position in the regenerative medicine and cell therapy market. Sernova holds patents in multiple jurisdictions, securing exclusive rights to its Cell Pouch technology, associated surgical implantation techniques, and cell transplantation methodologies. Sernova also holds a patent for differentiating stem cells into glucose-responsive, insulin-producing cells, as well as patented methods for conformally coating cells and cell clusters to prevent immune rejection. The company's collaboration with Evotec on iPSC-based beta cells further enhances its IP strategy, adding complementary protections and potentially strengthening Sernova's competitive advantage in diabetes treatment.

In addition to patent protections, Sernova's proprietary cell therapy processes and trade secrets are valuable components to our overall IP strategy, providing barriers to entry for competitors. The ongoing development of additional IP around the Cell Pouch platform, such as immunosuppression protocols for implantable devices for cellular transplantation, and partnerships for therapeutic cell sources are intended to broaden and extend Sernova's patent estate. As a result, Sernova's intellectual property portfolio is designed to protect its unique technological innovations, offering a robust foundation for the company's long-term growth and differentiation in the market.

Human capital

As of October 31, 2024, Sernova had 17 full-time employees based in the United States and Canada with employees operating remotely as well as in our offices in London, Ontario located at the Western University Research Park. In addition to our executive management team, the functions of our full-time employees include research and development, clinical and regulatory affairs, quality assurance, business development, finance, and stakeholder engagement.

We also employ consultants and advisors that support our ongoing clinical and regulatory development and provide insights as we execute our long-term strategy. Sernova continues to build relationships with well-known thought leaders that have significant experience in their respective fields as we work to expand our access to clinical and scientific advisors. We also leverage Evotec's staff in the joint development efforts to investigate our bio-hybrid organ system with Evotec iPSC islet-like clusters as a functional cure for type 1 diabetes.

Properties

We have separate laboratory and office leases in London, Ontario comprising approximately 2,300 square feet and 4,400 square feet, respectively, with lease terms expiring on December 31, 2026. We have the right to further extend the three-year lease terms for up to two renewal terms of one year each, on the same terms and conditions. The leases are subject to a 3% annual rent increase.

Legal Proceedings

We are not currently subject to any material legal proceedings.

RISK FACTORS

An investment in our common shares involves a high degree of risk and should be considered speculative. An investment in our common shares should only be undertaken by those persons who can afford the total loss of their investment. You should carefully consider the risks and uncertainties described below, as well as other information contained in this AIF. The risks and uncertainties below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition and results of operations could be seriously harmed and you could lose all or part of your investment. Further, if we fail to meet the expectations of the public market in any given period, the market price of our common shares could decline. We operate in a highly competitive and regulated environment that involves significant risks and uncertainties, some of which are outside of our control.

Risks Related to Our Business and Our Industry

If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and our product candidates are in preclinical or early clinical development. We have invested substantially all of our efforts and financial resources into our clinical studies as well as preclinical development of our product candidates.

Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales. The success of our current and future product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of investigational new drug, or IND, applications or comparable regulatory submissions outside of the US for our planned or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;
- maintenance of marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if and when approved;
- acceptance of the product candidate's benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- maintaining regulatory compliance post-approval if any of our product candidates are approved;
- maintaining a continued acceptable safety profile of the product candidates following approval;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- enforcing and defending intellectual property rights and claims.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for any of our product candidates that we develop, we may not be able to continue our operations.

Our prospects depend on the success of our product candidates which are at early stages of development, and we may not generate revenue for several years, if at all, from these products.

Given the early stage of our product development, we can make no assurance that our research and development programs will result in regulatory approval or commercially viable products. 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. To achieve profitable operations, we, alone or with others, must successfully develop, gain regulatory approval, and market our future products. We currently have no products that have been approved by the U.S. Food and Drug Administration, or FDA, Health Canada, or HC, or any similar regulatory authority. To obtain regulatory approvals for our product candidates being developed and to achieve commercial success, clinical trials must demonstrate that the product candidates are safe for human use and that they demonstrate efficacy. While we have commenced Phase 1/2 clinical trials for our Cell Pouch System in T1D, we have not yet completed later stage clinical trials for any of our product candidates.

Many product candidates never reach the stage of clinical testing and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Product candidates may fail for a number of reasons, including, but not limited to, being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the standard of treatment at the time of testing. Unsatisfactory results obtained from a particular study relating to a research and development program may cause us or our collaborators to abandon commitments to that program. The early stage of our product development makes it particularly uncertain whether any of our product development efforts will prove to be successful and meet applicable regulatory requirements, and whether any of our product candidates will receive the requisite regulatory approvals, be capable of being manufactured at a reasonable cost or be successfully marketed. If we are successful in developing our current and future product candidates into approved products, we will still experience many potential obstacles such as the need to develop or obtain manufacturing, marketing and distribution capabilities. If we are unable to successfully commercialize any of our products, our financial condition and results of operations may be materially and adversely affected.

Clinical product development involves a lengthy and expensive process, with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs;
- the number of patients required for clinical trials may be larger than we anticipate;
- it may be difficult to enroll a sufficient number of patients or enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- investigators may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; and
- the supply or quality of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or ethics committees, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition

of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates being stopped early.

We may expend our limited resources to pursue a particular program, product candidate or indication and fail to capitalize on programs, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other programs and product 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 discovery and preclinical and clinical development programs and product candidates for specific indications may not yield any commercially viable products.

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between

preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular completed study or clinical trial is typically based on extensive review of information, and certain of our shareholders or other third parties may not agree with what we determine is material or otherwise appropriate information to include in our interim, topline and preliminary disclosures.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Positive results from preclinical and early clinical research of our Cell Pouch System for T1D are not necessarily predictive of the results of later clinical trials of our Cell Pouch System for T1D. If we cannot replicate the positive results from preclinical and early clinical research in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our Cell Pouch System for T1D.

Positive results of preclinical and early clinical research of our Cell Pouch System for T1D may not be indicative of the results that will be obtained in later-stage clinical trials. For example, the immunosuppression protocol and the larger size Cell Pouch being used in our cohort B of our Phase1/2 trial are based on preliminary results of our cohort A patients. There can be no assurance that the preliminary results we have seen in a small number of type 1 diabetic patients will be reproducible in a larger population of patients. We can make no assurance that any future studies, if undertaken, will yield favorable results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. If we fail to produce positive results in our clinical trials, including identifying a beneficial immunosuppression protocol and achieving sufficient cell payload capacity, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

We rely and will continue to rely on third parties to plan, conduct and monitor our preclinical studies and clinical trials, and their failure to perform as required could cause substantial harm to our business.

We rely and will continue to rely on third parties to conduct a significant portion of our preclinical and clinical development activities. Preclinical activities include transplant studies in specific models, toxicology, pharmacology and assay development. Clinical development activities include trial design,

regulatory submissions, clinical patient and site recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. We will rely heavily on these third parties to conduct these activities and, as a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practice, or GCP, requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with pharmaceutical product (devices and cells) produced under current good manufacturing practice, or cGMP, requirements and will require a large number of test patients. Our failure or any failure by these third parties to comply with these requirements or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and non-clinical product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. 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 feasible 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, cancelled or rendered ineffective.

We rely on contract manufacturers over whom we have limited control. If we are subject to quality, cost or delivery issues with the preclinical and clinical grade materials supplied by contract manufacturers our business operations could suffer significant harm.

We have limited manufacturing experience and rely on contract manufacturing organizations, or CMOs, to manufacture our Cell Pouch and cell payloads for preclinical studies and clinical trials, and may continue to rely on third parties for commercial supply if any of our product candidates are approved. We rely on CMOs for manufacturing, filling, packaging, storing and shipping of our product candidates in compliance with cGMP requirements applicable to our product candidates. The FDA regulates the quality of medical products by monitoring manufacturers' compliance with cGMP requirements. The cGMP requirements for medical products contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packaging of each product.

We contracted with a U.S. manufacturer to supply our Cell Pouch for our clinical trials. The manufacture of our Cell Pouch requires specialized tooling and machinery, some of which we own and provide to our manufacturer for use. Our CMO has the capacity, the systems, and the experience to supply our Cell Pouch for our current clinical trials and we believe that they may be suitable for commercial production. The CMOs manufacturing facility has been inspected by regulatory authorities including the FDA for other products that they manufacture. Any manufacturing failures, delays or compliance issues could cause delays in the conduct of our preclinical and clinical trials.

We have an option to license iPSC-derived islet-like clusters from Evotec for our T1D program. We believe Evotec has the capacity, the systems, and the experience to supply these cells for our planned clinical trials and to support commercial manufacturing. They will be produced in a facility that has not been inspected post Evotec ownership by regulatory authorities including the FDA.

There can be no assurances that CMOs will be able to meet our timetable and requirements. We have not contracted with alternate suppliers for our Cell Pouch or for cell production in the event existing CMOs are unable to scale up production, or if the manufacturing facilities otherwise experience any other significant problems, or have limited production availability due to supply chain constraints, diversion of resources for production of vaccines which occurred during the COVID-19 pandemic, or otherwise. If any CMO with whom we contract fails to fulfil its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In this scenario, our clinical development plans, clinical trials and future commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidates that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

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 development of our product candidates. Further, CMOs must operate in compliance with cGMP and failure to do so could result in, among other things, the disruption of product supplies. Our dependence upon third parties for the manufacture of our products may adversely affect our financial condition and our ability to develop and deliver products on a timely and competitive basis.

We require commercial scale and quality manufactured product to be available for pivotal or registration clinical trials. If we do not have commercial grade Cell Pouch and iPSC supply when needed, we may face delays in initiating or completing pivotal trials and our business operations could suffer significant harm.

To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials by third-party manufacturers. In order to commercialize our product candidates, we need to manufacture commercial Cell Pouch and iPSC supply for use in registrational clinical trials. Most, if not all, of the clinical material used in Phase 3/ pivotal/registration studies must be derived from the defined commercial process including scale, manufacturing site, process controls and batch size. If we have not scaled up and validated the commercial production of our product candidates prior to the commencement of pivotal clinical trials, we may have to employ a bridging strategy during the trial to demonstrate equivalency of early stage material to commercial product, or potentially delay the initiation or completion of the trial until commercial supply is available. We may have to rely on third party manufacturers to enable us to produce the commercial supply necessary to commercialize our products, if approved.

The manufacturing of commercial quality product requires significant efforts including, but not limited to scale-up of production to anticipated commercial scale, process characterization and validation, analytical method validation, identification of critical process parameters and product quality attributes, multiple process performance and validation runs, has long lead times and is very expensive. If we do not have commercial supply available when needed for pivotal clinical trials, our regulatory and commercial progress may be delayed and we may incur increased product development costs. This may have a material adverse effect on our business, financial condition and prospects, and may delay marketing of the product.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. We do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any jurisdiction. Our product candidates may fail to demonstrate efficacy in humans. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk we face is the possibility that none of our product candidates under development will successfully gain market approval from the FDA or other regulatory authorities,

resulting in us being unable to derive any commercial revenue from them after investing significant amounts of capital in their development.

If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

While we are in the early stages of clinical trials with our product candidates, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, and our business may be substantially harmed.

We cannot predict whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before us, which would impair our ability to successfully commercialize our product candidates and may harm our financial condition, results of operations and prospects. The commencement and completion of clinical trials for our products may be delayed for a number of reasons, including delays related, but not limited, to:

- refusal by regulatory authorities to grant permission to proceed or placing the clinical trial on hold;
- patients not enrolling or remaining in our trials at the rate we expect;
- suspension or termination of clinical trials by regulators for many reasons, including concerns about patient safety or failure of our CMOs to comply with cGMP requirements;
- any changes to our manufacturing process that may be necessary or desired;
- delays or failure to obtain clinical supply from CMOs of our products necessary to conduct clinical trials;
- product candidates demonstrating a lack of safety or efficacy during clinical trials;
- patients choosing an alternative treatment for the indications for which we are developing any of our product candidates or participating in competing trials;
- patients not completing clinical trials due to dissatisfaction with the treatment, side effects or other reasons;
- reports of clinical testing on similar technologies and products raising safety and/or efficacy concerns;

- competing clinical trials and scheduling conflicts with participating clinicians;
- clinical investigators not performing our clinical trials on their anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner;
- failure of our CROs to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical trial sites by regulatory authorities or IRBs or ethics committees finding regulatory violations that require us to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more IRBs or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- failure to reach agreement on acceptable terms with prospective clinical trial sites.

Our product development costs will increase if we experience delays in testing or approval or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur, and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to regulatory authorities or IRBs or ethics committees for re-examination, which may impact the cost, timing or successful completion of that clinical trial. Delays or increased product development costs may have a material adverse effect on our business, financial condition and prospects.

We may not achieve our publicly announced milestones according to schedule, or at all.

From time to time, we may announce the timing of certain events we expect to occur, such as the anticipated timing of results from our clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, timing of the completion of clinical trials, problems with a CMO or a CRO or any other event having the effect of delaying the publicly announced timeline. We undertake no obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on our business plan, financial condition or operating results and the trading price of our common shares.

We may not be able to file INDs to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed in a timely manner, or at all.

Prior to commencing clinical trials in the United States for any of our product candidates, we may be required to have an authorized IND for each product candidate and to file additional INDs prior to initiating any additional clinical trials for our product candidates. We believe that the data from previous studies will support the filing of additional INDs, to enable us to undertake additional clinical studies as we have planned. However, submission of an IND may not result in the FDA allowing further clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, these regulatory authorities may change their requirements in the

future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. Failure to submit or have effective INDs and commence or continue clinical programs will significantly limit our opportunity to generate revenue.

If we have difficulty enrolling patients in clinical trials, the completion of the trials may be delayed or cancelled.

As our product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, we will need to enroll an increasing number of patients that meet our eligibility criteria. The timing of completion of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. There is significant competition for recruiting patients in clinical trials, and we may be unable to enroll the patients we need to complete clinical trials on a timely basis or at all. In addition to the potentially small populations, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their disease is either severe enough or not too advanced to include them in a study. Additionally, the process of finding and diagnosing patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidates may be delayed.

The factors that affect our ability to enroll patients are largely uncontrollable and include, but are not limited to, the following:

- size and nature of the patient population;
- eligibility and exclusion criteria for the trial;
- design of the study protocol;
- competition with other companies for clinical sites or patients;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians;
- the number, availability, location and accessibility of clinical trial sites; and
- current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future

product candidates may represent a departure from more commonly used methods for treatment, potential patients and their doctors may be inclined to use conventional therapies, rather than enroll patients in our ongoing or any future clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain FDA approval to market a new biological and/or combination product we must demonstrate proof of safety and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of programs that are the responsibility of third parties or our potential future partners over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on study design; and
- regulatory agencies not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, even if clinical trials do begin for our preclinical programs, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety and/ or efficacy to obtain the requisite regulatory approvals for any of product candidates we develop. Even if we obtain positive results from preclinical studies or early clinical trials, we may not achieve the same success in future trials.

We intend to develop our current product candidates and potentially future product candidates in combination with other agents, which exposes us to additional risks.

We intend to develop our current product candidate, Cell Pouch, and likely other future product candidates in combination with one or more other approved or unapproved agents. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing products, we would continue to be subject to the risks that the FDA, HC or

comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing products. If the products that we use in combination with our product candidates are discontinued as therapies for the indications we choose for any of our product candidates, the FDA, HC or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate our current product candidates or any other future product candidates in combination with one or more products that have not yet been approved for marketing by the FDA, HC or comparable foreign regulatory authorities. We will not be able to market and sell our current product candidates or any product candidate we develop in combination with an unapproved agent for a combination indication if that unapproved agent does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA, HC or comparable foreign regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the products we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

We may in the future conduct clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more clinical trials outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We may not be successful in our efforts to identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize product candidates. If we do not successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new product candidates

require substantial technical, financial and human resources, and we may fail to identify potential product candidates for numerous reasons.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Regulatory approval processes are lengthy, expensive and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

Our development and commercialization activities and product candidates are significantly regulated by a number of governmental entities, including the FDA, HC, and comparable authorities in other countries. Regulatory approvals are required prior to each clinical trial and we may fail to obtain the necessary approvals to commence or continue clinical testing. We must comply with regulations concerning the manufacture, testing, safety, effectiveness, labeling, documentation, advertising, and sale of products and product candidates and ultimately must obtain regulatory approval before we can commercialize a product candidate. The time required to obtain approval by such regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials. Any analysis of data from clinical activities we perform is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Even if we believe results from our clinical trials are favorable to support the marketing of our product candidates, the FDA or other regulatory authorities may disagree. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.
We could fail to receive regulatory approval for our product candidates for many reasons, including, but not limited to:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a biologics license application, or BLA, or other submission to obtain regulatory approval;

- deficiencies in the manufacturing processes or the failure of facilities of CMOs with whom we contract for clinical and commercial supplies to pass a pre-approval inspection; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

A regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects. The FDA, the European Medicines Agency, or EMA, and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Moreover, depending on any safety issues associated with our product candidates that garner approval, the FDA may impose a risk evaluation and mitigation strategy, thereby imposing certain restrictions on the sale and marketability of such products.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We face competition from other biotechnology and pharmaceutical companies and our financial condition and operations will suffer if we fail to effectively compete.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We are currently developing products that will compete, if approved, with other products and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, universities and other research institutions. Our competitors include large, well-established pharmaceutical companies, biotechnology companies, and academic and research institutions developing therapies for the same indications we are targeting and competitors with existing marketed therapies. Smaller and other early stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Many other companies are developing or commercializing therapies to treat the same diseases or indications for which our product candidates may be useful. Some competitors use therapeutic approaches that may compete directly with our product candidates. For example, our product candidates are in direct competition with stem cell derived beta cells and an implantable cell holding device from Vertex, and others.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain FDA, HC or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Many of our competitors have substantially greater financial, technical and human resources than we do and have significantly greater experience than us in conducting preclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of products. Accordingly, our competitors may succeed in obtaining regulatory approval for products more rapidly than we do. Our ability to compete successfully will largely depend on:

- the efficacy and safety profile of our product candidates relative to marketed products and other product candidates in development;
- our ability to develop and maintain a competitive position in the product categories and technologies on which we focus;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- our ability to obtain required regulatory approvals;
- our ability to commercialize any of our product candidates that receive regulatory approval;
- our ability to establish, maintain and protect intellectual property rights related to our product candidates; and
- acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers and payors.

If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will substantially suffer. In addition, the

biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our product candidates obsolete, less competitive or not economical.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy, or REMS, in order to approve our product candidates, which could entail requirements for physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good laboratory practice, or GLP, regulations and GCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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.

Our success will depend in large measure on the ability, expertise, judgment, discretion, integrity and good faith of our key executives and other personnel conducting our business. We have employment agreements with our President and Chief Executive Officer and other key members of our management team. Changes in the leadership team may cause some disruption to our business, and may have an adverse effect on our business, operating results or financial condition.

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, manufacturing, clinical, commercial 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.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. 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.

We may expand our business through the acquisition of companies or businesses or by entering into collaborations or by in-licensing product candidates, each of which could disrupt our business and harm our financial condition.

We have in the past and may in the future seek to expand our pipeline and capabilities by acquiring one or more companies or businesses, entering into collaborations, or in-licensing one or more product candidates. Acquisitions, collaborations and in-licenses involve numerous risks, including, but not limited to:

- substantial cash expenditures;
- technology development risks;

- potentially dilutive issuances of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- potential disputes regarding contingent consideration;
- diverting our management's attention away from other business concerns;
- entering markets in which we have limited or no direct experience; and
- potential loss of our key employees or key employees of the acquired companies or businesses.

We have experience in making acquisitions, entering collaborations, and in-licensing product candidates, however, we cannot provide assurance that any acquisition, collaboration or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions, collaborations and in-licenses. We cannot provide assurance that we would be able to successfully combine our business with that of acquired businesses, manage a collaboration or integrate in-licensed product candidates. Furthermore, the development or expansion of our business may require a substantial capital investment by us.

We expect to expand our organization and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We significantly reduced our staffing in 2024 as a cost containment measure. If we are successful at refinancing the Company, we expect to begin recruiting new staff, primarily in research and development, clinical development and CMC, to support the expansion and progression of our clinical programs. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to our limited financial resources and the attention required of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

Negative results from clinical trials or studies of others and adverse safety events involving product candidates of competitors in the field of cell therapy may have an adverse impact on our future commercialization efforts.

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to our product candidates, or the therapeutic areas in which our product candidates

compete, could adversely affect our share price and our ability to finance future development of our product candidates, and our business and financial results could be materially and adversely affected. In addition, the commercial success of our products will depend in part on public acceptance of the use of cell therapies. While a number of T1D therapies have been commercialized, and there are a number of cell therapies being investigated for use in clinical trials, there is only one approved cell therapy targeting T1D (Lantidra®; donislecel). Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of cell therapy that may occur in the future, could result in a decrease in demand for any product that we may develop. If public perception is influenced by claims that the use of cell therapies is unsafe, whether related to our therapies or those of our competitors, our products may not be accepted by the general public or the medical community.

Future adverse events observed in the use of cell therapy (with or without implantable devices), or with the use of other biopharmaceutical products could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for the product candidates we develop.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any current or future product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current approved treatments for T1D like insulin injections and insulin pumps in conjunction with blood glucose monitoring, are well established in the medical community, and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy; and
- the prevalence and severity of any side effects.

The market opportunities for any current or future product candidate we develop, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Insulin is a first line therapy for people with T1D and is usually adequate to prolong life and improve or maintain quality of life without providing a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective or desirable for the patient's circumstances. We may seek approval of certain product candidates we develop as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that product

candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the medical conditions that we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited, if and when our product candidates are approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional or expanded indications, including to be used as first-line therapy for T1D.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities.

If a prolonged government shutdown occurs (or if faced with conditions similar to the Covid-19 pandemic which disrupted or prevented regular inspections, reviews, or other regulatory activities conducted by regulatory agencies) in the U.S. or other jurisdictions where we plan to conduct our clinical trials, manufacturing, or other operations, it could significantly impact the ability of the relevant agency, such as the FDA, to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We face the risk of product liability claims, which could exceed our insurance coverage and produce recalls, each of which could deplete our cash resources.

We are exposed to the risk of product liability claims alleging that use of our product candidates caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing or sale of our product candidates and may be made directly by patients involved in clinical trials of our product candidates, by consumers or healthcare providers or by individuals, organizations or companies selling our products. Product liability claims can be expensive to defend, even if the product or product candidate did not actually cause the alleged injury or harm.

Insurance covering product liability claims becomes increasingly expensive as a product candidate moves through the development pipeline to commercialization. We currently maintain clinical trial liability insurance coverage of $5 million per claim and $10 million aggregate. However, there can be no assurance that such insurance coverage is or will continue to be adequate or available to us at a cost acceptable to us or at all. We may choose or find it necessary under our collaborative agreements to increase our insurance coverage in the future. We may not be able to secure greater or broader product

liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for damages resulting from a product liability claim could exceed the amount of our coverage, require us to pay a substantial monetary award from our own cash resources and have a material adverse effect on our business, financial condition and results of operations. Moreover, a product recall, if required, could generate substantial negative publicity about our products and business, inhibit or prevent commercialization of other products and product candidates or negatively impact existing or future collaborations.

If we are unable to maintain product liability insurance required by our third parties, the corresponding agreements would be subject to termination, which could have a material adverse impact on our operations.

Some of our licensing and other agreements with third parties require or might require us to maintain product liability insurance. If we cannot maintain acceptable amounts of coverage on commercially reasonable terms in accordance with the terms set forth in these agreements, the corresponding agreements would be subject to termination, which could have a material adverse impact on our operations.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Further, having a significant portion of our workforce working from home for extended periods of time following the COVID-19 pandemic puts us at greater risk of cyber-attacks. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or

deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyber-attack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

Risks Related to Our Financial Position and Need for Additional Capital

We expect to incur future losses and we may never become profitable.

We have incurred losses of $32.2 million and $39.0 million for the years ended October 31, 2024 and 2023, respectively. We have an accumulated deficit since inception through October 31, 2024 of $150.4 million. We believe that operating losses will continue as we are planning to incur significant costs associated with the clinical development and manufacturing of our product candidates. Our net losses have had and will continue to have an adverse effect on, among other things, our shareholders' equity, total assets and working capital. We expect that losses will fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial. We cannot predict when we will become profitable, if at all.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates.

As a medical products development company, our operations have consumed substantial amounts of cash since inception. We expect to spend substantial funds to continue the research, development and testing of our product candidates and to prepare to commercialize products subject to approval of the FDA, in the U.S. and similar approvals in other jurisdictions. We will also require significant additional funds if we expand the scope of our current clinical plans or if we were to acquire any new assets and advance their development. Therefore, for the foreseeable future, we will have to fund all of our operations and development expenditures from cash on hand, equity or debt financings, through collaborations with other biotechnology or pharmaceutical companies or through financings from other sources. We expect that our existing combined cash and cash equivalents and marketable securities as at October 31, 2024 of $6.0 million will enable us to fund our current operating plan requirements through February 2025. Additional financing will be required to meet our short-term and longer-term liquidity needs. If we do not succeed in raising additional funds on acceptable terms, we might not be able to complete clinical trials or pursue and obtain approval of any product candidates from the FDA and other regulatory authorities. It is possible that future financing will not be available or, if available, may not be on favorable terms. The availability of financing will be affected by the achievement of our corporate goals, the results of scientific and clinical research, the ability to obtain regulatory approvals, the state of the capital markets generally and with particular reference to medical product development companies, the status of strategic alliance agreements and other relevant commercial considerations. If adequate funding is not available, we may be required to delay, reduce or eliminate one or more of our product development programs, or obtain funds through corporate partners or others who may require us to relinquish significant rights to

product candidates or obtain funds on less favorable terms than we would otherwise accept. To the extent that external sources of capital become limited or unavailable or available on onerous terms, our intangible assets and our ability to continue our clinical development plans may become impaired, and our assets, liabilities, business, financial condition and results of operations may be materially or adversely affected.

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.

We currently have no product revenue and will not be able to maintain our operations and research and development without additional funding.

To date, we have generated no product revenue and cannot predict when and if we will generate product revenue. Our ability to generate product revenue and ultimately become profitable depends upon our ability, alone or with partners, to successfully develop our product candidates, obtain regulatory approval, and commercialize products, including any of our current product candidates, or other product candidates that we may develop, in-license or acquire in the future. We do not anticipate generating revenue from the sale of products for the foreseeable future. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through clinical trials.

We are exposed to the financial risk related to the fluctuation of foreign exchange rates and the degrees of volatility of those rates.

We may be adversely affected by foreign currency fluctuations. To date, we have been primarily funded through issuances of equity, proceeds from the exercise of warrants and stock options and from interest income on funds available for investment, which are denominated primarily in Canadian dollars. However, a growing proportion of our expenditures are in United States dollars, and we are therefore subject to foreign currency fluctuations which may, from time to time, impact our financial position and results of operations.

Risks Related to Intellectual Property

If we are unable to adequately protect and enforce our intellectual property, our competitors may take advantage of our development efforts or technology and compromise our prospects of marketing and selling our key products.

We control two main patent families relating to our Cell Pouch System. One family relates to a range of applications in regenerative medicine, including the use of therapeutic cells (like islets and stem cells) for treating chronic diseases. The other family relates to composition of matter for the Cell Pouch System involving a porous scaffold that allows the ingrowth of vascular and connective tissues facilitating the delivery of therapeutic cells into a vascularized space within the host body. We also have patented methods for conformally coating cells and cell clusters to prevent immune rejection, and a patent for differentiating stem cells into glucose-responsive, insulin-producing cells. We are continuing to file additional patent applications to strengthen our Cell Pouch System patent portfolio, including immunosuppression protocols for implantable devices for cellular transplantation. Our success will depend in part upon our ability to protect our intellectual property and proprietary technologies and upon the nature and scope of the intellectual property protection we receive. The ability to compete effectively and to achieve partnerships will depend on our ability to develop and maintain proprietary aspects of our technology and to operate without infringing on the proprietary rights of others. The presence of such proprietary rights of others could severely limit our ability to develop and commercialize our products, to conduct our existing research and could require financial resources to defend litigation, which may be in excess of our ability to raise such funds. There is no assurance that our pending patent applications or any that we intend to acquire will be approved in a form that will be sufficient to protect our proprietary technology and gain or keep any competitive advantage that we may have or, once approved, will be upheld in any post-grant proceedings brought by any third parties.

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Patents issued to us or our respective licensors may be challenged, invalidated or circumvented. To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors' products, our competitive position could be adversely affected, as could our business, financial condition and results of operations. Both the patent application process and the process of managing patent disputes can be time consuming and expensive, and the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States and Canada.

We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that our proprietary technologies, key products, and any future products are covered by valid and enforceable intellectual property rights including patents or are effectively maintained as trade secrets, and provided we have the funds to enforce our rights, if necessary.

If we lose our licenses from third-party owners we may be unable to continue a substantial part of our business.

We are party to licenses, or an option to license as we have with Evotec, that give us rights to intellectual property that is necessary or useful for a substantial part of our business. We may also enter into licenses in the future to access additional third-party intellectual property.

If we fail to pay annual maintenance fees, development and sales milestones, breach our obligations, or it is determined that we did not use commercially reasonable efforts to commercialize licensed products, we

could lose our licenses which could have a material adverse effect on our business and financial condition.

We may require additional third-party licenses to effectively develop and manufacture our key products and are currently unable to predict the availability or cost of such licenses.

A substantial number of patents have already been issued to other biotechnology and pharmaceutical companies. To the extent that valid third-party patent rights cover our products or services, we or our strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use or sell these products and services, and payments under them would reduce our profits from these products and services. We are currently unable to predict the extent to which we may wish or be required to acquire rights under such patents, the availability and cost of acquiring such rights, and whether a license to such patents will be available on acceptable terms or at all. There may be patents in the U.S. or in foreign countries or patents issued in the future that are unavailable to license on acceptable terms. Our inability to obtain such licenses may hinder or eliminate our ability to manufacture and market our products.

Changes in patent law and its interpretation could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. We seek patent protection globally, and legal standards pertaining to patents are often in flux in different jurisdictions. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Additionally, some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during US litigation, or in counterpart venues around the world, under the revised criteria which could also make it more difficult to obtain patents. Depending on decisions by the U.S. Congress, the federal courts, and the United States Patent and Trademark Office (USPTO) or counterparts worldwide, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors’ or collaborators’ ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. We cannot predict how these decisions or any future decisions by the courts, legislatures, and patent offices may impact the value of our patents. Any adverse changes in the patent laws of the US or other jurisdictions could have a material adverse effect on our business and financial condition.
Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors’ or collaborators’ issued patents. Under the Leahy-Smith America Invents Act (the “America Invents Act”), enacted in 2013, the U.S. moved from a “first to invent” to a “first to file” system. Under a “first to file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, establish a new post-grant review system, and may also affect patent litigation. The effects of these changes, as well as subsequent court decisions, are still unclear as the

USPTO continues to update new regulations and procedures. In addition, the courts have yet to address many of these provisions and the applicability of the Act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. Accordingly, it is not clear what, if any, impact the America Invents Act or similar current or future legislation will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

Litigation regarding patents, patent applications, and other proprietary rights may be expensive, time consuming and cause delays in the development and manufacturing of our key products.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. 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 regarding:

- the patentability of our inventions relating to our key products; and/or
- the enforceability, validity, or scope of protection offered by our patents relating to our key products.

If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action, or challenge the validity of the patents in court. Regardless of the outcome, patent litigation is costly and time consuming. In some cases, we may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our key products to market; and/or
- be precluded 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.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them.

Because we rely on third parties to develop our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic and clinical collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We may also conduct joint

research and development programs which may require us to share trade secrets under the terms of research and development collaboration or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets may impair our competitive position and could have a material adverse effect on our business and financial condition.

Risks Related to Our Common Shares

Our common share price has been volatile in recent years, and may continue to be volatile.

The market prices for securities of biopharmaceutical companies, including ours, have historically been volatile. In the year ended October 31, 2024, our common shares traded on the TSX at a high of $0.82 and a low of $0.20 per share. A number of factors could influence the volatility in the trading price of our common shares, including changes in the economy or in the financial markets, industry related developments, the results of product development and commercialization, changes in government regulations, and developments concerning proprietary rights, litigation and cash flow. Our quarterly losses may vary because of the timing of costs for manufacturing, preclinical studies and clinical trials. Also, the reporting of adverse safety events involving our products and public rumors about such events could cause our share price to decline or experience periods of volatility. Each of these factors could lead to increased volatility in the market price of our common shares. In addition, changes in the market prices of the securities of our competitors may also lead to fluctuations in the trading price of our common shares.

We have never paid dividends and do not expect to do so in the foreseeable future.

We have not declared or paid any cash dividends on our common shares to date. The payment of dividends in the future will be dependent on our earnings and financial condition in addition to such other factors as our Board of Directors considers appropriate. Unless and until we pay dividends, shareholders may not receive a return on their shares. There is no present intention by our Board of Directors to pay dividends on our shares.

Future sales or issuances of equity securities and the conversion of outstanding securities to common shares could decrease the value of the common shares, dilute investors' voting power, and reduce our earnings per share. There are a large number of common shares underlying our outstanding warrants, options and deferred share units and the exercise or redemption of these securities may depress the market price of our common shares and cause immediate and substantial dilution to our existing stockholders.

As of October 31, 2024, we had 325,324,786 common shares issued and outstanding, outstanding DSUs convertible into an additional 4,445,001 common shares, outstanding options to purchase 43,080,158 common shares, and outstanding warrants to purchase 21,257,050 common shares. The issuance of common shares upon exercise of our outstanding options and warrants, or the redemption of our DSUs, will cause immediate and substantial dilution to our stockholders.

We may sell additional equity securities in future offerings, including through the sale of securities convertible into equity securities, to finance operations, acquisitions or projects, and issue additional common shares if outstanding warrants or 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 conversion of outstanding convertible equity securities, could adversely affect the prevailing market prices for our securities and dilute 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.

We are likely a "passive foreign investment company," which may have adverse U.S. federal income tax consequences for U.S. shareholders.

U.S. investors should be aware that we believe we were classified as a passive foreign investment company, or PFIC, during the tax year ended October 31, 2024, and based on current business plans and financial expectations, we believe that we may be a PFIC for the current tax year and may be a PFIC in future tax years. If we are a PFIC for any year during a U.S. shareholder's holding period of our common shares, then such U.S. shareholder generally will be required to treat any gain realized upon a disposition of our common shares, or any so-called "excess distribution" received on our common shares, as ordinary income, and to pay an interest charge on a portion of such gain or distributions, unless the shareholder makes a timely and effective qualified electing fund election, or QEF Election, or a mark-to-market election with respect to our common shares. A U.S. shareholder who makes a QEF Election generally must report on a current basis its share of our net capital gain and ordinary earnings for any year in which we are a PFIC, which may or may not be readily available, whether or not we distribute any amounts to our shareholders. A U.S. shareholder who makes the mark-to-market election generally must include as ordinary income each year the excess of the fair market value of the common shares over the shareholder's adjusted tax basis therein. Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of our common shares.

Legislation or other changes in U.S. tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders’ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

It may be difficult for non-Canadian investors to obtain and enforce judgments against us because of our Canadian incorporation and presence.

We are currently a corporation existing under the laws of Canada and are planning to reincorporate under the Business Corporations Act (British Columbia), or BCBCA. Some of our officers, directors, and experts are Canadian or non-U.S. residents, and many of our assets or the assets of our officers and

directors are located outside the United States. It may be difficult for holders of our common shares who reside in the United States to effect service within the United States upon those directors, officers, and experts who are not residents of the United States. It may also be difficult for holders of our common shares 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 officers and directors 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.

Any failure to maintain an effective system of internal controls may result in material misstatements of our consolidated financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud; and in that case, our shareholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our common shares.

Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. If we fail to maintain an effective system of internal controls, we might not be able to report our financial results accurately or prevent fraud; and in that case, our shareholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our common shares. While we believe that we have sufficient personnel and review procedures to allow us to maintain an effective system of internal controls, we cannot provide assurance that we will not experience potential material weaknesses in our internal control. Even if we conclude that our internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with IFRS Accounting Standards as issued by the IASB, because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our results of operations or cause us to fail to meet our future reporting obligations.

If we fail to timely achieve and maintain the adequacy of our internal control over financial reporting, we may not be able to produce reliable financial reports or help prevent fraud. Our failure to achieve and maintain effective internal control over financial reporting could prevent us from complying with our reporting obligations on a timely basis, which could result in the loss of investor confidence in the reliability of our consolidated financial statements, harm our business and negatively impact the trading price of our common shares.

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 ofinterest.

DIVIDENDS

There are no restrictions in Sernova's Articles, By-Laws or elsewhere, which would prevent the Company from paying dividends. 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, 2024 and the date of this AIF there were 325,324,786 and 328,484,786 Common Shares issued and outstanding, respectively.

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). At the Company's annual shareholder meeting held April 30, 2024 the disinterested shareholders approved an increase to the fixed number maximum of Common Shares available for reserve under the Incentive Plan to a combined 15% of the then issued and outstanding Common Shares for an aggregate total of 45,511,153: 40,001,152 Common Shares (which represented 13.2% of the issued Common Shares as at March 19, 2024) were reserved for issuance upon exercise of options granted under the stock option plan; and 5,510,001 Common Shares (which represented 1.8% of the issued Common Shares as at March 19, 2024) were reserved for conversion of DSUs awarded under the deferred share unit plan.

MARKET FOR SECURITIES

Trading Price and Volume

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

Period	High ($)	Low ($)	Volume
November 2023	0.82	0.68	1,841,341
December 2023	0.77	0.61	2,938,215
January 2024	0.73	0.51	4,033,042
February 2024	0.70	0.55	2,352,678
March 2024	0.63	0.53	2,074,290
April 2024	0.60	0.38	4,041,356
May 2024	0.43	0.29	3,194,924
June 2024	0.40	0.27	4,093,821
July 2024	0.35	0.26	2,829,356
August 2024	0.28	0.20	8,561,908
September 2024	0.34	0.23	2,598,153
October 2024	0.28	0.23	2,268,318

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

Prior Sales

The following table summarizes details of each class of securities that is outstanding but not listed or quoted on a marketplace issued by the Company during the year ended October 31, 2024.

Date of Issuance	Exercise Price	Number of Securities	Description of Security
November 14, 2023	$0.80	200,000	Stock option
February 13, 2024	$0.65	100,000	Stock option
July 11, 2024	$0.31	60,000	Stock option
July 19, 2024	$0.30	331,500	Stock option
July 26, 2024	$0.29	2,495,000	Stock option
August 12, 2024	$0.26	13,860,633	Stock option
September 17, 2024	$0.27	420,000	Stock option
September 19, 2024	$0.26	651,000	Stock option
October 22, 2024	$0.26	5,500,000	Stock option

DIRECTORS AND OFFICERS

Name, Occupation and Security Holding

The following table sets out the name, residence, position with Sernova and principal occupations for the previous five years of each of the directors and executive officers of Sernova, as well as the period during which each has been a director and/or an officer of Sernova and the number of Common Shares of the corporation beneficially owned by each, directly or indirectly, or over which each exercised control or direction, as at October 31, 2024.

Name, Position and Residence	Principal Occupation Last Five Years[4]	Director/Officer Since	Common Shares[4]
Jonathan Rigby *Director, Chair and President & Chief Executive Officer* Louisiana, USA	Mr. Rigby is Sernova's President & CEO since August 2024 and a board member since May 2024. Previously until January 2024 was the Group CEO of Revolo Biotherapeutics, where he led a team focused on the development of therapies for autoimmune and allergic diseases. Previously, he was the CEO of SteadyMed Ltd., which he led through a NASDAQ listing and sale to United Therapeutics Corporation. Prior to his time at SteadyMed, Mr. Rigby co-founded Zogenix, Inc., a CNS-focused specialty pharmaceutical company that was acquired by UCB in a transaction valued at up to approximately U.S. $1.9 billion. Before co-founding Zogenix, Mr. Rigby held roles of increasing responsibility in commercial and business development functions at large pharmaceutical companies such as Merck, Bristol Myers Squibb, and Profile Therapeutics (now Phillips Medical). Mr. Rigby is also a member of the Board of Directors of BioPlus Acquisition Corp. and Oncolytics Biotech, Inc. He holds a B.S. with Honors in Biological Sciences from Sheffield University, UK, and an M.B.A. from Portsmouth University, UK.	Director: May 2024 Board Chair: August 2024	-

Name, Position and Residence	Principal Occupation Last Five Years[4]	Director/Officer Since	Common Shares[4]
Bernd Muehlenweg [1] [2] [3] *Director* Hamburg, Germany	Bernd Muehlenweg joined the Sernova board as an independent director in April 2024. He currently serves as Senior Vice President, Head of Global Business Development, Cell Therapy, at Evotec (Germany). During his tenure Bernd has been involved in establishing numerous collaboration and licensing agreements for the company and was also part of creating spin-off companies and M&A transactions. Before Evotec he served as Chief Business Officer for Nanobiotix S.A. (France), an oncology company listed on Euronext and NASDAQ. He is co-founder of Panoptes Pharma, an Austrian ophthalmology company that was acquired by NASDAQ listed Eyegate Pharmaceuticals (now Kiora Pharmaceuticals). Previously he worked at Wilex AG, an oncology company, spanning business development and alliance management roles. Bernd holds a PhD in chemistry from the Technical University of Munich, Germany.	April 2024	-

Name, Position and Residence	Principal Occupation Last Five Years[4]	Director/Officer Since	Common Shares[4]
James Parsons *Director and Chief Financial Officer* Ontario, Canada	Mr. Parsons has been Sernova's CFO since October 2024. Previously he was the CFO of Trillium Therapeutics Inc. until 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, device and diagnostics 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) and is chair of their audit committee and serves on the board of Oncolytics Biotech Inc (NASDAQ:ONCY). He has a Master of Accounting degree from the University of Waterloo and is a Chartered Professional Accountant, Chartered Accountant (CPA, CA).	Director: April 2012 Officer: October 2024	384,728

Name, Position and Residence	Principal Occupation Last Five Years[4]	Director/Officer Since	Common Shares[4]
David Paterson [1] [2] [3] *Director* Colorado, USA	Mr. Paterson joined the Sernova board as an independent director in September 2024. He is the Assistant Vice President for Research Translation and Commercialization at Colorado State University and is responsible for the translation and commercialization of research providing guidance to CSU faculty, research facilities and colleges in cultivating new industry-related partnerships. Prior to CSU, he served in a number of business and corporate development roles at Impax Laboratories, Inc including Head of Impax Laboratories, BV in the Netherlands; Vice President for Out-Partnering and Alliance Management and Vice President for Business Development at Impax Laboratories where he established a number of global industry partnerships. Previously he was Senior Director of Business Development at Sepracor (now Sunovion), and also served as the Director of Business Development at GlaxoSmithKline, and Vice President for Business Development at Skyepharma, Inc. He holds a Ph.D. in Plant Biology from the University of Illinois Urbana-Champaign and a B.Sc. (Hons) in botany from the University of Glasgow in Scotland. He has served on the boards of Impax Labs, B.V, Neurogastrx, Inc, and Lakeside Biotechnology, Inc.	September 2024	-

Name, Position and Residence	Principal Occupation Last Five Years[4]	Director/Officer Since	Common Shares[4]
Dr. Steven Sangha [1] [2] [3] *Director* British Columbia, Canada	Dr. Sangha joined the Sernova board as an independent director in April 2023. Dr. Sangha has over 25 years of experience in investment banking, business development, and asset management. Dr. Sangha's extensive experience with public companies and finance has led him to successfully run a Private Family Office since 1998. Dr. Sangha holds a Doctorate of Dental Surgery (DDS) from the University of Western Ontario in London, Ontario, and a Bachelor of Pharmaceutical Science (BscPharm) from the University of British Columbia, and has managed a professional dental practice since 1998. Dr. Sangha is a member of the Board of Directors of BlockchainK2 and Goldhills Holding Ltd., and is a corporate advisor for Better Life Pharma Inc.	April 2023	13,037,000

Name, Position and Residence	Principal Occupation Last Five Years[4]	Director/Officer Since	Common Shares[4]
Dr. Modestus Obochi *Chief Business Officer* Illinois, USA	Dr. Obochi is the Chief Business Officer of Sernova since September 2023. Prior to that he was EVP, Strategy and Business Development and General Manager, API Solutions at Phlow Corporation between November 2020 to September 2023; President and CEO and Board Member, Coeptis Therapeutics between February 2019 to March 2020; Strategy and Business Development Executive, Pfenex Inc. between September 2017 to February 2019; and has served in senior level positions in various pharma and biotech companies, including, Baxter, Pfizer, Hospira prior to it being acquired by Pfizer for US$15 billion, and QLT. He has also been an Advisor to 2Flo Ventures, LLC since August 2022; Board Member, Temprian Therapeutics since August 2022;; and Investment Committee Member, Accel-Rx (Canada's Health Science Accelerator) from January 2015 to August 2020. Dr. Obochi holds a Ph.D. in cell and organ transplant Immunology from the University of British Columbia; an MBA from Simon Fraser University; an M.Sc. in Radiobiology from Universite de Sherbrooke; and a B.Sc. (Hons) in Biochemistry & Microbiology from the University of Nigeria, Nsukka.	September 2023	50,000

Name, Position and Residence	Principal Occupation Last Five Years[4]	Director/Officer Since	Common Shares[4]
Marylyn Rigby *Chief Communications Officer* Louisiana, USA	Ms. Rigby has two decades of accomplished pharmaceutical, biotech and medtech experience. As an accomplished Business Development, Marketing and Investor Relations professional, she has navigated a progressive career trajectory into senior management roles and the Chief Executive Officer of Bioceptive. She has led strategic initiatives that have resulted in three private placements, an IPO, and two secondary follow-on rounds. Recently, as SVP, she was the creative force behind the brand marketing and identity for SteadyMed Therapeutics and Revolo Biotherapeutics where her accomplishments were industry recognized.	October 2024	-
Frank Shannon *SVP Clinical Development and Regulatory Affairs* Ontario, Canada	Mr. Shannon has more than 25 years of experience in clinical development and regulatory affairs. He has served in senior level positions within the medical device, pharmaceutical, and biologic industries where he achieved commercial goals through innovative risk management and execution strategies to obtain marketing approval of products. Mr. Shannon most recently served as VP Clinical Development, Regulatory Affairs and Quality at Ripple Therapeutics, a spin-out of Interface Biologics where he served in the same capacity since 2016. Prior to these appointments, he held various senior clinical/regulatory positions at Baxter International, St. Jude Medical, Boehringer-Ingelheim, Hoffmann-La Roche/Roche Laboratories, Inc., Genentech Canada, Inc., and Ciba-Geigy Canada, Ltd.	August 2021	-

Name, Position and Residence	Principal Occupation Last Five Years[4]	Director/Officer Since	Common Shares[4]
David Burke *VP, Investor Relations* North Carolina, USA	Mr. Burke has spent 20 years leading investor relations programs for public and private companies in the biotech space. Most recently he served as Head of Investor Relations at Aldeyra Therapeutics. Prior to that, Mr. Burke led investor relations at Rigel Pharmaceuticals, Dynavax Technologies, and Versartis. He is currently an advisor to Med-Kick, a remote patient monitoring company, as well as Crown Biome, a company creating a diagnostic for chronic illnesses using subgingival plaque. David was in the Capital Markets Intelligence group at Thomson Reuters and began his career working alongside the proprietary trading desk and prime brokerage services at Deutsche Bank.	October 2024	-

Notes:

1. Member of the Audit Committee of the Board. Dr. Sangha is the Chair of the Audit Committee.
2. Member of the Compensation Committee of the Board.
3. Member of the Nomination and Governance Committee of the Board.
4. The information as to principal occupation and shares beneficially owned or over which control or direction is exercised has been furnished by each director individually.

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 will be held on January 10, 2025.

Director and Officer Share Ownership

As at December 23, 2024, the directors and executive officers of Sernova, as a group, owned or exercised control and direction over 13,471,728 Common Shares, being approximately 4.1% 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 December 23, 2024, or has been within the last ten years, a director, or a chief executive officer or a chief financial officer of a company (including Sernova Corp.) which, while the director or executive officer was acting in such capacity, (i) was subject to a cease trade or similar order or was refused an exemption prescribed by securities legislation for more than 30 consecutive days, (ii) has, after the termination of duties as a director or executive officer, been subject to a cease trade or similar order or been denied an exemption under securities legislation for more than 30 consecutive days due to an event that took place while that person was in office, or (iii) has, while the director or executive officer held that office or within a year of ceasing to act in that capacity, became bankrupt, made a proposal under any bankruptcy or insolvency legislation, made a proposal under any legislation relating to bankruptcy or insolvency, or was subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver-manager or trustee appointed to hold his assets, or (b) within the ten preceding years, became bankrupt, made a proposal under any bankruptcy or insolvency legislation, made a proposal under any legislation relating to bankruptcy or insolvency, or became subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver-manager or trustee appointed to hold the assets of the director, officer or shareholder, or (c) has been the subject of (i) a penalty or sanction imposed by a court relating to securities legislation or by a securities regulatory authority or entered into a settlement agreement with it, or (ii) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor making an investment.

CONFLICTS OF INTEREST

Certain directors or officers of the Company are also directors, officers or shareholders of other companies and conflicts of interest may arise between their duties as a director or officer of the Company and their duties as a director, officer or shareholder of other companies. All potential conflicts of interest must be disclosed in accordance with the requirements of the *Canada Business Corporations Act*, and the directors and officers in question are required to comply with their legal obligations as well as all contractual provisions binding them. To the knowledge of the Company, no conflict of interest arose during the year ended October 31, 2024, or currently exists.

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.

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, 2024, 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 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 December 23, 2024, in respect of the Company's audited annual consolidated financial statements for the two most recent fiscal years ended October 31, 2024, and October 31, 2023. KPMG LLP has advised that they are independent of the Company within the meaning of the relevant rules and related interpretations prescribed by the relevant professional bodies in Canada and any applicable legislation or regulations.

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 November 30, 2024, a copy of which is available under the Company's SEDAR+ profile at www.sedarplus.ca.

Additional financial information relating to Sernova is included in the Company's consolidated audited financial statements for the Company's fiscal years ended October 31, 2024 and October 31, 2023, together with the accompanying auditor's report and management's discussion and analysis (the "Annual Financials"). Copies of the Annual Financials, Sernova's most current interim financial statements and management's discussion and analysis, and a copy of this Annual Information Form, as well as additional information relating to the Company, may be found under Sernova's SEDAR+ profile at www.sedarplus.ca.

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 is a committee of the Board of Directors (the "Board") of Sernova Corp. (the "Corporation").

The Audit Committee has a charter (the "Audit Committee Charter") that sets out its mandate and responsibilities.

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

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

II. Composition

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

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

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

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

III. Duties and Responsibilities

1. The Audit Committee shall:

   (a) Review and recommend to the Board for approval the annual audited financial statements.

   (b) Review with financial management and the external auditor the Corporation's financial statements, MD&A's and earnings releases to be filed with regulatory bodies such as securities commissions prior to filing or prior to the release of earnings. Review of quarterly results with the external auditor will be at the discretion of the Audit Committee.

   (c) Review documents referencing, containing or incorporating by reference the annual audited consolidated financial statements or interim financial results (e.g., prospectuses, press releases with financial results and Annual Information Form ("**AIF**") – when applicable) prior to their public release.

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

   (a) Periodically review the adequacy and effectiveness of the internal controls and procedures in place which allow the Chief Executive Officer and the Chief Financial Officer to certify financial statements and other disclosure documents as required under securities laws.

   (b) Recommend to the Board of Directors the selection of the external auditor, consider the independence and effectiveness and approve the fees and other compensation to be paid to the external auditor.

   (c) Monitor the relationship between management and the external auditor including reviewing any management letters or other reports of the external auditor, and discussing and resolving any material differences of opinion or disagreements between management and the external auditor.

   (d) Review and discuss, on an annual basis, with the external auditor all significant relationships they have with the Corporation to determine their independence and report to the Board of Directors.

   (e) Review and approve requests for any management consulting engagement to be performed by the external auditor and be advised of any other study undertaken at the request of management that is beyond the scope of the audit engagement letter and related fees.

   (f) Review the performance of the external auditor and approve any proposed discharge and replacement of the external auditor when circumstances warrant. Consider with management the rationale for employing accounting/auditing firms other than the principal external auditor.

   (g) Periodically consult with the external auditor out of the presence of management about significant risks or exposures, internal controls and other steps that management has taken

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

(h) Arrange for the external auditor to be available to the Audit Committee and the full Board of Directors as needed. Ensure that the auditors report directly to the Audit Committee and are made accountable to the Board and the Audit Committee, as representatives of the shareholders to whom the auditors are ultimately responsible.

(i) Directly oversee the work of the external auditors engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services.

(j) Pre-approve any permissible non-audit engagements of the external auditors, in accordance with applicable legislation.

(k) Review and approve hiring policies for employees or former employees of the past and present external auditors.

(l) Review the scope of the external audit, including the fees involved.

(m) Review the report of the external auditor on the annual audited financial statements.

(n) Review problems found in performing the audit, such as limitations or restrictions imposed by management or situations where management seeks a second opinion on a significant accounting issue.

(o) Review major positive and negative observations of the auditor during the course of the audit.

(p) Review with management and the external auditor of the Corporation's critical accounting policies, including the impact of alternative accounting policies and key management estimates and judgments that can materially affect the financial results.

(q) Review emerging accounting issues and their potential impact on the Corporation's financial reporting.

(r) Review with management, the external auditors and legal counsel, any litigation, claims or other contingency, including tax assessments, which could have a material effect upon the financial position or operating results of the Corporation, and whether these matters have been appropriately disclosed in the financial statements.

(s) Review the conclusions reached in the evaluation of management's internal control systems by the external auditors, and management's responses to any identified weaknesses.

(t) Review with management their approach to controlling and securing corporate assets (including intellectual property) and information systems, the adequacy of staffing of key functions and their plans for improvements.

(u) Review annually the code of ethics and legal and regulatory requirements that, if breached, could have a significant impact on the Corporation's published financial reports or reputation.

(v) Review with management relationships with regulators, and the accuracy and timeliness of filing with regulatory authorities (when and if applicable).

(w) Review annually the business continuity plans for the Corporation.

(x) Review the annual audit plans of the external auditors of the Corporation.

(y) Review annually general insurance coverage of the Corporation to ensure adequate protection of major corporate assets including but not limited to D&O and if applicable, Key Person coverage. The identification of Key Persons is reassessed from time to time.

(z) Review the effectiveness of the Company's risk management system to assure that material risks are identified, and appropriate risk management processes are in place.

(aa) Satisfy itself that adequate procedures are in place for the review of the Corporation's public disclosure of financial information (other than the documents under section 1(b) above) extracted or derived from the Corporation's financial statements and must periodically assess the adequacy of such procedures.

(bb) Perform such other duties as consistent with this Charter, the Company's Articles and applicable securities legislation and policies that the Board or the Committee determines are necessary or appropriate.

(cc) Assist in the preparation of the disclosure required to be included in the Corporation's AIF in accordance with Form 52-110F1.

(dd) Establish procedures for:

(i) the receipt, retention and treatment of complaints received by the Corporation regarding accounting, internal controls, or auditing matters; and

(ii) the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or audit matters.

3. The Audit Committee may engage and communicate directly and independently with outside legal and other advisors for the Audit Committee as required and the Corporation will provide for appropriate funding, as determined by the Audit Committee, to pay any such legal or other advisors. The Corporation will also pay ordinary administrative expenses of the Audit Committee that are necessary or appropriate in carrying out its duties.

4. On a yearly basis, the Audit Committee will review the Audit Committee Charter and where appropriate recommend changes to the Board of Directors.

IV. Delegation

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

V. Secretary

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

VI. Meetings

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

VII. Quorum

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

Composition of the Audit Committee

The Audit Committee, at the present time, is comprised of Chair Dr. Stephen Sangha, Bernd Muehlenweg and David Paterson. 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

Dr. Steven Sangha has over 25 years of experience in investment banking, business development, and asset management. Dr. Sangha's extensive experience with public companies and finance has led him to successfully run a Private Family Office since 1998. Dr. Sangha holds a Doctorate of Dental Surgery (DDS) from the University of Western Ontario in London, Ontario, and a Bachelor of Pharmaceutical Science (BscPharm) from the University of British Columbia, and has managed a professional dental practice since 1998. Dr. Sangha is a member of the Board of Directors of BlockchainK2 and Goldhills Holding Ltd and is a corporate advisor for Better Life Pharma Inc.

Bernd Muelenweg is the Senior Vice President, Head of Global Business Development, Cell Therapy, at Evotec (Germany). During his tenure Bernd has been involved in establishing numerous collaboration and licensing agreements for the company and was also part of creating spin-off companies and M&A transactions. Before Evotec he served as Chief Business Officer for Nanobiotix S.A. (France), an oncology company listed on Euronext and NASDAQ. He is co-founder of Panoptes Pharma, an Austrian

ophthalmology company that was acquired by NASDAQ listed Eyegate Pharmaceuticals (now Kiora Pharmaceuticals). Previously he worked at Wilex AG, an oncology company, spanning business development and alliance management roles. Bernd holds a PhD in chemistry from the Technical University of Munich, Germany.

David Paterson is the Assistant Vice President for Research Translation and Commercialization at Colorado State University and is responsible for the translation and commercialization of research providing guidance to CSU faculty, research facilities and colleges in cultivating new industry-related partnerships. Prior to CSU, he served in a number of business and corporate development roles at Impax Laboratories, Inc including Head of Impax Laboratories, BV in the Netherlands; Vice President for Out-Partnering and Alliance Management and Vice President for Business Development at Impax Laboratories where he established a number of global industry partnerships. Previously he was Senior Director of Business Development at Sepracor (now Sunovion), and also served as the Director of Business Development at GlaxoSmithKline, and Vice President for Business Development at Skyepharma, Inc. He holds a Ph.D. in Plant Biology from the University of Illinois Urbana-Champaign and a B.Sc. (Hons) in botany from the University of Glasgow in Scotland. He has served on the boards of Impax Labs, B.V, Neurogastrx, Inc, and Lakeside Biotechnology, Inc.

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, 2024	$452,416	$Nil	$49,665	$Nil
October 31, 2023	$327,338	$Nil	$Nil	$48,685

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.